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Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

14.7.2026

AMENDMENTS
2522 - 2801

Draft report
Vytenis Povilas Andriukaitis, Wouter Beke
(PE789.987v01-00)

Establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

Proposal for a regulation
(COM(2025)1022 – 2025/0406(COD))

Amendment 2522
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point a
Regulation (EU) No 536/2014
Article 2 – point (3) – point (b)

Text proposed by the Commission	*Amendment*
(b) according to the protocol of the clinical trial, the ***use of the*** investigational medicinal product is ***evidence-based and supported by published scientific evidence on*** the safety ***and efficacy of those investigational medicinal products concerned; and***	(b) according to the protocol of the clinical trial, the investigational medicinal product is ***used for the same clinical indication, in the same patient population, and according to the same route of administration as provided for in the marketing authorisation, and does not pose more than minimal additional risk or burden to*** the safety ***of the subjects compared to its authorised use;***

Or. en

Amendment 2523
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point a
Regulation (EU) No 536/2014
Article 2 – point (3) – point (b)

Text proposed by the Commission	*Amendment*
(b) according to the protocol of the clinical trial, the use of the investigational medicinal product is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products concerned; and	(b) according to the protocol of the clinical trial, the use of the investigational medicinal product is evidence-based and supported by ***peer-reviewed,*** published scientific evidence on the safety and efficacy of those investigational medicinal products concerned; and

Or. en

Amendment 2524
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point a
Regulation (EU) No 536/2014
Article 2 – point (3) – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) the investigational medicinal product is investigated at:
	(i)the same or lower dose, and/or
	(ii)the same or lower frequency, and/or
	(iii)the same or shorter duration;

Or. en

Amendment 2525
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point a
Regulation (EU) No 536/2014
Article 2 – point (3) – point (bb)new

Text proposed by the Commission	*Amendment*
	(bb) according to the protocol of the clinical trial, the use of the investigational medicinal product is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products concerned supported by internationally established clinical practice; and

Or. en

Amendment 2526
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point e
Regulation (EU) No 536/2014
Article 2 – point 21

Text proposed by the Commission	*Amendment*
(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;	(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed ***and having understood*** of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;***'Patients and participants shall be made explicitly aware of their rights, the scope of data usage, and their ability to withdraw consent at any time.Where informed consent is obtained through electronic systems, methods or processes, such systems shall be designed to reflect the continuous and evolving nature of informed consent. They shall ensure that the subject is able to review, modify and withdraw consent at any time in a manner that is as simple and accessible as the act of giving consent.'***

Or. en

Amendment 2527
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point e
Regulation (EU) No 536/2014

Article 2 – point 21

Text proposed by the Commission	*Amendment*
(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;	(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards***. When electronic formats are used, they shall incorporate functionalities that allow participants to manage their consent throughout the trial, ensuring that any decision to maintain, adapt or withdraw participation can be exercised easily and at any moment. The same should apply for all the other formats.***;

Or. en

Amendment 2528
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point e
Regulation (EU) No 536/2014
Article 2 – point 21

Text proposed by the Commission	*Amendment*
(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or	(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed ***in simple and understandable language*** of all aspects of the clinical trial***, including their rights and information on the processing of their personal data,*** that

agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;	are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;**'**

Or. en

Amendment 2529
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f – introductory part

Text proposed by the Commission	*Amendment*
(f) the following ***points (36), to 47 are*** inserted:	(f) the following ***point (36) is*** inserted:

Or. en

Amendment 2530
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 point 36

Text proposed by the Commission	*Amendment*
(36) 'Consideration' means a justified concern or divergent view raised by a Member State concerned in the process of an ***assessment*** of an application for an authorisation of a clinical trial or for a substantial modification on the aspects that, if unresolved, will result in a negative decision on the clinical trial or substantial modification application;	(36) 'Consideration' means a justified concern or divergent view raised by a Member State concerned in the process of an ***evaluation*** of an application for an authorisation of a clinical trial or for a substantial modification on the aspects that, if unresolved, will result in a negative decision on the clinical trial or substantial modification application;

Or. en

Amendment 2531
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (a)

Text proposed by the Commission	*Amendment*
(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials, or	(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials, ***and subsequent substantial modification(s) thereof,*** or

Or. en

Amendment 2532
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (a)

Text proposed by the Commission	*Amendment*
(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials, or	(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials ***and subsequent substantial modification(s) thereof***, or

Or. en

Amendment 2533
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014

Article 2 – point (37) – point (a)

Text proposed by the Commission	*Amendment*
(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials, or	(a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials ***and subsequent substantial modification(s) thereof***, or

Or. en

Amendment 2534
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (b)

Text proposed by the Commission	*Amendment*
(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification regarding aspects covered by Part I of the application dossier, or	(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification ***thereof*** regarding aspects covered by Part I of the application dossier, or

Or. en

Amendment 2535
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – point (37) – point (b)

Text proposed by the Commission	*Amendment*
(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification regarding aspects covered by Part I of the application dossier, or	(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification ***thereof*** regarding aspects covered by Part I of the application dossier, or

Or. en

Amendment 2536
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (b)

Text proposed by the Commission	*Amendment*
(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification regarding aspects covered by Part I of the application dossier, or	(b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification ***thereof*** regarding aspects covered by Part I of the application dossier, or

Or. en

Amendment 2537
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (c)

Text proposed by the Commission	*Amendment*
(c) is leading the assessment for the authorisation of a multinational combined study;	(c) is leading the assessment for the authorisation of a multinational combined study ***and subsequent substantial modification(s) thereof***;

Or. en

Amendment 2538
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (37) – point (c)

Text proposed by the Commission	*Amendment*
(c) is leading the assessment for the authorisation of a multinational combined study;	(c) is leading the assessment for the authorisation of a multinational combined study ***and subsequent substantial modification(s) thereof***;

Or. en

Amendment 2539
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – point (37) – point (c)

Text proposed by the Commission	*Amendment*
(c) is leading the assessment for the authorisation of a multinational combined study;	(c) is leading the assessment for the authorisation of a multinational combined study ***and subsequent substantial modification(s) thereof***;

Or. en

Justification

The role of the reporting Member State in Article 58(1) shall be clearly and exhaustively defined for all stages of the clinical trial lifecycle, with a view to reducing legal ambiguity and ensuring greater consistency in the application of clinical trials rules across the Union.

Amendment 2540
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (38)

Text proposed by the Commission	*Amendment*
(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***II*** of Annex I concerning the investigational medicinal product, established at the	(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***I*** of Annex I concerning the investigational medicinal product, established at the

request of the sponsor in view of supporting the development of the investigational medicinal product.

request of the sponsor in view of supporting the development of the investigational medicinal product ***and which may be used to support applications in corresponding clinical trials for the same investigational medicinal product via cross-referral in the EU Portal***.

Or. en

Amendment 2541
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (38)

Text proposed by the Commission	*Amendment*
(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***II*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product.	(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***I*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product***, and which may be used to support applications in corresponding clinical trials for the same investigational medicinal product via cross-referral in the EU Portal***.

Or. en

Amendment 2542
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – point (38)

Text proposed by the Commission	*Amendment*
(38) 'Investigational medicinal product	(38) 'Investigational medicinal product

core dossier' means a dossier, containing documents referred to in point (Ga), Part ***II*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product.	core dossier' means a dossier, containing documents referred to in point (Ga), Part ***I*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product***, and which may be used to support applications in corresponding clinical trials for the same investigational medicinal product via cross-referral in the EU Portal***.

Or. en

Amendment 2543
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
(EU) No 536/2014
Article 2 – point 38

Text proposed by the Commission	*Amendment*
(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***II*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product.	(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part ***I*** of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product.

Or. en

Amendment 2544
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – point (39)

Text proposed by the Commission	*Amendment*

(39) 'Core dossier depositary ***Member State***' means ***a Member State*** responsible for assessing suitability and completeness of the investigational medicinal product core dossier to be established and for the regulatory oversight of an already established dossier;	(39) 'Core dossier depositary ***Agency***' means ***the Agency, as established by Reg (EC) No 726/2004,*** responsible for assessing suitability and completeness of the investigational medicinal product core dossier to be established and for the regulatory oversight of an already established dossier;

Or. en

Justification

EMA is established as the sole depositary of the core dossiers.

Amendment 2545
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (41)

Text proposed by the Commission	*Amendment*
(41) 'Corresponding clinical trial' means a clinical trial ***tested to the investigational medicinal product*** for which ***an*** establishment of an investigational medicinal product core dossier has been requested and any subsequent clinical trial ***tested to*** that investigational medicinal product***;***	(41) 'Corresponding clinical trial' means a clinical trial for which ***the*** establishment of an investigational medicinal product core dossier has been requested and any subsequent clinical trial ***referring to the investigational medicinal product core dossier established for*** that investigational medicinal product***.***

Or. en

Amendment 2546
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – point (41)

Text proposed by the Commission	*Amendment*

(41) 'Corresponding clinical trial' means a clinical trial ***tested to the investigational medicinal product*** for which ***an*** establishment of an investigational medicinal product core dossier has been requested and any subsequent clinical trial ***tested to*** that investigational medicinal product***;***	(41) 'Corresponding clinical trial' means a clinical trial for which ***the*** establishment of an investigational medicinal product core dossier has been requested and any subsequent clinical trial ***referring to the investigational medicinal product core dossier established for*** that investigational medicinal product***.***

Or. en

Amendment 2547
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – point (44)

Text proposed by the Commission	*Amendment*
(44) ***'***Combined study' means a clinical trial concerning one or more medicinal products combined with a performance study of one or more in vitro diagnostic medical devices, ***as defined in*** Article ***2 point (42)*** of Regulation (EU) 2017/746 ***of the European Parliament and of the Council *and/or*** clinical investigation of one or more medical devices ***as defined in*** Article ***2 point (45)*** of Regulation (EU) 2017/745 ***of the European Parliament and of the Council **;***	(44) combined study' means a clinical trial concerning one or more medicinal products combined with a performance study of one or more in vitro diagnostic medical devices, ***including companion diagnostics where applicable, that is subject to authorisation pursuant to*** Article ***58(1)*** of Regulation (EU) 2017/746***, or combined with a*** clinical investigation of one or more medical devices ***that is subject to authorisation pursuant to*** Article ***62*** of Regulation (EU) 2017/745***.*** *(paragraph 1)*

Or. en

(Regulation (EU) No 536/2014/ Article 2, point (44))

Justification

Companion diagnostics are increasingly integral to the development and use of personalised medicines, particularly in oncology and advanced therapies. Explicitly recognising them in the definition of combined studies improves legal clarity and supports integrated medicine–diagnostic development without altering the scope of Regulation (EU) 2017/745 or Regulation (EU) 2017/746.

Amendment 2548
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) No 536/2014
Article 2 – Point (45)

Text proposed by the Commission	*Amendment*
(45) 'Regulatory sandbox' means a regulatory framework that allows for the development and testing of innovative or adapted regulatory approaches in a controlled environment pursuant to a specific plan, for a limited time and under regulatory supervision, that enables innovation driven approaches to an authorisation and conduct of clinical trials that otherwise would not be possible or appropriate given current legal framework;'	***deleted***

Or. en

Amendment 2549
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – Point (47a)new

Text proposed by the Commission	*Amendment*
	(47a) 'sex' means a biological construct based on anatomical, physiological, hormonal, and genetic (chromosomal) traits. Sex is generally assigned based on anatomy at birth and is usually categorised as female or male, but variations occur. Variations of sex refers to differences in sex development or intersex traits.

Or. en

Amendment 2550
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 1 – point f
Regulation (EU) 536/2014
Article 2 – Point (47b)new

Text proposed by the Commission	*Amendment*
	(47b) 'gender' means a multidimensional construct that encompasses how an individual self-identifies. Gender may be described across a continuum, may be nonbinary, and may change over the course of a lifetime. Gender may or may not

Or. en

Amendment 2551
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – Paragraph 1 – point (a)

Text proposed by the Commission	*Amendment*
(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and	(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests***, in line with the Declaration of Helsinki and the Declaration of Taipei*** ; and

Or. en

Amendment 2552
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – Paragraph 1 – point (a)

Text proposed by the Commission	*Amendment*
(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; ***and***	(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests;

Or. en

Amendment 2553
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – Paragraph 1 – point (b)

Text proposed by the Commission	*Amendment*
(b) it is designed to generate reliable and robust data.	(b) it is designed to generate reliable and robust data***, including sex- and gender-disaggregated data***.

Or. en

Amendment 2554
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – paragraph 1 – point (b)

Text proposed by the Commission	*Amendment*
(b) it is designed to generate reliable and robust data.	(b) it is designed to generate reliable and robust data***, including sex-disaggregated data***.

Or. en

Amendment 2555
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – paragraph 1 – point (b)

Text proposed by the Commission	*Amendment*
(b) it is designed to generate reliable and robust data**.**	(b) it is designed to generate reliable and robust data***; and***

Or. en

Amendment 2556
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – paragraph 1 – point b a new

Text proposed by the Commission	*Amendment*
	(ba) it follow the principles enshrined in the declaration of Helsinki and the declaration of Taipei.

Or. en

Amendment 2557
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 58 – paragraph 1 – point 2
Regulation (EU) No 536/2014
Article 3 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. For biological products addressing antimicrobial resistance, including bacteriophage therapies, clinical trial methodologies may include adaptive designs, pathogen-susceptibility guided allocation, predefined modification of product composition, platform protocols, and integration of microbiological and

realworld evidence, provided that patient safety, traceability, quality control, and scientific validity are ensured.

Or. en

Amendment 2558
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – first subparagraph

Text proposed by the Commission	*Amendment*
A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to scientific and ethical review.	A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to ***a risk-based*** scientific and ethical review. ***The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6. Other Member States concerned shall not conduct a separate assessment of the ethical aspects covered by Part I, without prejudice to their assessment of national, local or site-specific ethical aspects as part of Part II. Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a combined study, clinical trial and substantial modifications thereof, and do not result in duplication of the assessment of ethical aspects covered by Part I in multinational clinical trials.***

Or. en

Amendment 2559
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation No 536/2014
Article 4 – first subparagraph

Text proposed by the Commission	*Amendment*
A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to scientific and ethical review.	A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to ***a risk-based*** scientific and ethical review.

Or. en

Amendment 2560
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – first subparagraph

Text proposed by the Commission	*Amendment*
A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to scientific and ethical review.	A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to ***a risk-based*** scientific and ethical review.

Or. en

Amendment 2561
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014

Article 4 – (new) fifth subparagraph

Text proposed by the Commission	*Amendment*
	For clinical trials involving radiopharmaceuticals, where approval by a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Or. en

Amendment 2562
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – third subparagraph

Text proposed by the Commission	*Amendment*
The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6.	The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6. ***Other Member States concerned shall not conduct a separate ethical assessment of the ethical aspects covered by Part I, without prejudice to their assessment of national, local or site-specific ethical aspects as part of Part II.***

Or. en

Justification

This amendment clarifies the role of ethics committees in the coordinated assessment of multinational clinical trials. While the Regulation assigns a leading role to the reporting

Member State for Part I assessment, the current wording does not explicitly prevent parallel ethical assessments of the same aspects by other Member States. In practice, this has resulted in duplication and inconsistent requests. The amendment makes clear that ethical aspects covered by Part I are assessed by the reporting Member State, while preserving Member State competence for national or local ethical aspects under Part II, thereby improving consistency and efficiency without altering the balance of competences.

Amendment 2563
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – third subparagraph

Text proposed by the Commission	*Amendment*
The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6.	The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6. ***Other Member States concerned shall not conduct a separate assessment of the ethical aspects covered by Part I, without prejudice to their assessment of national, local or site-specific ethical aspects as part of Part II.***

Or. en

Amendment 2564
Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – third subparagraph

Text proposed by the Commission	*Amendment*
The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The	The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The

reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6.	reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6. ***Other Member States concerned shall not conduct a separate assessment of the ethical aspects covered by Part I, without prejudice to their assessment of national, local or site-specific ethical aspects as part of Part II.***

Or. en

Amendment 2565
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – third subparagraph

Text proposed by the Commission	*Amendment*
The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6.	The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6. ***The scientific review shall be be conducted by a panel of experts, selected for their expertise in the topical area which the medical product or treatment being tested belongs to.***

Or. en

Amendment 2566
András Tivadar Kulja

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.	Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof. ***For clinical trials involving radiopharmaceuticals, where approval by a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof, without prejudice to the requirements of radiation protection legislation.*** ***The Commission should therefore assess whether the interaction between this Regulation and the Union radiation protection framework, including Council Directive 2013/59/Euratom, remains appropriate in light of scientific and technological progress, while ensuring a high level of protection for patients, healthcare workers and the public.***

Or. en

Justification

Therapeutic radiopharmaceuticals are an increasingly important component of precision medicine and represent one of the fastest developing areas of health biotechnology. Their development requires the coherent application of Union legislation governing medicinal products, clinical trials and radiation protection. While the highest standards of radiation safety must continue to apply, technological developments in targeted radiopharmaceuticals, personalized dosimetry, including active real-time discriminating personalized multi-radiation dosimetry, digital radiation monitoring and advanced radiotherapy justify a continuous assessment of whether the existing regulatory framework remains fit for purpose.

Amendment 2567

Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.	Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof. ***Member States shall ensure that the competent authorities and ethics committees responsible for the scientific and ethical review are organised and operate in a manner that allows for the effective and timely completion of their tasks under this Regulation, while ensuring a high level of scientific and ethical quality that safeguards the protection of trial participants and the reliability of the assessment outcome.***

Or. en

Amendment 2568
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for	Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for

authorisation of a clinical trial and substantial modifications thereof.	authorisation of a ***combined study,*** clinical trial and substantial modifications thereof***, and do not result in duplication of the assessment of ethical aspects covered by Part I in multinational clinical trials***.

Or. en

Amendment 2569
Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.	Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a ***combined study,*** clinical trial and substantial modifications thereof***, and do not result in duplication of the assessment of ethical aspects covered by Part I in multinational clinical trials***.

