

Cenduit IRT - Position Paper

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Executive Summary

Today, IVRS Solution Providers trend toward 'vendor standards', requiring clients to adapt their business processes in an effort to conform to pre-formed models. This is a vendor-centric approach rather than a client-centered approach. While this certainly saves a vendor time and effort, it is an unrealistic expectation of a client whose project is uniquely complex. Frankly, most studies are unable to successfully fit themselves and their needs into such a generic "box". A successful partner learns about the needs of the client and performs with excellence in the provision of that support. Customization is inevitable in today's complex world and once that is factored in making a tailored solution, ***it is possible to achieve dramatically accelerated implementations of highly complex studies with improved quality and reduced cost.***

IRT Market Review

IVRS was first used in the clinical trials industry in 1989, facilitated only by phone or fax. In recent years, with the popularity and reliability of the web, IWRS has become the dominant interface. IWRS now commands over 80% of the earlier IVRS market. The primary applications of the combined IRT solution include; patient randomization, site management of clinical study medication, patient study medication assignment, and simple patient reported outcomes. More recently, IRT (Interactive Response Technology) has replaced IVRS as a means of reference.

More recent applications of IRT include sophisticated drug forecasting, expiration date management, ancillary supply management, and adaptive trial design support. Drug returns management, Electronic Data Capture (EDC) interface, Electronic Patient Reported Outcomes (ePRO) integration, and Help Desk Support are also more recent additions to this solution to support users in more effective management of trials resulting in increased efficiency.

An increasing number of pharmaceutical companies of all sizes are now requiring the use of IRT for their clinical trials and have grown to incorporate dedicated IRT outsourcing teams. The market is purported to be growing at a rate of 10%, keeping pace with average increases in IT R&D spending — signifying that IRT is becoming a must-have in the advancing world of clinical trials.

Who Invests in IRT?

Most commonly, company representatives involved in the outsourcing of IRT partnerships include Clinical Project Managers, Drug Management Representatives, Outsourcing Representatives, and Statisticians. These individuals directly benefit from IVRS support via enhanced efficiency and price estimation, information control, visibility of information, and randomization which is both flexible and complex.

Why is IRT Essential?

IRT systems automate data trials allowing users to interact via web-based computers to provide a reliable method of gathering standardized patient-related data at frequent intervals at study sites. IRT systems are commonly used in clinical trials to manage the flow of trial medication supplies to sites and to manage the allocation of these supplies to individual subjects. Other uses include access to real-time information for trial managers, collection of patient diary and in-clinic ePRO-data directly from subjects, and as an aid to

subject recruitment. Of additional value, IRT systems help facilitate randomization to treatment, stratification, managing enrolment – capping to avoid expensive over enrolment, automated supply management, real time reporting to aid timely decision making.

Custom Reporting and Analytics

Cenduit's Interactive Response Technology is instrumental in collecting, analyzing, and managing clinical trial data. In a complex and crowded industry, Cenduit has successfully differentiated itself by taking ownership of clients' IRT solutions to help define and ensure clinical study success. Of significant value to Pharmaceutical, Clinical Research, and Biotechnology organizations, Cenduit has strategically aligned with SAP® BusinessObjects™ to enhance custom reporting and analytics capabilities within its IRT solution.

By utilizing SAP BusinessObjects Enterprise reporting solution, Cenduit takes the business efficiencies of their proven IRT solution to the next level. These business efficiencies are achieved by utilizing real-time information on patient recruitment and drug supply management to enable project managers to proactively advise clients on decisions to improve study productivity. Business intelligence gleaned from trends in programs over time help clinical trial personnel devise meaningful strategies for running cost-efficient clinical trials. Together, Cenduit and SAP BusinessObjects provide best-in-class clinical trial solutions that focus on transforming data-driven decision-making throughout the drug supply chain management and drug development process to achieve substantial study efficiencies and dramatic cost savings.

