HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Procedural guidance for JCA medicinal products

V1.0

13 November 2024

Adopted on 28 November 2024 by the HTA CG pursuant to Article 3(7), point (d), of Regulation (EU) 2021/2282 on Health Technology Assessment

List of abbreviations

Abbreviation	Definition
ASR	Assessor
CG	Coordination Group
Co-ASR	Co-Assessor
EC	European Commission
F2F	Face-to-face
HTA	Health Technology Assessment
HTAR	HTA Regulation – Regulation (EU) 2021/2282
HTD	Health Technology Developer
IA JCA-MP	Implementing Regulation (ED) 2021/2282 on JCA for Medicinal Products
JCA	Joint Clinical Assessment
LoI	Letter of Intent
MAA	Marketing Authorisation Application
MS	Member States
NCE	New Chemical Entity
PICO	Population/Intervention/Comparator/Outcomes
SG	Subgroup

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1 Objective of this Procedural guidance

This procedural guidance describes the main steps of the procedure for the production of Joint Clinical Assessments (JCA) of medicinal products (MP) as defined in the Regulation (EU) 2021/2282 on health technology assessment (henceforth 'the HTA Regulation or 'HTAR').

1.1 Principles

Underlying principles for the procedure of JCA of medicinal products:

- The rules, procedures and timelines defined in the HTAR and the Implementing Regulation on JCA for MP (henceforth 'IA JCA-MP') form the basis of this document and must be respected.
- When a JCA is started, procedures, guidances, guidelines and templates should not be changed anymore. This aids the predictability of the process. Therefore, a system needs to be developed to keep track of which versions are applicable to the specific JCA.
- Once the JCA has begun, timelines should be kept as fixed as possible to allow predictability of the process. Moreover, as stated in IA JCA-MP Article 12(3): *'In justified cases, with the consent of the assessor and co-assessor and considering the timetable for the evaluation during the centralised procedure, the HTA secretariat may extend the deadline referred to in paragraph 2. However, that extension shall not exceed the deadline specified in Article 10(1) of Regulation (EU) 2021/2282'*.
- In this document, days refer to calendar days unless specified otherwise.
- The Assessment Scoping process will not start before the HTD has submitted their Marketing Authorisation Application (MAA) to EMA.

Please note that throughout this procedural guidance any referral to the HTA Secretariat is to the Secretariat at the European Commission (EC), who centrally coordinates the JCA and is the primary point of contact for the Health Technology Developer (HTD) and assessor/co-assessor. (All questions and communication related to the JCA should be sent to the HTA Secretariat.)

The current version only includes timelines and procedures for the standard MAA procedure and the accelerated procedure. The timelines and procedures for Type II variations are excluded from this document.

2 Procedure steps for JCA production of medicinal products

2.1 Initiation phase

2.1.1 Letter of Intent by HTD

When the HTD intends to submit an application for marketing authorisation to the EMA, they should indicate in the Letter of Intent (LoI) to the EMA whether their product is in scope for the JCA according to Article 7 of the HTAR. If the medicinal product is in scope, the HTD is requested to share their LoI also with the HTA secretariat. To arrange this, the HTD should inform the HTA secretariat about their planned submission of a LoI, after which the HTA Secretariat will create a specific IT Account for the HTD. Thereafter, the HTD can submit its LoI on the IT platform.

For eligibility criteria, please see the document ‘scientific specifications of medicinal products subject to joint clinical assessments’.

When the HTACG's confirmation is made, the JCA SG initiates the process of appointment of an assessor and co-assessor, and the HTA secretariat initiates the identification of patients and clinical experts. For this purpose, the relevant information from the LoI filed to EMA and the HTA secretariat will be shared with the JCA Subgroup members, as this aids their planning and decision making whether they intend to apply for the role as assessor or co-assessor.

2.1.2 Appointment of the assessor and co-assessor

Upon appointment of the assessor and co-assessor, the HTA secretariat will inform the HTD of the start of the JCA procedure and where all relevant documents (i.e., guidances and templates) valid for the current JCA can be found.

While the appointment of the assessor and co-assessor may be initiated prior to the submission of an application to EMA, the final confirmation of the assessor and co-assessor and therefore final confirmation of the start of the JCA will only be provided upon the submission of an application to EMA.

