Setting Diversity Goals and Measuring Success

Lessons learned and the path forward

Rachael Fones, Director, Government & Public Affairs;
Strategic Advisor, and Diversity in Clinical Trials, IQVIA
Chair, ACRO Diversity, Inclusion & Equity Committee
January 31, 2023

Pursuing Diversity in Context of Overall Trial Goals:

Proactive, concerted effort – setting diversity goals is critical to downstream success

Reflect in Trial Design › **Factor into Site Selection** › **Be Clear & Support Sites from the Start** › **Understand Needs & Factor Throughout** › **Monitor, Adjust & Maintain Engagement**

Operational Success Factors

Validated Goals, Established Early

Having defined goals (% ranges) is key to downstream success – setting and communicating goals

Predictability and Calibration

Starting with population and site selection, through recruitment/ retention.

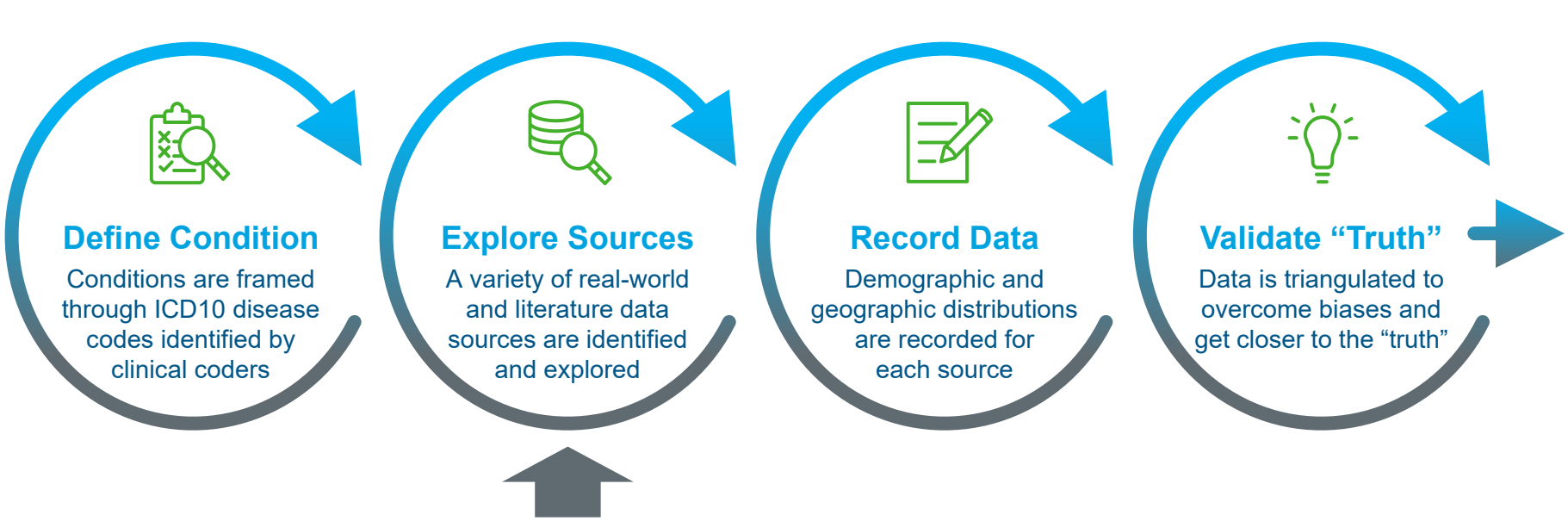
Understand site potential, site gaps, explore tradeoffs and calibrate accordingly

Monitoring and adjusting in real-time

Track and adjust; identify trouble spots, deploy support resources and realign contribution expectations to stay on course

Developed & Tested Real-world Demographic Assessment Process

Ran process against 27+ indications to identify data and build a better understanding of the true reality of disease burdens



Epidemiology Sources of Truth

- Evidence driven
- Transparent
- Triangulated

Data sources for building US disease-level demographics

- Claims + Consumer Data
- Registry Data
- Government Data (e.g., SEER, CDC)
- In-Patient and Ambulatory EMR
- Medical Literature

