Representation by Design: Enhancing Clinical Trial Access through Multi-Stakeholder Collaboration

April 24, 2025, 10:00 AM EST

TransCelerate BIOPHARMA INC.

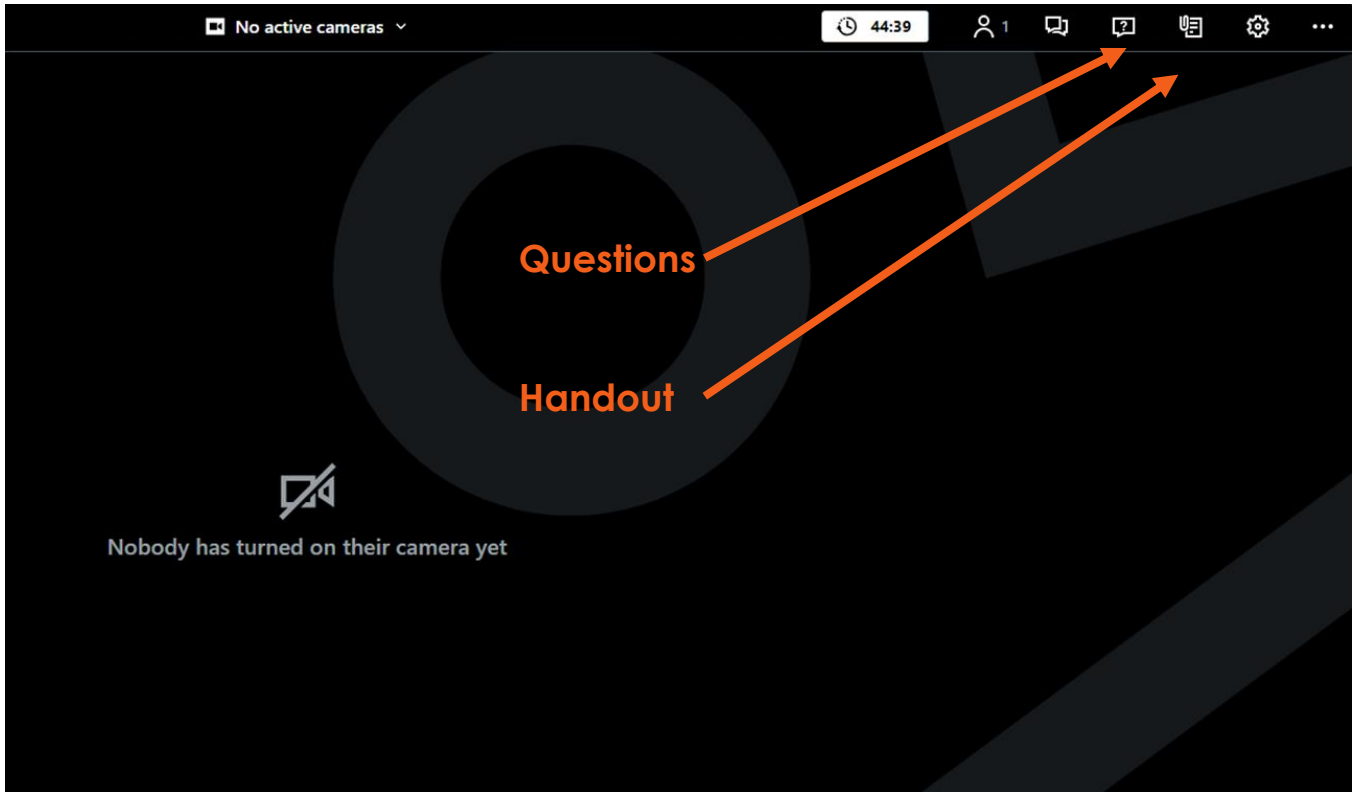
Agenda

Topic

- Welcome, Webinar Logistics & Ground Rules
- Overview of TransCelerate's Diversity of Participants in Clinical Trials Initiative
- Key Learnings and Tools to Support the Development of Clinical Trial Diversity Strategy
- Introduction of Expert Panelists and Q&A

Logistics for the Webinar

- **All participants will be muted for this call.**
- **For audio**: Connect to audio to listen to presentations via your computer or phone
- **Given the breadth of organizations represented on this webinar, time may not permit for live Q&A.**
  - Questions submitted during registration have been reviewed and incorporated into the panel discussion.



