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

Training Module: Illustrative Examples And Frequently Asked Questions

ICH E22 Expert Working Group

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Disclaimer

This presentation includes the authors' views on illustrative examples and frequently asked questions regarding general considerations for patient preference studies. The presentation does not represent official guidance or policy of authorities or industry and does not provide additional guidance beyond ICH E22.

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ICH E22 Illustrative Example 1

Using PPS To Support Endpoint Selection In A Clinical Trial

This example is provided solely for illustrative purposes to highlight part of the thinking process when considering patient preference studies (PPS) in drug development and evaluation, in accordance with the ICH E22 Guideline General Considerations for PPS, and related submissions in accordance with the ICH M4E(R2) Guideline. The example is not intended to be a comprehensive scientific or regulatory example. The example is not intended to replace or expand the ICH Guidelines, or to be a comprehensive or exhaustive representation of the ICH guidelines. Users should consult the relevant ICH Technical Documents for complete information.

Key Questions And Considerations

1. Would a PPS be informative for drug development?
2. Are relevant PPS already available?
3. What are the study objectives/research questions, and which methodology is appropriate?
4. Considerations on design and conduct
5. Considerations on analysis
6. Use of PPS results
7. How to submit results in the Common Technical Document (CTD)?

Would a PPS be informative for drug development?

"Patients … provide their perspective of living with a condition, which may contribute to the determination, for example, of endpoints that are meaningful to patients …. This ultimately supports the development of drugs that are better tailored to patients' needs." (ICH E8)

A researcher is developing a new medical product in Condition X. There is little experience with measuring efficacy in clinical trials in Condition X, although many endpoints have been discussed in the literature. The researcher is considering engaging patients to identify treatment priorities that address patients' unmet needs, potential endpoints for a future clinical trial, and the amount of change in the endpoints that would be meaningful (ICH E22 Section 3.2).

Assess need and use of PPS as early as possible in development (ICH E22 Section 2.6; 3.2).

- **The researcher is considering a PPS to support the choice of endpoints to be used in the clinical trial. The researcher believes the PPS results will be informative to assess how patients view the importance of different treatment outcomes.**

When available, interaction early in the process with regulatory authorities can be useful to ensure that the PPS meets regulatory expectations and scientific standards (ICH E22 Section 1.3).

Are relevant PPS already available?

The researcher conducts preliminary research, including a targeted literature review and landscape assessment to evaluate if a PPS is already available because if it is, *de novo* work may not be justified (ICH E22 Section 2.3; 2.4).

- **If the researcher identifies an existing PPS, it is important to assess whether it is applicable to the local setting (ICH E22 Section 2.5), was well-conducted, and provides sufficient information to address the research question.**
- **The researcher found that there were no relevant PPS available and decides to conduct one. The researcher forms a multidisciplinary study team (ICH E22 Section 2.8) and starts to develop a protocol.**

PPS participants should be protected in accordance with the applicable regulatory and legal requirements (ICH E22 Section 2.1).

What are the study objectives/research questions, and which methodology is appropriate?

The study team develops the research questions to address their research objective (ICH E22 Section 4.1).

- **Research objective: To identify efficacy endpoints most important to patients with Condition X**
- **Research questions:**
  - **To assess relative importance of treatment attributes among patients with Condition X**
  - **To determine the amount of change in attributes that would be meaningful to patients with Condition X**

The study team considers several methods to address the research questions. The team decides to use a discrete choice experiment (DCE) survey based on the research questions, patient population, and the expected number of attributes of interest. The study team also determines that a mixed methods approach is needed where qualitative interviews are first conducted to inform the quantitative DCE.

In a DCE, participants are asked to choose between different hypothetical treatment options that vary across several characteristics, called attributes. In this study, the attributes represent potential clinical trial endpoints.

The study team continues writing the PPS protocol. They next consider the study sample and attributes and levels.

There should be a clear rationale for the choice of method(s). Refer to published literature for the strengths & limitations of various methods (ICH E22 Section 4.2).

PPS are expected to follow the principles of good study design and conduct. This includes generation of study documents such as informed consent forms, protocols, interview guides, analysis plans, survey instruments, and study reports (ICH E22 Section 2.7).

