SUVODA®

WHITEPAPER

Unraveling the complexity of oncology trials: insights into the potential of eClinical solutions

Exploring the role of Interactive Response Technology and Electronic Clinical Outcome Assessment in enhancing oncology clinical research

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Introduction

Oncology trials are among the most challenging in clinical research today. On average, oncology trial programs span approximately 12 years, and in 2022, only 3.5% of these trials were successful.[1] With difficult recruitment processes, complex adaptive treatments, high mortality rates among cancer patients, and the inability to test on healthy volunteers, oncology trials present unique hurdles. Innovative eClinical technologies can support clinical trial operations and smooth the process of testing novel therapies to improve care for patients who need it most.

Interactive Response Technology (IRT) and electronic Clinical Outcome Assessment (eCOA) have emerged as crucial tools in addressing these challenges. This whitepaper explores how eClinical solutions, specifically IRT and eCOA, can be harnessed to navigate the complexities of oncology clinical trials. It also explores insights from real-world case study examples from across the many oncology trials we've supported since Suvoda began.

[1]"Precision Technologies for Precision Trials: Streamlining Patients', Sites' and Sponsors' Trial Experience," Suvoda, November, 2023.

Understanding the protocol and operational complexities of oncology trials

Oncology trials possess distinct elements that create unique challenges in clinical research, setting them apart from other clinical trials. These characteristics shape the strategies and methodologies employed to maintain study integrity and completion.

Protocol complexities in oncology trials

1 Adaptive treatment strategies

Early phase oncology trials often utilize adaptive treatment strategies,[2] allowing researchers to modify interventions based on patient responses and emerging data throughout the trial. As oncology trials progress, researchers must remain agile by adjusting cohort sizes, adding new groups or modifying dosing regimens in response to new findings. Some oncology trials may use a basket design, where many different indications are being researched at once, requiring researchers to discern regimen shifts for each indication. This level of adaptability is crucial for maintaining the integrity of trial data and ensuring patient safety.

2 Stringent enrollment criteria

Ethical considerations widely prevent the recruitment of healthy volunteers in Phase 1 oncology trials, as cancer treatments often carry significant risks and side effects. At the same time, many cancer patients experience significant co-morbidities, which often exclude them from clinical trial enrollment. These limitations restrict the trial patient pool to individuals with very specific disease burden, making recruitment more challenging and time sensitive.

3 Urgent timelines

Those diagnosed with late-stage cancer present with urgent and critical timelines for trial completion. Site teams need to collect data efficiently to monitor patient responses and adapt treatment strategies, such as adjusting dosages or treatment combinations based on observed efficacy and toxicity. For example, a patient may be treated with a combination of therapies but may need to discontinue one medication while continuing with another. Or, they may need to titrate doses up or down or skip doses entirely based upon their response to treatment.

4 Extensive endpoint data collection

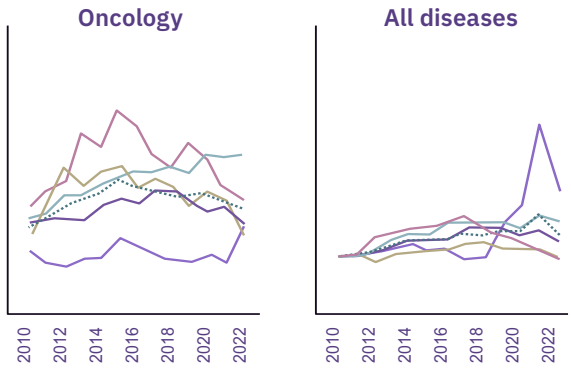
Oncology trials collect data on more clinical endpoints than trials in other therapeutic areas, and the number of endpoints measured has risen since 2010, particularly for rare cancers.[3] The increasing emphasis on collecting quality of life (QoL) endpoints underscores the necessity for sponsors to focus on these metrics.

[2]"A Brief Overview of Adaptive Designs for Phase 1 Cancer Trials," National Library of Medicine, March 18, 2022.
[3]"Precision Technologies for Precision Trials: Streamlining Patients', Sites' and Sponsors' Trial Experience," Suvoda, November, 2023.

Protocol complexities in oncology trials

In addition to the therapeutic and disease-specific challenges that cancer presents, oncology trials include more operational complexities than non-oncology trials *(see Figure 1)*.