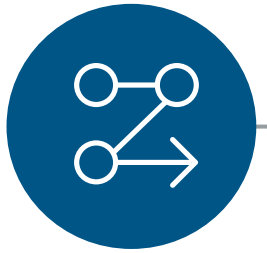
Key Takeaways: RWD for DICT Planning

RWD Informs, not answers

- Strengths and limitations transparent and clear
- Plan and enrollment goals informed by knowledgeable team – epi and clinical

Diversity is specific

- Each condition has a different path to DICT recommendations
- Improvements in representativeness is complex



Synthesize the evidence

- Background and contextualization of estimates through a synthesis of existing studies or cohorts

Variability inherent across data sources and by condition of interest

COPD- Example

Race/ Ethnicity	CDC/ NHIS	EMR In-Patient	EMR Ambulatory	Literature
White/ Caucasian	77.8%	86%	89%	69%
Black/ African American	11.0%	13.0%	8.3%	13.6%
Hispanic	6.9%	4.0%	0.2%	10.6%
Asian	1.0%	1%	0.7%	1.6%
Other	3.2%			5.3%

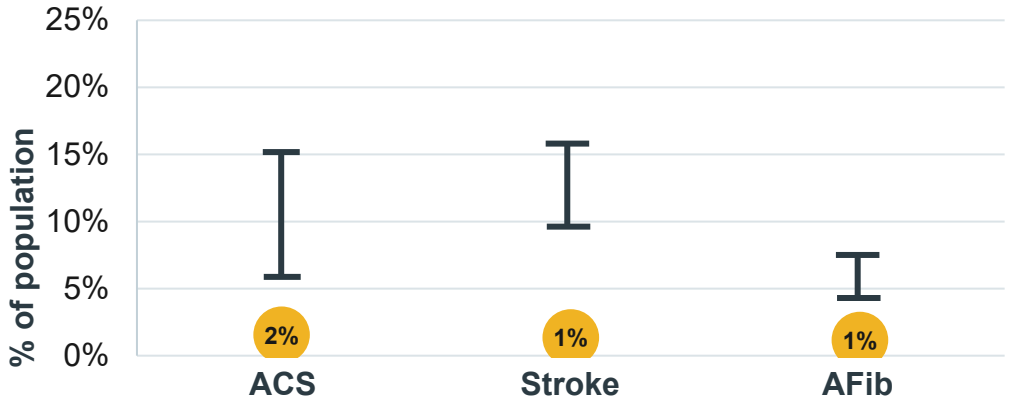
Context is key - apply scientific and clinical rationale

Setting goals will be subjective – interpretation and estimation

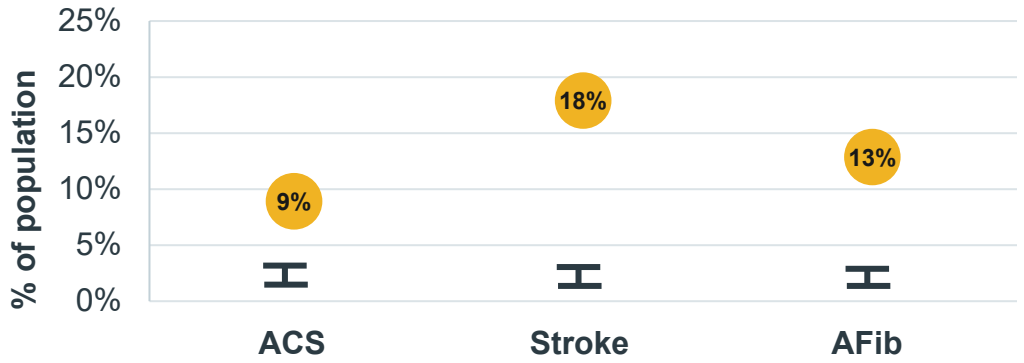
Setting Goals in Context – What Does Good Look Like?

