EUnetHTA 21 – Stakeholder Meeting

13 July 2022
14:00-16:00 CET

1. **Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting**

Niklas Hedberg, TLV

Upcoming stakeholder meetings

Meeting date	Objective
July 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
October 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
18 November 2022	4th General EUnetHTA 21 Stakeholder Meeting
February 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
12 May 2023	5th General EUnetHTA 21 Stakeholder Meeting
8 September 2023	6th & final General EUnetHTA 21 Stakeholder Meeting
September/October 2023	EMA/EUnetHTA 21 bilateral in accordance to work plan

Housekeeping of today's meeting

Alzbeta Tuckova, ZIN

Information for attendees

Entering the meeting:

- Please ensure you have logged in with your **name, surname, organisation and country** *i.e. Merle Tenberg (ZIN, The Netherlands)*.
- You can rename yourself after you have logged in.
- Please do not switch your webcam on.

Information for attendees

Questions:

- To ask questions, you may:
  - Post them in the chat or raise your hand during the dedicate timeslot (at the end of relevant presentations or during the Q&A item).
- Responses to all questions will be coordinated by the Chair and will be taken at the **end of relevant item**.
- Please note: for internal purposes this meeting will be recorded.

Information for attendees

Technical issues:

- If you experience problems with Zoom during the meeting, please:

  1. Go to www.zoom.com and search for help.
  2. Contact euenthta@zinl.nl or call Merle Tenberg on

     +31 6 51 06 80 53 for support (You may wish to take a picture of these contact details).

Today’s agenda

Niklas Hedberg, TLV

Agenda

ID	Time	Description	Presenter/s
#1	14:00-14:10	Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting	Niklas Hedberg, TLV
#2	14:10-14:20	Update from the European Commission	Julia Schmitz, EC Valentina Barbuto, EC
#3	14:20 -14:45	Update on status of deliverables a) Joint Scientific Consultations b) Joint Clinical Assessments c) Transversal Activities	Chantal Guilhaume, HAS Antje Behring, G-BA
#4	14:45-15:15	Content a) D7.1 HTD interaction b) b) D7.2/7.3 Patient/HCP	Anne Willemsen, ZIN Maggie Galbraith, HAS
#5	15:15-15:30	JCA pilot a) Objectives b) National uptake c) Template d) Timelines	Chantal Guilhaume, HAS Anne Willemsen, ZIN
#6	15:30-15:50	Q&A	Niklas Hedberg, TLV
#7	15:50-16:00	Closing remarks	Niklas Hedberg, TLV

2. **Update from the European Commission**

Julia Schmitz, EC
Valentina Barbuto, EC

Implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment

Valentina BARBUTO and Julia SCHMITZ
Policy officers, Unit B6, DG SANTE

EUnetHTA21 Stakeholder Meeting, 13 July 2022

EC conference on HTA Regulation (22 June 2022)

https://health.ec.europa.eu/events/conference-new-regulation-health-technology-assessment-hta-2022-06-22_en

Presentations

The implementation rolling plan – What's next
Flora Giorgio
European Commission - DG Health and Food Safety

EUnetHTA 21 - Supporting the future of European HTA cooperation
Marcus Guardian
National Health Care Institute (ZIN, The Netherlands)

Joint HTA on medical devices – Looking ahead
Rosanna Tarricone
Bocconi University

