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

<table>
<thead>
<tr>
<th>Meeting date</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2022</td>
<td>EMA/EUnetHTA 21 bilateral in accordance to work plan</td>
</tr>
<tr>
<td>October 2022</td>
<td>EMA/EUnetHTA 21 bilateral in accordance to work plan</td>
</tr>
<tr>
<td>18 November 2022</td>
<td>4th General EUnetHTA 21 Stakeholder Meeting</td>
</tr>
<tr>
<td>February 2022</td>
<td>EMA/EUnetHTA 21 bilateral in accordance to work plan</td>
</tr>
<tr>
<td>12 May 2023</td>
<td>5th General EUnetHTA 21 Stakeholder Meeting</td>
</tr>
<tr>
<td>8 September 2023</td>
<td>6th &amp; final General EUnetHTA 21 Stakeholder Meeting</td>
</tr>
<tr>
<td>September/October 2023</td>
<td>EMA/EUnetHTA 21 bilateral in accordance to work plan</td>
</tr>
</tbody>
</table>
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:


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

HTA Regulation
MS Coordination Group on HTA

**COORDINATION GROUP ON HTA (HTACG)**

**CG Sub-groups**

- **Joint clinical assessments (JCA)**
  - JCA reports
  - MP
  - MD

- **Joint scientific consultations (JSC)**
  - JSC reports
  - MP
  - MD

- **Identification of emerging health technologies**
  - Input for annual work programme
  - MP
  - MD

- **Methodology**
  - Guidance documents
  - MP
  - MD

**Voluntary joint work**

**EC SECRETARIAT**

- **Administrative support**
  (e.g. meetings, planning)

- **Technical support**
  (e.g. technical support to HTACG, procedural check)

- **IT support**
  (submission system, databases, intranet)

**Stakeholder Network**
(e.g. patients, healthcare professionals, health technology developers, payers)

- **Articles 3-6**

- **Article 29**

- **Articles 28,30**

**MP = medicinal products, MD = medical devices**
EC HTA implementation website

HTA Regulation Implementation timeline

Adoption
December 2021

Entry into force
January 2022

Preparatory phase
January 2025

Implementation phase
January 2030

Joint Clinical Assessment Full Scope

• Setting up the Coordination Group/HTACG (EC)
• Setting up the Stakeholder Network (EC)
• Drafting implementing and delegated acts (EC)
• Drafting guidance documents (CG)

Joint Scientific Consultations (JSC)
+ Stepwise build-up of Joint Clinical Assessments (JCA) scope for medicines:
  - From Jan. 2025: cancer drugs, ATMPs (from date of application)
  - From Jan. 2028: orphan drugs (3 years after date of application)

Service contract EUnetHTA21

Part of rolling Implementation plan

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)**

### Timeline

- **Individual HTA/EMA advice**
- **SEED**
- **EUnetHTA JA 2/3**
- **JSC EUnetHTA 21**
- **JSC HTAR**

- **2011**
- **2012 – 2015**
- **2016-2021**
- **2021 - 2023**
- **2025**
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

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Involvement type</th>
<th>Level</th>
<th>Method(s)</th>
<th>Information provided to the expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>External expert</td>
<td>National, generally</td>
<td>Approach 1: Interview (or written statement) based on questionnaire</td>
<td>No documents are shared</td>
</tr>
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<td></td>
<td>External expert</td>
<td>National, generally</td>
<td>Approach 2: Approach 1 + Respond to specific questions re: HTD development plan</td>
<td>Providing the briefing package or relevant sections of the briefing package when a specific contribution is required</td>
</tr>
<tr>
<td></td>
<td>External expert</td>
<td>European</td>
<td>Approach 3: Approach 2 + Review draft List of Issues and participate in meeting with EMA and HTD</td>
<td></td>
</tr>
</tbody>
</table>
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 Recommendation
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

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

Chantal Guilhaume, HAS
# EUnetHTA 21 Transversal Deliverables

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

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Purpose</th>
<th>Type</th>
<th>Level</th>
<th>Method(s)</th>
<th>Information shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before National PICO</td>
<td>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.</td>
<td>Patient stakeholder</td>
<td>European</td>
<td>(online) questionnaire</td>
<td>Indication and the questionnaire</td>
</tr>
<tr>
<td>Input during PICO development (National level – methods depend on the national procedures in place)</td>
<td>Obtain information on living with the disease; expectations of new treatment etc; Assist in defining national PICO</td>
<td>External experts and/or stakeholders (depends on the national procedure)</td>
<td>National</td>
<td>National procedures</td>
<td>As per national requirement</td>
</tr>
<tr>
<td>PICO consolidation, during scoping process</td>
<td>Patient and clinical expert input is used to support defining national PICO and as a validation tool for the consolidated PICO(s).</td>
<td>External experts</td>
<td>European</td>
<td>Including patient and clinical expert input templates, Interviews and meeting participation (as per guideline)</td>
<td>Details of indication under review. This is done early in scoping phase so no draft PICO available</td>
</tr>
<tr>
<td>Draft JCA report</td>
<td>Answer specific questions from the Assessor/Co-Assessor</td>
<td>External experts</td>
<td>European</td>
<td>ad-hoc questions, interviews if necessary</td>
<td>Depends on mode of involvement, but could be draft JCA report or specific information needed to understand the context of a question</td>
</tr>
</tbody>
</table>
Patient and Clinician Involvement in JSC

