Worldwide Clinical Trials

Health Equity in Clinical Research

In a diversity, equity, and inclusion (DEI) regulated drug development industry, you need a CRO who ensures DEI is at the forefront of study delivery and outcomes. At Worldwide Clinical Trials, we offer comprehensive solutions across clinical program development, regulatory strategy, diversity action planning, and operational solutions in trial delivery.

The Health Equity Task Force is comprised of experts at all functional levels who develop the framework of our Diversity Action Plans, ensuring operational implementation across all the study's teams.

Accessible Health Equity Knowledge

The Food and Drug Omnibus Reform Act (FDORA) was signed into law in December 2022, taking effect January 1, 2023. This recent legislation mandates all drug developers to create and submit a formal Diversity Action Plan no later than the end of Phase 2. An operational Diversity Action Plan brings numerous benefits to your drug development program, including:

- Mitigating long-term costs to drug development associated with post-market surveillance requirements
- Priming new drugs for commercial success by ensuring comprehensive efficacy data
- Informing protocol design and trial delivery

Adult and Pediatric Experience | Phases 1 – 4

Our Health Equity services have been applied across a range of therapeutic areas, including rare diseases, ophthalmology, and vitreoretinal diseases. Our adult and pediatric experience encompasses:

- **Neuroscience**
- **Nephrology**
- **Oncology**
- **Pulmonology**
- **Cardiovascular**
- **Infectious Diseases**

Our team's experience includes treatment modalities, such as:

- Oral compounds
- Infusion and injection biologics
- Gene therapy
- Topical lotions
- Intrathecal catheter/injection
- Nanoparticle
- Implantable
- Transdermal
- Inhalation

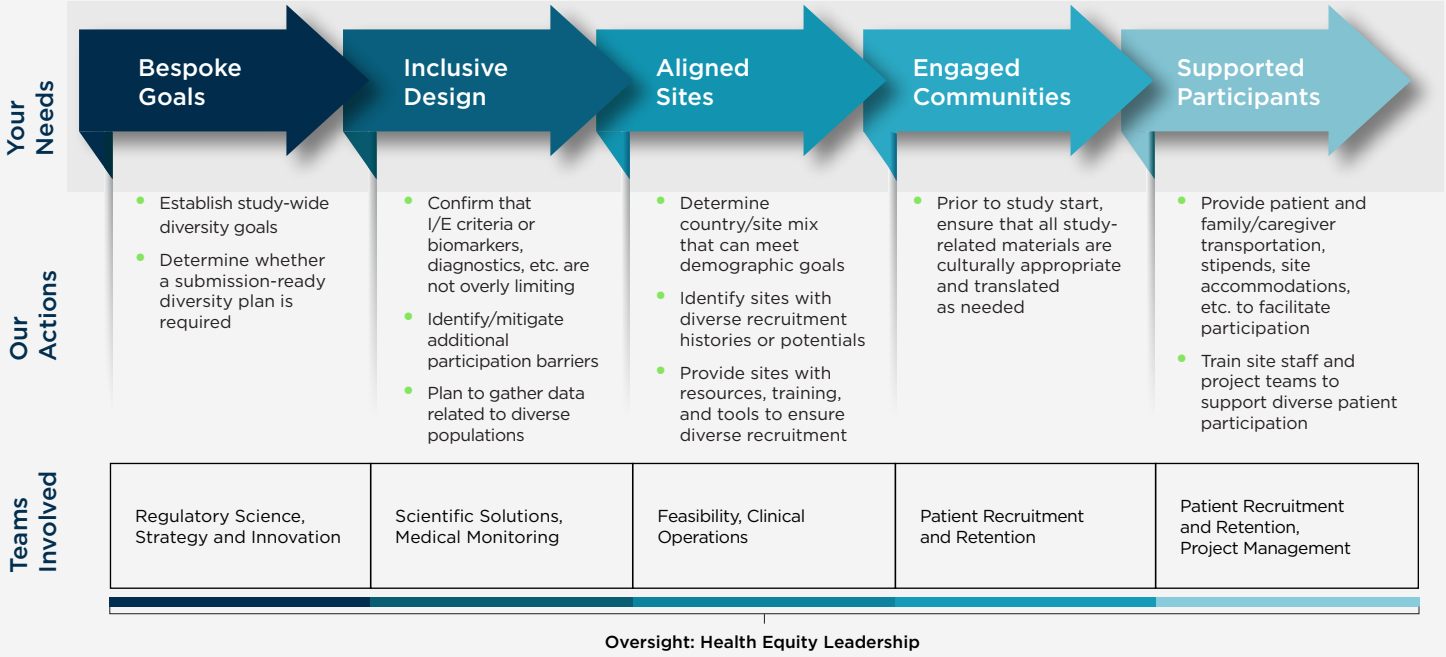
Our Integrated Approach to Health Equity

Worldwide's Health Equity leadership team has deep expertise in global regulatory and site-level clinical operations, which helps effectively operationalize Health Equity strategies into actionable solutions across all functional teams.

- **Development of Community-Based Sites** – Includes outreach, engagement, and partnerships with new community-based sites.
  - De-risking site operations
  - Design and delivery of site-level solutions and support
  - Early engagement and qualification for studies in the pipeline
- **Solutions Engineering** – Vendors and solution providers are vetted from a diversity & inclusion lens and then assembled/deployed with intentional design.
- **Cross-Functional Expertise** – Diversity Action Plans are effectively executed by the right expert team and as a larger effort to operationalize Health Equity strategies

Our Commitment to Patient Inclusion and Health Equity

Effective clinical trial populations must represent the patients we treat, and so must our organization. Our Health Equity Task Force is comprised of subject matter experts with global representation at all functional levels and therapeutic indications. The Task Force is dedicated to ensuring that diversity and inclusion strategies are intentionally designed for effective operationalization. The below figure captures how Worldwide is creating a new industry standard with our strategy-to-action approach.



Global & Regional Regulatory Expertise

We offer practical knowledge in the North American and International regulatory arenas through all phases of the drug development process. We additionally provide extensive industry experience shaping project plans to meet the evolving regulatory requirements.

Our Solutions

- Consultation and development of Diversity Action Plan
- Oversight of pre-award and post-award operations
- Ongoing monitoring of DEI performance

Operationalizing Health Equity Strategy

Our Solutions

- Review and confirm that protocol is not overly limiting
- Identify and mitigate barriers to participation
- Engage and deploy vendors and other solutions to support site-level operations and patient recruitment

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With diversity and inclusion requirements expected to be one of the biggest disruptions to drug development, Worldwide has you covered. For more information or to talk about your study, contact us.