Or. en

Amendment 2570
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and	Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and

procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof ***and do not result in duplication of the ethical assessment of aspects covered by Part I in multinational clinical trials***.

Or. en

Amendment 2571
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) No 536/2014
Article 4 – (new) fifth subparagraph

Text proposed by the Commission	*Amendment*
	For clinical trials involving radiopharmaceuticals, where approval by a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Or. en

Amendment 2572
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – (new) fifth subparagraph

Text proposed by the Commission	*Amendment*
	For clinical trials involving radiopharmaceuticals, where approval by

a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Or. en

Amendment 2573
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 4 – (new) fifth subparagraph

Text proposed by the Commission	*Amendment*
	For clinical trials involving radiopharmaceuticals, where approval by a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Or. en

Justification

Recent practice in certain Member States, including the alignment in July 2025 of radiation protection and clinical trial approval timelines in Germany, demonstrates the feasibility and benefits of coordinated regulatory procedures.

In order to future-proof the Union framework and avoid unnecessary administrative burden for sponsors of clinical trials involving ionising radiation, the updates introduced through the Biotech Act to the EU Clinical Trials Regulation should be leveraged to promote the alignment of radiation protection authority (RPA) timelines across all Member States where RPA approval is required, or may be required in the future.

As Article 4 of the Clinical Trials Regulation establishes coordinated timelines without being limited to ethics committee assessments, a corresponding provision for radiation protection authorities could be introduced. This would support consistent, timely and predictable approvals across the Union, reduce procedural delays in multinational clinical trials, and enhance regulatory coherence while fully preserving radiation protection standards.

Amendment 2574
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 5 – paragraph 2 – point (b)

Text proposed by the Commission	*Amendment*
(b) ***an*** assessment, that consists of:	(b) ***a concurrent*** assessment, that consists of:

Or. en

Amendment 2575
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 5 – Paragraph 2 – point (b)

Text proposed by the Commission	*Amendment*
(b) ***an*** assessment, that consists of:	(b) ***a concurrent*** assessment, that consists of:

Or. en

Amendment 2576
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 3
Regulation (EU) 536/2014
Article 5 – Paragraph 2 – point (b)

Text proposed by the Commission	*Amendment*
(b) ***an*** assessment, that consists of:	(b) ***a concurrent*** assessment, that consists of:

Or. en

Amendment 2577
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 4 – introductory part
Regulation (EU) 536/2014
Article 5 – Paragraph 4

Text proposed by the Commission	*Amendment*
(4) the following Articles ***5a and Article 5b*** are inserted:	(4) the following Articles ***5b, 5c and 5d*** are inserted:

Or. en

Amendment 2578
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 4 – introductory part

Text proposed by the Commission	*Amendment*
(4) the following Articles 5a and Article 5b are inserted:	(4) the following Articles 5a and Article 5b ***and Article 5c*** are inserted:

Or. en

Amendment 2579
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 4 – introductory part

Text proposed by the Commission	*Amendment*
(4) the following Articles ***5a and***	(4) the following Articles ***5b, 5c and***

Article 5b are inserted: ***5d*** are inserted:

Or. en

Amendment 2580
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5a

Text proposed by the Commission	*Amendment*
Article 5a	***deleted***

Or. en

Amendment 2581
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5a

Text proposed by the Commission	*Amendment*
Article 5a	***deleted***

Or. en

Amendment 2582
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5aa (new)

Text proposed by the Commission	*Amendment*
	Article 5b

Investigational advanced therapy medicinal products and vaccines containing or consisting of genetically modified organisms presenting no or negligible risks

1. By way of exemption from Article 5a, sponsors of clinical trials that concern (i) advanced therapy investigational medicinal products as defined in Article 2(7) of Regulation (EC) No 1394/2007 or (ii) vaccines as defined in Article 4(1) (28) of [revised Directive 2001/83/EC] consisting or containing GMOs, are not required to submit an environmental risk assessment, if those products belong to at least one of the following categories:

(a) non-viable or replication deficient viral vector that is used to deliver a genetic sequence of human origin, and the vector does not carry an antimicrobial resistance gene;

(b) genetically modified somatic cells, cannot secrete or produce infectious agents due to the genetic modification;

(c) genetically modified bacteria that do not carry an antimicrobial resistance gene;

(d) genetic material altered using genome editing techniques (ex vivo or in vivo), provided that it has generally negligible adverse effects on human health and the environment.

2. The exemption provided for in paragraph 1 of this Article is subject to the sponsor submitting, through the EU Portal and as part of the clinical trial application dossier, a declaration confirming that the investigational vaccine or the advanced investigational therapy medicinal product concerned falls into one or more of the categories referred to in points (a) to (d) of paragraph 1, of this Article. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation […] [revised Regulation No (EC) 726/2004] shall verify this declaration,

and the CHMP may, to this end, access the information on the clinical trial application in the EU portal. The CHMP shall communicate its opinion on the declaration to the sponsor and to the reporting Member State within 14 days after the submission date referred to in Article 5(1) of Regulation (EU) 536/2014 [as revised by European Biotech Act]. The Commission shall adopt guidance specifying the content and format of the declaration.

4. Sponsors of clinical trials concerning investigational vaccines or advanced investigational therapy medicinal products that fall under paragraph 1 of this Article are also exempted from complying with the GMO related requirements of Article 61(2), point (a), of Regulation (EU) 536/2014 [as introduced by the revised Regulation No (EC) 726/2004] regarding the authorisation of manufacturing and import of advanced investigational vaccines and advanced therapy medicinal products.

5. The exemptions provided for in this Article shall apply for the duration of the clinical trial, limited to the activities within the clinical trial. However, where the declaration referred to in paragraph 2 is relevant to more than one clinical trial, it may be cross-referenced in subsequent applications. The declaration shall form part of the investigational medicinal product core dossier and shall be referenced in all related clinical trial applications for which that dossier has been established in accordance with Article 27a. The maintenance and amendment of the declaration shall be carried out in accordance with Articles 27b.

6. To ensure that the exemptions under this Article 5b are adapted to technical progress and relevant new evidence relating to public health and environmental protection, the Commission shall be empowered to adopt

delegated acts in accordance with Article 89 to amend the product categories and criteria in paragraph 1. The Commission shall review and, where appropriate, update those categories and criteria at least every five years.

Or. en

Amendment 2583
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5c (new)

Text proposed by the Commission	*Amendment*
	Article 5c
	Appointment of the reporting Member State
	1. In clinical trials concerning only one Member State, this Member State is the reporting Member State.
	2. In clinical trials concerning more than one Member States, the sponsor shall propose one of the Member States concerned as the reporting Member State. All Member States concerned willing to become the reporting Member State shall declare their willingness through the EU portal. The sponsor shall, when applying for a low-intervention clinical trial propose one of the Member States concerned where the use of the investigational medicinal product is evidence-based as a reporting Member State.
	3. If the proposed Member State accepts the proposal by expressing willingness to become the reporting Member State, it shall be the reporting Member State.
	4. If the proposed Member State does not accept the proposal, the following rules shall apply, and their application shall be

supported by the EU Portal: (a) where there is only one other Member State concerned willing to become the reporting Member State, that Member State shall become the reporting Member State; (b) where there is more than one Member State concerned willing to become the reporting Member State or none of the Member States concerned is willing to become the reporting Member State, the reporting Member State shall be designated automatically by the EU Portal in application of the recommendation referred to in article 85(2)(c).

5. Within three days from the submission date, all Member States concerned, the sponsor and the reporting Member State shall be notified by the EU Portal of the appointment of the reporting Member State.

Or. en

Amendment 2584
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5d (new)

Text proposed by the Commission	*Amendment*
	Article 5d
	Validation of Part I of the application dossier
	1. Within seven days from the submission date, the reporting Member State shall validate Part I of application dossier referred to in Article 6 and notify the sponsor, through the EU portal, of the following: (a) whether the clinical trial applied for falls within the scope of this Regulation; (b) whether the application dossier is complete in accordance with Part I of Annex I; (c) whether it confirms that the clinical trial is a minimal-

intervention or a low- intervention clinical trial, respectively, if such a claim was made by the sponsor.

2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.

3. Where the reporting Member State finds that the application dossier is not complete, or that the clinical trial applied for does not fall within the scope of this Regulation, or, if applicable, has doubts whether the clinical trial is a minimal-intervention or low-intervention clinical trial, the reporting Member State shall: (a) inform the sponsor thereof through the EU portal and shall set a deadline of maximum seven days for the sponsor to comment on the application or to complete the application dossier through the EU portal; (b) within seven days from the submission of the comments or the completed application dossier referred to in point (a) notify the sponsor as to whether or not the application complies with the requirements set out in paragraph 1 points (a), (b) and (c). In case the reporting Member State requests the sponsor to comment on the application pursuant to this paragraph, the period referred to in paragraph 1 may be extended by a maximum of 14 days.

4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by

the sponsor.

5. Where the sponsor has not provided comments or completed the application dossier within the period referred to in paragraph 3, point (a), the application shall be deemed to have lapsed in all Member States concerned.

6. For the purpose of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or paragraph 3, point (b) shall be the validation date of the application. Where the sponsor is not notified within these time periods, the validation date shall be the last day of respective periods referred to in paragraph 1 or paragraph 3, point (b).

Or. en

Amendment 2585
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5c (new)

Text proposed by the Commission	*Amendment*
	Article 5c
	Clinical trials involving radiopharmaceuticals
	For clinical trials involving radiopharmaceuticals, where approval by a radiation protection agency is required, Member States shall ensure that the organisation, timelines and procedures for the review are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Or. en

Amendment 2586
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – paragraph 1 – point (c)

Text proposed by the Commission	*Amendment*
(c) whether it confirms that the clinical trial is a minimal-intervention or a low-intervention clinical trial, respectively, if such a claim was made by the sponsor.	(c) whether***, after consulting with its ethics committee,*** it confirms that the clinical trial is a minimal-intervention or a low- intervention clinical trial, respectively, if such a claim was made by the sponsor.

Or. en

Amendment 2587
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.	***deleted***

Or. en

Amendment 2588

Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.	***deleted***

Or. en

Amendment 2589
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.	***deleted***

Or. en

Amendment 2590

Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 6 – Paragraph– Point 5aa (new)

Text proposed by the Commission	*Amendment*
	Through the EU portal, the sponsor would be able to communicate with the Reporting Member State, including a request for a meeting, to accelerate the resolution of certain questions and to facilitate the resolution of potential issues arising from conflicting information.

Or. en

Amendment 2591
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – Paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor.	***deleted***

Or. en

Amendment 2592
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5b – Paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor.	***deleted***

Or. en

Justification

Clinical trial applications should not be validated automatically. Competent authorities must verify dossier completeness and correct trial classification, including low- or minimal-intervention status. Automatic validation by default risks misclassification, weaker safeguards and potential impacts on participant safety, which require expert assessment.

Amendment 2593
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) No 536/2014
Article 5 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-	***deleted***

intervention or a low-intervention clinical trial, if claimed by the sponsor.

Or. en

Amendment 2594
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 4
Regulation (EU) 536/2014
Article 5a – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. To ensure that the exemptions under this Article 5b are adapted to technical progress and relevant new evidence relating to public health and environmental protection, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the product categories and criteria in paragraph 1. The Commission shall review and, where appropriate, update those categories and criteria at least every five years.

Or. en

Amendment 2595
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – second subparagraph

Text proposed by the Commission	*Amendment*
– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of	– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated***, including adequate representation of different sexes pertaining to epidemiology and expected***

Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after adoption cf. COM(2023)196final];	***use of the medicinal product***, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after adoption cf. COM(2023)196final];

Or. en

Amendment 2596
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – second subparagraph

Text proposed by the Commission	*Amendment*
– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after adoption cf. COM(2023)196final];	– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated***, including adequate representation of different sexes pertaining to epidemiology and expected use of the medicinal product***, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after

adoption cf. COM(2023)196final];

Or. en

Amendment 2597
Sirpa Pietikäinen

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – second subparagraph

Text proposed by the Commission	*Amendment*
– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after adoption cf. COM(2023)196final];	– relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated***, including adequate representation of different sexes pertaining to epidemiology and expected use of the medicinal product***, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) …/…[reference to be added after adoption cf. COM(2023)196final]; *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. en

(See wording of article 6, paragraph 1, of the Regulation (EU) No 536/2014.)

Justification

Necessary to ensure adequate representation in clinical trials.

Amendment 2598
Sirpa Pietikäinen

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – third subparagraph

Text proposed by the Commission	*Amendment*
– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints;	– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints; ***including sex- and gender-stratified analyses of efficacy and safety.***
	(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. en

(See wording of article 6, paragraph 1, of the Regulation (EU) No 536/2014.)

Justification

Necessary to ensure adequate and reliable data in clinical trials.

Amendment 2599
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – third subparagraph

Text proposed by the Commission	*Amendment*
– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints***;***	– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints***, including sex- and gender-stratified analyses of efficacy and safety.***

Or. en

Amendment 2600
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – third subparagraph

Text proposed by the Commission	*Amendment*
– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints;	– reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints***, including sex-stratified analyses of efficacy and safety***;

Or. en

Amendment 2601
Peter Liese

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 1 – point (a) – point (i) – (new) fourth subparagraph

Text proposed by the Commission	*Amendment*
	(aa) Confirm that, where the data package supporting a Union marketing authorisation relies exclusively on clinical trials conducted in third countries, the sponsor has performed at least one pivotal confirmatory clinical trial that includes study sites in two or more Member States and recruits a patient population representative of the Union's demographic diversity.

Or. en

Justification

Ensures that pivotal safety data reflect EU public-health conditions and prevents marketing authorisations based solely on extra-EU trials.

Amendment 2602
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 1a(new)

Text proposed by the Commission	*Amendment*
	(da) Where information provided in accordance with point (c) of paragraph 17 of Annex I of this Regulation includes data on non-clinical studies or other clinical trials conducted outside the Union, the applicability of such information to the Union population to be treated and normal clinical practice in the Union.

Or. en

Justification

Art 58 (5), point 5 amending CTR Article 6 Assessment report – Aspects covered by Part I of the assessment report. Article 6 (1) of CTR sets out the aspects of a Clinical Trial application for assessment by the reporting Member State. Annex I of the Regulation, paragraph 17 sets out the required information for inclusion in the protocol by sponsors, to facilitate this assessment. (c) includes a summary of relevant findings from non-clinical studies and other clinical trials deemed relevant to the clinical trial proposed. Amendment 1(e) mandates an rMS to specifically consider the relevance and applicability of such non-clinical studies and clinical trials, when they have been conducted outside of the Union, considering the potentially different population and standard of care. To assist in this, as well as the similar consideration required when assessing an application for a marketing authorisation, 6a is inserted to require the EMA to develop guidance on this subject, in line with ICH guidelines. The amendment also requires clinical trial and MA applicants to justify why their non-Union data is relevant, in line with the guidance developed by the EMA.

Amendment 2603
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation

Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. For clinical trials assessed in accordance with Article 14b(2), the assessment referred to in paragraph 1 shall be carried out at Union level by the Voluntary Centralised Assessment Committee of the CTAG, in accordance with Article 85(5b).

Or. en

Amendment 2604
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – paragraph 2 – second subparagraph

Text proposed by the Commission	*Amendment*
The ethics committee of the reporting Member State shall review, from the ethical perspective, aspects covered by Part I of the assessment report. That ethical review shall complement the scientific and regulatory assessment and shall cover Part I of the application dossier in order to evaluate whether the subjects' rights, safety and well-being are being ensured in the clinical trial.**"**	The ethics committee of the reporting Member State shall review, from the ethical perspective, aspects covered by Part I of the assessment report. That ethical review shall complement the scientific and regulatory assessment and shall cover Part I of the application dossier in order to evaluate whether the subjects' rights, safety and well-being are being ensured in the clinical trial. ***Ethics committees shall, as part of their assessment, consider sex and gender aspects of the clinical trial, including the justification for excluding or under-representing women or men, including women of child-bearing potential, the treatment of pregnant and breastfeeding women, and the adequacy of information on sex-specific and pregnancy-related risks in the informed consent documents.***

Or. en

Amendment 2605
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors ***and to the other Member States concerned*** within ***42*** days from the submission date.	4. ***For clinical trials concerning only one Member State,*** the reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors within ***28*** days from the submission date.

Or. en

Amendment 2606
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors ***and to the other Member States concerned*** within ***42*** days from the submission date.	4. ***For clinical trials concerning only one Member State,*** the reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors within ***28*** days from the submission date.

Or. en

Amendment 2607
Ondřej Krutílek

Proposal for a regulation

Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors ***and to the other Member States concerned*** within ***42*** days from the submission date.	4. ***For clinical trials concerning only one Member State,*** the reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors within ***28*** days from the submission date.

Or. en

Amendment 2608
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors and to the other Member States concerned within ***42*** days from the submission date.	4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors and to the other Member States concerned within ***24*** days from the submission date.

Or. en

Justification

Shortening Part I assessment from 42 to 35 days by reducing the initial assessment phase to 21 days and running it in parallel with the rMS's initial validation.