Considerations on design and conduct (I)

Study Sample (ICH E22 Section 4.3)

The study team wants to ensure that the study sample is representative of the target population of a future regulatory submission, because a mismatch can limit generalisability and applicability of the findings (ICH E22 Section 4.3).

The study team decides to work with a patient advocacy group to ensure that the questions are relevant and to help with recruitment. In Condition X, the team feels that it is important to verify diagnosis by having patients provide a doctor's note to verify that they have Condition X.

Attributes and Levels (ICH E22 Section 4.5)

The study team understands that there is a limited number of attributes that can be asked about in a single PPS. The study team selects a short preliminary list of attributes that represent potential clinical trial endpoints they believe will both matter to patients and may be modified by the investigational treatment.

The study team thinks about the alternative treatments patients may take, including no treatment or standard of care, when considering the attributes and attribute levels to ask patients about. They do this to try to ensure that the attributes and levels provided are appropriate for the relevant treatment options.

Each attribute can take on different levels, which describe possible results or degrees of improvement for a potential endpoint. For example, attribute levels may be numbers or rates (e.g., proportion of people achieving a certain outcome) or potentially categories (e.g., "none," "mild," "moderate", or "severe").

The impact of recruitment strategies on the representativeness of the target population and potential bias should be described.

Considerations on design and conduct (II)

Attributes and Levels (ICH E22 Section 4.5)

Through qualitative interviews with patients, the study team gains an understanding of patients' perspectives of the preliminary list of attributes and their levels, and of their respective descriptions. Findings from the interviews demonstrate that patients viewed one of the proposed attributes as unimportant.

The study team knows that including irrelevant attributes can increase burden but that omitting relevant attributes from the PPS may limit the usefulness of the results. Following analysis of the interview data, the study team discusses their findings and whether they think regulators would see value in the attribute. They ultimately decide to eliminate the attribute.

The patients in the qualitative interviews identified three additional attributes that are important to them. One of these attributes is very unlikely to change with treatment, so the study team decides not to add it to their list. The other two new attributes are added to the list.

In addition to attributes, as part of the interviews the patients and research team also asked about appropriate levels for the new attributes. Using the patients' interview data and other information, the study team modifies the levels and descriptions of the final list of attributes, so they are more comprehensible to patients and align closely to potential clinical endpoints.

Attributes should be described such that they are interpreted as intended, consistently, and unambiguously across all participants (ICH E22 Section 4.6.2).

Considerations on design and conduct (III)

The study team develops a DCE survey instrument using the final list of attributes and levels. The DCE survey instrument will be administered electronically using a web-based platform.

<u>Quality checks (ICH E22 Section 4.6.3)</u>
The study team wants to make sure that quality checks are built into the DCE and adds a dominated-choice task to identify potentially illogical responses. The study team also plans to evaluate response times to identify if there are participants who are speeding through the survey questions and, therefore, not paying close attention.

It is useful to pre-register protocols using a registry, a comparable platform, or other formal mechanisms to enhance research credibility and transparency (ICH E22 Section 2.7).

Important issues highlighted by quality checks should be addressed. It should be noted that most data quality checks, in and of themselves, cannot definitively identify responses that should be removed from the analysis set (ICH E22 Section 4.6.3).

<u>Pretesting (ICH E22 Section 4.6.4)</u>
The study team wants to make sure that the survey instrument is interpreted as intended by participants and thus, pretests the survey instrument via think aloud, cognitive interviews. Feedback from the interviews is used to refine the instrument.

<u>Piloting (ICH E22 Section 4.6.5)</u>
The study team also conducts a pilot phase. During the piloting, they discover a problem with the programming of the skip logic in the survey and correct the problem before the study survey is available to the full population.

Justification should be provided for deviations from the pre-specified analysis plan (ICH E22 Section 4.7).

Considerations on analysis

Based on a pre-specified analysis plan that defines the statistical methods, the study team calculates the relative importance of the attributes and uses the PPS results to inform the amount of change in the attributes that would be meaningful (ICH E22 Section 4.7).

Use of PPS results

A drug developer plans to submit the study team's PPS results in a region where consultation with regulators is available.

During the discussion with the regulators about the choice of endpoints for the clinical trials in Condition X, the results of the PPS are used to justify the endpoint selection and inform the amount of change in endpoints that would be of meaningful in the design of their clinical trial.

The study team also shares the PPS results with the patient advocacy group that they worked with and drafts a manuscript for publication.

