Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM –12noon ET

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

LEANING IN: A WEBINAR SERIES

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December 9, 2020	Study Conduct (Recruitment, Retention)
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February 10, 2021	Role of Data in Diversity: Genetics & Real World Data

Today's topic

The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Leadership and Guidance

- RADM Richardae Araojo, PharmD, MS, U.S. FDA
- Barbara E. Bierer, MD, MRCT Center
- Luther T. Clark, MD, Merck & Co., Inc.
- Milena Lolic, MD, U.S. FDA
- David H. Strauss, MD, Columbia University
- Sarah White, MPH, MRCT Center

MRCT Center staff:

- Carmen Aldinger, PhD, MPH
- Hayat Ahmed, MS
- Laura Meloney, MS, MPH
- Joshua Smith-Sreen, MBE

Achieving Diversity, Inclusion, Equity In Clinical Research

And the invaluable contributions of >50 workgroup members, representing:

- Patients, Patient Advocates
- Academia
- Pharmaceutical companies
- CROs
- Non-profit organizations
- Trade associations
- Government agencies
- Research institutes

Each serving in their individual capacity.

Guidance Document

- Multi-stakeholder contributions and consensus
- Practical and actionable recommendations
- Accountability section considers how each stakeholder can change the paradigm
- Toolkit provides adaptable resources not easily found elsewhere

