HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Procedural Guidance for

Joint Scientific Consultations (JSC) on Medical Devices (MD) and *In Vitro* Diagnostic Medical Devices (IVD)

V4

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Preamble

To the reader, please note that writing in italics was used in the guidance to quote text from the Health Technology Assessment Regulation (EU) 2021/2282 or from the Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices.

Abbreviations

CE	Conformité Européenne
CECP	Clinical Evaluation Consultation Procedure
EC	European Commission
EU	European Union
EMA	European Medicines Agency
ExP	Expert Panels
HCP	Health Care Professional
HTA	Health Technology Assessment
HTAb	Health Technology Assessment body
HTACG	HTA Coordination Group
HTAR	HTA Regulation (EU) 2021/2282
HTD	Health Technology Developer
IR	Implementing Regulation
IVD	In Vitro Diagnostic Medical Device
IVDR	In Vitro Diagnostic Regulation (EU) 2017/746
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
LoI	List of Issues
MD	Medical Device
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation (EU) 2017/745
NB	Notified Body
NCA	National Competent Authority
PECP	Performance Evaluation Consultation Procedure
PICO	Population – Intervention – Comparator(s) – Outcome(s)
PMCF	Post-Market Clinical Follow-up
SG	Subgroup
ToR	Terms of Reference

1 Principles

1.1 Scope and objectives

The Member State Coordination Group on Health Technology Assessment (HTA Coordination Group, HTACG) adopted this guidance pursuant to Article 3(7), point (f), of the Health Technology Assessment Regulation (Regulation (EU) 2021/2282) ('the HTAR').

A Joint Scientific Consultation (JSC) constitutes an advice procedure for a health technology developer (HTD), which facilitates the discussion of the development plan of a medical device (MD) or *in vitro* diagnostic medical device (IVD). A JSC on MD or IVD focuses on advice for studies that are still in the planning phase. The studies which are in scope are:

- clinical investigations[1] or performance studies[2] of a MD/IVD not yet certified for the claimed intended purpose (new device or new intended purpose for an existing device). This includes studies that are part of the post-market clinical follow-up (PMCF)[3] or post-market performance follow-up (PMPF)[4] plan of a MD or IVD, respectively;
- post-market clinical investigations[1] or performance studies[2] of an already certified device where the HTACG has specified the need for a Joint Clinical Assessment (JCA) update or where the need for new evidence follows from the initial JCA report.

Thus, JSC promotes robust evidence generation that is fit-for-purpose.

In accordance with Article 16(1) of the HTAR, *the Coordination Group shall carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for a given health technology. Those consultations shall facilitate the generation of evidence that meets the likely evidence requirements of a subsequent joint clinical assessment on that health technology. […] Joint scientific consultations shall in particular concern all relevant clinical study design aspects, or clinical investigation design aspects, including comparators, interventions, health outcomes and patient populations*.

In accordance with Article 17(1) of the HTAR, *for health technologies referred to in Article 16(2), health technology developers may request a joint scientific consultation*, hereafter referred to as HTACG JSC.

In accordance with Article 17(2) of the HTAR, *health technology developers of medical devices may request that the joint scientific consultation take place in parallel with the consultation of an expert panel.* Joint scientific consultation taking place in parallel with the consultation of an expert panel (ExP) is referred to as Parallel HTACG/ExP JSC.

[1] Article 2(45) of the MDR
[2] Article 2(42) of the IVDR
[3] Annex XIV PART B of the MDR
[4] Annex XIII PART B of the IVDR

This guidance defines detailed procedural steps and the timeframe for the conduct of JSC. It is the primary reference for HTD and other stakeholders to comprehend key process steps and action points throughout the JSC procedure.

The document outlines the procedure for both formats: the HTACG JSC and the Parallel HTACG/ExP JSC. Information on the Parallel HTACG/ExP JSC procedures has been agreed with the European Medicines Agency (EMA).

All relevant guidance documents and templates of the HTACG for JSC are presented in Section 3 and can be found online on this website.

1.2 Roles and remits

This guidance describes timelines and actions for each actor undertaking a HTACG JSC for MD or IVD or a Parallel HTACG/ExP JSC for MD.

For the Parallel HTACG/ExP JSC, the HTA and ExP processes run in parallel. The HTACG and the ExP act separately but coordinate key steps of the procedure and share relevant information. Paragraphs in this procedure that describe process flow and practicalities regarding the ExP process are agreed by EMA. Relevant documents for the procedure for ExP advice to MD manufacturers can be found on the EMA website.

Each participating actor should adhere to the roles and responsibilities under their respective remit, established by the medical device Regulation (MDR) (EU) 2017/745, the *in vitro* diagnostic medical device Regulation (IVDR) (EU) 2017/746, Regulation (EU) 2022/123 and the Health Technology Assessment Regulation (HTAR) (EU) 2021/2282.

1.3 Outcome of the procedure

In accordance with Article 16(1) of the HTAR*, the joint scientific consultation shall […] result in an outcome document that outlines the scientific recommendation made*.

The HTD will receive the outcome document both in case of a HTACG JSC and of a parallel HTACG/ExP JSC. In case of a Parallel HTACG/ExP JSC, the HTD will also receive the ExP Advice Letter.

The consultation provided by the HTACG is based on the up-to-date documentation provided by the HTD.

In accordance with Recital 39 of the HTAR, *given the preliminary nature of the consultation, any guidance offered should not be legally binding either on the health technology developers or on HTA authorities and bodies. Such guidance, however, should reflect the state of the art of medical science at the time of the joint scientific consultation, in particular in the interest of patients*.

In accordance with Article 16(3) of the HTAR, *the joint scientific consultation outcome document shall not give rise to any legal effects on Member States, the Coordination Group or the health*

technology developer. Joint scientific consultations shall not prejudice the joint clinical assessment which may be carried out on the same health technology.

However, according to Annex II, section 1 (point g) of the HTAR on the HTD dossier for a JCA, *the dossier referred to in Article 9(2) of this Regulation shall for medical devices include: if a health technology has been subject to a joint scientific consultation, an explanation from the health technology developer on any deviation from the recommended evidence*. This relates to the proposition for evidence generation recommended by the HTACG in the outcome document.

2 Actors

2.1 HTACG, JSC SG, assessor, co-assessor, watcher and HTA secretariat

The HTACG is composed of Member States' HTA authorities and bodies which appoint their representatives. The HTACG is responsible for overseeing the joint work within the scope of the HTAR.

The JSC Subgroup (JSC SG) was established by the HTACG and has been designated by the HTACG for the selection of requests for JSC and for conducting the JSC. The members of subgroups are designated by the HTACG members.

According to Article 18(3) of the HTAR, *the designated subgroup shall appoint from among its members an assessor and a co-assessor from different Member States to conduct the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the consultation*. The role of the assessor and co-assessor is to lead on the scientific and technical tasks of the joint work on a specific product.