How to submit results in the Common Technical Document (CTD)?

When ready to seek marketing authorisation for the drug tested in the clinical trial, the applicant ponders how to include the PPS results in the CTD and decides to add the study report in CTD 5.3.5.4 "other clinical study reports". The study team develops the PPS report following the structure of a clinical study report (ICH E22 Section 4.8).

In this case, as the PPS was used by the applicant to justify decisions regarding the clinical trial endpoints, the PPS and a description of how the results were used are included in CTD 2.5.1 Product Development Rationale (ICH E22 Section 4.8).

A PPS report typically includes content that addresses the topics covered in ICH E22, e.g., research objective and question(s), study design, method selection, study sample, sample size (ICH E22 Section 4.8).

It is up to the applicant to explain how the results are intended to support their regulatory submission, and to justify that the data submitted meet the regulatory requirements (ICH E22 Section 4).

ICH E22 Illustrative Example 2

Using PPS To Inform Benefit-Risk Evaluation

This example is provided solely for illustrative purposes to highlight part of the thinking process when considering patient preference studies (PPS) in drug development and evaluation, in accordance with the ICH E22 Guideline General Considerations for PPS, and related submissions in accordance with the ICH M4E(R2) Guideline. The example is not intended to be a comprehensive scientific or regulatory example. The example is not intended to replace or expand the ICH Guidelines, or to be a comprehensive or exhaustive representation of the ICH guidelines. Users should consult the relevant ICH Technical Documents for complete information.

Key Questions and Considerations*

1. Would a PPS be informative for drug benefit-risk evaluation?
2. Considerations on design
3. Study population
4. Attributes and levels
5. Considerations on analysis
6. Use of the main analysis
7. How to submit results in the Common Technical Document (CTD)?
8. Benefit-risk evaluation (see ICH M4E (R2))

* For a more detailed example on aspects of PPS design, see ICH E22 Illustrative Example 1 - Using PPS to support endpoint selection in a clinical trial

Would a PPS be informative for drug benefit-risk evaluation?

PPS are generally not required but may be useful for benefit-risk assessment (ICH E22 Section 1.1).

A new treatment is being developed for Condition Z. Key efficacy endpoints are generally well established in this condition and will be used in the main efficacy clinical trial. However, severe side effects are anticipated based on early clinical studies. A good understanding of the acceptable benefit-risk trade-offs in Condition Z might inform the benefit-risk evaluation (ICH E22 Section 3.2). The developer is considering engaging patients to better understand how patients view the acceptability of the trade-offs between expected benefits and risks.

- The study team is considering a PPS to inform the interpretation of the clinical trial results. The study team expects that PPS results, when combined with the clinical data, will be useful to inform the benefit-risk assessment.

When available, interaction early in the process with regulatory authorities can be useful to ensure that the PPS meets regulatory expectations and scientific standards (ICH E22 Section 1.3).

Preference research is a large and evolving field. External resources may offer relevant insights and supplementary information (ICH E22 Section 1.3).

Generally, it is important to consider alignment between attributes and endpoints. It is particularly important when the objective of the PPS is to inform benefit-risk assessment (see ICH M4E(R2) and ICH E22 Section 4.5).

Considerations on design

(For a detailed example on PPS design aspects, see Example 1)

Given that the objective is to inform benefit-risk assessment, the study team is aware of the importance of particular design elements such as choosing a suitable method and the alignment between the PPS attributes, along with their levels and ranges, and endpoints in the clinical trial. The study team is considering choosing efficacy attributes based on trial efficacy endpoints and safety attributes based on early clinical data (ICH E22 Section 4.5).

Study population

A study population is chosen to match the target population for treatment for Condition Z. The study team believes that certain subgroups, such as people with more severe disease and people with prior experience with treatment for Condition Z, may have different preferences from those with less severe disease and without such experience (Section 3.2). Therefore, the study team made sure to recruit sufficient patients with and without severe disease, and with and without prior experience with treatment for Condition Z to allow for subgroup analyses (ICH E22 Section 4.4).

PPS may also help describe preference heterogeneity, which is the distribution of preferences within a population, or to compare distributions between pre-specified subpopulations (i.e., subgroups) with characteristics potentially associated with differences in preferences (ICH E22 Section 3.2).

