Representation of Diverse Populations in Clinical Trials

Ethical Foundation

The composition of the majority of clinical trials does not reflect the diversity of the population at large nor those likely to use the investigational product. Historically under-represented groups remain understudied, and variability in treatment response, safety, efficacy, and tolerability go undetected. The ethical foundations of justice, beneficence, and autonomy support inclusion such that the role of factors like age, sex, gender, race, ethnicity, and sociodemographic factors be considered in clinical trials.

Diverse stakeholders are tackling the issues from both a scientific and socioeconomic perspective to define guiding principles, establish standards of approach & practice, and explore practicable solutions

Demonstration of the Problem

Clinical Trial Participation Demographic Subgroups for 46 novel drugs that were approved by the FDA in 2017. Overall, 59,030 patients participated in these trials*

DEMOGRAPHIC SUBGROUPS	WOMEN	WHITE	ASIAN	BLACK or AFRICAN AMERICAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
PARTICIPANT AVERAGE	55%	77%	11%	7%	14%	32 %	34%

*Data presented in this report are from 47 snapshots as one drug was approved for 2 different diseases (populations).

* www.fda.gov/drugtrialssnapshot

Barriers to Participation

- Costs of participation
- Inadequate reimbursement
- Lack of child care support
- Research visits schedule
- Research center feasibility
- Research center location

- Inclusion/Exclusion Criteria that exclude diverse populations
  - Normal laboratory variants discounted
  - Co-morbidities excluded

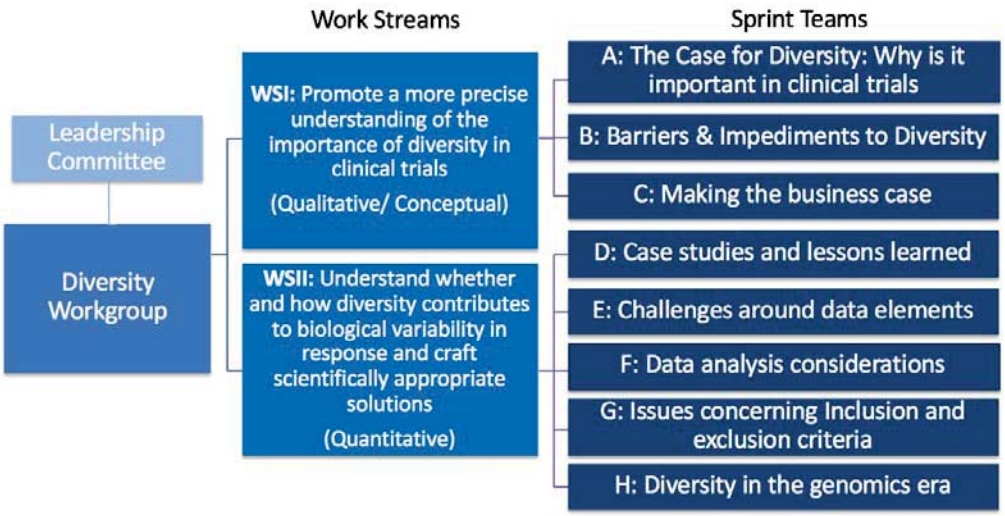
Awareness → **Access** → **Recruitment** → **Screening**

- Language barriers and inadequate translation
- Low health and research literacy among underserved communities
- Cultural differences
- Lack of community engagement
- Research advertisements fail to reach populations

- Poor/Inconsistent relationship between underserved communities and researchers
- Mistrust of academic medical research model
- Lack of cultural competency & representation among research faculty and staff
- Perceived operational/timeline costs to having representation mimicking general population

MRCT Center Approach

Workgroup Structure & Issues Addressed



Representative Workgroup Organizations

Accelerated Cure Project for Multiple Sclerosis
Advances in Health
Amgen
Biogen
Boehringer Ingelheim
Boston Scientific
Brigham and Women's Hospital
Cancer Connection
Case Western Reserve University
CDISC
Columbia University Medical Center
Emerson Clinical Research Institute
Genentech/Roche
GlaxoSmithKline
Harvard Medical School
IQVIA
Kinetiq
Massachusetts General Hospital
Merck & Co.
NIAID/NIH
Novartis
Parkinson's Foundation
Pfizer
Pinkie Hugs, LLC
Sanofi
Stanford University
Takeda
University of Illinois Cancer Center
Vivli
Yale Center for Clinical Investigation

Workgroup Leadership

Richardae Araojo, FDA
Barbara Bierer, MRCT Center
Luther Clark, Merck Co.
David Strauss, MRCT Center
Sarah White, MRCT Center
John Whyte, WebMD/ formerly FDA

Project Management

Hayat Ahmed, MRCT Center