For capacity building of JSC SG representatives, there is also the option of a watcher role. Watchers will be invited to join all meetings between the assessor and co-assessor, while they will not be expected to provide input. JSC SG representatives should declare their interest in the role of watcher to the HTA secretariat as well as the assessor and co-assessor at the beginning of the process. The number of watchers can be limited (at the assessor and co-assessor's discretion) to maintain feasibility.

The HTA Secretariat is responsible for procedural and administrative assistance around JSC procedures and is operated by the European Commission (EC).

2.2 Medical Device Expert Panels and EMA

The Expert Panels were established by Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) to advise on scientific matters related to MD and IVD. They have been designated by means of the Commission Implementing Decision (EU) 2019/1396. There are 12 expert panels including 10 thematic panels for MD according to medical areas. Some thematic

panels are further divided into subgroups. The organigram of the expert panels is available on the Commission website here.

The Expert Panels Secretariat has been provided by the EMA since the 1st of March 2022, as established by Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.
According to Article 106(10) point (e) and Article 61(2) of the MDR, the tasks of the expert panels include the provision of opinions in response to consultations by manufacturers on their intended clinical development strategy and proposals for clinical investigations. Such consultations concern all class III MD and class IIb active MD intended to administer and/or remove medical product(s) from the human body.

According to Article 16(5) of the HTAR, (*…) joint scientific consultations on medical devices may take place in parallel with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745.*

As mentioned in the ExP Rules of Procedure[5], manufacturer's requests for ExP consultation are handled by Ad Hoc Expert Groups in representation of the thematic panel or panel subgroup appropriate for the requested scientific consultation. Ad Hoc Expert Groups are created individually for each request and are chaired by the Chair or the Vice-Chair of the thematic panel or panel subgroup associated. The EMA suggests the Ad Hoc Expert Group composition based on expertise and declared conflicts of interests, to the Chair/Vice-Chair for confirmation. Any member of the ExP (advisor of the ExP) can be part of an Ad Hoc Expert Group irrespective of the panel they belong to.

Advisors of the ExP involved in the consultation address each question independently, taking into consideration the information provided by the HTD including its position on the different questions to be addressed. In case of already existing clinical data used by the HTD to build its clinical strategy, the ExP does not provide any assessment of this data as such but an advice on whether the envisaged clinical strategy would allow to generate the expected evidence.

In case of a Parallel HTACG/ExP JSC procedure, the advisors draft the ExP List of Issues, one of the advisors acts as one of the two co-chairs for the discussion meeting, and they draft the final ExP advice letter.

2.3 Health Technology Developer (HTD)

In accordance with Article 17(1) of the HTAR, *for health technologies referred to in Article 16(2), health technology developers may request a joint scientific consultation.*

In accordance with Article 17(2) of the HTAR, *health technology developers of medical devices may request that the joint scientific consultation take place in parallel with the consultation of an expert panel.*

[5] https://health.ec.europa.eu/system/files/2023-08/expamed_rules-procedure_en.pdf

2.4 Patients, clinical experts and other relevant experts

According to Article 18(6) of the HTAR, *the designated subgroup shall ensure that patients, clinical experts and other relevant experts are given an opportunity to provide input during the preparation of the draft joint scientific consultation outcome document.* According to Article 18(7) of the HTAR, *the designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the HTD and patients, clinical experts and other relevant experts*.

The selection and consultation of patients, clinical experts and other relevant experts ("individual experts") in JSC from the HTA side is further detailed by the Commission implementing regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedure for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices (IR JSC MD).

According to Article 6(2) of the IR JSC MD, *[…] the HTA secretariat shall identify individual experts to be consulted during the joint scientific consultation […].* According to Article 6(5) of the IR JSC MD, *the JSC Subgroup shall make the final selection of individual experts to be consulted during the joint scientific consultation from the list of individual experts provided by the HTA Secretariat […]. In making the final selection, the JSC Subgroup shall give priority to individual experts who have expertise across a number of Member States in the medical condition, the therapeutic area or the type of health technology that is the subject of the joint scientific consultation*.

The ExP consultation process does not currently involve any external experts or patients.

Where possible, individual experts are invited to attend the discussion meeting.

2.5 Stakeholder organisations

According to Article 12(1) of the IR JSC MD, *at any time during the joint scientific consultation, the JSC Subgroup, via the HTA secretariat, may seek input on the medical condition, therapeutic area or other areas relevant for the medical device or in vitro diagnostic medical device from patient organisations, healthcare professional organisations or clinical and learned societies via the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282, whilst respecting the confidential nature of the request for joint scientific consultation.*

The JSC SG may seek input on the medical condition, therapeutic area or other areas relevant to the selected MD or IVD via a questionnaire that will be shared via the HTA secretariat. To sufficiently discuss and reflect the feedback from stakeholder organisations, input should be received by the JSC SG no later than 10 days before the discussion meeting.

The EMA will be informed of the input from the stakeholder organisations in case of a Parallel HTACG/ExP JSC.

According to Article 12(2) of the IR JSC MD, *where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, the HTA secretariat shall share*

the input referred to in paragraph 1 with the European Medicines Agency at the same time as sharing it with the JSC Subgroup.

3 List of referenced documents

Please find below a description of the documents referred to in this guidance. The table indicates the documents which are available on the Commission website on this dedicated webpage.

Table 1. Description of documents

Documents	Description
Guidance for the selection of medical devices and *in vitro* diagnostic medical devices for Joint Scientific Consultations (JSC)	This guidance document describes the selection process of a MD or IVD for a JSC. It is available on the Commission website.
Submission request form	Form for the formal expression of interest by an HTD in a JSC, available on the EMA and Commission websites.
Briefing package	The briefing package is developed by the HTD and comprises: - the briefing document which includes notably the questions of the HTD and their positions, - as well as all the relevant information, annexes and references necessary for the JSC. Different templates of the briefing document are available on the Commission website: - Briefing Document for HTACG JSC for MD - Briefing Document for HTACG JSC for IVD - Briefing Document for HTACG/ExP JSC for MD. The draft briefing package is submitted by the HTD to the HTA secretariat before the start of the procedure. It is then amended by the HTD according to the written request for further specifications or clarifications from the HTACG. The submission of the amended briefing package to the HTA secretariat corresponds to the beginning of the JSC procedure.
List of Issues	Document outlining the concerns or disagreements of the JSC SG, and of the ExP in the case of a Parallel HATACG/ExP JSC, with the HTD's proposed development plan. The HTD is requested to provide further justifications or clarifications.
JSC Outcome document	Document with the scientific recommendations from the HTACG which address the HTD's questions. This confidential document is sent to the HTD at the end of the JSC.
Final Advice Letter	Document with the recommendations from the ExP which address the HTD's questions. This confidential document is sent to the HTD.

4 Requests and selection of health technologies for a JSC

According to Article 17(3) of the HTAR, *the Coordination Group shall publish the dates of request periods and state the planned number of joint scientific consultations for each of those request periods on the IT platform referred to in Article 30. […]*.