Attributes and levels

The study team is aware of the importance of engaging patients (ICH E22 Section 2.2) in the process of selecting attributes to include in the PPS. Even though endpoints in Condition Z are well established, the study team is considering using qualitative interviews to confirm that selected attributes are all relevant, and that no relevant attributes have been omitted. The study team makes sure that the range of attribute levels include the relevant values expected in the clinical studies.

Extrapolation of PPS data beyond the levels included in the study is generally not recommended (ICH E22 Section 4.5).

Considerations on analysis

A pre-specified analysis plan defines research question(s) and the statistical methods, including analysis sets and subgroups (ICH E22 Section 4.7).

A study protocol is developed together with a pre-specified analysis plan to define the statistical methods for the PPS and how to combine data from the PPS and clinical trial results. In the main analysis, the study team plans to estimate acceptable risk for the key efficacy endpoints. In a subsequent analysis, these estimates will be combined with the results from the clinical trial to derive information for benefit-risk assessment.

An exploratory analysis of heterogeneity was pre-planned. Statistical modelling is used for estimating how results vary by severity and prior experience with treatments for Condition Z.

Use of the main analysis

The analysis is expected to inform the benefit-risk evaluation to be presented in the submission. The main analysis of the PPS is used to provide information about the trade-offs patients are willing to make among specific attributes of the drug. The analysis of preference heterogeneity is provided in support of the main analysis.

How to submit results in the Common Technical Document (CTD)?

When ready to seek marketing authorisation for the drug tested in the clinical trial, the applicant ponders how to include the PPS results in the CTD and decides to add the PPS report in CTD 5.3.5.4 "other clinical study reports". The study team develops the PPS report following the structure of a clinical study report (ICH E22 Section 4.8).

A PPS report typically includes content that addresses the topics covered in ICH E22, e.g., research objective and question(s), study design, method selection, study sample, sample size (ICH E22 Section 4.8).

As the PPS study is used by the applicant to justify the benefit-risk evaluation, using a quantitative methodology, the PPS will be listed and described in Product Development Rationale (CTD 2.5.1) and a description of how the results are used will be included in Benefit and Risks Conclusions (CTD 2.5.6). The details of the main and exploratory analyses will be submitted in an appendix (CTD 2.5.6.5).

Benefit-risk evaluation (see ICH M4E (R2))

The regulatory assessment considered the applicant's conclusion on the benefit-risk assessment of the drug in the proposed indication(s), including the benefit-risk evaluation using descriptive, qualitative, and quantitative methodologies, in line with the ICH M4E(R2) guidance. The regulatory evaluation noted that:

- **A succinct explanation of the assessment of key benefits and key risks was provided using the results of the PPS and benefit-risk analysis.**
- **Uncertainties affecting the interpretation of the evidence due to heterogeneity in preferences were described using the PPS.**
- **The PPS was relevant to assess how severity of disease might influence the acceptability of the risks of the therapy and how the medicinal product may address a medical need.**
- **The methods used to express the benefit-risk assessment followed standard practice.**
- **Regulatory advice on using a PPS to inform the interpretation of the clinical trial results was sought & followed.**

Overall, the applicant's submission, presented in line with ICH M4E(R2), clearly explained the applicant's benefit-risk assessment of the product for its intended use. The regulatory evaluation considered the PPS together with efficacy and safety information in the benefit-risk assessment, as described in ICH guideline documents M4E and E2C, to inform the weighing of the key benefits and key risks of the drug from a patient perspective.

There are many approaches (both with and without a PPS) available for conducting a benefit-risk assessment. Before using any method, the applicant should consider its utility, complexity, the extent to which the method is established, and the ease of interpretation of the results. (See ICH M4E(R2), Section 2.5.6.4).

ICH E22 - Frequently Asked Questions

This Frequently Asked Questions section is provided solely for communication purposes to highlight certain key messages in the ICH E22 Guideline General Considerations for PPS. The section is not intended to replace or expand the ICH Guidelines and documents, or to be a comprehensive or exhaustive representation of the ICH Guidelines and documents. Users should consult the relevant ICH Technical Documents for complete information.

