eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

D5.1 Submission Dossier Guidance

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Document history and contributors

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Disclaimer

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group will be actively writing the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) will review and discuss several drafts of the deliverable before validation. The Consortium Executive Board (CEB) will then endorse the final deliverable before publication.

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List of abbreviations

Abbreviation	Meaning
AIMD	Active implantable medical device
ATC	Anatomical Therapeutic Chemical (code)
ATMP	Advanced therapy medicinal product
CE	Conformité Européenne
CEB	Consortium Executive Board
CHMP	Committee for Medicinal Products for Human Use
CSR	Clinical study report
CTD	Common technical document
DSM	Diagnostic and Statistical Manual of Mental Disorders
EMA	European Medicines Agency
EU	European Union
HTA	Health technology assessment
HTA R	Health technology assessment regulation (Regulation (EU) 2021/2282)
HTD	Health technology developer
ICD	International Statistical Classification of Diseases and Related Health Problems
IVD	In vitro diagnostic
IVD R	In vitro diagnostic regulation (Regulation (EU) 2017/746)
MD	Medical device
MD R	Medical device regulation (Regulation (EU) 2017/745)
MRI	Magnetic resonance imaging
PICO	Population, intervention, comparator, outcome
PRIME	Priority medicine scheme of the European Medicines Agency
SmPC	Summary of product characteristics
SSCP	Summary of safety and clinical performance
SSP	Summary of safety and performance
UDI-DI	Unique device identification-device identifier (according to Regulation (EU) 2017/745)

I Introduction

According to Regulation (EU) 2021/2282 on health technology assessment (HTA R), a dossier including the information required for health technology assessment (HTA) of a medicinal product or medical device (MD) should be submitted by the health technology developer (HTD). This dossier forms the basis for the assessment process and the joint clinical assessment report.

The current requirements for the content of a European HTA dossier are set out in Annex I and Annex II to the HTA R (Article 9.4): "The dossier for medicinal products shall include the information set out in Annex I. The dossier for medical devices and in vitro diagnostics medical devices shall include the information set out in Annex II".

This guidance indicates an appropriate format for the information and data that are required for submission in accordance with the HTA R. HTDs should not modify the overall organisation of the dossier as outlined in this guidance. The guidance only includes a high-level structure. Within this structure, the presentation of information and data can be developed to provide the best possible presentation of the information to facilitate understanding and assessment of the data.

This guidance is a first component of the overall framework of submission guidance. It describes the overall structure and the general requirements for the submission. In addition to the requirements laid down in this guidance, further guidance adopted by the Consortium Executive Board (CEB) has to be taken into consideration when preparing a dossier for a joint clinical assessment. This will comprise a template for the submission dossier and a set of table and figure templates further specifying technical requirements and methodological guidance.

II General requirements for the dossier

According to Regulation (EU) 2021/2282 (Article 9.3) the dossier shall meet the following requirements:

- The evidence submitted is complete with regard to the available studies and data that could inform the assessment.
- The data have been analysed using appropriate methods to answer all the research questions for the assessment.
- The presentation of the data is well structured and transparent, thereby allowing for appropriate assessment within the limited timeframes available.
- The dossier includes the underlying documentation with respect to the information submitted, thereby allowing the assessor and co-assessor to verify the accuracy of that information.

III Overview of the dossier structure

The dossier should inform the joint clinical assessment of the health technology in question. Thus, it should provide information for the clinical domains for HTA: the health problem addressed by the technology under assessment and the current use of other health technologies addressing the health problem, a description and technical characterisation of the health technology, and the relative clinical effectiveness and relative safety of the health technology.

The presentation of information in the dossier is organised into five sections as depicted in Figure 1.