Existence of any of these study elements presents an ideal situation for IRT:

- Phase III Study
- Global
- Regional Distribution Strategy
- Protocol Pooling (same medication inventory used across more than one protocol)
- Expensive Drug
- Scarce Drug
- "Use-by-Date" Management
- Multiple and/or frequent dosing schedule
- Update to Expiry Date not on label
- Stratified randomization designs
- Complex study design
- Decentralized or minimized randomization
- Cohort Management
- Variable and Adjustable Titration Selections
- Adaptive Design
- ePRO Data Collection

Our Competitive Distinction

Because the majority of IVRS vendors today "package" their systems to require clients to adapt to the vendors' "product model", our approach clearly offers a dramatically competitive value-added distinction by tailoring each solution to client-specific business requirements. A successful business partnership requires a thorough understanding of client needs, followed closely by iterative collaboration in order to achieve solution excellence. We believe that customization per client-specific requirements is paramount. In addition, Cenduit's global Project Management disciplines focus on analyzing study data to help facilitate substantial drug supply savings by prioritizing consumption of supplies which are nearing expiration, thus minimizing waste and expiry of materials prior to use. This is our unique approach.

What constitutes today's Best-of Breed Industry Solution: *IRT Custom Xpress*

IRT Custom Xpress — Goal

The specific goal of Interactive Response Technology - IRT Custom Xpress is to uniquely provide a customized and highly standardized IRT platform, tailored to meet specific requirements for Open Label and Double Blind studies, to create a roadmap for increased IRT implementation to support lean drug supply management, real time enrolment, patient management, study progression, resources, ePRO data collection, and system support. It is Cenduit's goal to provide a solution which is tailored to each client's specified study requirements, defining standards around client business flows and needs, implementing them with the richness and flexibility of *IRT Custom Xpress*.

IRT Custom Xpress — Return-On-Investment

Once internal business processes and stakeholders needs have been defined and captured as standard IRT requirements, our flexible system can build off of this study template to provide efficient, consistent system builds for similar future studies. This use of the template adds a percentage of savings which is expected or has been seen in other opportunities in which the tactic was implemented.

IRT Custom Xpress uniquely maximizes return-on-investment by reducing timelines, and yielding significant efficiencies in the following areas:

- IRT Custom Xpress increases study accuracy and efficiency
- IRT Custom Xpress implementations are dramatically accelerated from the 8-12 week industry standard to just 4-5 weeks
- Overall study cost reduction via IRT integration with Electronic Data Capture, Clinical Trial Management, and Drug Supply Inventory Management Systems, and Electronic Patient Reported Outcomes of invivodata EPX™ ePro
- Enhances custom reporting and analytics capabilities powered by SAP® BusinessObjects™

Cenduit's unique joint venture relationship with Fisher Clinical Services (FCS) allows for complete control of the Supply Chain Management Process. For over 20 years, FCS has exclusively focused on serving the sourcing, manufacturing, packaging and distribution requirements of clinical trials across the world. Due to this relationship, Cenduit has a direct link to FCS inventory management, distribution and returns management systems. This service includes expiry date management as well as IRT specifications that are aligned with the labelling, packaging and distribution strategies. Cenduit Project Management is co-located with FCS in the US and Europe, and the Project Management teams own and understand the responsibility they have to work closely with both the clinical and supply management teams to ensure that the requirements of Sponsors' clinical protocols are accurately represented in the IRT specifications, and that they are aligned with the statistical, packaging, and labelling strategies being employed.

Since Quintiles, Fisher Clinical Services, and Cenduit are formally linked in a joint venture, IRT Custom Xpress enhances efficiency and increases return-on-investment via streamlined global Project Management through Cenduit's proven processes. Additionally, ease of solution scalability offers our clients dynamic study designs and integrated data flow into Clinical Trial Management, EDC, Drug Supply Management, and ePRO systems to provide a genuine "total solution".