Amendment 2609
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 5 – third subparagraph

Text proposed by the Commission	*Amendment*
During the review phase, within seven days from the circulation of the draft assessment report all Member States concerned ***shall*** review the application based on the draft Part I of the assessment report and shall share considerations for their Member States relevant to the application. The consideration may be raised only on one of the ***following*** grounds:	During the review phase, within seven days from the circulation of the draft assessment report all Member States concerned ***may*** review the application***, to the extent necessary,*** based on the draft Part I of the assessment report and shall share ***any*** considerations for their Member States relevant to the application ***to the reporting Member State through the EU portal***. The consideration may be raised only on one of the grounds ***referred to in Article 8(2)***:

Or. en

Amendment 2610
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 5 – third subparagraph

Text proposed by the Commission	*Amendment*
During the review phase, within seven days from the circulation of the draft assessment report all Member States concerned shall review the application based on the draft Part I of the assessment report and shall share considerations for their Member States relevant to the application. The consideration may be raised only on one of the ***following*** grounds***:***	During the review phase, within seven days from the circulation of the draft assessment report all Member States concerned shall ***may*** review the application***, to the extent necessary,*** based on the draft Part I of the assessment report and shall share ***any*** considerations for their Member States relevant to the application ***to the reporting Member State through the EU portal***. The consideration may be raised only on one of the grounds ***referred to in Article 8(2).***

Or. en

Amendment 2611
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014

Article 6 – Paragraph 5 – third subparagraph – point (a)

Text proposed by the Commission	*Amendment*
(a) one of the grounds referred to in Article 8(2);	***deleted***

Or. en

Amendment 2612
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 5 – third subparagraph – point (b)

Text proposed by the Commission	*Amendment*
(b) issues that would lead to a negative opinion of the ethics committee of the Member State concerned.	***deleted***

Or. en

Amendment 2613
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 5 – third subparagraph – point (b)

Text proposed by the Commission	*Amendment*
(b) issues that would lead to a negative opinion of the ethics committee of the Member State concerned.	***deleted***

Or. en

Amendment 2614
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – paragraph 5aa (new)

Text proposed by the Commission	*Amendment*
	5aa. Through the EU portal, the sponsor would be able to communicate with the Member States concerned, including a request for a meeting, to accelerate the resolution of certain questions and to facilitate the resolution of potential issues.

Or. en

Amendment 2615
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – paragraph 6a (new)

Text proposed by the Commission	*Amendment*
	6a. The Agency shall, within six months of the entry into force of the [Biotech Act], adopt guidance to support the assessment of non-clinical studies and clinical trials conducted outside the Union, provided in accordance with point (c) of paragraph 17 of Annex I of this Regulation, or for the purposes of obtaining a marketing authorisation in accordance with [revised Regulation 726/2004]. This guidance shall include the methodology for assessing applicability and clinical significance of information from non-clinical studies and other clinical trials conducted outside the Union, with regard to:
	(a) demographic and clinical characteristics of the study population, including factors that may affect treatment response;

(b) the extent to which the standard of care, comparators and endpoints used in the clinical trial reflect those relevant to clinical practice within the Union;

(c) differences in intrinsic and extrinsic factors which may impact the efficacy or safety of the investigational medicinal product;

(d) the overall scientific validity and generalisability of the data to the intended population. This guidance shall be adopted in accordance with internationally harmonised scientific principles.

For the purposes of supporting the assessment of information from non-clinical studies and other clinical trials conducted outside the Union in accordance with this guidance, the sponsor submitting an application for authorisation of a clinical trial under this Regulation and the applicant seeking to obtain a marketing authorisation in accordance with [revised Regulation 726/2004] shall provide a justification of the applicability of such data to the Union population and and normal clinical practice in the Union.

Or. en

Justification

This amendment seeks to ensure that medicinal products that receive marketing authorisation in the EU are developed on the basis of clinical trial and non-clinical study data that is representative of the European population.

Amendment 2616
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 6a(new)

Text proposed by the Commission	*Amendment*
	6a. Where, during the assessment of Part II in accordance with Article 7, issues are identified that have a direct and unavoidable impact on elements assessed under Part I, the reporting Member State may, exceptionally and before the reporting date, request from the sponsor, through the EU portal, strictly limited clarifications or adaptations to those elements of Part I solely to the extent necessary to ensure consistency between Parts I and II of the assessment report. Such clarifications or adaptations shall not affect the conclusions of the assessment referred to in paragraphs 1 to 5 and shall not constitute a reopening of that assessment.

Or. en

Amendment 2617
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – paragraph 6a (new)

Text proposed by the Commission	*Amendment*
	6a. Where, during the assessment of Part II in accordance with Article 7, issues are identified that have a direct and unavoidable impact on elements assessed under Part I, the reporting Member State may, exceptionally and before the reporting date, request from the sponsor, through the EU portal, strictly limited clarifications or adaptations to those elements of Part I solely to the extent necessary to ensure consistency between Parts I and II of the assessment report.
	Such clarifications or adaptations shall not affect the conclusions of the assessment referred to in paragraphs 1 to

5 and shall not constitute a reopening of that assessment.

Or. en

Amendment 2618
András Tivadar Kulja

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – paragraph 7 – first subparagraph

Text proposed by the Commission	*Amendment*
Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 5.	Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 5. ***Requests for information shall be coordinated and issued by the reporting Member State through the EU Portal. Prior to issuing formal requests, the reporting Member State and the Member States concerned may seek informal clarifications with the sponsor via the EU Portal to limit the number and scope of formal requests.***

Or. en

Amendment 2619
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) No 536/2014
Article 6 – paragraph 7 – (new) seventh subparagraph

Text proposed by the Commission	*Amendment*
	Requests for information and related exchanges shall be coordinated and issued by the reporting Member State through the EU portal. Prior to issuing

formal requests, the reporting Member State and the Member States concerned may seek informal clarifications with the sponsor via the EU portal to limit the number and scope of formal requests.

Or. en

Justification

Propose Inroducing greater flexibility in CTIS by enabling informal clarifications between the rMS/cMS and the sponsor before formal RFIs are issued.This is intended to reduce the number and scope of formal RFIs.

Amendment 2620
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 7 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the requested additional information, the Member State concerned ***shall*** review additional information provided by the sponsor and shall identify and share with the reporting Member State any unaddressed considerations, relevant for the application. The coordinated review shall be performed within maximum 7 days of the receipt of the additional information and the further consolidation shall be performed within maximum seven days of the end of the coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.	Upon receipt of the requested additional information, the Member State concerned ***may*** review additional information provided by the sponsor and shall identify and share with the reporting Member State any unaddressed considerations, relevant for the application. The coordinated review shall be performed within maximum 7 days of the receipt of the additional information and the further consolidation shall be performed within maximum seven days of the end of the coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.

Or. en

Amendment 2621

Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 5
Regulation (EU) 536/2014
Article 6 – Paragraph 7 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the requested additional information, the Member State concerned ***shall*** review additional information provided by the sponsor and ***shall*** identify and share with the reporting Member State any unaddressed considerations, relevant for the application. The coordinated review shall be performed within maximum 7 days of the receipt of the additional information and the further consolidation shall be performed within maximum seven days of the end of the coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.	Upon receipt of the requested additional information, the Member State concerned ***may*** review additional information provided by the sponsor and ***srreviehall*** identify and share with the reporting Member State any unaddressed considerations, relevant for the application. The coordinated review shall be performed within maximum 7 days of the receipt of the additional information and the further consolidation shall be performed within maximum seven days of the end of the coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.

Or. en

Amendment 2622
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 1a(new)

Text proposed by the Commission	*Amendment*
	(ia) For clinical trials assessed in accordance with Article 14b(1), the assessment referred to in paragraph 1 shall be carried out at Union level by the Ethical Assessment Committee of the Clinical Trials Coordination and Advisory Group (CTAG), in accordance with Article 85(5a).

Or. en

Amendment 2623
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation 536/2014
Article 7 – Paragraph 1b(new)

Text proposed by the Commission	*Amendment*
	(ib) For clinical trials assessed in accordance with Article 14b(2), the assessment referred to in paragraph 1 shall be carried out at Union level by the Voluntary Centralised Assessment Committee of the CTAG, in accordance with Article 85(5b).

Or. en

Justification

Clinical trialsinvolving orphan medicinal products (OMPs) and SPC Candidate Products are oftenscientifically complex and may target small or vulnerable patient populations.Ethical assessments conducted separately at national level may therefore lead todivergent approaches and delays in the initiation of clinical trials. To ensure a consistentlevel of ethical assessment while improving the efficiency of the authorisationprocedure, an accelerated centralised ethical assessment at Union level isestablished for clinical trials involving such products. The ethical assessmentshall be carried out by the Clinical Trials Coordination and Advisory Group(CTAG), through an Ethical Assessment Committee composed of representatives ofthe ethics committees of the concerned Member States. In addition, MemberStates may participate in a voluntary centralised assessment mechanism withinthe CTAG, enabling the Union-level assessment of Part II of clinical trialapplications where all concerned Member States elect to participate

Amendment 2624
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*

Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor.	Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2625
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*
Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor.	Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2626
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) No 536/2014
Article 7 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*

Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor.	Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2627
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*
Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor.	Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2628
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) No 536/2014
Article 7 – Paragraph 2 – second subparagraph

Text proposed by the Commission	*Amendment*

Each Member State concerned may within the period referred to in this paragraph, and through EU portal, request on duly justified grounds additional information , from the sponsor regarding the aspects covered in paragraph 1 or to request to complement the documentation, required pursuant to Part II of Annex I, if such documentation is missing or documentation provided is not adequate or is incomplete.	Each Member State concerned may within the period referred to in this paragraph, and through EU portal, request on duly justified grounds additional information , from the sponsor regarding the aspects covered in paragraph 1 or to request to complement the documentation, required pursuant to Part II of Annex I, if such documentation is missing or documentation provided is not adequate or is incomplete. ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I.***

Or. en

Amendment 2629
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – third subparagraph

Text proposed by the Commission	*Amendment*
The Member State concerned ***may decide*** within 28 days of the submission date to rely on the ethical review of the ethics committee of the reporting Member State of the common elements of the application dossier of Part II and inform the sponsor accordingly.	The Member State concerned ***shall inform the sponsor*** within 28 days of the submission date ***their intent*** to rely on the ethical review of the ethics committee of the reporting Member State of the common elements of the application dossier of Part II and inform the sponsor accordingly. ***Where such reliance is not applied, the Member State concerned shall indicate the specific national ethical aspects justifying a separate assessment.*** ***Member States, coordinated by the European Commission and in consultation with stakeholders, shall develop guidance specifying which elements of Part II constitute 'common elements' for the purposes of this paragraph, in order to promote consistency and reduce divergence in ethical assessments.***

Or. en

Justification

The provisions introducing a greater role for the Ethics Committee of the reporting Member State in the assessment of the common elements of Part II of the application aim to promote efficiency and consistency in the assessment process. In order to ensure that this objective is achieved in practice, the amended framework should clearly specify what constitutes the "common elements" of Part II.

The amended provisions should further clarify the circumstances under which such common elements are to be assessed by the Ethics Committee of the reporting Member State. Where a Member State concerned does not rely on that assessment for elements identified as common, it should be required to explicitly justify its separate assessment by reference to specific national or local ethical considerations.

Amendment 2630
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – third subparagraph

Text proposed by the Commission	*Amendment*
The Member State concerned ***may decide*** within 28 days of the submission date to rely on the ethical review ***of the ethics committee*** of the reporting Member State of the common elements of the application ***dossier of Part II*** and inform the sponsor accordingly.	The Member State concerned ***shall inform the sponsor*** within 28 days of the submission date ***their intent*** to rely on the ethical review of the reporting Member State of the common elements of ***Part II of*** the application and inform the sponsor accordingly. ***Where such reliance is not applied, the Member State concerned shall indicate the specific national ethical aspects justifying a separate assessment.***

Or. en

Amendment 2631
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 2 – third subparagraph

Text proposed by the Commission	*Amendment*
The Member State concerned ***may decide*** within 28 days of the submission date to rely on the ethical review ***of the ethics committee*** of the reporting Member State of the common elements of the application ***dossier of Part II*** and inform the sponsor accordingly.	The Member State concerned ***shall inform the sponsor*** within 28 days of the submission date ***their intent*** to rely on the ethical review of the reporting Member State of the common elements of ***Part II of*** the application and inform the sponsor accordingly. ***Where such reliance is not applied, the Member State concerned shall indicate the specific national ethical aspects justifying a separate assessment.***

Or. en

Amendment 2632
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) No 536/2014
Article 7 – Paragraph 2 – third subparagraph

Text proposed by the Commission	*Amendment*
The Member State concerned ***may decide*** within 28 days of the submission date to rely on the ethical review ***of the ethics committee*** of the reporting Member State of the common elements of the application ***dossier of Part II and inform the sponsor accordingly***.	The Member State concerned ***shall inform the sponsor*** within 28 days of the submission date ***their intent*** to rely on the ethical review of the reporting Member State of the common elements of ***Part II of*** the application***. Where such reliance is not applied, the Member State concerned shall indicate the specific national ethical aspects justifying a separate assessment***.

Or. en

Amendment 2633
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 3 – point (b)

Text proposed by the Commission	*Amendment*
(b) to align with the timeline for the assessment referred to in Article 6, ***when it*** has been extended to allow for a request for information by the reporting Member State ***related to Part I*** assessment ***and its review***.	(b) to align with the timeline for the assessment referred to in Article 6, ***where the timelines*** has been extended to allow for a request for information by the reporting Member State ***including pursuant to Article 6(6a). […]The conclusion of the*** assessment ***of Part II shall be without prejudice to the application of Article 6(6a)***.

Or. en

Amendment 2634
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) 536/2014
Article 7 – Paragraph 3 – point (b)

Text proposed by the Commission	*Amendment*
(b) to align with the timeline for the assessment referred to in Article 6, ***when it*** has been extended to allow for a request for information by the reporting Member State ***related to Part I assessment and its review***.	(b) to align with the timeline for the assessment referred to in Article 6, ***where the timeline*** has been extended to allow for a request for information by the reporting Member State ***including pursuant to Article 6(6a)***.

Or. en

Amendment 2635
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 6
Regulation (EU) No 536/2014
Article 7– paragraph 3 – (new) last subparagraph

Text proposed by the Commission	*Amendment*
	The conclusion of the assessment of Part II shall be without prejudice to the application of Article 6(6a).

Amendment 2636
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 7
Regulation (EU) No 536/2014
Article 8

Text proposed by the Commission	*Amendment*
(7) in Article 8, paragraphs 1 and 2 are replaced by the following:	***deleted***
'1.	
Each Member State concerned shall notify the sponsor through the EU portal and by way of one single decision as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused.	
The notification shall be made within five days from the reporting date or from the last day of the assessment referred to in Article 7, whichever is later.	
2.	
Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member States concerned.	
A clinical trial subject to conditions may start, unless the Member State concerned specified that the condition is suspensive. Unless otherwise specified, a fulfilment of the condition shall not require a submission of a request for a substantial modification.	
Notwithstanding the first subparagraph of this paragraph, a Member State concerned may disagree with the conclusion of the reporting Member State	

as regards Part I of the assessment report only on the following grounds, provided that the corresponding consideration was raised during the process pursuant to Article 6(5) point (b) and the Member State concerned considers that it was not sufficiently addressed:

(a) participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned; or

(b) infringement of its national law as referred to in Article 90.

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States, and to the sponsor.'

Or. en

Amendment 2637
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 7
Regulation (EU) No 536/2014
Article 8 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	Where a Member State concerned intends to refuse authorisation, it shall, prior to adopting its decision, notify the sponsor of its draft conclusion and request a written response from the sponsor for consideration prior to issuing a refusal

Or. en

Justification

Allow sponsors to get advance notice if a MS is planning to issue a refusal, with the possibility to provide response / avoid refusal

Amendment 2638
Peter Agius

Proposal for a regulation
Article 58 – paragraph 1 – point 7
Regulation (EU) No 536/2014
Article 8 – Paragraph 1a(new)

Text proposed by the Commission	*Amendment*
	1a. Each Member State concerned shall inform all other Member States, other than concerned Member States, of its decision to authorise the clinical trial. The decision shall be accompanied with relevant information to identify potential subjects to participate in the trial.

Or. en

Amendment 2639
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 7
Regulation (EU) 536/2014
Article 8 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*
Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member States concerned.	***deleted***

Or. en

Amendment 2640
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 7 a (new)

Regulation (EU) 536/2014
Article 8 – Paragraph 5

Text proposed by the Commission	*Amendment*
	(7a) in Article 8, paragraph 5 is deleted

Or. en

Amendment 2641
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 8 – introductory part

Text proposed by the Commission	*Amendment*
(8) Article 9 is replaced by the following:	(8) Article 9 is replaced by the following***, while Article 9a is added***:

Or. en

Amendment 2642
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 8
Regulation (EC) No 1394/2007
Article 9a(new)

Text proposed by the Commission	*Amendment*
	'Article 9a
	Manufacturing flexibilities for ATMPs
	1. The Commission shall, after consulting the Agency, draw up:
	(a) guidelines on the details of the various categories of variations specific to the manufacture of advanced therapy medicinal products; and
	(b) guidelines on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 specific to the manufacture of advanced therapy medicinal products

as well as the documentation to be submitted pursuant to those procedures.

2. The guidelines referred to in paragraph 1 shall supplement the guidelines adopted by the Commission pursuant to Article 4 of Commission Regulation (EC) No 1234/2008 and shall allow the manufacturers of advanced therapy medicinal products the flexibility to apply a risk-based approach to implement appropriate measures having regard to the specific characteristics of the manufacturing process and of the product.'

Or. en

Justification

The rules on variations apply to advanced therapy medicinal products as they do to all medicines. Their categories and their application, however, were calibrated for products far more stable and standardised than living cell and gene therapies. As a result, manufacturing changes that carry little genuine risk are frequently treated as major variations, requiring extensive data and prior approval before they can be implemented. Dedicated, risk-based variation guidance for advanced therapies would ensure the level of review matches the actual risk, reducing avoidable delays and helping this production base develop in Europe rather than relocate to the United States or Asia.

Amendment 2643
Kateřina Konečná

Proposal for a regulation
Article 58 – paragraph 1 – point 8
Regulation (EU) No 536/2014
Article 9, paragraph 3

Text proposed by the Commission	*Amendment*
3. At least one layperson shall participate in the assessment.	3. At least one layperson shall participate in the assessment.
	Where a clinical trial concerns a medicinal product or advanced therapy medicinal product intended for the diagnosis, prevention or treatment of a specific chronic or long-term condition, the assessment shall further include at least one person with relevant lived

experience of that condition and at least one representative of an organisation representing such persons. Where the trial enrols a paediatric population, at least one person with expertise in paediatric ethical considerations shall also participate.

Persons referred to in the second subparagraph shall be identified through national channels and, where appropriate, by reference to the lists of patient and healthcare-professional experts maintained by the Agency. They shall receive the documentation, training and administrative support necessary to participate effectively, and shall be remunerated and reimbursed for travel and subsistence on terms equivalent to those applicable to other members of the assessment.