The roles of the assessor and co-assessor, JCA SG members and the watchers (optional) are described on a high level below. In accordance with the IA JCA-MP Article 12(8) the entire JCA SG shall have access to the full Submission Dossier and any other information shared by the HTD. This information shall be made available via the IT platform.

- Assessor and co-assessor:
  - Please note that the distribution of tasks between assessor and co-assessor is not described or standardised here. This should be decided on a case-by-case basis by assessor and co-assessor for each JCA. However, the leading principle is that the work should be split rather equally between assessor and co-assessor

- Responsible for data accuracy

- JCA SG members:
  - Responsible for quality assurance (i.e. methodological aspects) by thorough review of the assessment scope and (revised) draft JCA report.

- OPTIONAL: Watcher:
  - This role is specifically designed for JCA SG members who want to learn more about the JCA production process and this role is intended for capacity building purposes.
  - Watchers will be invited to join all meetings between the assessor and co-assessor.
  - JCA SG members should declare their interest in the role of watcher to 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.

2.1.3 Conflict of Interest

Conflict of Interest rules are laid down in the Implementing Regulation (EU) 2024/2745 on COI.

2.1.4 Public announcement of the start of the JCA

Pursuant HTAR Article 30(3), point (h), the publicly accessible webpage shall contain: "information on planned, on-going, and completed joint clinical assessments, including updates carried out in accordance with Article 14."

2.2 Scoping Phase

The IA JCA-MP defines the process steps for the scoping phase (Article 9, 10 and 11). Please also see the guidance on the scoping process for further details on how to define a PICO[1].

2.2.1 Development of the assessment scope

In order to allow sufficient time for developing the first draft JCA and summary reports, the assessor and co-assessor develop an assessment scope proposal immediately upon submission of an application to EMA (before the confirmation of a valid submission by EMA). All JCA SG members are invited to respond to this proposal via a PICO survey. After this input has been received, the assessor and co-assessor shall consolidate the input received on the assessment scope proposal. The assessment scope development process shall follow the respective guidance on the scoping process[1]. If the JCA SG considers it necessary, the HTD may be asked to provide further information (Article 2(3) JCA-MP IA).

1 Key documents – European Commission (europa.eu)

2.2.2 Involvement of experts and stakeholder organisations

2.2.2.1 Identification and selection

The identification and selection of experts follows the procedure defined in the IA JCA-MP. This document only further describes procedural tasks for the JCA SG and the assessor and co-assessor in case the IA JCA-MP does not provide sufficient details.

Table 1: identification and selection process for patients, clinical experts, other relevant experts and patient organisations or clinical and learned societies

IA JCA-MP Article	Who	How
Recital 17 “These members should consult national authorities and stakeholders in accordance with the procedural rules of the respective Member State”	JCA SG members	National procedures
Article 6.1 “The JCA subgroup shall specify, for each particular joint clinical assessment, the disease, the therapeutic area concerned and other specific expertise, based on which the HTA secretariat shall identify patients, clinical experts and other relevant experts to be consulted during that joint clinical assessment.”	Assessor and co-assessor together with the JCA SG chair/co-chair	A standardised table is to be completed by the assessor and co-assessor (if already identified) or the chair/co-chair (if no asr/co-asr are identified yet). Since the disease and therapeutic area are to be extracted from the submission to EMA, no formal JCA SG approval is required.
Article 6.5 “The JCA Subgroup shall make the final selection of patients, clinical experts and, where necessary, other relevant experts to be consulted during the joint clinical assessment. In making the final selection, the JCA Subgroup shall give priority to patients, clinical experts and other relevant experts who have expertise, covering several Member States, in the therapeutic area of the joint clinical assessment.”	Assessor and co-assessor together with the JCA SG chair/co-chair	assessor and co-assessor will propose the selection of patients, clinical experts and other relevant experts to the JCA SG, as they can judge best which identified patient and clinical expert has the most relevant expertise for the JCA.
Article 8 "At any time during the joint clinical assessment, the JCA Subgroup may seek input on the disease and therapeutic area from patient organisations, healthcare professional organisations or clinical and learned societies via the members of the HTA stakeholder network."	Assessor and co-assessor together with the JCA SG chair/co-chair	In case the JCA SG wishes to seek input according to Article 8, the JCA SG chair/co-chair inform the HTA Secretariat and provide them with the request for information.

2.2.2.2 Timepoints and procedures for involvement during the JCA

The table in Appendix C – Overview of Patient involvement in JCA MP describes the mandatory and optional timepoints at which patients, clinical experts, other relevant experts, patient organisations and clinical organisations could be involved during the JCA process.