Reminder: This webinar may be recorded in whole or in part.

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Ground Rules

- **We want to make this discussion helpful and answer as many of your questions as we can, so here are some quick ground rules:**
  - Participation is voluntary, as is using TransCelerate assets/tools
  - The responsibility for compliance with laws and regulations is owned by the solution adopter.
  - You don't have to identify what company you work for
- **Things we would ask you <u>not to discuss</u>:**
  - What vendors/sites/CROs/clinical trial sponsors you are working with or not working with
  - Any issues you have with any vendors/sites/CROs/clinical trial sponsors
  - Your long-term development plans
  - Anything related to pricing or costs
- **We can't answer questions about:**
  - Vendors
  - Costs of using/implementing TransCelerate assets/tools
  - Which member companies are using the assets/tools

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TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

A Member-Driven Mission

Experts from across our participating Member Companies dedicate their time to TransCelerate.

TransCelerate **identifies the issues and challenges** facing our industry.

TransCelerate **designs and delivers practical solutions** for global adoption by any stakeholder.

Who are our Members?

View a full list of our members

Membership* is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines

* to be eligible for membership, companies must meet specified eligibility criteria.

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Our Expert Speaker(s) Today

Binita Patel

Lead, Clinical Trials Representation

Bayer

Ubong Peters

Lead Clinical Scientist | gRED Early Clinical Development – Oncology

Genentech

Overview of TransCelerate's Diversity of Participants in Clinical Trials Initiative

Background on Diversity of Participants in Clinical Trials Initiative

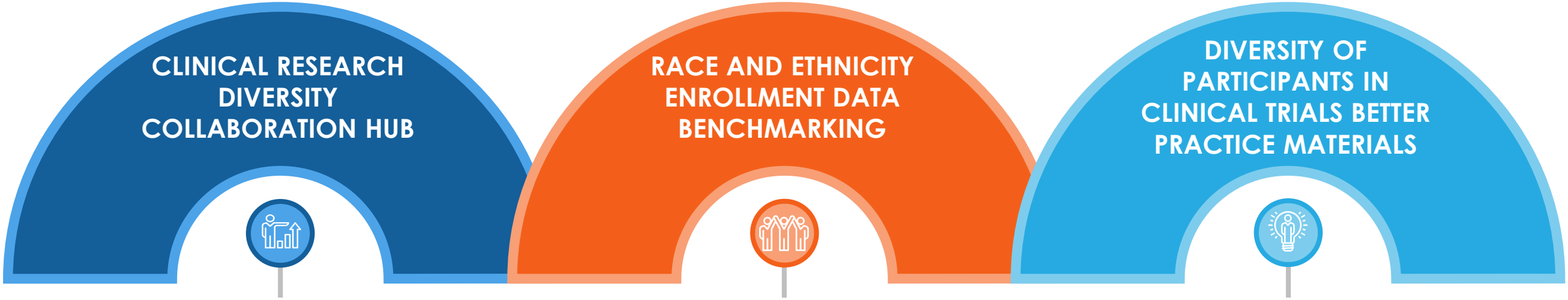
In 2014, TransCelerate first launched an initiative to promote **awareness of the need for increased diversity** and provide **considerations for sites and sponsors to facilitate greater trial participation by diverse populations** through the delivery of targeted **best practice materials** (e.g., patient engagement, cultural competency, community engagement, and IRB insights about reimbursement).

Since then, we have observed **increased industry, social and global recognition of underrepresentation in clinical trials**. TransCelerate conducted an exploratory analysis in 2020, which found widespread **consensus around the need for change**, in part fueled by increased public scrutiny of health inequities.

The Diversity of Participants in Clinical Trials initiative has moved beyond awareness to **equipping sponsors and ecosystem stakeholders** with **actionable tools and resources** to **improve outcomes for diversification** of participants in clinical trials.

Diversity of Participants in Clinical Trials

Focused on Three Connected Initiative Efforts



A compilation of solutions that collect and share information and insights across the ecosystem. It includes insights from **diversity roundtable events**, experience-based **considerations for sponsors**, a diversity **regulation landscape assessment**, and **pragmatic toolkits** inclusive of tools to be leveraged by the broader ecosystem.

To identify **priority disease states** with disparity between disease prevalence and study representation among racial or ethnic groups to establish a **benchmark** for tracking future progress.

