OpenClinica

OPENCLINICA CASE STUDY

Advancing Oncology Research: EHR-to-EDC Success in a Complex, Adaptive Platform Trial

Background

I-SPY 2, sponsored and operated by Quantum Leap Healthcare Collaborative (QLHC) is an interventional, randomized adaptive platform trial for newly diagnosed breast cancer patients, and was one of the first and is now one of the longest-running platform trials ever. The I-SPY series of trials are changing the way novel treatments are developed for breast cancer, helping make available new, better and more personalized treatments, faster. At the heart of the I-SPY program is the ground-breaking I-SPY 2 platform trial for neoadjuvant treatment of locally advanced breast cancer.

Platform trials are designed to test multiple treatments simultaneously with a single overarching trial structure and are a significant advancement in clinical research, offering a more efficient and flexible approach to testing new treatments. The study started in 2010 and by 2023, **grew to 35 sites with 5,000 participants**, successfully evaluating 25 agents, two of which gained accelerated approval and one granted breakthrough designation from the FDA. Study enrollment is still growing, with an anticipated study completion in 2031.

5,000
Participants

35
Sites

25
Investigational drugs

10+
Are more beneficial for patients than standard therapy

2
Accelerated approval

1
FDA Breakthrough Therapy Designation

> I-SPY 2 uses an adaptive master protocol that provides a regulatory framework to study multiple treatments in the same study – up to six agents or combinations of agents in parallel against a common control arm. It also allows new agents to enter and leave the study without having to halt enrollment or resubmit the entire clinical trial protocol for regulatory review, avoiding lengthy delays in getting much-needed treatments to the patients who need them.

How I-SPY 2 Works

I-SPY 2 breaks from the traditional randomized clinical trial model, employing an 'adaptive' clinical trial model designed to increase trial efficiency by minimizing the number of participants and time required to evaluate an experimental agent.

1 Randomize to Experimental or Control Arm

I-SPY 2's adaptive randomization engine assigns a participant to a study arm; it gives greater weight to arms that have been successful in the participant's tumor subtype.

5 Update Randomization Probabilities

The participant's serial MRI measures, RCB scores and tumor subtype are used to update the prior probabilities of the randomization engine — over time this refines the targeting of subsequent participants.

2 Patient Outcome (RCB/pCR)

The endpoint is assessed at time of surgery. Primary endpoint is RCB 0 or pathologic complete response meaning the tumor has disappeared completely.

4 Apply Termination Rules (Per Arm)

If predictive probabilities for an experimental agent reach a predetermined level of efficacy in one or more molecular subtypes, it is declared a success ("graduates"). Alternatively, it may be stopped for futility after reaching a maximum number of participants. At any point new agents can enter the trial through a protocol amendment.

3 Update Predictive Probabilities

Based on the participant's tumor subtype, outcome (i.e. MRI volume, pCR) and treatment received, the predictive probabilities of the agent in the various subtypes are updated in real time.

