FLEX ADVANTAGE
Trial Execution Enabled

FLEX ADVANTAGE, is a flexible and dependable Interactive Response Technology (IRT) platform which offers enhanced randomisation, clinical supply management and integration capabilities, as well as supporting the execution of adaptive trials.

Our experienced team will partner with you and the study stakeholders to identify the specific needs of the trial and to recommend the optimal IRT solution.

Flexible Randomisation Engine

FLEX ADVANTAGE has a range of enhanced features to support the demands of the most complex protocols.

This includes a flexible randomisation engine that can be adjusted mid-study or dynamically, enabling the execution of adaptive clinical trials as well as the more traditional protocol changes. It supports adaptive randomisation trials efficiently, while maintaining trial data integrity throughout.

Variety of Randomisation Methods

FLEX ADVANTAGE supports numerous randomisation methods, with easy configuration to suit the needs of each specific trial including:

– Central

– Blocked

– Stratification

– Adaptive

– Dynamic

– Re-Randomisation

– Pre-Randomisation

– Cohort Management

It also enables you to automate and simplify the implementation of any complex randomisation scheme. Study Statisticians can access a specific interface which enables them to configure and review the randomisation for all types of trials including adaptive trials.

Support for Emergency Unblinding

FLEX ADVANTAGE enables authorised persons to perform emergency unblinding throughout the trial and includes additional safeguards that prevent inappropriate sharing of blinded information.

Clinical Supply Management

FLEX ADVANTAGE supports the reduction of trial costs through its drug inventory management capabilities. It allocates drug on an as-needed basis, keeping sites stocked with only the amount required based on patient enrollment which is significant in trials with drug shortages or high manufacturing costs. Investigational drug or devices can be shipped as needed, and global tracking and monitoring, enables the Clinical Supplies Manager to monitor and adjust inventory levels as needed.

Range of Options include:

– Trigger Based Resupply

– Predictive Resupply

– Drug Pooling

– Central Pharmacy

– Temperature Control

– Bar-Coding

– Batch Recall

– Returns and Reconciliation

– Forecasting

Enhanced Reporting Capabilities

FLEX ADVANTAGE empowers study teams with a full complement of real time web reports available via a customisable dashboard. The ad hoc reporting capability enables users to easily create custom reports and drill down functionality for better interaction and analysis of study data.

Seamless Data Integration

FLEX ADVANTAGE can be integrated with ICON technology solutions, such as ADDPLAN, FIRECREST, ICONIK (including Laboratory) MIRA (Medical Imaging) enabling data to be passed seamlessly. It also has established integrations with the following systems, providing study teams with complete visibility of the clinical supply chain, from distributor to patients.

– EDC systems - eliminating duplicate data entry by sites and allowing for the timely availability of clean data

– Drug distributor systems - allowing for quicker shipment processing

– Drug supply forecasting systems

Accessibility

FLEX ADVANTAGE is accessible via the web and web-enabled mobile devices. The streamlined design is intuitive for the end user and adjusts automatically to suit the device including tablets and smart phones.

Reliable and Secure

FLEX ADVANTAGE features a high level of redundancy designed to automatically fail over to a separate secondary location in the event of a disaster, keeping your data safe and secure.

Experience and Expertise you can Trust

ICON's IRT team have the experience and expertise to partner with you to understand your business objectives. They will deliver the optimal IRT system to meet your clinical trial specifications and to achieve its research outcomes. With over 20 year's industry experience, we have a proven record of developing and implementing validated IRT systems, to meet or exceed customer expectations. Our project managers have an average of 6+ years' experience and are supported by comprehensive and consistent processes, that conform to ISO 9001:200.

Expert Support

You want the right help, at the right time, from operators who know the right details about the system developed for your study.

The ICON Help Desk is available 24 hours a day, 7 days a week via phone or email and is staffed by ICON employees. It supports over 140 languages and more than 90% of all issues are addressed on the first call.

Our Help Desk agents are individually trained to ensure an understanding of the technical aspects of your protocol.

Calls are monitored to ensure we provide the highest level of quality service and to identify trends and common issues. We utilise a custom call ticketing system which allows for retrieval and tracking of call information.

Users can access the Help desk through a toll free AT&T Access code or designated toll free number.

There have been 1,800+ study implementations worldwide

Over 50,000 sites in 85 countries

Over 25,000,000 patient transactions

Dosing Titration: 100+

Adaptive Randomisation: 75+

For more information, please contact:

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