

Proceedings of the First Patient Engagement (PE) and Patient Experience Data (PED) Roundtable in Japan: Advancing the Structured Implementation of PED

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On 18 October 2025, the first Patient Engagement (PE) & Patient Experience Data (PED) Roundtable in Japan was held. This international roundtable brought representatives from the patient community, academia, medical professionals, the regulatory agency, and the pharmaceutical industry.

The keynote address by Ms. Hayley Chapman provided a global overview of PE and PED, emphasizing that PED does not replace PE, but rather complements it through co-creation and contextualization. Her presentation highlighted the importance of working *with* patients to ensure the meaningful integration of PED for meaningful decision-making across healthcare systems and product development.

Subsequent discussions explored the current landscape and future potential for systematic implementation of PE and PED in Japan, as well as the challenges that remain within clinical research and regulatory frameworks. The roundtable reaffirmed the importance of clear and shared objectives and collaborative actions among stakeholders to ensure that PED genuinely benefits patient communities and healthcare outcomes. This meeting marked an important step toward advancing patient-centered innovation in Japan, where patients' voices are not only heard, but meaningfully reflected and acted upon in healthcare and research decision-making.

Key words: patient engagement, patient experience data, patient and public involvement, patient-focused drug development, health technology assessment, patient reported outcomes, patient preference, global PED navigator

Introduction

In recent years, patient experience data (PED) has emerged as a critical concept in the advancement of patient-focused healthcare. PED encompasses evidence collected directly from patients about their

lived experiences with diseases and treatments, including quantitative and qualitative information that can inform research and development, clinical practice, and policy. To promote understanding of PED and its relevance to Japan, YORIALab, in collaboration with Patient Focused Medicines Development (PFMD), and supported by *Rinsho Hyoka* and the Japan Partners for Patient-Centric Care (JPPaC), convened a roundtable discussion held on 18 October 2025 at AP Tokyo Yaesu in a multi-stakeholder format. The roundtable brought together stakeholders from diverse sectors—patient community, academia, medicinal professionals, regulatory bodies, industry, and think tanks—to explore definitions, challenges, and opportunities related to PED. This report presents a comprehensive summary of the roundtable, capturing the main presentations, discussions, and future directions identified during the meeting.

A group of invited individuals dedicated to systematic implementation of PE across various stages of healthcare—from early drug development and clinical practice to health policy making—came together for this initiative. All participants have been actively driving PE, also referred to as patient and public involvement (PPI)¹, and are keenly interested in PED and its implementation in Japan and the Asia Pacific region.

This was the first roundtable of this theme, comprising eleven panelists participating in the discussion, one graphic recorder, and additional individuals serving as organizing staff and observers. The roundtable featured Ms. Hayley Chapman of The Synergists, a globally recognized leader who has been spearheading international discussions on PE and PED. The discussion was conducted entirely in English, with translation into Japanese provided to virtual attendees. The objective of the roundtable is indicated in Table 1.

Table 1: The Roundtable Objectives

1. to understand what PED is for healthcare decision-making and how PE is integrated to ensure the value of PED;
2. to learn up-to-date global discussions including the concept of fit-for-purpose PED and practices in various healthcare stages;
3. to explore PE and PED opportunities and issues around the current patient and public involvement (PPI) landscape in Japan;
4. to prioritize the areas to focus on as the first step of systematic PED implementation;
5. to define the role of PE and PED initiatives in Japan, its goal, and who could be best suited, and interested, to be part of continuing discussions (act as a champion) after the roundtable.

The participants engaged in a forward-looking, three-hour live discussion covering several key topics.

¹ Throughout this document, the term patient engagement is used instead of PPI which is the term usually referred to as patient engagement in Japan.

The session began with a keynote address by Hayley Chapman titled “Designing Future Medicines Development with PE and PED”, which provided an overview of PED. This was followed by an overview of the current PPI landscape in Japan, with insights from representatives of the patient community, academia, medical practice, regulatory bodies, industry, and health technology assessment (HTA)². The discussion concluded by exploring opportunities for implementing systematic approaches to PE, as well as immediate practical cases.

Designing Future Medicines Development with PE and PED— A Keynote Address by Hayley Chapman

To open the roundtable, the keynote set the context for what PE and PED are, how and where PED is being used, who is using it, and what is happening globally, including the availability of practical tools to support PED activities.

The aim was not only to define concepts, but to anchor the discussion in real-world decision making and to explore how PE and PED, when meaningfully integrated, can strengthen regulatory, HTA, clinical, and policy decision-making and outcomes.

1. What Are PE and PED

A simple illustration shared an important perspective (Figure 1³).

