EUnetHTA 21 – Stakeholder Kick Off Meeting

3 December 2021
10:30-12:00 CET

Welcome from the Chair of the Consortium Executive Board (CEB)

Niklas Hedberg, TLV

Today’s agenda

Niklas Hedberg, TLV

Agenda

ID		Description	Presenter/s
#1	10:30-10:35	Welcome from the Chair of the Consortium Executive Board (CEB)	Niklas Hedberg, TLV
#2	10:35-10:45	Update on the HTA Regulation Setting the scene & next steps	Flora Giorgio, DG SANTE
#3	10:45-11:00	Introduction a) Objective of the meeting b) Intro EUnetHTA21 c) Meet the EUnetHTA 21 Secretariat at ZIN & G-BA	Marcus Guardian, ZIN
#4	11:00-11:15	Committee for Scientific Consistency and Quality (CSCQ)	Chantal Guilhaume, HAS Antje Behring, G-BA
#5	11:15-11:25	EUnetHTA 21 Deliverables & anticipated timelines for public consultation	Anne Willemsen, ZIN Annette Abraham, G-BA
#6	11:25-11:45	Stakeholder interaction within the Consortium	Anne Willemsen, ZIN
#7	11:45-11:55	Any other business	Niklas Hedberg, TLV
#8	11:55-12:00	Closing remarks	Niklas Hedberg, TLV

2. **Update on the HTA Regulation Setting the Scene & next steps**

Flora Giorgio, DG SANTE

HTA Regulation
key elements and next steps

Flora Giorgio

Deputy Head of Unit - B6 Medical Devices and HTA

DG SANTE

HTA during transitional time
3rd December 2021

HTA Regulation
Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Joint work **driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **use of joint work in national HTA processes**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health system
  - Taking **decisions on pricing & reimbursement**
- **Addresses stakeholders' engagement in joint work**
- **Progressive implementation**

HTA Regulation - Main areas of joint work

- **Joint clinical assessments/JCA**
  - ➢ Medicinal products with central marketing authorisation
  - ➢ Selection of high-risk medical devices, IVDs