Questions

1. Does this guideline require patient preference studies (PPS) to be conducted as part of every drug development program?
2. How can preference studies inform drug development?
3. Can PPS be informative to regulators before the marketing authorisation application is submitted?
4. How are PPS and Patient Reported Outcome (PRO) measures different?
5. Must the PPS be conducted in patients with the exact condition to which the preference results will be applied?
6. Why are caregiver preferences out of scope?
7. What does it mean that PPS are done with “hypothetical scenarios”?
8. Why are revealed-preferences out of scope of the guideline?
9. What are the different roles a patient or patient organisation may have related to a PPS?
10. Which preference methods are acceptable from a regulatory perspective?
11. Can PPS be part of a clinical trial rather than a standalone protocol?
12. Does the guideline discuss inclusion of PPS information in the product label?

1. Does this guideline require PPS to be conducted as part of every drug development program?

- This guideline **does not require** that patient preference studies be conducted for every drug development program. It provides general considerations and scientific principles for when PPS may be useful to inform both drug development and regulatory evaluation, but it does not establish a requirement to conduct such studies.
- The guideline **does** encourage the consideration of patient preference studies in cases where they can enhance the understanding of patient perspectives and inform decision-making across the drug development continuum.
- Sponsors are encouraged to evaluate whether a PPS would provide useful information for their specific program. In some cases, existing high-quality preference research may already address the relevant questions for a given program. In other cases, the potential value of conducting a new PPS may not justify the effort or burden if it is unlikely to generate information that would meaningfully inform development or evaluation decisions.
- ICH E22 recognises that PPS can inform a wide range of development activities — not only regulatory submissions or benefit-risk assessments.

2. How can preference studies inform drug development?

- PPS can generate insights about the importance of treatment characteristics considered by patients when making drug decisions. They may be used in various situations, including those in this guideline, to understand qualitative and quantitative insights for drug development.
- The use of PPS can depend on the stage of drug development.
  - For example, during an early stage, PPS may inform unmet needs, treatment characteristics that matter to patients and priorities for disease management.
  - In clinical trial design, PPS may inform endpoint development, selection, weighting, scoring, and interpretation, reflecting what magnitude of change in an endpoint patients consider meaningful.
  - In later stages, PPS can support interpretation of trial results and inform benefit-risk trade-offs and risk thresholds, especially when risks are high or uncertain.
- In all these applications, PPS can describe preference heterogeneity within populations or subgroups, such as differing risk tolerance between severity groups.

For further details, see ICH E22 Section 1 Background and ICH E22 Section 3.2 How Might PPS Inform Drug Development and Evaluation

3. Can PPS be informative to regulators before the marketing authorisation application is submitted?

- PPS may be used in various situations before submission of an application to gain insights from qualitative and quantitative studies, such as identifying unmet needs, designing clinical studies, and interpreting results.
- These aspects may be informative in discussing clinical trial design with regulatory authorities in view of a potential submission, including objectives and outcome/endpoint selection, meaningful change of an endpoint, and benefit-risk acceptability.

For further details, see ICH E22 Section 1 and ICH E22 Section 3.2 How might PPS inform drug development and evaluation.

4. How are PPS and Patient Reported Outcome (PRO) measures different?

PPS and PRO measures differ in both purpose and evidentiary role within patient-focused drug development.

- **PPS** are designed to elicit how patients value and prioritise different treatment characteristics or outcomes, and the trade-offs they are willing to make between benefits and risks. Using qualitative and/or quantitative methods, PPS generate structured evidence about the relative importance of treatment characteristics to patients. These data can inform endpoint selection, benefit–risk assessment, and broader development decisions (ICH E22).
- **PRO measures**, by contrast, are clinical outcome assessments that directly capture how patients feel, function, or survive in relation to a disease or treatment, without interpretation by clinicians or others. They quantify patient-experienced outcomes—such as symptoms, daily functioning, or quality of life (ICH Reflection Paper: Proposed ICH guideline work to advance patient-focused drug development.2021.).

In short, PPS assess patient values and trade-offs, whereas PROs measure patient-experienced outcomes — complementary but distinct components of patient experience data.

5. Must the PPS be conducted in patients with the exact condition to which the preference results will be applied?

- Typically, the PPS should include a sample that is representative of the target population of the regulatory submission – in patients with the same condition and under the same circumstances as those to whom the preference results are being applied, including demographic, disease and treatment characteristics.
- A mismatch between the PPS sample and the target patient population can limit the generalisability and applicability of the PPS findings.
- An exact match may not always be possible. For example, such patients may only be available briefly during an acute phase, burdening patients under those circumstances may be unethical, or the condition may preclude completing a survey at such a time.
- When a match is not possible, the Sponsor should discuss options for the PPS population and rationale with Health Authorities, and the study report should include a discussion supporting the relevance of the PPS to the research objective.