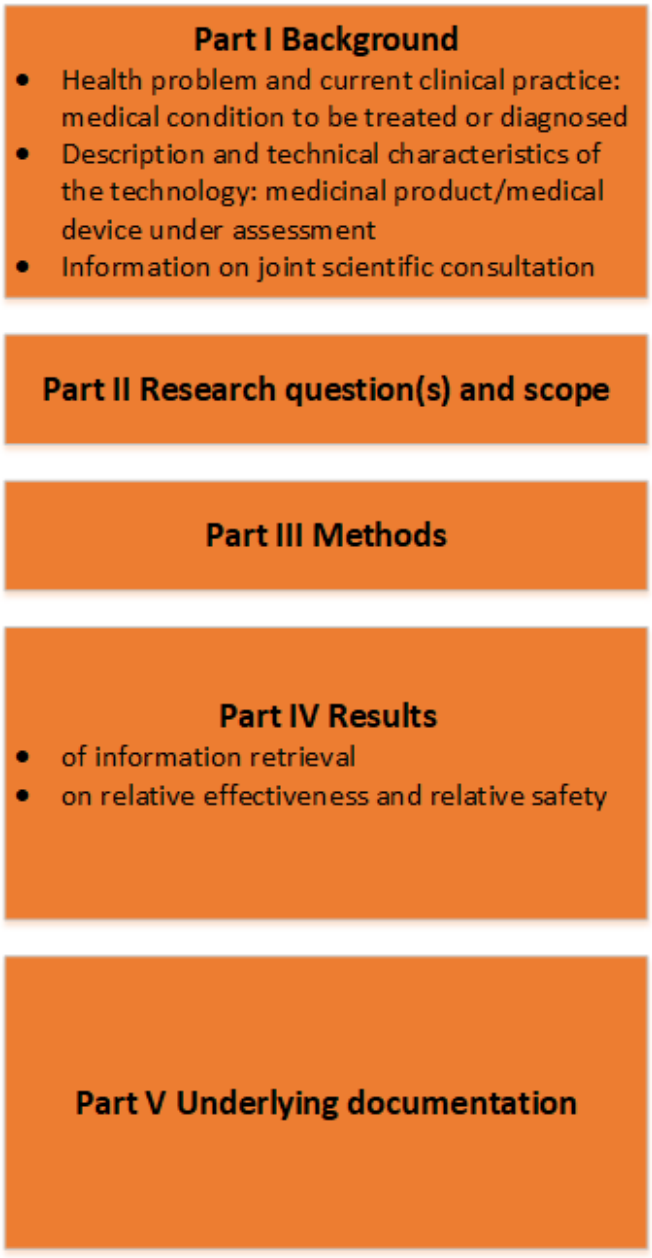

Figure 1. High-level structure of the dossier.

IV Structure and content of the dossier

1 Background

1.1 Characterisation of the health condition to be treated or diagnosed

1.1.1 Overview of the health condition to be treated

In order to provide an overview of the health condition, this section of the dossier should:

- Describe the disease or health condition in the scope of this joint clinical assessment, including criteria for diagnosis, if available, using a standardised code such as the International Statistical Classification of Diseases and Related Health Problems (ICD) code or Diagnostic and Statistical Manual of Mental Disorders (DSM) code (and the version of the code).
- If relevant, describe the main subtypes and/or stages of the disease or health condition.
- Include any prognostic factors that may affect the course of the disease or health condition and the prognosis of the health condition without the new treatment.
- Present an estimate of the prevalence and/or incidence for the health condition in Europe for the past 5 years including recent trends and, if applicable, describe any profound differences between European countries.
- Indicate if any essential changes with regard to the prevalence and incidence of the disease in Europe may be expected over the next 5 years and, if so, what these would be.
- Describe the symptoms and burden of the health condition for patients (including aspects such as pain, disability, psychosocial issues, and other determinants of morbidity and quality of life from a patient perspective).
- Briefly describe the organisational and societal impact of the health condition and its treatment, giving some context for interpretation of outcomes; this description is specifically relevant for health conditions that result in disability and/or a need for a family caregiver, and for treatments that result in major organisational changes to the health care system, for example, because of manufacturing constraints (e.g., chimeric antigen receptor T cells) or major associated procedures (e.g., organ transplantation).

References for the statements should be provided.

1.1.2 Characterisation of the target population

The target population(s) is (are) defined in the assessment scope. The default target population in the joint clinical assessment will be the claimed indication submitted by the HTD to the regulatory body or the indication wording from the Committee for Medicinal Products for Human Use (CHMP) positive opinion or summary of product characteristics (SmPC) for medicinal products, the Conformité Européenne (CE) marking, or the summary of safety and clinical performance (SSCP) for an MD or the summary of safety and performance (SSP) for an in vitro diagnostic (IVD). Based on the assessment scope, subpopulations of the population according to the indication wording may be relevant.

In order to characterise the target population(s) this section of the dossier should:

- Describe and justify the proposed position of the target population(s) in the patient pathway of care.
- If relevant, take into account gender- and age-specific characteristics.
- Describe any subpopulations (including the criteria for identifying them) if specifically defined in the assessment scope.
- Describe the natural progression of the disease (by subpopulation, if appropriate).

References for the statements should be provided.

