

Advancing HTA methodology for joint work

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Diagnostic from Joint Actions experiences

- Many methodological guides for evaluations developed during the joint actions from 2010 to 2021 but experienced discrepancies in their implementation
 - ⇒ methodological documents need to be accompanied with guidance for assessor and co-assessor and for technology developers preparing evidence submissions.
- External expert involvement including both patients and health care professionals should be:
 - Systematic, transparent and early in the process
 - Guided by a clear structured framework for engagement
- Development of a COI policy that supports participation of experts, but which maintains an acceptable level of independence that allows HTA agencies to use the output from the joint HTA activity.

EUnetHTA 21 Joint Clinical Assessment Deliverables

Deliverables	Start Public consultation
JCA PRODUCTIONS	2023
METHODOLOGICAL GUIDELINES	
<ul style="list-style-type: none"> D4.2.1 Scoping process 	Closed
<ul style="list-style-type: none"> D4.3.1/D4.3.2 Direct and Indirect Comparisons 	Closed/August 2022
<ul style="list-style-type: none"> D4.4.1 Endpoints 	October 3rd 2022
<ul style="list-style-type: none"> D4.5.1 Applicability of evidence 	July 4th 2022
<ul style="list-style-type: none"> D4.6.1 Validity of clinical studies 	July 4th 2022
<ul style="list-style-type: none"> D4.7.2. Assessment of High risk MD and IVD 	Closed
<ul style="list-style-type: none"> D4.7.3 + 4.7.4 EUDAMED Reporting template, Guidance for EUDAMED 	ongoing
TEMPLATES	
<ul style="list-style-type: none"> D5.1. Submission Dossier Template 	July 4th 2022
<ul style="list-style-type: none"> D5.2.1.JCA Report Template 	Aug 1st 2022
PROCEDURAL GUIDELINES	
<ul style="list-style-type: none"> D5.3.1 Selection criteria for assessor and co-assessor 	Closed
<ul style="list-style-type: none"> D5.3.2 HTAb Technical Expert Working Group 	Closed

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