Dedicated HTD meeting on D5.4 and D5.1

July 13, 2023

This meeting is recorded for internal purposes only

Household message

Juste

Practical information for the meeting

- Please note: you cannot switch on your camera or use your microphones.
- The meeting will be recorded for internal purposes only.

Questions:

- To ask questions, you may post them in the Q&A box. The chat box will not be checked for questions.
- Responses to all questions will be coordinated by the Chair
  - and will be taken at the **end of relevant presentations or during the Q&A item.**

Technical issues:

- If you experience problems with Zoom during the meeting, please:
  - Go to www.zoom.com and search for help.
  - Contact eunethta@zinl.nl or call Merle Tenberg on **+31 6 51 06 80 53** for support

Welcome and introduction

Roisin Adams

Objective of the meeting and agenda

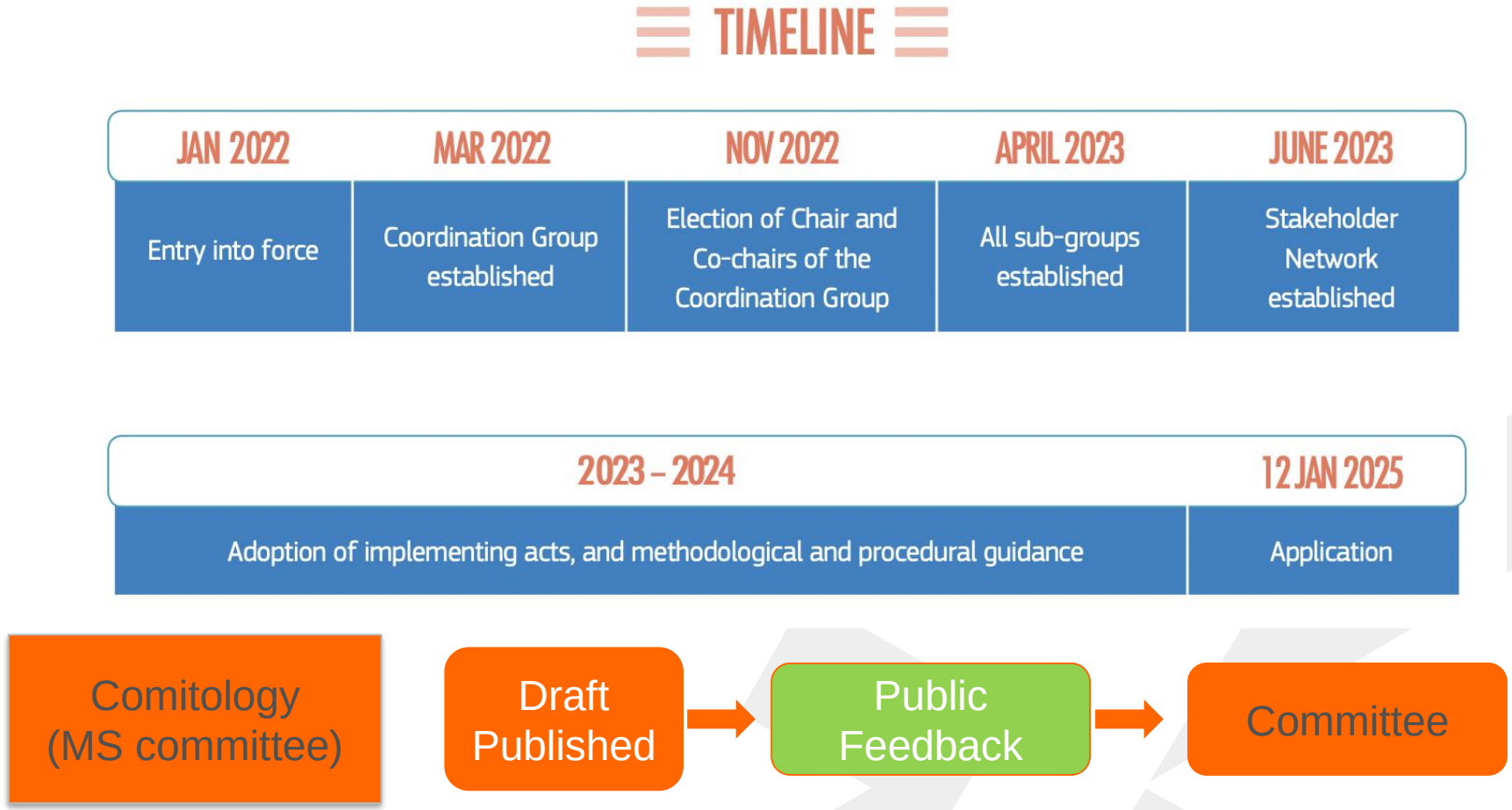
- Meeting for specific stakeholder input: HTD medicinal products (MP)
- Focus on 2 deliverables only: JCA MP timelines & Submission Dossier Template
  - No public consultation foreseen on these two documents, therefore discuss today
- Slides will be shared afterwards; recording is only for internal purposes
- No minutes will be shared

Time	Item	Presenter
10:00-10:10	Welcome and introduction	Roisin Adams
10:10-10:20	Status update EUnetHTA 21	Roisin Adams
10:30-11:10	D5.4 - JCA timelines for medicinal products, presentation and Q&A	Anne Willemsen
11:10-11:55	D5.1 - Submission Dossier Template, presentation and Q&A	Beate Wieseler
11:55-12:00	Closure of meeting	Roisin Adams

Status update EUnetHTA 21

Roisin Adams

State of Play with HTAR Implementation



Process flow for deliverable production

Creating deliverable

- Joint output produced and reviewed by EUnetHTA 21.
  - **Including HTAb outside the consortium**
- If relevant: specific stakeholder contribution.

Public consultation

- All comments answered and published together with the final deliverable

Final version

- Validated and endorsed by EUnetHTA 21 CSCQ and CEB

Publication

- EC to approve final version of the deliverable prior to publication

Uptake in HTACG

- EC to share final EUnetHTA 21 deliverables with HTACG for further work in the HTACG

Abbreviations:
CEB=Consortium Executive Board
CSCQ=Committee for Scientific Consistency and Quality
HTAb=HTA bodies
HTACG=HTAR Coordination Group
HTD=Health Technology Developer

EUnetHTA 21 content related deliverables

https://www.eunethta.eu/jointhtawork/

Deliverable	Title
D4.2	Practical Guideline – Scoping Process
D4.3.1	Practical Guideline Direct & Indirect Comparators and Comparisons
D4.3.2	Methodological Guideline Direct & Indirect Comparators and Comparisons
D4.4	Practical Guideline on Endpoints
D4.5	Practical Guideline Applicability of Evidence
D4.6	Practical Guideline Validity of Clinical Studies
D4.7.1, 4.7.2	Framework for JCA of high risk MD
D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process
D5.1	Submission Dossier Template Guidance (*Template is in progress)
D5.2	JCA report template Guidance & Template
D5.3.1	Selection criteria (co-)assessor JCA
D5.3.2	HTA body technical expert working groups
D5.4	Production: 2 MD JCA, MP JCA without HTD submission. Additional document: timelines for MP JCA production
D6.1	Production of 7 Joint Scientific Consultation (JSC)
D6.2/6.3&6.4	JSC briefing book template & procedural guidance
D7.1	Practical Guidelines HTD and HTA interaction
D7.2/7.3	Patient and HCP guidance & templates for interaction
D7.5	Guidance and templates for Declaration of Interest and confidentiality