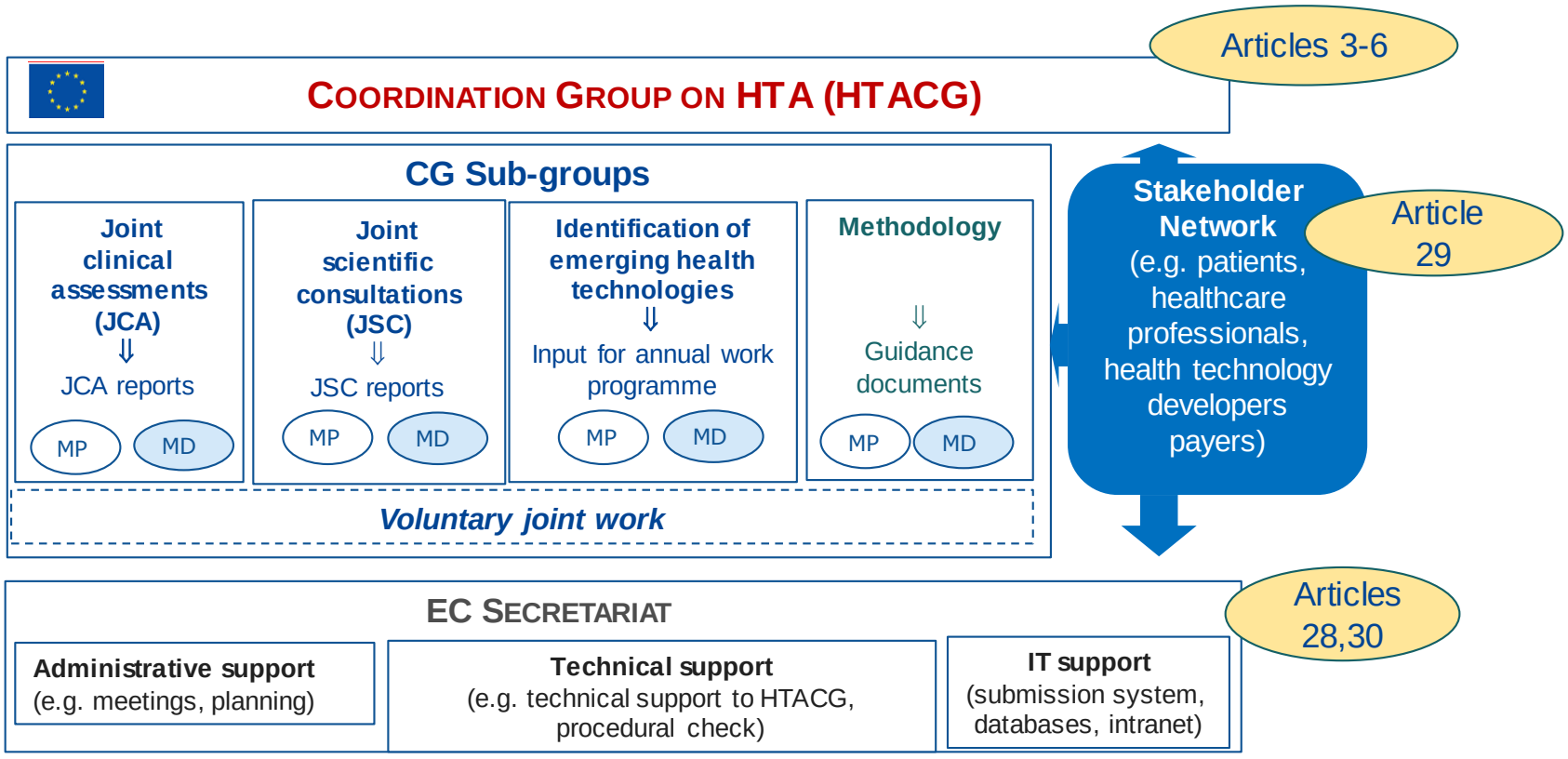
Patients and healthcare professionals as external experts in HTA
François Houÿez
EURORDIS

Advancing HTA methodology for joint work: Joint Scientific Consultations
Antje Behring
Federal Joint Committee (G-BA, Germany)

Advancing HTA methodology for joint work: Joint Clinical Assessments
Chantal Guilhaume
National Authority for Health (HAS, France)

European Commission

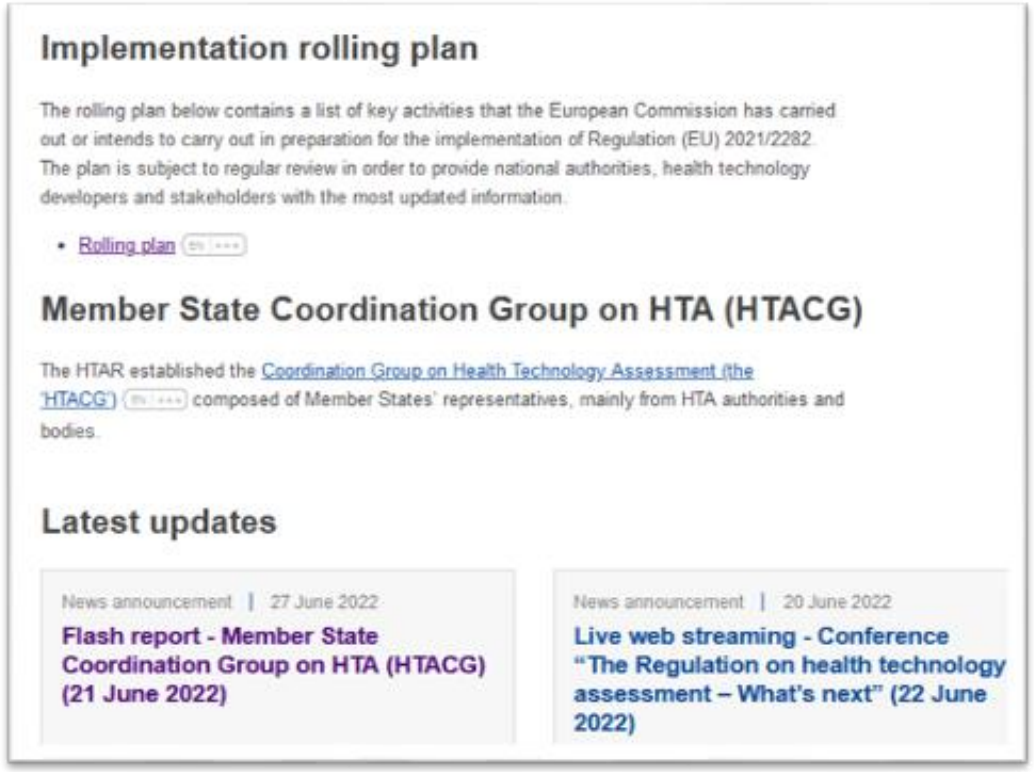
HTA Regulation
MS Coordination Group on HTA



MP = medicinal products, MD = medical devices

European Commission

EC HTA implementation website



Implementation rolling plan

The rolling plan below contains a list of key activities that the European Commission has carried out or intends to carry out in preparation for the implementation of Regulation (EU) 2021/2282. The plan is subject to regular review in order to provide national authorities, health technology developers and stakeholders with the most updated information.