The communicated request periods can be found on the Commission website on this dedicated webpage.

In order to apply for a JSC (HTACG JSC or Parallel HTACG/ExP JSC), the HTD should complete the Request template for HTACG JSC for medical devices and *in vitro* diagnostic medical devices and for Parallel HTACG/ExP JSC for medical devices available on this webpage of the Commission website and submit the request to the HTA secretariat via upload to the HTA IT platform.

Of note, IVD are not within the scope of Parallel HTACG/ExP JSC as they are not in the scope of ExP consultation according to Article 61(2) of the MDR.

According to Article 17(2) of the HTAR, *health technology developers of medical devices may request that the joint scientific consultation take place in parallel with the consultation of an expert panel. In such a case, when submitting the request for the joint scientific consultation, the health technology developer may make the request for a consultation with the expert panel, where appropriate.*

When submitting a request, the HTD should indicate whether a HTACG JSC or Parallel HTACG/ExP JSC is requested.

By the end of the request period, the HTA secretariat will check the compliance of the request with the template established by the HTACG. Where the request does not comply with the template, the HTA secretariat will invite the HTD to re-submit its request at the following request period.

According to Article 17(4) of the HTAR, *within 15 working days after the end of each request period, the Coordination Group shall inform the requesting health technology developer whether it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons, having regard to the criteria laid down in paragraph 3*.

For details on the eligibility and selection criteria and the selection process, please refer to the "Guidance for the selection of medical devices and *in vitro* diagnostic medical devices for Joint Scientific Consultations (JSC)".

According to Article 5(1) and (2) of the IR JSC MD, *with regard to joint scientific consultations on medical devices and in vitro diagnostic medical devices, the information referred to in Article 17(4) of Regulation (EU) 2021/2282 shall be provided by the JSC Subgroup via the HTA secretariat and shall, where applicable, include a timetable for the joint scientific consultation. Where the joint scientific consultation on medical devices is to be carried out in parallel with the expert panel consultation, the timetable referred to in paragraph 1 of this Article shall be agreed between the*

HTA secretariat, in consultation with the JSC Subgroup, and the European Medicines Agency, in consultation with the expert panel, and be synchronised with the timing of the process for the expert panel consultation as specified in Article 8(6), points (a) and (e), Article 10(2), point (a), Article 13(2) and Article 14, point (a).

The EMA proceeds in parallel with the acceptability check of the requests received. In the case of a request for a Parallel HTACG/ExP JSC, the request must be selected by the JSC SG and accepted by the EMA to be subject to Parallel HTACG/ExP JSC.

According to Article 4(2) of the IR JSC MD, *within 15 working days after the end of each request period, the HTA secretariat shall inform the European Medicines Agency which of the requests referred to in paragraph 1, point (b), were selected for joint scientific consultation and the European Medicines Agency shall inform the HTA secretariat which of the requests for the expert panel consultation to be carried out in parallel, in accordance with paragraph 1, point (b), were accepted*.

The HTD will receive a notification if the request is selected for a JSC. The HTA secretariat will also communicate to the HTD a timetable for the JSC including the date and time of the discussion meeting to the HTD. In the case of Parallel HTACG/ExP JSC, the timetable will be synchronised with the timing of the process for ExP consultation.

5 HTACG JSC procedure

The duration of the HTACG JSC procedure will be approximately 4.5 months, from the receipt of the draft briefing package, or 3 months from the receipt of the amended briefing package. Days in general correspond to calendar days and are indicative. Timelines expressed in working days are the timelines for the HTA secretariat actions as defined in the HTAR.

According to Article 8(2) of the IR JSC MD, *when submitting the request referred to in Article 3(1), the health technology developer may ask for a meeting with the assessor and co-assessor and the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup to seek assistance relevant for the preparation of the briefing package. The members of the JSC Subgroup shall be invited to that meeting.*

This **pre-submission meeting** can be organised at the request of the HTD to help them finalise the preparation of their briefing package. The need for a pre-submission meeting is expressed by the HTD in the submission request document, as well as the questions/issues to be discussed during the pre-submission meeting.

The HTACG JSC includes a **discussion meeting** (Day 60) for an exchange of views with the HTD.

Given the uncertainties associated with an early developmental stage and in the exceptional cases where the continuation of the JSC cannot be achieved from the HTD side, a notification as early as possible to the HTA secretariat is crucial. Additionally, it is not guaranteed that the JSC procedure can be re-scheduled in the future if the HTD deviates from the proposed timetable.

The full procedure for an HTACG JSC is detailed in **Table 2**.

5.1 Submission of briefing package for HTACG JSC

5.1.1 Submission of briefing package

The briefing package should be submitted approximately 45 days before the start date (Day 0) of the JSC procedure (see timetable) in the case a pre-submission meeting is organised or approximately one month before Day 0 if not.

The HTD submits the briefing document with annexes and references (briefing package) to the HTA secretariat via the HTA IT platform by the deadline indicated in the timetable for the start of the JSC. All relevant questions from the HTD should be included in the briefing package for the HTACG JSC.

The use of the briefing document template established by the HTACG is required.

Adherence to the deadlines is important to ensure that there is sufficient time for providing feedback to the HTD, and for the HTD to make any requested revisions of the briefing package before the agreed formal start of the procedure.

The HTD's questions should concern all relevant aspects of the clinical study design, including patient population(s), intervention(s), comparator(s) and health outcomes.

Questions on Health Economic (HE) Assessment may be asked by the HTD. Advice on HE may be provided as part of the voluntary cooperation on HTA pursuant to Article 23 of the HTAR and only by the members of the JSC SG with health economics in their remit.

The HTA secretariat will check the compliance of the briefing package with the template established by the HTACG. Where the briefing package does not comply with the template, the HTA secretariat will invite the HTD to re-submit the briefing package within five working days.

The written request from the assessor and co-assessor for further specifications or clarifications or additional information, data, analyses or other evidence (referred to as request for further specifications or clarifications) should be sent to the HTD by the HTA secretariat within 15 working days (if applicable). This request may concern, but is not limited to the following aspects: the scope, the wording and clarity of the questions, whether the material provided in the briefing package is sufficient to answer the questions posed, or if additional questions should be added etc.

In addition, the assessor and co-assessor may, through the HTA secretariat, request further clarification from the HTD at any time within the procedure, if needed.

5.1.2 Submission of amended briefing package

The HTD submits an amended briefing document with all annexes and references (amended briefing package) through the HTA IT platform having addressed the requests for further specifications or clarifications (if any), according to the timetable.

The amended briefing package should be submitted in a "track changes" version and a "clean" version.

The HTA secretariat will check the compliance of the amended briefing package with the template established by the HTACG. Where the amended briefing package does not comply with the template, the HTA secretariat will invite the HTD to re-submit the briefing package within five working days.

In case no changes to the briefing package have been requested, the HTD is still required to submit the amended briefing package with an updated cover page.

