SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

ACCELERATING DISCOVERY: TECHNOLOGY & SCIENTIFIC EXPERTISE TO POWER YOUR ONCOLOGY PROGRAM

Creating new, innovative cancer treatments, and ensuring their rapid approval and access, presents distinct challenges for all stakeholders involved. These often include:

- Navigating tumor heterogeneity and treatment resistance
- Accurately characterizing dose-response relationships in early phases to drive optimal dosing
- Interpreting findings from open label and single arm study designs
- Implementing and managing complex study designs
- Navigating the rapidly evolving regulatory landscape
- Generating sufficient clinical evidence to meet the needs of both regulatory and health technology assessment (HTA) bodies

Therefore, sponsors and CROs need partners who are:

Well-versed in each disease indication

Prepared with the right resources to adapt solutions and strategies to the changing profile of new treatments

Experienced in navigating the complexities of oncology trial designs while understanding the changing regulatory environment

Explore how Signant Health, with our combination of best-in-class technology, scientific leadership, global scale, and mature services, applies our **expertise in eCOA, RTSM, and eConsent solutions to assist partners in all phases of oncology clinical drug development.**

Electronic clinical outcome assessments (eCOA)

PROVEN eCOA EXPERIENCE IN ONCOLOGY DRUG DEVELOPMENT

Signant Health has **unrivaled experience** in the collection of reliable patient-reported outcomes (PRO) data in oncology drug development programs.

PAST 5 YEARS OF ONCOLOGY eCOA EXPERIENCE

212	45	91,000+	24,000+	95	74
STUDIES	INDICATIONS	PATIENTS	SITES	LANGUAGES	COUNTRIES

SIMPLIFY EARLY PHASE TOLERABILITY ASSESSMENT FOR OPTIMAL DOSE SELECTION

While patient-reported outcome measures (PROMs) are regularly incorporated into phase III clinical trials, there has been little, if any, use of PROMs in early phase trials. However, Project Optimus and the draft FDA guidance on optimal dose selection in oncology drug development is driving increasing collection of PROMs in early phase trials. This patient perspective is a vital element of fully understanding dose-toxicity and selecting an optimal dose for later phase development.

Responding to this, we continue to develop **innovative ePRO solutions to obtain a full picture of tolerability in early phase**, balancing the lack of *a priori* knowledge of the side-effect profile with careful consideration of completion burden for the patient.

ENSURE HIGH OUTCOME MEASURE SPECIFICITY IN PHASE III ONCOLOGY TRIALS

In recent draft guidance, the FDA have defined five specific core domains for COA measurement in cancer trials, with a drive towards discrete, specific measures for each domain. We anticipate that this may lead to acceptance of more COA-related labeling claims in new U.S. approvals.

As current practice often includes using PROMs that do not adequately measure these core concepts or measure at sub-optimal times for reliable insights (e.g., pre-cycle), **we are helping sponsors reconsider PROM selection and measurement strategy in cancer trials and programs**.

Click or scan to read more in our white paper:

FDA CORE COA MEASUREMENT DOMAINS

1. Disease-related symptoms
2. Symptomatic adverse events (AEs)
3. Overall side effect impact measure
4. Physical function
5. Role function

GENERATE EVIDENCE BEYOND APPROVAL

Newer oncology therapeutics have brought about significant advances in cancer care. Newer therapeutics, initially approved for progressive disease, have seen success in earlier lines of treatment. Many of these newer treatments are taken for longer periods of time while disease-free and overall survival are extended. **Collection of PROMs during long-term follow-up and post-marketing studies** will be required to fully characterize the impact of treatment on tolerability and quality of life over this extended timeframe. Our flexible solutions facilitate **continued assessment during long-term follow-up**.

OUR RESEARCH

Our scientists are working with our Scientific Advisory Board (SAB) members in the conduct of novel research in oncology COA strategy. This includes:

- Assessment of patient burden and feasibility of at-home weekly PROM collection during treatment.
- The use of computerized adaptive testing (CAT), using our unique implementation of the PROMIS CAT measures, to reduce patient burden.
- Passive measurement of physical activity and sleep using wearables as associated measures of treatment impact.

UNDERSTAND PATIENT BURDEN TO DRIVE COMPLETE DATASETS AND RELIABLE INFERENCES

Signant is more than a technology provider. Our scientists **understand the diseases and patient populations we study**, and this drives our solutions.

In oncology, our qualitative research with patients has provided insights into living with the disease and its treatment. We can account for these in optimal solution design and measurement strategy, thoughtfully considering patient burden.

RESOURCES: eCOA IN ONCOLOGY TRIALS

Click or scan the QR codes to learn more about each.

WEBSITE
Signant's Internal Medicine Scientific Advisory Board

WHITE PAPER
Computerized Adaptive Tests Using PROMIS CAT

ARTICLE
Optimizing ePRO Measures in Oncology Trials

BROCHURE
Signant SmartSignals® eCOA

Randomization and trial supply management (RTSM)

PROVEN RTSM EXPERIENCE IN ONCOLOGY DRUG DEVELOPMENT

Signant Health has **unrivaled experience** in the implementation of robust RTSM solutions to randomize patients and manage study- and program-specific medication supply chains in oncology drug development programs.

