MAPS Medical™ Affairs Professional Society
FOR Medical Affairs Professionals BY Medical Affairs Professionals

Patient Engagement and Patient Experience Data: Understanding Their Use in Medicines Regulation and Healthcare Decision Making and the Implications for Medical Affairs

Lumanity

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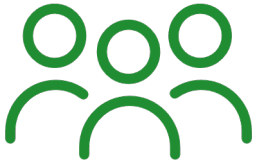
Housekeeping

A warm welcome to all!

This session is being recorded. Please mute your microphone when not speaking

Please ensure mobile phones are turned off or on silent throughout the meeting



If you need any assistance during the meeting, please message or email:
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Learning Objectives

Understand the importance of the role of Medical Affairs in creating meaningful and effective patient engagement

Share current best practice related to the use of patient engagement and patient experience data

Share insight on what patients and their advocates need from their industry partners for better patient engagement

Discuss how Medical Affairs is well positioned to support patient engagement and use of patient experience data post-launch

Agenda

Topic 1

Setting the Scene

Michael Parisi and Nicholas Brooke

Topic 2

Personal Perspectives: How is Medical Affairs Uniquely Placed to Explore Patient Engagement and Patient Experience Data

Whole panel discussion

Topic 3

Live Audience Q&A

Whole panel discussion

Topic 4

Concluding Remarks and Close

Michael Parisi

Topic 1 – Setting the Scene

Michael Parisi and Nicholas Brooke

Poll

Progress

Q1

Are you **personally involved** in patient engagement as part of your role?

Yes

No

Poll

Progress

Q2

Is there **alignment internally** on what patient experience data is used for and what it can help to inform?

Yes

No

PE and PED: Acceleration Continues in the Last 6 Months

October 2021

'Highlighting Recent Trends in the Fast-Evolving Patient Engagement (PE) & Patient Experience Data (PED) Landscape

PFMD
Made WITH Patients

January 2022

The Added Value of Patient Engagement in Early Dialogue at EMA: Scientific Advice as a Case Study

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

January 2022

360° HTA PATIENT INVOLVEMENT

HTAi
HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL

January 2022

FDA CDRH:

a) Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

b) Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation

FDA

January 2022

MHRA – Proposals for legislative changes for clinical trials

July 2022

"Building from Patient Experiences to Deliver Patient-Focused Healthcare Systems in Collaboration with Patients: A Call to Action

PFMD.org
Made WITH Patients

Sept 2022

Multi-stakeholder workshop: PED in medicines development and regulatory decision-making

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

May 2022

CADTH – Impact of Patient Involvement

cadth
Canada's Drug and Health Technology Agency

2019 (Translated 2022)

AMED – PPI Guidebook

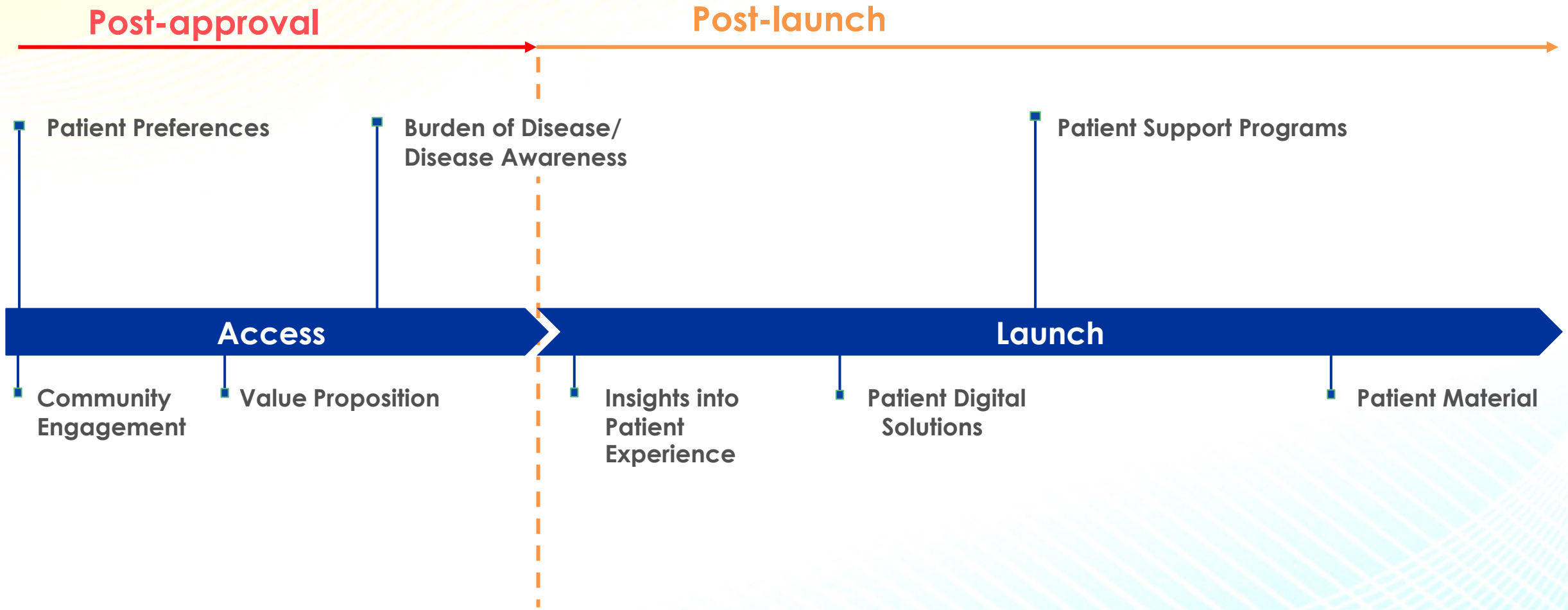
AMED
Japan Agency for Medical Research and Development

