

One Solution for Electronic Data Capture and Trial Supply Management

KEY BENEFITS

For Sponsors

- Streamlines user workflow
- Provides on-demand access to real-time subject and supply information
- Provides full traceability across applications
- Supports global multilingual studies
- Streamlines delivery and UAT process
- Eliminates multivendor coordination
- Helps reduce total cost of ownership

For Sites

- Streamlines workflow by performing transactions in a single solution
- Eliminates duplicate data entry—IRT to EDC
- Allows sites to interact in their native language—both phone and Web
- Enables more-efficient collaboration with study sponsors
- Provides one central 24/7 help desk

Today, most clinical research sites use an interactive voice response/ interactive Web response (IVR/IWR) system to enroll, randomize, and dispense medication to subjects and an electronic data capture (EDC) system to collect subject electronic case report form (eCRF) information. As a result, sites are forced to manually transcribe information, such as randomization and medication kit numbers, obtained from the IVR/IWR system into the EDC system at a later time. This manual process is inefficient and time consuming for sites and can lead to higher discrepancies for sponsors.

Bringing together award-winning Oracle Health Sciences InForm GTM with Oracle Health Sciences IRT On Demand streamlines workflow, reduces errors, and increases productivity by giving sites and sponsors an easy-to-use, unified technology solution. Through a single sign-on, site personnel can randomize subjects, dispense medication, and capture eCRF data. Study sponsors can access real-time data on demand, helping to monitor study progress and oversee clinical sites more efficiently.

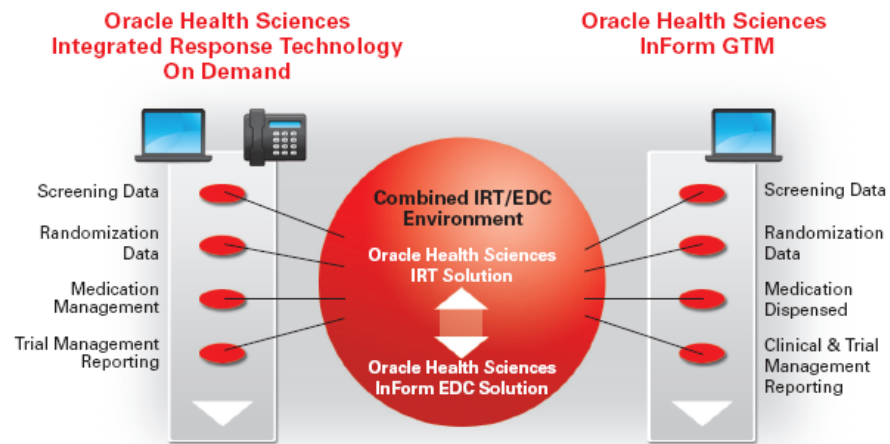


Figure 1. The IRT and EDC integration improves workflow and data convergence to help optimize the total cost of ownership and enhance the user experience.

Unified User Experience

Combining Oracle Health Sciences InForm GTM and Oracle Health Sciences IRT On Demand provides a more seamless user experience that streamlines workflow and reduces training efforts. Icons and layouts are consistent across the solution, harmonizing navigation. Information is grouped in a useful and meaningful way to allow users to make fast conclusions about what is happening.

The combined Oracle Health Sciences InForm GTM and Oracle Health Sciences IRT On Demand solution provides

- Out-of-the-box interoperability to simplify implementation
- Lower service delivery and integration costs
- Reduced time to first subject enrolled—the Oracle Health Sciences IRT On Demand system can go live in advance of Oracle Health Sciences InForm GTM
- Simplified contract process to help reduce administrative overhead
- Single project manager to eliminate multivendor coordination
- Streamlined user acceptance testing (UAT) process
- One central 24/7 help desk for sponsors and sites

The Ownership Experience

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry that can scale to the demands of the smallest to the largest companies. Clients looking to bring applications directly into their enterprise can also leverage Oracle Health Sciences full range of mentoring programs, training offerings and implementation services to transfer knowledge in-house for additional flexibility

Support for Global, Multilingual Clinical Studies

The growing importance of large-scale global trials and the acceleration of the number of studies being conducted in emerging regions underscores the need for clinical research technology with multilanguage capabilities. Enabling investigative sites to work in their native languages bolsters subject recruitment, increases site satisfaction, and improves data integrity. The combined Oracle Health Sciences InForm GTM and Oracle Health Sciences IRT On Demand solution provides multilingual access for site personnel over both the phone and the Web. The solution can be deployed in a single-study version and is able to support numerous languages, including Japanese and Chinese.

Streamlined Subject Management

From a single user name and password, site personnel can randomize subjects, associate them with particular treatment arms, assign them subject IDs, dispense medication, and capture eCRF data—all in their local languages. This simplified workflow eliminates the need to reconcile IRT data with the EDC record at a later point, saving time and reducing errors. Site personnel have direct access to operational reports and can exchange real-time data across systems.

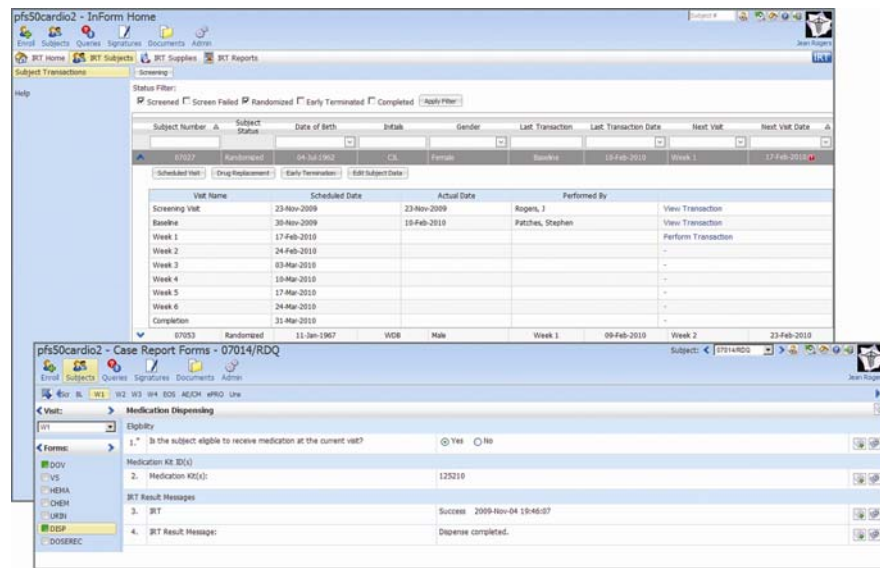


Figure 2. The integration of Oracle Health Sciences IRT On Demand and Oracle Health Sciences InForm GTM enhance operational efficiencies and streamline workflow across systems.

More Efficient and Accountable Delivery Process

Study sponsors can achieve increased efficiencies and cost savings through a tightly converged solution and a single point of contact and accountability, from project initiation to study closeout.

CONTACT US

For more information about Oracle Health Sciences InForm GTM and Oracle Health Sciences IRT On Demand, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.