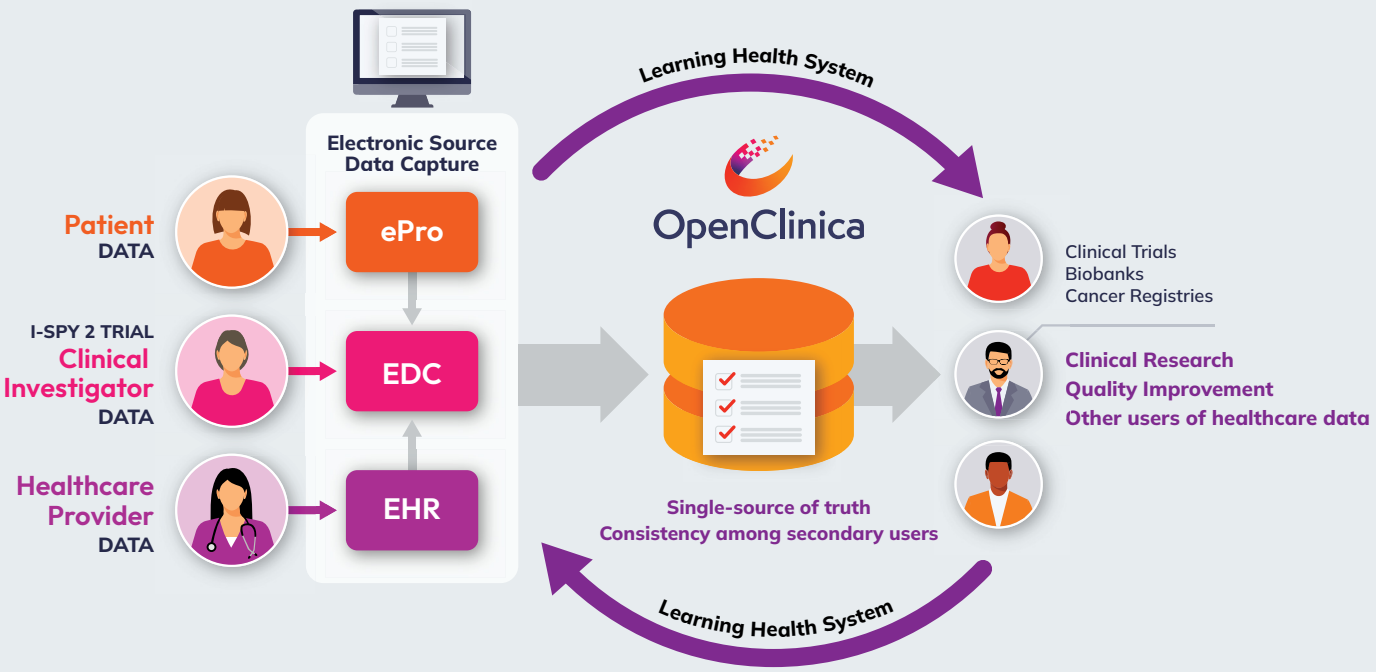
Challenge

The complexity of the I-SPY 2 study design requires an especially agile system to seamlessly add and remove study arms, each of which carry their own distinct requirements including treatment strategies and appointment scheduling. The legacy eClinical system I-SPY 2 started with lacked the dynamic capabilities needed to support the highly complex and nimble nature of the study. Additionally, I-SPY 2 needed a more effective way of engaging participants for surveys, quality of life (QOL) assessments and other patient-reported measures. Finally, I-SPY 2 required reporting and dashboard functionality to analyze outcomes and trends in real-time across all trial sites for a variety of stakeholders.

Solution

In close collaboration with the study sponsor, OpenClinica successfully migrated the I-SPY 2 trial (including all historical data) from its legacy system to the OpenClinica platform. Through meticulous processes and methodologies, the migration delivered uninterrupted study operations and upheld regulatory-grade standards for data integrity and validation.

The I-SPY 2 breast cancer study implemented OpenClinica Core™ EDC, Insight™ for its reporting and dashboards and Participate™ for electronic patient reported outcomes (ePRO). Later in the study, the success of a **large-scale COVID-19 platform trial** led to the decision to add OpenClinica's EHR-to-EDC eSource solution, Unite™ to enable EHR eSource integration for the SPY 2 trial.



EHR-to-EDC Integration

The Problem With Manual Data Transcription

In most clinical trials today, data are manually transcribed from each participant's electronic health record (EHR) into the research database (EDC). Because people make mistakes, transcribed records must undergo source data validation (SDV) to ensure accuracy. This labor-intensive review process can account for up to **25% of the total clinical trial cost**. With a **national median cost** of $41,413 per patient enrolled in a pivotal clinical study, that's an average of $10,353 per patient spent on SDV alone. For this study of 5,000 participants, the sponsor could expect to spend up to $52.6 million in SDV costs.

Perhaps even more importantly, SDV slows trials down in both the time it takes to complete SDV and in sending critical, trustworthy data to the sponsor to inform strategic decision making.