Patients and clinical experts

Patients and clinical experts

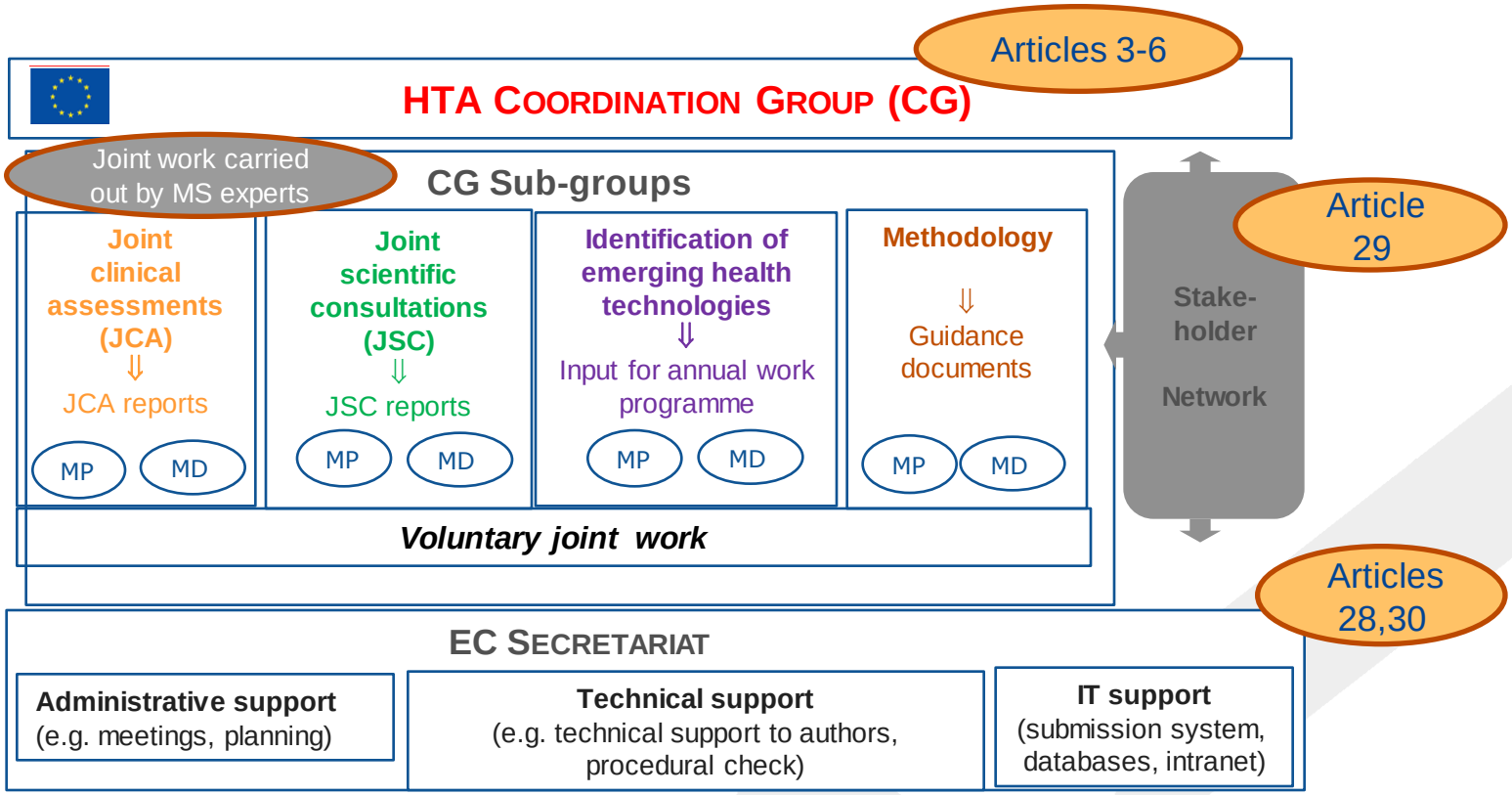
- **Joint scientific consultations/JSC** ("early dialogues")
  - ➢ Scientific advice to health technology developers (e.g. on CT design, evidence generation)
  - ➢ HTA only (JSC) or in parallel with regulators (parallel JSC)

Stakeholders

Stakeholders

- **Identification of emerging health technologies** ("horizon scanning")
- **Voluntary cooperation in other areas**
  (e.g. on other health technologies or non-clinical HTA aspects)

HTA Regulation - Governance



MP = medicinal products, MD = medical devices

HTA Regulation – Stakeholder Network (Art 29)

1. The Commission shall establish a stakeholder network. The stakeholder network **shall support the work of the Coordination Group and its subgroups upon request**.

2. The stakeholder network shall be established through an **open call for applications** addressed to all eligible stakeholder organisations, in particular **patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals**. The eligibility criteria shall be set out in the open call for applications and shall include:

(a) proof of current or planned engagement in HTA development;

(b) professional expertise relevant to the stakeholder network;

(c) geographical coverage of several Member States;

(d) communication and dissemination capabilities.

HTA Regulation – Stakeholder Network (Art 29)

3. Organisations applying to become part of the stakeholder network **shall declare their membership and sources of funding**. Representatives of stakeholder organisations participating in activities of the stakeholder network shall declare any financial or other interests in the health technology developers' industrial sector which could affect their independence or impartiality.

4. The list of stakeholder organisations included in the stakeholder network, the declarations of those organisations on their membership and sources of funding, and the declarations of interest of representatives of stakeholder organisations shall be made publicly available on the IT platform referred to in Article 30.

5. The **Coordination Group shall meet with the stakeholder network at least once each year** in order to: (a) update stakeholders on the joint work of the Coordination Group, including its main output; (b) provide for an exchange of information.