5.2 Consultation of individual experts

According to Article 11 of the IR JSC MD, *no later than 30 days after the submission of the amended briefing package referred to in Article 8(4) or, where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, no later than 30 days after the validation of the application referred to in Article 8(6), point (g), the JSC Subgroup, via the HTA secretariat, shall share the briefing package with the individual experts selected in accordance with Article 6 and give them the opportunity to provide input on the joint scientific consultation*.

It is intended to receive feedback from individual experts as early as possible during the JSC procedure via appropriate methods, e.g., interview or questionnaire. To sufficiently discuss and reflect the feedback from individual experts, input should be received by the JSC SG via the HTA secretariat no later than 10 days before the discussion meeting. Input of the individual experts will be reflected in the JSC outcome document.

5.3 List of Issues for HTACG JSC

According to Article 10(1) of the IR JSC MD, *after having assessed the briefing package and where applicable the documentation referred to in Article 8(5), the JSC Subgroup, via the HTA secretariat, shall share with the health technology developer the list of issues indicating the topics to be addressed at the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282 and where relevant the specific questions to be addressed only in writing before that meeting ('the list of issues')*.

For all JSC, a List of Issues (LoI) is created to facilitate the discussion during the discussion meeting. The LoI is structured by PICO (Population, Intervention, Comparator, Outcome) and developed through an exchange between the assessor, co-assessor and the JSC SG.

A **List of Issues meeting** (optional) of the JSC SG allows for a preliminary discussion on the main issues regarding the proposed development plan.

At this stage, there is no draft JSC SG positions required or shared with the HTD.

The HTA secretariat shares the LoI with the HTD at around Day 40 of the JSC procedure.

According to Article 10(1) of the IR JSC MD, *the health technology developer shall provide the JSC Subgroup, via the HTA secretariat, with written responses, if any, to the list of issues as well as any necessary materials or presentations for the meeting at the latest 10 days before that meeting*.

5.4 Discussion meeting for the HTACG JSC

The HTD should submit the final presentation (slides) and the HTD's list of participants to the HTA secretariat via the HTA IT platform by the deadline referred to in Article 10(1) IR JSC MD. Any changes to the presentation after this date will not be accepted. The presentation can include a very brief introduction, rationale and status of the development plan. An upper limit of five slides for the introduction is recommended to maximise the time available for the questions and discussion.

According to Article 18(7) of the HTAR, *the designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and patients, clinical experts and other relevant experts.*

According to Article 13(3) of the IR JSC MD, *the meeting referred to in paragraph 2 shall be held virtually. It shall be co-chaired by the assessor or co-assessor and one of the rapporteurs for the expert panel consultation*.

The discussion meeting of the HTACG JSC enables for a direct exchange between the HTD, the assessor and co-assessor, the JSC SG (optional), and individual experts. Representatives from the notified body chosen by the HTD may participate to the meeting as observers if requested by the HTD.

The main aim of the discussion meeting is to share and discuss preliminary positions on major aspects of the development plan including issues of concern or disagreement with the HTD's study design proposal.

The discussion meeting is chaired by the assessor or co-assessor. The meeting duration will depend on the range of issues to be discussed. However, the maximum length of the meeting is three hours. If the content for the discussion is limited, the meeting can be set to two hours. The HTD will be informed about the length of the discussion meeting in due time. The meeting is hosted by the HTA secretariat and is held virtually.

Before the HTD enters the meeting the JSC SG members and the assessor and co-assessor have the opportunity to have a closed meeting in order to exchange on organisational items and to interact on any possible changes of position after the HTD's responses and presentation. This pre-meeting could be extended if necessary.

The meeting with the HTD is interactive and structured by the issues raised in the LoI, and supported by HTD presentation. During the discussion meeting, the views of the different actors on each issue should be clearly presented by the respective party (as needed). It is usual to pause after each question/issue for discussion. Time should be allowed for summing up at the end of the meeting.

The HTD is expected to provide detailed minutes of the discussion meeting within five working days directly to the HTA secretariat. Minutes are regarded as the HTD's record of the meeting and will not, in general, be endorsed or commented on but are only submitted to the HTA secretariat for information.

5.5 Outcome document for HTACG JSC

According to Article 18(4) of the HTAR, *the assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation outcome document in accordance with the requirements set out in this Article and in accordance with the guidance documents and procedural rules established pursuant to Article 3(7), points (d) and (f), and Article 20.*

According to Article 18(5) of the HTAR, *the members of the designated subgroup shall have the opportunity to provide their comments during the preparation of the draft joint scientific consultation outcome document. Members of the designated subgroup may, as appropriate, provide additional recommendations specific to their individual Member State.*

The HTA secretariat sends out the final JSC outcome document to the HTD after approval by the HTACG at the end of the procedure, in accordance with the communicated timelines.

Table 2: HTACG JSC – Procedural steps and tasks per actor

Day	Health Technology Developer (HTD)	Assessor and co-assessor/JSC SG/HTA secretariat
Submission request		
	➢ **HTD submits** a submission request to the **HTA secretariat** via the HTA IT platform during a submission request period.	
Eligibility check and Selection process by the JSC SG		
		➢ Eligibility check ± selection process of the MD or IVD by the JSC SG ➢ **HTA secretariat** informs the requesting HTD whether the HTACG will engage in the JSC within 15 working days after the end of the request period.
Submission of briefing package ± pre-submission meeting (virtual meeting)		
D - 45 (if pre-submission meeting requested) D - 30 (otherwise)	➢ **HTD submits the briefing document with annexes and references (briefing package)** to the **HTA secretariat** via the HTA IT platform.	**Contact point for HTD: HTA secretariat** ➢ **HTA secretariat communicates receipt** to the HTD. ➢ **After a check of compliance with the template, the HTA Secretariat communicates the briefing package** to the assessor, co-assessor and JSC SG. ➢ **HTA secretariat initiates the process of identifying individual experts** who are selected by the JSC SG.
	Pre-submission meeting (virtual meeting), in case the need for a pre-submission meeting was expressed by the HTD in the submission request: ➢ The meeting is organised by the HTA secretariat. ➢ The meeting is chaired by the assessor or co-assessor. ➢ Attendees of the meeting are the HTD, the HTA secretariat, the assessor and co-assessor, and the JSC SG (*optional*).	

