

# POWERING CLINICAL TRIALS WITH ORACLE'S REMOTE DATA CAPTURE 4.6.2



ORACLE'S REMOTE DATA CAPTURE 4.6.2 ENABLES SPONSORS TO STREAMLINE SETUP AND EFFICIENTLY MANAGE THE EXECUTION OF COMPLEX CLINICAL TRIALS. BENEFITS OF ORACLE'S REMOTE DATA CAPTURE 4.6.2 INCLUDE:

- IMPROVED SITE PRODUCTIVITY
- OPERATIONAL EFFECTIVENESS
- TECHNOLOGY ENABLEMENT

Oracle's Remote Data Capture 4.6.2 enables sponsors and CROs to streamline study setup and efficiently manage the execution of complex clinical trials. Benefits of Remote Data Capture include improved staff and site productivity, increased operational effectiveness and IT efficiency via technology enablement.

## 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 results in faster and more accurate data collection and an improved site experience.

Select	Patient Number	Dose	PE	Hema	Vitals	Lab1	Lab2	Biopsy
<input type="checkbox"/>	1	6	7	8	9	10	11 N	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 enhanced discrepancy data management capabilities results in more streamlined operations for both site and clinical staff. It is designed to reduce duplicate work and deliver cleaner data earlier in the process. The improved data management experience allows for better decisions sooner in the trial.

## Increased Operational Effectiveness

Remote Data Capture's ability to easily model flexible trials provides a significant reduction in time and costs to set up a complex trial.

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

## 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 4.6.2 TECHNICAL SPECIFICATIONS

- Client:
  - Windows XP SP1,2 or 3 (IE 7 or 8), Vista SP1 (IE 7 or 8) client), Windows 7 (32 & 64-bit, IE 8 or 9) and Windows 2008 (IE 8)
- Middle Tier:
  - Oracle AS10gR2 patch set 10.1.2.3 + AS10gR3 patch set 10.1.3.5
  - Windows Server 2008 R2
- Database:
  - Oracle 11gR2 11.2.0.2
  - HP-UX Itanium 11.31
  - Sun Solaris (SPARC) 10
  - Oracle Enterprise Linux 5 update 5

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.

The screenshot displays the Oracle Remote Data Capture interface for a patient record. The main form contains the following fields and options:

- Sex:  Male  Female
- Is the subject pregnant?:  Yes  No
- Subject Initials: \_\_\_\_\_ Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Age (Calculated): \_\_\_\_\_
- Race:
  - American Indian or Alaska Native
  - Asian
  - Black or African American
  - Native Hawaiian or Pacific Islander
  - White
  - Other
- Ethnicity:  Hispanic  Not Hispanic

On the right, the 'Discrepancy' panel shows a message: 'Value for Ethnicity has not been supplied'. The discrepancy type is 'UNVARIATE' and it was created by 'Site1 Site1'.

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.

## Technology Enablement

Remote Data Capture is built on the latest Oracle database technology, delivering superior performance across all clinical trials and reducing risk from technology changes. Seamless integration enables trial changes from development to production without impacting end users.

Remote Data Capture utilizes the sophisticated Oracle Clinical database to support centralized 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 and performance, 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.

Certified for use with [Oracle VM](#), customers can reduce costs by taking advantage of the latest in virtualization technology, and [Oracle Active Data Guard](#), ensuring high availability of critical clinical trial data, as well as reducing the potential for data loss in the event of a disaster.

## Reduce project risk and cost with Oracle Consulting Services

Consultants from Oracle Health Sciences are part of a global consulting organization with extensive domain expertise and in-depth experience implementing Oracle's health care and life sciences solutions. Oracle's consultants complement Oracle Health Sciences products to provide a comprehensive solution. They can help organizations:

- *Reduce project risk and improve quality* with Oracle's distinctive resources and expertise
- *Lower total cost of ownership* with Oracle's complete solution
- *Realize faster time to business value* by leveraging Oracle's unique library of consulting assets and accelerators

Oracle Health Sciences' consultant team is 100% dedicated to Oracle Health Sciences products and have many years of experience implementing

these healthcare and life sciences solutions. It is composed of a global team of product experts who leverage their close ties to Oracle's product strategy and development teams, utilize standard Oracle methodologies (OUM aware and certified), participate in numerous international standards-setting bodies (such as HL7 steering committee, CDISC), and embrace a partner-friendly strategy. All while backed up by the power of Oracle Corporation's global consulting organization. Oracle Health Sciences consultants are uniquely positioned to ensure project success.

### Contact Us

For more information about Oracle's Remote Data Capture, please visit the [Oracle Health Sciences applications website](#) or call your [local Oracle office](#) or +1.650.506.7000 to speak to an Oracle representative.

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