6. The Coordination Group may invite members of the stakeholder network to attend its meetings as **observers**.

HTA Regulation - Timeline of implementation

- **Setting up the Coordination Group/CG (EC)**
- **Setting up Stakeholders' Network (EC)**
- **Drafting implementing and delegated acts (EC)**
- **Drafting guidance documents (CG)**

eunethta

Service contract EUnetHTA21

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)
From Jan. 2030: full scope
(5 years after date of application)

HTA Regulation
Next steps (to be confirmed)

- December 2021 – expected date of adoption
- Q1 2022 – call for Member States to nominate their representatives for the Coordination Group
- Mid-2022 – first meeting of the Coordination Group
- Q4 2022 – launch of the procedure for setting up the Stakeholder Network

(call for expression of interest)

- Q1 2023 – Evaluation of applications and publication of the members of the Stakeholder Network
- Q2/Q3 2023 – First meeting of the Coordination Group with the Stakeholder Network

3. **Introduction**

Marcus Guardian, ZIN

3a. **Objective of the meeting**

Marcus Guardian, ZIN

3b. **Intro EUnetHTA 21**

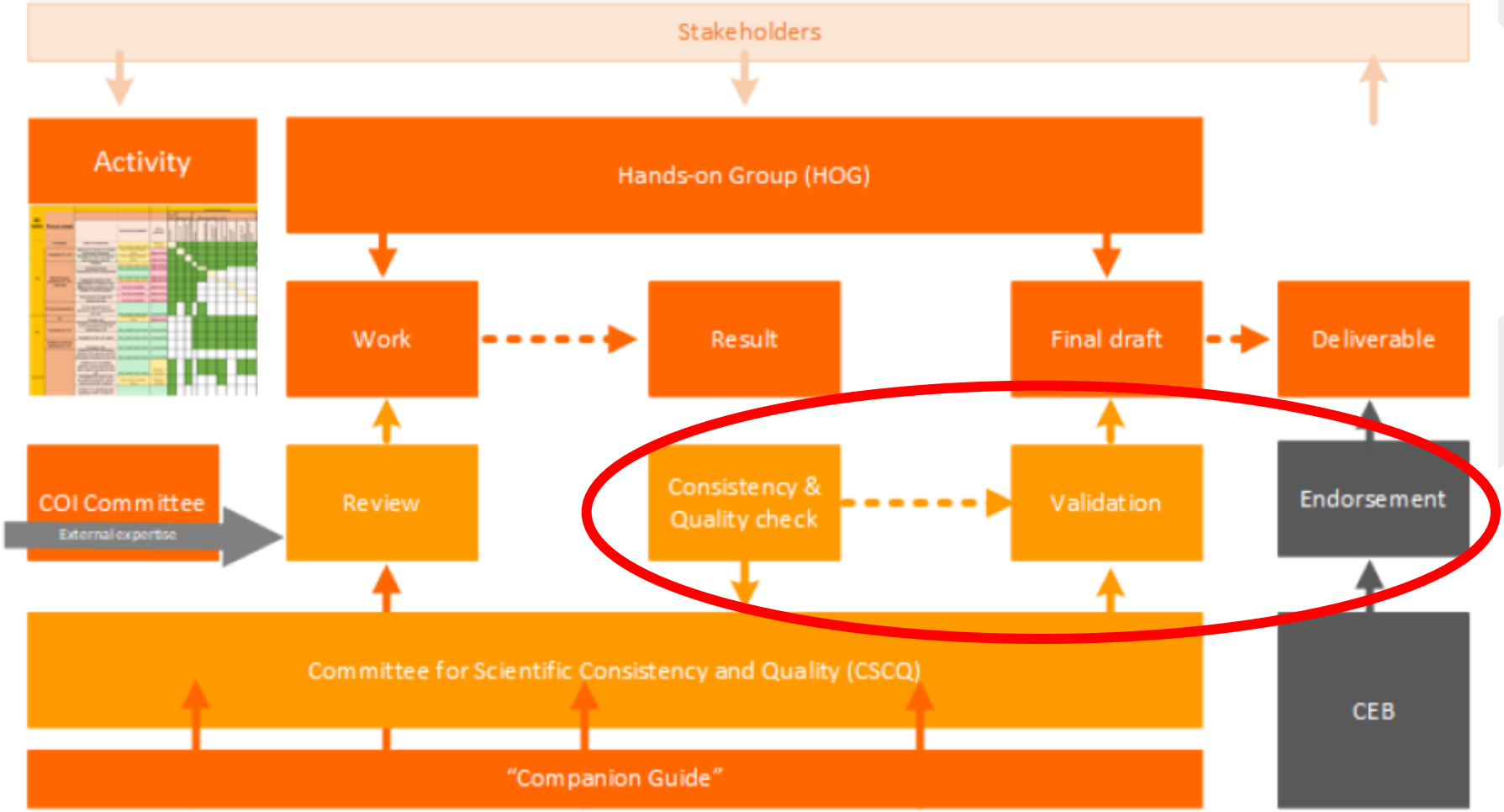
Marcus Guardian, ZIN

Objective of EUnetHTA 21/ Service Contract

- Deliverables in EUnetHTA21 are based on
  - **Requirements stated in the Service Contract**
  - Identified based on **FMC White Paper** and feedback surveys

- Supporting the development of guidance documents to be adopted by the **Coordination Group** and/or drafting of implementing legislation by the European Commission, thus facilitating the subsequent implementation of the HTA Regulation

EUnetHTA 21 Governance structure



3c. **Meet the EUnetHTA 21 Secretariat at ZIN & G-BA**

Marcus Guardian, ZIN

Marcus Guardian

Chief Operating Officer

Ali Hussain

Senior Project Manager

Merle Tenberg

Project Manager

Ewold van Elderen

IT Officer

For general queries, external communication and stakeholder engagement

eunethta@zinl.nl