Today's agenda

Recruitment

Study Conduct

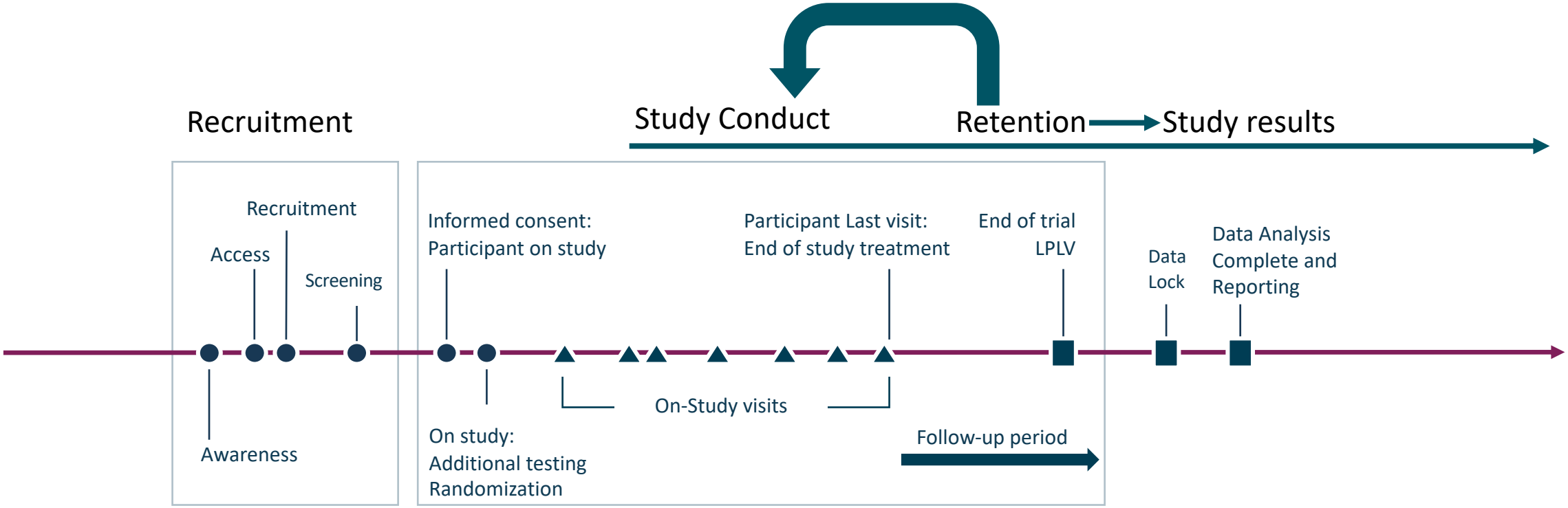
Retention

Results

Outcomes

Dissemination

Participant Trial Journey

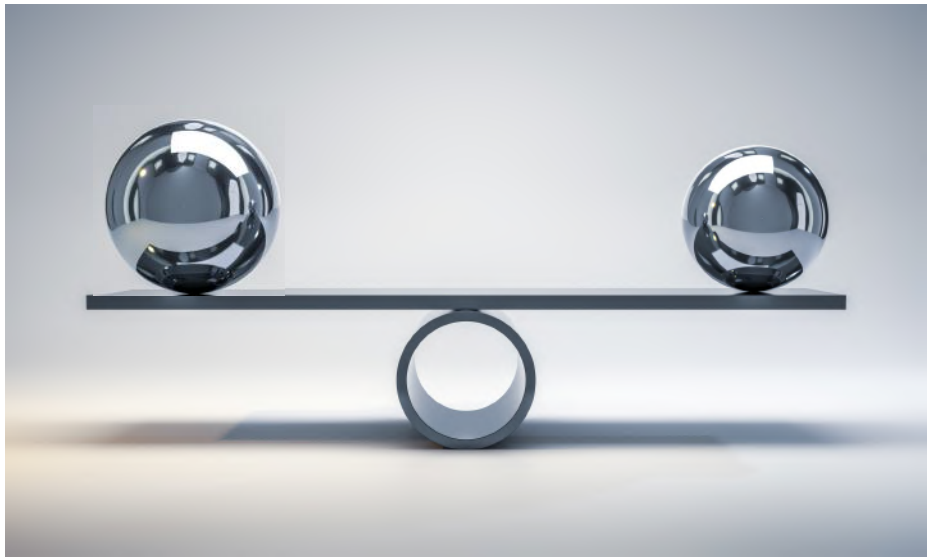


Study Design
Informed consent simplification
Logistical issues
Decentralized trials
Payment, transportation, childcare, etc.
Post-trial access to medicines
Return of results

