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The Patient Engagement Digital Roadmap: Co-Design Digital Health Solutions with People & Patients

The 'When, Why, and How' to Engage to Maximize Value

This document is a manual and guidance that will later be turned into a digital tool based on the feedback received in this open consultation. As with all PFMD tools, the PE Digital Roadmap will be openly accessible and free to use for all individuals.

INTRODUCTION

Digital health is the future. It has the potential to bolster traditional healthcare and improve health outcomes. From an electrocardiogram in your watch to preventative health applications, the possibilities to be empowered and take control of your own health are unlimited. However, despite what already exists, we're still not using digital health to its full potential - uptake has been low in clinical and research settings[1]. Why is this? Well, research highlights a disconnect between developing and implementing digital health tools and the patients they are created for[2].

Finding out what patients need and want requires meaningful and effective Patient Engagement (PE), but knowing how to do PE is not always clear. This is because the digital landscape is complicated and involves numerous steps, people, and organizations. After many interviews and Patient Engagement Open Forum (PEOF)[3] sessions with the patient community, regulators, digital stakeholders, and more, there was a clear call to action to create guidance to support better implementation of PE in digital.

Created together in a multi-stakeholder group and with digital stakeholders, the PFMD[4] **PE Digital Roadmap** aims to clarify the role of the patient community in designing and developing digital health solutions by establishing a step-by-step framework that showcases 'how to implement' and 'the value of' good patient engagement.Adapting the Patient Engagement Quality Guidance for medicines development to the digital health space, this frame will support meaningful implementation, increase acceptance of new digital solutions, enhance compliance, and ultimately lead to better health outcomes.
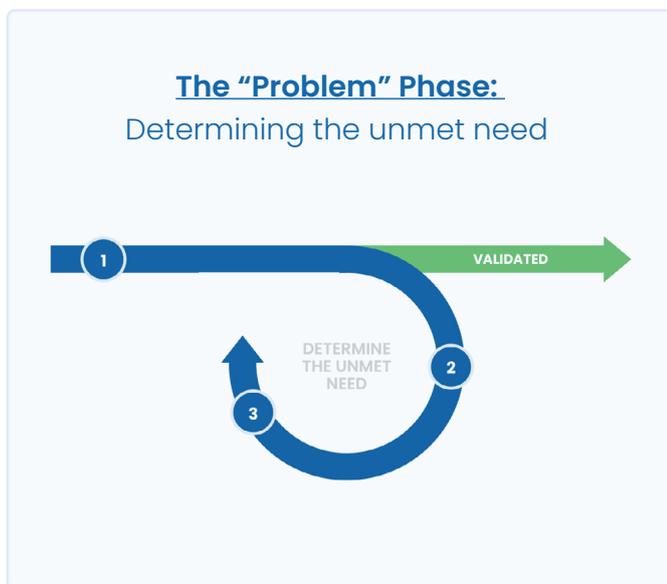

Patient Engagement Quality Criteria: 01 Shared purpose, 02 Respect and accessibility, 03 Representativeness of stakeholders, 04 Roles and responsibilities, 05 Capacity and capability for engagement, 06 Transparency in communication and documentation, 07 Continuity and sustainability — QUALITY

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8139413/

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10294099/

[3] The Patient Engagement Open Forum (PEOF) is a forum, co-organized by PFMD, EPF, and EUPATI, for co-creating ongoing initiatives in Patient Engagement. Find out more about the virtual and in-person sessions here.

[4] Established in 2015, PFMD is a global collaborative aiming to improve global health by co-designing the future of healthcare for patients WITH patients. Find out more at PFMD.org

The PE Digital Roadmap:

Based on the Patient Engagement Quality Guidance, and pulling insights from Design Thinking, The Lean Startup, there are 2 phases to designing an inclusive and patient-focused digital health solution for patients WITH patients:

The "Problem" Phase:
Determining the unmet need

1

VALIDATED

DETERMINE
THE UNMET
NEED

2

3

The "Solution" Phase:
Co-developing the solution

Learn → Ideas

Data

CO-DESIGN
THE SOLUTION

Build

Measure ← Product

Who can benefit from the PE Digital Roadmap:

Anyone creating a digital tool: To support the product design and development of a digital health solution, such as a start-up, application, digital therapeutic, or medical device.

