THE FORUM
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LF15 Updates:
Forum Data & Analysis Center
MASH Placebo Database

September 6, 2023

Veronica Miller
Michael Cooreman

Berkeley Public Health

Today: Brief Summary Overview
November: Full WG Meeting

The Data & Analysis Center Team

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Principal Investigator/Director Veronica Miller, PhD		Lead Data Scientist Margot Yann, PhD	
IT & Operations Director Chris Hoffman, PhD		Data Analyst Sammy Berman, MPH	
Strategy/Business Development Brenda Rodriguez, MBA, MS		Technical/Infrastructure Zach Rooney, MSCS	

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Regulatory Science
Data Science
Statistics
Novel Analytics

DAC Advisors

FCR Data & Analysis Center (DAC)
DAC Team and Platform

DAC Project Portfolio

MASH PDB

PSC Forum

PBC Forum

HBV Forum

Annual Workshops

Data Science
RWD-RWE
ML-AI
Causal Inference
ETC

Data Protection by Design & by Default

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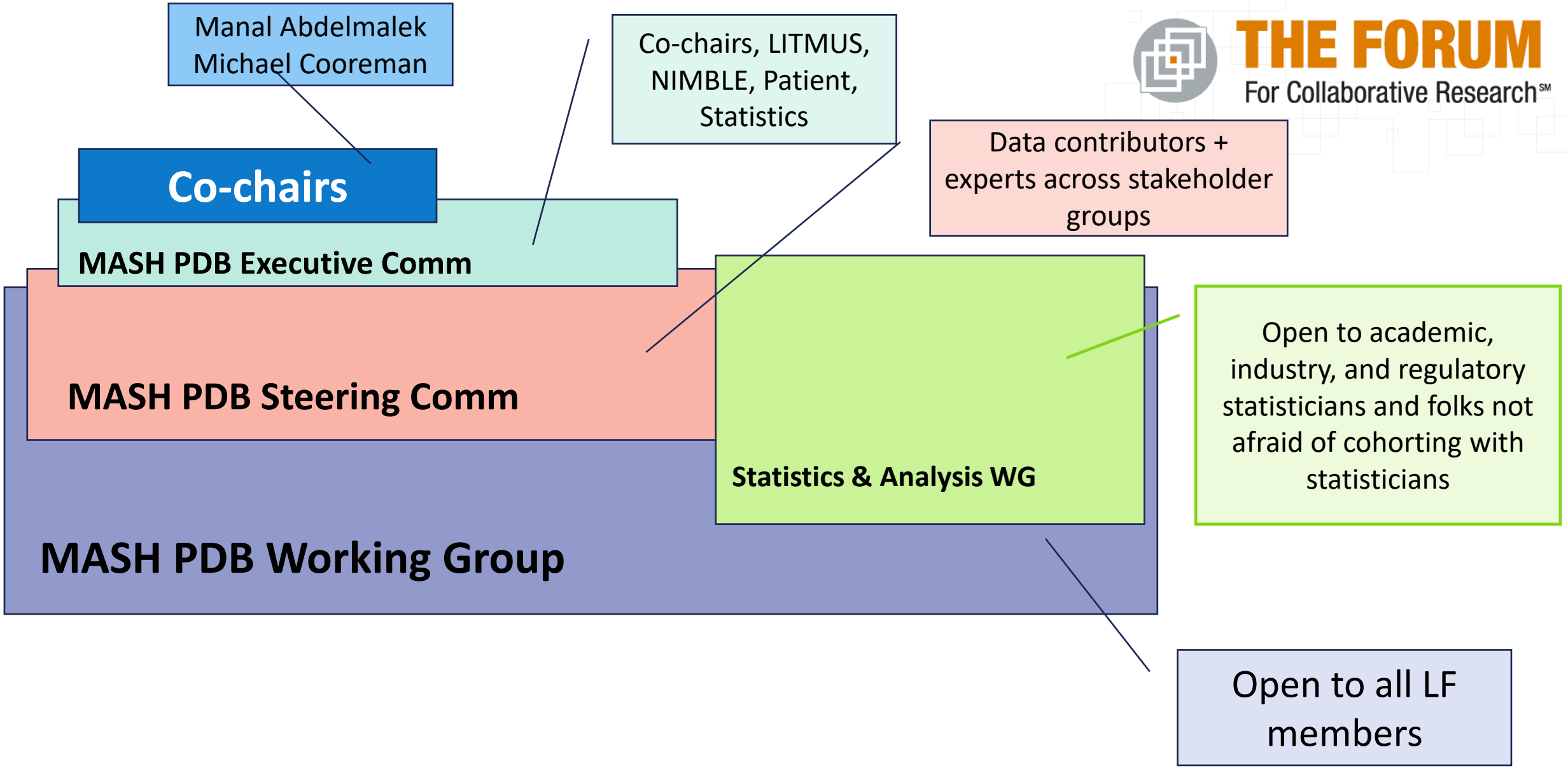
- DAC platform (SRDC) approved for highly sensitive data
- DAC Security Plan documents safe design and practice
  - Meets/exceeds US requirements for de-identified data
- GRDP
  - Pseudonymization
  - Working with Berkeley Compliance (Privacy Officer)

Questions?
Ask Chris Hoffman

MASH PDB Working Group/Project


Manal Abdelmalek
Michael Cooreman
Co-chairs
Co-chairs, LITMUS, NIMBLE, Patient, Statistics
MASH PDB Executive Comm
Data contributors + experts across stakeholder groups
MASH PDB Steering Comm
Statistics & Analysis WG
Open to academic, industry, and regulatory statisticians and folks not afraid of cohorting with statisticians
MASH PDB Working Group
Open to all LF members

MASH PDB Progress

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- Data Use Agreement
  - Distributed and under review
- CDISC standards
  - Potential collaboration for MASH standards
- Database infrastructure
  - Mapping data fields using CDISC and FDA technical standards for MASH

Questions?
Ask Chris Hoffman

Questions?
Ask Margot Yann and Sammy Berman

Themes/questions MASH PDB Project

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- Natural history of MASH in untreated trial patients
- Comparability of RCT patients to “real world” patients
- Predictors of disease improvement, stability, worsening
- Fluctuation in safety parameters in untreated patients
- Screen failures
- Application of AI/ML to paired biopsies
- Comparison of causal inference statistical methods
- Shared placebo arm in future trials
- Others?