Day	Health Technology Developer (HTD)	Assessor and co-assessor/JSC SG/HTA secretariat
	➢ The issues identified by the HTD during their briefing package preparation are sent to the HTA secretariat 10 working days before the meeting and communicated by the HTA secretariat to the assessor and co-assessor 10 working days before the meeting (EOB). **Discussion between the assessor, co-assessor and the HTD to help the HTD finalise their briefing package.** The meeting duration is 1 hour. The issues identified by the HTD are discussed with the assessor and co-assessor. Any issue identified by the assessor and co-assessor in a view to enhancing the quality of the briefing document may also be discussed with the HTD.	
D - 15		➢ **HTA secretariat sends a request for further specifications or clarifications from assessor and co-assessor/JSC SG on the briefing package to the HTD** via the HTA IT platform (*if applicable*). In addition, requests for further specifications or clarifications can be addressed to the HTD at any time within the procedure.
Submission of amended briefing package		
D 0	➢ **HTD submits the amended briefing package** in response to the request(s) for further specifications or clarifications to the **HTA secretariat** via the HTA IT platform, according to the communicated timeline. ➢ One version of the briefing package should be in "track changes" and the other should be a "clean" version.	➢ **After a check of compliance with the template, the HTA secretariat communicates receipt to the HTD and shares the amended briefing package** with the assessor, co-assessor and the JSC SG. ➢ There is no formal confirmation of the validation by the HTA secretariat but a proactive reach out if the template has not been followed or files are identified to be missing. ➢ The amended briefing package is shared with the selected individual experts for their input.
List of Issues		

Day	Health Technology Developer (HTD)	Assessor and co-assessor/JSC SG/HTA secretariat
~D + 37		➢ **A List of Issues meeting (*optional*)** of the JSC SG allows for a preliminary discussion on the main HTA issues regarding the proposed development plan. ➢ **Production of a List of Issues** through an exchange between the assessor, co-assessor and the JSC SG. The List of Issues outlines the topics of interest structured by PICO (Population, Intervention, Comparator, Outcome) to be addressed by the HTD in the discussion meeting.
~D + 40		➢ **HTA secretariat sends the List of Issues to the HTD.**
HTD's written response to List of Issues and preparation for discussion meeting		
D + 50	No later than 10 working days before the discussion meeting**:** ➢ **HTD submits written response to the List of Issues** via the HTA IT platform to the HTA secretariat. ➢ **HTD submits the presentation for the discussion meeting** to the HTA secretariat via the HTA IT platform. Changes after this date will not be accepted. ➢ **HTD submits list of participants for the discussion meeting**.	➢ **HTA secretariat distributes the HTD's written response** to the List of Issues, the presentation and the list of HTD's participants to the assessor, co-assessor and JSC SG.
Discussion meeting		

Day	Health Technology Developer (HTD)	Assessor and co-assessor/JSC SG/HTA secretariat
D + 60	**Discussion meeting between the HTD, the assessor and co-assessor, the individual experts, the JSC SG (*optional*), the HTA secretariat, and representatives from the notified body chosen by the HTD as observers (*if requested by the HTD*).** ➢ The meeting duration will depend on the range of issues to be discussed (maximum 3 h), with 15 minutes closed pre-, and 15 minutes closed post-discussion meeting (assessor, co-assessor, JSC SG internal). ➢ **The HTD addresses key issues** that were identified by the **assessor, co-assessor and JSC SG**. An interactive discussion follows on the key issues. ➢ The meeting is chaired by the **assessor or co-assessor**. ➢ The meeting is hosted by the **HTA secretariat.** **The individual experts are invited to attend the discussion meeting and share their perspective.**	
D + 70+X	➢ The HTD submits minutes of the discussion meeting within five working days to the HTA secretariat.	➢ Finalisation of **JSC outcome document** and approval by HTA Coordination Group (HTACG). ➢ **HTA secretariat shares JSC outcome document with HTD.**

6 Parallel HTACG/ExP JSC procedure

The duration of the Parallel HTACG/ExP JSC procedure will be approximately 4.5 months, from the receipt of the draft briefing package, or 3 months from the receipt of the amended briefing package. Days in general correspond to calendar days and are indicative. Timelines expressed in working days are the timelines for the HTA secretariat actions as defined in the HTAR.

According to Article 8(2) of the IR JSC MD, *when submitting the request referred to in Article 3(1), the health technology developer may ask for a meeting with the assessor and co-assessor and the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup to seek assistance relevant for the preparation of the briefing package. The members of the JSC Subgroup shall be invited to that meeting*.

According to Article 8(6) of the IR JSC MD, *[…], where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, the following shall apply:*

- *the health technology developer shall submit the briefing package containing the information necessary for the joint scientific consultation on medical devices and for the expert panel consultation at the same time to the HTA secretariat and the European Medicines Agency, by the deadline set in the timetable referred to in Article 5(1)* (Article 8 (6a));
- *one of the rapporteurs for the expert panel consultation and a staff member of the European Medicines Agency responsible for providing secretariat support to the expert panel shall participate in the meeting referred to in paragraph 2* (Article 8 (6b)
- *advisors of the expert panel involved in the consultation shall be invited to the meeting referred to in paragraph 2* (Article 8 (6c)).

This **pre-submission meeting** can be organised at the request of the HTD to help them finalise the preparation of their briefing package. The need for a pre-submission meeting is expressed by the HTD in the submission request document, as well as the questions/issues to be discussed during the pre-submission meeting.

The Parallel HTACG/ExP JSC includes a **discussion meeting (Day 60)** for an exchange of views with the HTD.

Given the uncertainties associated with an early developmental stage and in the exceptional cases where the continuation cannot be achieved from the HTD side, a notification as early as possible to both the EMA and the HTA secretariat is crucial. Additionally, it is not guaranteed that the JSC procedure can be re-scheduled in the future if the HTD deviates from the proposed timetable.

The full procedure for a Parallel HTACG/ExP JSC is detailed in **Table 3**.

Parallel consultation with the ExP can only take place for MD since IVD are not in the scope of ExP consultation to manufacturers.

6.1 Submission of the briefing package for Parallel HTACG/ExP JSC

6.1.1 Submission of briefing package

The briefing package should be submitted approximately 45 days before the start date (Day 0) of the Parallel HTACG/ExP JSC procedure (see timetable) in the case a pre-submission meeting is organised or approximately one month before Day 0 if not.

The EMA together with the HTA secretariat sets up a timetable for each procedure enabling for close interactions between them.

The HTD submits the briefing document with annexes and references (briefing package) to the HTA secretariat via the HTA IT platform and to the ExP through ExP IT platform, at the same time, by the deadline indicated in the timetable for the start of the procedure. All relevant questions from the HTD to the ExP and to the HTACG should be included in the briefing package.

A common briefing document template is used. Each question can be addressed to the HTACG or to the ExP or to both. The labelling of questions is a guide but does not prevent HTACG or ExP answering questions deemed also relevant and of interest although originally raised to the other party.

The HTD's questions should concern all relevant aspects of the clinical study design, including patient population(s), intervention(s), comparator(s) and health outcomes.

Questions on Health Economic (HE) Assessment may be asked by the HTD. Advice on HE may be provided as part of the voluntary cooperation on HTA pursuant to Article 23 of the HTAR and only by the members of the JSC SG with health economics in their remit.

The HTA secretariat will check the compliance of the briefing package with the common briefing document template. Where the briefing package does not comply with the template, the HTA secretariat will invite the HTD to re-submit the briefing package within five working days.