PAST 5 YEARS OF ONCOLOGY RTSM EXPERIENCE

300	44	82,000+	21,000+	42
STUDIES	INDICATIONS	PATIENTS	SITES	COUNTRIES

SUPPORT COMPLEX STUDY DESIGNS

Oncology clinical drug development often requires complex study designs including cohort studies, seamless adaptive (phase I-II) trials, master protocols (basket and umbrella designs), and trials with variable dosing regimens and visit schedules. Our configurable and flexible RTSM solution enables **robust and accurate randomization** supported by our **in-house biostatistics team**, and **proven, reliable and agile medication supply chain management** for even the most complex study design.

MANAGE CENTRAL AND LOCAL SOURCING OF STANDARD-OF-CARE TREATMENTS

In oncology clinical trials, patients typically receive new treatments in addition to the standard-of-care treatment. In global trials, the sourcing of standard-of-care medication may be done locally or centrally, and this may differ across countries and sites.

Our RTSM solution is able to track and **manage both centrally and locally sourced standard-of-care treatments**, ensure sufficient quantities are always available, and de-risk the possibility of insufficient stock affecting patient treatment.

OPTIMIZE SUPPLIES USE FOR EXPENSIVE, SHORT-SUPPLY, AND SHORT-EXPIRY DRUGS

Investigational products in cancer trials are often expensive, in limited supply, or associated with a short shelf life. Configured by our supply chain experts, our RTSM solution utilizes unique algorithms to **optimize lot usage and efficiency**, and drive down overage and wastage.

Our recent innovations include enhanced capabilities to implement **free-picking** (allowing depots to pick specific kit numbers to fulfill a requested order quantity), which provides a framework for **just-in-time labeling** or packaging at the time of the shipment request enabling greater ability to **pool supplies across studies/programs** and further reduce overage requirements.

Click or scan to read more in our free-picking press release:

MANAGESUPPLY LONGEVITY AMONGST TREATMENT PAUSES AND DELAYS, AND VARIABLE TREATMENT PERIODS

Oncology trials often accommodate variable treatment periods and dose adjustments, and enable patient treatment to pause to allow time for sufficient recovery before continuing. These introduce greater risk and complexity into the medication supply chain, in particular site inventory control, and managing drug expiry while limiting wastage.

We leverage our in-house supply experts and flexible RTSM solution to optimize each study solution and **reduce the risk of excessive drug wastage**, while **ensuring continued treatment availability for each patient** throughout the trial. This includes enabling seamless return to treatment, regardless of which visit/treatment schedule the patient returns to.

eConsent

FACILITATE EFFECTIVE INFORMATION TRANSFER WITH AT-HOME ACCESS

Oncology trial informed consent forms are on average 21.4 pages long, and sometimes much longer, and can be associated with complex treatment decisions for the patient and their family.

Our eConsent solution enables **full at-home access** with nothing to download. Patients can fully digest the study information in their own time, in their home environment, before attending a clinic visit to discuss the trial further with the Investigator. This is one of the ways that, at Signant, **we aim to optimize the trial participation experience for patients in oncology trials**.

Click or scan the QR code to read our oncology study eConsent case study:

OUR RESEARCH

Our scientists, working with sponsor-partners, reported that compared to paper eConsent is associated with better understanding of the clinical trial information, greater engagement with content, and greater patient acceptance.

Click or scan the QR code to read our eConsent research paper:

ENSURE EFFECTIVE PATIENT-INVESTIGATOR CONSULTATION

Dealing with cancer treatment and considering clinical trial participation can be an overwhelming process, and sometimes patients are unable to recall all the questions they would like to ask during a site visit.

Our eConsent solution enables patients to flag parts of the information to be discussed during consultation with the Investigator. In-application review means **no question goes unanswered**, leading to confident and fully-informed participants.

MANAGE MULTIPLE CONSENTS INCLUDING SUB-STUDIES AND BIOSAMPLES

Oncology trials are often associated with multiple consent documents and options, for example additional consenting associated with biosample collection, sub-study inclusion, and co-morbidity-specific study components.

Our eConsent solution **simplifies the full and accurate recording of multiple optional and mandatory consents** for each participant, and provides data to integrate with biosample management solutions.

SIMPLIFY RE-CONSENTING PROCESSES FOLLOWING PROTOCOL AMENDMENTS

Oncology trials are often associated with numerous protocol amendments. These can require updates to the consent information, making it imperative to use the correct consent form version for new patients, and to request existing patients to re-consent.

Consent form **version control is managed automatically** through our eConsent solution, and the **re-consenting process is simplified, tracked and made fully visible** to the study monitoring team. This simplifies trial management and reduces the risk of inspection findings.

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.