

i3 Statprobe has been working with clients to maximize the benefits of electronic data capture (EDC) technology since the days when it was a novelty within the industry. We've watched the technology grow and evolve, and have developed an approach to EDC that improves its effectiveness—whether we're using i3Cube™, our proprietary market-leading technology; Oracle® RDC Onsite v4.5.3; or any third-party system.

i3 Statprobe data managers have the depth and breadth of experience to make EDC work to meet the unique needs of each client and study. Our industry-leading experience gives us greater knowledge and flexibility to:

- Understand and adapt processes to maximize their effectiveness
- Anticipate and negotiate issues—both technological and project-related
- Foresee issues and meet needs not necessarily addressed by the typical EDC provider
- Consult with the client about how to apply any given EDC technology to maximum advantage

i3Cube Clinical Trial and Data Management System

i3Cube is a revolutionary new clinical trial and data management technology that automates the entire clinical process from beginning to end—allowing for shorter timelines, greater team collaboration, and superior cost control. i3Cube consolidates software and services under one best-of-breed solution, eliminating the need for multiple technology implementations and duplication of efforts.

i3Cube's state-of-the-art features include:

■ **Electronic data capture (EDC) and query management**

i3Cube streamlines EDC and query management in a centralized, fully integrated system for faster and better-coordinated start-ups and database design, rapid and intuitive form design, and easy form amendment and republishing. The system—which employs an automated workflow engine utilizing today's best-in-class technology, Adobe® Flex®, for a nimble and intuitive user experience—includes a comprehensive query management suite with a site-friendly query bar for single-point-of-entry query resolution, eliminating the need to locate data points by scrolling through forms.

■ **Intuitive dashboards**

i3Cube's dashboards, which are accessed from a single online logon, place real-time data—the pulse of a clinical trial—at users' fingertips, allowing sponsors to see and manage the entire clinical trial process like never before.

■ **Unprecedented visibility**

i3Cube takes transparency to a new level. By more closely linking sponsor, site, and CRO, i3Cube enhances trial collaboration, tracks milestones, and improves communication.

Oracle® RDC Onsite v4.5.3

i3 Statprobe led the entry of Oracle® Clinical RDC (OC RDC), our other in-house EDC offering, into the marketplace. The latest version, Oracle® Remote Data Capture (RDC) Onsite 4.5.3, provides sponsors with a powerful, commercial solution. It is a very stable, highly validated platform and one of the most respected and reliable systems in the industry. For customers who use RDC Onsite as their in-house data repository, direct acquisition of data into RDC Onsite allows for quicker and smoother sharing of data with their in-house systems.

The screens in RDC Onsite appear as electronic versions of paper CRFs, making them very intuitive and easy to work with for investigator site personnel who are accustomed to paper CRFs. We also have comprehensive training resources to guide users through every aspect of the system whenever additional help or more detailed knowledge is required.

Because the data capture screens are designed as electronic versions of paper CRFs, and because the RDC tool captures data directly into an Oracle Clinical database, RDC Onsite is uniquely well suited for studies that mix EDC with other forms of data collection (e.g., double data entry, fax forms, etc.) without the requirement to build separate databases.

Additionally, because CRFs are presented as PDFs, security during an inspection or audit by a regulatory agency is heightened. Inspectors do not need to log on to the live system, but can view PDFs of the study data. This also simplifies electronic submission to regulatory agencies, as the data is already in the required format.

We have fully integrated RDC Onsite with KnowledgePort™, i3's secure web portal. KnowledgePort seamlessly brings together multiple platforms to provide simple, immediate access to study information such as scanned CRFs (for paper CRF studies), SAS data sets, safety reports, and other customized reports and documents (e.g., data management plan, protocol, etc.).

Find out how i3 Statprobe's EDC solutions can improve data management for your next clinical trial.

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