Webinar for Stakeholder Engagement on the New Draft Guideline on General Considerations for Patient Preference Studies (ICH E22)

6 February 2026

Meeting Report

1. Webinar Summary

The ICH E22 Expert Working Group (EWG) held a webinar to present the draft ICH E22 Guideline on General Considerations for Patient Preference Studies, seeking to encourage stakeholder feedback during public consultation. The webinar and associated materials – including the ICH E22 explanatory video, *Step 2* presentation on the draft Guideline and explainer for the draft Guideline – are available online at the **ICH E22 webpage**.

The objectives of the webinar were to describe the draft ICH E22 Guideline and Training Materials, to hear experiences and feedback from cross-regional patient representatives and to encourage stakeholder feedback during the public consultation.

The first session of the webinar included a welcome, information on the ICH public consultation process and a keynote: Setting the stage for ICH E22 by T. Mullin (FDA, United States). In the second session, EWG members presented key aspects of the ICH E22 Guideline, focusing on use cases and general methodological considerations of Patient Preference Studies and introduced proposed Training Materials, including FAQs and illustrative examples.

In these two sessions, the speakers introduced Patient Preference Studies as formal studies that ask patients what matters to them, how much these things matter and the trade-offs that they are willing to make between different options. The information gained from these studies can inform various aspects of drug development, such as identifying unmet medical needs, designing and conducting clinical trials, and interpreting the results from clinical studies. The ICH E22 Guideline aims to further harmonise approaches to conducting Patient Preference Studies for use by regulatory authorities and the pharmaceutical industry in different countries, and support 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.

The speakers highlighted that Patient Preference Studies complement (but do not replace) efficacy and safety data. They outlined key methodological points these studies should address to generate robust findings. Available training materials and explanatory video were highlighted, and the ongoing public consultation was discussed.

The presentations in the first two sessions summarised ICH E22-related documents available on the ICH E22 webpage referenced above, and as such are not further summarised within this report.

The third session, moderated by R. Bent (FDA, United States), invited patient representatives across different regions: J. Harris (National Psoriasis Foundation); F. Houÿez (EURORDIS); N. Sakurai; (CSR Project, Japan Federation of Cancer Patient Groups) and A. Valentine (Sick Cells) to share their experiences with Patient Preference Studies and provide initial feedback on the Guideline. The goal of

the session was to foster meaningful engagement by encouraging comments, describing stakeholder perspectives and providing examples of substantive feedback during the public consultation process.

Overall, the panellists emphasised that Patient Preference Studies are most valuable when patients and community partners are engaged early and meaningfully in study design, recruitment, instrument testing and result interpretation; that representativeness, language and access barriers, participant burden and fair compensation must be proactively addressed; and that the ICH E22 Draft Guideline is a concise, welcome foundation whose impact will depend on practical implementation, publication of results and sharing of real-world examples. The panellists provided a clear, actionable roadmap for moving from principle to practice, emphasising that the success of patient preference studies depends on genuine, respectful partnership with patients and their communities from start to finish.

A detailed summary of the panel discussion and a case study presented during the discussion are provided below. Please consult the **ICH E22 webinar page** or the **ICH E22 webpage** for access to the recording of the panel discussion.

2. Summary of the panel discussion

2.1. Overall Assessment of the ICH E22 Guideline

2.1.1. Recognised Strengths

- **A foundational framework:** The Draft Guideline was praised as a "very strong start" that provides a much-needed, harmonised foundation for incorporating patient preferences into drug development.
- **Clarity and brevity:** The document was noted for being concise and clear, making its principles accessible to a wide range of stakeholders.

2.1.2. Opportunities for Improvement and Future Consideration

- **Reinforce the need for scientific rigour:** A critical caution was raised by **F. Houÿez** that the Guideline's accessibility might lead some to believe they can conduct these studies on their own. He stressed that they are scientifically demanding and are only useful if rigour applies from beginning to end, calling for strong partnerships between patients, academia and industry.
- **Address the full study lifecycle:** The panel identified a need for guidance on adapting or reusing studies at different stages of development to avoid redundant efforts.
- **Ensure transparency and publication:** A significant concern was the risk of sponsors not submitting unfavourable study results. The panel strongly recommended that, like clinical trials, all completed studies be published or submitted to ensure transparency.

2.2. From Lived Experience to Action: Core Recommendations for Implementation

2.2.1. Involve Patients Early and Authentically

- **Co-design the research:** Patients must be partners in creating the study. **N. Sakurai** articulated the goal that patients and patient organisations want to create high-quality clinical research and trials together.
- **Let patients define value: F. Houÿez** recalled how HIV patient advocates convinced a company to change a Phase 3 trial dose, prioritising the avoidance of a debilitating side effect over a maximum tolerated dose – a perspective that clinicians had missed.

2.2.2. Value Patient Contributions: From Ethics to Budget

- **Budget for fair compensation:** The Sick Cells case study demonstrated the need to budget for the entire ecosystem. They provided fair compensation not only to individual participants but also to the community-based organisations (CBOs) and their community health workers (CHWs).
- **Acknowledge the human cost:** Beyond finances, participation has an emotional toll. **A. Valentine** made a vital point that studies ask patients to relive complications of their disease, which can trigger trauma. This must be actively managed with support.

2.2.3. Build a Representative Sample Through Intentional Effort

- **Look beyond the clinic: A. Valentine** explained that social determinants of health – like insurance and regional access to care – must be accounted for.
- **Use trusted messengers:** As proven by the Sick Cells experience, using local, trusted community members is a powerful strategy to build trust and overcome access barriers.
- **Close the loop: J. Harris** stated a non-negotiable principle that we cannot ask people to do things and then just forget about them. Reporting results back to the community is a critical final step.

2.3. Conclusion

The panel discussion provided clear, actionable insights for the finalisation and implementation of the ICH E22 Guideline. A central theme that emerged was the importance of integrating patients as essential partners throughout the entire research lifecycle, not merely as subjects of a study. The panellists' feedback underscores that successful implementation of the Guideline requires more than adherence to technical standards; it necessitates a commitment to authentic co-design, careful management of participant burden, appropriate resourcing and intentional strategies to ensure representative participation.

The discussion affirmed that by applying the principles outlined in ICH E22 – and by directly engaging patients – the research community can better ensure the development of medicines that are meaningful to the patients they are intended to serve.

3. Case Study in Action: The Sickle Cell Patient Preference Study

A. Valentine's detailed account of a study with Sick Cells served as a powerful, real-world model for how to implement these recommendations effectively. It demonstrates how deep community partnership moves from a nice-to-have to a core driver of study success.

- **A community-led "train the trainer" model:** Rather than recruiting patients directly, the study partnered with community-based organizations (CBOs). They trained local community health workers (CHWs) – trusted messengers who already had rapport with patients – to understand the study and field the survey.
- **Overcoming multiple barriers at once:** This CHW-led approach solved several problems simultaneously:
  - **Trust:** Patients were more willing to be honest and complete a long survey with someone they knew.
  - **Access:** It bridged the digital divide and accommodated patients who were not feeling well or had lower literacy, as the CHW could read the survey to them.

    - **Support:** The CHW could provide real-time emotional support, recognising the burden of the questions being asked.
- **Strategic, representative recruitment:** They carefully selected CBOs in different United States regions to capture a variety of experiences shaped by different climates, insurance systems and access to specialists.
- **Budgeting for partnership:** The study's budget explicitly included fair compensation for the CBOs, the CHWs for their time, and the patient participants for their expertise and commitment.
- **Dissemination to the community:** The project produced both an academic paper and a lay summary to ensure the findings were accessible and returned to the community that made the research possible.