

What are YOU doing to increase diversity in clinical trials?



Rob Califf
Commissioner
FDA



Ricki Fairley (Moderator)
CEO
Touch, The Black Breast Cancer Alliance



Ashish Chaturvedi
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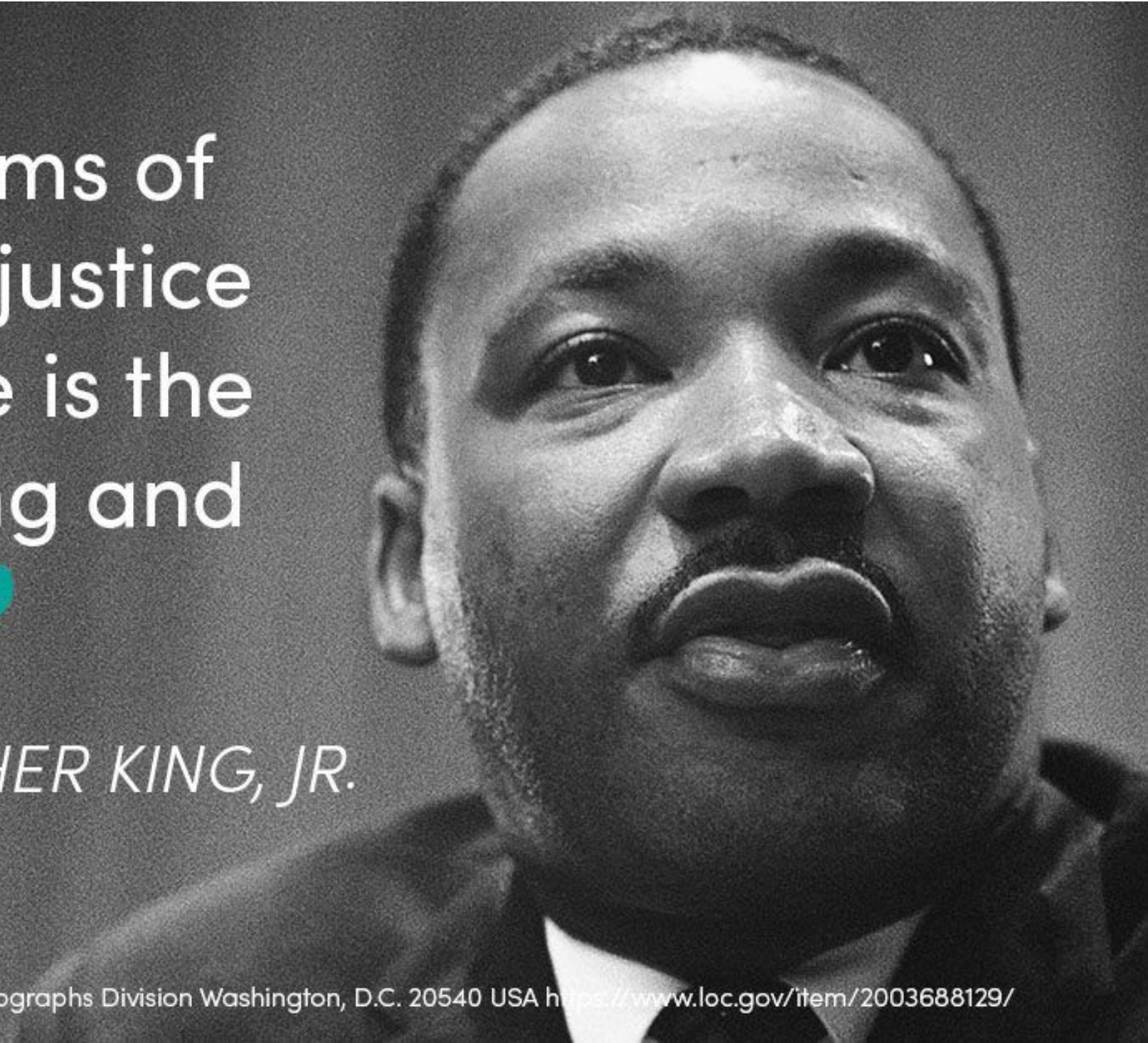


R'Kes Starling
Chief Executive Officer
Reveles Clinical Services

“Of all the forms of inequality, injustice in healthcare is the most shocking and inhumane.”