1.1.3 Clinical management of the health condition

In order to characterise the clinical management of the health condition, this section of the dossier should:

- Describe the clinical pathway of care for the health condition being considered in the joint clinical assessment, as well as, if relevant, for different stages and/or subtypes or subpopulations of the health condition, with diagrams of the care pathway(s) that include alternative interventions.
- Describe any relevant variations in care between European countries.
- Include a list of relevant clinical guidelines (at the European level).

References for the statements should be provided.

1.2 Characterisation of the medicinal product/medical device under assessment

1.2.1 Characteristics of the health technology

For medicinal products, the characteristics of the technology should include:

- The nonproprietary name;
- The proprietary name;
- The HTD submitting an application to the European Medicines Agency (EMA);
- The drug class;
- The active substance(s);
- A characterisation of the mechanism of action;
- Drug interactions;
- The pharmaceutical formulation(s); and
- The Anatomical Therapeutic Chemical (ATC) code.

For medicinal products, the characterisation of administration and dosing (by (sub)population or patient group, if appropriate) should include, as appropriate:

- The method of administration;
- The doses and dosing frequency;
- The average length of a course of treatment;
- The anticipated average interval between courses of treatment;
- The anticipated number of repeat courses of treatment;
- Information on dose adjustments;
- Criteria for the ending of treatment;
- Combination with other interventions;
- The monitoring required during administration or during the treatment period; and
- Concomitant treatments required or recommended, such as fluid support, antiemetic agents, antiviral agents or venous thromboembolism prophylaxis.

For MDs (including IVDs), the characteristics of the technology should include:

- The trade name of the MD;
- The product type according to the MD regulation (MD R; Regulation (EU) 2017/745) code for MDs or the IVD regulation (IVD R; Regulation (EU) 2017/746) code for IVDs;
- The function of the device (therapeutic, diagnostic, disability compensation, other);
- Models, references, or software version;
- The basic unique device identification-device identifier (UDI-DI; according to Regulation (EU) 2017/745).
- The MD risk class according to the MD R or IVD R;
- The HTD submitting the dossier (specify whether it is the MD manufacturer or an authorised representative);
- The date on which the MD was first placed on the EU market in the course of commercial activity (excluding investigational device use);
- A product description: composition, technologies involved and technical characteristics and, where applicable, conformity to guidelines, standards, specifications, common specifications (according to the MD R), tests or analyses;
- A description of the development process for the technology;

- If the MD includes connected technology because some or all of the device is software, a specific description is required;
- For medical devices with an embedded decision-making system based on machine learning processes (technologies falling within the scope of artificial intelligence): provide a description of the functions built or evolving using these technologies;
- Magnetic resonance imaging (MRI) compatibility: For implantable MDs liable to give rise to artefacts, the potential impact of these artefacts on MRI interpretation and the associated recommendations for use must be documented. For active implantable medical devices (AIMDs), specify the limits of compatibility with MRI procedures and the main precautions to be taken. Where applicable, the AIMD deactivation measures required to conduct the test must be specified.

For MDs (including IVDs), the characteristics of use (by (sub)population or patient group, if appropriate), should include, as appropriate:

- A description of the mode of action on the pathology or disability.
- The intended purpose and the labelling of the MD.
- The manufacturer's instructions for use.
- Information on whether the MD device is intended
  - To administer and/or remove a medicinal product,
  - To act as a companion diagnostic
  - To emit hazardous, or potentially hazardous, levels of ionising and/or nonionising radiation, or
  - To be operated together with other devices or products.
- A description of (surgical) procedures, services and organisational aspects (including specific technical facilities at hospital) associated with use of the MD should be provided; the suggested profile and training for users as outlined in the SSCP should be provided.

References for the statements should be provided.

1.2.2 Requirements/instructions for use

If applicable, the equipment required to use the technology should be described, including any specific tests or investigations required (e.g., biomarker testing, companion diagnostics, amount and type of biological material needed for IVD). If all such equipment is described in the section above, state here that there are no additional requirements.

If applicable, any supplies required to use the technology should be described (e.g., pharmaceuticals and contrast agents, syringes, needles, fluids or bandages).

References for the statements should be provided.

1.2.3 Regulatory status of the technology

For medicinal products, the regulatory status of the technology should be clarified in a tabular description of the marketing authorisation status applied for at the EMA, including any specific regulatory designations or approval schemes, such as orphan status, advanced therapy medicinal product (ATMP), conditional marketing authorisation, the EMA priority medicine scheme (PRIME), compassionate use or early access programme. Any marketing authorisations in Europe for other indications that are not included in the joint clinical assessment should also be described, as well as additional indications anticipated in the future (including the organisation issuing approval, the verbatim wording of the indication and the date of approval). An overview of the regulatory status outside Europe should be provided. Any contraindications or groups for whom the technology is not recommended should be listed.