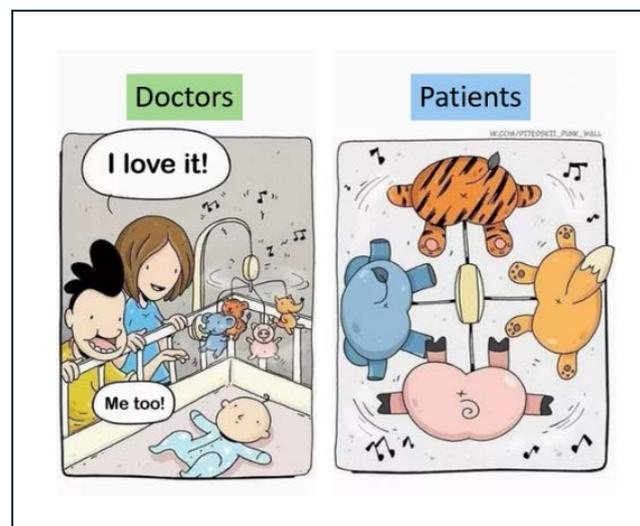


Figure 1: Perspectives are slightly different

From the viewpoint of a clinician or someone within the healthcare system, a mobile hanging over a

² The HTA in Japan is implemented as a supplemental process for price adjustment based on cost-effectiveness of a new product (health technology) with high impact on healthcare finance, no direct impact on decision if the product is reimbursed. <https://c2h.niph.go.jp/en/>. Accessed 2026 Jan 18.

³ Jill Feldman ISMPP Presentation, 2024.

crib might prompt the reaction: “Isn’t this wonderful? It’s making the baby happy.”

But when we pause and look from the patient’s perspective, the interpretation may be very different.

This shift in perspective is at the heart of PE. We could replace “doctor” with industry, regulator, or HTA body: the lesson remains the same. PE is about recognizing the point of connection between healthcare systems and the lived realities of patients and their families.

At its core, PE is about:

- Collaboration and mutual learning
- Being valued—and being valuable
- Active, intentional participation, not passive consultation

It involves not only patients, but also caregivers, families, and others who support people living with disease or undergoing treatment.

Defining Patient Experience Data (PED)

PED, as adopted by the US Food and Drug Administration (FDA)⁴, includes evidence about patients’:

- Symptoms and functional impact
- Quality of life
- Experiences with treatment
- Views on meaningful outcomes
- Preferences and trade-offs related to treatments



In other words, PED captures what patients experience and value, whether they are living with a

4 US Food and Drug Administration. US patient-focused drug development: collecting comprehensive and representative input. Silver Spring (MD): FDA; 2020 Jun. Available from: <https://www.fda.gov/media/139088/download>. Accessed 2026 Jan 18.

disease or navigating treatment.

Importantly, PED is not limited to patient preference studies or patient-reported outcomes (PROs). It can be generated through:

- Clinical outcome assessments (COAs)
- Digital health technologies
- Biomarkers
- Qualitative methods such as interviews, focus groups, and observation

While PED is often discussed in the context of regulatory submissions for new products, its value extends much further. PED can:

- Inform healthcare system design
- Support patient organization advocacy and policy work
- Enable shared decision-making in clinical practice

2. Why the Integration of PE and PED Matters

PE and PED are distinct concepts—but their real power lies in their integration.

As described, PED can be collected through surveys, focus groups, or PROs. However, without meaningful engagement with the patient community,

- to understand what questions to ask,
- how and when to ask them, and
- who should be asked,

the resulting data risks being incomplete, misaligned, or insufficiently meaningful.

Engaging patients in the design, interpretation, and contextualization of PED ensures that the evidence truly reflects what matters most to the patient community (Figure 2).