DR. MARTIN LUTHER KING, JR.

Library of Congress Prints and Photographs Division Washington, D.C. 20540 USA <https://www.loc.gov/item/2003688129/>



Diversity is receiving an invitation to a party.
Equity is possessing the resources to attend.
Inclusion is being asked to dance.

– Author Unknown



DIVERSITY, EQUITY & INCLUSION in Digitized Clinical Trials

Improving and increasing diversity,
equity, and inclusion in the clinical
trial design process

Partners



Our mission

DiMe is a global non-profit dedicated to advancing the **ethical, effective, equitable**, and **safe** use of digital medicine to redefine healthcare and improve lives.

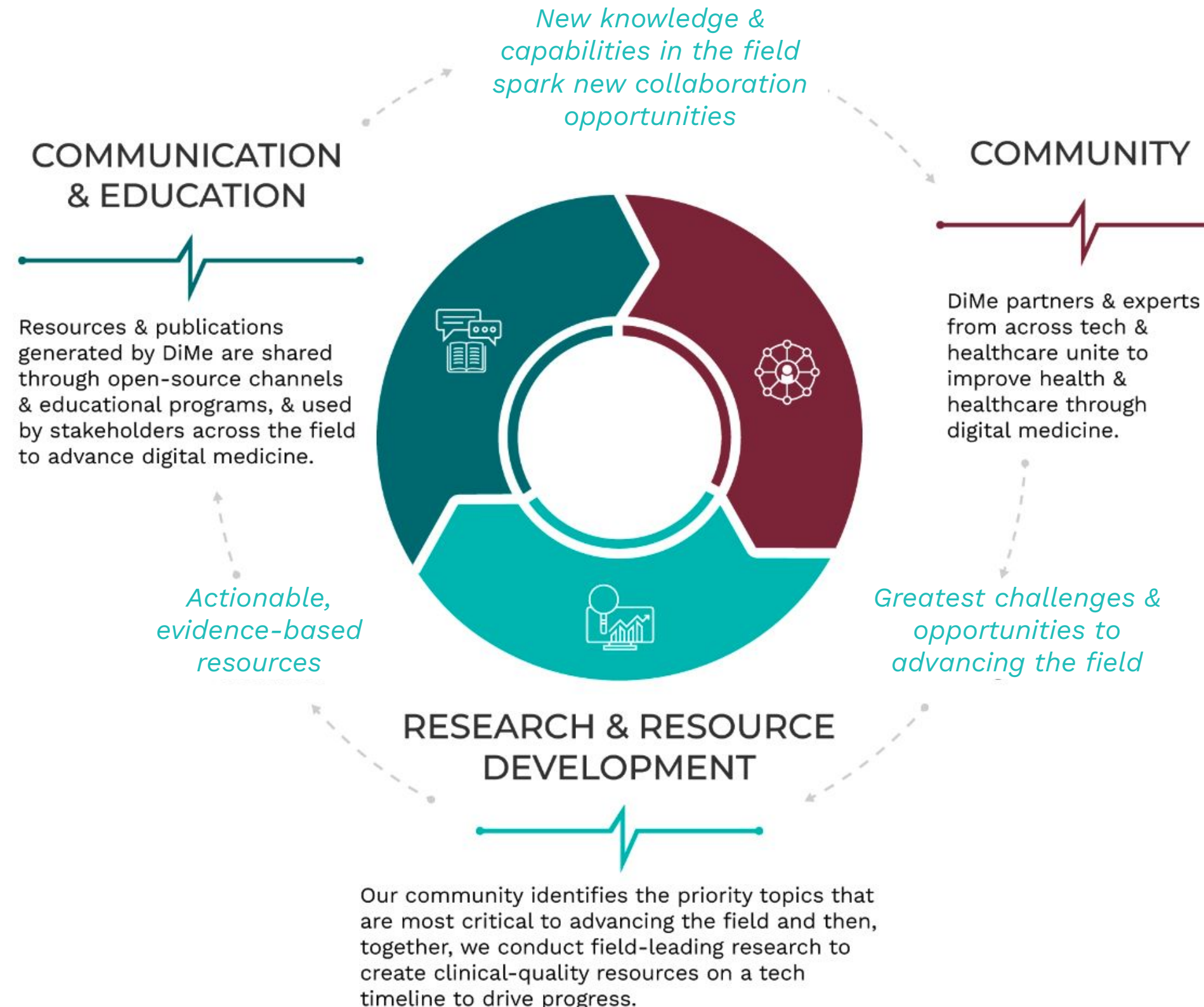
We sit at the intersection of global healthcare and technology



