ORACLE HEALTH SCIENCES
INTERACTIVE RESPONSE TECHNOLOGY (IRT)

Oracle Health Sciences IRT gives you added flexibility and control to better manage patient randomization and complex global supply chains by extending the operational capabilities of traditional interactive voice response/interactive Web response (IVR/IWR) systems. The application’s sophisticated clinical supply algorithms and intuitive user interface designed for today’s skilled clinical study personnel help you make decisions quickly, manage simple or complex supply chain parameters, change study parameters midstream, and drive workflow. And the integration of Oracle Health Sciences IRT with Oracle Health Sciences InForm – the industry’s leading clinical data capture and management cloud platform – enables you to manage operational and clinical data from one central location to increase efficiencies and help reduce costs.

Drive Greater Efficiency and Safety in the Clinical Supply Chain

Problems with drug supply can create havoc in a trial’s timeline and cause complications such as safety issues, loss of patients, and data unblinding. To increase efficiency and reduce risks in clinical supply management, Oracle Health Sciences IRT creates, assigns, and manages supply strategies through the Web. Its extensive investigator site functionality allows you to quickly screen, randomize, and dispense drugs via an interactive subject dashboard, using simplified drug receipt and inventory management.

Oracle Health Sciences IRT is built on an innovative Web-based technology that lowers event charges and reduces the number of change orders by allowing edits to subject and supply parameters at any time.

Designed for use on both the Web and telephone, the application enables seamless role-based access control for managing key areas such as:

- Patient randomization
- Clinical trial supply
- Temperature excursions
- Drug returns and reconciliation
Achieve Efficient Supply Management

Site supply orders are automatically generated and transmitted to the supply depot based on parameters created by the supply manager. These parameters—such as trigger levels, buffer levels, and visit projection windows—can be adjusted as needed during the course of the study and monitored online either by study personnel or Oracle Health Sciences service professionals. This flexibility allows just-in-time supply delivery and can reduce costs by minimizing drug waste and lowering the number of shipments required for each site.

The smart system intelligence feature further enhances site supply management by helping ensure trial supply availability at randomization. This feature uses predefined variables, such as stock-out threshold days and the study screen fail rate, to predict the drug need for subjects currently in screening. This added capability gives you the option to enable automatic consignments or simply generate an alert when a potential stock-out is predicted at randomization. This is beneficial in situations where there is a sudden increase in screening or if the supply strategy is difficult to predict.

Leverage Integrated Solutions for Cost and Time Efficiencies

Oracle Health Sciences IRT integrates with most other EDC systems, as well as with additional third-party data sources such as diaries, depots, and clinical trial management systems (CTMS). Through the integration of Oracle Health Sciences IRT with Oracle Health Sciences InForm, you can manage operational and clinical data from one central location, helping to increase efficiencies and reduce costs. Merging these two systems streamlines workflows, reduces errors, and increases productivity by giving sites and sponsors a unified technology solution. Through a single sign-on, site personnel can randomize subjects, dispense medication, and capture electronic case report form (eCRF) data. Study sponsors can access real-time data on demand, helping to monitor study progress and oversee clinical sites more efficiently.

The full integration of Oracle Health Sciences IRT with the market-leading InForm clinical data capture and management cloud platform lets you randomize subjects, dispense medication, capture eCRF data, and access real-time subject and supply information within InForm. You improve data accuracy with streamlined workflows and enhanced operational efficiencies.
Access Information on Demand

The easy-to-use reporting environment built into Oracle Health Sciences IRT provides on-demand access to trial information such as site enrollment and patient summaries. Graphical and tabular standard reports allow access to high-level study information as well as individual patient details. Through the ad hoc reporting feature, you can create standard and customized reports that can be easily exported to Microsoft Excel, SAS, ASCII, and PDF formats, as well as accessed and securely shared with other authorized participants over the internet.

Reduce Service Delivery and Change-Order Costs

Oracle Health Sciences IRT is highly flexible and configurable to meet study needs. Users with the appropriate roles and rights can manage clinical study and supply settings directly, reducing the need to call the help desk. Common study activities such as setting or modifying screening and randomization limits, activating or deactivating sites, and creating and modifying supply strategies, can all be performed over the internet from any desktop. Oracle Health Sciences IRT increases trial efficiency by providing your study team with comprehensive control over study parameters, allowing the always-available help and support team to concentrate on more-complex needs.
Reduce Help Desk Requests
Oracle Health Sciences IRT enables your site users to correct data entry errors without the assistance of help desk personnel. Following are examples of the activities that can be edited within the user interface – speeding up trials and reducing time and effort:

- Subject demographic data
- Approvals for protocol deviations
- Subject flags for improved data management reviews
- Skipped visits
- Visit rollback, including disposition of dispensed product
- Drug reallocation

Implement Complex Randomization Schemes
To ensure proper treatment arm balancing in blind and open-label studies, you can easily configure Oracle Health Sciences IRT to implement complex randomization including crossover, manual titration, and adaptive designs.

Oracle Health Sciences IRT automates the randomization process by utilizing predefined randomization schedules to assign patient treatments, identification numbers, and drugs associated with the treatments.

For adaptive algorithms, the Oracle Health Sciences team of service professionals can perform predictive randomization simulations to help anticipate the balancing results in a study.
Utilize Web-Based Drug Reconciliation

The Drug Accountability module within Oracle Health Sciences IRT automates the key processes involved in drug accountability, dramatically reducing the time and effort spent by study monitors and depot personnel managing the drug return, reconciliation, and destruction process. It can also mitigate the risk of errors associated with paper-based reconciliation. The Drug Accountability module gives sponsors and regulators real-time visibility into accountability documentation including inventory updates and a holistic view of the entire supply chain, helping to define a repeatable process that allows complete transparency during a trial audit.

Support Global Trials and Multilingual Clinical Studies

The importance of large-scale global trials and the rapidly increasing number of studies being conducted in emerging regions underscores the need for clinical research technology with multi-language capabilities. Enabling investigative sites to work in their native languages bolsters patient recruitment, increases site satisfaction, and helps improve data integrity. Oracle Health Sciences IRT provides multilingual access for site personnel over the phone and on the Web. The system can be deployed in a single-study version and supports numerous languages, including Japanese and Chinese.

Why Oracle Health Sciences

Backed by the resources of the largest business software company in the world, Oracle Health Sciences delivers advanced transformative value for clinical R&D in a modular, integrated and scalable cloud environment. We enable you to:

- **Optimize operations** with technology that helps you maximize efficiency across your clinical life cycle
- **Gain actionable insights** from aggregated clinical and healthcare data
- **Innovate** by incorporating genomics, biomarkers and real-world patient data
- **Future-proof** your business with a significant and ongoing commitment to research and development that evolves and grows with you and the industry

With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization’s goals today and in the future.

Contact Us

For more information about Oracle Health Sciences IRT, visit oracle.com, e-mail healthsciences_ww_grp@oracle.com, or call +1.800.633.0643 to speak to an Oracle representative.

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