JCA Secretariat (Zorginstituut Nederland): Project Management for JCA/CA related deliverables and transversal activities

JCA_Secretariat@zinl.nl

Anne Willemsen

Senior Project Manager

Catharina Helmink

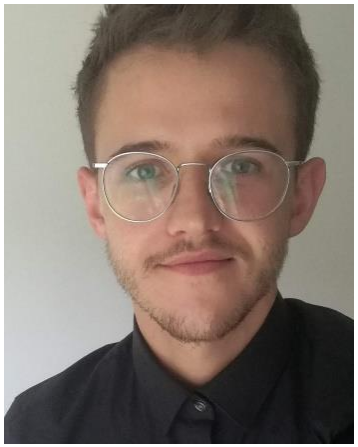
Project Manager

Project Management – JSC Deliverables

JSC Secretariat at Gemeinsamer Bundesausschuss (G-BA)

EUnetHTA21-JSC@g-ba.de

Annette Abraham, MSC
Project Manager



Dr. Daniel Ritter
Scientific Advisor

The Consortium Executive Board

Niklas Hedberg

TLV, Sweden

Chair of the Consortium Executive Board

Chantal Bélorgey

HAS, France

Vice-Chair of the Consortium Executive Board

Alric Rüther

IQWIG, Germany

Vice-Chair of the Consortium Executive Board

The Committee for Scientific Consistency and Quality – Chairs

Antje Behring

G-BA, Germany

Chair of the JSC-CSCQ & Transversal CSCQ

Chantal Guilhaume

HAS, France

Chair of the JCA-CSCQ & Transversal CSCQ

4. **Committee for Scientific Consistency and Quality (CSCQ)**

Chantal Guilhaume, HAS
Antje Behring, G-BA

CSCQ role in Quality Management System (QMS)

The CSCQ should ensure scientific consistency and quality of activities and deliverables covered by the EUnetHTA-21 service contract, starting **from the development of a project plan** for each deliverable and **finishing with the approval of its final version:**

- Ensuring **all relevant tools** compiled in the EUnetHTA Companion guide (process flows, procedures, templates, IT tools and methodological guidance) **are followed**

- Reviewing scientific **consistency between deliverables** jointly produced

- Ensuring a high standard level that is **acceptable and practicable to all HTA agencies** that will be involved in future HTA regulation and which should lead to high rates of adaptation and adoption of deliverables

- Ensuring a consistent **stakeholder approach**

CSCQ Responsabilities

The CSCQ is composed of representatives of all member organisations of the consortium. It can convene in 3 different configurations, depending on the topics discussed.