As part of earlier efforts to promote awareness of the need for greater representation in clinical trials, TransCelerate released a robust set of **considerations for sponsors and sites** to improve recruitment of diverse populations.

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Key Learnings and Tools to Support the Development of Clinical Trial Diversity Strategy

Diversity of Participants in Clinical Trials

Solutions & Value

SOLUTIONS & LINKS

★ 	2024	Benchmarking & Metrics Analysis (White Paper)
★ 	2024	FDA Diversity Plan Insights and Considerations v2.0
	2023	FDA Diversity Plan Early Insights and Considerations v1.0
	2022	Sponsor Toolkit Site Engagement and Capacity Building Considerations for Diversity, Equity and Inclusion of Participants in Clinical Trials (DEICT)
	2022	Diversity Community-Based Site Engagement and Capacity Building
	2022	Sponsor Toolkit Portfolio and Program-Level Considerations for Diversity, Equity and Inclusion of Participants in Clinical Trials (DEICT)
	2022	U.S Regulatory Landscape: Diversity in Clinical Trials
	2021	Reference Table and Landscape of Available Resources

BENEFITS

- Increase awareness of need for diversity of participants in clinical trials amongst sites and sponsors
- Accelerate industry-wide diversification of clinical trial participants by leveraging new insights to prospectively evolve trial design, enrollment, and participation strategy
- Improve ability of sponsors to understand their current state progress with regard to the wider ecosystem

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FDA Diversity Plan Insights and Considerations v2.0

Diversity of Participants in Clinical Trials Initiative

What is it?

Provides an **aggregated collection of insights and considerations** (as of Q1 2024) gathered from the member company interviews to further **inform operational strategies** and **identify how practical implementation of FDA Diversity Plans may progress** as industry thinking matures in this area.

Who might be interested?

- Clinical Operations
  - Study management/ Site feasibility
- Clinical Leadership (Compound/Asset Dev & Strategy)
- Patient/Insights/Engagement
- Diversity and Inclusion Teams

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Summary

FDA Diversity Plan Insights and Considerations v2.0

While some pharma companies implemented **interventions** prior to Apr 2022 guidance, **action and strategy to enhance representation in clinical research ramped up after the release of the guidance**.

The guidance has driven most companies to assign **dedicated resource** to support teams in completing plans and **created a governance framework to support implementation of guidance.**

Issues with data sources (lack of granularity and difficulty in covering data accurately for **ex-US countries) still exist**. Data sources don't always match the data to be collected.

There remain **opportunities for collaborations with healthcare stakeholders including regulators** (e.g. to support consistency in expectations and plans from Sponsors**.**

Assessing Representational Diversity in Industry-Sponsored Clinical Trials in the United States

Diversity of Participants in Clinical Trials Initiative

What is it?

This paper details **key findings from the analysis of aggregated historical enrollment data** for diverse race / ethnicities in select disease states against prevalence data, and **aims to provide additional comparisons to help improve data transparency** and **stimulate accountability** in the ecosystem for progressing clinical trial diversity.

Rationale

- Establish a benchmark to help understand industry-wide performance
- Identify opportunities to improve inclusion of underrepresented participants in trials

Who might be interested?

- Clinical Operations
- Clinical Leadership (Compound/Asset Dev & Strategy)
- Patient/Insights/Engagement
- Diversity and Inclusion Teams
- Data Analytics/Data Science Teams