2022 Q4 DiMe Scientific Leadership Board Meeting



We deliver clinical quality work on a tech timeline



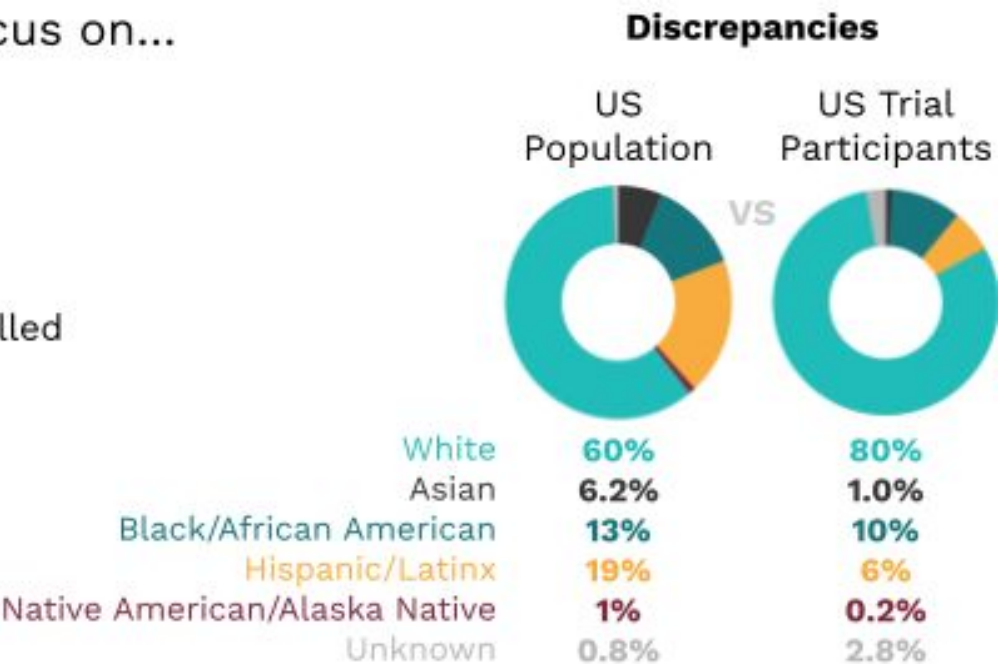
Clinical trials need to focus on...

Diversity

75% of participants enrolled in trials were **White**.

11% were **Hispanic**.

10% were **Black**.



Heart disease is the leading cause of death for women in the United States.

Of cardiovascular clinical trial participants:

38% are **women**.

6% are **Black or African American women**.

Oncology trials:


Only 2% of participants were **Black women**.


84% of participants were **White women**.


Equity

Less than **2%** of trials over a 2-year period had a **minority group** as its primary focus.

Of **7,000** known rare and ultra-rare diseases, **10%** have a trial.

 Sickle cell disease affects **>100,000 Americans**. Most are **Black or Hispanic**.

 Cystic fibrosis affects about **30,000 Americans**. Most are **White**.

 Cystic fibrosis research receives **10X more funding**.

Inclusion

50% of clinical trial participants find it **difficult to stay enrolled**.

86% of clinical trials **do not reach recruitment targets**.

<10% of Americans **participate** in clinical trials.

 **70%** of patients **live more than 2 hrs** from a research site.

“The U.S. population has become increasingly diverse, and ensuring **meaningful representation** of racial and ethnic minorities **in clinical trials** for regulated medical products is **fundamental to public health**.”