Conflict-of-interest requirements applicable to such persons shall be applied proportionately and shall not exclude them on grounds, such as membership of a patient organisation, or routine receipt of disease-related educational support, unrelated to the specific medicinal product or trial concerned.

Or. en

Amendment 2644
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 8
Regulation (EU) No 536/2014
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. At least one layperson shall participate in the assessment.	3. At least one layperson ***and at least one patient organisation representative*** shall participate in the assessment.

Or. en

Amendment 2645
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 8
Regulation (EU) No 536/2014
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. At least one layperson shall participate in the assessment.	3. At least one layperson ***and a patient organisation representative*** shall participate in the assessment.

Or. en

Amendment 2646
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 8
Regulation (EU) No 536/2014
Article 9 – Paragraph 3a(new)

Text proposed by the Commission	*Amendment*
	3a. Where a clinical trial concerns a medicinal product or advanced therapy medicinal product intended for the diagnosis, prevention or treatment of a specific chronic or long-term condition, the assessment shall further include at least one person with relevant lived experience of that condition and at least one representative of an organisation representing such persons. Where the trial enrols a paediatric population, at least one person with expertise in paediatric ethical considerations shall also participate. Persons referred to in the second subparagraph shall be identified through national channels and, where appropriate, by reference to the lists of patient and healthcare-professional

experts maintained by the Agency. They shall receive the documentation, training and administrative support necessary to participate effectively, and shall be remunerated and reimbursed for travel and subsistence on terms equivalent to those applicable to other members of the assessment. Conflict-of-interest requirements applicable to such persons shall be applied proportionately and shall not exclude them on grounds, such as membership of a patient organisation, or routine receipt of disease-related educational support, unrelated to the specific medicinal product or trial concerned.

Or. en

Justification

Article 9(3) of Regulation (EU) No 536/2014 currently requires that at least one "layperson" participate in the assessment of a clinical trial application. In practice, "layperson" has been interpreted across Member States as a person without scientific or medical training, without further requirement of relevance to the condition under study. This formulation does not capture the distinctive value of patient experience, which derives precisely from familiarity with the condition concerned, not from the absence of medical knowledge.In trials concerning chronic and long-term conditions, including the cell therapy trials for type 1 diabetes that this Regulation explicitly prioritises, the perspective of a person who manages the condition daily, and of organisations representing such persons, cannot be replicated by a generic layperson.

Amendment 2647
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In Article 10, paragraph 1 is replaced by the following:
	Where the subjects are minors, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of paediatric expertise or after taking advice on clinical, ethical and

psychosocial problems in the field of paediatrics. Where a paediatric patient requires participation in a clinical trial not available in the Member State of affiliation, the authorisation shall be subject to a shortened timeline, reflecting the time-criticality of the paediatric therapeutic window. The continuity of care of a paediatric patient shall be guaranteed through shared-care protocols. The reimbursement coordination frameworks shall extend to reasonable travel, accommodation and subsistence costs of at least one accompanying parent or legal guardian per paediatric patient, and shall address the practical consequences of family separation. The Commission shall, by means of implementing acts, establish the criteria for such costs and the modalities of their allocation between the Member State of affiliation and the Member State where the clinical trial is being administered.

Or. en

Amendment 2648
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 10
Regulation (EU) No 536/2014
Article 11– paragraph 2

Text proposed by the Commission	*Amendment*
2. When the sponsor submits a substantial modification of Part I of the application dossier with regard to clinical trial that is subject to a request referred to in paragraph 1 and has been authorised or authorised subject to conditions by at least one Member State concerned, ***all*** Member ***States concerned that received the initial application shall participate in the assessment of that*** substantial modification in accordance with Article 18 or 22 ***as***	2. When the sponsor submits a substantial modification of Part I of the application dossier with regard to clinical trial that is subject to a request referred to in paragraph 1 and has been authorised or authorised subject to conditions by at least one Member State concerned, ***the reporting*** Member ***State will assess the*** substantial modification in accordance with article 18 or 22.

appropriate.

Or. en

Amendment 2649
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point a
Regulation (EU) 536/2014
Article 14 – Paragraph 1 – first subparagraph

Text proposed by the Commission	*Amendment*
Where the sponsor wishes to extend an authorised clinical trial to another Member State (additional Member State concerned), the sponsor shall submit an application dossier to that Member State through the EU portal.	Where the sponsor wishes to extend an authorised clinical trial to another Member State (additional Member State concerned), the sponsor shall submit ***to the extent necessary*** an application dossier to that Member State through the EU portal. ***The original Part I submission and common elements of Part II submission may be cross referred to.***

Or. en

Amendment 2650
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point a
Regulation (EU) 536/2014
Article 14 – Paragraph 1 – first subparagraph

Text proposed by the Commission	*Amendment*
Where the sponsor wishes to extend an authorised clinical trial to another Member State (additional Member State concerned), the sponsor shall submit an application dossier to that Member State through the EU portal.	Where the sponsor wishes to extend an authorised clinical trial to another Member State (additional Member State concerned), the sponsor shall submit ***to the extent necessary*** an application dossier to that Member State through the EU portal. ***The original Part I submission and common elements of Part II submission may be cross referred to.***

Or. en

Amendment 2651
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point b
Regulation (EU) 536/2014
Article 14 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The additional Member State concerned shall notify the sponsor, through the EU portal, within ***47*** days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned.	3. The additional Member State concerned shall notify the sponsor, through the EU portal, within ***42*** days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned***, in particular regarding Part I of the application***.

Or. en

Amendment 2652
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point b
Regulation (EU) 536/2014
Article 14 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The additional Member State concerned shall notify the sponsor, through the EU portal, within 47 days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to	3. The additional Member State concerned shall notify the sponsor, through the EU portal, within 47 days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to

conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned.	conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned***, in particular regarding Part I of the application***.

Or. en

Amendment 2653
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point b
Regulation (EU) No 536/2014
Article 14 paragraph 3

Text proposed by the Commission	*Amendment*
3. The additional Member State concerned shall notify the sponsor, through the EU portal, within ***47*** days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned.	3. The additional Member State concerned shall notify the sponsor, through the EU portal, within ***42*** days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned.

Or. en

Amendment 2654
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) No 536/2014
Article 14– paragraph 6 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other	Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other

Member States concerned ***shall*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application***. The coordinated review shall be performed within a maximum of seven days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review.*** The reporting Member State ***shall take due account of the considerations of the Member States concerned and shall record how the considerations have been dealt with***.	Member States concerned ***may*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application ***to*** the reporting Member State ***through the EU portal***.

Or. en

Amendment 2655
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) 536/2014
Article 14– paragraph 6 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other Member States concerned ***shall*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application***. The coordinated review shall be performed within a maximum of seven days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review.*** The reporting Member State ***shall take due account of the considerations of the Member States concerned and shall record how the***	Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other Member States concerned ***may*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application ***to*** the reporting Member State ***through the EU portal***.

considerations have been dealt with.

Or. en

Amendment 2656
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) 536/2014
Article 14– paragraph 6 – fourth subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other Member States concerned ***shall*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application. The coordinated review shall be performed within a maximum of seven days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. The reporting Member State shall take due account of the considerations of the Member States concerned and shall record how the considerations have been dealt with.	Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other Member States concerned ***may*** review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application ***to the reporting Member State through the EU portal***. The coordinated review shall be performed within a maximum of seven days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. The reporting Member State shall take due account of the considerations of the Member States concerned and shall record how the considerations have been dealt with.

Or. en

Amendment 2657
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) 536/2014
Article 14– paragraph 7 – second subparagraph

Text proposed by the Commission	*Amendment*
Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***as far as its territory is concerned****.**'***	Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I****.*

Or. en

Amendment 2658
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation 536/2014
Article 14– paragraph 7 – second subparagraph

Text proposed by the Commission	*Amendment*
Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***as far as its territory is concerned***.'	Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I.*** .'

Or. en

Justification

The current wording does not explicitly prevent parallel assessment of Part I aspects by other Member States. In practice, this has resulted in duplication and inconsistent requests. This amendment makes clear that aspects covered by Part I are assessed by the reporting Member State, while preserving Member State competence for national or local ethical aspects under Part II, thereby improving consistency and efficiency without altering the balance of competences.

Amendment 2659
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) 536/2014
Article 14– paragraph 7 – second subparagraph

Text proposed by the Commission	*Amendment*
Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***as far as its territory is concerned***.***'***	Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2660
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point e
Regulation (EU) No 536/2014
Article 14– paragraph 7 – second subparagraph

Text proposed by the Commission	*Amendment*
Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***as far as its territory is concerned***.***'***	Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional information from the sponsor regarding aspects covered in Part II of the assessment report ***provided that such requests are limited to national, local or site-specific aspects and do not duplicate information already assessed under Part I***.

Or. en

Amendment 2661
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point g
Regulation (EU) 536/2014
Article 14 – paragraph 12

Text proposed by the Commission	*Amendment*
12. A sponsor ***shall not*** submit an application dossier in accordance with this Article ***where*** a procedure for a substantial modification of Part I of the assessment report***,*** set out in Chapter III***, is pending as regards that clinical trial***.	12. A sponsor ***may*** submit an application dossier in accordance with this Article ***notwithstanding that*** a procedure for a substantial modification of Part I of the assessment report set out in Chapter III ***is ongoing. The assessment and decision concerning the additional Member State concerned shall be based on the most recent final Part I assessment report in force at the reporting date. Where no such final report is available, the reporting Member State may align the timelines of the procedures accordingly.***

Or. en

Amendment 2662
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point g
Regulation 536/2014
Article 14 – paragraph 12

Text proposed by the Commission	*Amendment*
12. A sponsor ***shall not*** submit an application dossier in accordance with this Article ***where*** a procedure for a substantial modification of Part I of the assessment report***,*** set out in Chapter III***, is pending as regards that clinical trial***.	12. A sponsor ***may*** submit an application dossier in accordance with this Article ***notwithstanding that*** a procedure for a substantial modification of Part I of the assessment report set out in Chapter III ***is ongoing. The assessment and decision concerning the additional Member State concerned shall be based on the most recent final Part I assessment report in force at the reporting date. Where no such final report is available, the reporting Member State may align the timelines of***

the procedures accordingly.

Or. en

Justification

The current prohibition prevents sponsors from submitting applications to additional Member States while a substantial modification is ongoing, creating unnecessary delays and operational constraints. This amendment allows parallel submission while ensuring that the assessment relies on the latest final Part I assessment report at the time of decision, thereby preserving regulatory integrity and patient safety. It improves flexibility and efficiency without undermining coordinated oversight or Member State competence.

Amendment 2663
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 11 – point g
Regulation (EU) 536/2014
Article 14 – paragraph 12

Text proposed by the Commission	*Amendment*
12. A sponsor ***shall not*** submit an application dossier in accordance with this Article ***where*** a procedure for a substantial modification of Part I of the assessment report***,*** set out in Chapter III***, is pending as regards that clinical trial***.	12. A sponsor ***may*** submit an application dossier in accordance with this Article ***notwithstanding that*** a procedure for a substantial modification of Part I of the assessment report set out in Chapter III ***is ongoing. The assessment and decision concerning the additional Member State concerned shall be based on the most recent final Part I assessment report in force at the reporting date***. ***Where no such final report is available, the reporting Member State may align the timelines of the procedures accordingly.***

Or. en

Amendment 2664
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 12
Regulation (EU) 536/2014
Article 14a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).	4. ***For clinical trials involving more than one Member State, the sponsor shall propose one of the Member States concerned as the new reporting Member State.*** The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).

Or. en

Amendment 2665
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 12
Regulation (EU) 536/2014
Article 14a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).	4. ***For clinical trials involving more than one Member State, the sponsor shall propose one of the Member States concerned as the new reporting Member State.*** The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).***”***

Or. en

Amendment 2666
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 12
Regulation (EU) 536/2014
Article 14a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).	4. ***For clinical trials involving more than one Member State, the sponsor shall propose one of the Member States concerned as the new reporting Member State.*** The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).

Or. en

Justification

As currently drafted, there is no process for the sponsor to identify a new reporting Member State during ongoing trials from the pool of existing Member States concerned.

Amendment 2667
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) Article 14aa
	Accelerated assessment of clinical trials concerning orphan medicinal products
	1. Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 human use], the application shall be assessed in accordance with the accelerated procedure set out in this Article.
	2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier and each Member State concerned shall validate Part II of the application dossier for its territory within five days from the submission date.

3. Where the reporting Member State or a Member State concerned has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete and the validation date shall be the last day of that period.

4. Where the reporting Member State or a Member State concerned finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for the sponsor to complete the application dossier. The reporting Member State or the Member State concerned, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.

5. The reporting Member State shall assess Part I of the application dossier and each Member State concerned shall assess Part II of the application dossier for its territory within 26 days from the submission date.

6. The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be the conclusion of the Member States concerned, unless a Member State concerned raises considerations on one of the grounds referred to in Article 8(2).

7. Within 21 days from the submission date, each Member State concerned shall notify through the EU portal whether, for the purposes of Part II of the assessment report, it intends to rely on the assessment of the reporting Member State for common elements of the application dossier or to provide input concerning aspects specific to its territory.

8. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the

assessment report within 33 days from the submission date.

9. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

10. Upon receipt of the additional information, the reporting Member State and the Member States concerned, as applicable, shall review the additional information within a maximum of seven days. The reporting Member State shall finalise Part I of the assessment report and each Member State concerned shall complete Part II of the assessment report within a maximum of seven days from the end of that review.

11. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

12. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

13. By [OP please insert the date = 3 years from the date of application] the Commission shall present a report to the European Parliament, the Council, and the Clinical Trials Coordination and Advisory Group on the application of this Article. The report shall assess the impact of this procedure on clinical trial initiation timelines, sponsor behaviour and patient access. The Commission shall, if appropriate, present legislative proposals based on that evaluation to

expand, amend or delete this Article.

Or. en

Amendment 2668
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Chapter IIa

Text proposed by the Commission	*Amendment*
	Accelerated assessment of clinical trials concerning orphan drug designated medicinal product
	1. Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 Regulation (EU) …/… on medicinal products for human use], the application, at the request of the sponsor, may be assessed in accordance with the accelerated procedure set out in this Article.
	2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier and each Member State concerned shall validate Part II of the application dossier for its territory within five days from the submission date.
	3. Where the reporting Member State or a Member State concerned has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete and the validation date shall be the last day of that period.
	4. Where the reporting Member State or a Member State concerned finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for

the sponsor to complete the application dossier. The reporting Member State or the Member State concerned, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.

5. The reporting Member State shall assess Part I of the application dossier and each Member State concerned shall assess Part II of the application dossier for its territory within 26 days from the submission date.

6. The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be the conclusion of the Member States concerned, unless a Member State concerned raises considerations on one of the grounds referred to in Article 8(2).

7. Within 21 days from the submission date, each Member State concerned shall notify through the EU portal whether, for the purposes of Part II of the assessment report, it intends to rely on the assessment of the reporting Member State for common elements of the application dossier or to provide input concerning aspects specific to its territory.

8. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the assessment report within 33 days from the submission date.

9. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

10. Upon receipt of the additional information, the reporting Member State

and the Member States concerned, as applicable, shall review the additional information within a maximum of seven days. The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase as referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within a maximum of seven days from the end of that review.

11. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

12. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

13. By [OP please insert the date = 3 years from the date of application] the Commission shall present a report to the European Parliament, the Council, and Clinical Trials Coordination and Advisory Group on the application of this Article. This report shall be based, among others, on the information provided by the RMSs and sponsors regarding the impact of the accelerated procedure on the initiation of clinical trials. The Commission shall, if appropriate, present legislative proposals based on that evaluation to expand, amend, or delete this Article.

Or. en

Amendment 2669
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk,

Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen, Peter Liese, Tomislav Sokol

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14ba (new)

Text proposed by the Commission	*Amendment*
	Article 14ba
	Accelerated procedure for the authorisation of early-stage clinical trials
	1. Member States shall apply an accelerated procedure for the authorisation of multinational Early-Stage Clinical Trials.
	2. For the purposes of this Regulation, an Early-Stage Clinical Trial shall mean a clinical trial intended to generate initial clinical evidence on the safety, tolerability, pharmacokinetics, pharmacodynamics or preliminary efficacy of an investigational medicinal product, including:
	(a) first-in-human clinical trials;
	(b) single ascending dose studies;
	(c) multiple ascending dose studies;
	(d) proof-of-concept clinical trials;
	(e) other early phase clinical trials as specified by the Commission through delegated acts.
	3. The accelerated procedure shall apply where:
	(a) the clinical trial is conducted in at least two Member States;
	(b) the investigational medicinal product is intended for the treatment, prevention or diagnosis of a serious or life-threatening disease, or is based on an innovative technology platform, including biotechnology, advanced therapy medicinal products, gene therapies, cell therapies, RNA-based medicines or artificial intelligence-enabled medicinal

products or is developed using model-informed drug development approaches, including computational modelling, simulation and digital twin technologies

(c) the anticipated risks are proportionate to the objectives of the study and appropriate safeguards for participants are in place.

4. The Clinical Trials Expert Committee shall coordinate a single scientific assessment on behalf of all concerned Member States.

5. The assessment referred to in paragraph 4 shall be completed within 20 days from validation of the application. Requests for additional information shall be limited to issues essential for participant safety or scientific validity.

6.Concerned Member States shall ensure that ethical review is integrated into the accelerated procedure and completed within the timelines referred to in paragraph 5.

7. The Commission shall adopt delegated acts to establish detailed criteria for eligibility and proportionate documentation requirements.

Or. en

Amendment 2670
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation 536/2014
Article 14b – Paragraph 1a(new)

Text proposed by the Commission	*Amendment*
	1a. 1. Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 Regulation (EU) …/… on medicinal products for human use] or an SPC Candidate Product, the application,

at the request of the sponsor, may be assessed in accordance with the accelerated centralized procedure set out in this Article

2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier. Validation of Part II shall be carried out by the representatives of the concerned Member States of the Ethical Assessment Committee, in accordance with Article 85 within five days of submission.