The written requests from the assessor and co-assessor and/or from the ExP for further specifications or clarification or additional information, data, analyses or other evidence (referred to as request for specifications or clarification)) should be sent to the HTD by the HTA secretariat within 15 working days, respectively by the EMA (if applicable). These requests may concern, but are not limited to the following aspects: the scope, the wording and clarity of the questions, whether the material provided in the briefing package is sufficient to answer the questions posed, or if additional questions should be added etc.

In addition, both parties may contact the HTD in order to request further clarification at any time within the procedure, if needed.

6.1.2 Submission of amended briefing package

The HTD submits a revised briefing package with all annexes and references having addressed the JSC SG request for specifications or clarification and the ExP comments (if any) via the HTA IT platform and via the ExP IT platform, according to the shared timeline.

The amended briefing package should be submitted in a "track changes" version and a "clean" version.

The HTA secretariat will check the compliance of the amended briefing package with the common briefing document template. Where the amended briefing package does not comply with the template, the HTA secretariat will invite the HTD to re-submit the briefing package within five working days.

In case no changes to the briefing package have been requested, the HTD is still required to submit the amended briefing package with an updated cover page.

6.1.3 Consultation of individual experts

According to Article 11 of the IR JSC MD, *no later than 30 days after the submission of the amended briefing package referred to in Article 8(4) or, where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, no later than 30 days after the validation of the application referred to in Article 8(6), point (g), the JSC Subgroup, via the HTA secretariat, shall share the briefing package with the individual experts selected in accordance with Article 6 and give them the opportunity to provide input on the joint scientific consultation*.

It is intended to receive feedback from individual experts as early as possible during the JSC procedure via appropriate methods, e.g., interview or questionnaire. To sufficiently discuss and reflect the feedback from individual experts, input should be received by the JSC SG via the HTA secretariat no later than 10 days before the discussion meeting. Input of the individual experts will be reflected in the JSC outcome document.

6.2 List of Issues for Parallel HTACG/ExP JSC

According to Article 10(2a) of the IR JSC MD, *the JSC Subgroup, via the HTA secretariat, and the expert panel, via the European Medicines Agency, shall send their respective lists of issues to the health technology developer within the deadline set in the timetable referred to in Article 5(1)*.

According to Article 10(2b) of the IR JSC MD, *the HTA secretariat and the European Medicines Agency shall exchange with each other the lists of issues on the same day as sending them to the health technology developer*.

A **List of Issues meeting** (optional) of the JSC SG allows for a preliminary discussion on the main HTA issues regarding the proposed development plan. At this stage, there is no draft HTA positions required or shared with the HTD.

The HTA secretariat and the EMA both share their respective LoI with the HTD at around Day 40 of the JSC procedure.

According to Article 10(1) of the IR JSC MD, *[…] The health technology developer shall provide the JSC Subgroup, via the HTA secretariat, with written responses, if any, to the list of issues as well as any necessary materials or presentations for the meeting at the latest 10 days before that meeting.*

According to Article 10(2c) of the IR JSC MD, *the health technology developer shall send to the JSC Subgroup, via the HTA secretariat, a copy of their written responses, if any, to the list of issues provided by the expert panel at the same time as it sends those responses to the European Medicines Agency*.

According to Article 10(2d) of the IR JSC MD, *the health technology developer shall send to the European Medicines Agency a copy of their written responses, if any, to the list of issues provided by the JSC Subgroup at the same time as it sends those responses to the HTA secretariat*.

6.3 Preparation for discussion meeting for Parallel HTACG/ExP JSC

6.3.1 Bilateral meeting

In preparation of the discussion meeting, the assessor/co-assessor, the JSC SG (optional), the ExP, the EMA and the HTA secretariat can have a meeting to discuss their preliminary views on the proposed development plan to facilitate a comprehensive discussion with the HTD during the discussion meeting.

6.4 Discussion meeting for Parallel HTACG/ExP JSC

The HTD should submit the final presentation (slides) and the HTD's list of participants to the HTA secretariat via the HTA IT platform and to the EMA via the ExP IT platform by the deadline referred to in Article 10(1) IR JSC MD. Any changes to the presentation after this date will not be accepted. The presentation can include a very brief introduction, rationale and status of the development plan. An upper limit of five slides for this introduction is recommended to maximise the time available for the questions and discussion.

According to Article 18(7) of the HTAR, *the designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and patients, clinical experts and other relevant experts.*

According to Article 13(3) of the IR JSC MD, *the meeting […] shall be held virtually. It shall be co-chaired by the assessor or co-assessor and one of the rapporteurs for the expert panel consultation*.

The discussion meeting of a Parallel HTACG/ExP JSC enables for a direct exchange between the HTD, the assessor and co-assessor, the ExP advisors, JSC SG (optional), and individual experts.

Representatives from the notified body chosen by the HTD may participate to the meeting as observers if requested by the HTD.

The aims of the discussion meeting are:

- To discuss issues of concern or disagreement from JSC SG and/or ExP with the HTD's proposal regarding major aspects of the development plan.
- To get a mutual understanding of each party's constraints as it has to be acknowledged that the ExP and the JSC SG are operating within distinct remits (clinical benefits, performance and safety, and benefit-risk evaluation vs. relative effectiveness in comparison with other new or existing health technologies). Possible resulting divergences between the JSC SG positions and ExP's positions on major aspects of the development plan will be discussed.
- To discuss potential solutions that could facilitate a development plan that is fit for both HTA and regulatory purposes.

The discussion meeting has two co-chairs: one from the JSC SG (assessor or co-assessor) and one from the ExP (one of the rapporteurs for the ExP consultation). The meeting duration will depend on the range of issues to be discussed. However, the maximum length of the meeting is three hours. If it is agreed between the JSC SG and ExP prior to the discussion meeting that the content of the discussion is limited, the meeting can be set at two hours. The HTD will be informed about the length of the discussion meeting in due time. The meeting is hosted by the HTA secretariat and is held virtually.

Before the HTD enters the meeting, the JSC SG members and the ExP advisor have the opportunity to have a closed meeting in order to exchange on organisational items and to interact on any possible changes of position after the HTD's responses and presentation. This pre-meeting could be extended if necessary.

The meeting with the HTD is interactive, structured by the issues raised in the LoI, and supported by the HTD presentation. Wherever possible the issues listed by the JSC SG and ExP regarding similar topics should be grouped together and structured following PICO (Population(s), Intervention(s), Comparator(s), Outcomes) to enable for a joint discussion. During the discussion meeting, the views of the different actors on each issue should be clearly presented by the respective party (as needed). It is usual to pause after each question/issue for discussion. Time should be allowed for summing up at the end of the meeting.

The HTD is expected to provide detailed minutes of the discussion meeting within five working days directly to the ExP and the HTA secretariat. The minutes should reflect the views for each participating actor in the discussion meeting. Areas of agreement and divergence of opinion between the JSC SG and ExP can be summarised by the HTD. Minutes are regarded as the HTD's record of the meeting and will not, in general, be commented or approved by the participating parties.