Investors or companies looking to purchase/ implement a digital solution: Use this guidance to evaluate the level of patient engagement done to predict successful adoption and market impact.

Patient Organizations (POs): To better understand how engagement can shape digital health solutions and the benefits of participating in these processes.

What's next?

1. Review the PE Digital Roadmap.

2. Then, **take the survey** to share your feedback on the content, usability, and format of the roadmap. This should take less than 10 minutes!

3. For any questions, please email Aurora Lancha at **aurora@thesynergist.org**

Scan the QR Code or copy the bit.ly in the search bar
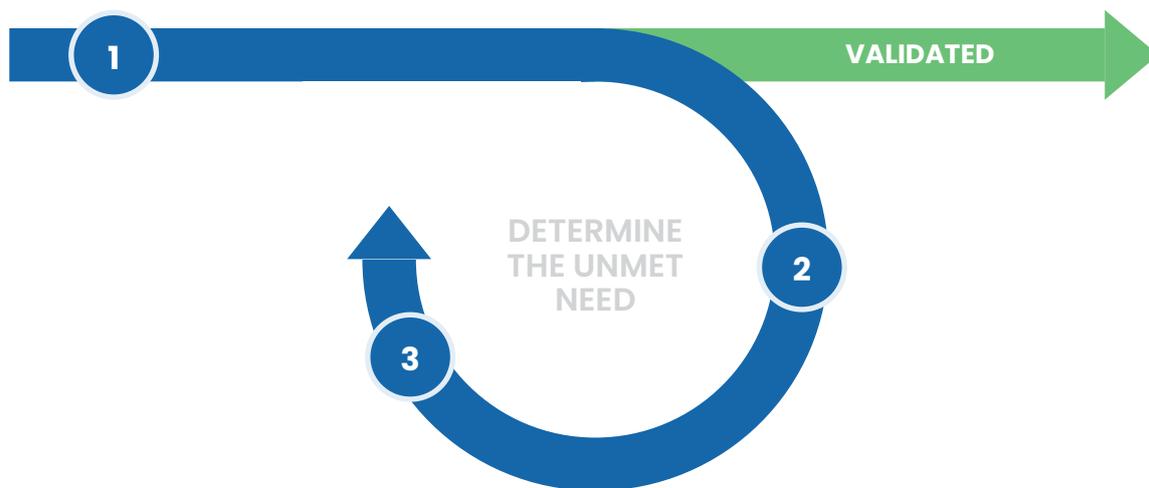
www.surveymonkey.com/r/Q2V6BHH

Specific value of PE in this phase:

Engaging patients in this phase ensures the insights gathered are relevant and accurate, the identified pain points are genuine and meaningful, and the validation process builds consensus and buy-in, leading to more effective and embraced solutions.

1

Gather insights & understanding

This can be done in a variety of ways including:

- Patient journey mapping with patients
- Design of data analysis and social media listening with patients;
- Contacting patient organizations for advice & input;
- Interviews & establishment of focus groups and patient advisory working groups;
- PEOF virtual sessions to engage and ask questions to the community
- Co-develop questions with the target patient population
- Incorporate a patient advocate on the research and development team
- Collaborate with patients to identify the most effective channels for gathering data

2

Define pain points & unmet needs

Identify the quality of life-related purpose, the gaps, needs, and patient perspectives. Determine which you want to address.

3

Validate pain points & unmet needs with key stakeholders and potential users

Involve the patient community to confirm pain points & unmet needs.

