WORLDWIDE CLINICAL TRIALS

HOW TO GET AHEAD IN THE MODERN WORLD OF ONCOLOGY RESEARCH

63%

increase in the number of oncology drugs in late-stage development from 2013 to 2018.[1]

Newly launched drugs also reached a record high in 2018, despite the overall success rate of fewer than 10% of all products entering development.

ONCOLOGY CLINICAL TRIALS ARE NOT WHAT THEY USED TO BE

IN THE PAST, CANCER THERAPIES FOCUSED ON...

- Surgery
- Radiation
- Chemotherapies
- Stem cells

NOW, MANY INVOLVE MODERN THERAPIES & IMMUNO-ONCOLOGY...

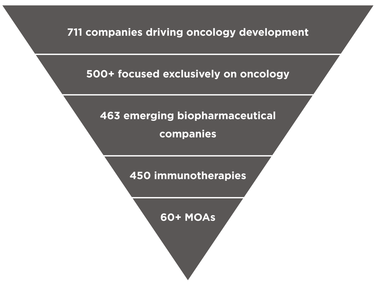
- Immune checkpoint modulators
- Cell therapies
- Oncolytic viruses
- Bispecific T-cell engagers
- Peptide vaccines

IS YOUR COMPANY STRATEGICALLY POSITIONED TO SUCCEED IN THE NEW WORLD OF ONCOLOGY DRUG DEVELOPMENT?

The sooner you tailor your efforts to the key features of the modern oncology research landscape, the better your chances of approval are. The new oncology research space involves:

1. DIVERSE DEVELOPMENT COMPETITION

The world of oncology development is no longer limited to the big players. Strategic planning and early-stage concepting work is now increasingly important for companies hoping to reduce risk and proceed through trials with few surprises and the best chance at commercializing their drug.



2. INCREASING TRIAL COMPLEXITY

In the past five years, Phase I trials alone have increased in complexity by 20%. Furthermore, Phase I studies averaged 2.8 indications per molecule in 2018, compared to 1.6 in 2010.

Clinical trial complexity is measured as a combination of:

- end points
- eligibility criteria
- number of subjects, trial sites, and countries

Successfully juggling complicated design, analysis, and regulatory requirements can prove challenging, even for the most experienced biopharmaceutical companies.

+20%

3. RECONFIGURED RECRUITMENT NEEDS

With a shift in trial design and end point complexity - as well as the nature of molecules under development - recruitment needs have dramatically altered. Trials that are not designed to enable smart progression and clear decision-making in their earliest stages run the risk of failing fast without good reason.

PAST: The "Cytotoxic" Age	PRESENT: The "Targeted/Molecular" Age
Dose to toxicity (maximum tolerated dose)	Dose to pharmacodynamic parameters (e.g., biologically effective dose)
First-in-human "3+3" design	First-in-human accelerated titration
Enroll "all comers" (heterogeneous sample)	Enroll specific tumor types (homogenous sample)
Predictive biomarker analysis	Predictive biomarker selection
Go/No-Go in Phase II	Go/No-Go in Phase I

4. ADVANCED OPERATIONAL AND REGULATORY CAPABILITIES

By planning development programs with a thorough knowledge of the oncology operational landscape, companies can expect fewer challenges on the way to commercialization or mergers and acquisitions. Keep in mind:

- **Study design** based on trial phase, population, and indication
- **Trial location and recruitment** considering site infrastructure, start-up speed, and technical experience with advanced therapies
- **Team expertise and training** on the specific molecule
- **Adaptation to monitoring and reporting requirements** that shift frequently and require stringent oversight from independent data and safety committees

SECURE YOUR FUTURE IN ONCOLOGY

Companies that can seize the changing landscape and turn it into an advantage for their approach to drug development have the best chance at achieving their goals.

Strategically align yourself with thoughtful, responsive research partners, such as the specialized oncology, end point, biomarker, adaptive design, and market access teams at Worldwide Clinical Trials.

Let Worldwide be your guide, from preclinical to post-market.

[1] All data come from *Global Oncology Trends 2019: Therapeutics, Clinical Development and Health System Implications.* IQVIA Institute for Human Data Science. May 2019. Analysis and commentary are original to Worldwide Clinical Trials.