WORLDWIDE CLINICAL TRIALS

6 WAYS WORLDWIDE CAN HELP YOU OVERCOME CHALLENGES IN EARLY-PHASE ONCOLOGY TRIALS

EARLY-PHASE ONCOLOGY RESEARCH FACES UNIQUE CHALLENGES

15%

Only 15% of oncology drugs that get started in clinical trials reach phase III studies, and the likelihood of approval (LOA) of any new anticancer drug entering clinical trials is just over 5%.[1]

Not only is this expensive but also frustrating and discouraging for all involved.

The high failure rate creates a deterrent to sites and patients who might be willing to participate if the odds of success were greater.

WHY IS THE SUCCESS RATE SO DISMAL?

The world of oncology clinical trials is changing.

Anticancer therapies hitting the realm of clinical research increasingly include molecularly targeted agents (MTAs)—small molecule inhibitors, monoclonal antibodies, and immunotherapies.

These new classes of therapies fail prior to approval at alarmingly high rates, in part due to the fact that the entire history of early-phase oncology trials evolved around the proper study of a different class of drugs: cytotoxic agents.

Oncology agents must demonstrate efficacy against end points that are a challenge from a timing, complexity, and surrogate measurement perspective.

HOW CAN WE REDUCE THE RATE OF EARLY-PHASE ONCOLOGY FAILURES?

By proactively working to avoid the common roadblocks in early-phase oncology trials—and bringing in trial planning and administration experts to lay out an optimal strategy for your drug development program—you can give your drug the best possible chance at success.

6 PROBLEMS THAT CAN CAUSE EARLY-PHASE ONCOLOGY TRIALS TO FAIL

1 | SCIENCE IS MISSING

Insufficient scientific knowledge to guide trials is common.[2,3]

This can come in the form of insufficient data in:

- Animal models
- Pharmacokinetics and bioactivity
- Dose estimations and toxicity
- Mechanism of action and pathways
- Likelihood of resistance
- Potential synergistic drug combinations

This can cause poor decision-making, difficulty setting dose tiers, suboptimal selection criteria, and improper end points.

2 | STATISTICS CAN ONLY DO SO MUCH

Great statistics cannot save a study based on bad or insufficient science. Even worse, bad statistics can lead to:

- Improperly sized studies
- Difficulty detecting significant changes
- Confusion over appropriate stopping points
- Expensive mistakes

3 | STUDY DESIGN IS FLAWED

Key threats to a successful study design include:

- Overtaxing participants with procedures and visits
- Improperly timing dose escalations
- Selecting the wrong parameters for population size, dosing levels, stopping points, and more
- Neglecting the idea of combination therapies
- Selecting the wrong end points

4 | SURROGATE END POINTS HAVE A DOWNSIDE

Surrogate end points rely on extrapolation and can be misleading.

- They can initially suggest that a treatment is promising when it may make no difference in clinically meaningful end points.
- They can result in inappropriate decisions for future study phases.

Programs may struggle as they advance if they base study sizing, dosing, and design approaches around anticipated drug efficacy that arose solely from a surrogate end point.

5 | SCREENING IS A DOUBLE-EDGED SWORD

- When criteria are overly restrictive or not highly customized, studies often fail to achieve recruitment targets.
- Selected participants may not be among the patient group most likely to benefit.
- Biomarkers and assays can help in selection and efficacy measurements, but they are often not used or are unvalidated.
- Screening problems can result in not knowing a drug's true impact.

6 | SITES NEED MORE SUPPORT

- Sites are not always selected properly or are selected without taking the time to develop a strong relationship with staff.
- Half or more of all study sites recruit one or no patients.[5,6]
- Sites may be overwhelmed by the administrative, procedural, and staffing burden of many studies.
- Struggling sites may lack resources, fail to engage eligible patients, or fail to follow protocol.

6 SOLUTIONS TO COMMON EARLY-PHASE TRIAL PROBLEMS

GET YOUR SCIENCE IN ORDER

Worldwide Clinical Trials offers preclinical and early-phase scientific support services, including preclinical pharmacokinetics and toxicokinetics, to make sure that dosing and bioavailability information is as complete as possible when you launch early-phase studies.

Get your science right by finding out what you need to know as you enter early-phase oncology trials in humans.

USE SMART STATISTICS

When properly utilized, statistics can guide study design and analyze data in the most effective, appropriate way for determining potential impact of a drug. Worldwide offers comprehensive biostatistical solutions, including study design support for randomization, dose-finding, sample size and power calculations, methodology planning and project management, parametric and non-parametric analysis of clinical and PK end points, and performance of interim and summary analyses.

SEEK EXPERT STUDY DESIGN SUPPORT

Worldwide offers highly rated early-phase study design support from start to finish. In fact, Worldwide was identified as a top performer in all rated categories in ISR Report's 2018 CRO Quality Benchmarking – Phase I Service Providers study.[7]

We stand by our record of successful trial design and satisfied customer relationships for every phase of research. Our Phase I-IIA clinical trial experts have outstanding experience in clinical pharmacology studies, complicated procedures, and special populations.

BUILD STRONG STUDY SITES

Worldwide can do the work for you, no matter where you want it done. We support trials in more than 60 countries, and we also operate more than 100 studies per year in our Clinical Research Unit (CRU) in San Antonio, TX. Our CRU has:

- 300 beds
- On-site cGMP Phase 1 compounding pharmacy services
- Local pharmacokinetic testing
- Capacity to facilitate a wide range of complicated testing, selection, and special population services

SELECT APPROPRIATE END POINTS

Surrogate end points are not all bad. In oncology, they can have definite advantages; the trick is using them effectively. Worldwide offers expertise in bioanalytical services that can help plan a study right—from the start—and keep it from derailing due to inconclusive findings or excessively extrapolated data.

We have teams dedicated to early-phase oncology to ensure that our experience benefits your drug development program through solid design, before it even launches.

EMBRACE VALIDATED BIOMARKERS

Early-phase oncology trials must walk a fine line in their selection of initial participants. That's why accurate, validated assays, biomarkers, and screening techniques matter. Make use of one of Worldwide's validated assays, or let us work with you to customize a bioanalytical method that is fit-for-purpose for your early-phase oncology needs.

Let our experts in bioanalysis and method validation guide you to a meaningful solution for your screening and study end point requirements.

THE BEST WAY TO SAVE A STUDY FROM FAILING IS TO...

...design it right in the first place.

If your early-phase oncology research has started floundering, Worldwide offers the expertise needed to rescue failing studies. But more importantly, we offer unparalleled experience in the design of new clinical trial programs with the most advanced strategic planning.

Give us the chance to get your early-phase research off to a healthy start—avoiding the common pitfalls of many early oncology endeavors—and we'll show you why we are the uncommon CRO.

CONTACT US

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