



Methodology Committee Meeting
March 7, 2023

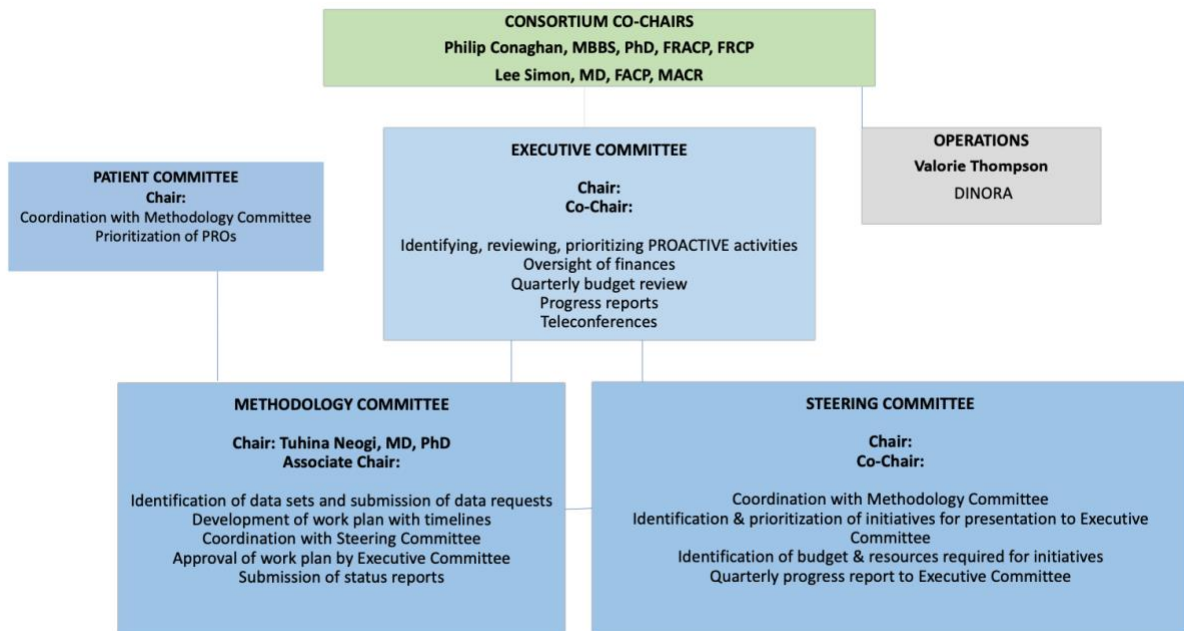
Participants

Jamie Collins, PhD	Elena Losina, PhD
Philip Conaghan, MBBS, PhD	Peter Mesenbrink, PhD
Jen Gewandter, PhD, MPH	Tuhina Neogi, MD, PhD
Francis Guillemin, MD, PhD	Nikolay Nikolov, MD
Mike LaValley, PhD	Lee Simon, MD
Jean Liew, MD, MS	Valorie Thompson
Unable to Participate	
Robin Christensen, PhD	Yura Kim, PhD
Chris Swearingen, PhD	

Agenda

- Introductions
- Overview of the PROACTIVE Mission and deliverables
- Group Discussion: Methodology Committee plans/approaches

PROACTIVE Governance Structure



Potential Datasets

OAI	Osteoarthritis Initiative
MOST	Multicenter Osteoarthritis Study
CHECK	Cohort Hip and Cohort Knee Study (Dutch Arthritis Foundation)
PROCOAC	Prospective Cohort of A Coruña
CAS-K	Clinical assessment study – knee (North Staffordshire)

Framingham Cohort
Chingford Study
Johnson County

Mikael Boesen/Dr. Alex Iakimov, MD

Several OA databases for surgery; OA cohorts using Radiobiotics technology on radiographs over the knee for 6-year timespan to investigate heal resources for knee OA

Clinical Trial Data

Ampio Pharmaceuticals – access to saline controlled data sets from RCTs
Nordic Bioscience Clinical Development – specific requests to be considered
FDA – To be determined

Key issues

1. What does disease progression mean? What does structural change mean? There is no regulatory definition of disease modification.
2. Presently, joint failure is the end game; is there the potential to identify an earlier indicator of structural change?
3. What should be measured?
4. Understanding the clinical benefit of what is being measured.
5. Increasing focus on a therapy's MOA; targeting specific pathways and identifying phenotypes.
6. Consideration of patient reported outcomes – i.e., illness assessment vs. disease assessment (clinician).

Next steps

1. Understanding the outcome measures in OA
 - a. Compile list of measures (e.g., pain, function, PRO)
 - i. Symptom & Structural outcome measures proposed groups - see below.
 - b. How is structure evaluated?
2. Identify potential datasets
 - a. Observational
 - b. Clinical Trials