

Our Interactive Response Technologies (IRT) automate randomization and clinical supplies management and offer easy-to-use reports and electronic patient diaries using the Web, telephone, and mobile devices. Our team of experienced specialists and statisticians provides expert IRT solution and randomization consulting, project management, and comprehensive support to ensure highly effective and reliable solutions.

## TECHNOLOGY

The inVentiv Health Clinical IRT technology platform supports rapid study configuration and deployment through an extensive library of reusable, plug-and-play components. This enables delivery of cost-effective solutions in shorter than average industry timelines with little or no programming. For study protocols that require custom capabilities, our IRT platform supports unlimited customizations ranging from the addition of unique edit checks to complex protocol-specific functions that are validated and delivered within typical study start-up timelines.

## EXPERIENCE

inVentiv Health Clinical has been providing clinical IRT solutions since 2002. Our IRT Services group has supported more than 140 studies, 5,200 sites, and 40,000 system users to date. Our solutions have served a wide range of therapeutic areas and geographies, with sites in over 30 countries, and solutions translated into more than 36 languages.

## QUALITY

We use a rigorous quality management plan for each IRT project. This begins with reviewing the quality of requirements and design information to ensure accuracy of deliverables. It then goes on to unit testing, validation testing, IRT project manager testing, and Client acceptance testing to ensure deliverables are carefully tested from a variety of perspectives. A quality control review of validation binders, which includes all documentation associated with each project, is then performed. Finally, our Quality Assurance department performs a second review on documentation associated with each project. In addition, our QA department conducts periodic process audits on inVentiv Health Clinical IRT processes.

## PROCESS EXCELLENCE

The inVentiv Health Clinical IRT solution project lifecycle is governed by a comprehensive set of SOPs that covers requirements, setup/programming, validation testing, deployment, user acceptance testing, project management, change control, handling of unblinding information, and closeout. Our change control and validation testing SOPs utilize a risk assessment process that dictates the level of process to follow when processing changes and performing validation testing on both new setups and system changes.

## INVENTORY MANAGEMENT SERVICES

- Drug supply ordering and tracking
- Shipments to sites/depots
- Predictive, target threshold, and just-in-time supply models
- Drug expiration date management
- Multi-study supply pooling
- Low inventory alerts

## RANDOMIZATION SERVICES

- Static and dynamic randomization schemes, stratification, and cohorts
- Adaptive trial designs
- Parallel and cross-over trials
- Variable dosing and titration
- Automatic randomization limit alerts
- Multilingual IRT systems and technical support
- Emergency unblinding service for authorized individuals
- Critical conditions and milestones achievement alerts

## CUSTOMER SERVICE

- 24x7x365 global technical support
- Experienced IRT Project Managers
- Expert support and guidance during the system specification creation process
- Exceptional planning, execution and coordination



## ROBUST HOSTING WITH COMPREHENSIVE DISASTER RECOVERY

inVentiv Health Clinical IRT is deployed on a resilient, fault tolerant hosting configuration within a power conditioned data center with generator backup. The system architecture utilizes parallel servers to eliminate all single points of failure. The inVentiv Health Clinical IRT also utilizes a fully functional hot standby disaster recovery system implemented at a secondary location. Our disaster recovery system is regularly tested in functional segments. Segments include the ability to switch over telephone circuits, database servers, and voice and web application servers.

## REAL-TIME WEB REPORTING

- Interactive web reports for subject and inventory information
- Downloadable Web reports in various formats
- Blinded and unblinded configured reports
- Transaction data capture on confirmation reports

## eDIARY SERVICES

- Patient reported outcomes capture
- Automatic eDiary compliance alerts
- Real-time reporting patient reported outcomes

## IRT SERVICES OPTIONS

- Major Electronic Data Capture (EDC) system integration
- Custom integrations with CTMS, ePRO, and other systems
- Drug assignment replacement and missed visit registration
- Site activation with IRB data capture and extension rules



inVentiv Health Clinical, formerly PharmaNet/i3, is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies. With 7,000 employees in more than 36 countries, inVentiv Health Clinical offers therapeutically specialized capabilities for all phases of clinical development, bioanalytical services, and strategic resourcing from a single clinical professional to an entire functional team.