

Summary of Stakeholder Engagement to Support the Development of ICH E22

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1. Introduction and rationale for stakeholder engagement approach

The ICH E22 guideline focuses on general considerations for patient preference studies (PPS) to inform drug development and regulatory submissions for pharmaceutical products. This guideline aims to optimize the use of PPS using a globally harmonized framework.

This document provides a summary of the stakeholder engagement activities aiming to support the development of ICH E22, to follow the release for public consultation, in line with the E22 Final Concept Paper.

In addition to the stakeholder engagement activities at global level outlined in this document, ICH members may also conduct additional engagement activities within their respective organisations and with third parties bound by confidentiality obligations.

2. Objective of the engagement approach

Stakeholders will be engaged early during guideline development to ensure that stakeholders' perspectives on and experiences with PPS are considered in developing ICH E22.

These activities aim to:

- Provide transparency about E22 development and timely engagement with stakeholders.
- Encourage feedback during public consultation.
- Inform development of training material and increasing preparedness for implementation.

3. Engagement between EWG and stakeholders and outcome

The current proposal is for EWG to engage with stakeholders in one global public online meeting early during the public consultation of the Step 2a/b document. The meeting will be organised by the E22 Rapporteur.

Recordings of presentations may be considered to be made available even after the meeting, as appropriate, if feasible with ICH support.

Following the meeting, a summary will be prepared by the EWG Rapporteur for consideration by the EWG during the consultation process.

Outside of this direct ICH engagement activity, members of ICH may also conduct engagement activities within their respective organisations and any third parties bound by confidentiality obligations, as appropriate. No version of the guideline will be shared publicly outside of the normal ICH process.

4. Timetable for stakeholder meeting 2025

All dates to be confirmed and to occur after publication of the Step 2a/b document.

- Announcement/Preliminary agenda: 5 January 2026
- Draft agenda: 19 January 2026
- Public meeting: date to be shared in due time