- Rolling plan

Member State Coordination Group on HTA (HTACG)

The HTAR established the Coordination Group on Health Technology Assessment (the 'HTACG') composed of Member States' representatives, mainly from HTA authorities and bodies.

Latest updates

News announcement | 27 June 2022

Flash report - Member State Coordination Group on HTA (HTACG) (21 June 2022)

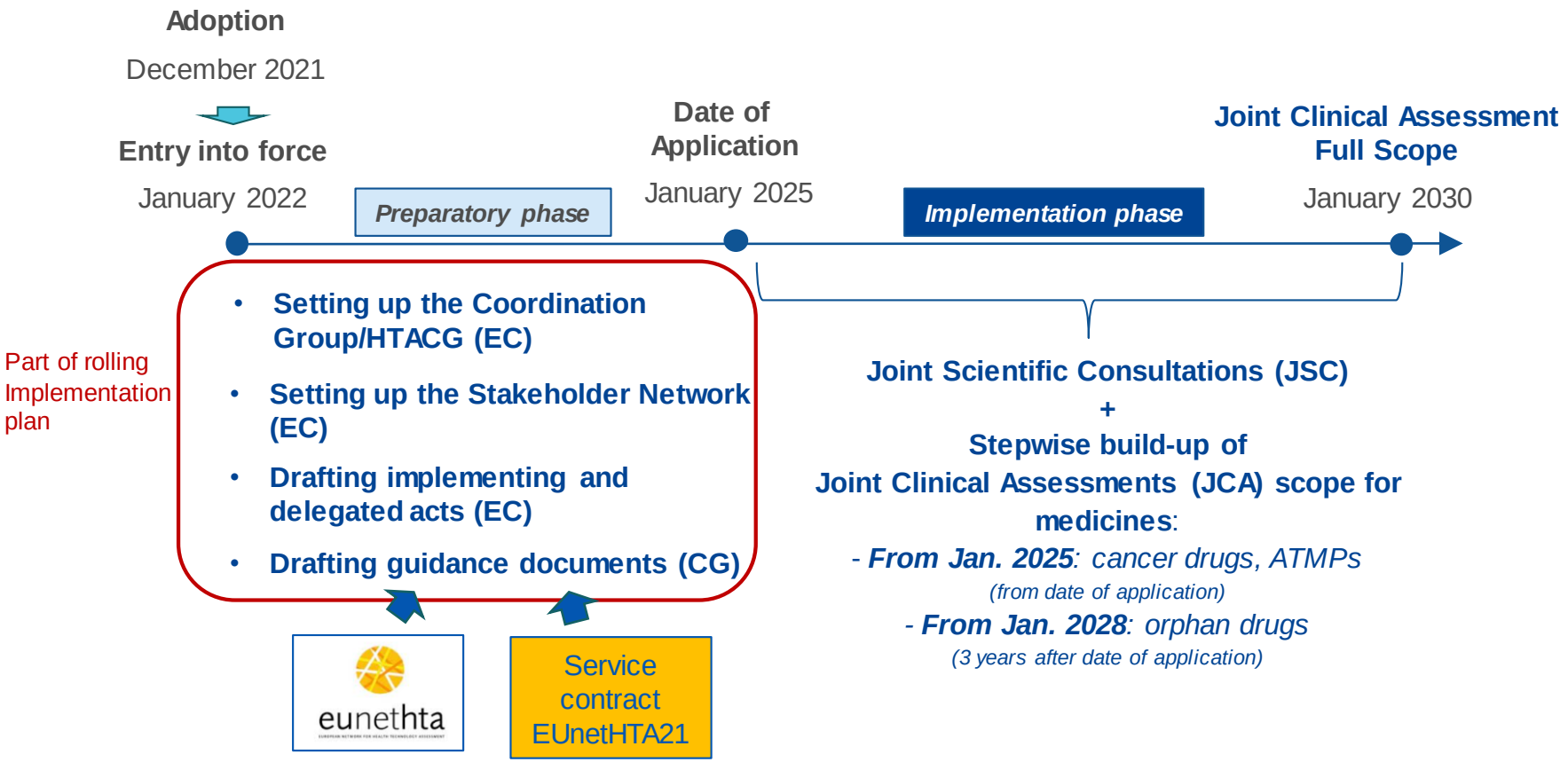
News announcement | 20 June 2022

Live web streaming - Conference "The Regulation on health technology assessment – What's next" (22 June 2022)

https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment/implementation-regulation-health-technology-assessment_en

