



# Leveraging Patient Experience Mapping to Drive Regulatory Success and Market Value

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Innovative Solutions that Enhance Patient-Enabled Trials

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# Patient Experience Data

01

**Patient Experience Data (PXD)** is transitioning from supplementary context to core regulatory evidence in conditions where patient-centered outcomes drive benefit-risk assessments.

02

The FDA's PFDD guidance documents and EMA's [Reflection Paper on Patient Experience Data](#), combined with multi-stakeholder tools, are creating a more predictable, structured environment for PXD integration.

03

Sponsors who invest early in representative, fit-for-purpose PXD collection and align it with regulatory and HTA expectations can **strengthen approvability, enhance labeling claims, and improve post-market value demonstration.**



*The trajectory is clear: patient voice is becoming a formalized, measurable, and decisive component of global health product evaluation.*



# If investing in one type of PXD, choose Patient Experience Mapping

A structured qualitative data collection and visualization method that organizes information about a patient's healthcare journey (i.e., symptom onset, diagnostic processes, treatment pathways) and lived experience factors (i.e., emotional health, social support, economic impact, etc.)



## Inputs: Patient-reported data & observed data

- Primary qualitative and/or quantitative data collection, supported by secondary literature review and social media listening



## Key Deliverable

- MG1**
- Synthesizes data into a chronological or thematic “map” that identifies patient experiences, moments that matter, and contextual life factors



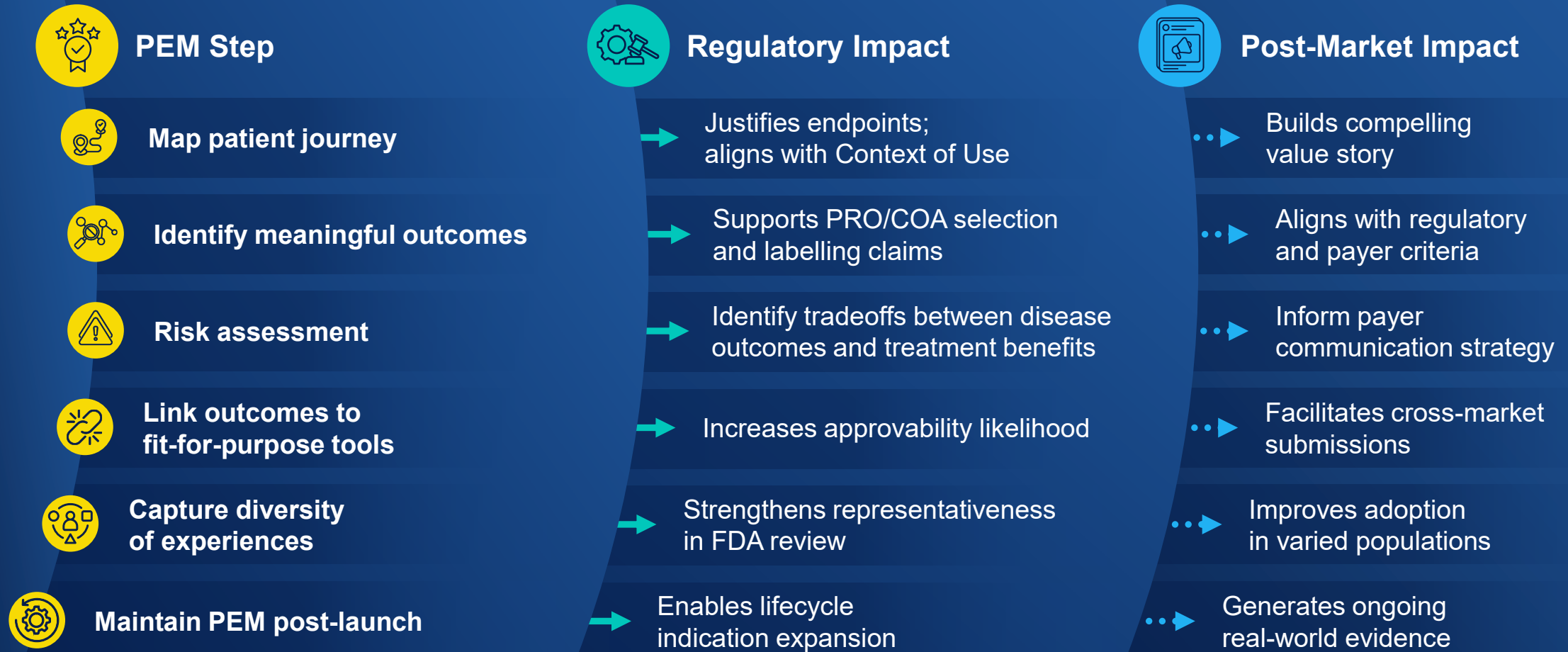
## Other Deliverables

- Identifies unmet needs, burden of disease, HCP interactions, health outcomes of importance