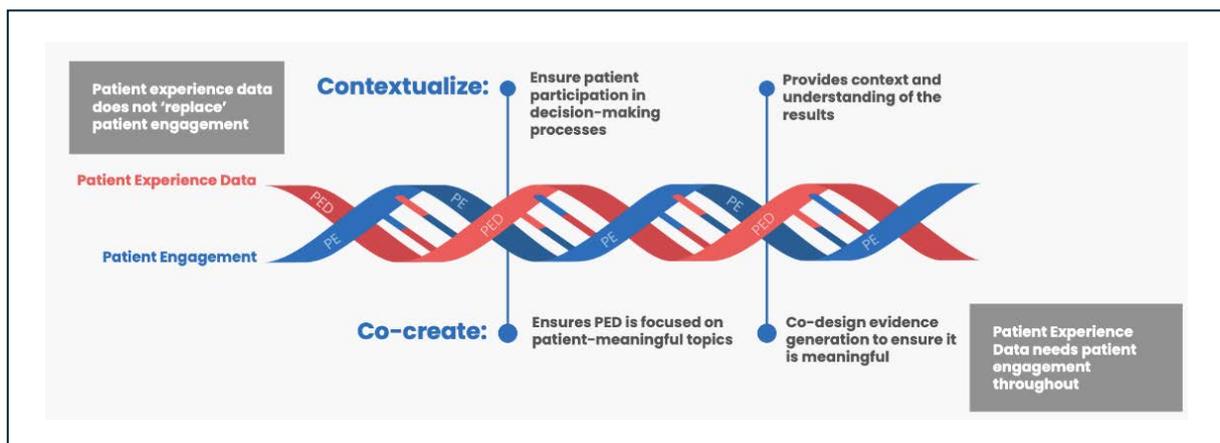


Figure 2: Integration of PE and PED

3. What's Happening Globally

Over recent years, we have seen a clear global shift particularly among regulators and HTA bodies toward greater consideration of PE and PED.

A review of publicly available regulatory and HTA documents and workshops (in English) shows that:

- Approximately 75% reference PE
- Around 46% reference PED
- Nearly 30% explicitly address the combination of PE and PED^{5,6}

Compared to similar analyses conducted just a few years earlier, this represents a meaningful increase.

This momentum is not limited to North America or Europe. It is increasingly evident in the Asia-Pacific region as well.

Recent examples include:

- **US FDA workshops⁷**, emphasizing the importance of engaging patients as early as possible—starting in the translational phase, even before clinical trials
- **EMA's reflection paper on PED⁸**, which explicitly calls for the systematic consideration of PED from the earliest stages of medicines development

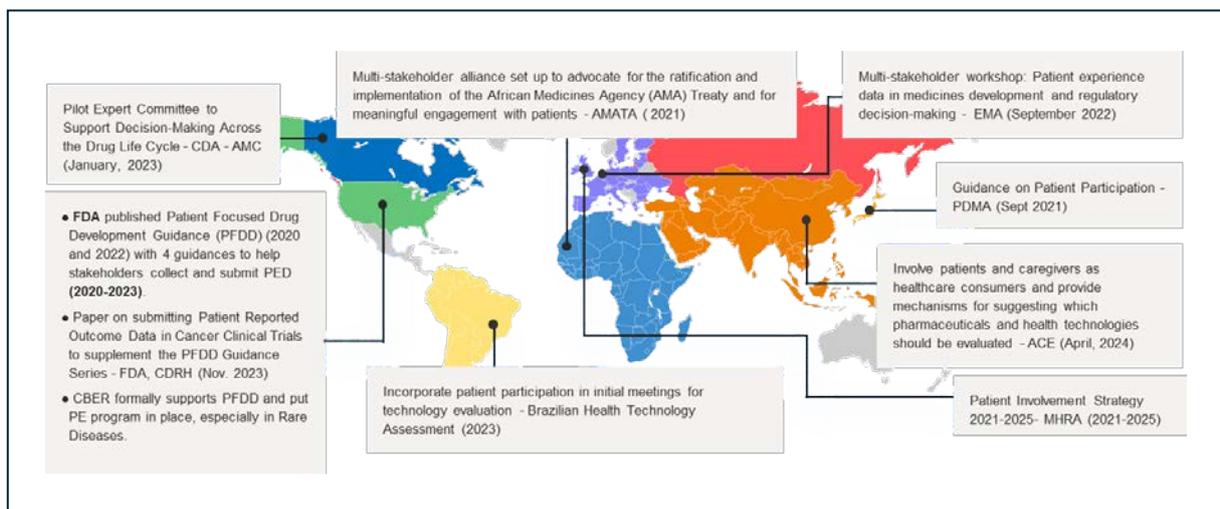


Figure 3: Regulators and HTAs Are Increasing Considerations of PE and PED

- Bertelsen N, Oehrlein E, Lewis B, Westrich-Robertson T, Elliott J, Willgoss T, et al. Patient engagement and patient experience data in regulatory review and health technology assessment: where are we today? *Ther Innov Regul Sci.* 2025 Jul;59(4):737–752. doi:10.1007/s43441-025-00770-6
- Bertelsen N, Dewulf L, Ferrè S, et al. Patient engagement and patient experience data in regulatory review and health technology assessment: a global landscape review. *Ther Innov Regul Sci.* 2024;58:63–78. doi:10.1007/s43441-023-00573-7
- US Food and Drug Administration. Patient-focused drug development: workshop #2 to discuss methodologic and other challenges related to patient experience data; 2025 Sep 18–19. Available from: <https://www.fda.gov>. Accessed 2026 Jan 18.
- European Medicines Agency. Patient experience data (PED): reflection paper. Amsterdam: EMA. Available from: <https://www.ema.europa.eu/en/patient-experience-data-ped-reflection-paper>. Accessed 2026 Jan 18.