Recruitment – Making the decision to participate

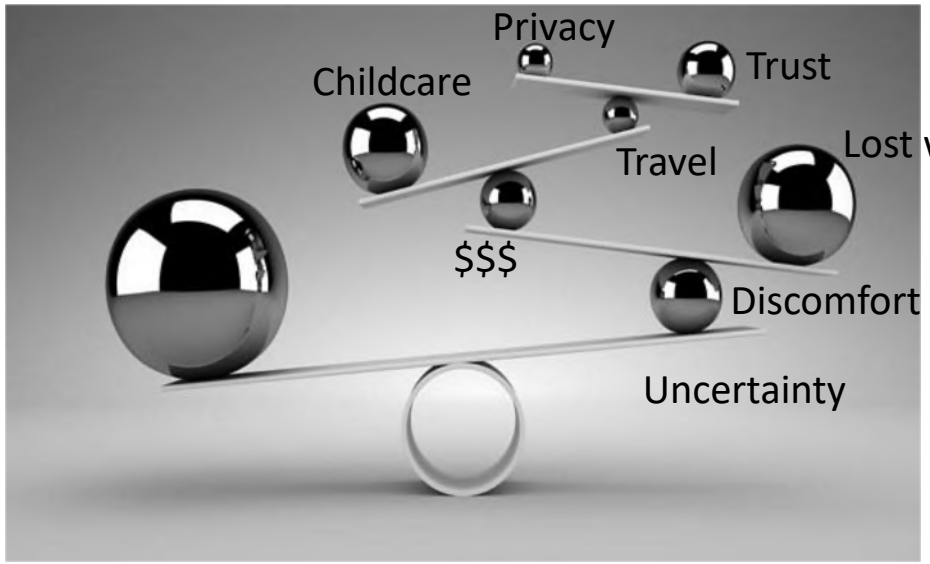
Sponsor/Investigator/IRB view

Benefit Risk

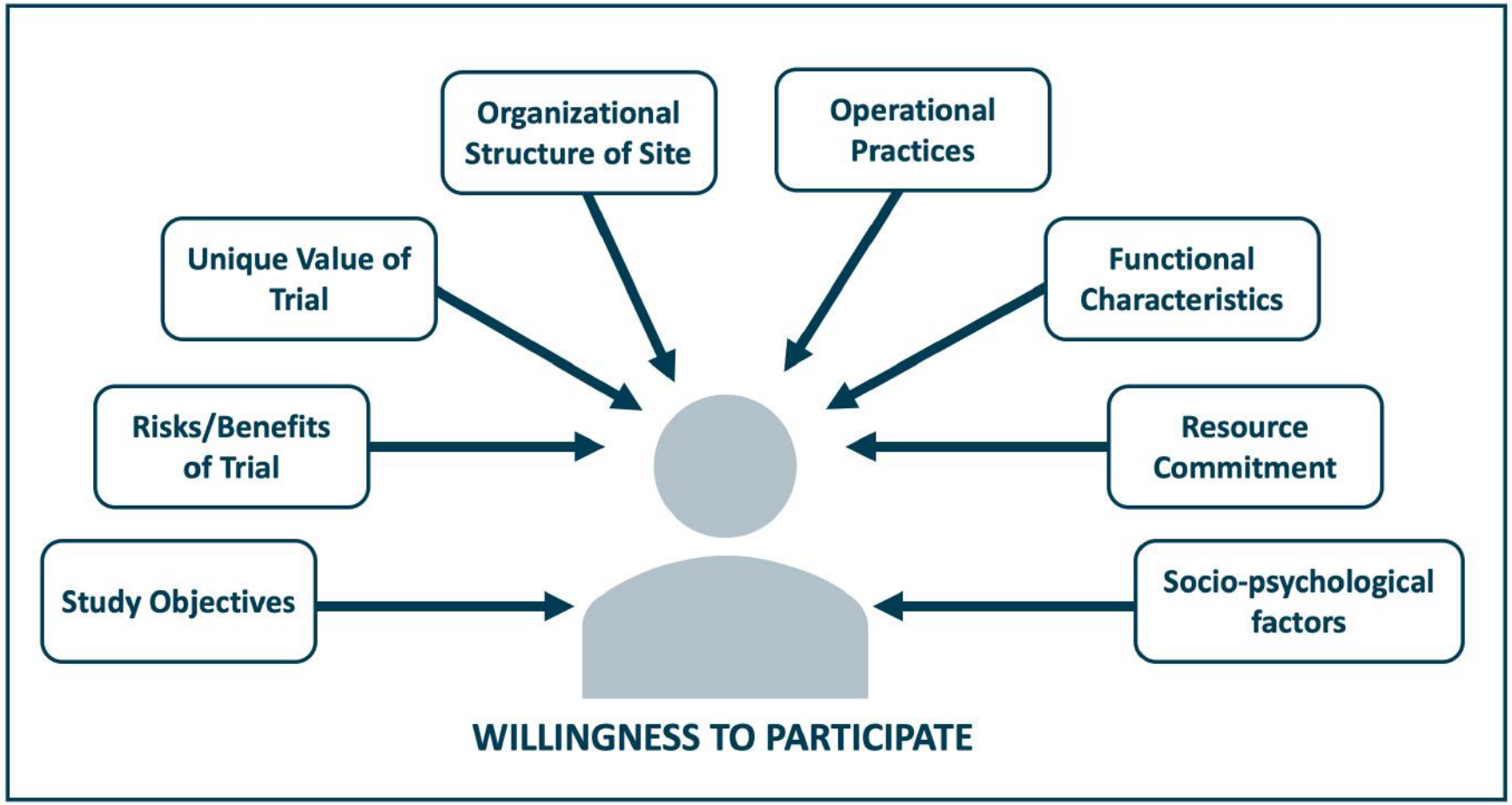


Potential participant's view

Benefit Risk



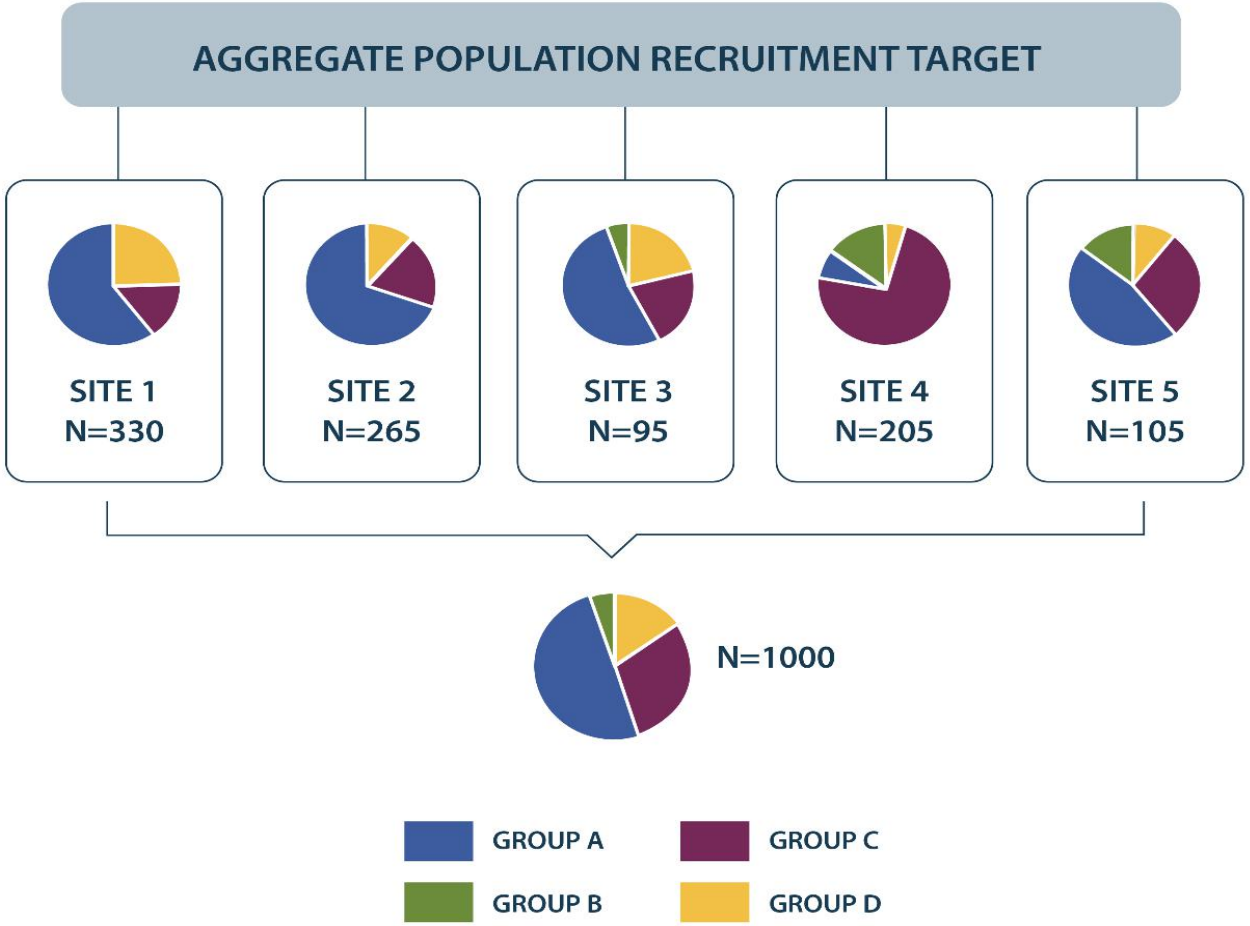
Study Conduct



All influential variables need to be considered in one's decision

Recruitment

- Requires advanced planning
- Specific to site population, trial population, and associated subpopulations
- Consider epidemiological data, as available, and in advance of implementation



Recruitment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Sponsor Logo

CRO Logo

Recruitment Strategy Document

Study Title

Protocol #

NCT #

Recruitment Strategy Document (RSD)
https://mrctcenter.org/diversity-in-clinical-trials/download/523/

Recruitment Strategy Documents – Potential Key Performance Indicators (KPIs)