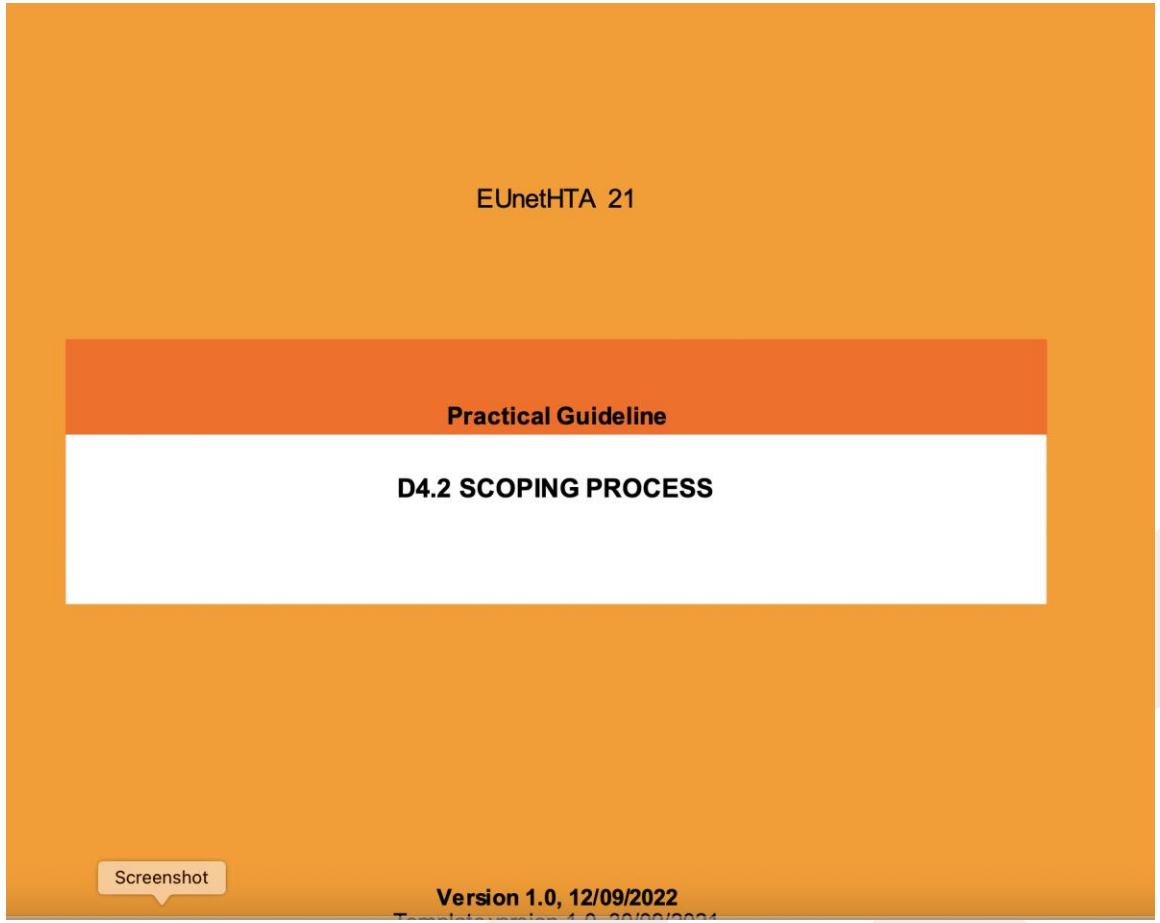
Status of JCA production in EUnetHTA 21

- 2 JCA for Medical Devices
  - JCAMD001: The Optilume® Urethral DCB Catheter for men ≥18 years of age with bothersome urinary symptoms associated with recurrent anterior urethral stricture.
  - JCAMD002: Saluda Medical Evoke® Spinal Cord Stimulation System as an aid in the management of chronic intractable pain of the trunk and/ or limbs
    - To be published next week
  - Both MD JCAs:
    - Followed the PICO process and consolidation
    - Based on submission dossier by the HTD
    - Followed the EUnetHTA 21 recommended process for external expert and stakeholder involvement
    - Publication expected in summer months

- Pharmaceutical JCA
  - PICO exercises to be conducted, to test the developed procedures and guidelines

Practical Pilot Work

PICO Preparation



Pilot PICO work for medicinal products

- To conduct several PICO exercises
  - On compounds with positive CHMP opinion
- To include some products that will be subject to the HTAR in 2025 i.e. cancer and ATMPs
- Associated HTAb invited to respond to survey
- Consolidated PICO(s) to be published

- Review of the process following this work and improvements to be incorporated.

Learnings

- Support the national HTAbs by providing some additional background information on the disease area.
- Clarification around common understanding.
- Consolidation process working really well.
- Testing a process where authors to propose PICOs for HTAbs
- Notification period of the upcoming PICO survey is important
- Online format to capture national PICOs is working well

