

Procedure description for EUnetHTA Multi-HTA Early Dialogues for Pharmaceuticals

Actions concern:

Applicant (company)

- ▶▶ The Applicant is the entity submitting the request for a Multi-HTA Early Dialogue (ED).

EUnetHTA HTA bodies (HTABs)

- ▶▶ **Early Dialogues Working Party¹ (EDWP):** The EUnetHTA working party of HTABs for the conduct of pharmaceutical Early Dialogues, including Multi-HTA ED.
- ▶▶ **ED Committee (EDC):** Composed of EDWP members and a maximum of 3 other EUnetHTA WP5A HTABs participating in the specific ED. Participation in the respective ED for non-EDWP members is on a voluntary basis, with EUnetHTA trying to accommodate the Applicant's preferences if possible.
- ▶▶ **EDC Scientific Coordinator:** Undertakes scientific coordination on behalf of HTAs. For all procedures, the EDC Scientific Coordinator coordinates the content (scientific) discussions from the HTABs' perspective, collates the HTAB List of Issues and positions/recommendations from the EDC in collaboration with the Rapporteur. The EDC Scientific Coordinator acts as a chair for HTABs for the F2F meeting, and presents consolidated HTAB answers.
- ▶▶ **EDC Rapporteur:** Works in close collaboration with the EDC Scientific Coordinator by reviewing consolidated documents and chairs the closed HTAB morning session ahead of the F2F meeting.
- ▶▶ **EUnetHTA ED Secretariat:** The central contact point for each EDC, responsible for all communication with the Applicant, and EDC.

Observers:

- ▶▶ Organisations including the EUnetHTA Directorate as well as the EUnetHTA ED Secretariat representatives, the EUnetHTA JA3 WP5A Lead and Co-Lead Partner and other HTABs of EUnetHTA WP5A will be invited as observers to the F2F meeting and TCs prior to the F2F meeting.

Selection Criteria : Please see [Guidance for Parallel Consultations](#)

¹ Current EDWP members list is available on the EUnetHTA website

DAYS (Calendar)	Applicant	HTABs
Pre-notification Phase/Letter of Intent		
D -60	<ul style="list-style-type: none"> ▶▶ Applicant submits a Letter of Intent, using the provided template to EUnetHTA ED Secretariat (eunetha-has@has-sante.fr). 	<p>Selection and prioritization of product by EDWP, General eligibility check by EDWP in 5 working days.</p> <ul style="list-style-type: none"> ▶▶ EDWP decision on eligibility communicated to Applicant by EUnetHTA ED Secretariat. ▶▶ Final composition of EDC communicated to Applicant by EUnetHTA ED Secretariat (approx. 10 working days).
Draft Briefing Book		
~D -30	<ul style="list-style-type: none"> ▶▶ Applicant submits the Draft Briefing Book, annexes and references simultaneously to the EUnetHTA ED Secretariat². 	<ul style="list-style-type: none"> ▶▶ EUnetHTA ED Secretariat communicates the Draft Briefing Book, annexes and references to EDC.
Written Request for Clarification and Further Justification of Planned Methods etc.		
~D -15		<ul style="list-style-type: none"> ▶▶ EUnetHTA ED Secretariat sends the consolidated EDC request for clarification to the Applicant with instructions for the preparation of the Final Briefing Book.
Submission and Validation of Final Briefing Book		
~D -2 D 0	<p>Submission</p> <ul style="list-style-type: none"> ▶▶ Applicant sends two versions of the Final Briefing Book to EUnetHTA ED Secretariat in response to the request for clarification. One version should be in “track changes” mode and the other should be “clean”. 	<p>Validation of Final Briefing Book</p> <ul style="list-style-type: none"> ▶▶ EUnetHTA ED Secretariat confirms reception to the Applicant. ▶▶ EUnetHTA ED Secretariat shares the Final Briefing Book with EDC members.
Evaluation Phase		
~D +30		<ul style="list-style-type: none"> ▶▶ EDC identifies and exchanges List of Issues (e-meeting). ▶▶ EDC starts to discuss the draft written positions.
~D +32		<ul style="list-style-type: none"> ▶▶ Finalisation of List of Issues ▶▶ EUnetHTA ED Secretariat sends the List of Issues to the Applicant.

² The use of a secure link system (for authorized personnel only) will ensure proper transmission of large files and the confidentiality of sensitive documents.

DAYS (Calendar)	Applicant	HTABs
Applicant's Response to List of Issues (optional)		
~D +45	<p>▶▶ Applicant sends their written responses (optional) to the List of Issues raised by EUnetHTA to EUnetHTA ED Secretariat (if applicable: notification of amended development plan with changes and justifications).</p>	<p>▶▶ EUnetHTA ED Secretariat distributes the Applicant's written response (if applicable) to EDC.</p>
Preparation for Face to Face meeting		
~D +56	<p>▶▶ Applicant sends power point presentation to EUnetHTA ED Secretariat, at least 4 full working days before F2F meeting, addressing the Lists of Issues for both HTABs and regulators. The Applicant should group related issues together. A list of Applicant's participants should be enclosed.</p>	<p>▶▶ EUnetHTA ED Secretariat shares the Applicant's slides with EDC.</p>
~D +55 – D +59		<p>▶▶ Optional: E-meeting of the EDC (would replace the 2-hour EDC meeting immediately prior to the F2F meeting).</p>
Face to Face meeting and finalisation		
~D +60	<p>▶▶ The meeting is organised and hosted by the EDC Scientific Coordinator. The chair for the HTABs will be the EDC Scientific Coordinator.</p> <p>▶▶ Closed HTAB morning session (2 hours): discussion among EDC (if no EDC e-meeting has occurred at D +55/ D +59), chaired by the EDC Rapporteur.</p> <p>▶▶ Afternoon session (max. 3 hours): F2F meeting of EDC with the Applicant The Applicant addresses issues that were identified by EDC. An interactive discussion follows on the issues. The EDC Scientific Coordinator presents common positions, other EDC members and if applicable patient representative(s) to present individual positions.</p>	
~D +70		<p>▶▶ Finalisation of EDC Written Recommendations.</p>
~D +75		<p>▶▶ EUnetHTA ED Secretariat sends the Final Consolidated HTA ED Written Answers to Applicant³.</p>

³ Note: D +70 and D +75 could fluctuate if there are late changes to the development plan by the Applicant