… as identified by our Working Group

Data Sources & Data Availability

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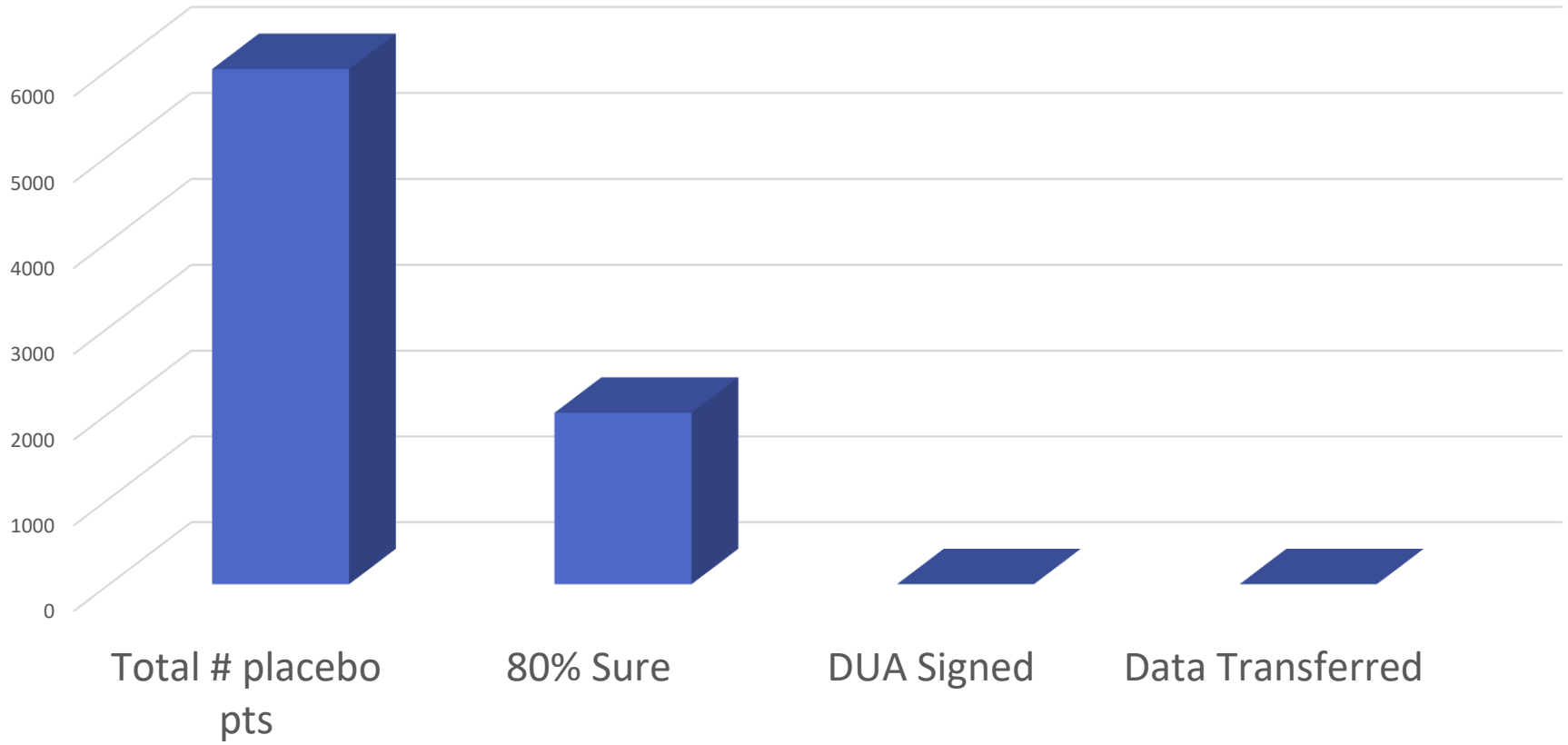
- Invited to participate:
  - All completed phase 2 and phase 3 studies
- Potential total # of placebo patients: ~5,500*
- Strong commitment: ~1,950
  - Verbal, “handshake”, reviewing DUA
- Negative: 0

Questions?
Ask Brenda Rodriguez or Chris Hoffman

* Azza Karrar LF14 Presentation

Data Contribution Tracker



Special Announcement

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- Excellence in Collaboration Award
  - To first company to sign DUA!

First Proposed Research Use Case
Analysis of Biomarker Fluctuation

- Over time/across studies
- Circulating
  - Clinical
  - Liver function
  - Fibrosis
  - Metabolic
- Imaging
- Specialized biomarkers (next phase)

Patient demographics
Co-morbidities
Other key characteristics

Questions?
Ask Margot Yann

Next Steps

- Discuss proposal with SC and full WG
- Write data analysis plan
- Publication plans
- Develop next questions!

Thank You!