D5.4 – JCA production timelines medicinal products

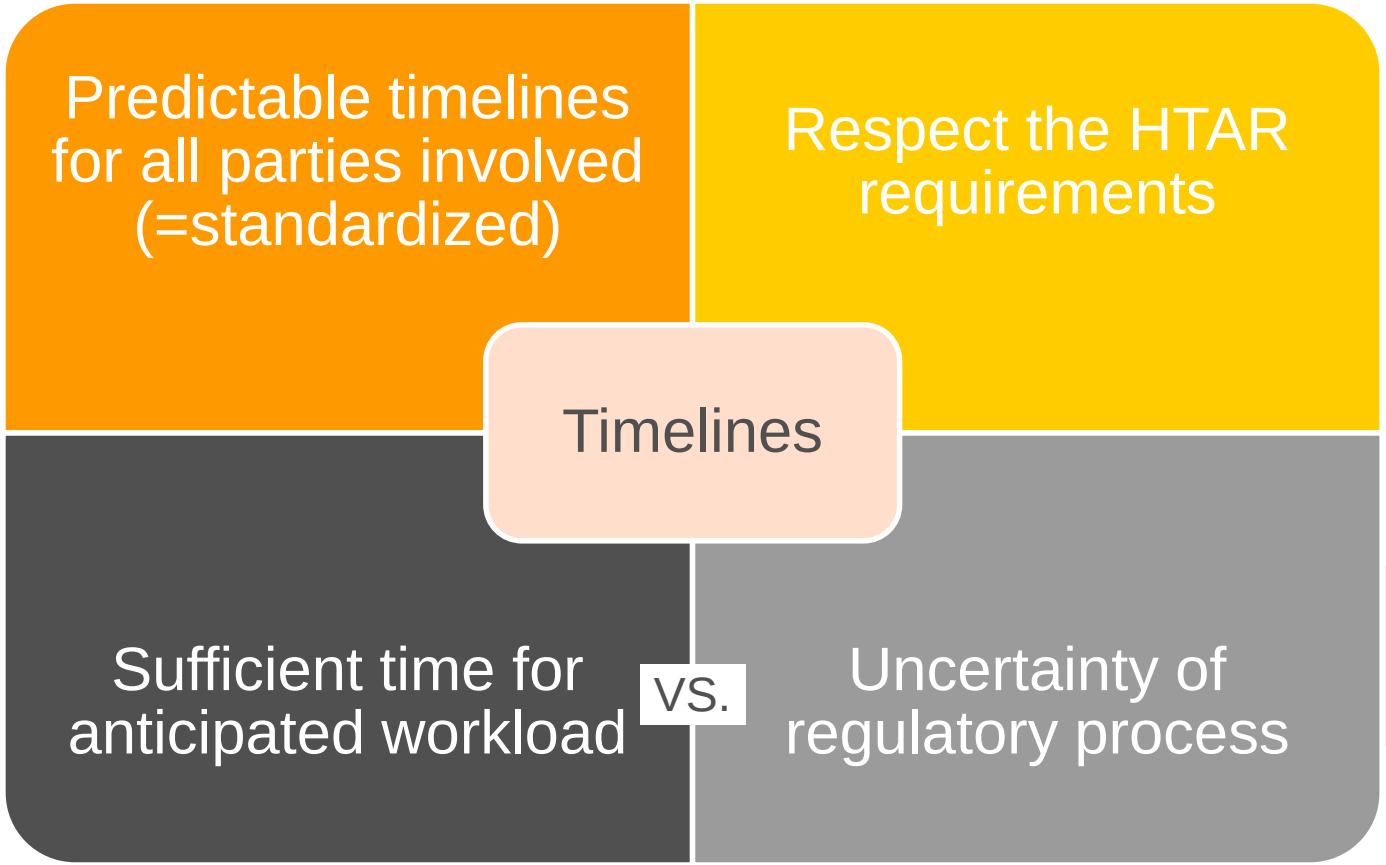
Anne Willemsen

Deliverable on JCA timelines for medicinal products

- Published in June, as draft, so changes may still be made
- Additional document delivered by EUnetHTA 21, it was not an official deliverable
  - It was felt such document was required, to better map required resources on a national/stakeholder level
  - Content is based on experiences from EUnetHTA JA3, requirements HTAR and new EUnetHTA 21 deliverables

- Today, we present the structure and content of the deliverable
- Happy to take your questions and comments
  - But please note, we are bound by the HTAR
- The revision of the pharma legislation has not been considered to date

Principles leading to general assumptions



General assumptions

Assumed, average standard regulatory process & JCA report not available before CHMP opinion

- Timelines based on an assumed, average standard regulatory process
  - Potential changes following the revision of the pharma legislation are not considered

- To publish the JCA report 30 days after EC decision on the regulatory outcome
  - The JCA has to be conducted partly in parallel to the EMA assessment
- The timeline is based on average regulatory process
  - Average duration of EMA clock-stops
- JCA production will not be interrupted before its finalisation, but
  - JCA report only to be endorsed after final CHMP opinion
    - to allow for a check of the approved indication compared to the claimed indication (which is the basis for the start of the PICO)
  - Thus, in case of prolonged time between EMA submission and CHMP opinion:
    - The JCA procedure (i.e. the HTACG review) will be resumed once the CHMP opinion becomes available

General assumptions

Two scenarios: NCE & Type II variations/accelerated assessment

- Two regulatory scenario's considered for the timelines
  1. New Chemical Entities (NCE)
  2. Type II variations and Accelerated Assessments
- For scenario 2, the regulatory timelines are much shorter
- We are aware an accelerated assessment can revert back to a standard procedure

- The JCA timelines consider these regulatory scenario's in the following way:
  - a different start date for the JCA is considered
    - NCE: start JCA ~2 months after the regulatory dossier submission to EMA
    - Type II/accelerated assessment: start JCA process at the point of regulatory submission to EMA
  - Publication deadline remains the same
    - 30 days after EC decision

General assumptions

JCA without relevant change in the claimed indication

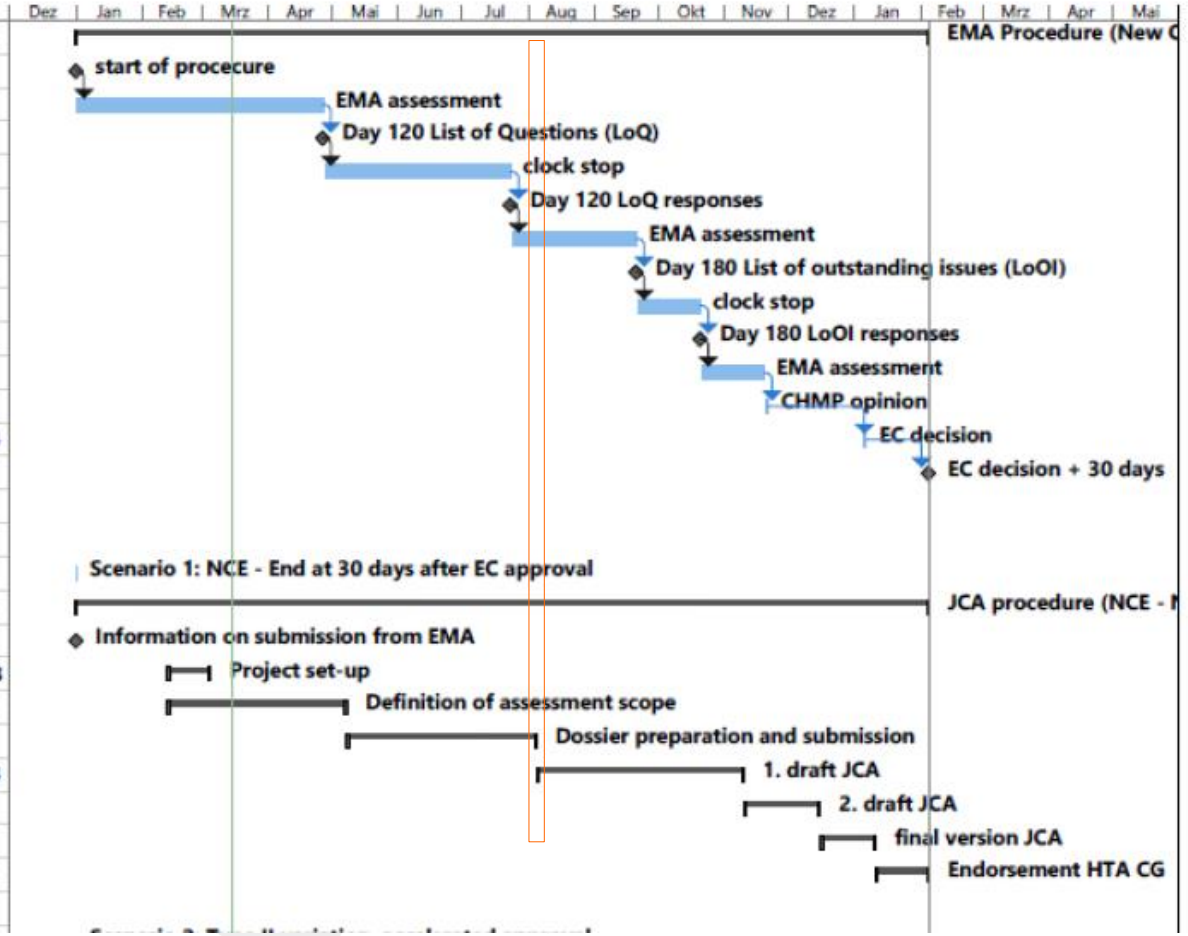
- The timeline only covers JCA without a relevant change in the claimed indication (by HTD)
  - It is assumed in the majority of procedures, no relevant change to the claimed indication
    - Therefore, decision was made to create a JCA production process optimized for this situation