European Commission

HTA Regulation
Implementation timeline



European Commission

Thank you

European Commission

3. **Update on status of deliverables**

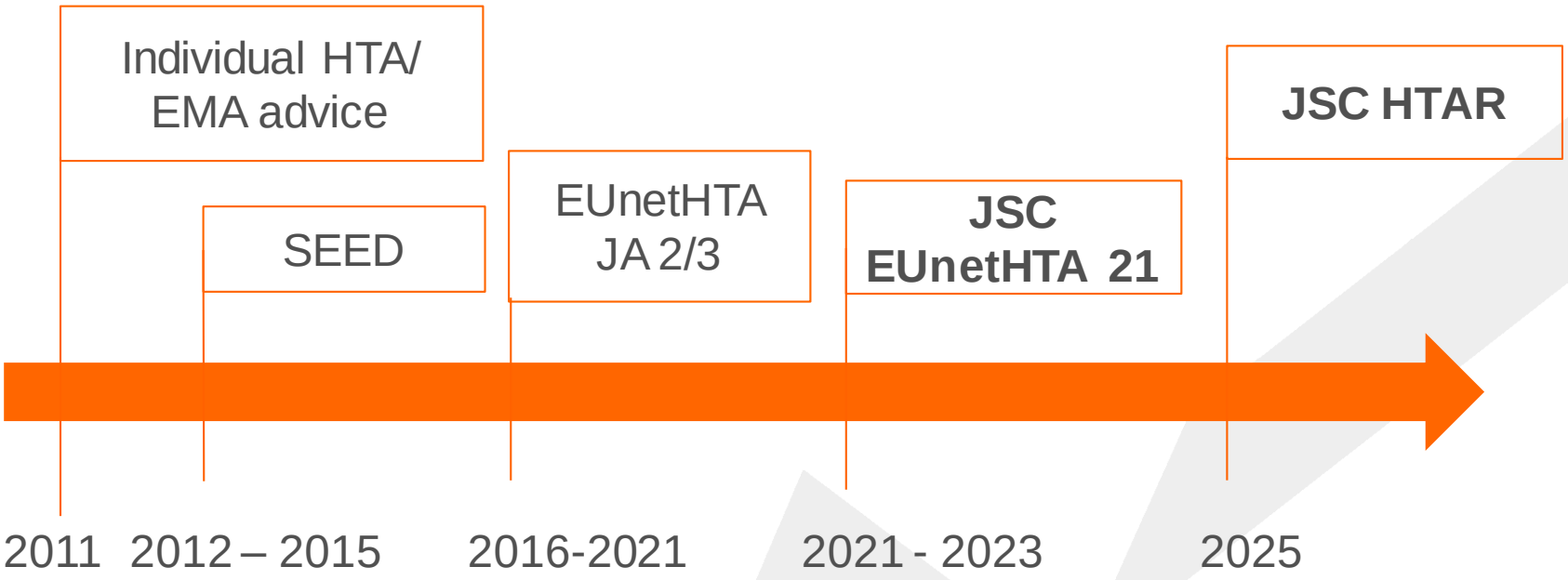
Antje Behring, G-BA
Chantal Guilhaume, HAS

3a. **Joint Scientific Consultations**

Antje Behring, G-BA

History and future of HTA advice

- From the beginning in collaboration with EMA
- EUnetHTA (21) project phase → **Continuation via HTA Regulation (HTAR)**



JSC in EUnetHTA 21

- **Last project phase before continuation within the framework of HTAR**
- **HTA will remain a relevant topic for the future**

- Parallel EMA/EUnetHTA 21 JSCs: consultations together with EMA
- According to EUnetHTA 21 service contract: max. 8 JSCs planned
- 1st Open Call: 3 candidates accepted (selection criteria)
  - 1 JSC already completed, 2 ongoing
  - Indications: oncology, orphan drugs
- 2nd Open Call open now: from June 6th to August 31st 2022
  - 5 JSCs are planned

❖ **New guidance for patient and HCP involvement currently under revision**

❖ **Public consultation: 1-30 August 2022**

Expert involvement in JSC

Expert involvement JSC

Purpose	Involvement type	Level	Method(s)	Information provided to the expert
– **Obtain information on living with the disease/expertise with the treatment of the disease and expectations of new treatment;** – **Getting input following the PICO scheme**	External expert	**National**, generally	**Approach 1: Interview (or written statement) based on questionnaire**	No documents are shared
	External expert	**National**, generally	**Approach 2: Approach 1 + Respond to specific questions re: HTD development plan**	Providing the briefing package or relevant sections of the briefing package when a specific contribution is required
	External expert	**European**	**Approach 3: Approach 2 + Review draft List of Issues and participate in meeting with EMA and HTD**	

JSC key steps and expert identification / involvement – European level

Identification & Recruitment
D-30

- **D-30 Identification process is initiated to find appropriate experts**
- Started as early as possible in the JSC process
- Identification will be initiated at both national and European level, using both individual national mechanisms and the networks developed under EUnetHTA 21

Interview & Questionnaire
D+30

- **Ideally before D+30 JSC HOG e-meeting on EUnetHTA 21 LoI (List of Issues)**
- Experts provide their input orally (via interview) or in writing on the basis of an appropriate questionnaire
- Experts receive the LoI for information before it is sent to EMA and the applicant, with the opportunity to provide feedback

Face to Face meeting
D+60

- **D+60 Face to Face meeting with HTD, HTAb and EMA**
- Experts are invited to the meeting to give their input

Final Written Recommen-dation
D+82

- **D+82 Final Written Recommendation sent to Applicant**
- Final Written Recommendation is shared with experts

Expenses to contribute in JSC as expert

- **EUnetHTA 21 DOI and ECA form have to be filled in**
  - **Central approval by Conflict of Interest Committee**

National level expert:

- Interview (or written statement) based on questionnaire
  - Questionnaire shared beforehand
  - Duration 30-60min, validation of minutes
  - Written feedback mostly preferred by HCPs

European level expert (recruited by JSC Secretariat, member of European patient organisation):

- Interview (or written statement) based on questionnaire
- Review draft List of Issues – feedback optional, 30min?
- Participate in meeting with EMA and HTD – 3 hours

Expert recruitment for JSC

- Expert recruitment within tight timelines
- If you are contacted by the JSC Secretariat or one of our HTA partners, please respond in a timely manner
- Challenges of expert recruitment – patients and HCPs: collaboration of JSC Secretariat with other HTABs of the JSC HOGs and also EMA to find experts

➢ At the moment we are in the process of building a functional network of contacts: sources, e.g. EUnetHTA 21 stakeholder pool, EMA eligible patient organisations etc.