March 2022

NIHR – Shared commitment to public involvement

NHS
Health Research Authority

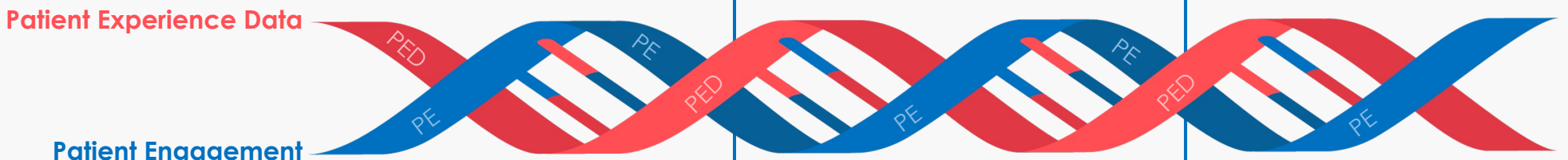
A Framework to Build on Solutions for PE in Post-launch



Adapted from Geissler J, Ryll B, di Priolo SL, et al. Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Ther Innov Regul Sci. 2017;51(5):612–679.

PE and PED Fusion: Meaningful PED Needs PE for Co-creation and Contextualization

Patient experience data does not "replace" patient engagement



Contextualize:

- Ensure patient participation in decision-making processes
- Provides context and understanding of the results

Co-create/Create:

- Ensures PED is focused on patient-meaningful topics
- Co-design evidence generation to ensure it is meaningful

Patient experience data needs patient engagement throughout

Both PE and PED Are Currently Used to Answer Patient-related Questions

Patient Experience Data		Patient Engagement
FDA Guidance on Patient Experience Data		**Questions during HTA Patient Engagement**
Signs and symptoms and impact on everyday life	⟷	Signs and symptoms and impact on everyday life
Changes in disease and its impact over time	⟷	Burden of disease
Experience with treatments and disease management approaches	⟷	Experience with current treatments and disease management approaches
Expectations and views and desired treatment outcomes	⟷	Expectations of the new treatment and its outcomes Perceptions of downsides of the new treatments
Trade-offs between outcomes, benefits, and risks	⟷	Potential impact (positive and negative) on family and caregivers

We've Heard of Challenges with PE and PED from Many Stakeholders

PATIENT ORGANIZATION

"**Clinical outcome assessments and patient preferences do not collectively reflect** all patient experience"

"We have the capacity to collect patient evidence, but **will it be considered?**"

"There is a **duplication of efforts**, with many parallel initiatives, and stakeholders that want similar things"

SPONSORS

"How are **other companies** defining and including PED and PE in their submissions?"