Output indicators

- ☐ Trial-level recruitment plan for diversity available at site, including all the proposed elements to consider (See Achieving Diversity, Inclusion and Equity in Clinical Trials Guidance Document, Table 12, Part E, Section 13.5)
- ☐ Site-specific recruitment plan for diversity available at site
- ☐ Monitoring mechanisms for recruitment targets by demographic established
- ☐ Suggested recruitment strategies tailored to target population(s) available at site

Outcome indicators

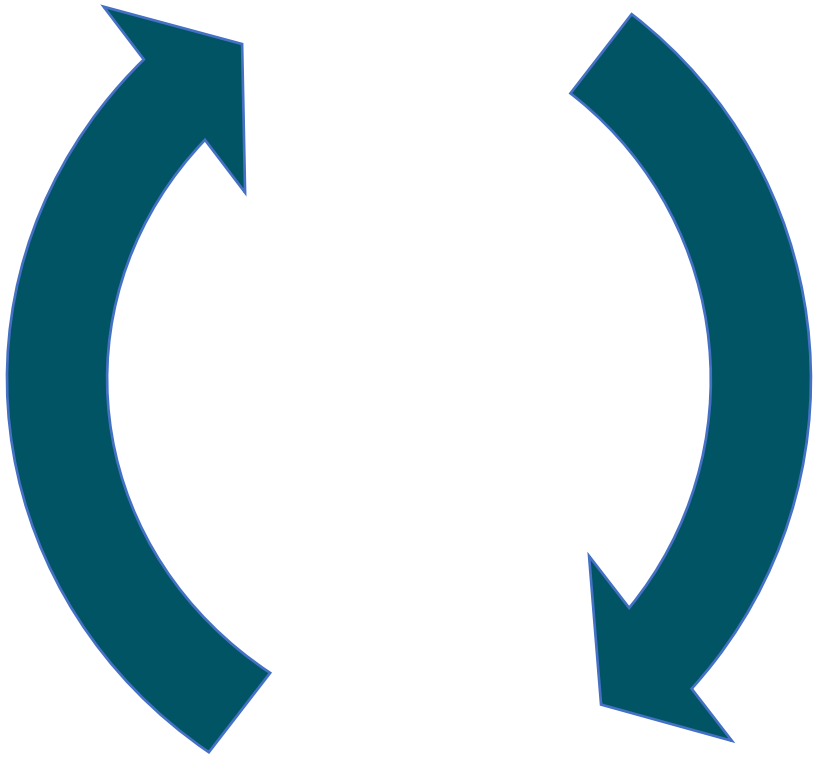
- ☐ Site investigator-reported understanding of diversity enrollment objectives
- ☐ Data on demographic profile of enrolled participants available to sponsor in a suitable amount of time
- ☐ In the case that demographic profile data indicate site will not meet target enrollment of target subpopulation, contingency plan implemented