For MDs (including IVDs), the regulatory status of the technology should be clarified in a tabular description, including: the MD risk class according to the MD R; name, identification number and country of the notified body that issued the CE marking; date of the initial CE marking and the expiry date of the current certificate; the verbatim wording of the CE marking indication (i.e., the intended use according to the conformity assessment, including indications and contraindications; and the date of the expert panel opinion.

References for the statements should be provided.

1.3 Joint scientific consultation related to the joint clinical assessment

Any joint scientific consultations for the health technology under assessment at the European level should be listed. If a health technology has been the subject of a joint scientific consultation, any deviation from the recommendations of the joint scientific consultation should be explained.

2 Research question and assessment scope

In the context of European HTA, the assessment scope reflects policy questions from the different health care systems in which the HTA should be used. It translates the policy

question(s) into research question(s) with a standard format, called PICO question(s). The assessment scope means the set of parameters for joint clinical assessment in terms of:

- The patient population or populations (P),
- The intervention or interventions (I),
- The comparator or comparators (C) and
- The health outcomes (O)

requested jointly by member states. This scope is identified in a scoping process initiated by the designated subgroup for a given joint clinical assessment.

The assessment scope shall be inclusive and reflect the needs of member states in terms of parameters and the information, data, analysis and other evidence to be submitted by the HTD.

The HTD is informed about the assessment scope with a request for submission of the dossier on which the joint clinical assessment will be based. The assessment scope as requested specifies the research question elaborated in the submission dossier, that is, it forms the basis for the content of the submission dossier and should be provided in the corresponding section of the dossier (Research question and assessment scope). The dossier submitted by the HTD must address all the PICO questions included in the assessment scope and provide the evidence available to appropriately answer all the PICO questions.

For cases in which the scoping process identified more than one PICO question, these should be presented separately and transparently.

3 Methods used in the development of the dossier content

A description of methods used in the development of the dossier content is required to allow assessment of the appropriateness of the methods and of the validity and certainty of the results presented in the dossier.

The methods used in the development of the dossier content should be based on the international standards of evidence-based medicine. The methods should also follow methodological guidance adopted by the CEB.

The data presented in the dossier should have been analysed using appropriate methods to answer all research questions of the joint clinical assessment.

3.1 Criteria for selecting studies for joint clinical assessment

Based on the assessment scope and the methodological guidance applicable, inclusion and exclusion criteria for studies to be considered in the joint clinical assessment should be specified. This specification has to be provided for each PICO question, as appropriate. These

criteria should be used to select the studies from the results of the systematic information retrieval process for the joint clinical assessment.

3.2 Information retrieval and selection of relevant studies

The joint clinical assessment should be based on the complete evidence available. Specifically, the submission dossier that forms the basis of the joint clinical assessment should be complete with regard to the studies and data available that could inform the assessment. This completeness can only be achieved via systematic information retrieval.

Systematic information retrieval

The HTD should conduct a systematic information retrieval process to identify the evidence to be used for preparation of the dossier. This information retrieval should include the following sources:

- Studies performed or sponsored by the HTD

  To meet the requirements of the HTA R, the HTD must provide with the dossier all up-to-date published and unpublished information, data, analyses and other evidence from studies on the health technology for which the HTD was a sponsor. Furthermore, all information available on ongoing or discontinued studies with the health technology for which the HTD is a sponsor or otherwise financially involved has to be made available. Corresponding information on studies by third parties, if available, should also be provided.
- Bibliographic databases
- Study registries and study results registries (clinical trial databases)
- For medicinal products, the clinical safety and efficacy data included in the submission file to the EMA
- For MDs, the clinical evaluation assessment report and the manufacturer's clinical evaluation documentation submitted to the notified body

These sources should be systematically searched for studies and analyses that are relevant for the joint clinical assessment according to the assessment scope. Full documentation for the searches should be included in the dossier.

In addition, the HTD should include information on HTA reports available on the health technology subject to the joint clinical assessment and on studies based on (patient) registries in the dossier. This information should also be provided based on systematic searches in appropriate sources.

Acceptable search dates (latest date for a search for a given joint clinical assessment) are defined in the applicable guidance adopted by the CEB.