The True Cost of SDV in Clinical Trials

$41,413
Median cost per patient in a pivotal clinical study

25%
Portion of total trial cost spend on SDV

$10,353
Per Patient
Cost attributed to SDV alone

$52.6
Million
Enough to fund an entirely new Phase II trial.

SDV costs alone in a pivotal study can exceed $50M – equivalent to funding an entirely new Phase II trial.

"The I-SPY 2 breast cancer trial is an extraordinarily complex trial on the leading edge of clinical science. OpenClinica has provided us with a robust set of solutions that work to meet the needs of our growing, adaptive platform trial, helping us to advance the availability of personalized medical care for breast cancer patients."

Adam Asare
Chief Data Officer, QuantumLeap Healthcare Collaborative

How EHR-to-EDC Integration Works

OpenClinica Unite™ is a standards-based, plug-and-play app that connects leading EHRs and EDCs. It is widely accepted by hospital IT departments and backed by major EHR vendors.

As an organization, OpenClinica specializes in enabling EHR-to-EDC eSource integration through a rapid, cookie-cutter standardized implementation model, leveraging a technology approach based on industry standards, rigorous quality and compliance. OpenClinica demonstrates industry leadership through prominent roles in HL7 Vulcan, the SCDM eSource Consortium, the eClinical Forum and similar interoperability initiatives.

> **Unite™ simplifies eCRF completion by automatically extracting and applying data from the patient's medical record, eliminating the need for manual entry. Activated within a participant's EHR chart, it directly populates the correct eCRF fields with source data.**

The ability to launch the eCRF from within the patient chart means researchers and patient-facing clinicians don't have to bounce between medical and research systems, delivering a better experience for clinicians, researchers and participants alike. An embedded clinician workflow enables data review and entry, creating the desired 'human-in-the-loop' process.

Next-Generation Agility & Data Mapping

With treatments cycling on and off at varying intervals for each trial participant – and the resulting different requirements for various visit windows, tests and arm/drug-specific criteria – the I-SPY 2 trial needed a way to quickly adapt, using third-party ontologies and less hard-coded logic than within traditional eCRFs. OpenClinica's exceptional features to handle repeating data structures further streamlined workflows and facilitated downstream data analysis.

Using patient health record data in a clinical trial requires the ability to pull in multiple types of structured and narrative data from the EHR, then map it to the correct timepoints and fields in the clinical trial dataset. Unite™'s sophisticated mapping technology includes out-of-the-box mapping for many data types, plus the ability to configure study and site-specific mapping workflows. Mapping occurs in automated fashion, while supporting the ability of the site user to intervene and decide on the right value when multiple data points exist in the health record that meet the protocol criteria. Full chain-of-custody back to the source data is maintained by Unite™ in the audit trail.

For the I-SPY 2 trial, OpenClinica supports multiple randomizations per participant: two active randomizations along with a third and ultimately a fourth randomization, based on a patient's progress. That means each participant can be randomized to different therapies at different points in the trial.

> **OpenClinica's one-click real-time publishing of eCRFs from the design environment to the test environment facilitates quick turnarounds of evolving trial needs. This means forms, study logic, and workflows are tested faster and more thoroughly, resulting in higher quality deployments of study amendments.**

Awards

I-SPY COVID-19

In the I-SPY COVID-19 trials, the QLHC's OneSource system leveraged Unite™ to automatically transfer daily lab and medication data from Epic and Cerner EHRs to the OpenClinica Core™ EDC. Unite™ demonstrated an overall data entry time savings of 50% while eliminating associated queries and SDV. Sites and sponsors agreed that the savings were significant. In fact, in 2022, BioIT World honored the technology as an Innovative Practices Award Winner.

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The I-SPY 2 trial redefines breast cancer research by embracing adaptability and efficiency. With OpenClinica’s flexible platform, we’ve facilitated swift evaluation of new treatments, fostering personalized care for patients.

Since its inception in 2010, the trial has evolved, currently boasting 5,000 participants and 37 amendments. Through this collaboration, we’ve tested 25 agents, achieving accelerated approval for three, all while prioritizing patient outcomes and advancing oncology.