2.2.3 Inform the HTD of the assessment scope

Pursuant JCA MP-IA Article 10(3): “The HTA secretariat shall share the assessment scope finalised by the JCA Subgroup with the health technology developer in the Commission's first request referred to in Article 10(1) of Regulation (EU) 2021/2282.”

Upon that communication the period for the HTD to develop their dossier starts, please see section 2.3.2 for further details.

2.2.4 Assessment scope explanation meeting

Pursuant IA JCA-MP Article 11: *'Upon request of the health technology developer, the HTA Secretariat shall invite the health technology developer to an assessment scope explanation meeting with the JCA Subgroup. The meeting shall take place no later than 20 days from the day on which the JCA Subgroup finalises the assessment scope'*.

This is a virtual meeting that only can take place once per JCA following fixed meeting dates (e.g. 2 days a month) and the HTD will be given a meeting slot.

Table 2: Assessment scope explanation meeting

Duration	1 hour maximum
Location	Virtual
Attendees	JCA Subgroup, HTD The HTD is advised to bring a representative from regulatory affairs. Please note that any patient and/or clinical experts brought to the meeting by HTD are considered as HTD representative and therefore their input will not be considered as patients, clinical experts and other relevant experts referred in IA JCA-MP Article 6 input.
Agenda	For reasons of fairness, all HTD will have the same time for this explanation meeting, which will be limited to 60 minutes.
Objective	Information meeting to explain the final consolidated assessment scope to the HTD. The meeting is not intended to make changes to the PICO, nor will any opinion or advice be given on the appropriateness of data/methods/analysis to be submitted to answer to the PICOs.
Preparation	The HTD will receive the final assessment scope.
Outcome	No minutes will be taken, nor will the meeting be recorded.

2.3 Dossier Submission Phase

2.3.1 Submission Requirements

The submission requirements can be found in the HTAR, the IA JCA-MP and the Annex I of the IA JCA-MP. These requirements shall be used to determine the completeness of the submission dossier. Please see section 2.3.4 'Check for Completeness' for further details.

2.3.2 Timelines for the submission dossier

Pursuant JCA MP-IA Article 12(1): *"the health technology developer shall submit the dossier for joint clinical assessment of the medicinal product, requested by the Commission in its first*

request referred to in Article 10(1) of Regulation (EU) 2021/2282, to the HTA secretariat in a digital format. (...).”

The timelines for the submission dossier are stated in the HTAR and IA JCA-MP. These timelines are binding:

- IA JCA-MP Article 12(2): *’The deadline to submit the dossier […] shall be 100 days from the date of the notification of the first request to the health technology developer’.*
- *IA JCA-MP Article 12(2):’However, that deadline shall be 60 days where: (a) the application […] is assessed under the accelerated procedure […]’*.
- IA JCA-MP Article 12(3): *’In justified cases, with the consent of the assessor and co-assessor and considering the timetable for the evaluation during the centralized procedure, the HTA secretariat may extend the deadline referred in paragraph 2. However, that extension shall not exceed the deadline specified in Article 10(1) of Regulation (EU) 2021/2282’*.
- HTAR Article 10(1): *‘[…] For medicinal products, the deadline for submission shall be at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use […]’*.

2.3.3 Submission Dossier Template

The lay-out and criteria of the Submission Dossier Template can be found in Annex I of the IA JCA-MP and Annex I of the HTAR. Pursuant the JCA-MP IA, Annex I: “the provision of information, data, analysis and other evidence in the dossier shall follow international standards of evidence-based medicine and take into account, if available, the methodological guidance adopted by the HTACG under Article 3(7), point (d), of the HTAR where applicable.”[2].

The HTD shall follow all legal requirements and additional guidance when developing their submission dossier and shall adhere to the order presented[2]. Where necessary, tables can be added or, in existing tables, the HTD can change the layout to improve data presentation. However, all requested content needs to be completed.

2.3.4 Check for Completeness

Pursuant IA JCA-MP Article 13: *“Within 15 working days from the date on which the health technology developer submitted the dossier, and as appropriate in consultation with the assessor and co-assessor, the commission shall confirm whether, based on the information available at the time, the dossier for a joint clinical assessment of the medicinal product meets*

2 Key documents – European Commission (europa.eu)

the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282. However, that deadline shall be 10 working days where:

(a) The application for a marketing authorisation for a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2204; (...)"