Robert M. Califf, M.D., FDA Commissioner

Design a person-centered strategy with digital tools to increase diversity, equity, and inclusion in clinical trials

1

Assess



Assess opportunities for utilizing digital tools to be more diverse, equitable, and inclusive with your clinical trial design

2

Identify



Identify which digital tools are best suited to each step of your design process

3

Implement



Implement specific actions guided by person-centered principles

- **Diversity** is critically needed, due to decades-long lack of equity
- **Inclusivity** must be central to each step in the clinical trial lifecycle
- **Accountability** is a requirement for success

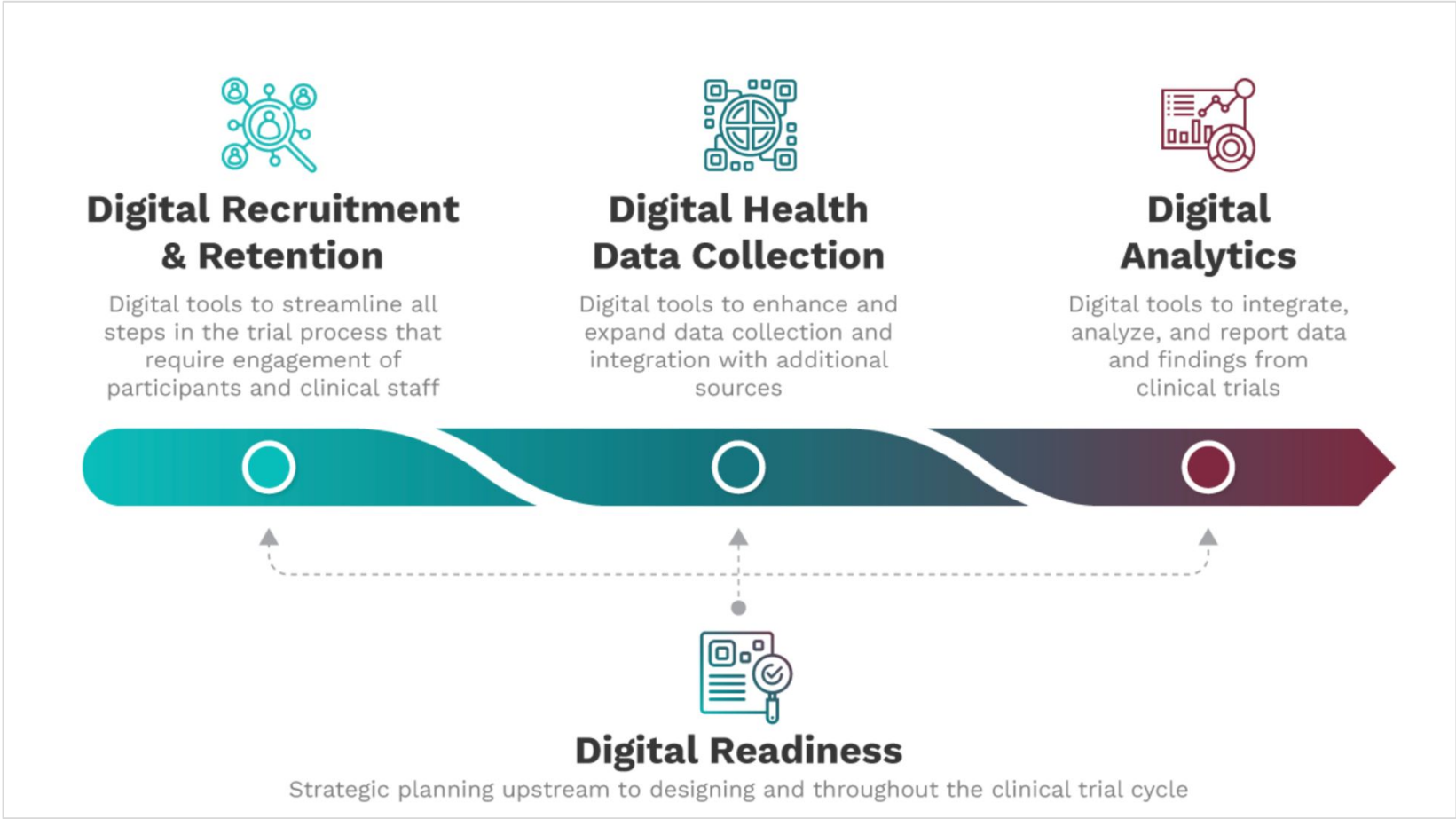


Specific Actions to Enroll & Retain Diverse Participants

A Digital Tools Workbook



Why should you use digital tools?