1. CSCQ JCA (Joint Clinical Assessment) members are responsible of validation of JCA deliverables (Methodological guidelines; JCA procedural guidelines; JCA templates; JCA/CA reports)

2. CSCQ JSC (Joint Scientific Consultation) members are responsible of validation of JSC deliverables (JSC procedural guidelines; JSC template; JSC reports)

3. CSCQ Transversal members are responsible of validation of transversal deliverables (General guidance on communication, interaction with stakeholders, GDPR, Declaration of interest & Confidentiality Agreement, etc)

Deliverables under JCA CSCQ responsabilities

Deliverables	Stakeholder interaction
JCA PRODUCTIONS	Contribution according to JCA procedure for HTD*, PC/HCP**
METHODOLOGICAL GUIDELINES	
• D4.2 Scoping	Public consultation & additional contribution during project from HTAb
• D4.3.1/D4.3.2 Comparators and Comparisons	Public consultation & additional contribution during project from HTAb
• D4.4 Endpoints	Public consultation & additional contribution during project from HTAb
• D4.5 Applicability of evidence	Public consultation & additional contribution during project from HTAb
• D4.6 Validity of clinical studies	Public consultation & additional contribution during project from HTAb
• D4.7.1 + 4.7.2 Assessment of High risk MD and IVD	Public consultation & additional contribution during project from HTAb; HTD and regulatory bodies
• D4.7.3 + 4.7.4 EUDAMED Reporting template, Guidance for EUDAMED	Public consultation & additional contribution during project from HTAb; HTD; PC/HCP and regulatory bodies
TEMPLATES	
• D5.1 Submission Dossier Template	Public consultation & additional contribution during project from HTAb; HTD
• D5.2 JCA Report Template	Public consultation & additional contribution during project from HTAb
PROCEDURAL GUIDELINES	
• D5.3 JCA Guidelines for co-assessors	Public consultation & additional contribution during project from HTAb

*HTD: Health Technology Developer **PC/HCP: Patient;Consumer/Health Care Professional

Deliverables under JSC CSCQ responsabilities

Deliverables	Stakeholder interactions
D6.1 JSC PRODUCTIONS	Contribution according to JSC procedure for HTD, PC/HCP
TEMPLATES	
• D6.2 Briefing Book Template	Public Consultation
• D6.2 Letter of intent	N/A
• D6.3 JSC common recommendation template	N/A
PROCEDURAL GUIDELINES	
• D6.4 Updated procedural guideline for HTD, patients, HCP and participants (different roles)	Public Consultation
• D6.4 checklist for quality assurance in accordance with the Quality Management System	N/A

Deliverables under Transversal CSCQ responsabilities

Deliverables	Stakeholder interaction
D7.1 Guidance for the interaction between HTA experts and HTD during JCA and JSC	Public consultation & additional contribution during project from HTAb and HTD
D7.2 Guidance for consulting patients, clinical experts and other experts during JCA and JSC	Public consultation & additional contribution during project from HTAb and HC/HCP
D7.3 Expert input templates	Public consultation & additional contribution during project from H TAb and HC/HCP
D7.5 Guidance for identifying and handling conflict of interest (COI), declaration of interest and confidentiality agreement form	Contribution during project from HTAb and information shared with other stakeholders

CSCQ Review: Content

To ensure overall validity and consistency for any deliverable, the CSCQ review should particularly consider the following aspects:

1. Completeness of the document
2. Structure and readability of the document
3. Consistency
    a. Formal Consistency (e.g. the CSCQ members must ensure whether defined terms are used consistently and no contradictory statements are made in the document)
    b. Consistency with QMS SOP
4. Acceptability and practicability to all HTA agencies with a view to the future HTA regulation should be considered during the review.