- In case of major deviations
  - Changes to the PICO may be required
    - This impacts also the content of the Submission Dossier
    - And therefore also the content of the JCA report
  - It is suggested to stop & re-start the JCA procedure, as the time available to address these changes may be insufficient
  - A separate procedure has to be developed and it should be confirmed if the HTAR allows for this

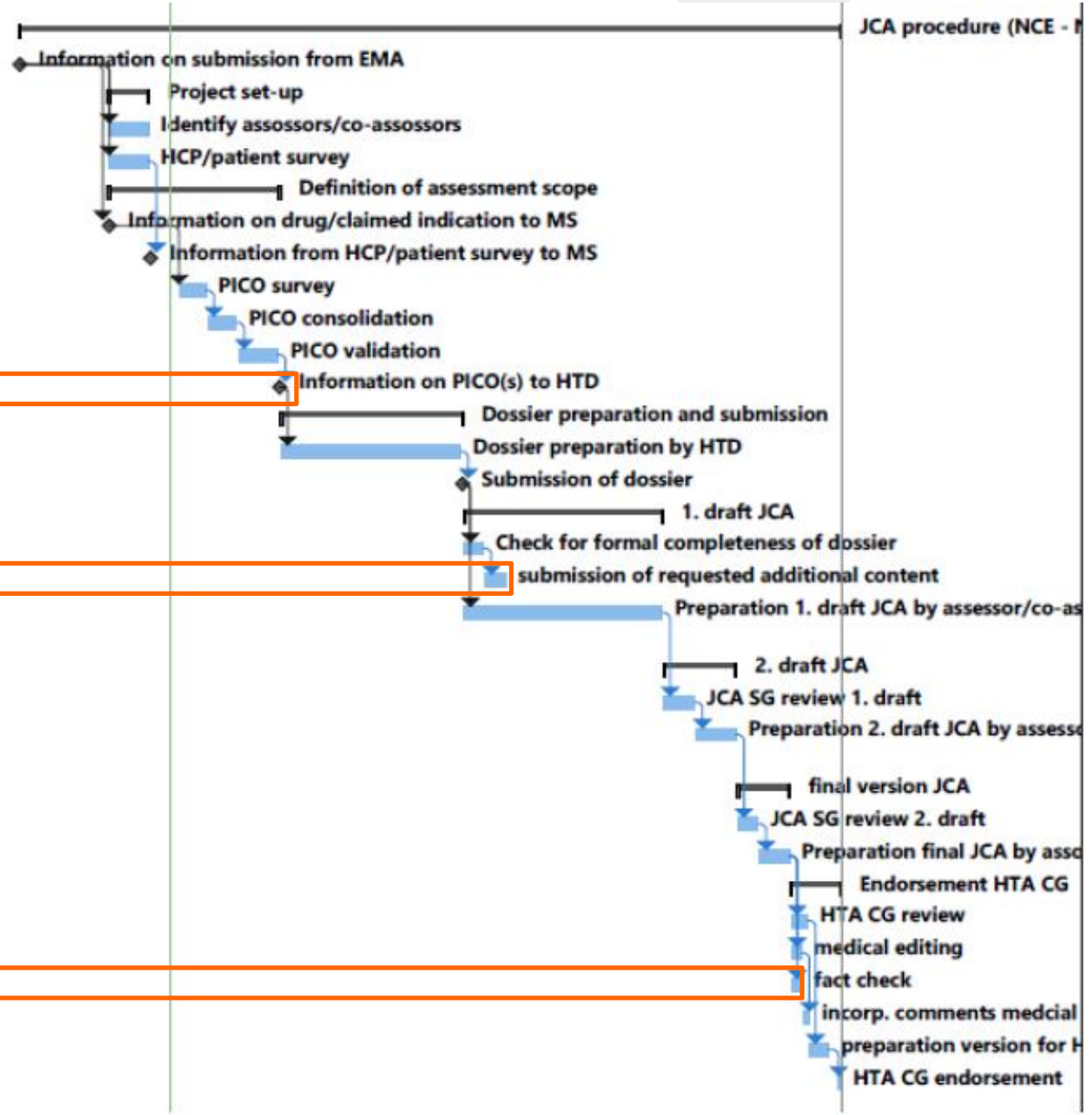
Scenario I – New Chemical Entities

In comparison to average, standard EMA process

EMA Procedure (New Chemical Entity, standard procedure)	**414 Tage?**	**Son 01.01.23**	**Son 04.02.24**
start of procecure	0 Tage	Son 01.01.23	Son 01.01.23
EMA assessment	120 Tage	Son 01.01.23	Mit 26.04.23
Day 120 List of Questions (LoQ)	0 Tage	Mit 26.04.23	Mit 26.04.23
clock stop	90 Tage	Don 27.04.23	Son 23.07.23
Day 120 LoQ responses	0 Tage	Son 23.07.23	Son 23.07.23
EMA assessment	60 Tage	Mon 24.07.23	Mit 20.09.23
Day 180 List of outstanding issues (LoOI)	0 Tage	Mit 20.09.23	Mit 20.09.23
clock stop	30 Tage	Don 21.09.23	Fre 20.10.23
Day 180 LoOI responses	0 Tage	Fre 20.10.23	Fre 20.10.23
EMA assessment	30 Tage	Sam 21.10.23	Son 19.11.23
CHMP opinion	1 Tag	Mon 20.11.23	Die 21.11.23
EC decision	1 Tag	Fre 05.01.24	Sam 06.01.24
EC decision + 30 days	0 Tage	Son 04.02.24	Son 04.02.24
Scenario 1: NCE - End at 30 days after EC approval	1 Tag?	Son 01.01.23	Son 01.01.23
JCA procedure (NCE - New Chemical Entity)	**414 Tage**	**Son 01.01.23**	**Son 04.02.24**
Information on submission from EMA	0 Tage	Son 01.01.23	Son 01.01.23
Project set-up	**20 Tage**	**Mon 13.02.23**	**Sam 04.03.23**
Definition of assessment scope	**86 Tage**	**Mon 13.02.23**	**Son 07.05.23**
Dossier preparation and submission	**91 Tage**	**Mon 08.05.23**	**Fre 04.08.23**
1. draft JCA	**100 Tage**	**Sam 05.08.23**	**Don 09.11.23**
2. draft JCA	**36 Tage**	**Fre 10.11.23**	**Fre 15.12.23**
final version JCA	**26 Tage**	**Sam 16.12.23**	**Mit 10.01.24**
Endorsement HTA CG	**25 Tage**	**Don 11.01.24**	**Son 04.02.24**