Across regulatory and HTA systems globally (Figure 3), there is a growing recognition that early patient input supports better planning, more relevant evidence generation, and ultimately better alignment with unmet patient needs.

Notably, the investment community is also paying closer attention to PE and PED, recognizing their role in de-risking investment decisions and strengthening long-term value.

4. Barriers That Still Need to Be Addressed

Despite this progress, significant challenges remain (Figure 4), including:

- Limited recognition of the role of patient organizations
- Insufficient integration between PE and PED
- Uncertainty about regulatory and HTA expectations

These gaps highlight the need for clearer frameworks, shared language, and practical tools

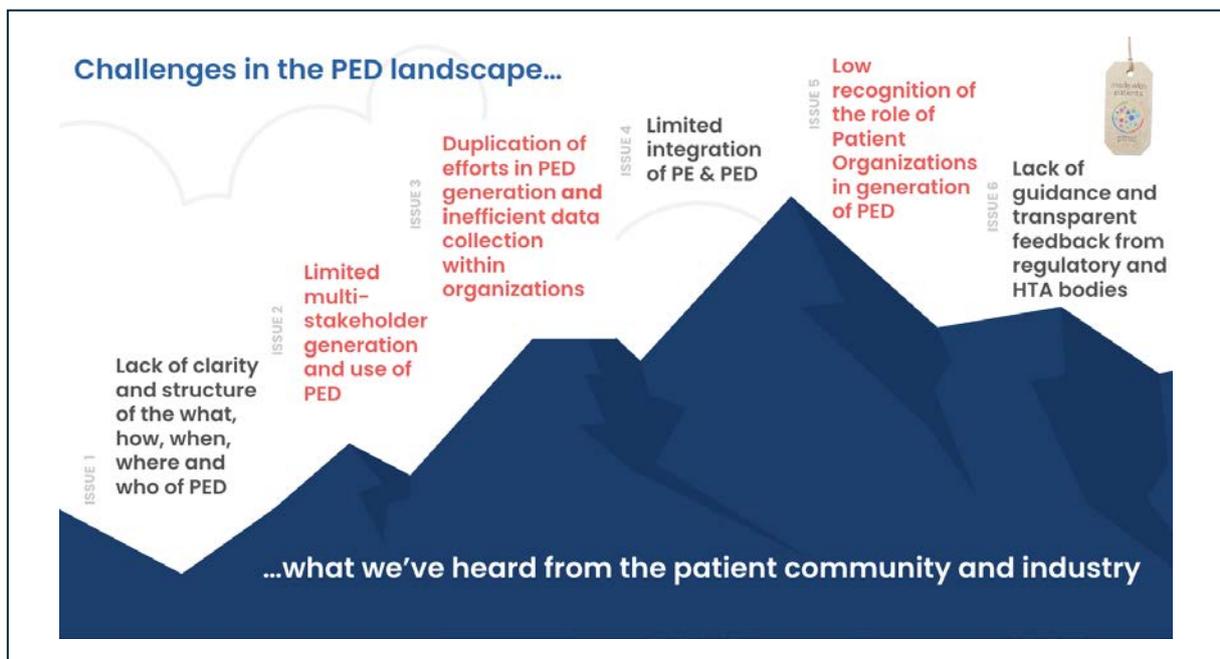


Figure 4: Barriers to PE and PED in Regulatory and HTA Decision-Making

PFMD's Contribution: From Principles to Practice

PFMD's collective efforts on PE and PED directly addresses these challenges by focusing on four core principles:

1. Integrating PE across all stages of PED from design to dissemination
2. Measuring what matters most to patients as the foundation of PED
3. Co-developing and using PED for evidence-based decision-making across stakeholders
4. Streamlining PED collection and use across industry, patient organizations and others for

efficiency and impact

This project has engaged over five hundred individuals from more than fifty organizations, contributing to shared resources and publications that aim to bring greater clarity and consistency to the field.

5. The Global PED Navigator: A Practical Response

One key PFMD resource is the Global PED Navigator, co-created to support practical implementation. Originally developed in English, it is now also available in Japanese

The Navigator helps users answer five essential questions:

- What matters most to patients?
- How is it measured?
- Who is involved?
- When is PED used?
- Why is it being used?