➢ Differences in EMA vs. EUnetHTA 21 COI policy!

Your help and support upon initial contact is much appreciated!

Thank you in advance!

You are kindly invited to raise questions now or send them anytime to the EUnetHTA 21 JSC Secretariat: EUnetHTA21-JSC@g-ba.de

3b. **Joint Clinical Assessments**

Chantal Guilhaume, HAS

EUnetHTA 21 Joint Clinical Assessment Deliverables

Deliverables	Start Public consultation
JCA PRODUCTIONS	**2023**
METHODOLOGICAL GUIDELINES	
• D4.2.1 Scoping process	**Closed**
• D4.3.1/D4.3.2 Direct and Indirect Comparisons	**Closed/August 2022**
• D4.4.1 Endpoints	**October 3rd 2022**
• D4.5.1 Applicability of evidence	**Ongoing**
• D4.6.1 Validity of clinical studies	**Ongoing**
• D4.7.2. Assessment of High risk MD and IVD	**Closed**
• D4.7.3 + 4.7.4 EUDAMED Reporting template, Guidance for EUDAMED	**Closed**
TEMPLATES	
• D5.1. Submission Dossier Template	**Ongoing**
• D5.2.1.JCA Report Template	**Aug 1st 2022**
PROCEDURAL GUIDELINES	
• D5.3.1 Selection criteria for assessor and co-assessor	**Closed**
• D5.3.2 HTAb Technical Expert Working Group	**Closed**

3c. **Transversal Activities**

Chantal Guilhaume, HAS

EUnetHTA 21 Transversal Deliverables

Deliverables	Start Public consultation
D7.1 Guidance for the interaction between HTA experts and health technology developers (HTD) during JCA and JSC	**20-07-2022**
D7.2.1 Guidance for consulting patients, clinical experts and other experts during JCA and JSC	**01-08-2022**
D7.3 Expert input templates	**01-08-2022**
D7.4 Workplan for Interaction with Regulators of medicinal products and of medical devices (section 7.4)	Published
D7.5 Guidance for identifying and handling conflict of interest (COI), declaration of interest and confidentiality agreement form	Published

4. **Content**

Anne Willemsen, ZIN
Maggie Galbraith, HAS

4a. **D7.1 HTD interaction**

Anne Willemsen, ZIN

Upcoming public consultation

The deliverable D7.1 on interaction between HTD and HTA will go for public consultation between

July 20 and August 19, 2022

Consists of 3 sub-deliverables:

- D7.1.1 – practical guideline for interaction between HTD and HTA
- D7.1.2 – process for a factual accuracy check
- D7.1.3 – process for confidential data

Please note, in EUnetHTA 21 some procedures may look different then under the HTA Regulation. This is pointed out in the sub-deliverable when relevant

HTA Regulation articles

The sub-deliverables are based on:

- the requirements laid down in the HTA Regulation;
- as well as experiences from Joint Action 3 and;
- recommendations expressed in the FMC work.

D7.1.1 – Practical Guideline for interaction between HTD and HTA

- It defines the role of HTA bodies, Secretariat and Health Technology Developer (HTD) in JCA and JSC procedures
- It defines the process steps for the JSC and JCA procedures
- Time points for interaction and the objective thereof, before during and after the procedure. E.g:
  - For JSC:
    - Application and selection of a JSC, submission of briefing book, list of issues, the F2F meeting, final recommendations and evaluation
  - For JCA:
    - Selection of a technology, submission of PICO to HTD, submission of a dossier and the check for completeness, publication of a JCA and evaluation procedure (under EUnetHTA 21)

D7.1.2 – Process for factual accuracy check by HTD

- Defines the time points and process for the factual accuracy check by a HTD for a JCA process
  - Notification of the process, sharing of the draft JCA report for the factual accuracy check, collecting the comments from HTD and providing answers to the HTD comments
- It holds a checklist on what can be reviewed by the HTD

D7.1.3 – Process for handling of commercial and academic in-confidence data

- Defines the concept of commercially in-confidence data and personal data for both JSC and JCA
  - It stipulates what information can and cannot be shared externally
- Defines the process for marking data confidential and what happens
- Explains why academic in-confidence is not accepted for JSC and JCA purposes