For further details, see ICH E22 Section 4.3 Study Sample.

6. Why are caregiver preferences out of scope?

- While important and potentially informative for regulatory assessment, caregiver preferences are out of scope for this guideline, which focuses on patient preference studies. Many of the methods and some of the general considerations for collecting caregiver preferences are the same as for patient preferences.
- It is important to note that caregiver preferences are not a replacement for eliciting patient preferences. Caregiver preferences would typically be collected in a separate study from patient preferences, and the studies are expected to have different research questions.

See ICH E22 Section 1.3 Scope and Direction.

7. What does it mean that PPS are done with "hypothetical scenarios"?

- This guideline focuses on methods called stated-preference methods, which use hypothetical scenarios requiring patients to express (state) their choices or acceptable thresholds for trade-offs for specific outcomes or treatment alternatives. The alternative, revealed-preference methods, are not in scope of ICH E22 (see FAQ 8).
- For stated preference methods, hypothetical scenarios are used since patients are evaluating characteristics of potential drugs, and not actual drugs. This allows preferences to be evaluated for drugs that may not yet exist in the market, or for which real-world revealed preference data are unavailable, unethical to obtain, or confounded by external factors (e.g., access barriers, provider influence).
- Where applicable, hypothetical scenarios allow for systematic variation of individual treatment characteristics, such as efficacy and safety outcomes, to evaluate how each affects preference. This may not be possible with real-world revealed preference data (see FAQ 8).

For further details, see ICH E22 Section 1.3 Scope and Direction.

8. Why are revealed-preferences out of scope of the guideline?

- Revealed-preference methods are those in which patient preferences are obtained from the actual observed behaviour or choices made by patients (e.g., did they use one drug or a different one).
- Revealed preferences demonstrate what patients chose from currently available options, which makes it hard to infer how they might respond to new or potential drugs that do not have the same characteristics as existing drugs. Therefore, this may limit the use of revealed preference methods to inform the development of future, novel drugs.
- Currently, there is limited experience using revealed preference methods to inform drug development.
- While this guidance does not preclude the use of revealed-preference methods if they are appropriate, they are not in the scope of ICH E22.

See ICH E22 Section 1.3 Scope and Direction.

9. What are the different roles a patient or patient organisation may have related to a PPS?

- Patient or patient organisation input is valuable in the development of a PPS in multiple activities, including **but not limited to**
  - Designing the PPS
  - Identifying feasibility challenges in the conduct of a PPS
  - Developing PPS protocols
  - Selecting PPS attributes and levels

For further details, see ICH E22 Section 2.2 Patient input in the development of PPS.

10. Which preference methods are acceptable from a regulatory perspective?

- Preference research is a large, evolving field; this guideline provides general principles rather than detailed instructions and methods.
- In principle,
  - Research objectives and questions should guide methods, protocol, analysis, data management, and reporting.
  - Researchers are encouraged to refer to published literature for more information on the methods available, points to consider for method selection, and the respective strengths and limitations of various methods.
  - A clear rationale for method selection is essential, explaining why a specific technique supports answering the research objectives and questions.
- When available, early interaction with regulatory authorities can help ensure PPS meets regulatory expectations and scientific standards.

For further details, see ICH E22 Section 3.1 Types of PPS and ICH E22 Section 4.2 Study Design and Method Selection.

11. Can PPS be part of a clinical trial rather than a standalone protocol?

- In principle, preference studies can be conducted within a clinical trial or as a stand-alone study.
- When available, sponsors should discuss options in advance for the PPS and rationale with health authorities.

For general considerations about the PPS population, see ICH E22 Section 4.3 Study Sample.

12. Does the guideline discuss inclusion of PPS information in the product label?

- The placement of PPS data in labelling is considered a regional matter outside the scope of this guideline.
- Interaction early in the process with regulatory authorities can be useful to ensure that the PPS meets regulatory expectations and scientific standards.

See ICH E22 Section 1.3 Scope and Direction.

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Contact

- **For any questions, please contact the ICH Secretariat:**

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