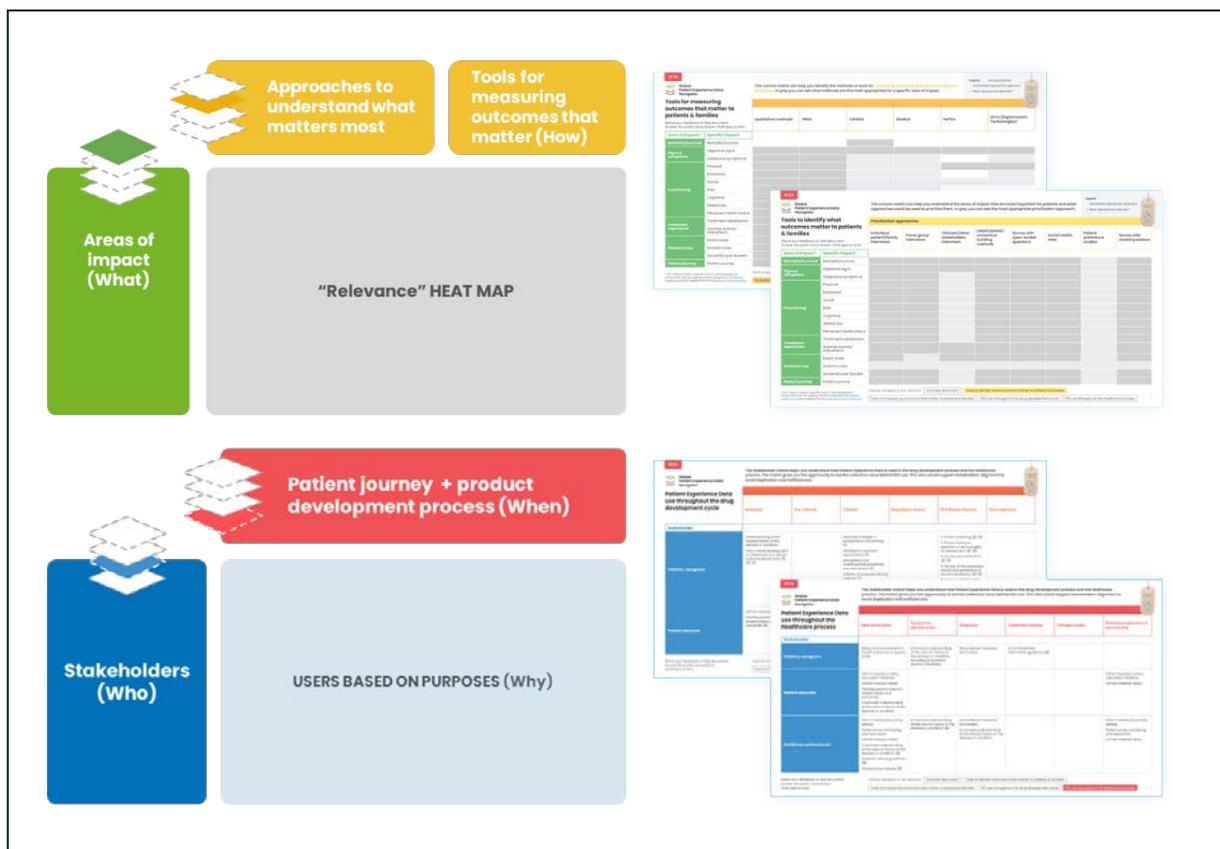


Figure 5: Global PED Navigator Consists of Four Templates

It consists of four interconnected templates (Figure 5):

- Identifying areas of patient impact

- Mapping measurement approaches and methodologies
- Understanding stakeholder involvement
- Clarifying when PED informs decision-making across the patient journey

The working group has also defined four key stages of PED:

1. Design and planning
2. Data generation and collection
3. Analysis and interpretation
4. Communication and use (Figure 6)