Selection of relevant studies

Relevant studies to be included in the dossier, specifically for description of the relative effectiveness and relative safety, should be selected according to inclusion and exclusion criteria defined for the joint clinical assessment of the health technology. The selection process should be performed according to methodological guidance adopted by the CEB and should be documented in the dossier.

3.3 Data analysis and synthesis

The data presented in the dossier should have been analysed using appropriate methods. Evaluation of the methods applied by the HTD is part of the joint clinical assessment process. This evaluation addresses the appropriateness of the methods and the validity and certainty of the results on relative effectiveness and relative safety generated using these methods. To allow this assessment, the dossier should include a transparent description of the methods used. Therefore, the section on data analysis and synthesis should, among others, cover the following topics:

- A description of the design and methodology of the studies included

  The description of the design and methodology of the included studies should follow the standards of evidence-based medicine and the guidance adopted by the CEB. This section should specify the items used to describe the design and methodology of the studies.

- A description of the results from the individual studies

  First, the results from individual studies should be presented separately in the dossier, irrespective of any potential synthesis of these results (e.g., in meta-analyses). This section should describe the patient characteristics and endpoints that will be covered by this presentation.

- Meta-analyses

  If appropriate, the studies available should be synthesised quantitatively via meta-analyses. The methods applied should be described in this section. The methods used for meta-analyses should follow the guidance adopted by the CEB.

- Indirect comparisons

  If indirect comparisons are considered, these should be conducted using appropriate methods. Any assumptions underlying the analyses should be specified and the degree to which these assumptions are met should be described. The methods used for indirect comparisons should follow the guidance adopted by the CEB.

- Sensitivity analyses

  Sensitivity analyses should be performed, if required, to investigate the impact of methodological factors on the robustness of the results. The methods used for sensitivity analyses should follow the guidance adopted by the CEB.

- Subgroup analyses and other effect modifiers

  Effect modification should be investigated via subgroup analyses. The methods used for subgroup analyses should follow the guidance adopted by the CEB.

- Specification of further methods as required

  Any methods used in deriving results in the dossier should follow the guidance adopted by the CEB, if available.

4 Results

The presentation of results should use text, figures and tables as appropriate. The results presentation should consider guidance adopted by the CEB.

4.1 Results from the information retrieval process

Results from the different steps of the information retrieval process should be presented transparently in the submission dossier. This presentation should include:

- A list of studies conducted by the HTD

  The list of studies conducted by the HTD should include all studies submitted to the regulatory body for medicinal products (marketing authorisation studies from the clinical safety and efficacy data included in the submission file to the EMA) or submitted to the notified bodies for MDs (studies from the clinical evaluation documentation), as well as all studies sponsored by the HTD or in which the HTD was or is financially involved. The listing should be restricted to studies involving patients in the indication (for medicinal products) or intended use (for MDs/IVDs) for which the submission dossier is prepared.

- Studies identified in searches in bibliographic databases

  The results from searches in bibliographic databases should be presented according to the methodological standards.

- Studies from searches in study registries/study result registries (clinical trial databases)

  The results from searches in study registries/study results registries should be presented according to the methodological standards.

  For each of the information retrieval steps, the studies not considered in the joint clinical assessment should be identified. For each of these studies, the reason for exclusion should be specified.

List of studies included overall and by PICO question

The study pool resulting from all searches should be presented transparently. In addition to an overall study pool used in the submission dossier, the study pool(s) used to inform the individual PICO question(s) should be specified.

4.2 Characteristics of the studies included

An overall description of the study design and the study population should be provided for all studies included in the description of relative effectiveness and safety in any of the PICO questions according to the requirements laid down in guidance adopted by the CEB.

4.3 Study results on relative effectiveness and relative safety

The HTD must provide aggregate data (results on relative effectiveness and safety) according to the assessment scope in the submission dossier. The analyses presented in the dossier should take the guidance adopted by the CEB into consideration.

The assessment scope might include one or more PICO question(s) for which the available evidence has to be provided in the dossier. To achieve a transparent data presentation, the results for effectiveness and safety should be described by PICO question.

The first defining item of a PICO question is the patient population in which the relative effects of an intervention versus a comparator are investigated. The data presentation should first be structured by patient population. Within a given population, more than one PICO question(s) might have to be investigated, for example, because of different comparators. These can be sequentially presented within one chapter as depicted in the following structure of sections.

4.3.1 Results for the patient population < to be specified>

For each patient population specified in the PICO question(s) in the assessment scope, a separate section should be provided. Within this section, the results for all PICO question(s) addressing this patient population should be presented in subsections.