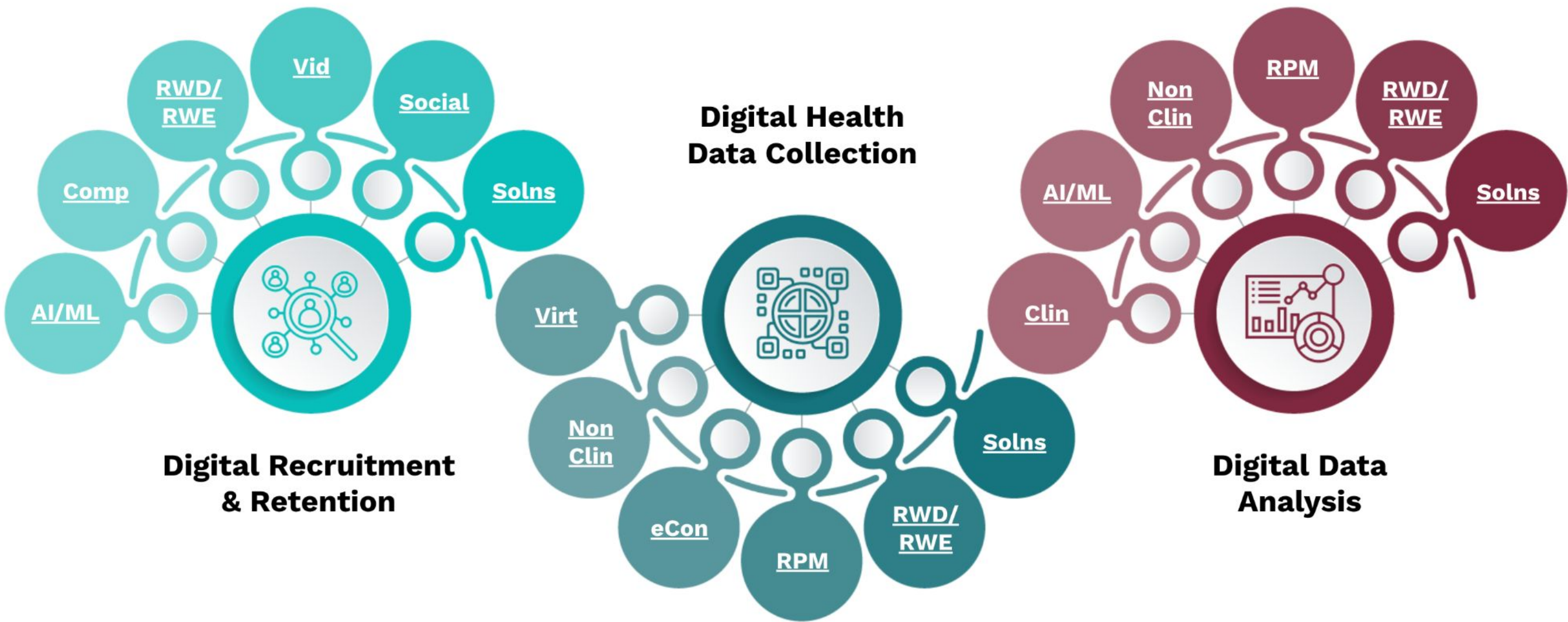
DIGITAL TOOLS	CHALLENGES						
	Low recruitment & retention rates	Extended time for trial completions	Missed enrollment milestones	Populations excluded due to insufficient data on disease epidemiology	Building trust & transparency bw patients & investigators	Incomplete data collection	Time intensive work for data cleaning & analysis
AI/ML	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Clin	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Comp	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
eCon	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Non Clin	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
RWD/E	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Social	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Solns	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Vid	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●
Virt	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●

● Digital Recruitment & Retention ● Digital Health Data Collection ● Digital Analytics