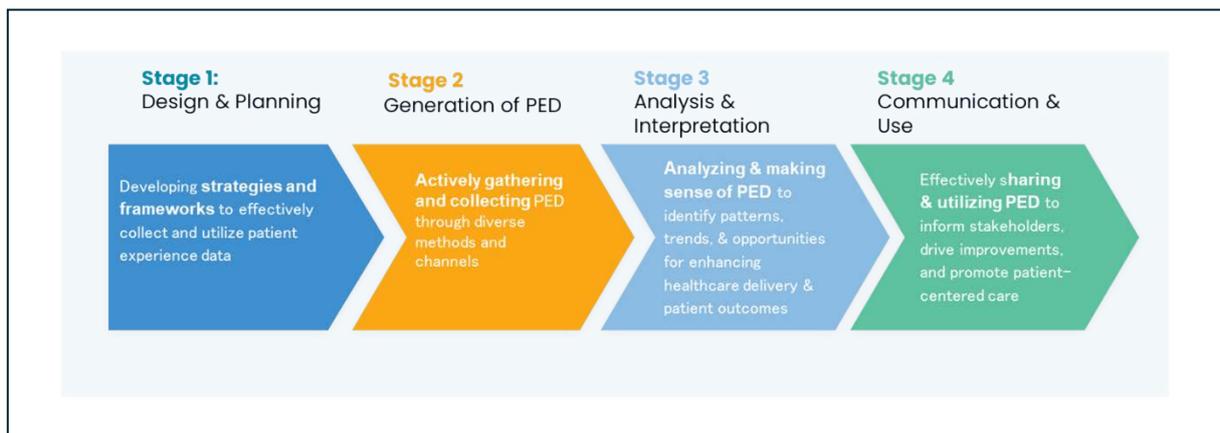


Figure 6: Four Stages in Generation and Use of PED

At each stage, there are specific opportunities for PE. Building on this, PFMD is now co-creating an Integrated PE and PED Navigator to recommend engagement activities aligned with each PED stage.

Additional work focuses on broadening areas of impact—such as emotional and social functioning and caregiver burden—and considering societal impact, particularly from an HTA perspective.

6. Empowering the PE Community in Japan and Aisa-Pacific

Finally, there has been strong and growing engagement from the Asia-Pacific community, with active participation in global initiatives.

This has enabled:

- Translation of key PE tools and resources
- Webinars, virtual sessions, and in-person meetings
- Regionally relevant discussions tailored to Japan and the broader Asia-Pacific context (Figure 7).

Together, these efforts are helping to strengthen local capacity while contributing to a more aligned global approach to PE and PED.



Figure 7: PFMD's PE Toolkit Available in Japanese

Behind the Keynote—Live Q&A

Quality is a key to implement PED in clinical trial, but how is it ensured?

- It is very challenging and what regulators are now saying are “come and talk to us early”, which makes sense for the particular clinical trial and the product that is in development, and this is from an industry perspective. Besides, there is also incredible work being done by patient organizations, identifying methods and tools that can be used to complement the work that has been done previously. An example of GlobalSkin was to develop their own PRO⁹, which it went through a very comprehensive process to ensure that the patients were defining it themselves. And now it is being recognized as a validated robust tool.

How do we engage with the patient community to pull forward PE and PED?

- It depends on the patient organization and community as there are different levels of maturity. Capacity and capability need to be considered. The PE and PED integrated navigator will provide recommendations or suggestions on a number of different activities including a self-assessment tool to better understand the situation. Have you ever done any type of PE before? Are you a small organization or a large organization? A pharmaceutical company? What are the resources and the

9 GlobalSkin. PRIDD Tool [Internet]. GlobalSkin.org; 2024 [cited 2025 Jan 18]. Available from: <https://globalskin.org/research/pridd>

capacity to be able to do this? Those answers act as filters on all of the different activities. It is important is to start small and gradually build strength and increase experience, not to set your sights too high.

Are there any advantages to submit PED for new drug approval?

- Currently, PED is not mandated anywhere globally through either regulatory or HTA processes. It is up to you to include it. The MHRA in the UK once proposed making it mandatory. It lasted for about six months, but then they removed it, because they felt that making it mandatory would turn it into a tick-box exercise—just “yes, we’ve done it,” with no consideration for quality or what it actually means. More recently, regulatory submissions in the US FDA, the EMA, and the HTA process in Canada highly recommend that PED is included. What’s interesting, though, is that both the FDA and EMA have said: if you start having those conversations early on, and we can build our confidence through this process that the patient voice has been integrated, then you may not need to do a large PED study around Phase 3 for submission. If sufficient engagement and involvement have occurred through early dialogue and early clinical trial phases, the patient voice has already been included and integrated, and there may be no further need for additional PED studies.
- From a regulatory perspective, the focus is primarily on safety and efficacy. If a product is not safe or not effective, no amount of PED will change the decision. However, if an assessor is provided with PED, and all other things being equal, the product is safe and effective, PED can influence the balance. There is evidence to suggest that at the HTA level, when a product has already been shown to be safe and effective, PED can make a significant difference in terms of access and availability, because the data can be compelling—it can make a substantial impact on patients’ lives, caregivers’ lives, productivity, and other areas. Ultimately, PED can also show a greater societal impact.

Is there data from which we can learn to what extent PED has been included in submission?

- There is data. Both the FDA and EMA have published reports. The challenge for the FDA is that they often do not know where to find the data when it comes from companies—either because it is not labelled correctly in the submitted files, or because it is not clearly indicated where the data can be found, what question you were trying to answer, and what the data shows.