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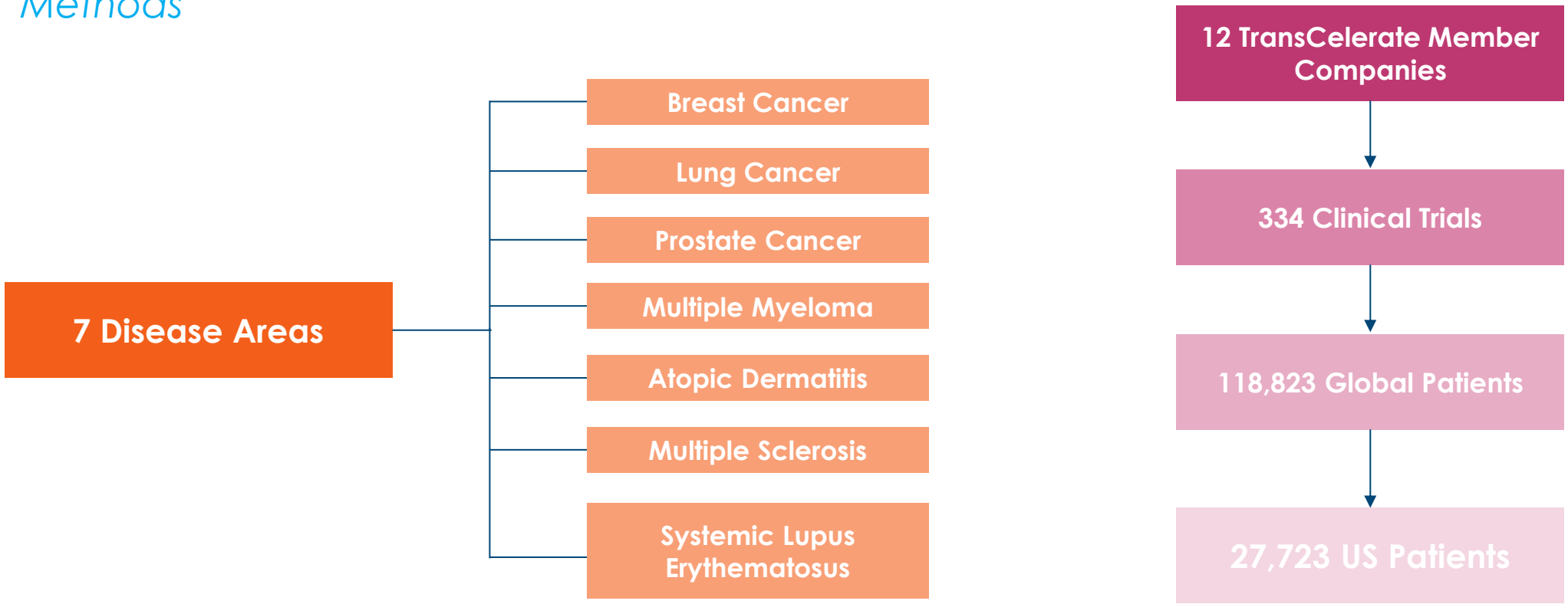
Assessing Representational Diversity in Industry-Sponsored Clinical Trials in the United States

Methods



- Aggregated clinical trial enrollment data from 334 clinical trials sponsored by 12 TransCelerate member companies, across 7 disease areas listed above
- Analyzed the demographics data extracted from the 27,000+ US patients that participated in those clinical trials as compared to real-world data, focusing on race, ethnicity, age, and sex
- RWD sources (e.g., SEER, TriNetX, Optum and an EHR database)

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Summary

Assessing Representational Diversity in Industry-Sponsored Clinical Trials in the United States

More diverse representation was seen in the autoimmune disease trials while **sex representation aligned with benchmarks for all indications**

Across most oncology indications, the trials had an **overrepresentation of White patients and patients between 18 to 64 years old** as well as an **underrepresentation of racial and ethnic minority patients and patients above 64 years**

Identified **data gaps on patients whose race or ethnicity were unknown or not reported**

Future research is needed and **more robust efforts from industry, government, regulators, and academia may help improve the collection of standardized demographic data** to close the gap between trial representation and the epidemiology of disease

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Actions to Improve Diversity in Clinical Trials

- Apply tools provided to implement and enhance representative clinical trials
- Utilize available tools to support in standardizing the collection of race and ethnicity data to ensure consistency and accuracy
- Improve data collection to reduce volume of data with ‘unknown’ or ‘unreported’ race and ethnicity in clinical trials and RWD sources to support accurate determination of trial representation

Guest Speakers

Meet Our Guest Speakers

Sabrena Mervin-Blake
Senior Project Manager
Clinical Trials Transformation Initiative (CTTI)

Carla Rodriguez-Watson
Director of Research
Reagan-Udall Foundation for the Food and Drug Administration

Alberto M. Borobia
Head of the Clinical Trial Unit
La Paz University Hospital
&
Coordinator
IHI READI Initiative

The Clinical Trials Transformation Initiative (CTTI)

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.