Oncology trials are substantially more complex than other disease areas - but often have fewer participants



Source: Citeline Trialtrove, Jan 2023; IQVIA Institute, Apr 2023.

Figure 1

1 Multiple disease types and tumor types

Managing trials involving various cancer types and subtypes requires a sophisticated approach to randomization, drug supply management, and data collection. For example, randomization needs to maximize the number of participants receiving the investigational medicinal product while maintaining statistical power and controlling for potential confounding variables like location, age, and gender, often among very small participant populations.

2 Variable cycle and visit schedules

The variability in the number of treatment cycles and patient visit schedules presents a unique logistical challenge. Oncology trial protocols may dictate that the patient receives treatment for an unlimited number of cycles, depending upon the patient's needs. Effective trial execution requires flexible scheduling systems to accommodate the diverse needs of participants and account for treatment responses.

3 Complex drug supply management

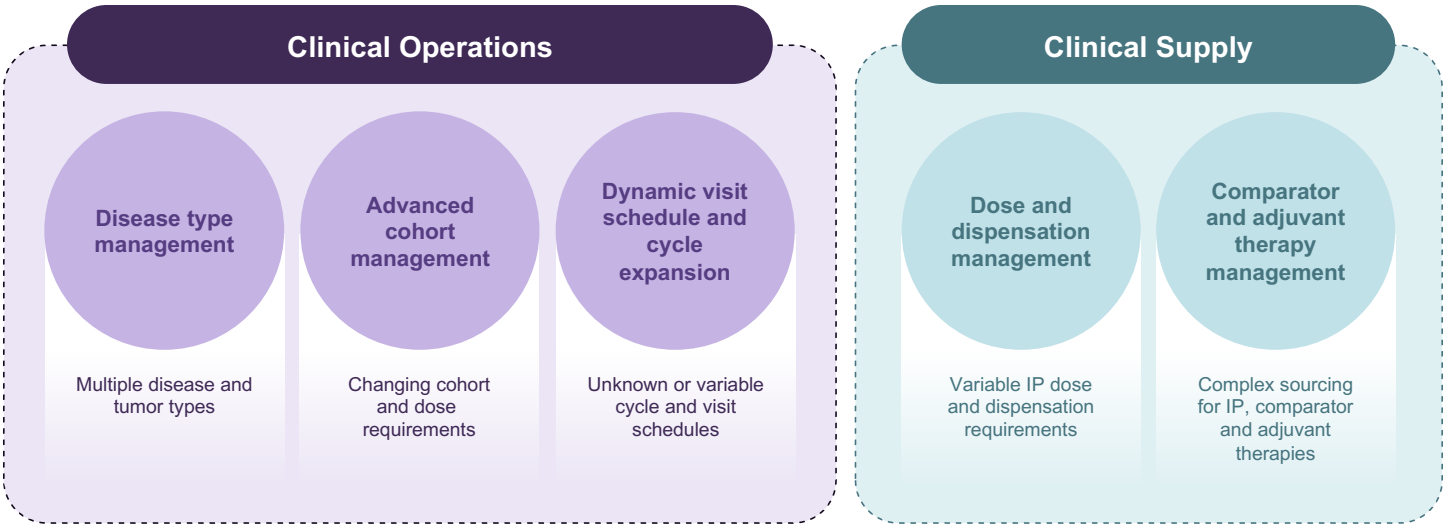
Given the high cost of investigational products and necessary comparators, oncology trials demand precise inventory management and forecasting. This complexity is further enhanced by the need to capture patient-reported outcomes and link them to drug administration schedules for more sophisticated analysis of outcomes data.

4 Adherence to patient-reported outcomes

Oncology study participants often experience heightened levels of fatigue and distress, which can impact their adherence to outcomes reporting. Oncology trials often need to measure patient reported outcomes more frequently to accurately estimate symptom progression and severity.[4]

[4]Bellinda L King-Kallimanis et al., "Timing Is Everything: The Importance of Patient-Reported Outcome Assessment Frequency When Characterizing Symptomatic Adverse Events," Clinical Trials 19, no. 3 (May 15, 2022): 267–73.

