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Cenduit; Interactive Response Solutions

...Improving lives by accelerating clinical discoveries.

CENDUIT: The Central Conduit of Data to accelerate decision making in clinical trials.

Cenduit's Interactive Response Technology (IRT) is not just about 'technology'. It's about clinical study solutions that focus on transforming data-driven decision-making throughout the drug development process. Cenduit's consultative approach and innovative portfolio of products and services allow us to connect sponsors, investigator sites, clinical trial suppliers and clinical research organizations — with measurable efficiencies.

In partnership with our clinical study professionals, business and investor stakeholders, we help ensure measurable clinical trial success in these primary areas:

- I. **Site Efficiency & Productivity**
- II. **Clinical Trial Productivity**
- III. **Clinical Supply Chain Efficiency**
- IV. **Sponsor Return-on-Investment**

Cenduit offers flexible site communications with two interfaces that can be used interchangeably: Internet and Telephone. Simply, Cenduit's world-class domain consulting expertise, coupled with our applied technology, measurably improves patient enrollment, streamlines access to data, and reduces study timelines — with the singular goal of simplifying clinical trials, ensuring accuracy, and accelerating time-to-market.

Cenduit's IRT solutions gather, analyze, and integrate data from clinical trials faster and more efficiently than ever before. This truly seamless integration of multiple systems provides total study control, more timely information, and better decision-making through a consolidated reporting format that provides 100% visibility from anywhere in the world.

Whether recruiting, enrolling, randomizing, adapting patient treatment, forecasting, managing or delivering clinical trial supplies, Cenduit is the data management hub offering a new level of control, efficiency and cost-effectiveness in drug development — simply and seamlessly. Cenduit is all about ensuring that our customers "Get Business Value from their Data."

Site Efficiency & Productivity

- Accurate Resupply ensuring no drug shortages or site concerns on this front which can waste their site personnel and CRA time in tracking
- Careful understanding of the visit plan, and tracking of site enrollment rates by Cenduit APMs, to ensure that resupply strategy is updated based on individual site performance and study stage based on enrollment targets.
- Liaising with CRAs to gather as much information as possible about site storage space, especially important in cold or frozen storage, and applying that knowledge to ensure sites are not oversupplied for their storage capacity.
- Consolidation of supplies into shipments – ancillary, lab kit and IP - to minimize the number of individual shipments sites need to receipt and process. Also enables the management of complimentary supplies to be automated, saving CRA and site time.
- Reporting of lab results into Cenduit system via a data feed, automating the dosage calculations appropriately and auto branching to collect additional site data when appropriate, or notifying site of additional resulting testing needed.
- Reporting and web form reconciliation functionality to aid in the accountability of drug at site, and triggering courier pick-up to site.
- Feeding data to EDC minimizes data entry errors and saves site time by avoiding double entry of site, patient, drug assignment, and demographic data into two systems.
- Knowledgeable, attentive, responsive help for site personnel, as well as escalation from Global Helpdesk when necessary. This includes email requests from sites in Japan so that HD can call site with translator already on the line with them.
- Template monitoring reporting through the Cenduit system allows for rapid disposition of the materials, quarantining, and reordering in an automated way.

Clinical Trial Productivity

- **Cenduit is a joint venture between Quintiles and Fisher Clinical Services** which uniquely positions Cenduit as the only IVR/IWR provider whose Project Managers come with such a rich heritage of clinical drug development and supply chain expertise.
- **Cenduit's unique relationship with Quintiles** allows for the effortless exchange of study requirements, queries and innovative solutions. www.Quintiles.com
- Real time enrollment, randomization, and dispensing information via the web, enables more accurate and efficient planning of site monitoring visits.
- Notifications via email of significant events at site together with successful and rejection attempts enables real time awareness of site actions.
- Cenduit maintenance of Project Management ownership for supply management monitoring at site frees up CRA to focus on more important areas.
- On-line automated drug reconciliation tools for CRA, with emailed reports which can be run the night before a site visit, including returns packing list, airway billing details by courier, etc.