Pursuant HTAR Article 10(5): *'Where the Commission finds that the dossier fails to meet the requirements laid down in Article 9(2), (3) and (4), it shall request the missing information, data, analyses and other evidence from the health technology developer (second request). In such a case, the health technology developer shall submit the requested information, data, analyses and other evidence in accordance with the timeframe established pursuant to Article 15'*.

Pursuant IA JCA-MP Article 12(4): *'The health technology developer shall submit the missing information, data, analyses and other evidence indicated in the Commission's second request referred to in Article 10(5) of Regulation (EU) 2021/2282 within 15 days from the date of notification of the Commission's second request to the health technology developer. However, that deadline shall be 10 days where:*

the application for a marketing authorisation for a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2004; or [...].

The deadlines referred to in the first subparagraph shall be 7 days for cases where only minor information is missing.'

Pursuant HTAR Article 10(6): *'Where, after the second request referred to in paragraph 5 of this Article, the Commission deems that a dossier was not submitted in a timely manner by the health technology developer, or attests that it fails to meet the requirements laid down in Article 9(2), (3) and (4), the Coordination Group shall discontinue the joint clinical assessment. If the assessment is discontinued, the Commission shall make a statement on the IT platform referred to in Article 30, justifying the reasons for the discontinuation and shall inform the health technology developer accordingly. In the case of discontinuation of the joint clinical assessment, Article 13(1), point (d), shall not apply.'*

In case an amended submission dossier is required, the HTD shall submit:

- A version with track changes
- A clean version without track changes
- A cover note explaining how the missing items have been addressed

2.3.5 Requests by the ASR/Co-ASR during the drafting of the JCA report

Pursuant JCA MP-IA Article 12(5): *"where the assessor, with the assistance of the co-assessor, at any time during the preparation of the draft joint clinical assessment and summary reports, considers, under Article 11(2) of Regulation (EU) 2021/2282, that further specifications or clarifications or additional information, data, analyses, or other evidence are necessary, the HTA secretariat shall request the health technology developer to provide such information, data, analyses or other evidence within the deadline set by the assessor and co-assessor depending on the nature of the information requested. That deadline shall be set at minimum 7 days and maximum 30 days counting from the date of notification of the request to the health technology developer."*

Pursuant JCA MP-IA Article 12(7): *"if during the joint clinical assessment, the health technology developer submits new data from clinical studies to the European Medicines Agency, it shall notify the HTA secretariat thereof and provide this data upon request of the assessor, with the assistance of the co-assessor. The deadline referred to in paragraph 5 apply to that request."*

2.3.6 Amended dossier in case of changes to the indication

There are no clock stops in the JCA procedure, also not in the event of changes to the indication. Therefore, the HTD is advised to liaise closely with their Regulatory Affairs department in order to predict if indication changes may be likely and what their impact may be.

In the event of changes to the therapeutic indication(s), Article 16 of the JCA MP-IA applies:

- Article 16(1): *"where during the centralised procedure, there is a change of the therapeutic indication(s) initially submitted to the European Medicines Agency, the assessor, with the assistance of the co-assessor, shall assess whether the change affects the assessment scope and inform the JCA Subgroup."*
- Article 16(2): *"the JCA Subgroup shall decide whether the joint clinical assessment shall continue, or whether the assessor, with the assistance of the co-assessor, shall prepare a new assessment scope proposal. The HTA secretariat shall inform the health technology developer of the JCA Subgroup's decision."*
- Article 16(3): *"if a new assessment scope proposal is prepared, Article 9 and 10(1) of this Regulation shall apply with the necessary modifications."*
- Article 16(4): *"the HTA secretariat shall inform the health technology developer of the new assessment scope finalised by the JCA Subgroup and shall request the health technology developer to submit an updated dossier. The deadlines referred to in Article 12(5) shall apply to that request. Article 14 and 15(1) of this Regulation shall apply with the necessary modifications."*

In case an updated submission dossier is requested, modifications can only be made to those sections impacted by the updated assessment scope.

When an updated submission dossier is required, the HTD shall submit:

- A version with track changes
- A clean version without track changes
- A cover note explaining how the change in indication and new assessment scope have been addressed

2.3.7 Methodological guidance documents

Please see an overview of all Methodological and procedural guidance documents that are applicable on the publicly accessible webpage[3].