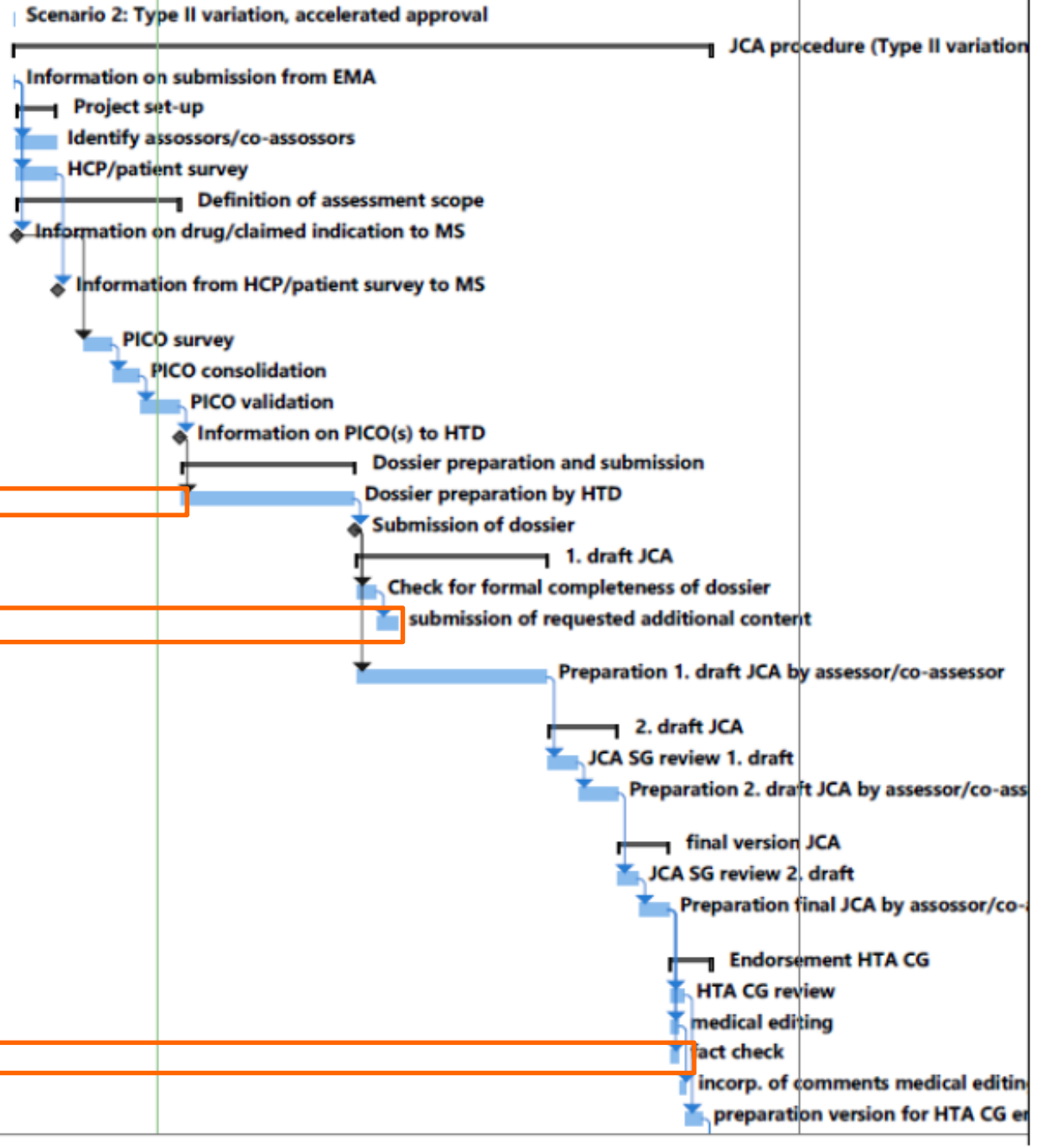
JCA procedure (NCE - New Chemical Entity)	414 Tage	Son 01.01.23	Son 04.02.24
Information on submission from EMA	0 Tage	Son 01.01.23	Son 01.01.23
Project set-up	**20 Tage**	**Mon 13.02.23**	**Sam 04.03.23**
Identify assossors/co-assossors	20 Tage	Mon 13.02.23	Sam 04.03.23
HCP/patient survey	20 Tage	Mon 13.02.23	Sam 04.03.23
Definition of assessment scope	**86 Tage**	**Mon 13.02.23**	**Son 07.05.23**
Information on drug/claimed indication to MS	0 Tage	Mon 13.02.23	Mon 13.02.23
Information from HCP/patient survey to MS	0 Tage	Son 05.03.23	Son 05.03.23
PICO survey	14 Tage	Son 19.03.23	Sam 01.04.23
PICO consolidation	14 Tage	Son 02.04.23	Son 16.04.23
PICO validation	20 Tage	Mon 17.04.23	Sam 06.05.23
Information on PICO(s) to HTD	0 Tage	Son 07.05.23	Son 07.05.23
Dossier preparation and submission	**91 Tage**	**Mon 08.05.23**	**Fre 04.08.23**
Dossier preparation by HTD	90 Tage	Mon 08.05.23	Don 03.08.23
Submission of dossier	0 Tage	Fre 04.08.23	Fre 04.08.23
1. draft JCA	**100 Tage**	**Sam 05.08.23**	**Don 09.11.23**
Check for formal completeness of dossier	10 Tage	Sam 05.08.23	Mon 14.08.23
submission of requested additional content	10 Tage	Die 15.08.23	Fre 25.08.23
Preparation 1. draft JCA by assessor/co-assessor	100 Tage	Sam 05.08.23	Don 09.11.23
2. draft JCA	**36 Tage**	**Fre 10.11.23**	**Fre 15.12.23**
JCA SG review 1. draft	15 Tage	Fre 10.11.23	Sam 25.11.23
Preparation 2. draft JCA by assessor/co-assessor	20 Tage	Son 26.11.23	Fre 15.12.23
final version JCA	**26 Tage**	**Sam 16.12.23**	**Mit 10.01.24**
JCA SG review 2. draft	10 Tage	Sam 16.12.23	Die 26.12.23
Preparation final JCA by assossor/co-assossor	15 Tage	Mit 27.12.23	Mit 10.01.24
Endorsement HTA CG	**25 Tage**	**Don 11.01.24**	**Son 04.02.24**
HTA CG review	8 Tage	Don 11.01.24	Fre 19.01.24
medical editing	5 Tage	Don 11.01.24	Die 16.01.24
fact check	5 Tage	Don 11.01.24	Die 16.01.24
incorp. comments medcial editing/fact check	3 Tage	Mit 17.01.24	Sam 20.01.24
preparation version for HTA CG endorsement	10 Tage	Sam 20.01.24	Mon 29.01.24
HTA CG endorsement	1 Tag	Sam 03.02.24	Son 04.02.24