Recruitment – informing activities and strategies

- Relationship between qualitative and quantitative strategies

Quantitative

- Methods of referral and referral source
- Points of contact for participants
- Pre-screening efficiency
- Screen failures
- Recruitment & enrollment
- Refusals



Qualitative

- Physician engagement
- Social media postings
- Language and culturally appropriate materials
- Bilingual staff and translators
- Participant navigators
- Informed consent process
- Outreach activities

Retention

- The longer a participant is in a research study, the more valuable their information
- Reduce attrition by identifying impediments and barriers in advance

> *What should we understand to make your participation easier?*

Retention - Reducing Burden

- Provide information in a language understandable to the participant
- Maintain engagement with the individual
- Minimize disruptions
- Maximize flexibility
- Provide support (e.g., childcare, eldercare, transportation, etc.)
- Reimburse promptly, preferably prepay or debit card

Recommendations – Study Conduct, Recruitment, and Retention

- Understand the participants (i.e., their needs, their culture, their values)
- Train staff – conduct, bias, and behaviors
- Flexibility in scheduling and conducting study visits – offer choices
  - Minimize asks, visits, and procedures (e.g., sample collection)
  - Decentralize trials to the extent possible
  - Utilize technology if helpful
- Use quantitative metrics and tracking to inform qualitative strategies and approaches for recruitment and retention
- Develop an agile, continuous improvement cycle to learn and improve

Recruitment and Retention – Key Performance Indicators

Recruitment, Conduct and Retention – Potential Key Performance Indicators (KPIs)

Output indicators

- ☐ Proportion screen failures of target population(s) (available during study implementation)
- ☐ Tailored recruitment materials for target population(s) available at site
- ☐ Tailored recruitment strategies piloted in target population(s)
- ☐ Evidence of prioritization of participant convenience in study protocol and site-specific recruitment plan
- ☐ Evidence of patient input in recruitment strategies

Outcome indicators

- ☐ Data on screen failures informs recruitment modifications
- ☐ Tailored recruitment strategies/materials inform targeted recruitment at site
- ☐ Recruitment and retention of target subpopulation(s) meet enrollment objectives as defined in recruitment plan

Today's speaker

Quita Beeler Highsmith, MBA

Vice President and Chief Diversity Officer, Genentech

Please refer to the webinar recording for presentation.

Today's speaker

Anne Marie Inglis, PhD

Senior Director

Global Development Operations

Mallinckrodt

From a Sponsor Clinical Operations Professional……

- Have a goal, a plan to get there and track progress against it!
- Design and operationalize your study to be attractive to underrepresented diverse participants
  - Know your population
  - Consider inclusion/exclusion criteria
  - Make study procedures as flexible as possible to fit into as many different lives as possible
  - Provide health literate materials in multiple languages from the start
  - First ask, and then be considerate of the barriers to enrolment and continued participation

The Clinical Trial Site – Where the Rubber Meets the Road

- Select sites with access to the population
  - Keep metrics for sites regarding their access to, enrolment of and retention of different demographic populations
  - Geomapping can help to identify sites not previously used

- Select sites with a desire to recruit and retain that population
  - "Human touch" changes behavior and supports building trust in communities!
  - Site staff looks like the patient population
  - Site staff is culturally competent – understands how decisions are made within the community, and key barriers to participation
  - Site staff asks curious questions throughout the study process – "What barriers exist for you?"
  - Site staff have links to the community or links to others close to the community

The Clinical Trial Site – Where the Rubber Meets the Road

- Supporting Sites
  - Engage with sites during study design
  - Clarity on both what is expected, and why
  - Help sites to understand barriers and facilitators to participation within the population
  - Develop a shared recruitment and retention plan with each site independently
  - Share ongoing metrics routinely

Support People Bringing Research to Underserved Communities

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Discussion and Questions

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