

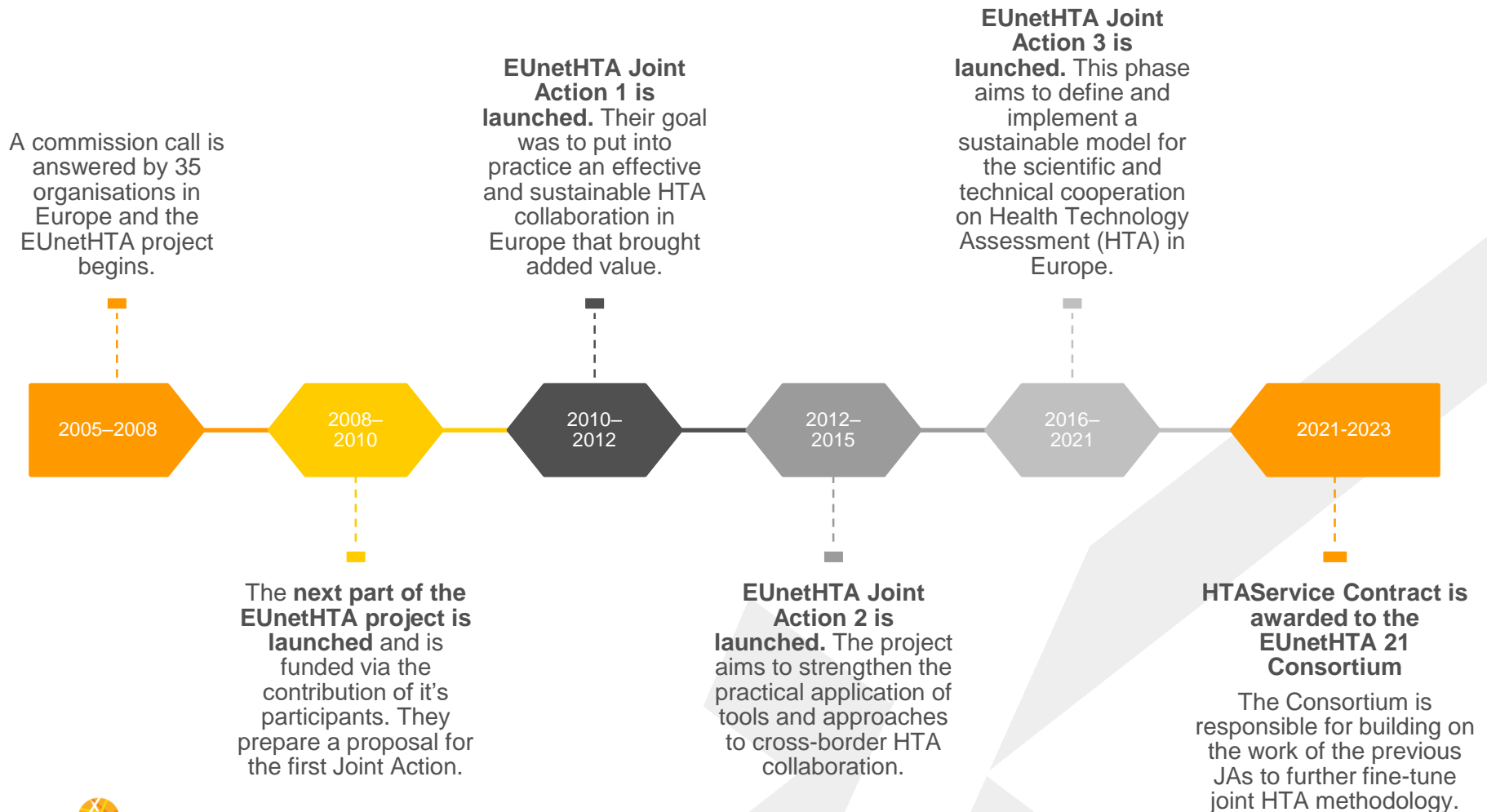
# EUnetHTA 21

European Network for Health Technology Assessment

EC Service Contract | 2021-2023

## Welcome

# The history of EUnetHTA



# Objectives

Support the future EU HTA System by developing methodology, templates, guidelines and other elements fit for purpose to be used by the **HTACG**.

\*FMC-HTA: Future Model of Cooperation on HTA – A comprehensive White Paper produced in JA3 evaluating all previous modes of HTA cooperation and making recommendations for the future.