The Convergence Project
Increasing Access to Clinical Trials

8 Domains

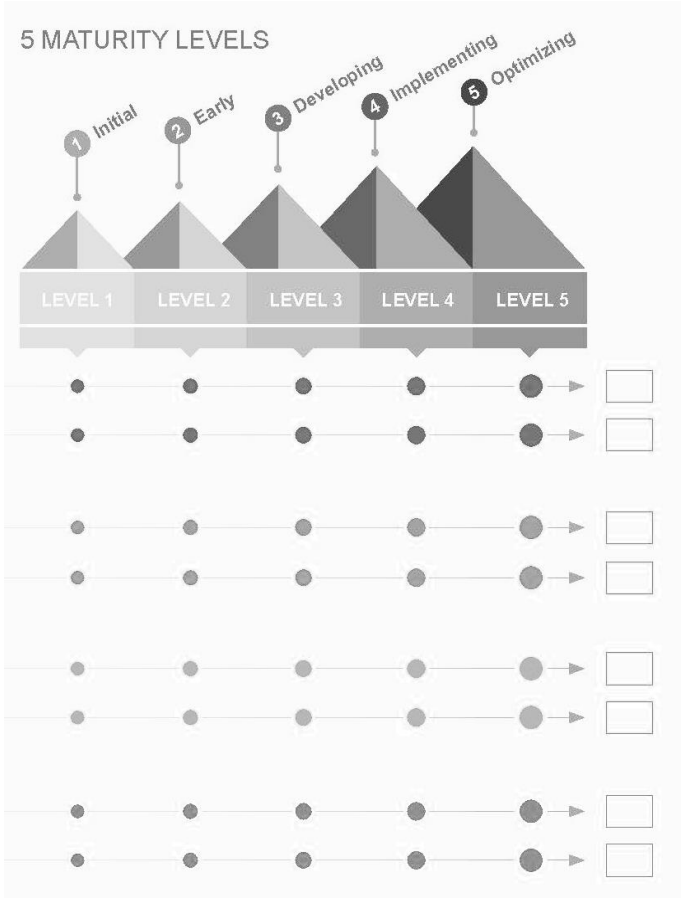
CTTI 2023 Clinical Trials Diversity Recommendations: Organizational Strategies and Maturity Model

COMMITMENT
- Leadership
- Culture

PARTNERSHIPS
- Bidirectional Community
- Patients & Patient Groups

RESOURCES
- Dedicated Personnel
- Sufficient Investments

ACCOUNTABILITY
- Data Driven Strategies
- Continuous Improvement



November 2023:
Public Workshop to Enhance Clinical Study Diversity

Workshop Required by Food and Drug Omnibus Reform Act (FDORA) 2022

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RAISE

REAL-WORLD ACCELERATOR TO IMPROVE THE STANDARD OF COLLECTION AND CURATION OF RACE AND ETHNICITY DATA IN HEALTHCARE

RAISE

REAL-WORLD ACCELERATOR TO IMPROVE THE STANDARD OF COLLECTION AND CURATION OF RACE AND ETHNICITY DATA IN HEALTHCARE

PRIORITIES & STRATEGIES

The priorities to better collect and manage race and ethnicity data are not sequential. Organizations can enter the framework at the priority that most aligns with their current needs.

THE PRIORITIES

We have mapped each priority to the strategies that can advance it. The priorities are not sequential, but meant to be applied as needed.

STANDARDIZE DATA COLLECTION

TRAIN THE WORKFORCE ON DATA COLLECTION PROCEDURES

INCENTIVIZE DATA COLLECTION

COLLECT DATA LOCALLY THEN AGGREGATE

Address the need for cultural humility in healthcare

- Develop & implement standardized training protocols that include key concepts:
  - The purpose of collecting the data
  - The data's relation to health equity
  - Who can access the data and why
  - How collecting the data benefits the community

Improve representativeness without overwhelming respondents & existing information architecture

- Tailor data options to local contexts; involving community stakeholders for patient-centered options and data governance:
  - Identify and validate race & ethnicity categories
  - Engage community to custom-fit for locale
  - Use a process to develop tools to prioritize data options
  - Update and pilot data options in the community

Address distrust & misalignment between question & answer

- Be transparent in why race and ethnicity data are collected, how it will be used, & who can access. Build tools & training resources that incorporate:
  - Messaging about the purpose and intended use of the data
  - A choice to opt out of providing the data
  - Information in diverse formats (e.g., web-based, tablet, paper, video) and languages