Laura Esserman, MD
Co-founder of Quantum Leap Healthcare Collaborative and Professor at UCSF

Results: Transforming Oncology Research with EHR-to-EDC Integration

OpenClinica’s collaboration with Quantum Leap Healthcare Collaborative on the I-SPY family of trials has demonstrated how advanced technology can help overcome the challenges of complex, adaptive platform trials. Together, Quantum Leap Healthcare Collaborative and OpenClinica successfully transitioned the intricate I-SPY 2 platform trial from a legacy system to a highly scalable, long-term solution. The study benefited immensely from OpenClinica’s EHR-to-EDC integration, advanced data management capabilities, frictionless ePRO, real-time reporting, streamlined workflow automation, and seamless integration with internal and third-party systems.

By replacing manual data transcription with automated EHR-to-EDC integration, Unite™ continues to lessen site burden, improve CRC satisfaction, and deliver early, trustworthy data to trial stakeholders while directly addressing the unique challenges of the I-SPY trials.

Operational Excellence for Dynamic Study Arms

The I-SPY 2 trial’s need for agility in adding and removing study arms with distinct treatment strategies and scheduling requirements were met through OpenClinica’s easily adaptable and user-friendly Study Designer. Critical trial workflows became more agile, enabling the seamless addition and removal of study arms without disruption to ongoing operations. Enhanced eCRF design and real-time data capture ensure accurate updates, supporting the nimble nature of the trial.

Engagement with Patient-Reported Outcomes

OpenClinica Participate™ boosted participant engagement in surveys, QOL assessments, and other patient-reported outcomes. By automating data collection, Participate™ minimizes manual entry for coordinators, enhances response rates, streamlines study workflows, and improves data quality—delivering reliable patient insights for all trial stakeholders.

Real-Time Reporting and Insights

OpenClinica Insight™ places real-time reporting and actionable dashboards in the hands of the I-SPY 2 study team, making it easy for them to monitor outcomes and trends across all trial sites. Insight™ graphs on the participant's detail page give site staff a clear view of key metrics over time, helping them quickly assess patient progress. This gives all stakeholders instant, real-time access to insights for better decision-making throughout the study.

Efficiency Gains Across Trials

In the I-SPY COVID-19 trial, Unite™ demonstrated an impressive 50% reduction in data entry time by automating just some of the daily eCRF fields and eliminating associated queries and SDV requirements. These advancements exemplify the potential for significant cost savings and faster decision-making across OpenClinica-supported trials.

Advancing Personalized Medicine

By automatically pulling patient medical records into the study database, OpenClinica helped accelerate the development of personalized breast cancer treatments. These innovations pave the way for future trials to deliver faster, more reliable results – driving breakthroughs that improve patient outcomes.

I-SPY 2 + OpenClinica Unite™ Trial Stats

(As of March 2025)

5,000
Participants

37
Amendments

25
Agents Evaluated

3
Agents Receiving Accelerated Approval

147,645
Forms automated

20M +
Data values automated

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative

As an organization that endeavors to improve healthcare for all, every choice we make is driven by our mission: to better serve patients by accelerating and innovating health care through approaches that challenge the status quo of science and care.

The culmination of our daily efforts guides our long-term vision: to improve human health for all through personalized medicine by bridging the gap between research and care.

Our core foundational values of integrity, collaboration, transparency, and innovation form the basis of who we hire, how we operate, and everything we believe.

Learn more at www.quantumleaphealth.org

About OpenClinica

OpenClinica

OpenClinica makes clinical trials more efficient and effective with advanced technology and recruitment solutions. Our industry-leading EHR-to-EDC connectivity automates source data acquisition, reduces errors, and eliminates delays, while our precision recruitment solutions help teams enroll the right participants with ease.

Trusted by the world's leading life sciences companies, academic institutions, and government agencies, OpenClinica bridges the gap between healthcare and research. Our technology has powered over 15,000 studies and supported more than three million patients worldwide.

From biotech startups to global pharma, research teams rely on OpenClinca to run more efficient clinical trials and bring new treatments to patients faster.

Learn more at www.openclinica.com