4.3.1.1 Patient characteristics

The patient characteristics from all studies covering the relevant patient population included in any of the PICO question(s) addressing this population should be presented. The data presentation should take guidance adopted by the CEB into consideration.

4.3.1.2 Outcomes for the PICO <to be specified>

For each PICO question addressing the patient population specified in Section 4.3.1, a list of the studies included in the investigation should be provided. Furthermore, an overview of available outcomes by study should be presented. The presentation of any outcomes not included in the PICO should be justified. The data presentation should include the results from all individual studies as well as any syntheses of results, for example, from meta-analyses. The presentation of information for the individual outcomes and the certainty of results should follow the submission dossier guidance and the submission dossier template.

For any additional PICO question for a given patient population required according to the assessment scope, a new subsection presenting the results for outcomes for this PICO question should be added.

Appendix A Tabular listing of all studies included in the description of relative effectiveness and safety

Appendix B Underlying documentation for medicinal products

B.1 Full texts of references

Full texts of any references provided in the dossier and listed in the respective reference lists should be provided. The reference list of the submission dossier should be provided in a standard format that can be read by literature management programs.

B.2 Documentation of information retrieval

The documentation of information retrieval should be provided in a standard format that can be read by literature management programs.

B.3 Programming code for programs used for analyses

Program code should be provided if the analyses and corresponding calculations cannot be described by a specific standard method (e.g. Mantel-Haenszel).

B.4 Study reports

The Clinical Study Reports (CSR), including study protocols and statistical analysis plans, required by the Regulation and any guidance adopted by the CEB must be provided as part of the underlying documentation of the dossier. The technical specifications to be followed for submitting the CSRs will be provided by guidance from the CEB.

B.5 Clinical safety and efficacy data included in the submission file to the European Medicines Agency

Clinical safety and efficacy data included in the submission file to the EMA should be provided as sections 2.5, 2.7.3 and 2.7.4 from the Common Technical Document (CTD, format of submission to EMA) and as CSRs (see section D.4 Study reports).

B.6 HTA reports of the health technology subject to the joint clinical assessment

If HTA reports from earlier joint clinical assessments or from other jurisdictions are available, these should be included.

B.7 Information on studies based on registries

If any studies with the health technology under assessment from patient registries are available, these should be included.

B.8 Information on joint scientific consultations

If a health technology has been subject to a joint scientific consultation, the recommendations should be provided.

Appendix C Underlying documentation for medical devices

C.1 Full texts of references

Full texts of any references provided in the dossier and listed in the respective reference lists should be provided. The reference list of the submission dossier should be provided in a standard format that can be read by literature management programs.

C.2 Documentation of information retrieval

The documentation of information retrieval should be provided in a standard format that can be read by literature management programs.

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Program code should be provided if the analyses and corresponding calculations cannot be described by a specific standard method (e.g. Mantel-Haenszel).

C.4 Study reports

The Clinical Study Reports (CSR), including study protocols and statistical analysis plans, required by the Regulation and any guidance adopted by the CEB must be provided as part of the underlying documentation of the dossier. The technical specifications to be followed for submitting the CSRs will be provided by guidance from the CEB.

C.5 For medical devices: clinical evaluation documentation

The documentation provided should include the clinical evaluation assessment report, the manufacturer's clinical evaluation documentation submitted to the notified body pursuant to Section 6.1, points (c) and (d), of Annex II to Regulation (EU) 2017/745 and the scientific opinion provided by the relevant expert panels in the framework of the clinical evaluation consultation procedure. In addition, the EU declaration of conformity of the medical device, the CE marking certificate(s) relating to the medical device, the instructions for use and the validated SSCP (for MD) and SSP (for IVD) should be provided.

C.6 For in vitro diagnostic medical devices: performance evaluation documentation

The documentation provided should include the performance evaluation report of the manufacturer, the manufacturer's performance evaluation documentation, referred to in Section 6.2 of Annex II to Regulation (EU) 2017/746, the scientific opinion provided by the relevant expert panels in the framework of the performance evaluation consultation procedure and the report of the Union reference laboratory.

C.7 HTA reports of the health technology subject to the joint clinical assessment

If HTA reports from earlier joint clinical assessments or from other jurisdictions are available, these should be included.

C.8 Information on studies based on registries

If any studies with the health technology under assessment from patient registries are available, these should be included.

C.9 Information on joint scientific consultations

If a health technology has been subject to a joint scientific consultation, the recommendations should be provided.