Continue the cycle until the unmet need is clear & validated with patients

Once the unmet need is validated, proceed to the 'solution phase' to address the pain point & need.
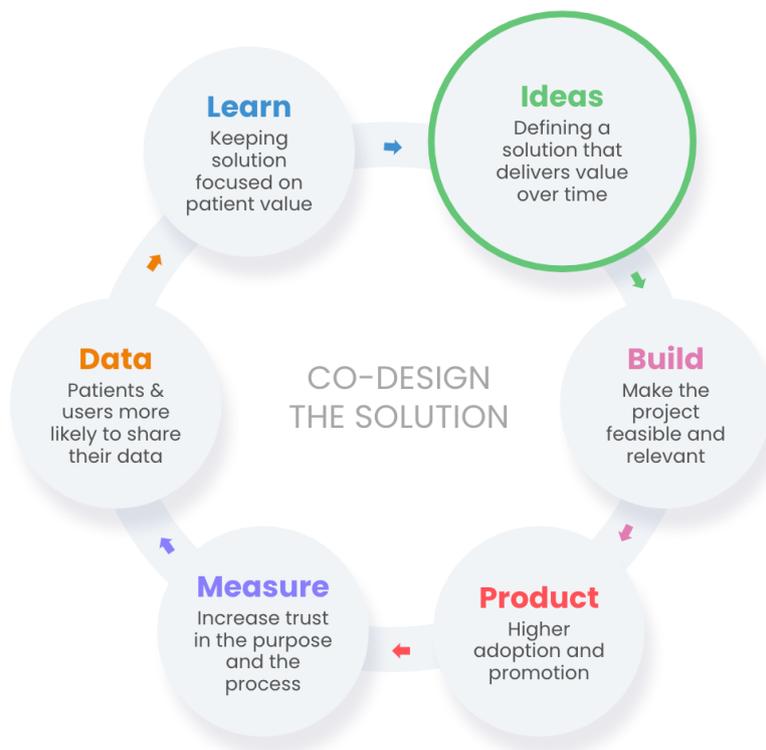
Specific value of PE in this phase:

Engaging with patients throughout the development process fosters trust in the co-designed solution, laying a robust foundation for product launch and uptake. Patient insights drive innovation, ensuring the solutions are aligned with real needs and are more effective than the current standard of care. The lean start-up methodology provides a great structure for development, as the process aims at "eliminating uncertainty." When combined with meaningful patient engagement, it also creates a base of users who are ready to engage with your product before it has even launched.
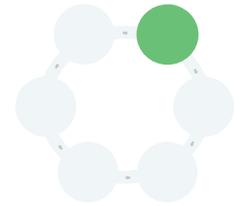
What you need to know:

- This phase is **designed to be flexible and can be tailored to the specific needs** of your digital health solution. The approach emphasizes incremental PE to enhance value over time, allowing for continuous improvement and adaptation throughout the different iterations of the development cycle and going through the loop as many times as necessary.

- Remember **to consider the type of product you want to develop** to ensure you observe the appropriate regulatory requirements. This process applies to medical devices and digital therapeutics, where effective Patient Engagement can "better inform medical product development and regulatory decision-making"[5].

Click to navigate to each section

Learn — Keeping solution focused on patient value

Ideas — Defining a solution that delivers value over time

Build — Make the project feasible and relevant

Product — Higher adoption and promotion

Measure — Increase trust in the purpose and the process

Data — Patients & users more likely to share their data

CO-DESIGN THE SOLUTION

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5 https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

Define a Solution that Delivers Value over time for Patients

Once the unmet need has been validated, the ideas step is where you start looking for and validating solutions!

Value of PE:
The value of PE in this step is to **ensure you are seeing the full picture and understanding what you may not know about your target audience**. This is the perfect time to engage with patients, patient organizations, patient advocates, caregivers, and HCPs to determine what kind of solutions would work and where they can add value to development. Engaging at this step will ensure you see future mishaps before they happen, saving you time, money, and effort - all things that should be conserved when starting a project!

Risk of no PE:
Without PE, the solution may address irrelevant or secondary needs, leading to poor alignment with what patients truly value, resulting in wasted resources and low engagement from the outset.

Roles the patient community can play:

- Understand how PE can add value throughout development and who is best to involve

- Patient Organizations can match your needs with patient champions and advocates who can add the most value to your project

- Determine what is important to the patient and where specifically they want to engage

- Brainstorm solutions and help you understand why proposed solutions may or may not work

- Share actual lived experience, and discover other potential outcomes with related stakeholder opinions (HCPs, Carers, etc)

- Patient organizations can support matching unmet needs with research by utilizing patient registries, databases, etc.

