synteract®

We Are Committed to the Quest to Cure Cancer

In the past 5 years, Synteract has conducted:

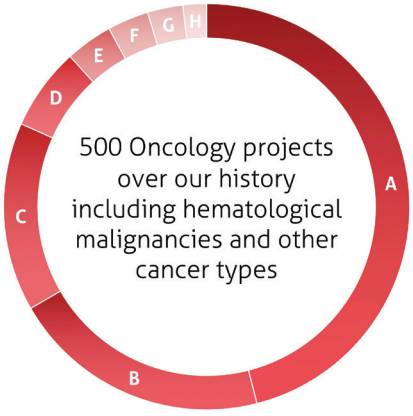
180+	35+	2,900	14,200
ONCOLOGY CLINICAL TRIALS	INDICATIONS	SITES	PATIENTS

Managing the Landscape of Oncology Clinical Trials

In the highly-dynamic and evolving cancer research landscape, we bring our longstanding oncology acumen to bear. Over our history we have managed more than 500 oncology projects, including hematological, skin, breast, lung, gastrointestinal, and other cancers, with more than 180 trials in just the last 5 years alone. Our oncology trial knowledge spans the entire clinical process and the full continuum of trial phases.

Tackling Trending Areas in Oncology and Immunotherapy

Every cancer trial is unique. Experience in multiple indications and new areas of research are critical requirements. Synteract was the first CRO to begin working in innovative immunotherapy clinical development more than 10 years ago. We have first-hand experience and specialized expertise in both precision medicine trials matched to specific patient biomarkers, and personalized treatments customized to the individual.



Diverse Oncology Experience

We can assist with all aspects of oncology trials, from design and execution of proof-of-concept trials to submissions and regulatory approval.

A - Pathway-targeted therapies: 49%
B - Other areas of oncology: 22%
C - Immunotherapy: 16%
D - Chemotherapy: 4%
E - Cells and gene therapies: 3.5%
F - Dermatology: 7%
G - Diagnostic: 3%
H - Hormonotherapy: 2%

Contact us to leverage our three decades of Oncology experience to advance your clinical trial.

Etienne Drouet, Vice President, Oncology Development

- 25-year career focused on curing cancer, beginning as a research scientist at a biotechnology company and through all levels of operational leadership
- On the forefront of innovation, with personalized therapies and genomic information transforming clinical trials
- Proponent of assessing data-based evidence to suggest advanced approaches

CASE STUDY

Synteract Adapts to Evolving Needs in Phase III Immunotherapy Clinical Trial

A biotechnology company focused on personalized immunotherapy products needed to find, qualify, and enroll patients in a complex Phase III blinded clinical trial for an innovative dendritic cell vaccine for aggressive, solid tumors. Synteract managed the project and performed safety, data management, biostats analysis, and regulatory work, including investigator and safety submissions. Synteract also rescued the sponsor's European clinical trial.

Though this initial clinical trial was projected to last less than two years, its scope expanded significantly—from a small study with a handful of sites to a much larger one, with changes in protocol, all of which often needed to be done quickly.

Immunotherapy – Great Promise and Great Challenges

- With the drug produced in parallel to selection and screening for each patient, there were as many treatments as subjects. Numerous intricate, involved processes needed coordination to make the vaccine.
- Screening and enrollment were critical, as due to the 3-month screening process and aggressive nature of the disease, screen failure was extremely high at 80 percent.
- Timing was exacting. Patients had to be screened just after being diagnosed and before having surgery, then had surgery, chemo, and radiation prior to introduction of the product.
- Multiple vendors needed to be coordinated in North America and Europe.
- Patients had to be followed throughout treatment for an extended period.

Our Solutions

- We coordinated 90 sites in the U.S., Germany, UK, and Canada, to find and continuously screen patients, adding them as required as the study grew in scope.
- We helped maintain morale across the sites, despite the high failure rate, implementing a full communications strategy, including targeted roundtable discussions for all study personnel to brainstorm on challenges.
- We asked investigators to refer other physicians with appropriate patients, using "Dear Doctor" material to inform them about the trial.
- The study protocol was shrunk into manageable quick reference lists. Recruitment and CRA surveys enabled assessment of potential issues and successes at sites.
- We developed study specific plans and data cleaning tools to ensure completeness/accuracy of data.
- We made sure tumor kits were available at sites in need – assisting with the transferring of equipment as necessary.

Responsiveness and Flexibility Enable Program Success

- Synteract closed the gap on missing potential subjects, increased the number of subjects in prescreening and screening phases, implemented communication best practices, and set realistic projections in trial timelines.
- It was pivotal in accommodating sponsor requests and refocusing resources and efforts as needed.
- Synteract continues to follow patients in this ongoing Phase III trial that could hold promise for less invasive treatments for cancer patients.