3. The Agency shall provide guidance for sponsors and reporting Member States for making a determination on an SPC Candidate Product.

4. Where the reporting Member State or the Ethical Assessment Committee has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete.

5. Where the reporting Member State or the Ethical Assessment Committee finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for the sponsor to complete the application dossier. The reporting Member State or the Ethical Assessment Committee, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.

6. The reporting Member State shall assess Part I of the application dossier and prepare a draft Part I assessment report. The ethics committee of the reporting Member State shall review, from the ethical perspective, aspects covered by Part I of the assessment report according with Article 6(2). The draft report shall be circulated to the concerned Member States within 15 days from the submission date. The concerned Member

States shall provide their considerations within five days of receipt of the draft report. The reporting Member State shall take due account of those considerations and shall finalise Part I of the assessment report within 26 days from the submission date.

7. The Ethical Assessment Committee shall assess Part II of the application dossier within 26 days from the submission date. The representative of the reporting Member State on the Ethical Assessment Committee shall act as lead assessor (hereinafter referred to as the "lead assessor"). The representatives of the concerned Member States sitting on the Ethical Assessment Committee shall carry out the assessment of the aspects referred to in Article 7(1) for their respective territories and shall submit their assessment to the leas assessor within 15 days from the submission date. The concerned Member States shall rely on the ethical review carried out by the ethics committee of the reporting Member State in respect of the common elements of Part II of the application dossier.

8. The lead assessor shall consolidate those assessments into a single Part II assessment report within 26 days from submission. The Ethical Assessment Committee shall issue that report, reflecting the opinions expressed by the representatives of the concerned Member States. Where divergent views remain, those views shall be recorded in the report. The single Part II assessment report shall constitute Part II assessment for all concerned Member States participating in the procedure.

9. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and the Ethical Assessment Committee shall complete Part II of the assessment report within 27 days from the submission date. The Ethical Assessment Committee shall issue

a single Part II assessment report reflecting the opinions expressed by the representatives of the Member States concerned. 10. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within seven days from receipt of the request. For Part II, additional information may be requested only on duly justified grounds relating to the aspects referred to in Article 7(1), including where the information submitted is incomplete, inaccurate, inconsistent or insufficient to permit completion of the ethical assessment. Such requests shall not duplicate information already assessed under Part .

11. Upon receipt of the additional information, the reporting Member State and the Ethical Assessment Committee, as applicable, shall review that information within a maximum of seven days. Within that period, the reporting Member State shall finalise Part I of the assessment report and the Ethical Assessment Committee shall complete Part II of the assessment report. The Ethical Assessment Committee shall issue a single Part II assessment report reflecting the opinions expressed by the representatives of the concerned Member States.

12. The reporting Member State shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within one day from the reporting date or from the completion of the assessment, whichever is later.

Or. en

Justification

The proposed accelerated centralised procedure allows sponsors of clinical trials involving an orphan-designated investigational medicinal product and an SPC candidate product to request a streamlined assessment. Under this procedure, the reporting Member State

validates and assesses Part I of the application dossier, while Part II is assessed through the Ethical Assessment Committee composed of representatives of the concerned Member States. Part I assessment runs as defined in Article 6. For Part II cach concerned Member State representative performs the ethical assessment for its own territory in relation to the aspects listed in Article 7(1). The representatives of the reporting Member State act as lead assessor and co-assessor and consolidate those national assessments into a single Part II assessment report. The Ethical Assessment Committee then issues a single Union-level Part II assessment report reflecting the views of the concerned Member States and recording any remaining divergent views. That report constitutes the Part II assessment for all concerned Member States participating in the procedure.

Where additional information is required, requests may be made only on justified grounds relating to Part II aspects and without duplicating matters already assessed under Part I. Following completion of Parts I and II, the reporting Member State adopts and notifies a single decision on the clinical trial through the EU portal.

Amendment 2671
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation 536/2014
Article 14b – Paragraph 2a(new)

Text proposed by the Commission	*Amendment*
	1b. 1. Where a clinical trial is conducted exclusively in Member States represented in the Voluntary Centralised Assessment Committee referred to in Article 85(5b), the sponsor may request that Part I and Part II of the application dossier be assessed at Union level in accordance with this paragraph.
	2. The Voluntary Centralised Assessment Committee shall validate Parts I and II of the application dossier within five days from the submission date
	3. Where the Voluntary Centralised Assessment Committee has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete.
	4. Where the Voluntary Centralised Assessment Committee finds that the relevant part of the application dossier is

not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for the sponsor to complete the application dossier. The Voluntary Centralised Assessment Committee as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.

5. For each application, a sponsor shall propose one of the Member States concerned within the Voluntary Centralised Assessment Committee as a lead assessment panel, in accordance with the process set out in Article 5. The lead assessment panel (hereinafter referred to as the "lead assessor"), shall consist of no more than ten experts designated by the concerned Member States. The lead assessor shall perform the tasks assigned to them under this Regulation.

6. The lead assessor shall coordinate the assessment of Parts I and II of the application dossier and prepare the draft assessment reports for consideration by the Committee

7. The lead assessor shall carry out the assessment of the aspects referred to in Article 6 and shall prepare a draft Part I assessment report. The lead assessor shall review, from an ethical perspective, the aspects covered by Part I of the assessment report in accordance with Article 6(2).

8. The draft Part I assessment report shall be circulated by the lead assessor to the representatives of the concerned Member States within 15 days from submission. Representatives may submit considerations within five days of circulation of the draft report. Considerations may be submitted only on duly justified grounds relating to significant scientific concern, or information likely to affect the benefit-risk assessment of the clinical trial.

9. The lead assessor shall take due account of any considerations submitted in accordance with paragraph 8 and shall prepare the final Part I assessment report within 26 days.

10. The Voluntary Centralised Assessment Committee shall issue the final Part I assessment report. That report shall constitute the Part I assessment for all concerned Member States.

11. The representatives of the concerned Member States with expertise in ethical review and assessment of clinical trials shall carry out the assessment of the aspects referred to in Article 7(1) for their respective Member States.

12. The representatives of the concerned Member States referred to in paragraph 11 shall submit their assessments to the lead assessor within 15 days from the submission date. The representatives from concerned Member States shall rely on the ethical review carried out by the ethics committee of the lead assessor in respect of the common elements of Part II of the application dossier.

13. The lead assessor shall consolidate those assessments into a single Part II assessment report within 26 days from the submission date.

14. The Voluntary Centralised Assessment Committee shall issue a single Part II assessment report reflecting the opinions expressed by the representatives of the concerned Member States. Where divergent views remain, those views shall be recorded in the report. That report shall constitute the Part II assessment for all Member States participating in the procedure.

15. The Voluntary Centralised Assessment Committee may request additional information from the sponsor only on duly justified grounds relating to the aspects referred to in Articles 6 and 7. Requests relating to Part I shall be limited to matters affecting the scientific validity,

quality, safety or benefit-risk assessment of the clinical trial. Requests relating to Part II shall be limited to the aspects referred to in Article 7(1). Such requests shall be proportionate and shall not duplicate information already assessed during the procedure.

16. The sponsor shall submit any additional information requested pursuant to paragraph 15 within seven days from receipt of the request. Where the sponsor fails to provide the requested information within that period, the application shall be deemed to have lapsed.

17. Upon receipt of the additional information, the lead assessor shall review that information and update the draft Part I assessment report and the draft Part II assessment report, as applicable. The Voluntary Centralised Assessment Committee shall issue the final Part I assessment report and the final Part II assessment report within seven days of receipt of the additional information.

18. The Member State of the lead assessor shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within one days from the completion of the assessment.

Or. en

Justification

These amendments establish a centralised ethicsassessment pathway within CTAG.

Amendment 2672
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014

Article 14b – paragraph 2

Text proposed by the Commission	*Amendment*
2. To address an emergence or development of a serious cross-border threat to health as defined in Article 3(1) of Regulation 2022/2371 that is likely to lead to the recognition of a public health emergency at Union level in accordance with Article 23(1) of Regulation (EU) 2022/2371, Member States shall apply an accelerated procedure for the authorisation of multinational clinical trials when this procedure is declared applicable in accordance with the criteria in paragraph 3 of this Article. The application of the accelerated procedure shall ensure the availability of medicinal products in order to prevent or swiftly contain the emerging serious cross-border health threat, to provide timely treatment options grounded in scientifically robust evidence or to facilitate medical diagnosis of the disease or condition directly related to the specific serious cross-border health threat.	***deleted***

Or. en

Amendment 2673
Ingeborg Ter Laak

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14b – paragraph 3a(new)

Text proposed by the Commission	*Amendment*
	3a. Where, due to the scale or urgency of a public health emergency at Union level or a serious cross-border threat to health referred to in paragraph 1, points (a) and (b), or where the number of eligible applications exceeds the assessment capacity available within the applicable timelines, applications falling

under paragraph 1, points (a) and (b), shall be assessed as a matter of priority over other applications, to the extent necessary and proportionate to ensure the timely assessment of clinical trials addressing such emergencies or threats. The Member States and the Agency shall, within their respective responsibilities, cooperate to organise the assessment process so as to ensure the effective implementation of this accelerated procedure during such emergencies and threats.

Or. en

Justification

This amendment establishes a proportionate prioritization mechanism where assessment capacity is constrained. It ensures that clinical trials addressing public health emergencies or serious cross-border health threats are assessed without delay, while preserving the accelerated procedure for other eligible applications and strengthening preparedness for future health crises.

Amendment 2674
Ingeborg Ter Laak

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14b a (new) – paragraph 4a(new)

Text proposed by the Commission	*Amendment*
	4a. Applications falling under paragraph 1, points (a) and (b), shall be subject to the following timelines: validation within five days of submission (with one request to complete an incomplete dossier within five days, and validation within three days of receipt); a draft Part I assessment report within 25 days of validation; considerations from Member States concerned within 15 days of validation; completion of Part II within 25 days of validation; and notification of the Part I conclusion and of each national decision within five days of completion.

Where further information on Part I is needed, the reporting Member State or Rapporteur shall issue a single consolidated request through the EU portal, replacing separate national requests on the same issues; the sponsor shall reply within ten days and the assessment shall be completed within ten days of receipt.

Or. en

Justification

This amendment establishes dedicated timelines for clinical trials addressing public health emergencies and serious cross-border health threats. It ensures the fastest possible assessment where rapid action is essential to protect public health, while maintaining a coordinated and efficient assessment procedure across Member States.

Amendment 2675
Ingeborg Ter Laak

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14b – paragraph 4b (new)

Text proposed by the Commission	*Amendment*
	4b. Applications falling under paragraph 1, points (c) and (d), shall be subject to the following timelines: validation within seven days of submission (with one request to complete an incomplete dossier within seven days, and validation within three days of receipt); a draft Part I assessment report within 35 days of validation; considerations from Member States concerned within 30 days of validation; completion of Part II within 35 days of validation; and notification of the Part I conclusion and of each national decision within five days of completion. Where further information on Part I is needed, the reporting Member State or Rapporteur shall issue a single consolidated request through the EU portal, replacing separate

national requests on the same issues; the sponsor shall reply within ten days and the assessment shall be completed within ten days of receipt.

Or. en

Justification

This amendment introduces proportionate timelines for clinical trials addressing rare diseases and critical medicinal products. It recognizes their strategic importance while distinguishing them from public health emergencies, ensuring faster assessment than the standard procedure without compromising the priority given to urgent public health needs.

Amendment 2676
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14b – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall adopt delegated acts in accordance with Article 89 to supplement this Regulation by setting out the procedures for an accelerated authorisation of multinational clinical trials, including timelines, criteria for evaluating whether a clinical trial qualifies for an accelerated procedure and an integrated ethical review, and by laying down simplified requirements for the application dossier.	5. The Commission shall adopt delegated acts in accordance with Article 89 to supplement this Regulation by setting out the procedures for an accelerated authorisation of multinational clinical trials, including timelines, criteria for evaluating whether a clinical trial qualifies for an accelerated procedure and an integrated ethical review, and by laying down simplified requirements for the application dossier. ***Such delegated acts shall not reduce standards of informed consent, ethical review, patient safety, pharmacovigilance, adverse-event reporting, data protection, transparency, liability or judicial protection. Trial protocols, assessment summaries, conflicts of interest and non-confidential safety information shall be made public without delay. Accelerated procedures shall not be used to override, bypass or unduly influence the independent ethical review of an ethics committee.***

Or. en

Amendment 2677
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14 ba(new)

Text proposed by the Commission	*Amendment*
	5a. Article 14 ba (new)
	In support of the accelerated procedure established under this Article, the Agency shall act as the single Union scientific coordination authority for innovative technologies and therapeutic combination products for areas of special needs, providing a single point of entry for sponsors and maintaining a Union-level real-world evidence repository interoperable with the European Health Data Space and European Reference Network registries. Sponsors of trials authorised under this Article shall benefit from targeted incentives including accelerated assessment with a maximum timeline of 30 days for multinational trial authorisations, full or partial fee waivers for academic sponsors, university hospitals, European Reference Networks acting as sponsor or co-sponsor, and small and medium-sized enterprises, priority scientific advice with binding effect available free of charge to non-profit sponsors, and access to Union research infrastructure including biobanks and the European Health Data Space; transparent pricing obligations, non-exclusive licences for cross-border procurement and priority access conditions.

Or. en

Amendment 2678
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14c – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Article applies to combined studies in which a clinical trial is combined with a performance study of an in vitro diagnostic medical device that is subject to authorisation pursuant to Article 58(1) of Regulation (EU) 2017/746, or is combined with a clinical investigation of a medical device that is subject to authorisation according to Article 62 of Regulation (EU) 2017/745.	1. This Article applies to combined studies in which a clinical trial is combined with a performance study of an in vitro diagnostic medical device***, including companion diagnostics where applicable,*** that is subject to authorisation pursuant to Article 58(1) of Regulation (EU) 2017/746, or is combined with a clinical investigation of a medical device that is subject to authorisation according to Article 62 of Regulation (EU) 2017/745.

Or. en

Justification

Clarifies that companion diagnostics, where applicable, fall within the scope of combined studies, supporting integrated development of medicinal products and diagnostics while maintaining consistency with Regulations (EU) 2017/745 and (EU) 2017/746.

Amendment 2679
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14 d a(new)

Text proposed by the Commission	*Amendment*
	1a. 1.Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 Regulation (EU) …/… on medicinal products for human use], the application, at the request of the sponsor, may be assessed in accordance with the accelerated procedure set out in this

Article

2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier and each Member State concerned shall validate Part II of the application dossier for its territory within five days from the submission date.

3. Where the reporting Member State or a Member State concerned has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete and the validation date shall be the last day of that period.

4. Where the reporting Member State or a Member State concerned finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for the sponsor to complete the application dossier. The reporting Member State or the Member State concerned, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.

5. The reporting Member State shall assess Part I of the application dossier and each Member State concerned shall assess Part II of the application dossier for its territory within 26 days from the submission date.

6. The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be the conclusion of the Member States concerned, unless a Member State concerned raises considerations on one of the grounds referred to in Article 8(2).

7. Within 21 days from the submission date, each Member State concerned shall notify through the EU portal whether, for the purposes of Part II of the assessment report, it intends to rely on the assessment

of the reporting Member State for common elements of the application dossier or to provide input concerning aspects specific to its territory.

8. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the assessment report within 33 days from the submission date.

9. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

10. Upon receipt of the additional information, the reporting Member State and the Member States concerned, as applicable, shall review the additional information within a maximum of seven days. The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase as referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within a maximum of seven days from the end of that review.

11. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

12. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

13. By [OP please insert the date = 5 years

from the date of application] the Commission shall present a report to the European Parliament, the Council, and Clinical Trials Coordination and Advisory Group on the application of this Article. This report shall be based, among others, on the information provided by the RMSs and sponsors regarding the impact of the accelerated procedure on the initiation of clinical trials. The Commission shall, if appropriate, present legislative proposals based on that evaluation to expand, amend, or delete this Article.

Or. en

Amendment 2680
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14c – paragraph 3

Text proposed by the Commission	*Amendment*
3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating sponsor.	3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating sponsor. ***The coordinated assessment procedure shall seek to minimise unnecessary administrative duplication between the applicable Union regulatory frameworks while maintaining the respective requirements of this Regulation, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.***

Or. en

Justification

Strengthens coordination of the assessment of combined studies by reducing unnecessary administrative duplication between the applicable Union regulatory frameworks, while preserving the respective requirements and safeguards established under Regulation (EU) No 536/2014, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Amendment 2681
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 3

Text proposed by the Commission	*Amendment*
3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating ***sponsor***.	3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating ***applicant***.

Or. en

Amendment 2682
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 3

Text proposed by the Commission	*Amendment*
3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating ***sponsor***.	3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating ***applicant***.

Or. en

Amendment 2683
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 4

Text proposed by the Commission	*Amendment*
4. The Member States concerned shall assess the single application by means of a coordinated assessment procedure under the direction of ***a*** reporting Member State chosen from among the Member States concerned. If a combined study involves only one Member State, that Member State shall be the reporting Member State.	4. The Member States concerned shall assess the single application by means of a coordinated assessment procedure under the direction of ***one single*** reporting Member State chosen from among the Member States concerned. If a combined study involves only one Member State, that Member State shall be the reporting Member State.

Or. en

Amendment 2684
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 4

Text proposed by the Commission	*Amendment*
4. The Member States concerned shall assess the single application by means of a coordinated assessment procedure under the direction of a reporting Member State chosen from among the Member States concerned. If a combined study involves only one Member State, that Member State shall be the reporting Member State.	4. The Member States concerned shall assess the single application by means of a coordinated assessment procedure under the direction of a ***one single*** reporting Member State chosen from among the Member States concerned. If a combined study involves only one Member State, that Member State shall be the reporting Member State.

