



WORLDWIDE
CLINICAL TRIALS

LEVERAGING CRO SITE RELATIONSHIPS TO DRIVE YOUR STUDY FORWARD

STEVE CHRISCOE

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CURRENT ONCOLOGY CLINICAL TRIAL LANDSCAPE



Current US oncology site landscape is competition heavy

Large academic centers are limited on resources while balancing restrictions

Potential lengthy activation periods with multiple committees required before IRB

Pharma & Biotech are under increasing pressure to meet aggressive milestones

The same pharma and biotech companies are more resource constrained than ever, and are relying on CRO partners to deliver

THE TRADITIONAL SPONSOR-SITE ENGAGEMENT

Historically, sponsor engagement with sites during the clinical development process has focused on Key Opinion Leaders (KOLs)

- While this can be critical for medical community engagement, as well as publication strategy, there ARE limitations:
 - KOLs may not be a fit to participate in every study
 - Your KOL sites are not always strong enrollers, AND
 - KOL sites typically are not your fastest to activate



YOU ARE FACED WITH...



Challenging
patient
population

A small team

Budget
constraints

Aggressive
timelines

Limited site
relationships

INSIGHTS INTO SITE CHALLENGES

The Top Issues Impacting Sites Today



Source: WCG Q1 2022 Site Survey

“The new environment will require evolution of the current collaborations between sponsors, CROs, third-party clinical research vendors and experienced physician investigators. This collaboration’s success will depend on a shared focus to cultivating a redesigned clinical research landscape...”

Source: *Redesigning the Clinical Research Landscape*, Jamie Harper (WCG Director of Site Engagement & Relations)

Over 75% of sites want to participate in protocol review/early Engagement discussions in order to positively impact how easy (or not) a protocol is to operationalize at their site

THE OLD SCHOOL CRO APPROACH

- Traditionally, CROs have had a more transactional relationship with sites.
 - The CRO utilizes the site when there is a study or studies that fit the profile
 - The sites become engaged in site start up
 - While sites may have feedback on the protocol, it is typically only shared following protocol finalization and study start
 - The approach is TACTICAL instead of STRATEGIC



A DIFFERENT STRATEGY



CASE STUDY 1: CHALLENGING MILESTONES



1

An all-comer solid tumors study, FIH phase I/II run in the US

2

The sponsor is an emerging biotech whose operations are all outside of the US

3

Sponsor does not have relationships with sites in the US and relies solely on Worldwide to identify appropriate study centers

4

First IRB approval was within 12 weeks of the start of work and final protocol

5

All 5 study centers were activated less than 7 months from the beginning of work and final protocol

6

To date, enrollment is tracking AHEAD of schedule

7

The study center who was the first to activate and enroll is a Worldwide alliance site, and is also the highest enroller

CASE STUDY 2: FAST MOVING, COMPLEX TRIAL



1

Phase 1b/2 Umbrella design in patients with various solid tumor combinations

2

The sponsor is a fast-paced US biotech with strong industry collaborations outside the US

3

While the sponsor had existing site relationships, they relied on Worldwide to provide our recommendations

4

Final protocol was delayed, but sponsor and Worldwide agreed to do work at risk and hold to timelines

5

First site initiated & database live in under 3 months from the final protocol receipt

6

First patient was screened 2 days following activation

7

The study center who was the first to activate and enroll is a Worldwide alliance site. This site was activated in **6 WEEKS** after being selected for the trial!

CASE STUDY KEYS TO SUCCESS



Case study 1: All study centers were CRO recommendations!

PARTNERSHIP PRESS RELEASE

Through Worldwide's Site Alliance Collaboration a partnership with The Christ Hospital was announced

Emphasis of partnership is focusing on placing advanced cancer clinical studies for local community patients

Always keeping the patient cancer journey in mind understanding innovation and access is key