Process flow for deliverable production

Creating Deliverable

- HOG to create first draft
- CSCQ & HTAb stakeholder to review
- Depending on deliverable: specific stakeholder contribution

Public consultation

- All stakeholders can provide comments
- HOG to consider all comments
- CSCQ to review and agree

Final version

- CSCQ validates final version
- CEB endorses final version
- Leads to publication

5. **EUnetHTA 21 Deliverables & anticipated timelines for public consultation**

Anne Willemsen, ZIN

Publication of Project Plans

- All project plans that have been endorsed, will be published today (3 Dec) EOB
  - https://www.eunethta.eu/jointhtawork/
  - All dates presented today, will be available in the project plans
    - When we need to deviate from these timelines (especially public consultation), it will be announced in advance
- The project plans inform you about the objectives of the deliverables
  - If you have any specific question, please send an e-mail to eunethta@zinl.nl
  - Please note, we do not accept comments or requests for revisions
- For all deliverables, the HTA Regulation and EUnetHTA JA3 experiences will form the basis

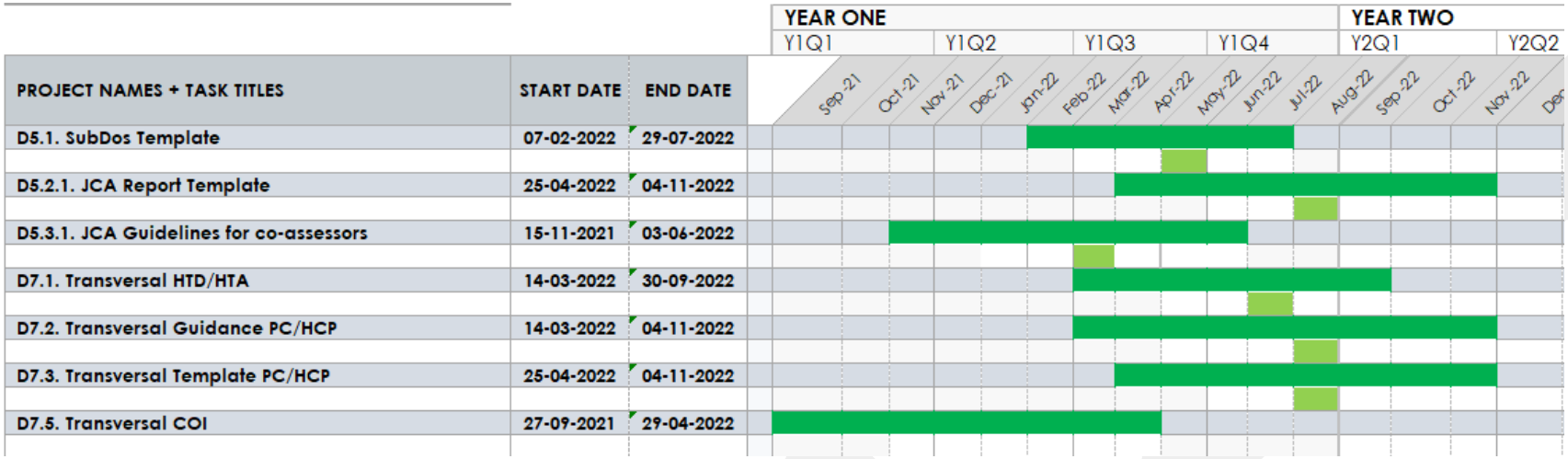
Deliverables Methodology (D4)

- Anticipated public consultation is in light green

PROJECT NAMES + TASK TITLES	START DATE	END DATE
D4.2.1 Scoping GL	28-09-2021	29-07-2022
D4.3.2 ITC Method GL	28-09-2021	29-07-2022
D4.3.1 Comparator - practical	25-02-2022	04-11-2022
D4.4.1 Endpoints	22-04-2022	13-01-2023
D4.5.1 Applicability of evidence	21-01-2022	04-11-2022
D4.6.1 Validity of clinical studies	21-01-2022	04-11-2022
D4.7.2. Assessment of High risk MD and IVD	28-09-2021	29-07-2022
D4.7.3 + 4.7.4 EUDAMED Reporting template, Guidance	26-10-2021	30-09-2022