# EUnetHTA 21 Deliverables

*“not a Joint Action”*



# Governance

The EUnetHTA 21 Consortium is made up of **13** partners:



AEMPS



AIFA



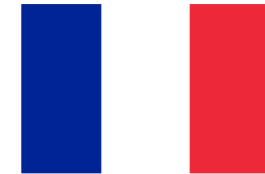
AIHTA



GBA



HAS



INFARMED



IQWIG



KCE



NCPE



NIPN



NOMA

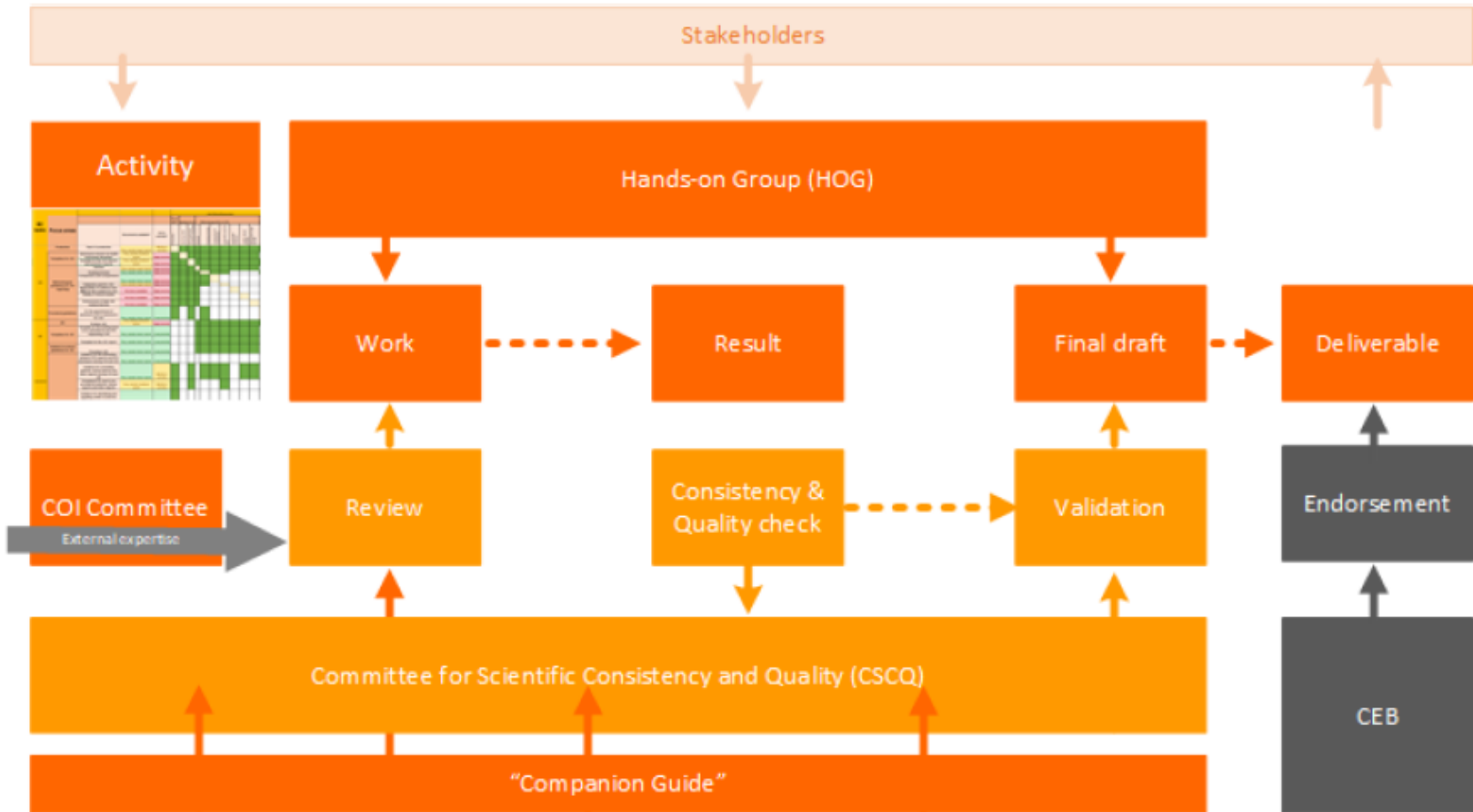


TLV



ZIN

# Governance continued



# Stakeholder meetings

Stakeholder meetings serve as a platform for exchange and allow the Consortium to present updates and gain vital feedback.

There are **three meetings a year**.

The meeting can be divided into two parts (depending on the attendees), or to address a specific topic.

The current schedule is as follows:

<b>Year 1</b> Sept 2021 – Sept 2022	03/01/2021	19/04/2022	17/07/2022
<b>Year 2</b> Sept 2022 – Sept 2023	18/11/2022	12/05/2023	08/09/2023

# Public consultations

- The expected periods for public consultations are known in advance via the project plans published on the EUnetHTA 21 Consortium website ([www.eunetha.eu](http://www.eunetha.eu)).
- Any deviations will be announced accordingly.
- Further notice of public consultations will be announced a month in advance on social media and via e-mail to our stakeholder repository.





# Public consultations continued

- Public consultations will be published on the [EUnetHTA 21 website](#).
  - They will be online for 30 calendar days (start and end date included).
  - **Comments must be submitted via the comment form** to the General Secretariat ([eunetha@zinl.nl](mailto:eunetha@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 are welcome, but may not be considered.
- A consolidated response per organisation is requested.
- 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.