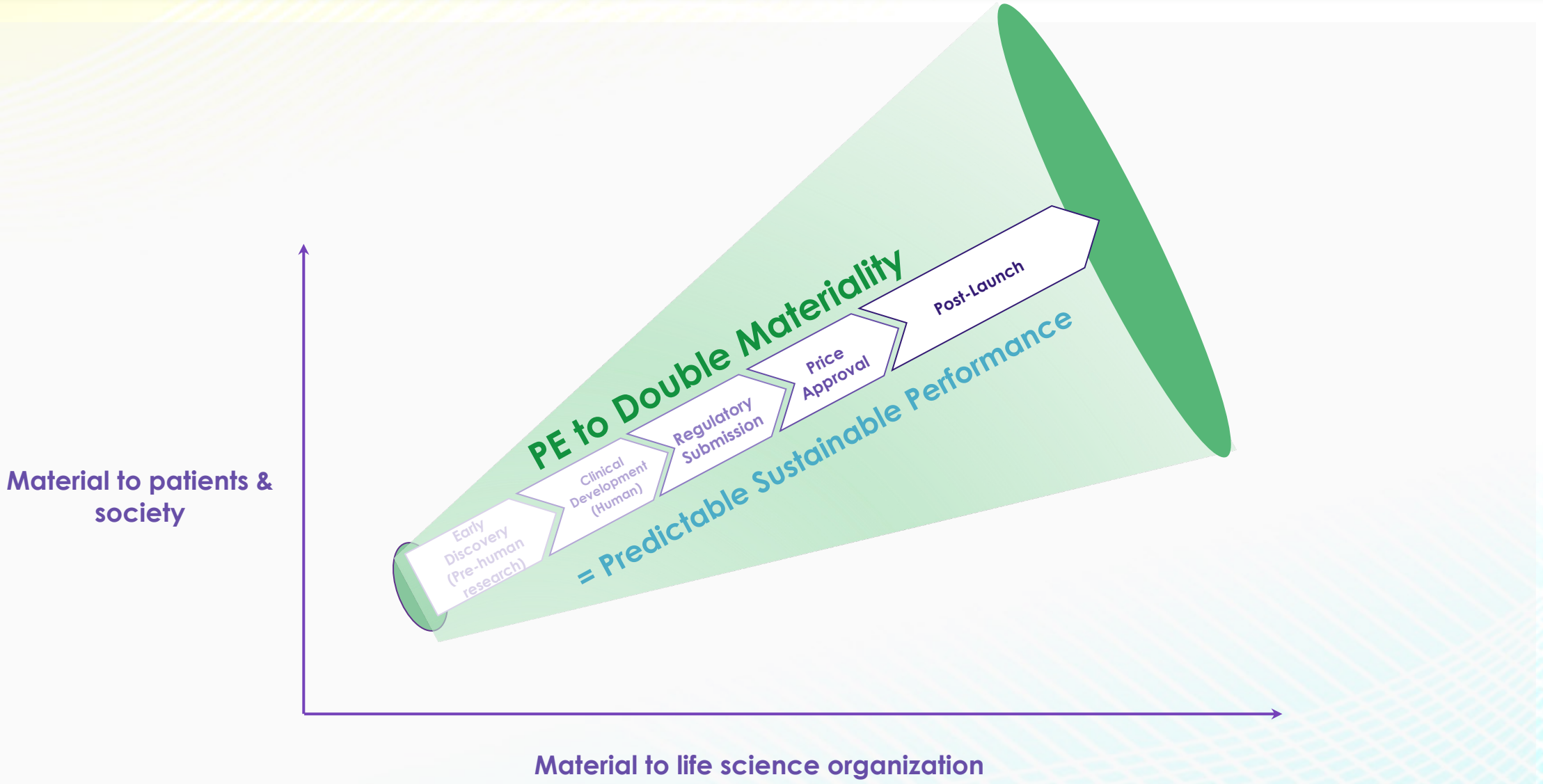
"The point of submitting PED is speculative as we are **not clear how it is being used or evaluated**"

REGULATORS

"We need to address the **disconnect between guidance and what is actually done** in practice"

"Diverse perspectives and opinions make PED difficult to define and a bigger picture is needed for collaboration"

PE initiatives can amplify the Cone of Double Materiality



Topic 2 – Personal Perspectives

Whole Panel Discussion

Personal Perspectives

Progress

Q1

Why is it important to not only collect patient experience data and insights, but to also **engage directly** with individuals with lived experiences?

Answers

Personal Perspectives

Q2

How do we **streamline patient engagement** and data collection in the industry?

Personal Perspectives

Q3

What are patient associations doing to **prepare for new regulation** in patient engagement, particularly in the post-launch period?

Personal Perspectives

Q4

What are the **common barriers** you experience when implementing patient engagement strategies, and how might Medical Affairs help to overcome these?

Personal Perspectives

Progress

Q5

What **resources or guidance** are available for Medical Affairs to better understand or address these barriers?

Answers

Personal Perspectives

Q6

What would be the **one thing** you would suggest to Medical Affairs colleagues to make a material difference in their organizations now?