What to do to Engage here?

- Contact patient organizations related to the target patient population or umbrella organizations such as the European Patients Forum, National Health Council, and International Alliance of Patients' Organizations to identify advocates who can provide diverse insights throughout the idea-generation process

- Generate and refine ideas with a broad patient base, either in individual interviews or group workshops, in order to establish a **shared purpose**[6] and ensure **representativeness**[7].

- Select and onboard patient representatives[8] and include them in decision-making, such as on a research team (not just for feedback, review, or as beta-testers)

- Document patient interactions, goals and expectations starting now to ensure transparency in the PE process

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[6] PEQG Criteria 1 - Shared purpose: This refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project

[7] PEQG Criteria 3 - Representativeness of stakeholders: This refers to the mix of people you involve, which should reflect the needs of the project, and the interests of those who may benefit from project outputs (for example, target population).

[8] Consider the PFMD Fair Market Value Tools for PE activities remuneration
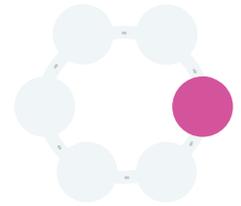
Empower patients/caregivers to manage their health better and easier with the new digital solution

Once you have defined the type of digital solution you will develop, it's time to start building your Minimum Viable Product (MVP) in co-design with patients. The MVP should be the bare minimum required to align with patient capabilities and expectations.

Value of PE:
During the build phase, PE ensures that the product's design and functionality are tailored to patient capabilities and real-world use, resulting in a solution that is both practical and effective in daily life.

Risk of no PE:
Skipping PE here could result in a product that is difficult for patients to use or that fails to address their daily challenges, leading to low adoption and frustration.

Roles the patient community can play:

- Engage with patient experts, patient organizations, and HCPs to ensure that the back-end technology supports the previously validated unmet needs and that the front-end is user-friendly.

- Determine digital health literacy needs to ensure the target patients can effectively engage with the solution.

- Ensure the solution is built with sufficient transparency and feedback mechanisms according to the patient/end-user from the beginning

- Start to articulate data governance framework needs

What to do to Engage here?

- Co-create the development process with patient experts to ensure PE is built into your roadmap & budget[9]

- Establish a Patient Advisory Board, and validate with them the roadmap for the development process, including the different engagement activities to involve them as project partners, ensuring **inclusive participation and respectful interactions**[10]

- Conduct workshops with patients and the developers so they can participate in usability testing to validate the functionalities

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[9] Check out PFMD legal and contractual tools. These will help you in the development of reasonable legal agreements and contract templates, as well as support you in understanding the Country Codes of Conduct and other regulation that impact interactions between pharmaceutical companies and the patient community

[10] PEQG Criteria 2 - Respect and accessibility: This refers to (1) respecting each other, and respectful interactions within the project to be established among partners, and (2) openness to and inclusion of individuals and communities (to the project) without discrimination.
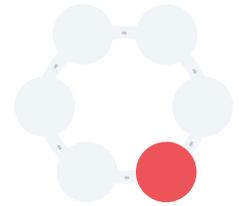
Higher adoption and promotion within the patient community

The product step is where you experiment and validate your MVP! Your MVP should represent the essential core of your solution, allowing you to test it early in the development lifecycle.

Value of PE:
Increase the potential for widespread adoption and adherence. PE helps refine the product by testing it with real users, ensuring that it is not only usable but also highly valued and recommended within patient communities, driving organic growth and adoption.

Risk of no PE:
Without this validation, the product may face poor reception and adoption, as unaddressed usability issues or unmet expectations emerge, damaging both the product's reputation and its market potential.

Roles the patient community can play:

- Prototype and MVP decision-making & testing

- Key usability testers in front-end UX design, including content, visual design, readability, language, dissemination channels, interoperability, Interfaces and innovative features, accessibility, etc.

- Help determine patient user scenarios & personas ensuring the product is deeply aligned with the real needs and experiences of diverse patient groups.

