



**THE FORUM**

For Collaborative Research<sup>SM</sup>

*Berkeley's Hub for Regulatory Science*

# What is Meaningful to the Patients?

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Berkeley Public Health

# Disclosures



- **Advisory Board**

- Madrigal Pharmaceuticals, Novo Nordisk, and Regeneron Pharmaceuticals

- **Honoraria**

- Asian Health Foundation, Mount Sinai School of Medicine

- **Equity Holdings/Stock Options**

- PharmaNest

- **Research and Education Grants to Fatty Liver Foundation**

- 89bio, Akero Therapeutics, Altimune, Allergan, Applied Clinical Education, Athena Tung, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Fibronostics, First Line Creative Media, Galectin Therapeutics, Gilead Sciences, GYRT Health, Healthy Trucking Association of America, Intercept Pharmaceuticals, Madrigal Pharmaceuticals, M3 USA, Merck, Novo Nordisk, Perspectum, Pfizer, Regeneron Pharmaceuticals, Sonic Incytes

# Overview



- Grounding the discussion in the legacy of The Denver Principles
- Centering the voices of people living with MASH: *“Nothing about us without us”*
- Highlighting what patients value most:
  - Non-invasive options
  - Early diagnosis and clarity about progression
  - Outcomes that help them feel, function, and survive
- Exploring how NITs for RLSE can empower patients and advance equity
- Concluding with specific requests to ensure NITs for RLSE reflects patient needs and priorities

# The Denver Principles (1983)

*A Foundational Manifesto of Patient Empowerment*

## Context

- In 1983, during the Fifth Annual Gay and Lesbian Health Conference in Denver, a group of people living with HIV/AIDS drafted a powerful statement to confront stigma and demand dignity, rights, and representation.



# The Denver Principles (1983)



## Key Principles

- **“Nothing About Us Without Us”**  
People with lived experience must be central to decisions that affect them.
- **Inclusion and Participation**  
People with AIDS should be included in all forums, with equal credibility to share their insights and knowledge.
- **Human Rights**  
The right to full emotional and sexual lives, quality healthcare, and non-discriminatory services.
- **Empowerment and Self-Determination**  
The ability to choose their own representatives, form caucuses, and define their own strategies.

## Legacy

The Denver Principles became a cornerstone of the global patient advocacy movement and continue to shape how we center the patient voice in healthcare.

# Why We Must Start with the Patient



- **“Nothing about us, without us”**
- Patients are not endpoints – they are people with lives, families, and futures
- Regulatory innovation must reflect patient priorities
- Without patient centeredness, innovation risks being misaligned with real-world value

# What Patients Tell Us They Want



- Avoiding liver biopsy
- Clarity about progression and prognosis
- Early diagnosis and treatment
- Therapies that improve how they feel, function, and survive
- Trustworthy, non-invasive monitoring

# Non-Invasive Testing = Empowerment



- Patients want to track their liver health
- NITs offer understandable, longitudinal feedback
- Builds trust and promotes active participation

# Meaningful Outcomes from the Patient Perspective



- Patients care about:
  - Stabilization or regression of fibrosis
  - Better quality of life
  - Avoidance of cirrhosis or liver cancer

**These define what a “responder” is**

# Advancing Equity Through NITs



- Portable, repeatable tools
- Usable in rural and underserved areas
- Enable earlier interventions for more people

# What We Ask from this LF Meeting

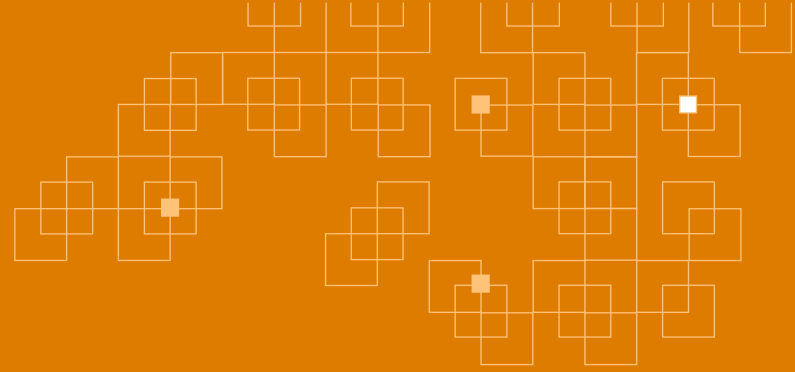


- Include patient-defined value in RLSE criteria
- Use tools patients trust and accept
- Commit to parallel progress in validation and adoption



**PEDDLE**

Patient Engagement in Drug  
Development: Leading through Example



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**Thank You**