



# Digital Biomarkers Decision Making Working Group

CHAIRS:

DIANE HOFFMAN (BRIAN KIRKPATRICK)

VIKAS M SHARMA

**Please be seated at the table corresponding  
to your group color on the back of your badge.**

# Agenda

- ▶ 10 min: Overview of previous working group held in Feb 2022
- ▶ 30 min: Breakout groups (tables assigned by color – back of badge)
- ▶ 45 min: High level summary reports (5 min per group)
- ▶ 5 min: Next steps

# Summary from our last meeting in Feb 2022

- ▶ Start collecting digital BMx experience; database/focus review/meta-analysis
- ▶ Challenges/opportunities
  - ▶ Validation efforts/challenges
  - ▶ Regulatory directions
  - ▶ Replicability
- ▶ Possible outputs:
  - ▶ Focused symposium on Digital BMx at one of the ISCTM meeting
  - ▶ Use cases of Digital BMx e.g. in Clinical development, clinical practice etc.
  - ▶ Decision/Guidance tool/s for various end users e.g. industry, academia, biotechs, health techs etc.

# Expertise and the experience in the group

- ▶ Identify with the use of a Survey to be sent out prior to the Fall meeting.
- ▶ Obtain the various sectors of the members of the Working group i.e. academia, industry, small biotech, digital tech companies or regulatory .
- ▶ Gather interest and commitment to the WG

# Agreeing on the objective/s of the WG

- ▶ Lay of the land; learn and share
- ▶ Education/awareness on Digital BMx development and validation
- ▶ High level discussion on objective/s and divide people into small breakouts
- ▶ Obtain expectations of the group

# Breakout sessions

- ▶ Divide groups based on possible needs e.g. Academia, Industry, small biotech, DTx/Digital tech companies? (*pre survey by ISCTM*)
- ▶ Discuss in your group
  - ▶ Your needs to be addressed by a Digital BMx decision tool/guidance
  - ▶ Format of decision tool/s
  - ▶ What will help make such tool/guidance applicable in your work
  - ▶ What inputs/source of data needed for development of such tool/s
- ▶ Summary from each group (high level 5-min bulleted summary)
- ▶ Please provide notes and attendance to chair

# Next steps

- ▶ Identification of the WP members and the coordinators/leads
  - ▶ First step literature review?
- ▶ Next milestones, timelines and the agreed outputs
- ▶ Possible white paper or physician paper

Thank You!