Historical share of trial population vs RW diagnosed population*

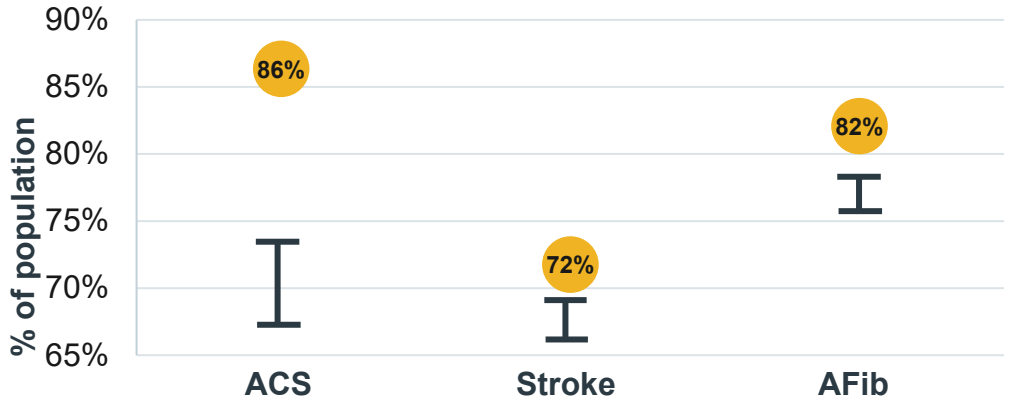
Black / African-American Patients



Asian Patients



White / Caucasian Patients



Hispanic Patients

No Hispanic data available for Afib Trials

I = % Range of Real-World Indication Population (AMB, IHN and CDC*)

● = % of Clinical Trial Population Includes global and US only trials

*As available

Observations & Opportunities – Setting Goals

IQVIA Recommended Approach (now expected)

Identify trial population goals upfront, communicate and monitor throughout

Observation/ Common issues

Having a defined goal is key to downstream success, BUT:

- Specific numbers cause angst: Perceived risk and trial delays; constrained enrollment
- Lack of clarity on what good looks like; No one source of truth, US vs Global site contribution, historical results

Path Forward

- Enrollment goals set, measured and reported as ranges: within x% = good, better, best
- Moving past diversity as an ‘either/or’ tradeoff with time and cost; set goal and plan to achieve alongside other goals
- Regulator clarity on ‘representative’; on what not meeting goals means, US vs Global %s
- Adopt an industry metric for measuring progress and success

To Maintain Momentum and Achieve Lasting Change: Need to Measure and Report Diversity in Context

A systematic way to measure performance, understand strategy impact, and track improvement

1 Quantification
Need for a simple, intuitive metric to evaluate and compare inclusiveness, through a validated approach

2 Standardization
Importance for a consistent perspective and language on what inclusiveness in clinical trials looks like

3 Actionability
Need for visibility into drivers of representativeness to enable strategic solutioning and tactical planning

4 Monitoring
Urgency for a mechanism to track D&I within a clinical study, to inform rapid decision making

Without a standardized measure, there can be no common and shared targets, commitments or measures of progress...

ACRO's Diversity, Equity, and Inclusion Principles

- Associated actions CROs and Tech can take to support DE&I

Improving Health Equity Through Access to Trials

- **Increase awareness and opportunities** for clinical trial participation among diverse populations
- **Reduce the burden** of participation for diverse communities through innovative methodologies, decentralized trial support services, and digital technologies
- **Work with** predominantly underrepresented **communities** to build trust between stakeholders

Partnering with Stakeholders & Policymakers

- **Work with policymakers and regulators** around the world to promote policies that improve diversity and inclusion of underrepresented study participants
- Embed a patient-centric mindset in policy recommendations by partnering with patient and minority advocacy groups
- **Collaborate with other industry groups** to drive progress towards inclusive clinical trials

Empowering Research Partners

- **Educate and engage patients** as research partners throughout the clinical development lifecycle
- **Harness data to better characterize relevant patient populations**
- **Support sites** with training and culturally relevant materials to work with diverse communities
- Use data to **identify investigators with** access to clinically relevant, **diverse patients**