Deliverables JCA/CA (D5) & Transversal activities

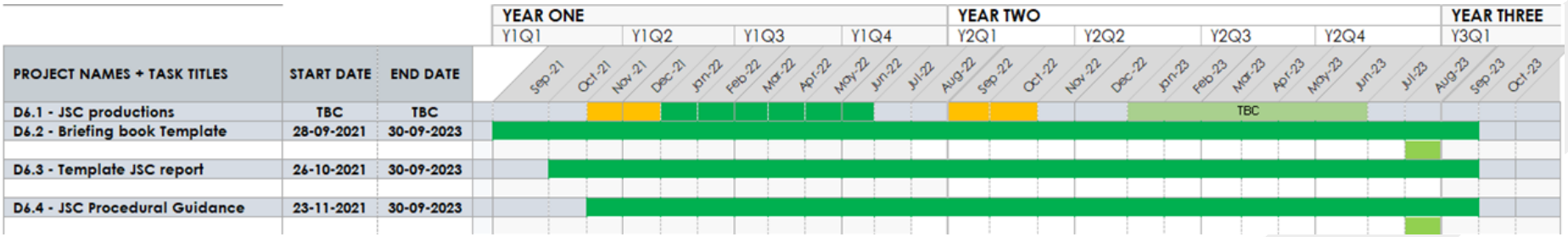
- Anticipated public consultation is in light green



PROJECT NAMES + TASK TITLES	START DATE	END DATE
D5.1. SubDos Template	07-02-2022	29-07-2022
D5.2.1. JCA Report Template	25-04-2022	04-11-2022
D5.3.1. JCA Guidelines for co-assessors	15-11-2021	03-06-2022
D7.1. Transversal HTD/HTA	14-03-2022	30-09-2022
D7.2. Transversal Guidance PC/HCP	14-03-2022	04-11-2022
D7.3. Transversal Template PC/HCP	25-04-2022	04-11-2022
D7.5. Transversal COI	27-09-2021	29-04-2022

Deliverables JSC (D6)

- Anticipated public consultation is in light green



6. **Stakeholder interaction within the Consortium**

Anne Willemsen, ZIN

Communication with EUnetHTA 21

- The general EUnetHTA 21 Secretariat at ZIN (eunethta@zinl.nl) is responsible for all stakeholder communication
  - Outreach can be on:
    - invitations to the stakeholder fora
    - information on public consultations
  - In case of project specific requests you may be contacted by
    - the Joint Clinical Assessment (JCA) Secretariat (ZIN) and
    - Joint Scientific Consultation (JSC) Secretariat (G-BA)

Stakeholder Repository

- For EUnetHTA 21 purpose
- All stakeholder groups are invited
  - patient, healthcare professionals, pharma & Med Tech industry, payers, academic, HTA bodies, regulatory
- Ongoing call on our website, so that new organisations can join
  - Will be reviewed every 3 months
  - Call for updates and potential amendments will be send out every six month to the stakeholder pool

- Aim to have organisations represented
  - We do not limit the number of individuals in our pool or meetings (as longs as for meetings feasible logistics can be ensured)
  - We ask for a general contact & main contact
  - If you respond on a call from the repository, please make sure you represent your organisation

Stakeholder Fora – meeting dates

- Three stakeholder fora a year
  - Two-hour meeting
  - Platform for regular exchange
- Fora can be divided into two parts, or address a specific topic

Year 1 Sept 2021 – Sept 2022	Dec 3, ‘21	April 19, ‘22	July 17, ‘22
Year 1 Sept 2022 – Sept 2023	Nov 18, ‘22	May 12, ‘23	Sept 8, ‘23

Public consultations - principles

- As per presented timeline, the expected period for public consultation is known in advance
  - Dates will become available in project plans
    - Anticipated publication date today (3 Dec) EOB
  - When we need to deviate from this, it will be announced
- Public consultations will be announced a month in advance
  - On social media & via e-mail to our stakeholder repository

Public consultations - principles

- Public consultations will be published on our website
  - They will be online for 30 calendar days (start and end date included)
  - Please submit your comments in the comment form via e-mail (eunethta@zinl.nl)
  - Comments not received in time, or not in the comment form will not be considered
  - Comments received from organisations in non-EU/EEA countries may not be considered
- We kindly request a consolidated response per organisation
- All comments received will be reviewed for validity, but not necessarily incorporated in the final deliverable
- All comments received & answers provided will be published on the website together with the final deliverable

7. **Any other business**

Niklas Hedberg, TLV

8. **Closing remarks**

Niklas Hedberg, TLV