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## **ICH E22: General Considerations For Patient Preference Studies (PPS)**

**Step 2 draft Guideline – to be released for comments**

**04 December 2025**

International Council for Harmonisation of Technical Requirements  
for Pharmaceuticals for Human Use

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## Background

- **The ICH E22 Technical Document has been signed off as a *Step 2a/b* draft Guideline (19 November 2025) to be issued by the ICH Regulatory Members for public consultation**
- **This draft Guideline was developed based on the MC-approved Concept Paper (2 June 2024) and a Business Plan (19 August 2024)**
- **Anticipating finalisation as a *Step 4* final Guideline to be implemented in the local regional regulatory system: December 2026**

## Key Principles

- **Patients who have experience or knowledge of a disease and its treatments provide relevant perspectives**
- **Understanding these qualitative and quantitative insights is important for various aspects of drug development, such as identifying unmet needs, designing clinical studies, and interpreting results**
- **PPS may be considered together with the efficacy and safety information in the benefit-risk assessment of drugs and related regulatory submissions**

## Guideline Objectives

- **To outline general considerations about the use, design, conduct, analysis, and submission of PPS aimed at informing drug development, regulatory submission and evaluation, drug approvals, and maintenance of such approvals**

## Scope Of The Guideline

- **The focus of the ICH E22 Guideline is on patient preference studies using stated-preference methods (studies where patients are asked to state their choice through surveys or interviews)**
- **The ICH E22 Guideline may be applicable to similar and potentially useful studies (e.g., caregiver or revealed- preference studies), but these are outside the scope**
- **The placement of PPS data in labelling is considered a regional matter outside the scope of the ICH E22 Guideline**

# Summary Of Guideline Content

## Table Of Contents Of The ICH E22 Guideline

- 1. Introduction**
- 2. General Principles**
- 3. PPS in Drug Development and Post-marketing Evaluations**
- 4. Recommendations and Practical Considerations for PPS**

## 1. Introduction

- **PPS aim to assess the relative desirability or acceptability of actual or potential health interventions, or their characteristics and outcomes (e.g., efficacy and safety outcomes)**
- **The qualitative and quantitative insights provided by PPS may be informative for various aspects of drug development, such as identifying unmet needs, designing clinical studies, and interpreting results**
- **Note: The information provided by PPS does not replace the information provided by efficacy and safety studies**

## 2.1 Protection Of Study Participants

- **Principles applicable to other types of studies involving human subjects, such as ethical conduct, compliance with the protocol, and protection of personal data, are applicable to PPS as well**
- **PPS participants should be protected in accordance with the applicable regulatory and legal requirements**

## 2.2 Patient Input In The Development Of PPS

**Patient input is valuable throughout the development, including:**

- **Identifying the use for a PPS**
- **Identifying feasibility challenges in the conduct of a PPS**
- **Designing a PPS; developing PPS protocols; selecting attributes and levels**

## 2.3-2.4 Preliminary Research And *De Novo* Work

- **Thorough preliminary research ensures that all relevant information is identified and included in the PPS design**
- ***De novo* work may not always be justified aiming to avoid unnecessary burden on the patient community**

## 2.5-2.6 Global Applicability And Early Consideration And Planning

- **In some circumstances, PPS conducted in other region(s) may be informative**
- **The degree of applicability of PPS results from other region(s) should be evaluated and justified**
- **The applicant may find this topic useful to discuss prospectively with the relevant regulatory authorities**
- **Beginning as early as possible, the usefulness of PPS should be considered systematically throughout drug development**

## 2.7-2.8 Quality Standards And Ensuring Multidisciplinary Expertise

- **PPS are expected to follow the principles of good study design and conduct, including study documents such as informed consent forms, protocol, analysis plan, etc.**
  - **Study design and statistical analysis should be pre-specified**
- **It may be useful to pre-register protocols using a registry, a comparable platform, or other formal mechanisms to enhance research credibility and transparency**
- **The conduct of PPS should align with the principles of the “quality by design” approach to ensure the generation of reliable and meaningful results, using a risk-proportionate approach (see ICH E8)**
- **PPS should be undertaken by a cross-functional study team with the relevant PPS methodology and clinical expertise**

## 3.1 Types Of PPS

- **Available methodologies can be classified as**
  - Qualitative studies (narrative information)
  - Quantitative studies (statistical estimation)
  - Mixed methods approaches
- **Qualitative research produce insights for the design of Quantitative PPS**
- **Quantitative PPS can be used, for example, to estimate the degree to which patients state they are willing to make trade-offs among different attributes**
  - *Attributes*: The characteristics and outcomes of health interventions (e.g., efficacy and safety outcomes)