- Import of site and user data from Q CTMS removes the need for separate tracking, entry, and coordination.
- Training for site personnel by Cenduit staff including ongoing provision of training by Helpdesk.”
- Cenduit ownership of the process to ensure coordination with packaging and distribution vendors, making sure that the packaging, material types, and quantities being packaged match the requirements of the randomized treatments in the clinical protocol being conducted as well as the enrollment expectations and assumptions.
- Reporting into Q CTMS system via data transfer, close to real time, for patient enrollment and visits.
- Cenduit Project Management staff dotted line reporting into global Project Management for duration of study. Accountable to Global Project Management for issue, budget, and communication management.

Clinical Supply Chain Efficiency

- **Cenduit’s unique relationship with Fisher Clinical Services** allows for complete control of the supply chain management process. www.FisherClinicalServices.com
- Collaborating and consulting on the most efficient and optimal packaging, labeling, and distribution strategies based on the clinical protocol, enrollment targets, and IRT system design.
- Providing material listing necessary for clinical labeling and packaging operations, as well as ensuring it is aligned to the requirements of the clinical protocol.
- Reporting back real time use data by warehouse, depot and site to drive the supply chain activities, making adjustments based on the difference between assumptions to actual enrollment realities.
- Auto supply management of depot supplies, using the enrollment and supply burn rates of the sites supplied from each to forecast the depot inventory needs.
- Monitoring warehouse levels against demand and forecast need, and using this to drive the initiation of manufacturing, label printing, and packaging activities.

Sponsor Return-on-Investment

- Cenduit Project Management will perform a careful analysis of the protocol visit plan, drug availability, expiry dating, value of product, regional spread of sites, and enrollment targets. Through this analysis they should then be providing recommendations on quantities, the most effective labeling, packaging and distribution strategy, the selection of depots, the country coverage of labeling, and most cost effective resupply strategy for sites and depots.
- The Cenduit Project Management will be a collaborative contributor to these decisions, as the player that touches all aspects of the trial, and is coordinating with the clinical and supply chain personnel.
- Cenduit Project Management will provide information back and forth, enrollment targets and expectations, sites selection goals by region, timing by country, etc. from the CRO, added to the supply chain data from the clinical packaging vendor — with the ultimate

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goal of making maximum use of the available data - to reduce costs, minimize packaging overages, find the most efficient distribution strategy, and make optimal and most flexible use of all supplies.

- Mining historical IVR data from previous studies for the sponsor in the study indication to further improve intelligence and to test assumptions about overages and distribution lead times, etc.
- Using historical system utilization of interfaces and translations to guide sponsor in making decisions during system design, and the need for expensive voice transactional forms and translations.
- Drug reconciliation functionality which can manage and drive the full study drug pool reconciliation and disposition with automation, on-line tools, and real time visibility for study teams, and depot staff.
- Recalls – maintaining links back to the manufacturing bulk lot numbers through packaging steps, warehouse ordering, depot storage, QP release, site supply, all of the way to patient allocation and dispensing. This enables speedy recalls, triggered by a failure at any stage, and full real time visibility to the entire drug supply life cycle.
- Using enrollment rates, supply burn rate at sites, depots and warehouses, Cenduit should be driving subsequent manufacturing, labeling and packaging campaigns once the study is up and running. This is based on the actual study conduct, not the assumptions which would be used to advise on pre-study go live and during planning.
- Similarly, Cenduit should be continuously looking for opportunities to add value for the clinical decision makers based on the data mentioned in the previous bullet, for example, whether to open a new country prior to a second packaging campaign being completed, and whether there are sufficient supplies left since the other countries currently are over enrolling to plan.
- Real time reports exportable into CSV and PDF, with custom reporting added during design to match exact senior mgmt reporting needed and sponsor's unique business needs. Often lengthy time is spent by clinical or drug supply staff, combining data from multiple reports to get exactly what they really need. Let Cenduit do that for you and run it for up to date, accurate real time data reporting. This can also be automated to supply needed reports via email to a set schedule; for example, every Monday morning at 9am.
- Cenduit statisticians daily monitoring of the study to ensure alignment to the statistical requirements of the clinical protocol – ensuring any issues or anomalies are addressed proactively and in a extremely timely way, which there is still time to address.
- Driving the auto supply and resupply of depots globally based on the sites supplied from each, as well as their expected and actual enrollment rates.