IRT solutions for oncology trial management



A purpose-built IRT solution can offer a range of solutions to address the specific challenges of oncology trials, focusing on streamlining processes for sites and sponsors. These solutions aim to optimize drug supply management, enhance data collection accuracy, and maintain study integrity throughout the trial lifecycle, all while supporting a smooth experience for patients.

By leveraging advanced IRT capabilities, organizations can efficiently manage complex trial designs, support timely drug distribution, and capture critical data points. This approach reduces operational burdens and supports the overarching goal of accelerating the path to regulatory submission while maintaining cost-effectiveness and scientific rigor.

The following sections will explore how IRT addresses key operational challenges in oncology trials, supporting both clinical operations and clinical supply management.

Clinical operations

1 Disease type management

Advanced IRT systems provide the ability to add new disease and tumor types in real-time within the interface, ensuring that study designs remain flexible and responsive to emerging insights. This functionality allows study teams to open and close disease types for enrollment while setting specific enrollment limits and parameters for each disease type, such as doses or dosing regimens. Taken together, these tools enhance patient recruitment efficiency.

2 Advanced cohort management

Modern IRT platforms simplify cohort management with easy control over opening and closing cohorts, and allowing adjustments to enrollment limits, randomization schemes, doses, and dosing regimens by cohort. This advanced capability enables trial teams to add new cohorts and dose levels mid-study without necessitating extensive programming changes, streamlining processes and optimizing resource allocation.

3 Dynamic visit scheduling and cycle expansion

The most sophisticated IRT systems offer flexible visit scheduling and automated cycle expansion capabilities, crucial features for oncology trials. These tools allow real-time adjustments to patient visit timetables and treatment cycles, accommodating the unpredictable nature of cancer progression and treatment responses.

For example, if a patient experiences severe side effects, their visit schedule can be promptly modified; or if a treatment shows promise, additional cycles can be added without disrupting the overall trial structure. This flexibility enables clinical trials to remain responsive to individual patient needs while maintaining protocol integrity, ultimately supporting more patient-centric and scientifically robust studies.

Clinical supply

1 Dose and dispensation management

IRT systems offer sophisticated dose and dispensation management capabilities, crucial for the dynamic nature of oncology trials. These functionalities allow:

- Real-time dose adjustments. Clinicians can modify dosages based on patient responses, ensuring each participant receives the optimal amount of medication.
- Flexible kit allocation. The system can adjust the number of drug kits dispensed at each visit, accommodating protocol changes or patient-specific needs.
- Inventory optimization. By tracking drug usage and forecasting needs, IRT helps maintain appropriate stock levels at each site, reducing waste and ensuring treatment continuity.

2 Comparator and adjuvant therapy management

Effective IRT systems can manage different sourcing of medications by site or country. The system allows for the addition of doses and the configuration of dispensations for comparators mid-study, ensuring that all patient groups receive appropriate therapies as required by the protocol.

By implementing these tailored IRT features, oncology trials can achieve enhanced efficiency and rapid study implementation while adapting to mid-study changes. This comprehensive approach supports the ongoing evolution of clinical research methodologies.

