FHI 360: Supporting the clinical research industry in high-quality clinical trials

FHI 360 is a global human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. We advance the science that saves lives. Our clinical trials consistently break new ground in many critical global public health areas including HIV, TB, malaria, other infectious and noncommunicable diseases and family planning.

In collaboration with global networks and partner organizations, FHI 360 designs, implements, manages and monitors complex studies, including multisite and multicountry clinical trials. Our clinical trials gather information on the safety and effectiveness of drugs, devices and vaccines. Our studies also provide data for regulatory approvals for product marketing in the U.S., the E.U. and many other countries worldwide.

Full Service Contract Research Organization

In addition to providing clinical research services to governments and foundations, FHI 360 acts as a full service research organization (CRO) to the pharmaceutical industry, setting up and managing studies for them in the Americas, Asia Pacific and Africa. Our team of global clinical research specialists includes:

- Clinical project managers
- Clinical research associates
- Regulatory affairs and quality assurance specialists
- Laboratory technologists
- Document specialists
- Biostatisticians
- Data management specialists
- Medical writers

Our clinical research professionals have worked across all phases of clinical trials, from preclinical to post- marketing/Phase IV studies. The majority of these staff are local nationals and have a thorough understanding of the in-country environment. They understand local regulations, know how to meet the challenges associated with clinical trials in a given country, and are experts at working with local health care systems and institutions for successful trial completion.

Regulations and Standards

FHI 360 staff work to the highest scientific and ethical standards, and are fully compliant with the principles embodied in International Conference on Harmonization, Good Clinical Practice (ICH-GCP E6). Our understanding of the regulations of many countries allows us to work effectively in multiple contexts on a variety of projects, including investigational new drugs and devices in the U.S., the E.U. and countries across Asia and Africa. In addition, our award-winning research ethics training curriculum is used throughout the world.

Services to the CRO Industry

FHI 360 also provides services to CROs to strengthen their capacity to compete in an international research market. The number of local CROs offering services to

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international and local pharmaceutical and research and development groups has increased worldwide. However, CROs face challenges in implementing and conducting research in accordance with international and GCP standards as required by their sponsors. FHI 360 can help CROs meet this challenge. We have conducted thousands of clinical trials in over 100 hundred countries and know what it takes to meet regulatory requirements across multiple countries. We support local CROs in strengthening their systems and capacities to meet international regulations and sponsor requirements.

FHI 360 services to the CRO industry:

- A comprehensive understanding of the regulatory landscape within a given country or region
- Developing a successful regulatory strategy to obtain marketing approval
- Advice on how to select and choose the best clinical sites and how to implement a site capacity-building strategy
- Development of successful recruitment and retention strategies in both urban and rural settings and across subpopulations, including those less easy to reach
- Training in GCP and research ethics and avoiding common pitfalls
- Developing site quality-management systems and metrics
- Evaluating clinical and central laboratories and recommending quality and capacity enhancements
- Establishing GCP-compliant study implementation systems, even in non-U.S. and non-E.U. settings
- Setting up a research pharmacy
- Establishing GCP-compliant source documentation and verification systems
- Building a data management unit for a trial
- Establishing randomization and emergency unblinding systems
- Developing and implementing a clinical monitoring plan
- Establishing safety reporting and pharmacovigilance systems including expedited reporting systems

FHI 360 works with CROs to evaluate their strengths and weaknesses. Together, we develop a tailored training and capacity-building program to enhance the internal capacity of the CRO to meet international standards. The international clinical research market opens up to local CROs when they have demonstrated their comprehensive capacity to work at an international quality level underpinned by GCP.

For more information about FHI 360's clinical research support services, contact:

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About FHI 360 FHI 360 is a nonprofit human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. Our staff includes experts in health, education, nutrition, environment, economic development, civil society, gender, youth, research and technology — creating a unique mix of capabilities to address today's interrelated development challenges. FHI 360 serves more than 60 countries, all 50 U.S. states and all U.S. territories.

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