Cenduit's IRT platform uniquely integrates both the patient interaction systems for clinical development and the supply chain services of clinical labeling, packaging, and distribution. This industry exclusive is achieved by Cenduit's interactive web and voice response solutions (IWR/IVRS) — boasting impressive industry statistics:

Cenduit Experience and Success:

- 350+ studies built on the Cenduit IRT Platform
- 16 to 26,000 Patients at 4 to 2,500 Sites per study
- >230,000 Patients enrolled
- >32,000 Sites interacting with the system globally
- 50+ Languages both web and phone, including Unicode fonts for Japanese, Arabic, etc.
- Sites in close to 100 Countries
- 95% utilization of IRT Web over phone

Cenduit Competitive Differentiators:

- **Cenduit is a joint venture between Quintiles and Fisher Clinical Services** which uniquely positions Cenduit as the only IVR/IWR provider whose Project Managers come with such a rich heritage of clinical drug development and supply chain expertise.
- **Cenduit 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 labeling strategies being employed.
- **Generic Resupply Tool**, configurable to meet specific study needs
 - **Maximizing Efficiencies**
 - Reducing costs by using a functionally rich configurable resupply tool to create a customized study algorithm.
 - Ensuring kits supply at site is always sufficient to meet demands of subjects and cutting drug overage using a forecasting algorithm.
 - Cost savings by optimizing quantities of kits on orders when an order is required.

Capping properties ensure sites do not get over stocked, avoiding wastage (e.g. cold storage).
 - **Trial Integrity**
 - Automatically suppressing the potential unblinding of orders (can be configured to **automatically** add stock to order to ensure order does not unblind).
 - Strong visibility on problems found with site stock, etc. Automated alerts and email notifications ensuring prompt action and consultation.
 - Single / multi / mixed block packaging handled for when drug manufacturing & packaging is inconsistent across global scope of trial.
 - **Tool Approach**
 - Default strategy is study wide, but can be overridden with site specific strategy (i.e. execute logic A for all sites in study but for site in country X execute logic B rather than A).
 - Easy to reconfigure as trial travels through its life span and adjust configuration accordingly.

- Conditional criteria can be applied to a specific material type and a specific site ensuring drug management is optimized.
- Coded very defensively with strong logging, error trapping, and communication to internal and external study teams and distribution partners.
- **Integrated Ancillary and Laboratory Kit Management**
 - **Proactive:** Utilizing study data to calculate which supplies are needed and when. This allows ancillaries to be shipped with study drug, reducing shipment fees and product management activities at the investigator site.
 - **Reactive:** Intrinsically linked to the IRT system, an ancillary supplies ordering system is available which allows sites to order supplies while placing controls such as maximum order quantities and client approval steps into the process .
- **Cenduit QUALITY Commitment**
 - **Comprehensive, full life cycle Quality System and Procedures** governing all IRT consulting and solution deployments — from study setup to study completion.
 - **Study Validation Lifecycle** includes independent Quality Control gating and review.
 - **Independent Quality Assurance Organization** reporting directly to CEO responsible for regulatory compliance, Quality System monitoring and maintenance, and internal auditing. Quality Management Review presented to Executive team quarterly. Liaises directly with Quintiles and Fisher Clinical Services quality organizations.
- **Dedicated Data Control Group**
 - Staffed by statisticians
 - Manage the receipt (or generation), review against specification, and post-upload verification of all Patient Randomization and Material Listings.
 - Verification of all interim data extracts and data sets for final database locks

Design Automated SAS checks, tailored for each study design, to run daily on every, study database, to verify ongoing alignment with the statistical and dispensing rule requirements of the clinical protocol.



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