IRT integration with eCOA

Enhancing patient engagement through eCOA

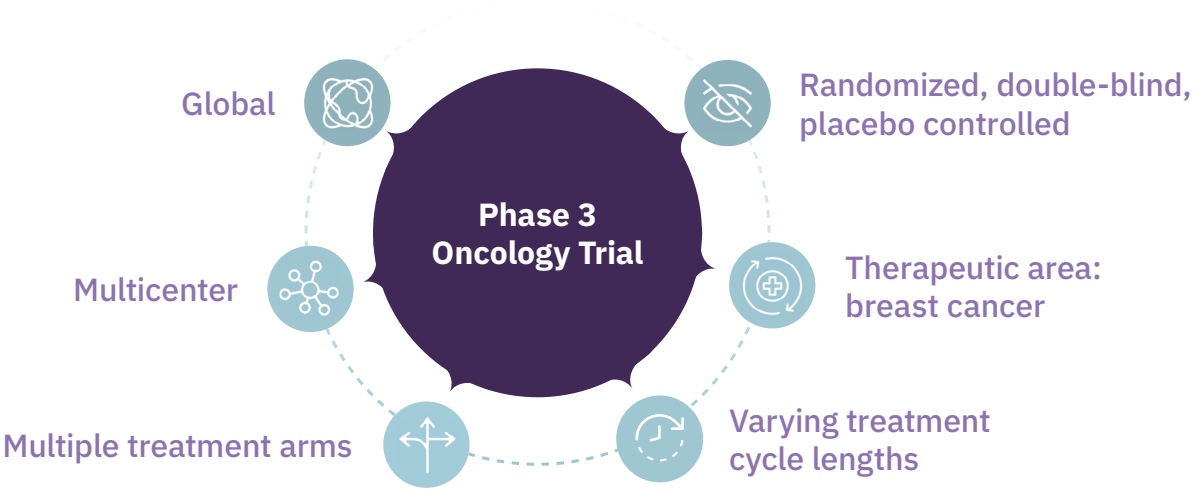
Regulatory authorities such as the FDA increasingly emphasize the importance of patient-reported outcomes in clinical trial submissions, especially around patient quality of life and symptom relief.[5] eCOA enables the collection of timely patient-reported data on treatment experiences and side effects, facilitating regulatory compliance, supporting patient engagement, and offering a more complete picture of the patient's experience.

While quality of life questionnaires collected through eCOA are relatively straightforward in oncology trials, uniting eCOA with IRT on the same platform streamlines the workload for study teams and sponsors, which can help improve data quality and efficiency throughout the trial.

[5]U.S. Food and Drug Administration. "FDA In Brief: FDA Provides Guidance on Measuring Patient-Reported Outcomes in Cancer Clinical Trials." Last modified June 2023.

Suvoda case studies: IRT enhancements in oncology trials

Case study 1: Phase 3 breast cancer trial



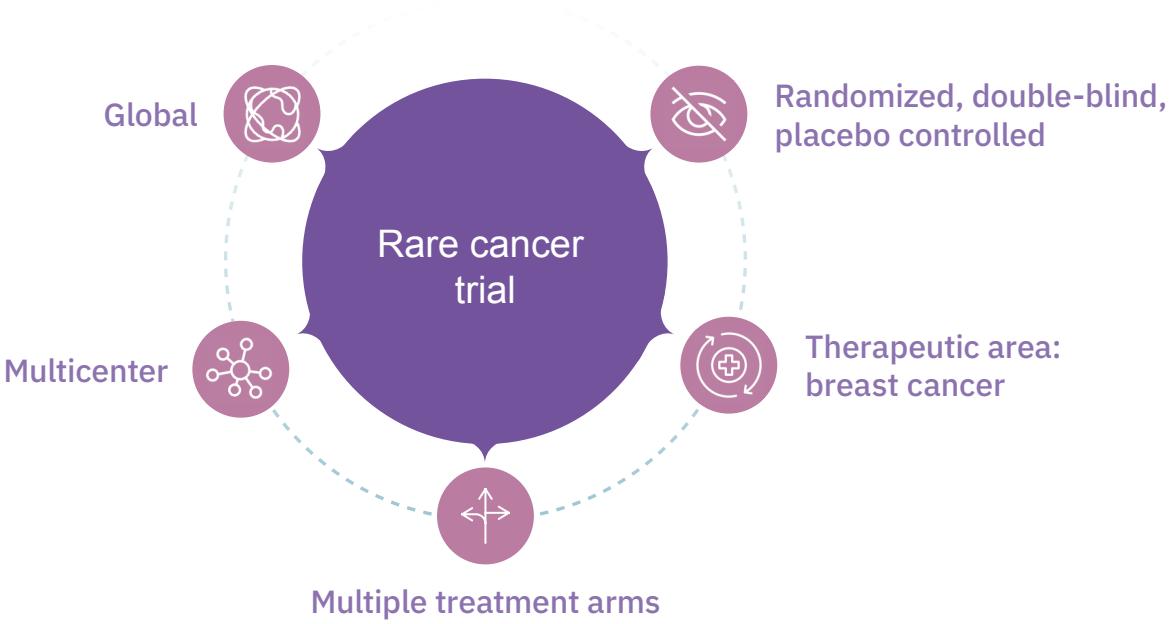
This global, multi-center Phase 3 oncology trial aimed to evaluate an investigational product (IP) through various combinations and dosages to improve treatment options for breast cancer patients.