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Purpose</th>
<th>Type</th>
<th>Level</th>
<th>Method(s)</th>
<th>Information shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approach 1</td>
<td>Prior to draft written recommendations</td>
<td>External experts</td>
<td>National, generally</td>
<td>Approach 1: Interview (or written statement) based on questionnaire</td>
<td>No documents are shared</td>
</tr>
<tr>
<td></td>
<td>Obtain information on living with the disease; expectations of new treatment etc; getting input following the PICO scheme</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Approach 2</td>
<td>Prior to draft written recommendations</td>
<td>External experts</td>
<td>National, generally</td>
<td>Approach 2: Approach 1 + Respond to specific questions re: HTD development plan</td>
<td>Providing the briefing package or relevant sections of the briefing package when a specific contribution is required</td>
</tr>
<tr>
<td>Approach 3</td>
<td>Prior to draft List of Issues</td>
<td>External experts</td>
<td>European</td>
<td>Approach 3: Approach 2 + Review draft List of Issues and participate in meeting with EMA and HTD</td>
<td></td>
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</tbody>
</table>
D7.3 Subjects Addressed in Questionnaires

For Patients

• Developed Based on HTAi questionnaire and JA3
## D7.2/D7.3 Timelines

<table>
<thead>
<tr>
<th>Task</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOG began work</td>
<td>14/03/2022</td>
</tr>
<tr>
<td>First CSCQ Consensus Meeting</td>
<td>17/05/2022</td>
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<tr>
<td>Patient and clinical expert round table</td>
<td>25/05/2022</td>
</tr>
<tr>
<td>Second CSCQ Consensus Meeting</td>
<td>13/07/2022</td>
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<tr>
<td>Multi-stakeholder meeting</td>
<td>13/07/2022</td>
</tr>
<tr>
<td>Public Consultation</td>
<td>01/08/2022-31/08/2022</td>
</tr>
<tr>
<td>Expected Publication Date</td>
<td>04/11/2022</td>
</tr>
</tbody>
</table>
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 minimize overlap
Submission dossier guidance

- Submission dossier guidance document
- Submission dossier template
- Appendix: Table templates

Currently under public consultation
EUnetHTA 21 JCA production timelines

Medicinal Products JCA

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

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

*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
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

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Month</th>
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<tbody>
<tr>
<td>Letter of Intent</td>
<td>August/September, 2022</td>
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<tr>
<td>Consolidated PICO</td>
<td>October, 2022</td>
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<tr>
<td>Submission Dossier</td>
<td>December, 2022 - January, 2023</td>
</tr>
<tr>
<td>Publication JCA report</td>
<td>May, 2023</td>
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</table>
Who will be the EUnetHTA 21 JCA team?

Assessor & co-assessor
- HAS (France) & AIHTA (Austria)

EUnetHTA 21 joint report
- All CSCQ members will be involved throughout the production and act as reviewers
- In total, 12 countries

JCA coordination
- ZIN (Netherlands)

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/joinhtawork/](https://www.eunethta.eu/joinhtawork/)

<table>
<thead>
<tr>
<th>Status</th>
<th>Deadline</th>
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<td>March 7 – April 5, 2022</td>
<td>D5.3.1</td>
<td>Selection criteria (co-)assessor JCA</td>
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<td>May 20, 2022, EOB</td>
<td>D5.3.2</td>
<td>HTA body technical expert working groups</td>
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<td>May 2 – May 31, 2022</td>
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<td>Practical Guideline – Scoping Process</td>
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<td>June 6 – July 7, 2022</td>
<td>D4.7.1, 4.7.2</td>
<td>Framework for JCA of high risk MD</td>
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<td>D4.3.2</td>
<td>Methodological Guideline – Direct &amp; Indirect Comparators and Comparisons</td>
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<td>D4.7.3, 4.7.4</td>
<td>EUDAMED data reporting template/Guidance for EUDAMED-based TISP process</td>
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<td><strong>Ongoing</strong></td>
<td>July 4 – Aug 2, 2022</td>
<td>D5.1</td>
<td>Submission Dossier Template (guidance)</td>
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<td>Applicability of Evidence</td>
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<td>Validity of Clinical Studies</td>
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<td><strong>Announced</strong></td>
<td>July 20 – Aug 19, 2022</td>
<td>D7.1</td>
<td>HTD and HTA interaction</td>
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<td>Patient and HCP guidance &amp; templates for interaction</td>
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<td>Oct 3 – Nov 1, 2022</td>
<td>D4.4</td>
<td>Endpoints</td>
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6. Q&A

Niklas Hedberg, TLV
7. Closing remarks

Niklas Hedberg, TLV