2.4 Assessment Phase

2.4.1 Assessment process and timelines

The assessment phase starts when the HTD submits their submission dossier via the IT platform. The assessor and co-assessor jointly write the JCA report, and they decide upon the specific work distribution between the two MS. It is advised that the work is distributed rather equally. The assessor and co-assessor have to develop their own interim deadlines between them, to allow for discussion and review among the assessor and co-assessor prior to the JCA SG review.

Key timepoints of the JCA drafting process can be found below (appendix A and B). Please note that the preliminary timelines for the JCA will be shared with the HTD by the HTA Secretariat when the JCA is officially started (upon appointment of assessor and co-assessor. The timelines are based on assumptions from the CHMP procedure. Overall, the JCA subgroup and the HTCAG shall respect the deadlines mentioned in the HTA Regulation and Implementing Regulation.

In order to allow sufficient time for developing the first draft JCA and summary reports, the scoping process starts immediately upon submission of an application to EMA. Further, the JCA SG review of the draft JCA and summary reports takes place in writing. During that, any bilateral exchanges between the assessor and co-assessor and SG members can take place to clarify questions or comments. For the final validation of the JCA report by the JCA SG, the revised draft JCA and summary reports will be discussed and validated at a JCA SG meeting.

3 Key documents – European Commission (europa.eu)

Lastly, the JCA SG meeting schedule has to be defined and this may impact some of the timelines presented during the preparation and review of the draft JCA and summary reports.

2.4.2 Factual Accuracy Check

Pursuant JCA-MP IA Article 14(4): *"the HTA secretariat shall provide revised draft joint clinical assessment and summary reports to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies and any information it considers to be confidential within 7 days from the date on which it received the revised draft joint clinical assessment and summary reports. The health technology developer shall demonstrate the commercially sensitive nature of the information it considers to be confidential.*

The deadline referred to in the first subparagraph shall be 5 days [...] where:

(a) The application for a marketing authorisation for a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2004;

(b) [...]

(c) A new assessment scope was developed during the joint clinical assessment, pursuant to Article 16 of this Regulation."

Where available, the HTA Secretariat shall inform the HTD about the timelines for the factual accuracy check of the JCA report. Comments submitted after the deadline or in a different format will not be considered. The HTD can only comment on fact-related typos/mistakes (e.g., numbers) and the HTD can flag any information they deem commercially confidential and provide a justification thereof.

Only comments within the scope of a factual accuracy check will be considered and answered by the assessor and co-assessor. Comments that, according to the JCA SG, do not belong to a factual accuracy check, will not be considered, answered or published. The comments made by the HTD and the answers of the assessor and co-assessor to the comments will be published on the IT platform at the same time the JCA report and summary reports are published.

2.4.3 Endorsement by HTACG

Pursuant the JCA-MP IA Article 15(2): *"the JCA Subgroup shall finalise the revised draft joint clinical assessment and summary reports at the latest on the date of the adoption of the Commission decision granting the marketing authorisation and submit them to the Coordination Group for endorsement."*

Pursuant the HTAR Article 11(1), point (a): *"[...] The Coordination Group shall endorse the draft reports in accordance with the timeframe set out pursuant to Article 3(7), point (e). Those timeframes shall be:*

(a) For medicinal products, no later than 30 days following the adoption of a Commission decision granting a marketing authorisation; [...]."

Pursuant the HTAR Article 12(2): *"The Coordination Group shall [...], endeavour to endorse the revised draft reports by consensus. By way of derogation from Article 3(4), where a consensus cannot be reached, divergent scientific opinions, including the scientific grounds on which those opinions are based, shall be incorporated in the reports and the reports shall be deemed endorsed."*

After the HTACG's endorsement, pursuant HTAR Article 12(3): *"The Coordination Group shall submit the endorsed reports to the Commission for procedural review pursuant to Article 28, point (d). Where the Commission, within 10 working days of receipt of the endorsed reports, concludes that those reports do not comply with the procedural rules laid down pursuant to this Regulation or that they depart from the requirements adopted by the Coordination Group pursuant to this Regulation, it shall inform the Coordination Group of the reasons for its conclusion and request a review of the report."*

2.5 Publication

2.5.1 Announcement of Publication

Pursuant the HTAR Article 12(4): *"The Commission shall publish, in a timely manner, the procedurally compliant reports endorsed or re-endorsed by the Coordination Group on the publicly accessible webpage of the IT platform referred to in Article 30(1), point (a), and shall inform the health technology developer of the publication."*