## 3.2 How Might PPS Inform Drug Development And Evaluation

- **During early stage of development, for example:**
  - Informing about unmet needs, and patients' willingness to participate in clinical studies
  - Informing the choice of endpoints for clinical trials
- **At a later stage, for example:**
  - Informing the interpretation of the trial results (trade-offs among attributes or if benefits outweigh the risks) or development of risk-mitigation strategies
- **PPS may also help describe preference heterogeneity (the distribution of preferences within a population or between subgroups)**

## 4. Recommendations And Practical Considerations

- **Many methods are available for designing PPS**
  - External resources may offer relevant insights and supplementary information
- **It is up to the applicant to explain how the results of PPS are intended to support their regulatory submission**
- **Applicants to regulatory authorities are ultimately responsible for all aspects of studies submitted to regulatory authorities**

## 4.1 Research Objective And Research Question

- **The research question(s) should align with the research objective(s), which drive the methods chosen**
- **Objective: What the PPS is intended to inform**
  - For example, informing benefit-risk assessment
- **Questions: Related to the answers needed to address objective**
  - For example, what are the levels of acceptable risks in exchange for benefit?

## 4.2 Study Design And Method Selection

- **The choice of method can depend on several factors, including the research question(s), the patient population, and the number of attributes or scenarios to be assessed**
  - A PPS is not limited to one method and can include both quantitative and qualitative approaches
- **PPS should follow internationally recognised scientific standards and recommended practices**
- **Researchers are encouraged to refer to published literature for more information on the methods available, and the respective strengths and limitations**

## 4.3-4.4 Study Sample And Sample Size

- **The PPS sample should be guided by the research objective(s) and question(s)**
- **A sample that is representative of the target population of the regulatory submission may minimise generalisability/applicability issues**
- **There are different types of recruitment strategies; researchers should justify the recruitment strategy and describe potential bias**
- **The sample size for PPS varies based on research question(s), type of method, and complexity of the study (e.g., number of attributes and levels)**

## 4.5 Attributes And Levels

- **Particular attention should be paid to the attributes and levels when designing the instrument**
- **Attributes included should be relevant for the patients, research objective, and question(s)**
  - Including irrelevant attributes might increase burden
  - Omitting relevant attributes may limit the usefulness of the results
  - The range of attribute levels should cover the values expected in clinical studies (treatment and control groups)
- **Patient engagement in the attribute selection is encouraged**

## 4.6 Instrument Design

- **Instruments (e.g., interview guides, surveys) should be clear, comprehensible, and relevant; potential bias should be minimised**
- **Appropriate consideration should be given to, e.g.,**
  - Numeracy; complexity; translations in multilingual studies; description of attribute levels; minimising cognitive bias
- **Implementing quality checks**
  - Data quality checks are a critical aspect of PPS, which may highlight potential data and study limitations
  - Important issues highlighted by quality checks should be addressed

## 4.6 Pretesting And Piloting

- **Pretesting and piloting an instrument serve different purposes, and both are essential steps in developing the instrument**
  - Pretesting: Initial evaluation to identify any issues with comprehension or interpretation
  - Piloting: Testing under study conditions to identify issues of feasibility, data quality, or logistics

## 4.7 Analysis Plan

- **The analysis, as detailed in the pre-specified analysis plan, should address the research objective and question(s) and follow recommended practices**
- **In some situations, such as quantitative benefit-risk analysis, data from quantitative PPS may be combined with clinical data**
- **The analysis plan should specify all primary and exploratory analyses, and handling the outcome of quality checks, as appropriate**

## 4.8 Submission To The Common Technical Document (CTD)

- **PPS can be listed in CTD 2.5.1 “Product Development Rationale”**
- **The PPS report should be included in CTD 5.3.5.4 “Other Clinical Study Reports”**
  - The PPS report can be based on the structure of clinical study reports (ICH E3(R1)), adapted as appropriate
- **If applicable, PPS results can be included in Benefits and Risks Conclusions along with a critical assessment of the PPS (CTD 2.5.6)**
  - PPS results and/or quantitative benefit-risk analyses can be included in the appendix to the Clinical Overview (CTD 2.5.6.5; see ICH M4E for details)

## Conclusions

- **E22 general considerations provide guidance when considering the need for PPS, and to ensure that PPS are based on sound methodology and produce rigorous results**

## Contact

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