* days are calendar days

Scenario II – Type II variations & Accelerated Assessments

Scenario 2: Type II variation, accelerated approval	1 Tag?	Son 01.01.23	Son 01.01.23
JCA procedure (Type II variation, accelerated approval)	**368 Tage**	**Son 01.01.23**	**Fre 22.12.23**
Information on submission from EMA	1 Tag	Son 01.01.23	Son 01.01.23
Project set-up	**20 Tage**	**Mon 02.01.23**	**Son 22.01.23**
Identify assossors/co-assossors	20 Tage	Mon 02.01.23	Son 22.01.23
HCP/patient survey	20 Tage	Mon 02.01.23	Son 22.01.23
Definition of assessment scope	**86 Tage**	**Mon 02.01.23**	**Son 26.03.23**
Information on drug/claimed indication to MS	0 Tage	Mon 02.01.23	Mon 02.01.23
Information from HCP/patient survey to MS	0 Tage	Mon 23.01.23	Mon 23.01.23
PICO survey	14 Tage	Son 05.02.23	Son 19.02.23
PICO consolidation	14 Tage	Mon 20.02.23	Son 05.03.23
PICO validation	20 Tage	Mon 06.03.23	Sam 25.03.23
Information on PICO(s) to HTD	0 Tage	Son 26.03.23	Son 26.03.23
Dossier preparation and submission	**91 Tage**	**Mon 27.03.23**	**Fre 23.06.23**
Dossier preparation by HTD	90 Tage	Mon 27.03.23	Don 22.06.23
Submission of dossier	0 Tage	Fre 23.06.23	Fre 23.06.23
1. draft JCA	**100 Tage**	**Sam 24.06.23**	**Fre 29.09.23**
Check for formal completeness of dossier	10 Tage	Sam 24.06.23	Die 04.07.23
submission of requested additional content	10 Tage	Mit 05.07.23	Sam 15.07.23
Preparation 1. draft JCA by assessor/co-assessor	100 Tage	Sam 24.06.23	Fre 29.09.23
2. draft JCA	**36 Tage**	**Sam 30.09.23**	**Sam 04.11.23**
JCA SG review 1. draft	15 Tage	Sam 30.09.23	Sam 14.10.23
Preparation 2. draft JCA by assessor/co-assessor	20 Tage	Son 15.10.23	Sam 04.11.23
final version JCA	**26 Tage**	**Son 05.11.23**	**Don 30.11.23**
JCA SG review 2. draft	10 Tage	Son 05.11.23	Die 14.11.23
Preparation final JCA by assossor/co-assossor	15 Tage	Mit 15.11.23	Don 30.11.23
Endorsement HTA CG	**22 Tage**	**Fre 01.12.23**	**Fre 22.12.23**
HTA CG review	8 Tage	Fre 01.12.23	Fre 08.12.23
medical editing	5 Tage	Fre 01.12.23	Die 05.12.23
fact check	5 Tage	Fre 01.12.23	Die 05.12.23
incorp. of comments medical editing/fact check	3 Tage	Mit 06.12.23	Sam 09.12.23
preparation version for HTA CG endorsement	8 Tage	Sam 09.12.23	Son 17.12.23



* days are calendar days

Recommendations

Recommendations

- Evaluation of timelines after a few JCA have been conducted under the HTAR, to assess the feasibility
  - Once a JCA is started, procedure and timelines should not be amended to ensure predictability for the HTD and assessors
- Develop a process to deal with major deviations in claimed indication
- A timeline calculation tool should be developed
- Where possible, weekend days should be avoided
  - but when there are several tasks of a short duration this cannot be avoided.

D5.1 – Submission Dossier Template

Beate Wieseler

Agenda

- Relevance of the HTD submission
- Legal requirements according to the HTAR
- Components of the submission guidance
- Overall structure of the dossier
- Submission dossier template
  - More granular structure of the dossier
  - Examples of specifications from the template
  - Table template collection
  - Further topics for clarification

Relevance of the HTD submission

- The assessment is based on a submission by the HTD

- The submission dossier should reflect the scope of the assessment
  - the assessment scope should be inclusive, reflect Member States needs
  - the HTD will be informed of the assessment scope with the request for the submission dossier

- To support a complete submission, information on the required content and format of the submission dossier will be made available

HTAR Article 9 - Joint clinical assessment reports and the dossier of the health technology developer

2. The reports referred to in paragraph 1 shall be based on a dossier that contains complete and up-to-date information, data, analyses and other evidence **submitted by the health technology developer** to assess the parameters included in the **assessment scope**.

3. The dossier shall meet the following **requirements**:

(a) the submitted **evidence is complete** with regard to the available studies and data that could inform the assessment;

(b) the data has been **analysed using appropriate methods** to answer all research questions of the assessment;

(c) the presentation of the data is **well structured and transparent**, thereby allowing for an appropriate assessment within the limited timeframes available;

(d) it includes the **underlying documentation** in respect of the submitted information, thereby allowing the assessor and co-assessor to verify the accuracy of that information.

4. The dossier for medicinal products shall include the **information set out in Annex I**. The dossier for medical devices and in vitro diagnostic medical devices shall include the information set out in Annex II.

ANNEX I Dossier specifications for medicinal products

The dossier referred to in Article 9(2) of this Regulation shall for medicinal products include the following information:

(a) the clinical safety and efficacy data included in the submission file to the European Medicines Agency;

(b) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and study protocols and analysis plans from studies with the medicinal product for which the health technology developer was a sponsor and all available information on ongoing or discontinued studies with the medicinal product for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about studies by third parties if available, relevant to the assessment scope as set out in accordance with Article 8(6), including the clinical study reports and clinical study protocols if available to the health technology developer;

(c) HTA reports on the health technology subject to the joint clinical assessment;

(d) information on studies based on registries;

(e) if a health technology has been subject to a joint scientific consultation, the explanation from the health technology developer on any deviation from the recommended evidence;

ANNEX I Dossier specifications for medicinal products

(f) the characterisation of the medical condition to be treated, including the target patient population;

(g) the characterisation of the medicinal product under assessment;

(h) the research question elaborated in the submission dossier, reflecting the assessment scope as set out pursuant to Article 8(6);

(i) the description of methods used by the health technology developer in the development of the content of the dossier;

(j) the results of information retrieval;

(k) the characteristics of included studies;

(l) the results on effectiveness and safety of the intervention under assessment and the comparator;

(m) the relevant underlying documentation related to points (f) to (l).

Objectives of submission dossier guidance

https://www.eunethta.eu/wp-content/uploads/2022/12/EUnetHTA-21-D5.1-Submission-Dossier-Guidance-v1.0.pdf