Opportunities for Systematic Approaches and Immediate Cases, and Next Steps: PE and PED in Japan

The roundtable subsequently explored the current landscape of PE and identified opportunities to enhance an understanding of PED and implement PE and PED systematically. PED has emerged as an essential component of patient-focused drug development and healthcare system. As structured and robust insights into patients’ experiences and perspectives on diseases, treatments, and outcomes,



PED can be integrated into clinical development, regulatory evaluation, health technology assessment (HTA), clinical practice, and health policy making. This integration enables the development of more patient-centered healthcare innovations, a trend increasingly observed in North America and Europe. In Japan, awareness of PED has gradually increased recently; however, systematic implementation that ensures engagement with the patient community remains suboptimal. The roundtable highlighted opportunities for structured approaches to PED in Japan, emphasizing the need for actionable strategies to move from conceptual understanding to practical implementation.

The adoption of PED and the extent of PE vary in scope and depth among stakeholders and organizations. Nevertheless, there is consensus that with structured approaches, clear objectives, measurable outcomes, and integration of PE at each stage of PED generation and utilization, PED can be robust and valid for patient-centered decision-making in drug development and healthcare evaluation. Participants further emphasized that patient perspectives should be operationalized into concrete, actionable points, such as the disease's impact on daily life, treatment side effects, and patient priorities. Clearly defining the types of patient input to collect enhances the effectiveness of engagement and ensures that insights inform decisions.

One immediate opportunity identified was early-phase engagement in drug development, including formulation of the target product profile (TPP) and planning of clinical development programs. Early engagement allows patient experience to inform the identification of patient-relevant endpoints,

assessment of patient burden, and optimization of subsequent clinical trials. While some practices are already applied during protocol preparation, integrating patient insights earlier—before the clinical phase begins—can make clinical trials more patient-centered, efficient, and aligned with real-world needs.



The discussion also emphasized the need to train researchers and healthcare professionals in PE. Non-clinical researchers often focus narrowly on substance-level outcomes, overlooking patient-centered perspectives. Integrating PED into early strategic planning requires researchers to understand patient needs and priorities, ensuring that early development decisions reflect the real-world impact of interventions.

Participants also discussed extending PED beyond clinical trial design. Incorporating patient insights into regulatory review, HTA, and clinical practice can improve understanding of treatment benefits, tolerability, and burden in real-world settings. However, Japan currently lacks systematic mechanisms to integrate these insights into such decision-making processes.

Another critical topic was the importance of documenting and publishing PED initiatives. Much of Japan's PED activity remains internal, limiting visibility and preventing broader adoption. Publications serve as credible evidence validating methodologies, demonstrating practical impact, and facilitating dissemination to stakeholders. Reports should capture not only data but also the consequences of PE, showing how patient input directly improves study design, including endpoint selection and operational feasibility, reduces the burden of participation, and enhances the relevance and quality of study outcomes. Such dissemination will increase understanding the value of PE and PED as essential for healthcare decision-making.

Transparency and feedback mechanisms were repeatedly emphasized. In Japan, patient input is often collected but rarely accompanied by communication regarding how it was used, which diminishes trust and limits further engagement. By contrast, international practices demonstrate

structured feedback, where organizations communicate which suggestions were implemented and provide explanations for those not implemented. Implementing similar mechanisms in Japan is essential for sustainable PED integration.

Next Steps

Building on the discussion of opportunities and immediate examples, participants identified several priority actions to advance systematic PED implementation in Japan.

First, structured frameworks for PED collection, analysis, and integration must be established. These frameworks should define objectives, methods, and reporting standards to ensure that patient insights are systematically captured and translated into actionable outcomes. The framework developed by PFMD, emphasizing planning, analysis, reporting, and communication, as well as the Global PED Navigator or the enhanced PE and PED Integrated Navigator, were cited as practical assets. Patient organizations should be supported to provide concrete, actionable feedback on treatment burden, disease impact, and healthcare priorities. Together, these efforts will foster a culture in which PED is systematically applied and valued across all stages of healthcare development and decision-making, rather than relying on fragmented practices of collecting feedback from a few patients. A comprehensive learning and hands-on program should be developed to reflect the local healthcare environment and sociocultural context.

