

Interactive Voice/Web Response System

Interactive Voice/Web Response System (IVRS) Solutions

Bilcare provides a state-of-the-art Interactive Voice and Web Response System (IVRS/IWRS) which is an innovative, value-based product for managing data, including automatic patient enrollment and randomization, capturing data, patient enrollment management and drug supply management as well as patient diaries.

The exclusively provided IVR/IWR System is 21 CFR Part 11 compliant, is user-friendly and proves its value to customers through cycle time reductions for study start up. Bilcare's IVR/IWR System ensures data integrity, accelerates clinical site initiations and provides real-time patient, site and study metrics via an interactive website.

Services provided include:

- + Customized IVRS/IWRS programming
- + Accelerated implementation
- + 24/7 operation
- + Patient enrollment and randomization
- + Patient diaries
- + Site administration and tracking
- + Clinical supply management including automated supply and re-supply, site and depot Inventories, individual kit status and activation notification, and expiry management
- + Secure web-enabled reports
- + Supports multi-lingual voice recordings in an unlimited number of languages
- + Real time reporting and tracking via web
- + Technical support and training for staff and investigators
- + Outbound faxes and emails
- + Adaptive trials
- + Predictive inventory

Interactive Voice/Web Response System (IVRS/IWRS)

Bilcare's System measurably reduces setup and maintenance costs associated with the overall IVR/IWR process. Our clinical services provide:

- + Simulation and test modes
- + Support of multi-lingual voice recordings
- + Real time reports and tracking
- + XML integration with CDISC standards
- + Integration with other data sources
- + Technical support and training

21 CFR Part 11 Compliance

All IVRS/IWRS applications and systems have been developed to operate in compliance with 21 CFR Part 11 and FDA requirements, especially as they pertain to systems validation, systems security, data integrity, audit trails and encryption.

- + Data capture, validation and retrieval
- + Patient enrollment and randomization
- + Clinical supply management
- + Site administration and tracking
- + Web-enabled clinical trial management reports

A web-accessible reporting application offers authorized users timely access to current and accurate study information. The system provides a standard reporting package.

Authorized users can also create and prepare custom reports. Reports can be delivered via web, fax, email or telephone. Standard reports include:

- + Enrollments
- + Site status report
- + Drug distribution report

- + Drug consignment report
- + Subject discontinuation report
- + Patient summary report
- + Reporting by phone, fax, email and web
- + Tracking of treatment schedule
- + Kit status tracking

Testing Validation and Training

Each study-specific IVRS/IWRS implementation is tested and validated to meet compliance requirements for FDA regulations. Documentation for each study is maintained on-site in our documentation library for review and audit. A test system is available for user and site investigator training throughout the life of the study.

Why Bilcare IVRS/IWRS?

- + World-class speed for setup and validation of new studies – less than four weeks from User Requirement Specification (URS) approvals to User Acceptance Testing (UAT)
- + Rapid scale out for new sites, dial in locations (point of presence)
- + Easy to validate, easy to purchase, and easy to modify
- + Ease of access to study metrics
- + Extremely flexible
- + Prevents drug wastage
- + Prevents patient over-enrollment
- + Minimizes per-patient cost of trial