Improve exchangeability of race & ethnicity information

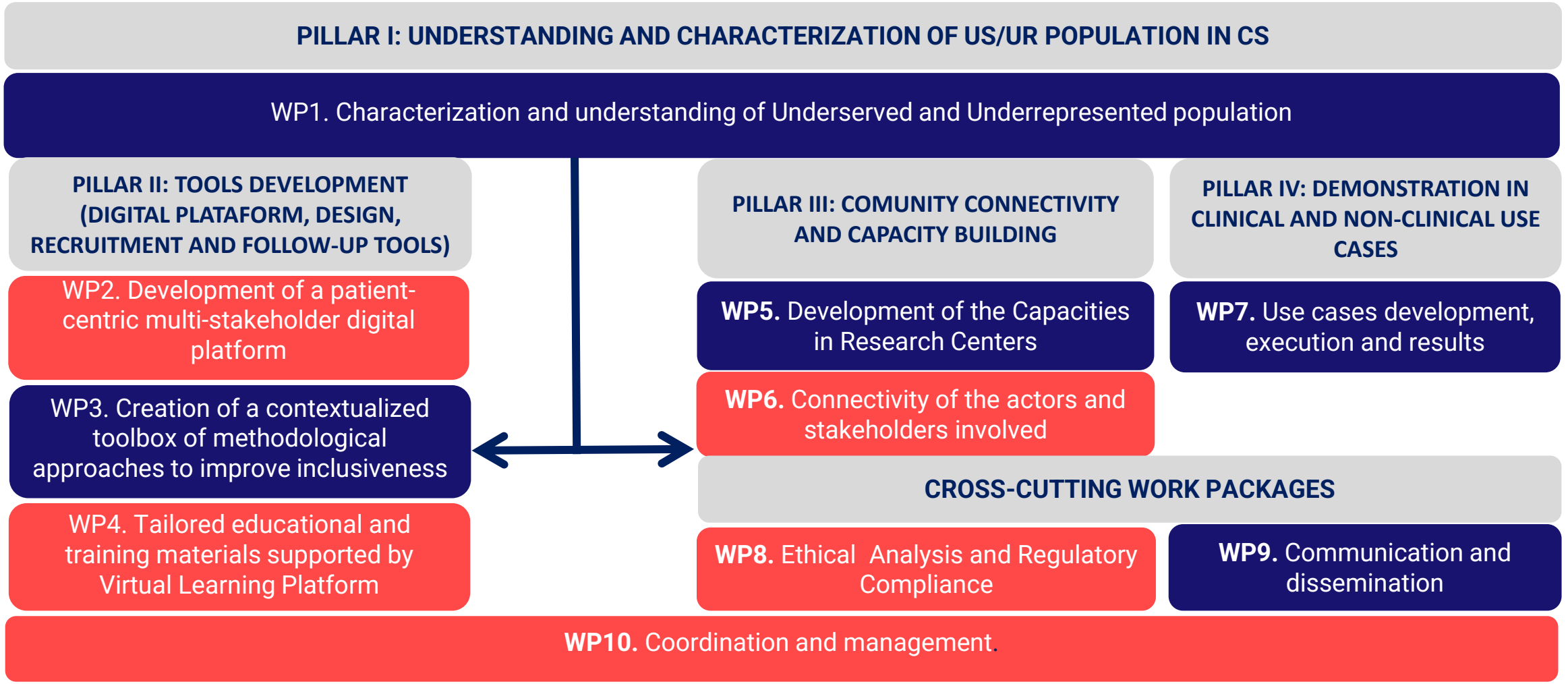
- Promote standardized collection and exchange methods to align information and overcome technical hurdles:
  - Identify technical stress points to understand the causes
  - Develop strategies to alleviate technical stress points
- Incentivize the implementation of data standards

Address resource limitations

- Commitment from the top to address health equity, share available resources to do so, and map out required investments to access funding (e.g. adoption of alternative payment models):
  - Familiarize top executives with unmet need and opportunity posed by disparities in health equity & the role of race and ethnicity data to address gaps and Identify & share funding sources
  - Discuss opportunities, required investments, and return on investment
  - Prepare funding proposals

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Engaging critical stakeholders in the process of inclusion of underserved and underrepresented populations in clinical studies.