Pursuant the HTAR Article 30(3), point (d), publicly accessible webpage shall contain: *"all documentation under Article 9(1), Article 10(2) and (5) and Article 11(1) at the time the joint clinical assessment report is published, under Article 10(7) in the event that the joint clinical assessment was discontinued, and under Articles 15, 25 and 26."*

Pursuant IA JCA-MP Article 20: *'The Commission shall publish the joint clinical assessment and summary reports as referred to in Article 12(4) of Regulation (EU) 2021/2282, together with other documentation listed in Article 30(3), points (d) and (i), thereof, after having considered the views of the JCA Subgroup as to the commercially sensitive nature of the information contained in that documentation, which the health technology developer has requested to be treated as confidential. Before publishing the documentation referred to in paragraph 1, the Commission shall provide the health technology developer with the list of information that it does not consider as confidential, having assessed the justification provided by the health*

technology developer and considered the views of the JCA Subgroup. It shall inform the health technology developer of the right to appeal the refusal to redact this information'.

2.5.2 Erratum Procedure

In case a factual error in the published JCA report is identified, an erratum procedure may be started. By means of this procedure, the JCA SG will assess the error and decide whether the JCA report needs to be updated.

3 Supporting groups

To support assessors and co-assessors, supporting groups could be set up. The purpose of such supporting groups is to provide advice and assistance to the assessor and co-assessor on specific procedural and methodological topics, when requested by assessor and co-assessor. The supporting groups will not be included by default in discussions on the JCA. Supporting groups may be created within the JCA SG or within the MPG SG from their representatives, alternates and ad-hoc representatives.

Any final decisions based on the advice remain the responsibility of the assessor and co-assessor.

Supporting group can be set up for (non-exhaustive list):

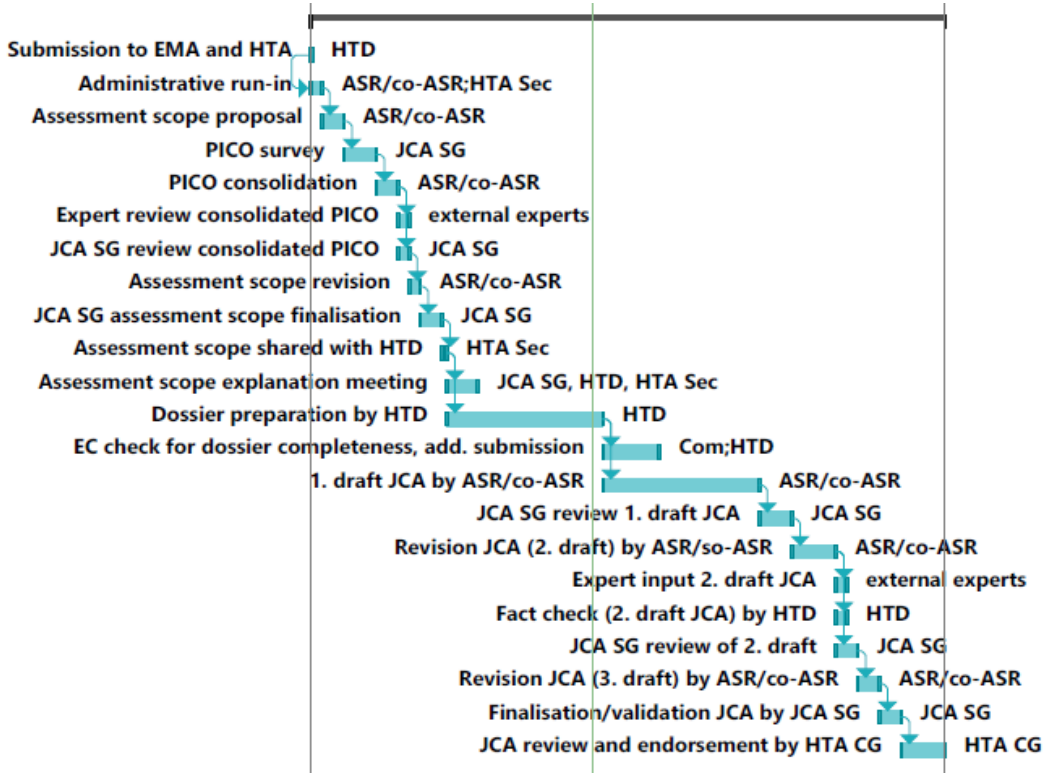
- Scoping process;
- Statistical consideration;
- Checking of the information retrieval.