Topic 3 – Live Audience Q&A

Whole panel discussion

Topic 4 – Concluding Remarks and Close

Michael Parisi and Nicholas Brooke

Personal Perspectives

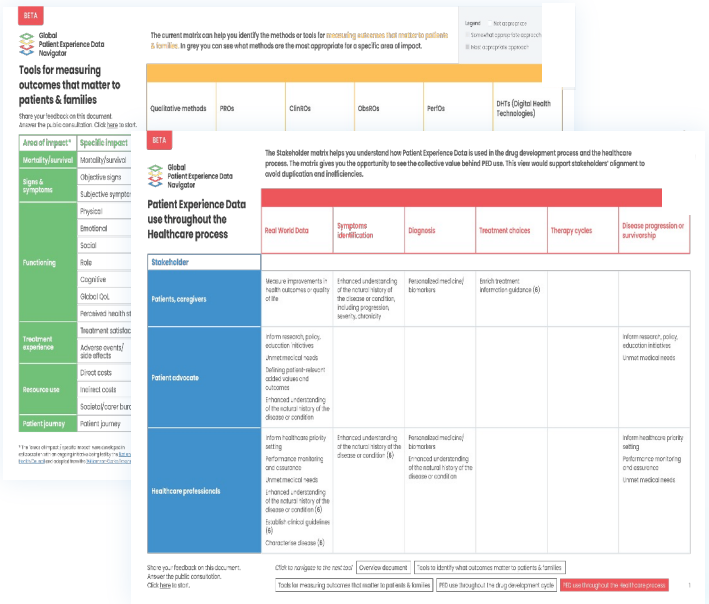
Q7

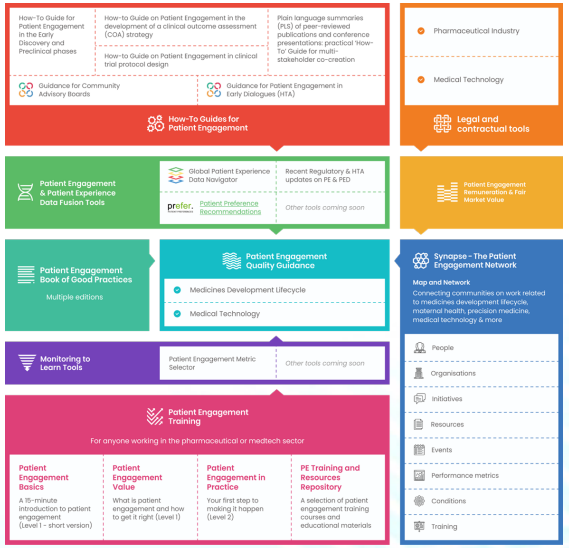
What resources or guidance are available for Medical Affairs to better understand the topics or address the barriers?

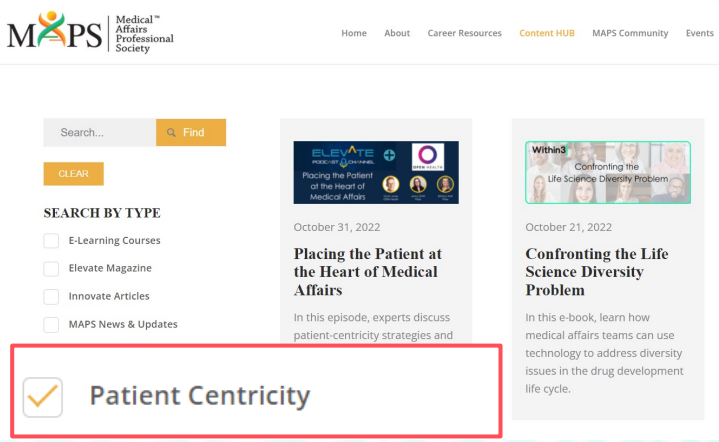
Answers

Recommended tools to aid patient engagement implementation

- **Patient Engagement Management Suite** PEMsuite.org
- **Global PED navigator** (via PEMsuite)
- **MAPS website** – Content Hub (search by Patient Centricity) medicalaffairs.org/content-hub
- **National Health Council (NHC)** - Resources nationalhealthcouncil.org/resources







Closing Poll

Progress

Q1

Do you feel **more confident**
to become personally involved
in patient engagement
as part of your role?

Yes

No

Closing Poll

Progress

Q2

Can you see a role for Medical Affairs in **driving patient engagement** and patient experience data in your organization?

Yes

No

Thank you!