Or. en

Amendment 2685
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 5 – point (a)

Text proposed by the Commission	*Amendment*
(a) the grounds referred to in Article ***14a(5)*** of this Regulation, Article 78(8) of Regulation (EU) ***2017/746*** or Article 74(8) of Regulation (EU) ***2017/745; or***	(a) the grounds referred to in Article ***8(2)*** of this Regulation, Article 78(8) of Regulation (EU) ***2017/7465*** or Article 74(8) of Regulation (EU) ***2017/7456; or*** ***(b) issues that would lead to ethics committee of the Member State concerned issuing a negative opinion.***

Or. en

Amendment 2686
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 5 – point (a)

Text proposed by the Commission	*Amendment*
(a) the grounds referred to in Article ***14a(5)*** of this Regulation, Article 78(8) of Regulation (EU) ***2017/746*** or Article 74(8) of Regulation (EU) ***2017/745***; or	(a) the grounds referred to in Article ***82(2)*** of this Regulation, Article 78(8) of Regulation (EU) ***2017/745*** or Article 74(8) of Regulation (EU) ***2017/746***; or

Or. en

Amendment 2687
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 5 – point (b)

Text proposed by the Commission	*Amendment*
(b) issues that would lead to ethics committee of the Member State concerned issuing a negative opinion.	(b) issues that would lead to ethics committee of the Member State concerned issuing a negative opinion. ***For combined studies, where the medical device presents only minimal risks to subjects, the sponsor shall apply, as part of the clinical trial application under the coordinated assessment procedure, a risk-based evaluation supported by evidence to determine the extent of the clinical investigation application or performance study application documentation required to ensure patient safety, in accordance with criteria to be further specified pursuant to paragraph 9 and without prejudice to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.***

Or. en

Amendment 2688
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c– Paragraph 5 – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) For combined studies, where the medical device presents only minimal risks to subjects, the sponsor shall apply, as part of the clinical trial application under the coordinated assessment procedure, a risk-based evaluation supported by evidence to determine the extent of the clinical investigation application or performance study application documentation required to ensure patient safety, in accordance with criteria to be further specified pursuant to paragraph 9 and without prejudice to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Or. en

Amendment 2689
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14(c) new– paragraph 5a new

Text proposed by the Commission	*Amendment*
	5a. For combined studies, where the medical device presents only minimal risks to subjects, the sponsor shall apply, as part of the clinical trial application under the coordinated assessment procedure, a risk-based evaluation supported by evidence to determine the extent of the clinical investigation application or performance study application documentation required to ensure patient safety, in accordance with criteria to be further specified pursuant to paragraph 9 and without prejudice to Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Or. en

Amendment 2690
Peter Agius

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14c – Paragraph 6 – point (ca)new

Text proposed by the Commission	*Amendment*
	(ca) considerations as regards data reliability and robustness submitted

Or. en

Amendment 2691
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c – Paragraph 7

Text proposed by the Commission	*Amendment*
7. Where a Member State concerned disagrees with the conclusion on the basis of paragraph 5, it shall communicate its disagreement, together with a detailed justification, through the EU Portal, to the Commission, to all other Member States concerned, and to the coordinating ***sponsor*** referred to in paragraph 2.	7. Where a Member State concerned disagrees with the conclusion on the basis of paragraph 5, it shall communicate its disagreement, together with a detailed justification, through the EU Portal, to the Commission, to all other Member States concerned, and to the coordinating ***applicant*** referred to in paragraph 2.

Or. en

Amendment 2692
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c – Paragraph 7

Text proposed by the Commission	*Amendment*
7. Where a Member State concerned disagrees with the conclusion on the basis of paragraph 5, it shall communicate its disagreement, together with a detailed justification, through the EU Portal, to the Commission, to all other Member States concerned, and to the coordinating ***sponsor*** referred to in paragraph 2.	7. Where a Member State concerned disagrees with the conclusion on the basis of paragraph 5, it shall communicate its disagreement, together with a detailed justification, through the EU Portal, to the Commission, to all other Member States concerned, and to the coordinating ***applicant*** referred to in paragraph 2.

Or. en

Amendment 2693
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation

Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c – Paragraph 8

Text proposed by the Commission	*Amendment*
8. Each Member State concerned shall issue a single decision as to whether the combined study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused and shall notify the coordinating ***sponsor*** referred to in paragraph 2.	8. Each Member State concerned shall issue a single decision as to whether the combined study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused and shall notify the coordinating ***applicant*** referred to in paragraph 2.

Or. en

Amendment 2694
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c – Paragraph 8

Text proposed by the Commission	*Amendment*
8. Each Member State concerned shall issue a single decision as to whether the combined study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused and shall notify the coordinating ***sponsor*** referred to in paragraph 2.	8. Each Member State concerned shall issue a single decision as to whether the combined study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused and shall notify the coordinating ***applicant*** referred to in paragraph 2.

Or. en

Amendment 2695
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) 536/2014
Article 14c – Paragraph 9 – point (b)

Text proposed by the Commission	*Amendment*

(b) set the requirements applicable during the conduct of the combined studies, including as regards to the specific safety reporting requirements;	***deleted***

Or. en

Amendment 2696
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 13
Regulation (EU) No 536/2014
Article 14(e)new

Text proposed by the Commission	*Amendment*
	Article 14 (f)
	1. Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 Regulation (EU) …/… on medicinal products for human use], the application, at the request of the sponsor, may be assessed in accordance with the accelerated procedure set out in this Article.
	2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier and each Member State concerned shall validate Part II of the application dossier for its territory within five days from the submission date. 3. Where the reporting Member State or a Member State concerned has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete and the validation date shall be the last day of that period.
	4. Where the reporting Member State or a Member State concerned finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for

the sponsor to complete the application dossier. The reporting Member State or the Member State concerned, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2. 5. The reporting Member State shall assess Part I of the application dossier and each Member State concerned shall assess Part II of the application dossier for its territory within 26 days from the submission date. 6. The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be the conclusion of the Member States concerned, unless a Member State concerned raises considerations on one of the grounds referred to in Article 8(2).

7. Within 21 days from the submission date, each Member State concerned shall notify through the EU portal whether, for the purposes of Part II of the assessment report, it intends to rely on the assessment of the reporting Member State for common elements of the application dossier or to provide input concerning aspects specific to its territory.

8. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the assessment report within 33 days from the submission date.

9. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

10. Upon receipt of the additional information, the reporting Member State and the Member States concerned, as applicable, shall review the additional

information within a maximum of seven days. The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase as referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within a maximum of seven days from the end of that review.

11. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

12. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

13. By [OP please insert the date = 5 years from the date of application] the Commission shall present a report to the European Parliament, the Council, and Clinical Trials Coordination and Advisory Group on the application of this Article. This report shall be based, among others, on the information provided by the RMSs and sponsors regarding the impact of the accelerated procedure on the initiation of clinical trials. The Commission shall, if appropriate, present legislative proposals based on that evaluation to expand, amend, or delete this Article.

(:)

Or. en

Amendment 2697
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13

Regulation (EU) 536/2014
Article 14(e) new

Text proposed by the Commission	*Amendment*
	1. Where a clinical trial concerns an investigational medicinal product with an orphan designation in accordance with [Article 63 Regulation (EU) …/… on medicinal products for human use], the application, at the request of the sponsor, may be assessed in accordance with the accelerated procedure set out in this Article.
	2. For the purposes of this Article, the reporting Member State shall validate Part I of the application dossier and each Member State concerned shall validate Part II of the application dossier for its territory within five days from the submission date.
	3. Where the reporting Member State or a Member State concerned has not notified the sponsor within the period referred to in paragraph 2, the relevant part of the application dossier shall be considered complete and the validation date shall be the last day of that period.
	4. Where the reporting Member State or a Member State concerned finds that the relevant part of the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a deadline of maximum five days for the sponsor to complete the application dossier. The reporting Member State or the Member State concerned, as applicable, shall notify the sponsor within five days from the submission of the completed application dossier whether the application complies with the requirements referred to in paragraph 2.
	5. The reporting Member State shall assess Part I of the application dossier and each Member State concerned shall assess Part II of the application dossier for its territory within 26 days from the submission date.

6. The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be the conclusion of the Member States concerned, unless a Member State concerned raises considerations on one of the grounds referred to in Article 8(2).

7. Within 21 days from the submission date, each Member State concerned shall notify through the EU portal whether, for the purposes of Part II of the assessment report, it intends to rely on the assessment of the reporting Member State for common elements of the application dossier or to provide input concerning aspects specific to its territory.

8. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the assessment report within 33 days from the submission date.

9. Where additional information is requested from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

10. Upon receipt of the additional information, the reporting Member State and the Member States concerned, as applicable, shall review the additional information within a maximum of seven days. The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase as referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within a maximum of seven days from the end of that review.

11. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or

whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

12. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

13. By [OP please insert the date = 5 years from the date of application] the Commission shall present a report to the European Parliament, the Council, and Clinical Trials Coordination and Advisory Group on the application of this Article. This report shall be based, among others, on the information provided by the RMSs and sponsors regarding the impact of the accelerated procedure on the initiation of clinical trials. The Commission shall, if appropriate, present legislative proposals based on that evaluation to expand, amend, or delete this Article.

Or. en

Amendment 2698
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 13 a (new)
Regulation (EU) 536/2014
Article 15

Present text	*Amendment*
15. A substantial modification***, including the addition of a clinical trial site or the change of a principal investigator in the clinical trial site,*** may only be implemented if it has been approved in accordance with the procedure set out in this Chapter.	"15. A substantial modification may only be implemented if it has been approved in accordance with the procedure set out in this Chapter."

Or. en

Amendment 2699
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014
Article 16a – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor may submit to ***the same*** Member ***State*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***State*** concerned.	2. The sponsor may submit to ***all relevant*** Member ***States*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***States*** concerned.

Or. en

Amendment 2700
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014
Article 16a – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor may submit to ***the same*** Member ***State*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***State*** concerned.	2. The sponsor may submit to ***all relevant*** Member ***States*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***States*** concerned.

Or. en

Amendment 2701
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) No 536/2014
Article 16a – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor may submit to ***the same*** Member ***State*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***State*** concerned.	2. The sponsor may submit to ***all relevant*** Member ***States*** concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member ***States*** concerned.

Or. en

Amendment 2702
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014:
Article 16a – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The reporting Member State or Member state concerned, as applicable, shall accept the application for a parallel substantial modification ***if*** the parallel substantial modification ***concerns*** distinct and independent aspects of the application dossier ***and may*** be assessed concurrently by the same Member State concerned or reporting Member State.	3. The reporting Member State or Member State concerned, as applicable, shall accept the application for a parallel substantial modification***. Where*** the parallel substantial modification ***does not concern*** distinct and independent aspects of the application dossier ***or cannot*** be assessed concurrently by the same Member State concerned or reporting Member

State***, the parallel modification may be refused***.

Or. en

Amendment 2703
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014
Article 16a – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The reporting Member State or Member state concerned, as applicable, shall accept the application for a parallel substantial modification ***if*** the parallel substantial modification ***concerns*** distinct and independent aspects of the application dossier ***and may*** be assessed concurrently by the same Member State concerned or reporting Member State.	3. The reporting Member State or Member State concerned, as applicable, shall accept the application for a parallel substantial modification***. Where*** the parallel substantial modification ***does not concern*** distinct and independent aspects of the application dossier ***or cannot*** be assessed concurrently by the same Member State concerned or reporting Member State***, the parallel modification may be refused***.

Or. en

Amendment 2704
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) No 536/2014
Article 16a – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The reporting Member State or Member state concerned, as applicable, ***shall accept the*** application for a parallel substantial modification ***if*** the parallel substantial modification ***concerns*** distinct	3. The reporting Member State or Member state concerned, as applicable, application for a parallel substantial modification***. Where*** the parallel substantial modification ***does not concern***

and independent aspects of the application dossier ***and may*** be assessed concurrently by the same Member State concerned or reporting Member State.	distinct and independent aspects of the application dossier ***or cannot*** be assessed concurrently by the same Member State concerned or reporting Member State***, the parallel modification may be refused***.

Or. en

Amendment 2705
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014
Article 16a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. When scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the ***sponsor shall seek the agreement of both, the*** reporting Member State ***and the relevant Member States concerned***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment.	4. When ***the*** scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the reporting Member State ***will consider if the scope of the modifications can be assessed concurrently, or if the sponsor is required to submit the modifications sequentially***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment ***only where the substantial modification gives rise to substantiated concerns regarding compliance with Part II requirements that cannot otherwise be addressed through the ongoing assessment***.

Or. en

Amendment 2706
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) No 536/2014

Article 16a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. When scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the ***sponsor shall seek the agreement of both, the*** reporting Member State ***and the relevant Member States concerned***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment.	4. When ***the*** scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the reporting Member State ***will consider if the scope of the modifications can be assessed concurrently, or if the sponsor is required to submit the modifications sequentially***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment ***only where the substantial modification gives rise to substantiated concerns regarding compliance with Part II requirements that cannot otherwise be addressed through the ongoing assessment***.

Or. en

Amendment 2707
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 15
Regulation (EU) 536/2014
Article 16a – Paragraph 4

Text proposed by the Commission	*Amendment*
4. When scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the ***sponsor shall seek the agreement of both, the*** reporting Member State ***and the relevant Member States concerned***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment.	4. When ***the*** scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the reporting Member State ***will consider if the scope of the modifications can be assessed concurrently, or if the sponsor is required to submit the modifications sequentially***. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment ***only where the substantial modification gives rise to substantiated concerns regarding***

compliance with Part II requirements that cannot otherwise be addressed through the ongoing assessment.

Or. en

Amendment 2708
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 16 – point a
Regulation (EU) 536/2014
Article 17 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. The reporting Member State for the authorisation of the substantial modification shall be the reporting Member State for the initial authorisation procedure.	1. The reporting Member State for the authorisation of the substantial modification shall be the reporting Member State for the initial authorisation procedure***, or the current reporting Member State in the event of the appointment of a new reporting Member State as per the procedure laid out in Article 14a***.

Or. en

Amendment 2709
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 16 – point a
Regulation (EU) 536/2014
Article 17 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. The reporting Member State for the authorisation of the substantial modification shall be the reporting Member State for the initial authorisation procedure.	1. The reporting Member State for the authorisation of the substantial modification shall be the reporting Member State for the initial authorisation procedure***, or the current reporting Member State in the event of the appointment of a new reporting Member State as per the procedure laid out in Article 14a***.

Or. en

Amendment 2710
Anja Hazekamp, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 16 – point b
Regulation (EU) No 536/2014
Article 17 – paragraph 4

Text proposed by the Commission	*Amendment*
Where the reporting Member State has not notified the sponsor within the period referred to in the second subparagraph, the substantial modification applied for shall be deemed to concern an aspect covered by Part I of the assessment report, the application dossier shall be deemed to be complete and, when applicable, the parallel substantial modification shall be deemed to be acceptable taking into account the requirements of Article 16a.	***deleted***

Or. en

Amendment 2711
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 17
Regulation (EU) No 536/2014
Art 18

Text proposed by the Commission	*Amendment*
(17) [...]	***deleted***

Or. en

Amendment 2712
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation

Article 58 – paragraph 1 – point 17 – point a
Regulation (EU) No 536/2014
Article 18 – Paragraph 3

Text proposed by the Commission	*Amendment*
The reporting Member State shall submit, through the EU portal, the final assessment report including its conclusions, to the sponsor and to the other Member States concerned within ***28*** days from the submission date.	The reporting Member State shall submit, through the EU portal, the final assessment report including its conclusions, to the sponsor and to the other Member States concerned within ***14*** days from the submission date.

Or. en

Amendment 2713
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point a
Regulation (EU) No 536/2014
Article 18 – Paragraph 4 – point (a)

Text proposed by the Commission	*Amendment*
(a) an assessment phase performed by the reporting Member State within ***21*** days from the submission date. The assessment phase shall end when the reporting Member State circulates the draft assessment report;	(a) an assessment phase performed by the reporting Member State within ***14*** days from the submission date. The assessment phase shall end when the reporting Member State circulates the draft assessment report;

Or. en

Amendment 2714
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) 536/2014
Article 18 – Paragraph 6 – first subparagraph

Text proposed by the Commission	*Amendment*
Between the validation date and the reporting date, only the reporting Member	Between the validation date and the reporting date, only the reporting Member

State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***4***.	State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***5***. ***Upon receipt of such a request, the sponsor may inform the reporting Member State, through the EU portal, where it considers that the nature, volume or technical complexity of the information requested may require additional time for its preparation. For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the fourth and fifth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days. Where a longer period for the submission of additional information is set in accordance with the fourth subparagraph, the reporting Member State may extend that period accordingly. The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request, except in duly justified cases related to the nature, volume or technical complexity of the information requested, where the reporting Member State considers that a longer period is strictly necessary. In such cases, that period shall not exceed a maximum of twenty-eight days. The reporting Member State shall record the justification for applying a longer period in the assessment report.***

Or. en

Amendment 2715
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) 536/2014
Article 18 – Paragraph 6 – first subparagraph

Text proposed by the Commission	*Amendment*
Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***4***.	Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***5***. ***Upon receipt of such a request, the sponsor may inform the reporting Member State, through the EU portal, where it considers that the nature, volume or technical complexity of the information requested may require additional time for its preparation.***

Or. en

Amendment 2716
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18 – Paragraph 6 – first subparagraph

Text proposed by the Commission	*Amendment*
Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***4***.	Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph ***5***. ***Upon receipt of such a request, the sponsor may inform the reporting Member State, through the EU portal, where it considers that the nature, volume or technical complexity of the information requested may require additional time for its preparation.***

Or. en

Amendment 2717

Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18– paragraph 6a (new)

Text proposed by the Commission	*Amendment*
	Upon receipt of such a request, the sponsor may inform the reporting Member State, through the EU portal, where it considers that the nature, volume or technical complexity of the information requested may require additional time for its preparation.