What to do to Engage here?

- Implement training programs to support patients in building **skills and knowledge**[11] so they are well informed to take their role in testing the design, and they understand the different features that are being tested

- Organize focus groups and panels, using both previous and new participants, to conduct pilot tests to refine the MVP and ensure it is fit for purpose

- Launch a survey for patients to further assess digital health literacy needs with other groups of patients to be able to anticipate future challenges not currently discovered with your patients' partners

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[11] PEQG Criteria 5 - Capacity and capacibility for engagement: This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (for example, providing a dedicated point of contact by the sponsor and having allocated sufficient time by all stakeholders to allow genuine engagement); and (2) capabilities for all stakeholders to enable meaningful engagement (for example, the level of knowledge, expertise and training stakeholders might need to deliver PE activities throughout the project).
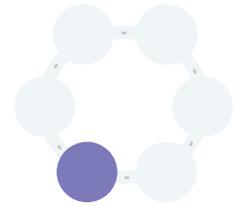
Increase trust in the purpose and the process

The measuring step is where you should gather information and data that will allow you to draw conclusions about your product's success in upcoming iterations—determining 'what to measure.' This is a key step for engagement so you understand what information and "metrics" are important to the patient community!

Value of PE:
Engaging patients in defining success metrics ensures that the evaluation criteria are meaningful to them, which increases their trust in the product and the company behind it. This trust translates into sustained usage and positive word-of-mouth.

Risk of no PE:
If patient perspectives are not considered, the metrics used may be irrelevant to them, leading to a disconnect that could erode trust and make it harder to maintain engagement over time.

Roles the patient community can play:

- Determine Key Performance Indicators (KPIs) to demonstrate value to patients & other users, and measure health outcomes

- Rate patients' expectations before and their experience upon completion

- Evaluate product usage for individual health and explore benchmarking reports

- Better understand demographics of target patient population compared to reach of the product

What to do to Engage here?

- Gather patient feedback on what metrics are important to them through surveys, co-creation workshops, or advisory boards and validate it with a focus group

- Create a comprehensive communication plan and ongoing project documentation that is **accessible to all stakeholders[12]**: to ensure transparency, and regularly update stakeholders and patient groups involved about project progress, metrics, and findings

- To ensure patients' perspectives are considered, include them in the analysis of data and metrics. You could do this with the previously established Patient Advisory Board

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[12] PEQG Criteria 6 - Transparency in communication and documentation: This refers to the establishment of communications plan and ongoing project documentation that can be shared with stakeholders. Communication among stakeholders must be open, honest and complete.
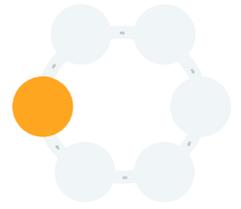
Patients & users more likely to share their data

Following the measurement (essential for improvement throughout the iterations), a crucial step involves defining the solution's management of patient data—the 'how' you measure and share data with third parties. This phase is fundamental to sustaining patients' trust and involvement in the development process, learning and improving while being compliant with regulatory frameworks (such as GDPR).

Value of PE:
Patients willingly share data due to trust, enabling informed decision-making, innovation, and improved personalized medicine.

Risk of no PE:
This could lead to privacy concerns and reluctance to share data, limiting the potential for personalized treatments and innovation, and potentially leading to regulatory issues.

Roles the patient community can play:

- Discuss patient data ownership with patients

- Ensuring data is still accessible and usable when commercial interests and academic funding ends (sustainability)

- Ensure data privacy and the need of patients to remove their consent for their data to be used/ enable them to delete their data (Opt-in/Opt-out Options)

- Explore the role of patient organizations as health data fiduciaries providing analytics to all stakeholders on an aggregated data level

What to do to Engage here?