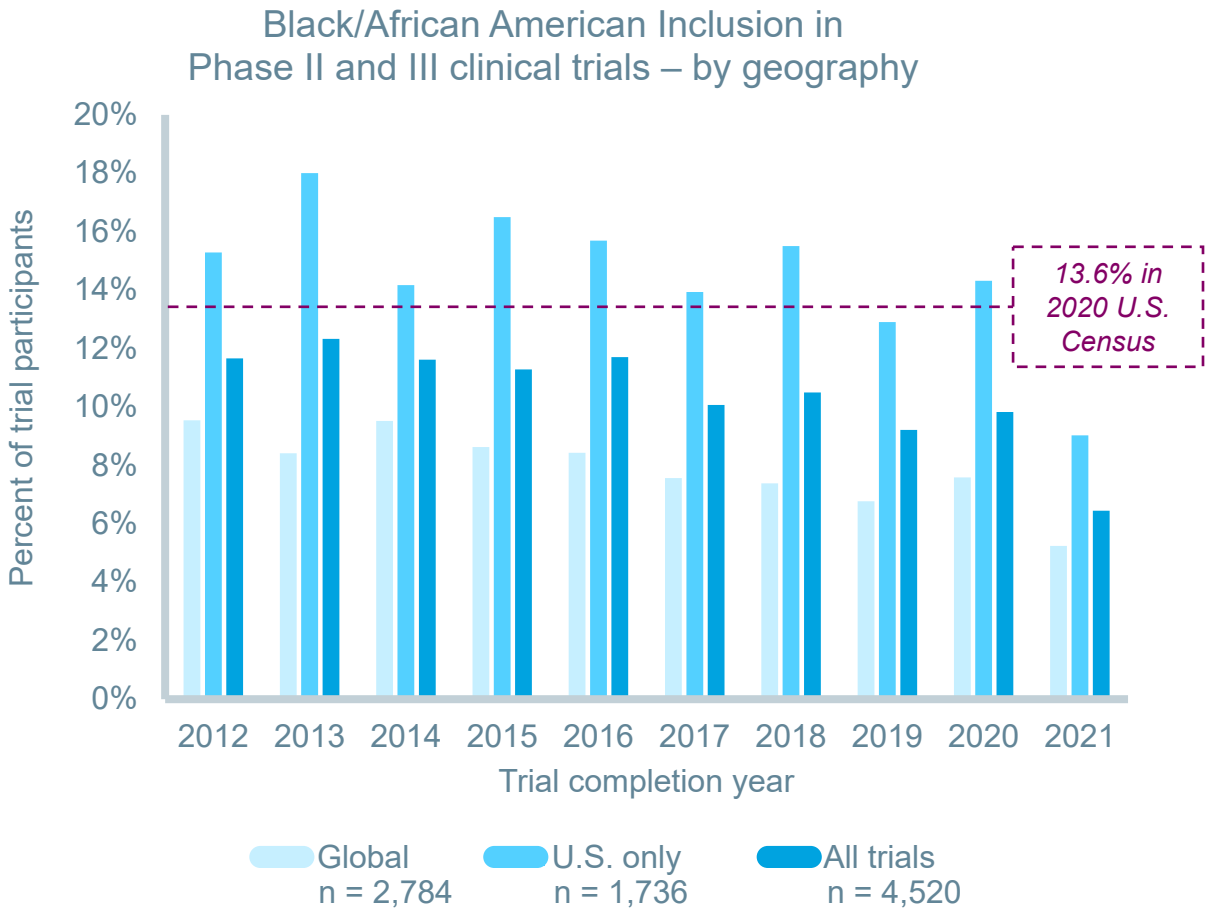
Driving Workforce Diversity, Equity, & Inclusion