4b. **D7.2/7.3 Patient/HCP**

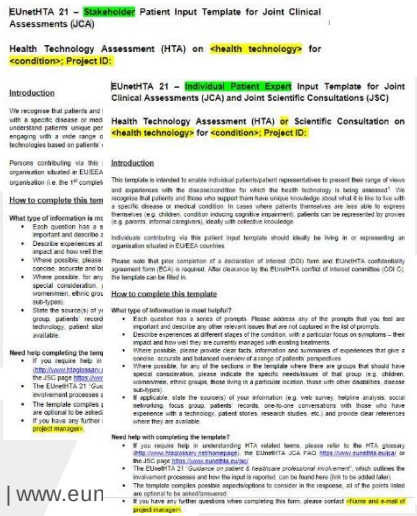
Maggie Galbraith, HAS

Upcoming public consultation

Deliverables 7.2/7.3 – Involvement of Patients, Healthcare Professionals, and other experts will go for public consultation between **August 1 and August 30, 2022**

- D7.2 Guidance for involvement of patients and clinical experts in JCA and JSC

- D7.3 Template for patient input and template for HCP input which consists of 3 questionnaires:
  1. Patient stakeholder
  2. Patient expert
  3. Clinical expert


EUnetHTA 21 – Stakeholder Patient Input Template for Joint Clinical Assessments (JCA)

Health Technology Assessment (HTA) on <health technology> for <condition>; Project ID:

Introduction

How to complete this tem

What type of information is mo

Need help completing the temp

EUnetHTA 21 – Individual Patient Expert Input Template for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)

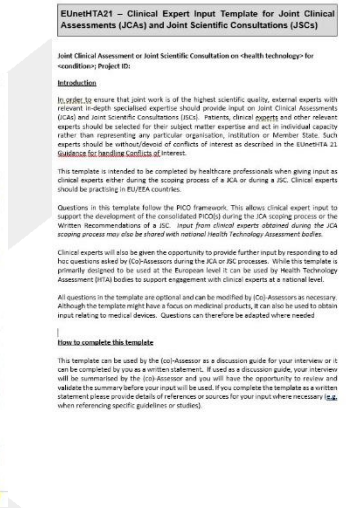
Health Technology Assessment (HTA) or Scientific Consultation on <health technology> for <condition>; Project ID:

Introduction

How to complete this template

What type of information is most helpful?

Need help with completing the template?


EUnetHTA21 – Clinical Expert Input Template for Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs)

Joint Clinical Assessment or Joint Scientific Consultation on <health technology> for <condition>; Project ID:

Introduction

How to complete this template

Objectives and General Principles D7.2/3

Objectives are to develop:

- Guidance for the interaction with and involvement of external experts (patient experts and clinical experts) and patient representatives in JSC and JCA
- A template for patient expert /patient representative input into JSC and JCA.
- A template for clinical expert input into JSC and JCA.

General Principles:

- Early engagement
  - Stakeholders via open call at the very beginning of the JCA process
  - Experts beginning with PICO consolidation (JCA)/List of Issues (JSC)
- Sharing of information with experts based on needs of Assessor/ coAssessor and the expert's skillset
- Summary of input validated by the experts

D7.2 Subjects Addressed in Guidance

- Distinction between stakeholders and experts
- Recruitment of stakeholders and experts
- Confidentiality and conflict of interest
- Creation of a EUnetHTA 21 expert database (patient and clinician)
- Timepoints and methods for involving clinicians and patients
- Reporting on expert involvement in the JSC Recommendations or JCA Report
- Naming of experts
  - Clinical experts to be named if they want
  - Patient experts not to be named and identifying information not to be published
- Considerations for the future (HTAR)
  - Need to expand guidance to cover other types of experts and consumers
  - Adaptations needed for medical devices

Patient and Clinician Involvement in JCA

Timepoint	Purpose	Type	Level	Method(s)	Information shared
Before National PICO	Obtain information on living with the disease; expectations of new treatment etc. This information is obtained well in advance before the JCA scoping starts, so that HTA bodies who do not have a national procedure in place to involve patients can still benefit from patient input.	Patient stakeholder	European	(online) questionnaire	Indication and the questionnaire
Input during PICO development (National level – methods depend on the national procedures in place)	Obtain information on living with the disease; expectations of new treatment etc; Assist in defining national PICO	External experts and/or stakeholders (depends on the national procedure)	National	National procedures	As per national requirement
PICO consolidation, during scoping process	Patient and clinical expert input is used to support defining national PICO and as a validation tool for the consolidated PICO(s).	External experts	European	Including patient and clinical expert input templates, Interviews and meeting participation (as per guideline)	Details of indication under review. This is done early in scoping phase so no draft PICO available
Draft JCA report	Answer specific questions from the Assessor/Co-Assessor	External experts	European	ad-hoc questions, interviews if necessary	Depends on mode of involvement, but could be draft JCA report or specific information needed to understand the context of a question

Patient and Clinician Involvement in JSC

Timepoint	Purpose	Type	Level	Method(s)	Information shared
Approach 1 Prior to draft written recommendations	Obtain information on living with the disease; expectations of new treatment etc; getting input following the PICO scheme	External experts	National, generally	Approach 1: Interview (or written statement) based on questionnaire	No documents are shared
Approach 2 Prior to draft written recommendations		External experts	National, generally	Approach 2: Approach 1 + Respond to specific questions re: HTD development plan	Providing the briefing package or relevant sections of the briefing package when a specific contribution is required
Approach 3 Prior to draft List of Issues		External experts	European	Approach 3: Approach 2 + Review draft List of Issues and participate in meeting with EMA and HTD	

D7.3 Subjects Addressed in Questionnaires

For Patients

- Developed Based on HTAi questionnaire and JA3

D7.2/D7.3 Timelines

Task	Date
HOG began work	14/03/2022
First CSCQ Consensus Meeting	17/05/2022
Patient and clinical expert round table	25/05/2022
Second CSCQ Consensus Meeting	13/07/2022
Multi-stakeholder meeting	13/07/2022
Public Consultation	01/08/2022- 31/08/2022
Expected Publication Date	04/11/2022

Thank you!