Additional IRT Custom Xpress Efficiencies:

Program Management:

- Site selection: Typically 30% of sites never recruit a single patient
- Most common indications have more than 5 concurrent projects running in EU and US
- Estimated 25% typical wastage on the clinical side of program management

Site/Patient Management:

- Inclusion/Exclusion criteria enforceability
- Uniform site communication
- Streamlined eDiary setup/assignment for sites and patients
- Timing of CRA visits synchronized with patient enrollment
- Deliver right drug to right patient at right time
- Controlled un-blinding process
- Electronic audit trail of drug dispensation

Data Management:

- IRT is the first point of entry for patient data
- Patient data is entered in > 4 different places by four different layers of personnel handling a trial
- Significant reduction in ePRO data queries by eliminating redundant data entry
- Duplication of data queries estimated to be in the region of 25% in trials without a “single source of truth”

Supplies Management:

- Typical Overage in clinical trials can exceed 200%
- Huge regulatory impact of expiry date inaccuracy
- Integrated inventory management for device-based patient eDiaries
- Sophisticated algorithms are required to configure supplies management and require supply chain core competence in IRT personnel

The Strength of Cenduit

Cenduit is a joint venture between Fisher Clinical Services and Quintiles. The combined reach and expertise of these two global industry leaders ensures that Cenduit IRT is driven by a broad and accurate view of the total clinical development process and our customers' immediate needs. Through our unique relationship with Fisher Clinical Services and Quintiles, Cenduit has created an IRT solution with global reach to support multi-continent Pharma clinical programs. The seamless partnership integrates the supply chain processes of Fisher Clinical Services packaging and distribution with Quintiles clinical processes of patient enrolment and treatment.

Cenduit also represents a commitment by both founding companies to invest in and accelerate the development and implementation of new and enhanced tools that improve the overall clinical trial management process and increase the speed and efficiency of clinical trials worldwide. Given the opportunity to support a project together, the synergy of Fisher Clinical Services, Quintiles, invivodata and Cenduit enables the Cenduit IRT platform to offer unprecedented linkage and visibility via automatic access to clinical development and clinical supply streams.

Integrated ePRO Solution

Through its strategic alliance with invivodata, the leading provider of ePRO solutions for clinical research, Cenduit's solution incorporates a fully integrated ePRO solution that allows key ePRO data to be captured through IVRS, Web, handheld devices, or tablet PCs and is fully integrated with Cenduit's IRT platform. From randomization, device assignment, ePRO data capture, data management, to delivery and archive, the combination of Cenduit's IRT platform integrated with invivodata's EPX™ ePRO management system, supported by invivodata's global consulting, ePRO site readiness, and data management services, provides sponsors with a uniquely integrated and streamlined approach to collecting the highest quality ePRO data in clinical trials.

Experience

The Cenduit IRT solution is currently being used in +300 Phase I through Phase IV clinical trials, by over 22,000 sites in 78 countries, to enroll more than 260,000 subjects for over 30 indications. There are currently 46 languages in use in the platform; and it supports all languages in the ISO country list, including those using Unicode fonts such as Japanese, Korean, and Mandarin, etc.

Staff Qualifications and Locations

Cenduit is dedicated to Quality, Partnership, Efficiency, and Exemplary Customer Service. We have over 200 dedicated project management, technical, validation, programming, IT and quality control and assurance staff in five geographical locations; RTP, North Carolina USA, Allentown, Pennsylvania USA, Horsham, London UK, Basel, Switzerland, and Bangalore, India. The Cenduit headquarters and global sites are located within or next to Fisher Clinical Services and Quintiles physical locations and our global personnel provide the technical and support expertise needed to ensure all of our customers receive the highest quality of service.

Cutting Edge Technology

Study set-up uses an extremely flexible reconfigurable pre-validated software platform. This platform minimizes the need for customized coding, shortening timelines, reducing risk, and can be tailored to meet reconfigurable system tool requirements.

Cenduit: The central conduit of data to accelerate decision making in clinical trials.