Or. en

Amendment 2718
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) 536/2014
Article 18 – Paragraph 6 – second subparagraph

Text proposed by the Commission	*Amendment*
For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the ***third and*** fourth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days.	For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the fourth ***and fifth*** subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days. ***Where a longer period for the submission of additional information is set in accordance with the fourth subparagraph, the reporting Member State may extend that period accordingly.***

Or. en

Amendment 2719

Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18 – Paragraph 6 – second subparagraph

Text proposed by the Commission	*Amendment*
For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the ***third and*** fourth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days.	For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the fourth ***and fifth*** subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days. ***Where a longer period for the submission of additional information is set in accordance with the fourth subparagraph, the reporting Member State may extend that period accordingly.***

Or. en

Amendment 2720
Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18 – Paragraph 6 – second subparagraph

Text proposed by the Commission	*Amendment*
For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the ***third and*** fourth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days.	For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the fourth ***and fifth*** subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days. ***Where a longer period for the submission of additional information is set in accordance with the fourth subparagraph, the reporting Member State may extend that period accordingly.***

Or. en

Amendment 2721
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18 – Paragraph 6 – third subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request.	The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request***, except in duly justified cases related to the nature, volume or technical complexity of the information requested, where the reporting Member State considers that a longer period is strictly necessary. In such cases, that period shall not exceed a maximum of twenty-eight days. The reporting Member State shall record the justification for applying a longer period in the assessment report.***

Or. en

Amendment 2722
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) 536/2014
Article 18 – Paragraph 6 – third subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from	The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from

the receipt of the request.	the receipt of the request***, except in duly justified cases related to the nature, volume or technical complexity of the information requested, where the reporting Member State considers that a longer period is strictly necessary. In such cases, that period shall not exceed a maximum of twenty-eight days. The reporting Member State shall record the justification for applying a longer period in the assessment report.***

Or. en

Amendment 2723
Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 17 – point c
Regulation (EU) No 536/2014
Article 18 – Paragraph 6 – third subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request.	The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request***, except in duly justified cases related to the nature, volume or technical complexity of the information requested, where the reporting Member State considers that a longer period is strictly necessary. In such cases, that period shall not exceed a maximum of twenty-eight days. The reporting Member State shall record the justification for applying a longer period in the assessment report.***

Or. en

Amendment 2724
Peter Agius

Proposal for a regulation

Article 58 – paragraph 1 – point 18 – point a
Regulation (EU) 536/2014
Article 19 – Paragraph 1 – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) [1c] considerations as regards data reliability and robustness submitted

[1c] To be added as new letter c

Or. en

Amendment 2725
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 18 – point a
Regulation (EU) 536/2014
Article 19 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*
Where the Member State concerned disagrees with the conclusion on the basis of the ***second*** subparagraph, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.	Where the Member State concerned disagrees with the conclusion on the basis of the ***fifth*** subparagraph ***[of Article 19(1)]***, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.

Or. en

Amendment 2726
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 18 – point a
Regulation (EU) 536/2014
Article 19 – Paragraph 2 – first subparagraph

Text proposed by the Commission	*Amendment*
Where the Member State concerned disagrees with the conclusion on the basis of the ***second*** subparagraph, it shall	Where the Member State concerned disagrees with the conclusion on the basis of the ***fifth*** subparagraph ***[of Article 19(1)]***,

communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.	it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.

Or. en

Amendment 2727
Michele Picaro

Proposal for a regulation
Article 58 – paragraph 1 – point 18 – point a
Regulation (EU) No 536/2014
Article 19 – Paragraph 2 – second subparagraph

Text proposed by the Commission	*Amendment*
A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds referred to in the second paragraph or where an ethics committee has issued a negative opinion which, in accordance with the law of that Member State concerned, is valid for the entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.	***deleted***

Or. en

Amendment 2728
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 18 – point a a (new)
Regulation (EU) 536/2014
Article 19 – Paragraph 3

Text proposed by the Commission	*Amendment*
	(aa) Paragraph 3 is deleted

Or. en

Amendment 2729
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 19 – point a
Regulation (EU) No 536/2014
Art 20 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the Member State concerned has not notified the sponsor within the period referred to in paragraph 1, the substantial modification applied for shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete and, when applicable, the parallel substantial modification shall be deemed to be acceptable taking into account the requirements of Article 16a.	***deleted***

Or. en

Amendment 2730
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 19 – point a
Regulation (EC) No 883/2004
Article 20, paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. The authorization should not be refused except on duly justified grounds where the request concerns an ATMP authorised at Union level for the treatment of an ultra-rare condition and where no equivalent treatment can be provided within a medically acceptable timeframe.

Or. en

Justification

Complex therapies such as most ATMPs can be administered only at specialized clinical centers. When the number of patients treated per year is in the tens, they must be concentrated in few centers around Europe to ensure that the medical staff treating those patients has the necessary expertise and experience with both the disease and the products. For most ultra-rare diseases or n-of-1 conditions, the number of intended to treat population is so small that each step should be optimized to reduce the burden and the costs incurred by developers to make those business cases more robust. Thus considered, the request to developers to submit 27 (or even more) different price and reimbursement dossiers is unrealistic. Moreover, in some MS the price and reimbursement negotiation will be completely useless due to the absence of treatment centers.

Amendment 2731
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point a
Regulation (EU) 536/2014
Article 22 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days.	1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days ***or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 28 days***.

Or. en

Amendment 2732
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point a
Regulation (EU) No 536/2014
Article 22 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days.	1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days***, or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 28 days***.

Or. en

Amendment 2733
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point a
Regulation (EU) 536/2014
Article 22 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days.	1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days***, or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 28 days***.

Or. en

Amendment 2734
Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point a
Regulation (EU) No 536/2014
Article 22 – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in	1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in

conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days.	conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days ***or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 28 days***.

Or. en

Amendment 2735
Michele Picaro, Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) No 536/2014
Article 22 – Paragraph 3 – first subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request.	The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request ***, or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 14 days*** .

Or. en

Amendment 2736
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) 536/2014
Article 22 – Paragraph 3 – first subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request.	The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request***, or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 14 days***.

Or. en

Amendment 2737
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) No 536/2014
Article 22 – Paragraph 3 – first subparagraph

Text proposed by the Commission	*Amendment*
The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request.	The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request***, or in duly justified cases related to the nature, volume of technical complexity of the information requested, where the Member State concerned considers that a longer period is strictly necessary, a period of 14 days***.

Or. en

Amendment 2738
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation

Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) No 536/2014
Article 22 – Paragraph 3 – second subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor.	Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor***, or 14 days in duly justified cases***.

Or. en

Amendment 2739
Michele Picaro, Kristoffer Storm

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) No 536/2014
Article 22 – Paragraph 3 – second subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor.	Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor***, or 14 days in duly justified cases***.

Or. en

Amendment 2740
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 21 – point c
Regulation (EU) 536/2014
Article 22 – Paragraph 3 – second subparagraph

Text proposed by the Commission	*Amendment*
Upon receipt of the additional information, the Member State concerned shall	Upon receipt of the additional information, the Member State concerned shall

complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor.	complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor***, or 14 days in duly justified cases***.

Or. en

Amendment 2741
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point a – point ii
Regulation (EU) 536/2014
Article 25 – Paragraph 1 – second subparagraph

Text proposed by the Commission	*Amendment*
The list of required documentation and information for Part I is set out in Part I of Annex I. The list of required documentation for Part II is set out in Part II of Annex I.***;***	The list of required documentation and information for Part I is set out in Part I of Annex I. The list of required documentation for Part II is set out in Part II of Annex I. ***The sponsor shall, where appropriate, cross-refer to any previous applications. If these applications have been submitted by another sponsor, the written agreement from that sponsor shall be submitted. Where the sponsor cross-refers to information or documentation included in previous applications, that information or documentation shall not be re-submitted.***

Or. en

Amendment 2742
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point a – point ii
Regulation (EU) 536/2014
Article 25 – Paragraph 1 – second subparagraph

Text proposed by the Commission	*Amendment*
The list of required documentation and information for Part I is set out in Part I of	The list of required documentation and information for Part I is set out in Part I of

Annex I. The list of required documentation for Part II is set out in Part II of Annex I.;	Annex I. The list of required documentation for Part II is set out in Part II of Annex I. ***The sponsor shall, where appropriate, cross-refer to any previous applications. If these applications have been submitted by another sponsor, the written agreement from that sponsor shall be submitted. Where the sponsor cross-refers to information or documentation included in previous applications, that information or documentation shall not be re-submitted***;

Or. en

Amendment 2743
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point a – point ii
Regulation (EU) No 536/2014
Article 25 – Paragraph 1 – second subparagraph

Text proposed by the Commission	*Amendment*
The list of required documentation and information for Part I is set out in Part I of Annex I. The list of required documentation for Part II is set out in Part II of Annex I.;	The list of required documentation and information for Part I is set out in Part I of Annex I. The list of required documentation for Part II is set out in Part II of Annex I. ***The sponsor shall, where appropriate, cross-refer to any previous applications. If these applications have been submitted by another sponsor, the written agreement from that sponsor shall be submitted. Where the sponsor cross-refers to information or documentation included in previous applications, that information or documentation shall not be re-submitted.***;

Or. en

Amendment 2744
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point a – point ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) Where information or documentation has previously been submitted via the EU Portal and continues to be valid and current, the sponsor should be permitted to refer back to that material rather than resubmitting it, except where renewed submission is genuinely necessary and properly justified.

Or. en

Amendment 2745
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) 536/2014
Article 25 – Paragraph 1b

Text proposed by the Commission	*Amendment*
1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this Regulation.	1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this Regulation. ***Member States shall ensure that national competent authorities and ethics committees accept and assess Part II submissions on the basis of the harmonised templates and shall not require parallel national templates or additional documentation beyond the harmonised set, unless explicitly provided for in Union law.***

Or. en

Amendment 2746
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) No 536/2014
Article 25 – Paragraph 1b

Text proposed by the Commission	*Amendment*
1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this ***Regulation***.	1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this ***Regulation.Member States shall ensure that national competent authorities and ethics committees accept and assess Part II submissions on the basis of the harmonised templates and shall not require parallel national templates or additional documentation beyond the harmonised set, unless explicitly provided for in relevant laws***.

Or. en

Amendment 2747
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) 536/2014
Article 25 – Paragraph 1b

Text proposed by the Commission	*Amendment*
1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of	1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of

this Regulation.	this Regulation. ***Member States shall ensure that national competent authorities and ethics committees accept and assess Part II submissions on the basis of the harmonised templates and shall not require parallel national templates or additional documentation beyond the harmonised set, unless explicitly provided for in Union law.***

Or. en

Amendment 2748
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) No 536/2014
Article 25 – Paragraph 1b

Text proposed by the Commission	*Amendment*
1b. The sponsor shall use harmonised ***templates, where such templates are available, for*** the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this Regulation.	1b. The sponsor shall use harmonised ***templatesfor*** the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this Regulation. ***National competent authorities and ethics committees shall not require the submission of parallel national templates or additional documentation beyond the harmonised template, unless explicitly provided for in Union law.***

Or. en

Amendment 2749
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) 536/2014
Article 25 – Paragraph 1c

Text proposed by the Commission	*Amendment*
1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates may include standardised sections for documents referred to in Article 7(2) and in Annex I.	1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates may include standardised sections for documents referred to in Article 7(2) and in Annex I. ***The implementing acts referred to in this paragraph shall also lay down methodological guidance to ensure uniform interpretation and application of the harmonised templates by national competent authorities and ethics committees.***

Or. en

Amendment 2750
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) 536/2014
Article 25 – Paragraph 1c

Text proposed by the Commission	*Amendment*
1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates may include standardised sections for documents referred to in Article 7(2) and in Annex I.	1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates may include standardised sections for documents referred to in Article 7(2) and in Annex I.***'*** ***The implementing acts referred to in this paragraph shall also lay down methodological guidance to ensure uniform interpretation and application of the harmonised templates by national competent authorities and ethics committees.***

Or. en

Amendment 2751
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) No 536/2014
Article 25 – Paragraph 1c

Text proposed by the Commission	*Amendment*
1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates ***may*** include standardised sections for documents referred to in Article 7(2) and in Annex I**.**	1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The ***implementing acts referred to in this paragraph shall also lay down methodological guidance to ensure uniform interpretation and application of the*** harmonised templates ***by national competent authorities and ethics committees. The harmonised templates shall*** include standardised sections for documents referred to in Article 7(2) and in Annex I

Or. en

Amendment 2752
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) No 536/2014
Article 25 – Paragraph (1ca)new

Text proposed by the Commission	*Amendment*
	1ca. Member States shall take measures to develop and use national templates for site contracting and budgeting in clinical trials.
	Member States shall endeavour to ensure that such templates are aligned, where appropriate, with the harmonised templates referred to in paragraphs 1b

and 1c

Or. en

Amendment 2753
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b
Regulation (EU) No 536/2014
Article 25 – Paragraph (1ca)new

Text proposed by the Commission	*Amendment*
	1ca. Member States shall take measures to develop and use national templates for site contracting and budgeting in clinical trials. Member States shall endeavour to ensure that such templates are aligned, where appropriate, with the harmonised templates referred to in paragraphs 1b and 1c.'

Or. en

Justification

These amendments ensure consistent interpretation through EC implementing acts that define application and scope, including clarifications on which national elements are confined to Part II. Support Member States in adopting and using these harmonised templates for all Part II submissions.

Amendment 2754
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point b a (new)
Regulation (EU) No 536/2014
Article 25 – Paragraph (1ca)new

Text proposed by the Commission	*Amendment*
	(ba) National competent authorities and ethics committees shall not require the submission of parallel national templates or additional documentation

beyond the harmonised template, unless explicitly provided for in Union law

Or. en

Justification

Ensure consistent interpretation through EC implementing acts that define application and scope, including clarifications on which national elements are confined to Part II. Support Member States in adopting and using these harmonised templates for all Part II submissions.

Amendment 2755
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point d
Regulation (EU) 536/2014
Article 25 – Paragraph 8

Text proposed by the Commission	*Amendment*
8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*	8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data ***from sources outside the clinical trial, including data*** accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*

Or. en

Amendment 2756
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point d
Regulation (EU) No 536/2014
Article 25 – Paragraph 8

Text proposed by the Commission	*Amendment*
8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data accessed under	8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data ***from sources***

Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*	***outside the clinical trial, including data*** accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council *

Or. en

Justification

The amendment clarifies that the provision does not imply that EHDS access is the only pathway for obtaining relevant health data.

Amendment 2757
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 23 – point d
Regulation (EU) 536/2014
Article 25 – Paragraph 8

Text proposed by the Commission	*Amendment*
8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*	8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data ***from sources outside the clinical trial, including data*** accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*

Or. en

Amendment 2758
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27a – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor shall submit the request for the establishment of the investigational medicinal product core	2. The sponsor shall submit the request for the establishment of the investigational medicinal product core

dossier to all Member States concerned of the initial trial***. The sponsor may extend this request to other Member States than the Member States concerned. The reporting Member State of the initial clinical trial*** shall become the depositary ***Member State***.	dossier to all Member States concerned of the initial trial ***and to the Agency. The Agency*** shall become the ***core dossier*** depositary.

Or. en

Amendment 2759
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27a – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***depositary Member State*** shall verify the completeness and suitability of the core dossier for the purposes of the initial clinical trial***. At the latest by the time when the conclusion of the assessment of Part I is due*** in accordance with Article ***6(3) the depositary*** Member State shall notify the sponsor and the other core dossier competent Member States through the EU portal of the establishment of the investigational medicinal products core dossier where the assessment is positive.	3. The ***Agency*** shall verify the completeness and suitability of the core dossier for the purposes of the initial clinical trial***, according to the report*** in accordance with Article ***6(4) by the first Core dossier assessing*** Member State***, appointed as per Article 5a for Reporting Member State. The Agency*** shall notify the sponsor and the other core dossier competent Member States through the EU portal of the establishment of the investigational medicinal products core dossier where the assessment is positive.

Or. en

Amendment 2760
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27a – Paragraph 5

Text proposed by the Commission	*Amendment*

5. Once established, the investigational medicinal product core dossier shall be ***referred to*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***products*** core dossier was established and any other corresponding clinical trial.	5. Once established, the investigational medicinal product core dossier shall be ***relied upon*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***product*** core dossier was established and any other corresponding clinical trial. ***If the investigational medicinal product core dossier has been submitted by another sponsor, the written agreement from that sponsor shall be submitted to allow use by the other sponsor in subsequent corresponding clinical trials.***

Or. en

Amendment 2761
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Chapters IVa– Article 27a– paragraph 5

Text proposed by the Commission	*Amendment*
5. Once established, the investigational medicinal product core dossier shall be ***referred to*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***products*** core dossier was established and any other corresponding clinical trial.	5. Once established, the investigational medicinal product core dossier shall be ***relied upon*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***product*** core dossier was established and any other corresponding clinical trial. ***If the investigational medicinal product core dossier has been submitted by another sponsor, the written agreement from that sponsor shall be submitted to allow use by the other sponsor in subsequent corresponding clinical trials.***

Or. en

Amendment 2762
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27a – Paragraph 5

Text proposed by the Commission	*Amendment*
5. Once established, the investigational medicinal product core dossier shall be ***referred to*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***products*** core dossier was established and any other corresponding clinical trial.	5. Once established, the investigational medicinal product core dossier shall be ***relied upon*** in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal ***product*** core dossier was established and any other corresponding clinical trial. ***If the investigational medicinal product core dossier has been submitted by another sponsor, the written agreement from that sponsor shall be submitted to allow use by the other sponsor in subsequent corresponding clinical trials.***

Or. en

Amendment 2763
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27b – Paragraph 2

Text proposed by the Commission	*Amendment*
2. When new information, relevant to maintain the suitability and completeness of an established investigational product core dossier becomes known to the sponsor, the sponsor shall submit to the ***depositary Member State***, through the EU portal, a request for a change of the investigational medicinal product core dossier.	2. When new information, relevant to maintain the suitability and completeness of an established investigational product core dossier becomes known to the sponsor, the sponsor shall submit to the ***Agency***, through the EU portal, a request for a change of the investigational medicinal product core dossier.