5. **JCA pilot**

Chantal Guilhaume, HAS
Anne Willemsen, ZIN

Objectives JCA production in EUnetHTA 21

- Continue to improve quality, consistency and uptake of JCA
  - Further standardize production process in line with HTA R articles
  - Pilot work developed during EUnetHTA 21
    - Practical guidelines, procedure and templates
    - Evaluate and adjust based on experiences
  - Refine interaction in line with the HTA Regulation
    - CSCQ review/validation and CEB endorsement
  - Explore interaction with stakeholders
    - Health Technology Developer (HTD), patients, clinical experts and regulators
  - Identify potential changes to national systems to use JCA

Consolidated PICO at the center of the JCA

Direct consequences:

- Inclusive scope
  - All requests from MS need to be included
  - Assessment teams might have to answer more questions than in a national process (more work)
  - MS using the assessment need to extract the relevant information from the JCA for further use in national assessment and appraisal
- The PICO format will be used to request data requirements from HTD and for MS to inform the assessment scope

Indirect consequences:

- A process equivalent to a PICO survey required to collect MS scope
- No separate PICO's per MS, but consolidated form to minimalize overlap

Submission dossier guidance

Submission dossier guidance document

Currently under public consultation

Submission dossier template

Appendix: Table templates

EUnetHTA 21 JCA production timelines *Medicinal Products JCA*

- Timelines are dependent on regulatory assessment timeline
  - Eligible products: initial marketing authorisation

Milestone	Month
Letter of Intent	August, 2022
Consolidated PICO	26 October, 2022
Submission Dossier	9 January, 2023 *45 days before CHMP opinion, as per HTA Regulation*
CHMP opinion	February, 2023 *Last CHMP meeting day = 23 Feb*
Publication JCA report	31 May, 2023 *Allowing 4-5 months for EUnetHTA21 to revise and update their deliverables before closing in September 2023*

**timelines for earlier or later start can be discussed bilaterally*

Who will be the EUnetHTA 21 JCA team?

Assessor & co-assessor

- HAS (France) & INFARMED (Portugal)

JCA coordination

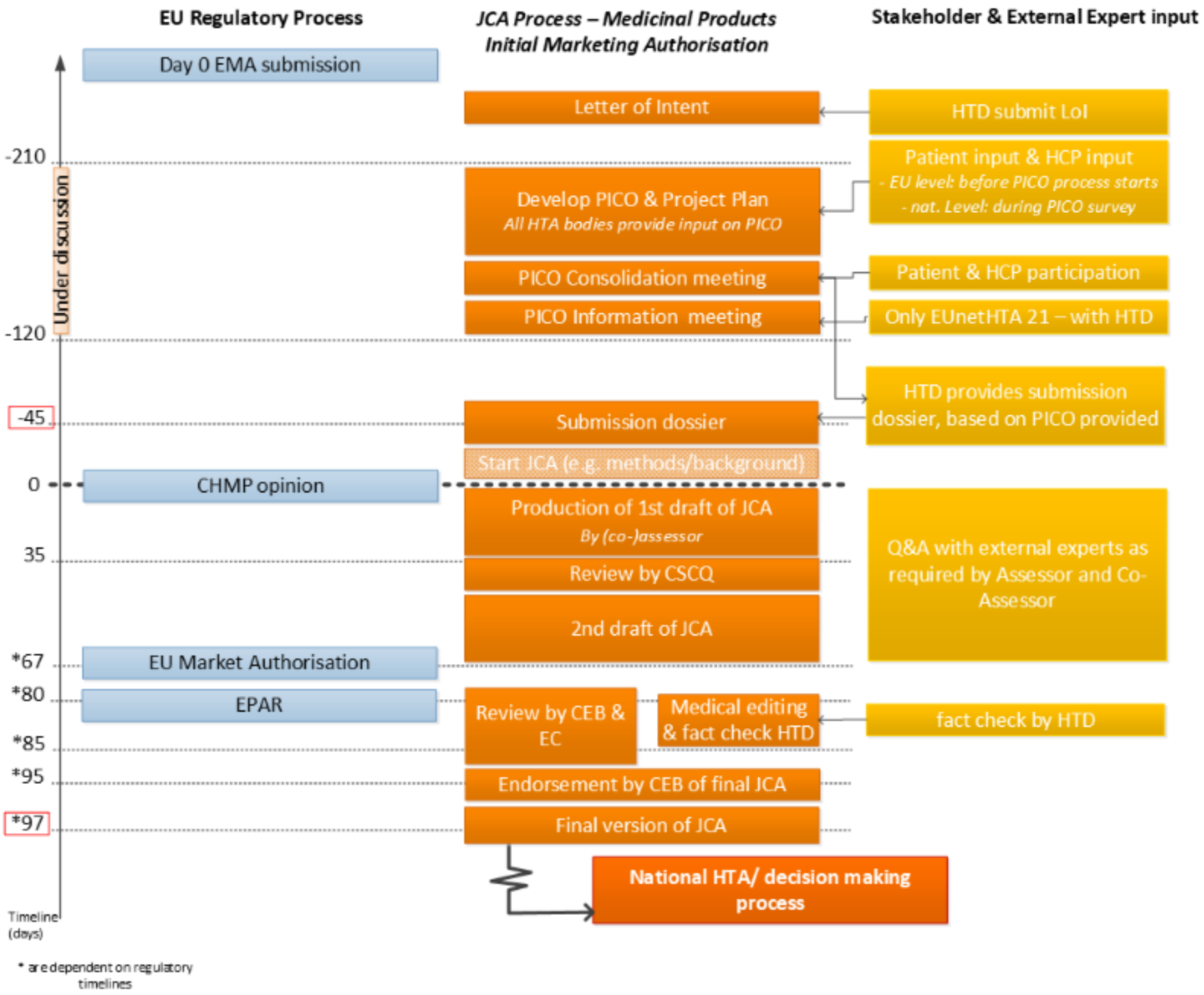
- ZIN (Netherlands)