- Organise educational workshops for patients and stakeholders on data privacy and benefits to empower informed decisions

- Involve a group of patient experts in designing data systems to ensure usability and relevance, defining the roles and responsibilities. More specifically, clearly agreed-upon and ideally **co-created roles and responsibilities for data management, governance, and stewardship**[13]

- Form a data governance committee and include patient representatives in committees to align data policies with patient interests, and be transparent

- Review and update data policies regularly with patients' input to adapt to new regulations and needs

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[13] PEGQ Criteria 4 - Roles and responsibilities: This refers to the need for clearly agreed, and ideally co-created roles and responsibilities, in writing, addressing that all aspects of project (in this case data) needs will be established upfront and revisited regularly.
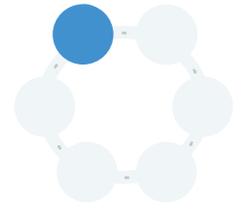
Keep the project focused on patient value as a priority

The learning step is the final point of a development iteration to ensure that the solution is under continuous improvement, efficiently addressing the initially identified problem/pain points for the patients and evolving in response to changing needs, ensuring relevance. It is all about taking your metrics and learnings to determine how to build a sustainable business. At the end of this step, you should have a clear understanding about whether to "pivot or persevere"[14].

Value of PE:
There is a continuous feedback loop with patients, ensuring that the product evolves in line with their needs and expectations, allowing for ongoing improvements that keep the product relevant and valuable.

Risk of no PE:
The product may stagnate, failing to adapt to changing patient needs, which could lead to decreased user satisfaction, lower adoption rates, and missed opportunities for future enhancements.

Roles the patient community can play:

- Determine training and technology supports needed for target users and patients
- Actively participate in continuous feedback loops, providing current and real-world insights and suggestions[14]
- A seat for patients, HCPs & carers at the table when overarching reviews of a 'system' are being conducted and to define new user requirements/ use cases for enhancements
- Discuss (future) re-use of data
- Ask for additional relevant analyses

What to do to Engage here?

- Include patient representatives in the committee that oversees ongoing development, to ensure alignment with patient needs, and foster a sense of ownership and accountability
- Hold workshops and training sessions to educate patients and stakeholders about the insights gained and how they will be applied to improve the solution
- Implement systems for ongoing patient feedback through surveys, interviews, and usability testing. This would have been done during the process, but now is the moment to ensure **their sustainability and continuity**[15] by nurturing those relationships

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[14] https://theleanstartup.com/principles

[15] PEQG Criteria 7 - Continuity and sustainability: This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationship with stakeholders.

"The Solution" Phase Summary

Click *here* for a printable version of the roadmap to use at your next patient engagement activity.

- Participate in feedback loops
- Include patients, HCPs & carers in system-wide reviews
- Ask for additional relevant analyses
- Ensure diversity, equity, and inclusion criteria as product evolves

- Understand how PE can add value throughout development (plan ahead for feedback loops, when to involve a PO, etc)
- Discover other potential outcomes with related stakeholder opinions (HCPs, Carers, etc)
- Match unmet needs with research

- Discuss patient data ownership and sharing dynamics
- Ensuring sustainability and reusability of data
- POs serve as health data fiduciaries providing analytics to all stakeholders on an aggregated data level
- Ensure patient data privacy and determine needs to revoke consent

Learn
Keeping solution focused on patient value

Ideas
Defining a solution that delivers value over time

CO-DESIGN THE SOLUTION

Data
Patients & users more likely to share their data

Build
Make the project feasible and relevant

Measure
Increase trust in the purpose and the process

Product
Higher adoption and promotion

- Ensure solution is built with sufficient transparency and feedback mechanisms according to the patient/end-user
- Determine data governance framework including patients
- Engage with patient experts, patient organizations, and HCPs to verify back-end technology supports goal need
- Determine Digital health literacy support

- Determine which KPIs to use to demonstrate value
- Understand demographics of target patient population & compare to reach of the product
- Evaluate product usage for individual health, explore benchmarking reports, and rate patients' expectations

- Use focus groups and panels for product feedback
- Prototype and MVP decision making & testing
- Key usability testers in front-end UX design
- Determine patient user scenarios & personas

What's next?

1. Review the PE Digital Roadmap.

2. Then, **take the survey** to share your feedback on the content, usability, and format of the roadmap. This should take less than 10 minutes!

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