Implement a Digitized Clinical Trial

Address Clinical Trial Challenges

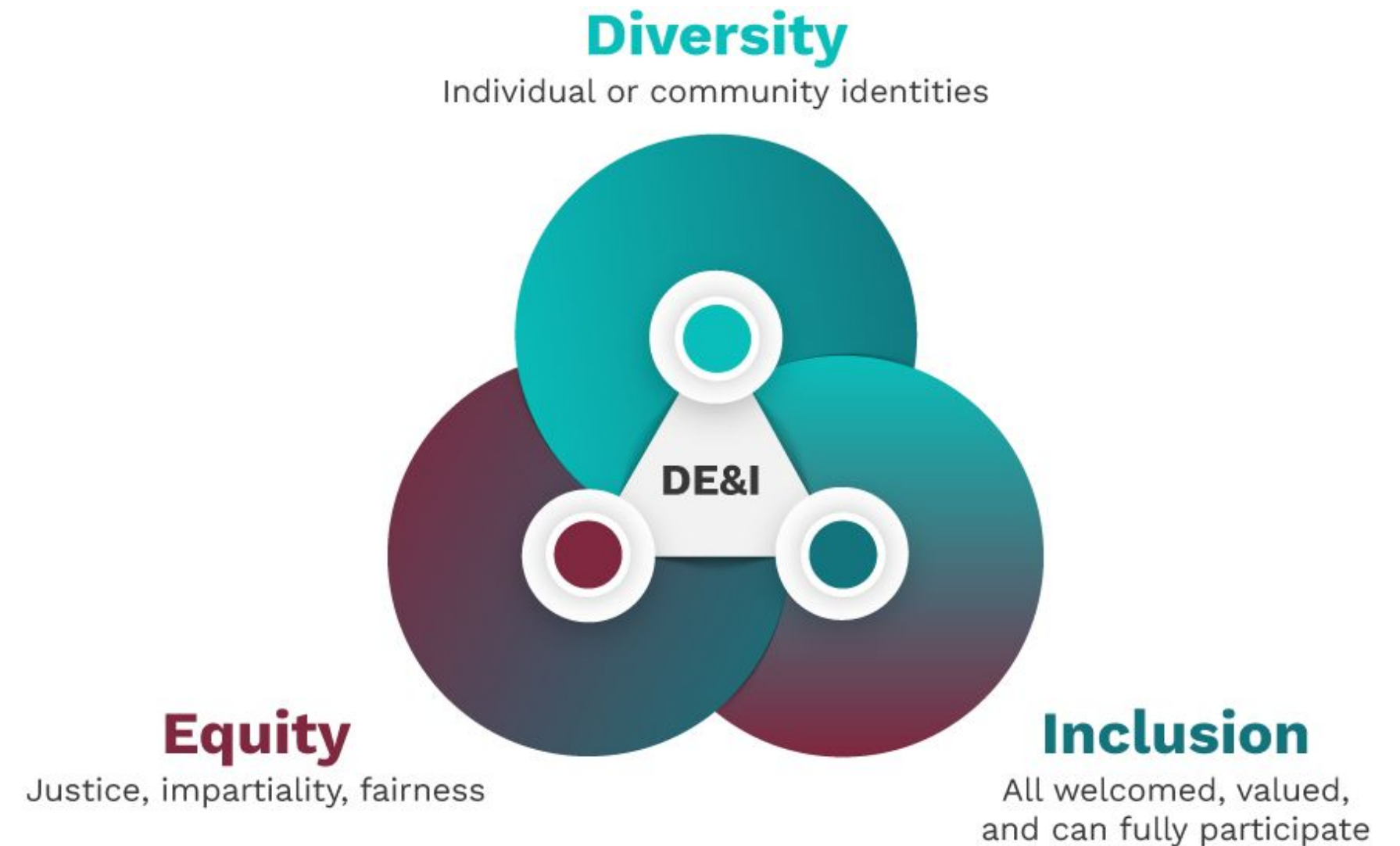
How you can use digital tools?



Elements of a Digitized Clinical Trial

Advance diversity, equity, and inclusion with digital tools

- Identify populations who can benefit from your trial
- Design and implement inclusive engagement plans
- Build trust
- Empower participants
- Support clinical site teams
- Hold the industry accountable
- Collaborate and share



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Project Team Accomplishments

- Submitted a comment for the FDA draft guidance on improving diversity in clinical trials
- Hosted an external Subject Matter Expert workshop - 17 external (non-project) organizations participated
- Project Team Panel discussion on accountability for increasing diversity, equity, and inclusion in clinical trials - 140 registered
- Guest column in Clinical Leader on how digital tools that can advance diversity efforts, now
- Deployed a patient survey to learn how prepared patients are to use digital tools in clinical trials
- Developed 20 resources that can be integrated into the FDA Diversity Plan
- 50 Resources in action, demonstrating how leading organizations are using digital tools to address diversity, equity, and inclusion challenges for clinical trials