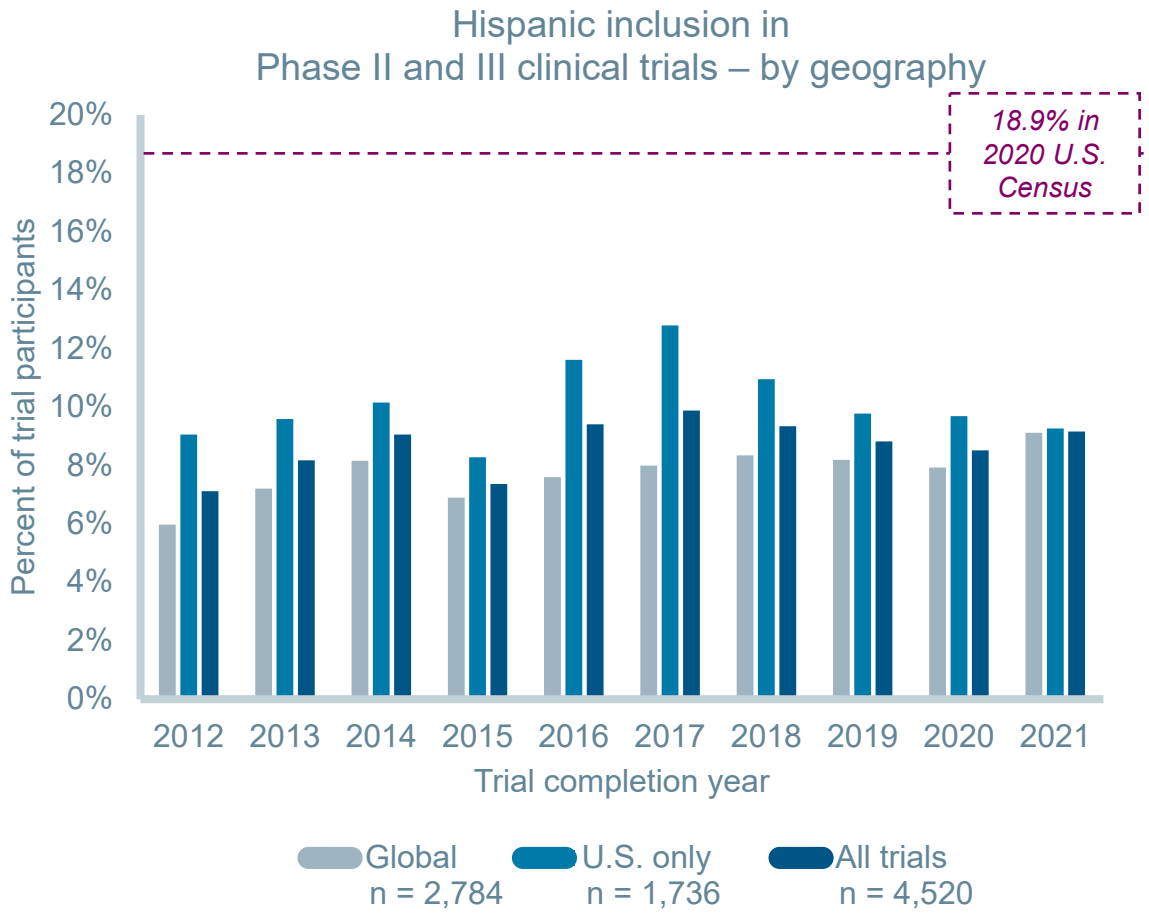
- **Support programs** that drive diversity and inclusion in the clinical research industry workforce including employee retention, recruitment, and development
- **Foster relationships** with minority healthcare associations and other groups to bring new generations into clinical research

ACRO
CELEBRATING 20 YEARS

Appendix

Selectivity: Site selection by geography impacts inclusivity





Notes: Includes all interventional Phase II and III trials with industry involvement and any U.S. sites listed on ClinicalTrials.gov as starting after 2009 and completing in 2020. Global includes any trial that had U.S. sites and ex-U.S. sites; U.S. Only are trials with only U.S. sites and All Trials is all of the trials in the data set (Global and U.S. Only combined).
Source: ClinicalTrials.gov June 1, 2022; U.S. Census Bureau.
Advancing Diversity in Clinical Development through Cross-Stakeholder Commitment and Action. Report by the IQVIA Institute for Human Data Science.

IQVIA INSTITUTE