

POWERING CLINICAL TRIALS WITH ORACLE'S REMOTE DATA CAPTURE 4.6



ORACLE'S REMOTE DATA CAPTURE 4.6 ENABLES SPONSORS TO STREAMLINE SETUP AND EFFICIENTLY MANAGE THE EXECUTION OF COMPLEX CLINICAL TRIALS. BENEFITS OF ORACLE'S REMOTE DATA CAPTURE 4.6 INCLUDE:

- FASTER TIME TO MARKET FOR NEW PRODUCTS
- IMPROVED STAFF PRODUCTIVITY
- INCREASED CLINICAL IT EFFICIENCY

Oracle's Remote Data Capture 4.6 enables sponsors and CROs to streamline study setup and efficiently manage the execution of complex clinical trials. Benefits of Remote Data Capture include improving staff and site productivity, increasing clinical IT efficiency and reducing time to market for new products.

Improved Sponsor, Clinical Staff and Site Productivity

Remote Data Capture improves productivity by reducing study set up time and maintenance of complex trials through its flexible study support capability. The Remote Data Capture user interface enables studies with multiple treatment arms and cohorts with different assessment schedules and frequencies. The system provides the ability to define multiple potential pathways a patient might take through a complex study and display only the relevant CRF pages expected for the patient, based on reported patient data. Intelligent guidance through patient treatment path enables site personnel to quickly identify and respond to data for each patient, while minimizing checks for required and missing data. This yields faster and more accurate data collection.

Select	Patient Number	Dose	PE	Hema	Vitals	Lab1	Lab2	Biopsy
<input type="checkbox"/>	1	6	7	8	9	10	11	12
<input type="checkbox"/>	2	6	7	8	9	10	-	12
<input type="checkbox"/>	3	6	7	8	9	10	11	-
<input type="checkbox"/>	4	6	7	8	9	10	-	-
<input type="checkbox"/>	5	6	7	8	9	10	-	12
<input type="checkbox"/>	6	-	-	-	-	-	-	-
<input type="checkbox"/>	7	-	-	-	-	-	-	-

Oracle's Remote Data Capture reduces the burden of setting up and maintaining complex trial designs and maintaining treatment pathways, thus greatly increasing clinical data management productivity. It allows project teams to focus on monitoring patient and study progress, as well as track expenses. By enabling better project decisions, it improves staff productivity and helps reduce the time from patient visit to clean visit data.

Remote Data Capture supports electronic data capture and hybrid studies by using the same study definitions and page layouts for both electronic and paper environments. The enhanced Patient Data Report includes the functionality to generate submission-ready patient CRFs directly from the system. This significantly reduces the time required to prepare the clinical trial for regulatory submission. Streamlined study management functionality allows staff to assign multiple patients to a study book, while also providing complete control over protocol amendments. The rollout of



CONSULTING SERVICES

Oracle offers a complete suite of consulting and training services that help customers become productive with Oracle's Remote Data Capture as quickly as possible.

ORACLE'S REMOTE DATA CAPTURE 4.6 TECHNICAL SPECIFICATIONS

- Client:
 - Windows 2000 SP4 (IE 6), XP SP1,2 or 3 (IE 7 or 8), Windows 2003 SP1 or 2 (IE6 or 7), and Vista SP1 (IE7 or 8) client)
- Middle Tier:
 - Oracle AS10gR2 patch set 10.1.2.3
 - Windows 2003 Server
- Database:
 - Oracle 11g
 - HP-UX Itanium 11.31
 - Sun Solaris (SPARC) 9, 10
 - Windows 2003 Server

amendments to sites can now be carefully staggered and scheduled in accordance with local regulatory timelines.

Increased Clinical IT Efficiency

Remote Data Capture delivers advanced functionality to improve clinical IT efficiency and reduces the resources required to support complex trials. It increases IT staff productivity and enables faster set up of complex studies.

Remote Data Capture utilizes the sophisticated Oracle Clinical database to support back-end data management. Using Oracle Clinical and Remote Data Capture, companies need to support only a single environment, considerably simplifying the IT maintenance burden.

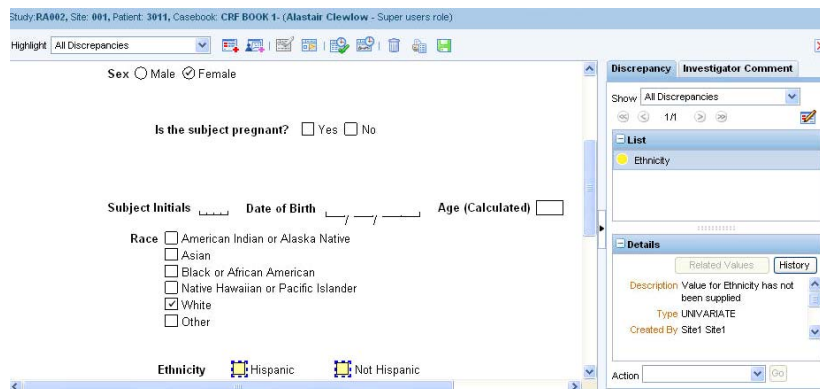
Built on powerful Oracle technology, Remote Data Capture has proven scalability, having successfully conducted thousands of clinical studies. These have included studies across all development phases and vast patient populations, with submissions approved across many therapeutic areas and geographies.

Remote Data Capture also includes the ability to run batch validation concurrently with data entry, delivering zero system downtime and enabling around the clock usage and back office processing to support global trials.

Reduced Time to Market

Remote Data Capture improves the availability and quality of clinical trial information, therefore enabling faster study decisions and timely feedback to clinical and site personnel. This helps sponsors to reduce time to market for new products.

The Remote Data Capture user interface has been ergonomically designed to improve the efficiency and accuracy of CRF data collection. This leads to a reduction in the volume and cost of data queries, which reduces the overall cost and time for the clinical trial. Combined with Clinical Data Management Analytics, Remote Data Capture enables sponsors and sites to receive faster and clearer insight into study and patient data.



Contact Us

For more information about Oracle's Remote Data Capture 4.6, please visit the [Oracle Health Sciences applications website](#) or call +1.800.ORACLE1.

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