



IVRS/IWRS.

Premier Research provides a reliable, fully validated, 21 CFR Part 11 compliant Interactive Voice/Web Response System (IVRS/IWRS) including ePRO capabilities that allows our clients to automate many aspects of their trials with added flexibility and confidence.

Services

- Patient Randomization including Centralized, Stratified, Dynamic, and Adaptive Algorithms
- Titration/Dose Escalation
- Clinical Supplies Management including Predictive Algorithms
- Subject Diary Capture (ePRO) including Compliance Monitoring
- Visit Tracking

Expertise: The People

- Employed IVRS for more than 130 Phase 2, 3 and 4 trials in North America, Europe, South Africa, Asia, and Australia
- Strong, stable team of developers and support personnel
- Extensive experience with Schedule II and Schedule III substances

ezRand

ezRand Interactive Web Response (IWR) system provides clients with a rapidly deployed, cost effective solution for performing automated randomization, subject tracking, study medication dispensing, and clinical supplies management. This system is built upon our robust IWRS platform and is comprised of a comprehensive suite of commonly used modules. Each module can be configured via 'data-driven' parameters drastically reducing costs and timelines.

Benefits

- Randomization for complex protocols made simple for the investigator whether centralized, stratified, dynamic or adaptive algorithms
- Multi-mode access by phone or standard internet browser
- Data exports and customized reporting available via secure internet connection
- Oversight of patient enrollment by project teams to prevent over-enrollment
- System provides study coordinators with improved drug accountability and expiry information
- Less drug wastage with inventory management provides cost control
- Improved data accuracy and availability of patient diary data (ePRO)
- Use of robust, scalable technology allows for timely development of protocols
- Flexible systems allows for adaptive design
- 24/7 multilingual capability and support
- Full Business Continuity Plans and Disaster Recovery Plans in place ensuring maximum system availability

Case Study:

Real-time Access to Study Data

Premier Research managed two concurrent pivotal Irritable Bowel Syndrome studies for a sponsor. With each study needing to randomize 600 patients, Premier Research collected the primary efficacy data using our proprietary IVRS Diary System (ePRO). Using this in conjunction with our clinical trial management system, both Premier Research and the sponsor were able to monitor and view diary compliance data ensuring protocol adherence.

The IVRS also interfaced with our proprietary drug supply management system. The system employed a predictive drug ordering algorithm ensuring adequate supply of investigational product at each of the study sites.

As a result of these successes, the sponsor awarded Premier Research a follow-up study utilizing our IVRS.

Premier Research

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