6.5 Outcome documents for Parallel HTACG/ExP JSC

According to Article 18(4) of the HTAR, *the assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation outcome document in accordance with the requirements set out in this Article and in accordance with the guidance documents and procedural rules established pursuant to Article 3(7), points (d) and (f), and Article 20.*

According to Article 18(5) of the HTAR, *the members of the designated subgroup shall have the opportunity to provide their comments during the preparation of the draft joint scientific consultation outcome document. Members of the designated subgroup may, as appropriate, provide additional recommendations specific to their individual Member State.*

According to Article 14(a) of the IR JSC MD, *the Coordination Group shall approve the joint scientific consultation outcome document and the expert panel shall issue the advice letter to the health technology developer within the deadline set in the timetable referred to in Article 5(1)*.

The HTA secretariat sends out the final JSC outcome document to the HTD after approval by the HTACG at the end of the procedure, in accordance with the communicated timelines.

The EMA provides the final advice letter to the HTD in accordance with the communicated timelines.

According to Article 14(b) of the IR JSC MD, *the HTA secretariat and the European Medicines Agency shall exchange with each other the outcome document approved by the Coordination Group and the advice letter issued by the expert panel on the same day as sending them to the health technology developer*.

Table 3: Parallel HTACG/ExP JSC – Procedural steps and tasks per actor

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
Submission request			
	➢ **HTD submits** a submission request for Parallel HTACG/ExP JSC to the **HTA secretariat** via the HTA IT platform during a submission request period		
Eligibility check and Selection process by the JSC SG			
		➢ Eligibility check by the EMA	➢ Eligibility check ± selection process of the MD by the JSC SG
		EMA and **HTA secretariat** share their output of the eligibility check and the JSC SG selection process they both conducted.	
			➢ **HTA secretariat** informs the requesting HTD whether the HTACG will engage in the Parallel HTACG/ExP JSC within 15 working days after the end of the request period.
Submission of briefing package ± pre-submission meeting (virtual meeting)			
D - 45 (if pre-submission	**HTD submits the briefing document with annexes and references (briefing package)** at the same time to the HTA	ExP IT platform automatically confirms receipt.	➢ **HTA secretariat** communicates receipt to the HTD. ➢ **HTA secretariat is the contact point for the HTD regarding all HTA matters.**

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
meeting requested) D - 30 (otherwise)	secretariat via the HTA IT platform and to the EMA via the ExP IT platform ➢	➢ Communication of the EMA to HTD and HTA secretariat.	➢ **After a check of compliance with the template, the HTA secretariat** communicates the briefing package to **assessor, co-assessor and JSC SG**. ➢ **HTA secretariat initiates process of identifying individual experts** who are selected by the JSC SG.
	Pre-submission meeting (virtual meeting), in case the need for a pre-submission meeting was expressed by the HTD in the submission request: ➢ The meeting is organised by the HTA secretariat. ➢ The meeting is co-chaired by the assessor or co-assessor and one of the ExP rapporteurs. ➢ Attendees of the meeting are the HTD, the HTA secretariat, the assessor and co-assessor, the EMA, one of the ExP rapporteurs, the JSC SG (*optional*), and advisors of the ExP (*optional*). ➢ The issues identified by the HTD during their briefing package preparation are sent by the HTD to the HTA secretariat and EMA 10 working days before the meeting and communicated by the HTA secretariat to the JSC SG 10 working days before the meeting (EOB). **Discussion between the assessor, co-assessor**, **the ExP and the HTD to help the HTD finalise their briefing package.** The meeting duration is 1 hour. The issues identified by the HTD are discussed with the assessor and co-assessor and the ExP. Any issue identified by the assessor and co-assessor or the ExP in a view to enhancing the quality of the briefing document may also be discussed with the HTD.		

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
D - 15		➢ **EMA sends a request on the briefing package to the HTD** via ExP IT platform and to the **HTA secretariat** *(if applicable)*	➢ **HTA secretariat sends a request for further specifications or clarifications from assessor and co-assessor/JSC SG on the briefing package to the HTD** via the HTA IT platform and to the EMA (*if applicable*). In addition, requests for further specifications or clarifications can be addressed to the HTD at any time within the procedure.
Submission of amended briefing package			
D 0	➢ **HTD submits the amended briefing package** in response to the request(s) for specifications or clarifications to the **EMA** via the ExP IT platform and to the **HTA secretariat** via the HTA IT platform, according to the communicated timelines. ➢ One version of the briefing package should be in "track changes" and the other should be a "clean" version.	➢ **EMA validates amended briefing package.** ➢ **EMA notifies the HTD** of a positive validation of the amended briefing package via ExP IT platform and informs of HTA secretariat thereof at D -2 together with final instructions.	➢ **After a check of compliance with the template, the HTA secretariat communicates receipt to the HTD and shares the amended briefing package** with the assessor, co-assessor and JSC SG. ➢ There is no formal confirmation of the validation by the HTA secretariat but a proactive reach out if the template has not been followed or files are identified to be missing. ➢ The amended briefing package is shared with the selected individual experts for their input.
List of Issues			

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
~D + 37		➢ Discussion of the first reports during ExP meeting focusing on controversial issues followed by **production of an ExP List of Issues**, which outlines the topics of interest to be addressed by the HTD in the discussion meeting.	➢ **A List of Issues meeting (*optional*)** of the JSC SG allows for a preliminary discussion on the main HTA issues regarding the proposed development plan. ➢ **Production of a List of Issues** through an exchange between the assessor, co-assessor and the JSC SG. The List of Issues outlines the topics of interest structured by PICO (Population, Intervention, Comparator, Outcome) to be addressed by the HTD in the discussion meeting.
~D + 40		➢ **The EMA and the HTA secretariat exchange their respective Lists of Issues and send the lists to the HTD.**	
HTD's written response to List of Issues and preparation for discussion meeting			
D + 50	No later than 10 working days before the discussion meeting**:** ➢ **HTD submits written responses to the HTA List of Issues** to the HTA secretariat via the HTA IT platform. ➢ **HTD submits written responses to the ExP List of Issues** to the EMA via ExP IT platform. ➢ **HTD submits the presentation for the discussion meeting** to the HTA	➢ The EMA distributes the HTD's written response to the List of Issues, the presentation and the list of HTD's participants to the **ExP**.	➢ **HTA secretariat distributes the HTD's written response** to the List of Issues, the presentation and the list of HTD's participants to the assessor, co-assessor and the JSC SG.