Challenges	IRT solutions implemented
Significant protocol complexity	Efficient comparator and adjuvant therapy management and tailored enrollment logic geared towards a pharmacokinetic sub-study
Multiple treatment combinations and dosages	Dose modifications allowing independent drug hold/discontinuation
Need for precise weight-based dosing	Weight-based dosing calculations
Managing dynamic visit schedules	Custom visit scheduling and cycle expansion
Custom rules for dose adjustments	Custom dose change rules based on participant criteria

Outcome :

Suvoda IRT facilitated adept handling of the trial's complexities. The system's flexibility in dosing and treatment management played a vital role in fulfilling the trial's objectives, and the investigational drug was ultimately approved.

Case study 2: rare blood cancer trial



This global, multi-center trial focused on testing novel treatments for rare blood cancers, facing unique hurdles due to its small patient population and intricate randomization needs.

Challenges	IRT solutions implemented
Limited patient population (<200 participants)	Advanced cohort management for enrollment complexities across 100+ sites
Complex randomization requirements	Minimization randomization techniques for treatment arm balance while accommodating multiple stratification factors
Need for timely randomization confirmation	Custom real-time reporting for randomization confirmations
Dynamic scheduling to maintain treatment	Dynamic visit schedules and cycle expansions for ongoing treatment options
Specific patient needs	Weight-based dosing calculations with bespoke dosage adjustment rules

Outcome :

Suvoda IRT's adept management of intricate randomization and cohort assignments helped with accurate management of clinical supplies and efficient clinical operations.

Case study 3: multi-arm Phase I oncology trial

Multi-site study with:

3	3	2	5+
Treatment regimens	**Disease types**	**Study stages**	**Cohorts**
• 1: IP single dose • 2: IP single dose and adjuvant • 3: IP step-fractionated dose	• Type A • Type B • Type C	• Dose escalation • Dose expansion	Per treatment arm, disease type and study stage

Complexities:

- Managing multiple cohorts across treatment regimens and disease types
- Managing variable dosing across treatment regimens, cohorts and stages
- Managing sourcing of IP and adjuvant therapies across multiple sites
- Managing retreatment options and uncertain end dates

This multi-site Phase I study involved 3 treatment regimens, 3 disease types, 2 study stages, and over 5 cohorts across various treatment arms, disease categories, and study stages.

Challenges	IRT solutions implemented
Coordination across multiple treatment regimens	Site user management at treatment regimen, disease type, and cohort/ disease/treatment combinations
Complex cohort and disease type management	Functionality to create new cohorts and set/update enrollment limits
Accurate dosing and dispensation for varied regimens	Separate functions for IP and adjuvant therapy dosing
Real-time calculation of drug quantities needed	Flexible definition of drug quantities to dispense as the study progressed
Unique visit schedules for different cohorts	Dynamic visit schedules allowing flexibility for up to 6 retreatment cycles
Retreatment options with uncertain end dates	Patient retreatment options after study completion available

Outcome :

Suvoda IRT helped support proper trial randomization, correct drug dispensation, and a well-managed drug supply. This led to enhanced control and visibility for study managers and established a client standard that could be incorporated in subsequent studies.

Emerging trends in oncology trials

As the field of oncology continues to innovate, the integration of advanced technologies and methodologies becomes increasingly important.

1 Advancements in cancer treatments

Oncology trials are undergoing significant transformation due to advancements in cancer treatments, including new progress in the field of immunotherapy.[6] Cell therapies, particularly CAR T-cell and NK cell therapies, are gaining traction, providing new hope for patients with resistant cancers. RNA therapeutics and RNA/DNA vaccines are being investigated as promising strategies for targeting difficult cancer types, highlighting the potential of genetic therapies. Gene editing and gene therapy techniques are expected to revolutionize cancer treatments by enabling more precise interventions.

2 Implications for IRT in clinical trial management

Advances in oncology treatments present new challenges that require flexible and adaptive approaches in clinical trial management. Given the intricate requirements of personalized therapies – such as manufacturing and shipping drugs on a per-patient, per-visit basis – IRT provides the agility needed to respond to complex logistical demands by enabling dynamic dosing adjustments and real-time dose calculations. By integrating with existing clinical workflows and systems, IRT is an effective solution for facilitating data sharing across systems, streamlining patient visits and drug dispensation, and delivering robust reporting.