Or. en

Amendment 2764
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27b – Paragraph 3

Text proposed by the Commission	*Amendment*
In case of a new application for an authorisation of a new corresponding clinical trial, the reporting Member State of that clinical trial together with the ***depositary Member State*** shall assess the suitability of the investigational product core dossier for the purpose of the authorisation of the trial application, that is;	In case of a new application for an authorisation of a new corresponding clinical trial, the reporting Member State of that clinical trial together with the ***Agency*** shall assess the suitability of the investigational product core dossier for the purpose of the authorisation of the trial application, that is;

Or. en

Amendment 2765
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27b – Paragraph 3 – point (a)

Text proposed by the Commission	*Amendment*
(a) whether the investigational product core dossier is complete as regards the information on the characteristics and knowledge about the investigational medicinal products;	***deleted***

Or. en

Amendment 2766
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014

Article 27b – Paragraph 3 – point (a)

Text proposed by the Commission	*Amendment*
(a) whether the investigational product core dossier is complete as regards the information on the characteristics and knowledge about the investigational medicinal products;	***deleted***

Or. en

Amendment 2767
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27b – Paragraph 3 – second subparagraph

Text proposed by the Commission	*Amendment*
The reporting Member State of the corresponding clinical trial shall communicate the results of its assessment to the ***depositary Member State***.	The reporting Member State of the corresponding clinical trial shall communicate the results of its assessment to the ***Agency***.

Or. en

Amendment 2768
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27b – Paragraph 4

Text proposed by the Commission	*Amendment*
4. After receiving the request for a change to the core dossier, ***independently of whether a*** change is submitted in the context of an assessment of an application related to a corresponding clinical trial ***or independently, the depositary*** Member State ***shall*** verify whether the core dossier,	4. After receiving the request for a change to the core dossier, ***when the*** change is ***not*** submitted in the context of an assessment of an application related to a corresponding clinical trial***, the Agency shall shall request to last submitted corresponding clinical trial or substantial***

once changed, will continue to fulfil the requirements listed in paragraph 3 points (a), (b) and (c). The Member State concerned with the core dossier shall not duplicate the assessment of the ***depositary*** Member State. The ***depositary*** Member State may consult the Member State concerned as appropriate.	***modification first core dossier assessing*** Member State ***to*** verify whether the core dossier, once changed, will continue to fulfil the requirements listed in paragraph 3 points (a), (b) and (c). The Member State concerned with the core dossier shall not duplicate the assessment of the ***reporting*** Member State. The ***reporting*** Member State may consult the Member State concerned as appropriate.

Or. en

Amendment 2769
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27b – Paragraph 6

Text proposed by the Commission	*Amendment*
6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification in corresponding clinical trials that are ongoing.	6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification in corresponding clinical trials that are ongoing. ***Where such a substantial modification is necessary, the sponsor may submit the request for a change of the investigational medicinal product core dossier and the substantial modification in parallel. The assessment of the change of the investigational medicinal product core dossier and of the substantial modification may be carried out under aligned timelines and concluded through a coordinated procedure, without requiring the prior approval of the change of the investigational medicinal product core dossier.***

Or. en

Justification

This amendment proposes to allow the core dossier change and any related trial specific substantial modification to be submitted and assessed in parallel under aligned timelines, with a single conclusion.

Amendment 2770
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27b – Paragraph 6

Text proposed by the Commission	*Amendment*
6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification ***in*** corresponding clinical trials that are ongoing.	6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification ***to the necessary documentation, which will be reflected in all*** corresponding clinical trials that are ongoing.

Or. en

Amendment 2771
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27b – Paragraph 6

Text proposed by the Commission	*Amendment*
6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification ***in*** corresponding clinical trials that are ongoing.	6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification ***to the necessary documentation, which will be reflected in all*** corresponding clinical trials that are ongoing.

Or. en

Amendment 2772
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27c

Text proposed by the Commission	*Amendment*
The Commission shall set out the detailed rules governing the submission of a request for the establishment of an investigational product core dossier, its assessment and maintenance by means of implementing acts, including the rules for cooperation between the core dossier competent Member States ***and the change of depositary*** Member State. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88."	The Commission shall set out the detailed rules governing the submission of a request for the establishment of an investigational product core dossier, its assessment and maintenance by means of implementing acts, including the rules for cooperation between the core dossier competent Member States***, the reporting*** Member State ***and the Agency***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88."

Or. en

Amendment 2773
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU)No 536/2014
chapter IVb

Text proposed by the Commission	*Amendment*
Chapter IVb	***deleted***

Or. en

Amendment 2774
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation

Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Chapter IVb

Text proposed by the Commission	*Amendment*
Chapter IVb	***deleted***

Or. en

Amendment 2775
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU)No 536/2014
chapter IVb

Text proposed by the Commission	*Amendment*
REGULATORY SANDBOXES AND USE OF AI	***deleted***

Or. en

Amendment 2776
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU)No 536/2014
chapter IVb

Text proposed by the Commission	*Amendment*
Article 27d	***deleted***

Or. en

Amendment 2777
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU)No 536/2014
chapter IVb

Text proposed by the Commission	*Amendment*
Regulatory sandbox	***deleted***

Or. en

Amendment 2778
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 24
(EU) No 536/2014
Article 27d – Paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission may, pursuant to the procedure set out in paragraph 7, establish and operate a regulatory sandbox at Union level that provides a controlled and time-limited framework to enable, under real-world conditions, the testing of innovative approaches in clinical trials to which the full application of certain requirements of this Regulation is not possible or appropriate and which therefore may require adaptations.	1. The Commission may, ***on a case-by-case basis and*** pursuant to the procedure set out in paragraph 7, establish and operate a regulatory sandbox at Union level that provides a controlled and time-limited framework to enable, under real-world conditions, the testing of innovative approaches in clinical trials to which the full application of certain requirements of this Regulation is not possible or appropriate and which therefore may require adaptations.

Or. en

Amendment 2779
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27d – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The regulatory sandbox under this Regulation may encompass approaches to the authorisation and conduct of the clinical trials and where appropriate, maybe be implemented in coordination and synergies with the regulatory sandboxes established pursuant to Regulation (EU) 2024/1689 with full involvement of competent authorities supervising the sandbox under Regulation (EU) 2024/1689 and in accordance with the relevant procedures and rules for participating in those AI regulatory sandboxes.	2. The regulatory sandbox under this Regulation may encompass approaches to the authorisation and conduct of the clinical trials and where appropriate, maybe be implemented in coordination and synergies with the regulatory sandboxes established pursuant to Regulation (EU) 2024/1689 with full involvement of competent authorities supervising the sandbox under Regulation (EU) 2024/1689 and in accordance with the relevant procedures and rules for participating in those AI regulatory sandboxes. ***. The use of artificial intelligence within such sandboxes shall comply with all applicable Union safety, ethical and legal standards, including those laid down in Regulation (EU) 2024/1689, and shall not result in bias or discrimination against any individual or group, in particular as regards the protected grounds referred to in Article 21 of the Charter of Fundamental Rights of the European Union***

Or. en

Amendment 2780
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 24
(EU) No 536/2014
Article 27d – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The regulatory sandbox under this Regulation may encompass approaches to the authorisation and conduct of the clinical trials and where appropriate, maybe be implemented in coordination and synergies with the regulatory sandboxes established pursuant to Regulation (EU) 2024/1689 with full involvement of	2. The regulatory sandbox under this Regulation may encompass approaches to the authorisation and conduct of the clinical trials and where appropriate, maybe be implemented in coordination and synergies with the regulatory sandboxes established pursuant to Regulation (EU) 2024/1689 with full involvement of

competent authorities supervising the sandbox under Regulation (EU) 2024/1689 and in accordance with the relevant procedures and rules for participating in those AI regulatory sandboxes.	competent authorities supervising the sandbox under Regulation (EU) 2024/1689 and in accordance with the relevant procedures and rules for participating in those AI regulatory sandboxes. ***Processed data shall meet high standards in terms of quality, ethics and integrity.***

Or. en

Amendment 2781
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 24
(EU) No 536/2014
Article 27d – Paragraph 3

Text proposed by the Commission	*Amendment*
3. The activities within a regulatory sandbox shall take place pursuant to a specific plan, for eligible clinical trials, which may be conducted under enhanced regulatory oversight of the Member States concerned. The plan shall clearly identify the requirements of this Regulation that are temporarily adapted or derogated from in the sandbox and that may relate to, as necessary, to source data and documentation requirements, recruitment and informed consent procedures, monitoring and reporting requirements, trial design rules, investigational medicines handling rules, safety reporting rules, site requirements. The plan shall also identify the roles and responsibilities of sponsors, investigators, and manufacturers.	3. The activities within a regulatory sandbox shall take place pursuant to a specific plan, for eligible clinical trials, which may be conducted under enhanced regulatory oversight of the Member States concerned***, whilst respecting ethical standards***. The plan shall clearly identify the requirements of this Regulation that are temporarily adapted or derogated from in the sandbox and that may relate to, as necessary, to source data and documentation requirements, recruitment and informed consent procedures, monitoring and reporting requirements, trial design rules, investigational medicines handling rules, safety reporting rules, site requirements. The plan shall also identify the roles and responsibilities of sponsors, investigators, and manufacturers.

Or. en

Amendment 2782
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Chapter IVb, Article 27d, paragraph 4, (a)

Text proposed by the Commission	*Amendment*
(a) it is not possible to authorise or conduct a clinical trial in full compliance with the requirements of this Regulation due to innovative approaches in the clinical trial or due to the specificity of the investigational medicinal product***;**	(a) it is not possible to authorise or conduct a clinical trial in full compliance with the requirements of this Regulation due to innovative approaches in the clinical trial or due to the specificity of the investigational medicinal product***, including, where relevant, situations where the clinical intervention involves the interaction of pharmacological and non-pharmacological elements, specific conditions of administration, structured therapeutic support, or the need to generate evidence based on patient-reported or functional outcomes, such as in certain mental health conditions;***

Or. en

Amendment 2783
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27d – Paragraph 4 – point (b) – point (ii)

Text proposed by the Commission	*Amendment*
(ii) considerably decreasing clinical trial length***, and increasing the efficiency of the clinical trial***;	(ii) considerably decreasing clinical trial length;

Or. en

Amendment 2784
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24

Regulation (EU) 536/2014
Article 27d – Paragraph 4 – point (b) – point (ii)

Text proposed by the Commission	*Amendment*
(ii) considerably decreasing clinical trial length***, and increasing the efficiency of the clinical trial***;	(ii) considerably decreasing clinical trial length;

Or. en

Amendment 2785
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 24
(EU) No 536/2014
Article 27d – Paragraph 4 – point (c)

Text proposed by the Commission	*Amendment*
(c) the sandbox provides safeguards to ensure the safety, well-being, and fundamental rights of clinical trial participants, data robustness, and maintained integrity of the clinical trials within the sandbox.	(c) the sandbox provides safeguards to ***to upholding ethical standards and*** ensure the safety, well-being, and fundamental rights of clinical trial participants, data robustness, and maintained integrity of the clinical trials within the sandbox.

Or. en

Amendment 2786
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27d – Paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	8a. The Commission shall assess the effectiveness and added value of the regulatory sandboxes every two years and publish its findings.

Or. en

Amendment 2787
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Chapter IVb – Article 27d – Paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	9a. The Commission shall assess the effectiveness and added value of the regulatory sandboxes every two years and publish its findings.

Or. en

Amendment 2788
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 2024/1689
Article 27d – Paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	9a. The Commission shall assess the effectiveness and added value of the regulatory sandboxes every two years and publish its findings.

Or. en

Justification

To foster the use of regulatory sandboxes, their added value should be regularly assessed.

Amendment 2789
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 24

Regulation (EU) No 536/2014
Art 27e – Paragraph 1

Text proposed by the Commission	*Amendment*
1. For those clinical trials where the sponsor ***plan*** to use AI models or systems, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].	1. For those clinical trials where the sponsor ***plans*** to use AI models or systems, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act]. ***Where the AI model or system may affect subject selection, dosing, endpoint assessment, safety monitoring, data interpretation or clinical decision-making, the sponsor shall ensure independent auditability, human oversight and appropriate explainability.***

Or. en

Amendment 2790
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 1

Text proposed by the Commission	*Amendment*
1. ***For those clinical trials where*** the sponsor ***plan to use*** AI models or systems***, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].	1. The sponsor ***shall assess whether the specific context of use of*** AI models or systems ***used in clinical trials may pose a high risk to patients or high regulatory impact*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].

Or. en

Amendment 2791
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 1

Text proposed by the Commission	*Amendment*
1. ***For those clinical trials where*** the sponsor ***plan to use*** AI models or systems***, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].	1. The sponsor ***shall assess whether the specific context of use of*** AI models or systems ***used in clinical trials may pose a high risk to patients or high regulatory impact*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].

Or. en

Amendment 2792
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 2024/1689
Article 27e – Paragraph 1

Text proposed by the Commission	*Amendment*
1. ***For those clinical trials where*** the sponsor ***plan to use*** AI models or systems***, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].	1. The sponsor ***shall assess whether the specific context of use of*** AI models or systems ***used in clinical trials may pose a high risk to patients or high regulatory impact*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].

Or. en

Amendment 2793
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation 536/2014
Article 27e– paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.	2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial. ***The guidelines referred to in paragraph 1 shall include details on the information that the sponsor shall provide on the protocol on the specific purpose of the use of AI model. In particular, not all AI use may need information to be included in the protocol, and it should only apply to those that have been assessed as posing a high risk to patient or high regulatory impact.***
	(me)

Or. en

Amendment 2794
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.	2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems ***that have been assessed as posing a high risk to patients or high regulatory impact*** and the description of the process in the context of the specific clinical trial***, taking into consideration guidance proposed in Article 31. The level of detail provided shall be proportionate to the level of risk***

associated with the specific use of AI.

Or. en

Amendment 2795
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.	2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems ***that have been assessed as posing a high risk to patients or high regulatory impact*** and the description of the process in the context of the specific clinical trial***, taking into consideration guidance proposed in Article 31***.

Or. en

Amendment 2796
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 2024/1689
Article 27e – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.	2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems ***that have been assessed as posing a high risk to patients or high regulatory impact*** and the description of the process in the context of the specific clinical trial***, taking into consideration guidance proposed in Article 31***.

Or. en

Justification

Given the widespread use of AI in clinical trials, including in low-risk or non-regulatory contexts, the Article should avoid imposing disproportionate reporting obligations for uses with no meaningful impact (e.g. AI-assisted drafting with human oversight). Aligning the language with EMA guidance would ensure legal clarity, regulatory coherence, and consistency across Member States. A risk-based, context-specific approach would focus requirements on AI uses relevant to patient safety and regulatory decision-making, while avoiding unnecessary administrative burden.

Amendment 2797
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) No 536/2014
Article 27e – Paragraph (2a)new

Text proposed by the Commission	*Amendment*
	2a. AI systems and models used in clinical trials shall remain assistive tools. They shall not replace medical judgment, investigator responsibility, ethical assessment, informed consent or regulatory accountability. Trial subjects shall be informed in clear and plain language where AI systems or models are used in a manner that may affect their participation, safety monitoring or the interpretation of data concerning them.

Or. en

Amendment 2798
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 3

Text proposed by the Commission	*Amendment*
3. When the investigation of a	3. When the investigation of a

medicinal product in a clinical trial is combined with a performance study of an AI in vitro diagnostic medical device or a clinical investigation of an AI medical device, the provisions of Article ***14*** on coordinated assessment for authorising combined studies shall apply.	medicinal product in a clinical trial is combined with a performance study of an AI in vitro diagnostic medical device or a clinical investigation of an AI medical device, ***that is also subject to the AI Act, Regulation (EU) 2024/1689,*** the provisions of Article ***14 58(13)*** on coordinated assessment for authorising combined studies shall apply.

Or. en

Amendment 2799
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation (EU) 536/2014
Article 27e – Paragraph 3

Text proposed by the Commission	*Amendment*
3. When the investigation of a medicinal product in a clinical trial is combined with a performance study of an AI in vitro diagnostic medical device or a clinical investigation of an AI medical device, the provisions of Article ***14*** on coordinated assessment for authorising combined studies shall apply**.**	3. When the investigation of a medicinal product in a clinical trial is combined with a performance study of an AI in vitro diagnostic medical device or a clinical investigation of an AI medical device, ***that is also subject to the AI Act, Regulation (EU) 2024/1689,*** the provisions of Article ***14 58(13)*** on coordinated assessment for authorising combined studies shall apply

Or. en

Amendment 2800
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 24
(EU) No 536/2014
Article 27e – Paragraph 4

Text proposed by the Commission	*Amendment*

4. In cooperation with the CTAG and, where appropriate, the Medical Device Coordination Group, the Artificial Intelligence Board, the Agency shall develop guidelines referred to in paragraph 1 of this Article.	4. In cooperation with the CTAG and, where appropriate, the Medical Device Coordination Group, the Artificial Intelligence Board, the Agency shall develop guidelines referred to in paragraph 1 of this Article. ***Such guidelines shall include the principles of human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability. Without prejudice to the legally binding requirements of this Regulation and any other applicable Union law, those guidelines should contribute to the design of coherent, trustworthy and human-centric AI, in line with the Charter of Fundamental Rights of the European Union and with the values on which the Union is founded.***

Or. en

Amendment 2801
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 24
Regulation EU No 536/2014
Article 27e – Paragraph 4

Text proposed by the Commission	*Amendment*
4. In cooperation with the CTAG and, where appropriate, the Medical Device Coordination Group, the Artificial Intelligence Board, the Agency shall develop guidelines referred to in paragraph 1 of this Article.	4. In cooperation with the CTAG and, where appropriate, the Medical Device Coordination Group, the Artificial Intelligence Board, the Agency shall develop guidelines referred to in paragraph 1 of this Article. ***Such guidelines shall include the principles of human oversight, technical robustness and safety, privacy and data governance, transparency, diversity, non-discrimination, fairness, accountability, data security, traceability and scientific reliability and should contribute to the design of coherent,***

trustworthy and human-centric AI, in line with the Charter of Fundamental Rights of the European Union and with the values on which the Union is founded.

Or. en