EUnetHTA 21 joint report

- All **CSCQ members** will be involved throughout the production and act as reviewers
- In total, 12 countries

Further inclusion of HTA perspective by

- Non-consortium HTAb from EU/EEA countries


EU Regulatory Process
JCA Process – Medicinal Products Initial Marketing Authorisation
Stakeholder & External Expert input
Day 0 EMA submission
Letter of Intent
HTD submit LoI
-210
Under discussion
Patient input & HCP input
- EU level: before PICO process starts
- nat. Level: during PICO survey
Develop PICO & Project Plan
All HTA bodies provide input on PICO
PICO Consolidation meeting
Patient & HCP participation
PICO Information meeting
Only EUnetHTA 21 – with HTD
-120
HTD provides submission dossier, based on PICO provided
-45
Submission dossier
Start JCA (e.g. methods/background)
0
CHMP opinion
Production of 1st draft of JCA
By (co-)assessor
35
Review by CSCQ
Q&A with external experts as required by Assessor and Co-Assessor
2nd draft of JCA
*67
EU Market Authorisation
*80
EPAR
Review by CEB & EC
Medical editing & fact check HTD
fact check by HTD
*85
*95
Endorsement by CEB of final JCA
*97
Final version of JCA
National HTA/ decision making process
Timeline (days)
* are dependent on regulatory timelines

EUnetHTA 21 JCA production, selection & timelines
Medical Devices JCA

- Focus on high risk MD (class IIb, III)
  - With or without expert panel opinion
- Not many time constraints based on HTA Regulation
  - No publication deadline given
    - Important to consider no parallel assessment on EU and national level
  - Submission dossier should include information from scientific opinion
    - To avoid duplication between regulatory and HTA submission dossier

Milestone	Month
Letter of Intent	August/September, 2022
Consolidated PICO	October, 2022
Submission Dossier	December, 2022 - January, 2023
Publication JCA report	May, 2023

Who will be the EUnetHTA 21 JCA team?

Assessor & co-assessor

- HAS (France) & AIHTA (Austria)

JCA coordination

- ZIN (Netherlands)

EUnetHTA 21 joint report

- All **CSCQ members** will be involved throughout the production and act as reviewers
- In total, 12 countries

Further inclusion of HTA perspective by

- Non-consortium HTAb from EU/EEA countries

Next steps

Next steps

- Please reach out to JCA_Secretariat@zinl.nl if you are interested in a JCA for medicinal products or medical devices
  - Submit Letter of Intent by August the latest
  - We will proceed with a call to explain the procedure

- For HTD who submitted a Letter of Intent
  - PICO information meeting: we explain the consolidated PICO
  - Exchange on submission dossier template
  - Factual Accuracy Check of the final draft JCA report
  - Evaluation of the JCA procedure

Public Consultations

Anne Willemsen, ZIN

Ongoing & Anticipated Public Consultations

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

Status	Deadline	Deliverable	Title
Closed	March 7 – April 5, 2022	D5.3.1	Selection criteria (co-)assessor JCA
	May 20, 2022, EOB	D5.3.2	HTA body technical expert working groups
	May 2 – May 31, 2022	D4.2	Practical Guideline – Scoping Process
		D4.7.1, 4.7.2	Framework for JCA of high risk MD
		D4.3.2	Methodological Guideline – Direct & Indirect Comparators and Comparisons
	June 6 – July 7, 2022	D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process
Ongoing	July 4 – Aug 2, 2022	D5.1	Submission Dossier Template (guidance)
		D4.5	Applicability of Evidence
		D4.6	Validity of Clinical Studies
Announced	July 20 – Aug 19, 2022	D7.1	HTD and HTA interaction
	Aug 1 – Aug 30, 2022	D5.2	JCA report template
		D7.2/7.3	Patient and HCP guidance & templates for interaction
		4.3.1	Comparators and comparisons
Planned	Oct 3 – Nov 1, 2022	D4.4	Endpoints
	Aug 1 – Aug 31, 2023	D6.2/6.3 & 6.4	JSC briefing book template & procedural guidance

6. **Q&A**

Niklas Hedberg, TLV

7. **Closing remarks**

Niklas Hedberg, TLV