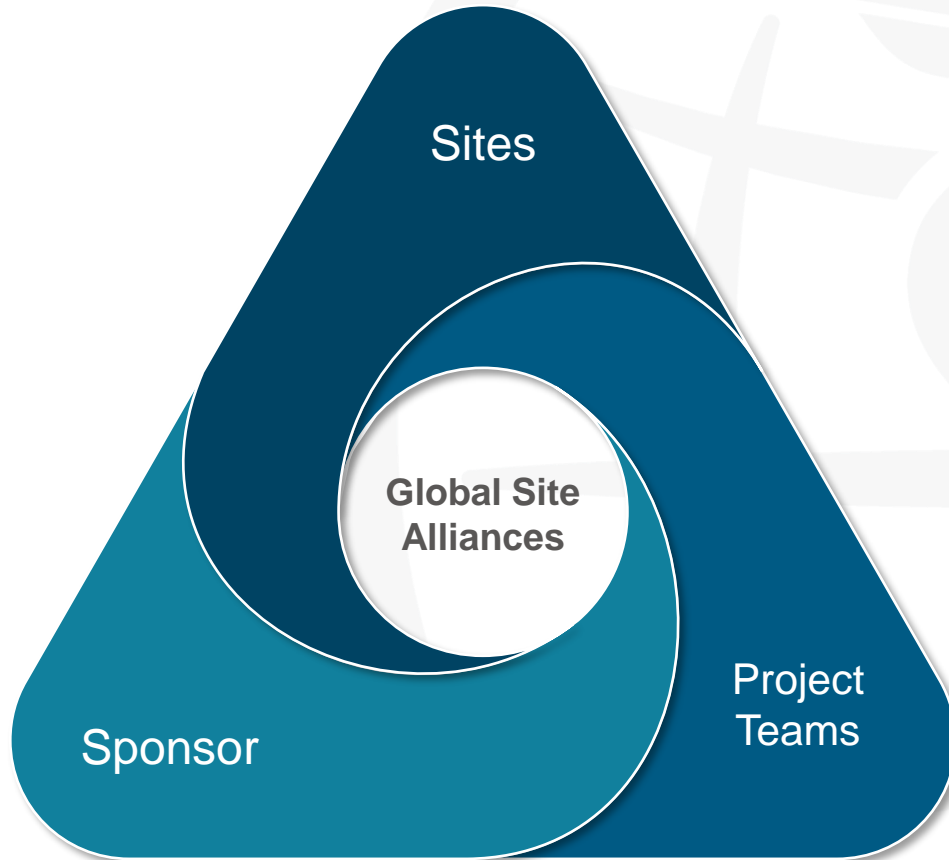
The Christ Hospital Health Network Announces Partnership with Worldwide Clinical Trials in a Collaboration for Leading-Edge Breakthroughs in Oncology Cancer Treatments

The Christ Hospital Health Network (TCHHN) takes another unwavering step forward in its commitment to provide innovative treatment for regional cancer patients.

10/20/2021

Cincinnati (October 14, 2021) – The Christ Hospital Health Network (TCHHN) takes another unwavering step forward in its commitment to provide innovative treatment for regional cancer patients. Today, TCHHN announced a partnership with Worldwide Clinical Trials, through Worldwide's Site Alliance Collaboration, which will increase access to oncology clinical trials and bring revolutionary cancer treatments to regional patients—without traveling beyond the tristate area. "We at The Christ Hospital Health Network are very proud and appreciative of our relationship with Worldwide Clinical Trials," said Alexander N. Starodub, MD, PhD, Medical Director of Oncology Clinical Trials. "They are an outstanding contract research organization that represents some of the most innovative biotechnology companies in the world." Dr. Starodub, an oncology and hematology physician, specializes in clinical trials, research, and medical oncology. He holds a PhD in biophysics and is board-certified by the American Board of Internal Medicine with an additional subspecialty certification in medical oncology and hematology. He explained that Worldwide's talent and infrastructure extend across 60 countries and include a full range of therapies, including access to oncology's most groundbreaking clinical trials and revolutionary cancer treatments. "This is a global company that has the opportunity to engage in a partnership with any hospital system around the world. Their decision to award us with a partner relationship confirms our program as highly credible and affirms our stance as a health network delivering unparalleled quality healthcare to our patients." According to Worldwide, oncology clinical trials are notoriously plagued by lengthy study activation periods, which can delay the availability of advanced treatments for cancer patients. Through this partnership, Worldwide Clinical Trials and The Christ Hospital will focus on addressing time-limiting hurdles to reduce the activation period to less than three months on average, ensuring patients with critical needs have faster access to advanced clinical trial options. Worldwide's mission is to foster the

SITE ALLIANCE BENEFITS



Alliance Sites

- Early Engagement – medical and operational input into protocol / project
- Pipeline visibility for resource planning
- Proactively share challenges & opportunities during monthly meetings
- Single point of contact at Worldwide for needs and quicker resolution of issues

Sponsor

- Real PI feedback on their protocol during pre-award / development phase
- Quality engagement with PI/sites to increase publicity/awareness for your project / pipeline
- Expedited Feasibility / Selection process (master CDA & quicker decisions)

Worldwide Project Team

- Trusted site partnerships for more efficient delivery
- Direct insight into site challenges and opportunities
- Allowing Site Alliance contacts to identify their best PI based on Phase, indication, staff availability and proven enrollment history



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QUESTIONS?