Patient Experience Mapping informs medical product development, clinical trial design, endpoint strategy, regulatory submission, regulatory decisions, and healthcare delivery improvement

# Patient Experience Mapping: Impact Pathway

PEM strengthens drug approvability, supports labeling claims and enhances post-market value of an asset



# Lumaneity Patient Experience Mapping

## IMPACT Examples:

Custom designed to deliver one or more of these cross-functional outputs

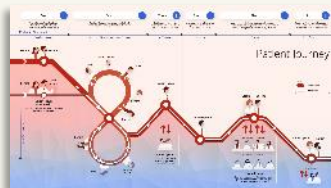
### Patient Journey

- Chronological healthcare journey (presentation, diagnosis, management, treatment experience)
- Moments that matter
- Pain points



### Burden of Illness

- Physical impact
- Cognitive impact
- Emotional impact
- Socio-economic impact



### Needs Assessment

- Chronological assessment of needs (met and unmet)



### HCP Buying Process

- Who, when, role?
- From presentation through management



### Trial Design

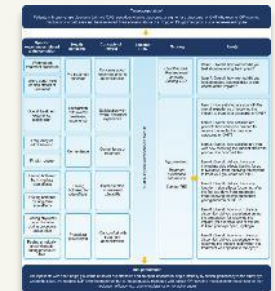
- Protocol development
- Recruitment strategy
- Participation experience
- Patient support needs



MG1

### Endpoint Strategy

- Identification of what matters to patients and how patients define meaningful treatment outcomes
- Selection, modification, or development of PRO measures

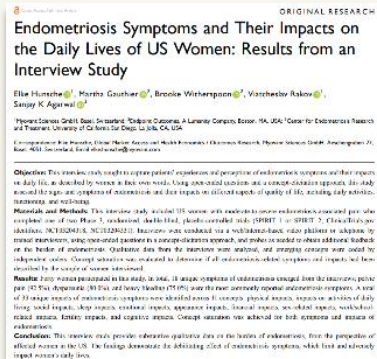


# Lumaniy Patient Experience Mapping: Impact Pathway

## Additional Use Cases

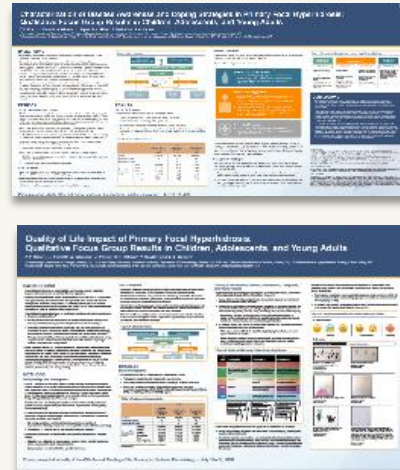
## Publication

- IJWH A 409733  
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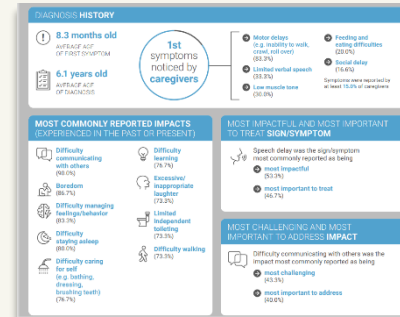
## Disease State Education

- Posters for Society for Pediatric Dermatology, 2020



## Infographics for Patient Groups

- [https://pitthopkins.org/wp-content/uploads/2024/07/PHS-infographic\\_v56.pdf](https://pitthopkins.org/wp-content/uploads/2024/07/PHS-infographic_v56.pdf)



## Commercial Strategy

- <https://livmarli.com/alagille-syndrome-itch/results-with-livmarli/>



## Patient Support Services

- Channel utilization
- Service utilization
- Educational content
- Access assistance

# Q&A

01

**What do you see as the value of this PEM approach?**

02

**Who is most likely to own this process?**

03

**What are potential barriers or challenges to the process?**

Connect with us to learn more about how Lumanity can elevate your patient programming?

[contact@lumanity.com](mailto:contact@lumanity.com)