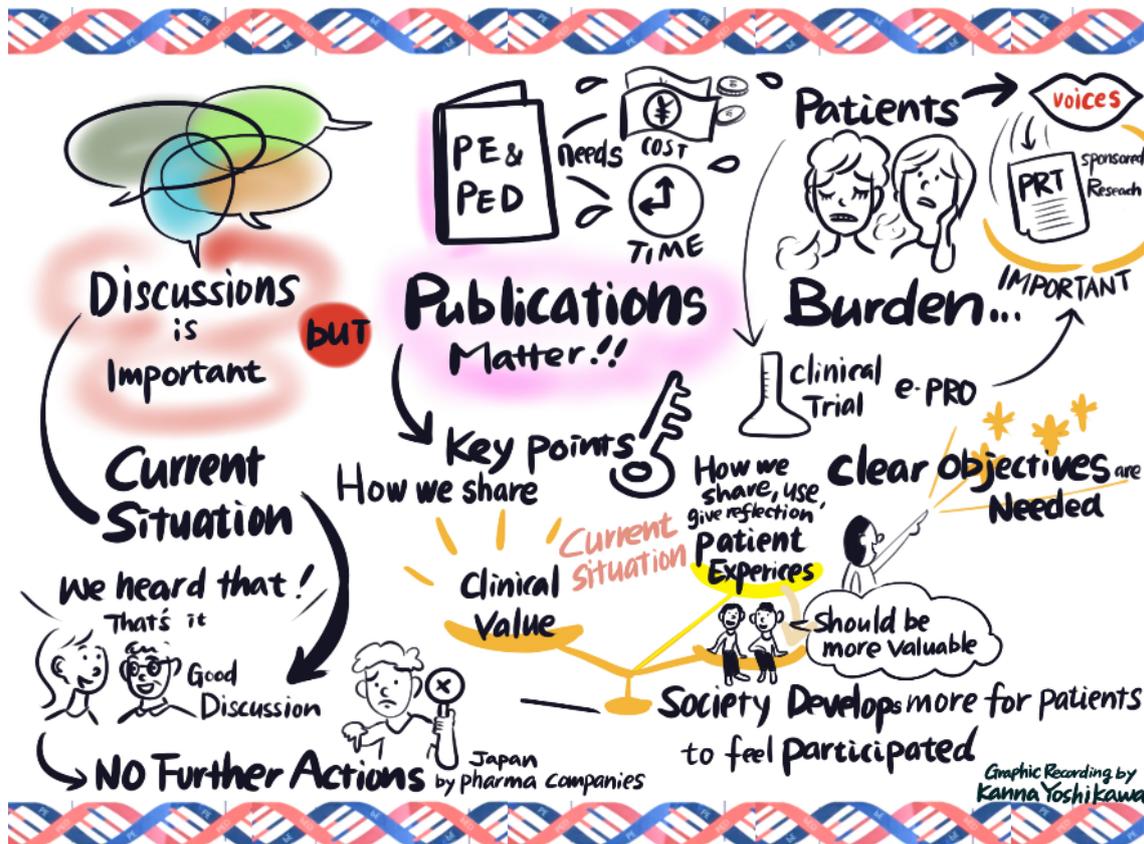
Second, dissemination of case studies and publications is essential. Reporting should document both patient data collected and the consequences of engagement, such as improvements in study recruitment and study participants' satisfaction. Such publications not only validate PED practices but also provide replicable models for other organizations to adopt.

Third, transparent feedback and communication mechanisms must always be implemented. Patients should be informed about how their input was considered, which suggestions were incorporated, and the rationale for decisions not implemented. Providing this information fosters trust, encourages further engagement, and ensures that patient insights are valid and meaningful for healthcare decisions. Feedback loops should extend across different stakeholders and organizations to optimize PED generation and use.

Fourth, PED should be applied early and continuously across the development lifecycle. From strategic planning and TPP formulation to protocol design, clinical execution, regulatory review, and HTA, early engagement allows patient priorities to shape decisions, enhancing trial relevance, efficiency, and quality. This approach reduces the need for resource-intensive efforts to generate PED at later stages. Capacity and capability building and cultural change are critical for all relevant stakeholders.

Finally, continuous multi-stakeholder dialogue is essential. Ongoing collaboration among industry, academia, regulatory authorities, and patient communities is necessary to refine PED methodologies, share best practices, and evaluate impact. Establishing regular platforms for discussion, knowledge

exchange, and feedback will ensure that PED evolves into a robust and sustainable tool for improving clinical development and healthcare programs in Japan.



Conclusion

Participants appreciated this first roundtable produced a forward-looking discussion and reaffirmed the importance of PE for generating and using robust PED. The roundtable concluded that advancing PED requires a combination of structured approaches, early and meaningful PE, transparent feedback, dissemination and publication of outcomes, capacity and capability building, and cultural change across all stakeholders. Participants endorsed continuing the initiative and emphasized the need for sustained dialogue and resources to further implement PED practices in Japan.

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The Roundtable Participants and the Onsite Organizing Team, 2025 Oct 18, AP Tokyo Yaesu



Meeting Highlight Reel