SUVODA®

CASE STUDY:

Developing a Standardized IRT System: BAYSYS IRT

How Bayer focused on improving IRT consistency, quality, and efficiency for all trials

Bayer

- Consistency across studies
- Flexibility for customization for each trial protocol
- Pre-validated functions to drive efficiency and quality

About Suvoda

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. To learn more, visit suvoda.com. Follow Suvoda on LinkedIn.

As one of the global leaders in life sciences, Bayer routinely runs large and complex clinical trials to bring the very best medicines to patients in need. As trial complexity and functionality increased over the years, Bayer needed to evolve its IRT processes and systems to adapt to increasingly complex clinical trials. The result was "BAYSYS IRT," a standardized, validated IRT baseline for transactions common across all Bayer clinical trials. With BAYSYS IRT, Bayer aims to drive efficiency, consistency, flexibility, and quality across their studies.

Challenges

Eliminating Setup Redundancies

In 2014, Bayer established a set of standards for how IRT systems were to be configured for all studies. This ensured consistent, quality execution in every trial, and as a result of these standards, IRT consistency improved.

However, as trial complexity increased over the years, Bayer found that even with their IRT standards, the clinical trial technology practice of configuring and validating a new IRT system for each and every study was becoming time-consuming and inefficient. Each trial used the same IRT standards, which meant that the same IRT configuration was being developed for each study. While this ensured the consistency Bayer wanted, repeating the same processes each time was inefficient.

Solution

Standardized IRT Baseline Drives Efficiency Gains

In its partnership with Suvoda, Bayer set out to develop a system that reduced duplicative efforts by creating an IRT baseline that Bayer could use for all studies.

The first step was to identify, configure, and validate Bayer-specific IRT modules common across its clinical trials. Once this step was complete, it provided a foundation for Bayer and Suvoda to build a core IRT system that all trials would start from.

The core system, referred to as BAYSYS IRT, incorporates the Bayer standards into the programming. This creates and maintains the essential consistency across studies that Bayer seeks. What's more, it allows the IRT-build to focus more deeply on the protocol and move more quickly to implementation.

A strong partnership was critical for the successful development and launch of BAYSYS IRT. While many responsibilities overlapped, both Bayer and Suvoda took ownership of the project, leveraging each team's expertise, to deliver the solution.

Developing BAYSYS IRT

1. Gather input from Bayer stakeholders to ensure BAYSYS IRT met their requirements as well as quality and usability standards
2. Identify repeatable transactions to include in BAYSYS IRT
3. Build a baseline for each IRT transaction included in BAYSYS IRT
4. Develop comprehensive UAT scenarios to cover during testing, bringing in study and country team members when necessary to ensure the system is aligned with varied user needs
5. Ensure BAYSYS IRT met requirements for multiple indications and user experiences
6. Evaluate internal processes and procedures to ensure consistency with BAYSYS IRT

Suvoda Process to Develop BAYSYS

- Assemble a dedicated, cross-functional services team to manage BAYSYS IRT from requirements gathering through to UAT
- Review and consolidate Bayer IRT standards and create SOPs to enable its team to build a core system used exclusively by Bayer
- Develop project management and maintenance standards that comply with Bayer's functional and operational standards
- Implement and validate BAYSYS IRT
- Create comprehensive tests based on Bayer's comprehensive UAT scenarios
- Consistently use knowledge across Bayer protocols and clinical programs to deliver high-quality, multi-level service

Results

Driving Efficiency in IRT Setup and Deployment

Bayer rolled out BAYSYS IRT at the end of 2021, and they've used it for several studies to date. The new approach drives the following benefits:

Increased Quality and Compliance

Bayer can rest easy knowing every trial complies with their IRT standards. Continuous improvement processes ensure BAYSYS IRT is operating at peak performance.

Improved Efficiency

With standardized, pre-validated baseline IRT functions in place, both the system build and UAT are expected to move faster, which could reduce overall IRT setup time.

More Flexibility

BAYSYS IRT only includes modules common across all studies, which leaves sufficient space to focus on building customizations necessary for each protocol. The ability to reuse certain features creates a more agile and efficient development lifecycle for all phases.

Bayer believes that standardizing its IRT systems will improve efficiency and quality. They anticipate BAYSYS IRT will not only ease the burden on study teams but also help the company continue to develop the highest-quality products for patients worldwide.

What to expect when developing a base IRT: Time & Planning

1

Rigorous documentation

Developing procedures and documentation for the project is one of the first steps for developing a base IRT. It provides the starting point to build from, and can help make base system development simpler.

2

Meaningful time investment

Developing BAYSYS IRT took time, from the initial discussions to the first study implementation. That system development time can be as efficient as possible when working with IRT partners with superior customer service, expert project management, and an end-to-end consultative approach.

3

Extensive UAT

UAT for BAYSYS IRT took longer than the typical clinical trial due to the nature of the testing; however, UAT for specific study builds should move much faster.

4

Long-term planning

Upfront internal planning to identify needs and configurations can help make the base system build more efficient. Considering the time saved in UAT and overall build, companies will see a return on that upfront investment.

> At Bayer, we're passionate about what we do and how we can improve. BAYSYS IRT is a big achievement that we will continue to build on and improve upon in the years to come.
>
> — **Julia Redgate,** *IRT System and Supplier Manager*

BAYSYS IRT

SETTING A NEW IRT STANDARD

BAYSYS IRT at a Glance

- Suvoda formally configured and validated Bayer's IRT standards
- Includes several Bayer standard IRT transactions and contains set requirements that can be used for each study
- Pre-validated and version-controlled with built-in quality aspects
- Optimized for each trial protocol

Some functionalities include:


Patient randomization


Inventory Release


Temperature Excursion Management


Drug Accountability


Supply Transfer

What Comes Next: Standardizing IRT to Remove Risks

Now in its second year, the BAYSYS IRT project continues. Both Suvoda and Bayer are working on oversight and agreements for future platform updates and maintenance, as well as new features that can be added in the future for continuous improvement.

The implications of the BAYSYS IRT system are important. The teams are able to maintain quality and high standards, which makes Bayer sites' and study teams' jobs easier. The system is expected to reduce time spent in the IRT setup. Overall, BAYSYS IRT supports continuous, uninterrupted supply of medications to the patients who need them most.

For Suvoda this has been a great opportunity. Bayer was a pioneer of this model. However, as clients come to us with comparable needs, we are applying a similar approach and beginning to see the benefits felt by more sponsors, sites, and patients on their clinical trial journeys.

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