



MILKEN  
INSTITUTE  
*FasterCures*

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# MDUFA V Public Meeting

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# FasterCures' Mission

With our partners, we are building a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly as possible.

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# MDUFA V – FasterCures’ Priority Areas

- Diversity
- Patient Engagement
- Digital Health
- Transparency
- Lessons from COVID-19

# MDUFA V – FasterCures’ Priority Areas



## Diversity and Patient Engagement

- Diversity in clinical trials and patient engagement
- Diverse sources of patient input
- Feedback on impact of patient engagement and use of patient input

## Digital Health

- Artificial Intelligence/ Machine Learning
  - Minimizing Bias
- Wearables and Patient-Generated Data
  - Clarity and transparency
- Real world evidence and advanced clinical studies

## Transparency and COVID-19 Lessons

- Transparency
  - Central Transparency Office
  - Sharing of information across the agency and externally
- Lessons from COVID-19
  - Collaboration
  - Accelerated guidance development
  - Patient generated data