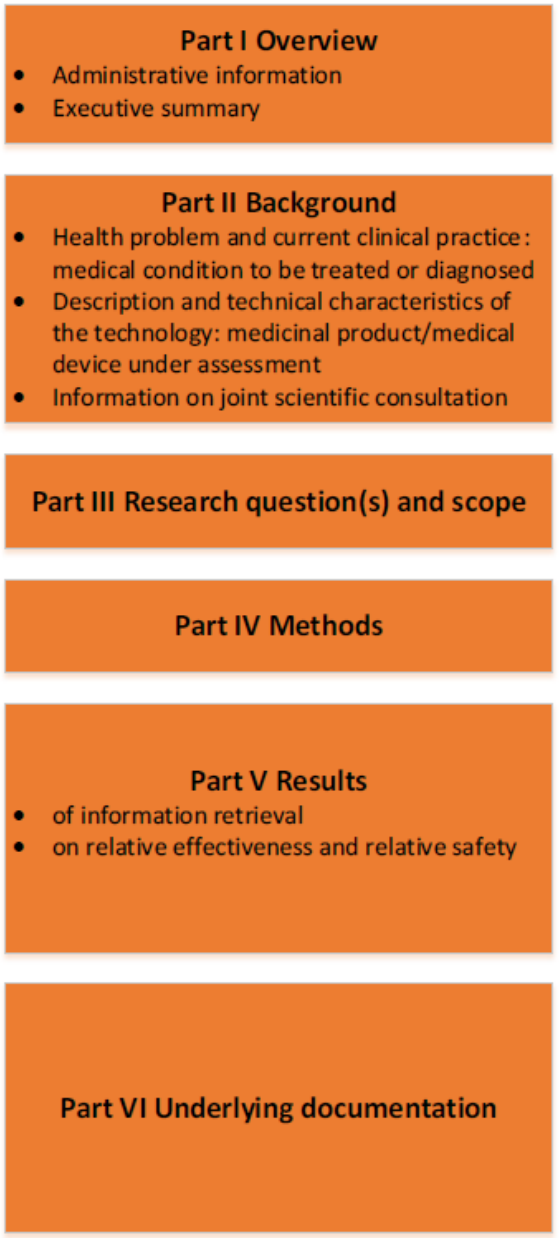
- enable HTD to submit a complete dossier
- support an efficient dossier preparation by the HTD
- ensure that the dossier includes the information that is required for the assessment
- ensure that the information is organised in a well-structured and transparent manner to support assessors
- support decision making at the European and national level

Components of submission dossier guidance

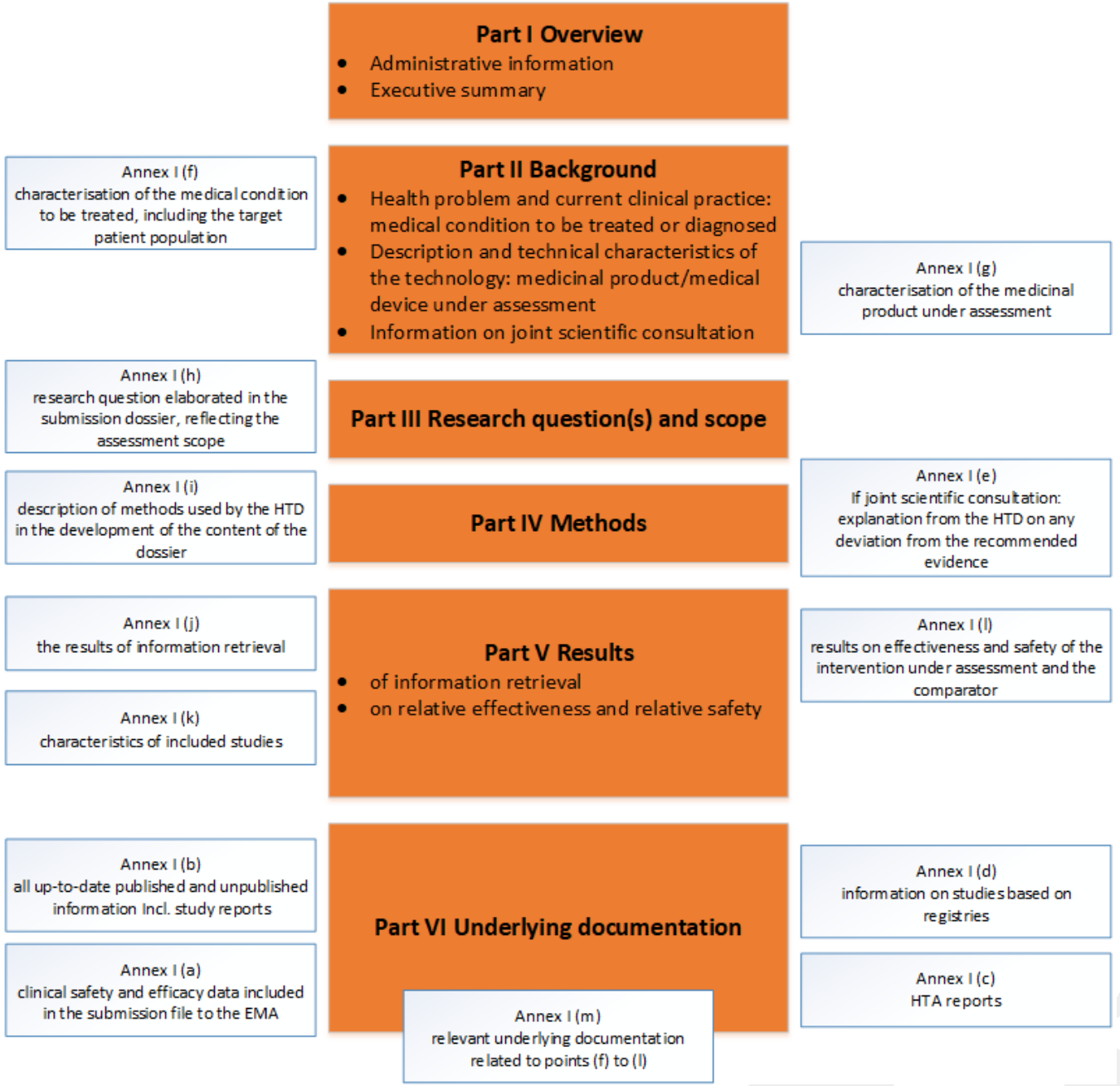
- Submission dossier guidance document (EUnetHTA21 finalised)
- Submission dossier template (document and ready to use file) (EunetHTA21 under development, for medicinal products)
- Technical table template collection (ready to use file) (EUnetHTA21 under development)
- (Technical support document)
- (Q&A document)

Submission dossier guidance

- High-level structure of the submission dossier



Mapping of Regulation requirements to the high-level dossier structure



IV Structure and content of the dossier

Submission dossier guidance

- High-level Table of Contents of the submission dossier
- Clarification of general content of the dossier

Table of Contents

Submission dossier template (1)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Submission dossier template (2)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Submission dossier template (3)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Submission dossier template (4)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Submission dossier template (5)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Appendix D Underlying documentation for medicinal products

D.1 Full texts of references

D.2 Documentation of information retrieval

D.2.1 Documentation of search strategies for each information source

D.2.2 Results of the information retrieval in standard format

D.3 Programming code for programs used for analyses

D.4 Study reports for original clinical studies

D.5 Study reports for evidence synthesis studies

D.6 Clinical safety and efficacy data included in the submission file to the European Medicines Agency

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

D.8 Information on studies based on registries

D.9 Information on joint scientific consultations

Submission dossier template (6)

- More granular Table of Contents of the submission dossier
- Clarification of more specific content of the dossier

Examples of specifications from the template

4.3.3 Direct comparisons by pairwise meta-analyses

If appropriate, the studies available shall be synthesised quantitatively via meta-analyses. All information in this section shall be assigned to the appropriate PICO question(s), if applicable. The protocol for evidence syntheses, including the relevant statistical analysis plan, should be provided as an appendix.