The consultation of supporting groups created within the MPG SG will not involve making available to the MPG SG the full HTD dossier and further data submitted by the HTD. Certain information from the HTD dossier may be shared with the MPG SG and the confidentiality of this data will be ensured.

Appendix A Gantt chart for standard procedure

Table 3: Gantt chart for medicinal product undergoing the EMA standard procedure

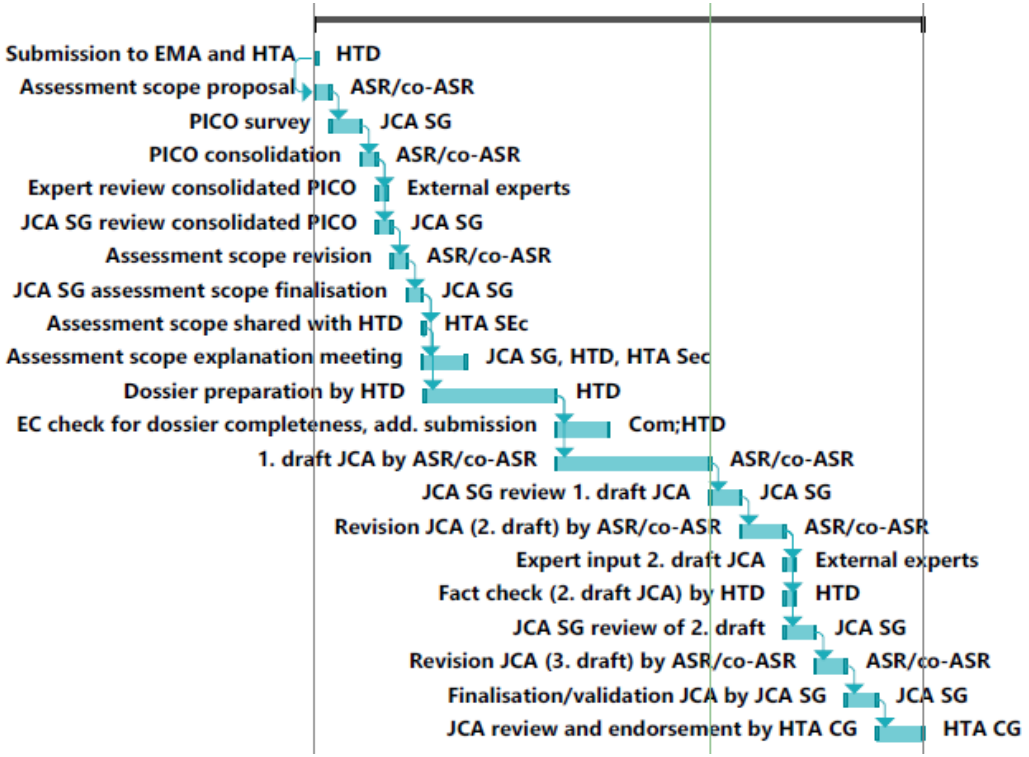
JCA procdure - NCE; standard procedure	406 dys
Submission to EMA and HTA	1 dy
Administrative run-in	7 dys
Assessment scope proposal	14 dys
PICO survey	21 dys
PICO consolidation	14 dys
Expert review consolidated PICO	7 dys
JCA SG review consolidated PICO	7 dys
Assessment scope revision	7 dys
JCA SG assessment scope finalisation	14 dys
Assessment scope shared with HTD	3 dys
Assessment scope explanation meeting	20 dys
Dossier preparation by HTD	100 dys
EC check for dossier completeness, add. submission	36 dys
1. draft JCA by ASR/co-ASR	100 dys
JCA SG review 1. draft JCA	21 dys
Revision JCA (2. draft) by ASR/so-ASR	28 dys
Expert input 2. draft JCA	7 dys
Fact check (2. draft JCA) by HTD	7 dys
JCA SG review of 2. draft	14 dys
Revision JCA (3. draft) by ASR/co-ASR	14 dys
Finalisation/validation JCA by JCA SG	14 dys
JCA review and endorsement by HTA CG	28 dys



Appendix B Gantt chart for accelerated procedure

Table 4: Gantt chart for medicinal products undergoing the EMA accelerated procedure