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
	secretariat via the HTA IT platform and to the EMA via the ExP IT platform, addressing the Lists of Issues for both HTA and ExP. The HTD should group related issues together. ➢ **HTD submits list of participants for the discussion meeting**.		
D + 55		**A bilateral meeting** in preparation of the discussion meeting allows for the assessor/co-assessor, the JSC SG (*optional*), the ExP, the EMA and the HTA secretariat to discuss their preliminary views on the proposed development plan to facilitate a comprehensive discussion with the HTD during the discussion meeting.	
Discussion meeting			
D + 60	**Discussion meeting between the HTD, the assessor and co-assessor, the individual experts, the JSC SG (*optional*), the HTA secretariat, the advisors of the ExP, the EMA and representatives from the notified body chosen by the HTD as observers (*if requested by the HTD*).** ➢ The meeting duration will depend on the range of issues to be discussed (maximum 3 h), with 15 minutes closed pre-, and 15 minutes closed post-discussion meeting. This pre-meeting could be extended if necessary (internal). ➢ **The HTD addresses key issues** that were identified by the **assessor, co-assessor, JSC SG and the ExP**. An interactive discussion follows on the key issues. ➢ The meeting has 2 co-chairs: one from the HTA side (assessor or co-assessor) and one from the ExP (one of the rapporteurs for the ExP consultation).		

Day	Health Technology Developer (HTD)	Expert Panels (ExP)/EMA	Assessor and co-assessor/JSC SG/HTA secretariat
	➢ The meeting is hosted by the **HTA secretariat**. **The individual experts are invited to attend the discussion meeting and share their perspective.**		
D + 70+X	➢ The HTD submits minutes of the discussion meeting within five working days to the EMA via the ExP IT platform and to the HTA secretariat via the HTA IT platform.	➢ The **Final ExP advice Letter** is made available to the **HTD** via the ExP IT platform and shared with the **HTA secretariat.**	➢ Finalisation of **JSC outcome document** and approval by the HTA Coordination Group (HTACG). ➢ **HTA secretariat shares JSC outcome document with HTD and EMA.**

7 Practical issues

7.1 Fees

The HTACG JSC is not subject to any fees.

There is the possibility of the EMA levying fees for this type of consultation. The EMA will inform the HTD accordingly.

7.2 Contact points

The HTA secretariat is the single point of contact in relation to all HTA aspects. The HTD should keep the HTA secretariat up to date with changes in terms of contact details.

The EMA's scientific officer and the procedure's assistant managing the procedure will be identified to the HTD.

7.3 Processing of documents

The HTD is responsible for sending all relevant documents directly to the HTA secretariat and the EMA in a simultaneous manner. The HTD should ensure that receipt of documents has been confirmed by both parties.

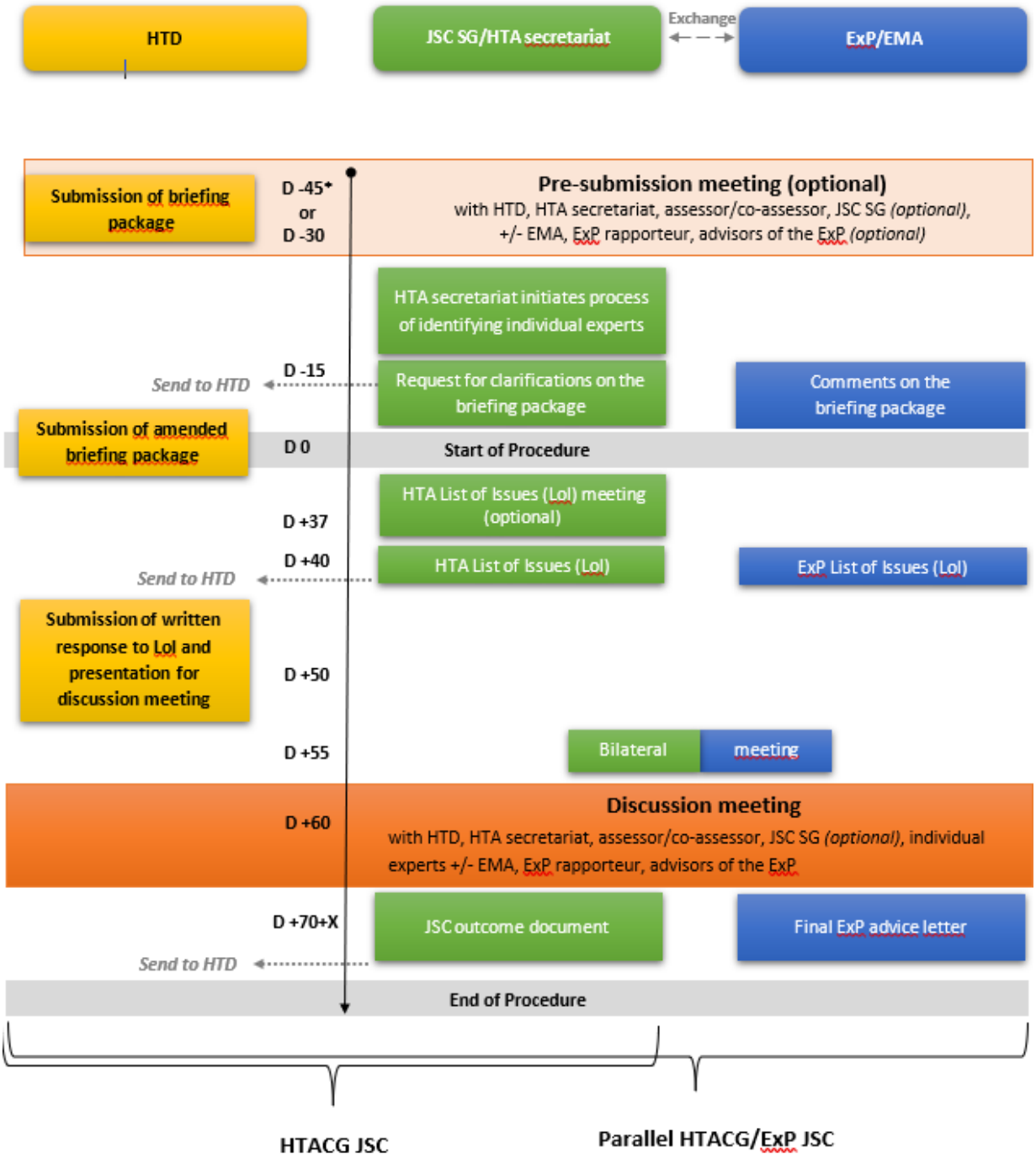
The exchange of documentation with the HTA secretariat should take place via the HTA IT platform. Document exchange between the HTD and the EMA takes place via the ExP IT platform. The exchange of documents between the HTD and the HTA secretariat takes place via the HTA IT platform.

Document version control, numbering, and adherence to timelines are essential to ensure all parties have the appropriate document at the correct time.

7.4 Annex 1 - Schematic overview of HTD, SG JSC/HTA secretariat and ExP/EMA interaction

Figure 1: Overview of the interaction and the procedural steps for JSC.

For HTACG JSC, without Expert Panels participation, the Expert Panels/EMA interaction does not apply (in blue).



*Submission of briefing package at D -45 if a pre-submission meeting is requested by the HTD, if not submission at D -30.

Abbreviations: D=days (expressed in calendar days); EMA=European Medicines Agency; ExP=Expert Panels; HTA=Health Technology Assessment; HTD=Health Technology Developer; JSC SG=JSC Subgroup.