The validity of pooling studies as well as the exclusion of particular studies from the study pool, if applicable, shall be justified. Details on the process used to identify potential treatment effect-modifiers should be described.The methods applied shall be described in this section, the choice of methods shall be justified.This includes methods used to assess the exchangeability assumptions (i.e., similarity, homogeneity), plausibility of underlying assumptions, methods for estimating effect measures, description and methods used to deal with any apparent failure of the exchangeability assumption (e.g., meta-regression, restriction to subgroups), methods for dealing with missing data.

All conducted sensitivity-analyses (on methodological parameters) shall be listed here (respective methods shall be described in section 4.3.5).

<content by the HTD>

- High-level requirements on description of methods
- More detailed specifications in methodological guidances

Examples of specifications from the template

5.1.5 HTA reports

This section shall list HTA reports available on the health technology subject to the joint clinical assessment from EEA countries and from Australia, Canada, the United Kingdom and the United States of America. The HTA reports shall be provided in appendix D.7.

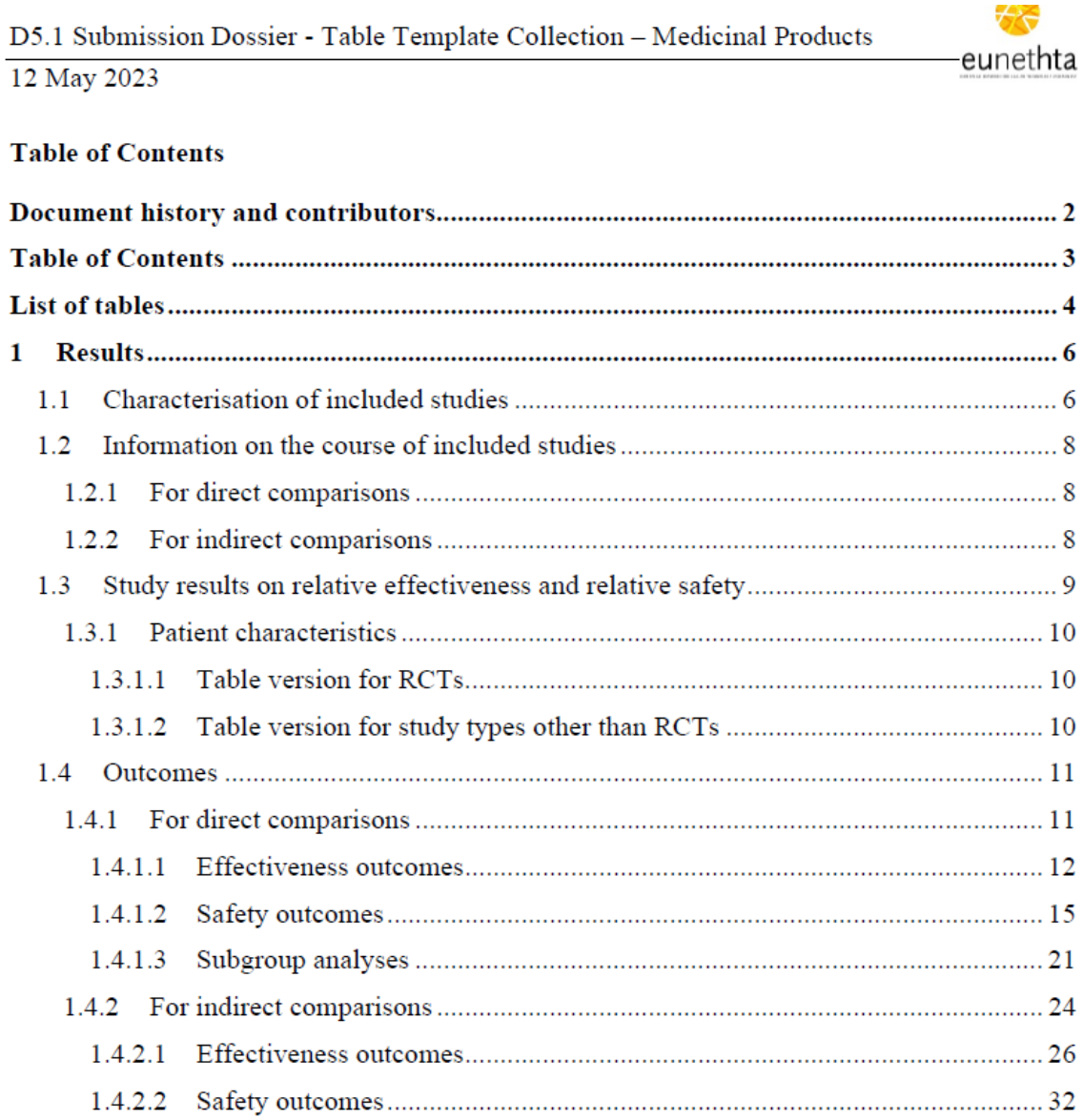
The latest date of the search(es) shall be documented.

Table 17: HTA reports on the health technology subject to the joint clinical assessment

HTA report title	**Country affiliation**
<report 1>	*<specify>*
<report 2>	
footnotes (this line can be deleted, if it is not needed	
abbreviations (this line can be deleted, if it is not needed	

<content by the HTD>

- HTAR ANNEX I (c): HTA report on the health technology subject to the joint clinical assessment
- Template clarifies which HTA reports shall be provided



D5.1 Submission Dossier - Table Template Collection – Medicinal Products
12 May 2023

Table of Contents

Table template collection

- Separate technical document with table templates for study characterisation and study results
- Templates optimised for various types of data
- Tables also reflecting methodological guidance

1.3.1 Patient characteristics

1.3.1.1 Table version for RCTs

Table 6: Patient baseline characteristics including treatment / study discontinuations for population <x>

Study reference / ID Characteristics Category	Study intervention	Relevant comparator
<Study 1>	<intervention> N =	<comparator> N =
Age [years], mean (SD) Sex [f / m], % <more characteristics>, n (%) <Category 1> <Category 2> <Category 3> …		
Treatment discontinuation, n (%) Study discontinuation, n (%)		
<Study 2>	<intervention> N =	<comparator> N =
…		
footnotes (please delete this line if it is not needed)		
f: female; m: male; n: number of patients in the category; N: number of randomized patients; ND: no data;; RCT: randomized controlled trial; SD: standard deviation		

1.3.1.2 Table version for study types other than RCTs

Table 7 Patient baseline characteristics including treatment / study discontinuations for population <x>

Study reference / ID Characteristics Category	Study intervention	Relevant comparator	Standardized difference
<Study 1>	<intervention> N =	<comparator> N =	
Age [years], mean (SD) Sex [f / m], % <more characteristics>, n (%) <Category 1> <Category 2> <Category 3> …			
Treatment discontinuation, n (%) Study discontinuation, n (%)			
<Study 2>	<intervention> N =	<comparator> N =	
…			
footnotes (please delete this line if it is not needed)			
f: female; m: male; n: number of patients in the category; N: number of randomized patients; ND: no data;; RCT: randomized controlled trial; SD: standard deviation			

Table template collection - example

- Separate technical document with table templates for study characterisation and study results
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Further topics for clarification

- Specification of the language of the dossier

- Technical specifications for submission
  - Technical format
  - Process (taking into consideration the IT platform)

- Publication of the dossier

Closing remarks

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