3 Implications for eCOA in future oncology trials

As the emphasis on patient-reported outcomes intensifies with emerging therapies, the role of eCOA in oncology trials will continue to expand. A focus on patient centricity may mean that patients are given more choices as to how they want to engage in a trial, which becomes even more important for sponsors targeting specific therapies which may have smaller patient pools and therefore larger impacts when participants drop out of the study. Personalized therapies may require leveraging eCOA to capture nuanced patient experiences efficiently.

There will likely be a heightened focus on assessing quality of life as part of treatment evaluations, aligning with the increasing importance placed on patient experiences in clinical trials. The adaptability of eCOA methods will be crucial in capturing meaningful data that reflects patients' perspectives in this evolving landscape, ensuring that the evidence gathered remains relevant and accurate.

[6]Rathmell WK, Beg S. Leading change in cancer clinical research, because our patients can't wait. Cancer Currents Blog. May 31, 2024.

Conclusion: the future of IRT and eCOA in oncology trials

Oncology clinical trials are becoming more complex, driven by advancements in cancer treatments and the increasing complexity of trial designs. Purpose-built IRT and eCOA systems play a crucial role in addressing the unique challenges faced by oncology researchers, sponsors, and patients.

Key takeaways

1. **Addressing complexity:** Modern IRT systems offer solutions for managing multiple disease types, complex cohorts, and adaptive treatment strategies essential for the intricate nature of oncology trials.
2. **Enhancing patient-centricity:** eCOA tools facilitate the capture of crucial patient-reported outcomes, supporting a more comprehensive understanding of treatment efficacy and patient quality of life.
3. **Improving operational efficiency:** The integration of IRT with other eClinical technologies streamlines processes, from patient randomization to drug supply management, significantly reducing operational burdens.
4. **Supporting innovative trial designs:** Advanced IRT systems can adapt to the needs of complex, multi-arm trials and rare disease studies, enabling more flexible and efficient research.
5. **Preparing for future trends:** With the rise of personalized medicine, cell therapies, and gene editing techniques, IRT and eCOA systems will need to evolve to support increasingly sophisticated trial designs and data management requirements.

Looking ahead, the continued development and integration of these technologies will continue to support accurate and efficient oncology trials. By providing more accurate real-time data and enabling more adaptive trial designs, IRT and eCOA have the potential to contribute to accelerating the development of new cancer treatments, with the possibility of benefiting patients worldwide.

This acceleration is even more pronounced when software solutions are united on one platform. In today's increasingly complex clinical trials, sponsors, sites, and patients need systems that work together seamlessly and are efficiently deployed. The Suvoda Platform brings together eConsent, IRT, eCOA, and ePatient in a purpose-built and dynamic ecosystem that operates on a single, robust data model for improved data workflow and reduced integrations. The platform ensures that interactions and data from one product can automatically direct and drive sponsors, sites, and patients to take required actions in another, maximizing control during the most urgent clinical trial moments.

As the field progresses, it will be crucial for technology providers, researchers and regulatory bodies to collaborate closely, ensuring that these systems continue to meet the evolving needs of oncology research while maintaining the highest standards of patient safety and data integrity.

By embracing technological advancements and continuing to innovate, the oncology research community can look forward to more efficient and patient-centric clinical trials in the years to come.

Suvoda is a global clinical trial technology company working to transform patients' experience in complex, life-sustaining studies in therapeutic areas like oncology, central nervous system (CNS), and rare diseases. Founded in 2013 by experts in eClinical systems, Suvoda empowers sponsors, CROs, sites, and patients to manage even the most urgent moments in the most urgent trials through advanced software solutions delivered on a single platform. Headquartered outside Philadelphia, Suvoda also maintains offices in Portland, OR, Barcelona, Spain, Bucharest and Iasi, Romania, and Tokyo, Japan. The company's Net Promoter Score (NPS) consistently exceeds the technology industry average, contributing to the company being selected by trial sponsors and CROs to support more than 1,800 trials across more than 95 countries. To learn more, visit suvoda.com. Follow Suvoda on LinkedIn.