# Ongoing & Anticipated Public Consultations

<https://www.eunetha.eu/jointhtawork/>

Status	Deadline	Deliverable	Title
<b>Closed</b>	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
		D4.3.2	Methodological Guideline – Direct & Indirect Comparators and Comparisons
		D4.7.1, 4.7.2	Framework for JCA of high risk MD
<b>Ongoing</b>	June 6 – July 7, 2022	D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process
<b>Planned</b>	July 4 – Aug 2, 2022	D4.5	Applicability of Evidence
		D4.6	Validity of Clinical Studies
		D5.1	Submission Dossier Template
	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
	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

# Process flow for deliverable production

## Creating deliverable

- HOG to create first draft.
- CSCQ & (optional) HTAb outside of the Consortium to review.
- Depending on deliverable: specific stakeholder contribution.

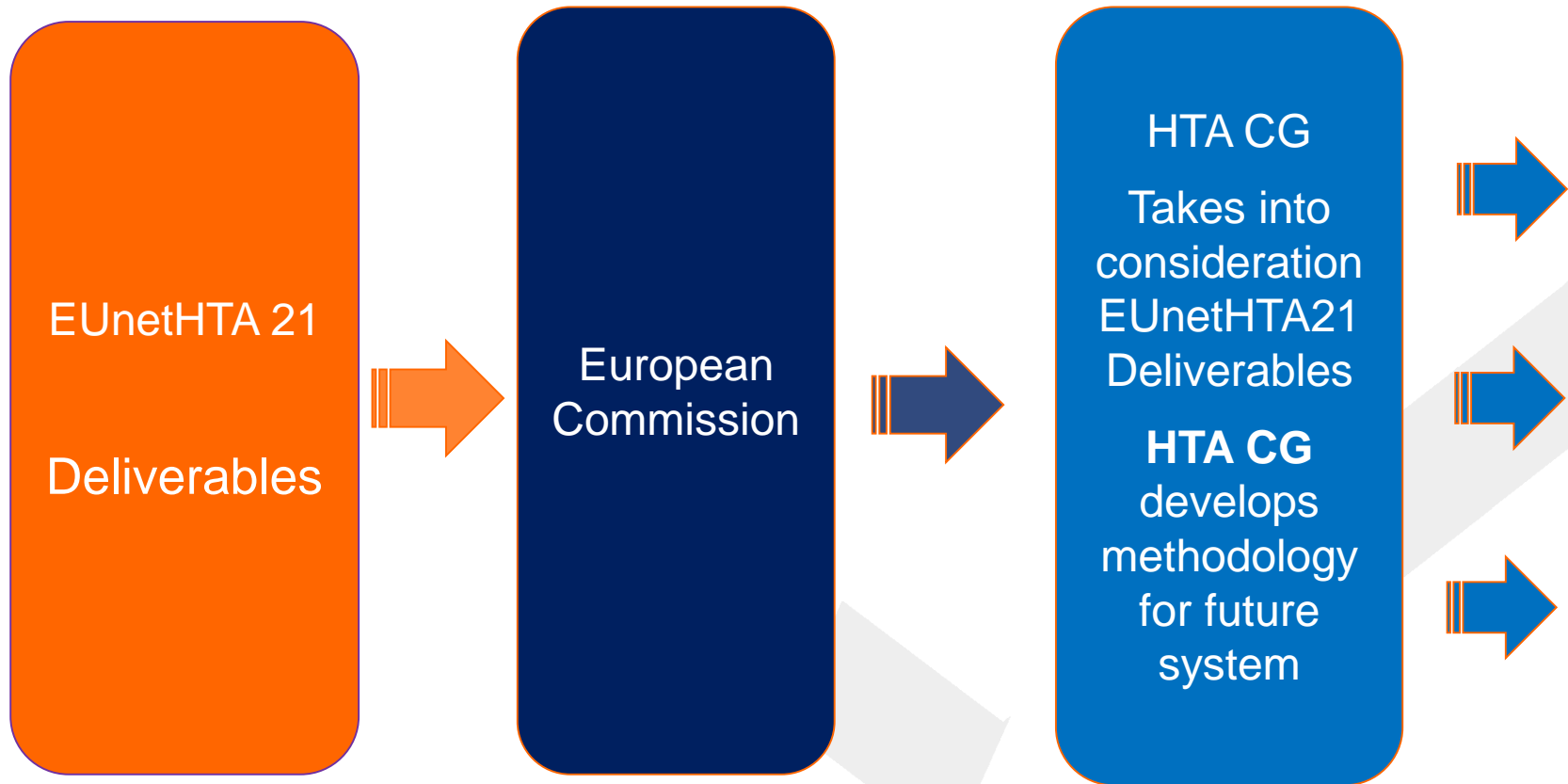
## Public consultation

- 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.

# EUnetHTA 21 Deliverables



# 1<sup>st</sup> HTA Coordination Group meeting



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