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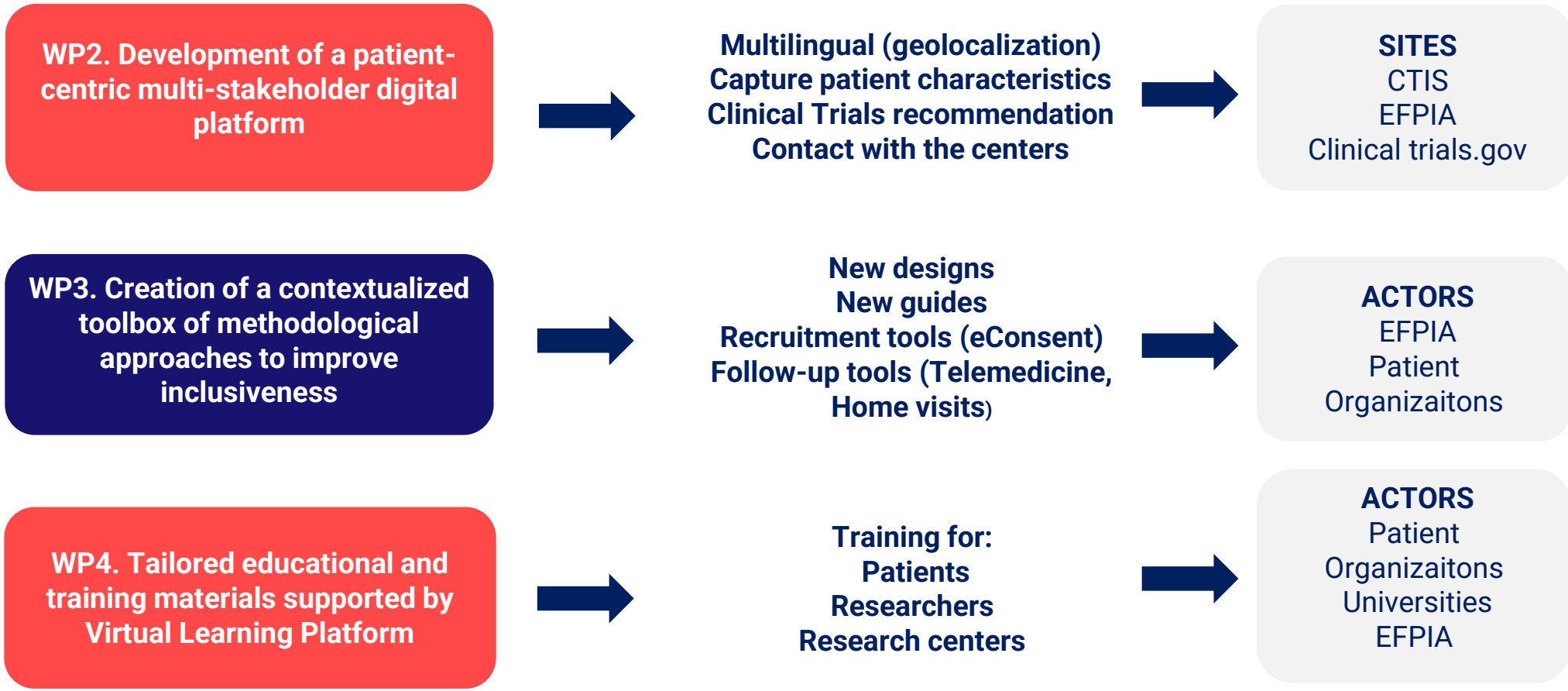

Thank you!

Contact Us!
Events@transceleratebiopharmainc.com

Diversity of Participants in Clinical Trials Initiative

Please reach out with any additional questions regarding TransCelerate's Diversity of Participants in Clinical Trials initiative.

Panel Introductions

Disclaimer

Responses have been sourced from a variety of panelists and do not necessarily represent the views of all (or their respective organisations)

Meet Our Expert Panel

Katherine Langridge
TransCelerate
Program Director

Ruma Bhagat
Senior Director, Health Equity & Population Science (HE&PS)
Genentech

Carla Rodriguez-Watson
Director of Research
Reagan-Udall Foundation for the Food and Drug Administration

Sabrena Mervin-Blake
Senior Project Manager,
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If you have a question for a certain speaker, **please include their name.**
Note: depending on time, we will not be able to answer all questions

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- Which member companies are using the assets/tools

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Thank you for joining us!