JCA procdure - accelerated procedure	277 dys
Submission to EMA and HTA	1 dy
Assessment scope proposal	7 dys
PICO survey	14 dys
PICO consolidation	7 dys
Expert review consolidated PICO	5 dys
JCA SG review consolidated PICO	7 dys
Assessment scope revision	7 dys
JCA SG assessment scope finalisation	7 dys
Assessment scope shared with HTD	1 dy
Assessment scope explanation meeting	20 dys
Dossier preparation by HTD	60 dys
EC check for dossier completeness, add. submission	24 dys
1. draft JCA by ASR/co-ASR	70 dys
JCA SG review 1. draft JCA	14 dys
Revision JCA (2. draft) by ASR/co-ASR	20 dys
Expert input 2. draft JCA	5 dys
Fact check (2. draft JCA) by HTD	5 dys
JCA SG review of 2. draft	14 dys
Revision JCA (3. draft) by ASR/co-ASR	14 dys
Finalisation/validation JCA by JCA SG	14 dys
JCA review and endorsement by HTA CG	21 dys



Appendix C Overview of Patient, clinical expert, other relevant expert, patient organisation, clinical organisation or learned society involvement in JCA MP

Table 5: overview of Patient, clinical expert, other relevant expert, patient organisation, clinical organisation or learned society involvement in JCA MP

Timing	Mandatory/ Optional	Patient, clinical expert or organisations	Method	Usage of input received	Information provided
Scoping phase					
Assessment scope proposal	Optional (Article 9.1), if the assessor and co-assessor deem it relevant and appropriate	Patient, clinical expert, other relevant expert	Input from patients and clinical experts to be collected via a standardised questionnaire, that can be used in a written format or an interview	The input is used to support development of the assessment scope proposal. Input should be shared with the JCA SG	Indication under assessment
Assessment scope proposal	Optional (Article 8), if the JCA SG or the assessor and co-assessor deem it relevant and appropriate	Patient organisations and/or clinical organisations – as required by the asr/co-asr	Input to be collected via a standardised questionnaire, which is to be completed in writing.	Input from patients, clinical experts and other relevant experts used to support development of the assessment scope proposal. This information is obtained well-before the scoping starts so that HTA bodies who do not have a national procedure in place can still benefit from stakeholder-level patient and healthcare professional input.	Information on the therapeutic area under assessment, but no information on the intervention is shared due to confidentiality reasons

Timing	Mandatory/ Optional	Patient, clinical expert or organisations	Method	Usage of input received	Information provided
Answer specific questions from the assessor/co-assessor	Optional	Patient, clinical expert, other relevant expert	Relevant individual questions (to be developed by assessor and co-assessor) to be answered in written format	Answers to be shared with the JCA SG	Depends on the mode of involvement, but could be specific information needed to understand the context of a question
Provide input to the consolidated assessment scope proposal	Mandatory to share the consolidated assessment scope (Article 9.3)	Patient, clinical expert, other relevant expert	Duration: 7 days Written input via a standardized format	Input to be made available to the JCA SG	Consolidated assessment scope proposal
Provide input during a dedicated part of the assessment scope consolidation meeting	Optional (Article 10.1)	Patient, clinical expert, other relevant expert	Participation to a dedicated part of the meeting	N/A	Consolidated assessment scope proposal
Assessment phase					
Answer specific questions from the assessor and co-assessor	Optional (Article 14.1) if the asr/co-asr deem it relevant and approrpiate	Patient, clinical expert, other relevant expert	Relevant individual questions (to be developed by assessor and co-assessor) to be answered in written format	Answers to be shared with the JCA SG	Depends on the mode of involvement, but could be specific information needed to understand the context of a question
Opportuntiy to provide input on the revised draft joint clinical assessment and summary reports	Mandatory to share the revised draft joint clinical assessment and summary reports (Article 14.3)	Patient, clinical expert, other relevant expert	Duration: 7 days Written input, via a standardised format	Input to be made available to the JCA SG	Revised draft JCA report and summary report

Timing	Mandatory/ Optional	Patient, clinical expert or organisations	Method	Usage of input received	Information provided
Provide input during a dedicated part of the meeting discussing the relevant revised draft reports	Optional (Article 15.1)	Patient, clinical expert, other relevant expert	Participation to a dedicated part of the meeting	N/A	JCA subgroup meeting in which the revised draft JCA report is being discussed