

# POWERING CLINICAL TRIALS WITH ORACLE CLINICAL AND REMOTE DATA CAPTURE ONSITE



TOGETHER, ORACLE  
CLINICAL AND ORACLE  
REMOTE DATA CAPTURE  
ENABLE SPONSOR  
COMPANIES TO STREAMLINE  
SETUP AND MANAGE  
EXECUTION OF THEIR FULL  
PORTFOLIO OF STUDIES  
THROUGH A SINGLE  
TECHNOLOGY INVESTMENT.

*Oracle's Remote Data Capture (RDC) Onsite is fully integrated with Oracle Clinical (OC) – the leading clinical data management system. Together, these products enable sponsor companies to streamline setup and manage execution of their full portfolio of studies through a single technology investment.*

## **Support for Electronic, Paper, and Hybrid Studies**

While the life sciences industry has seen a tremendous uptake in electronic data capture (EDC) in clinical trials, many organizations are still running a percentage of paper-based trials, paper components for EDC trials, and/or facing the need to enroll paper-based sites in an EDC study.

OC/RDC enables support for exclusive electronic data capture or paper data collection and a combination of both capture methods commonly referred to as “hybrid” studies. Using a single study definition and layout editor to drive both online data entry screens and paper-based case report forms (CRFs), OC/RDC eliminates redundant setup and the need for multiple applications to conduct hybrid studies.

OC/RDC is the only solution that provides comprehensive support for both electronic and paper data capture workflows, availability of data in a single location for processing, and a single data management repository and combined representation of the final data as a patient data report (PDR).

## **Optimize Study/Revision Deployments**

There is increasing pressure to greatly reduce study startup times, including initial study definition and deployment, and the ability to quickly make changes to ongoing studies with minimal impact to site users.

After a study is defined in OC, it can be quickly reviewed and tested using Oracle's embedded “test” environment. Any issues or changes identified during testing can be corrected immediately by performing a single update to study definition. Each change can then be retested granularly until all issues are resolved and the study is released and activated for production use. There is no porting of study between environments required, and therefore no full regression testing each time a change, small or large, is made to a study.

Similarly, as changes or amendments are required for ongoing studies, the study definition can be modified or updated **without interrupting** the study. The changes can be made and tested in parallel to site activity and deployed without any downtime. This minimizes site disruption since the changes to a study are simply reflected at the time of the next log-on.

#### CONSULTING AND TRAINING SERVICES

Oracle offers a complete suite of consulting and training services that help customers become productive with RDC Onsite as quickly as possible.

#### IMPLEMENTATION SERVICES

- System implementation and upgrades
- Study modeling workshops
- Assistance with initial studies
- Advice on process changes and best practices
- System configuration, including programming of activities presented on home page
- Complete validation kit

#### TRAINING OFFERINGS

- RDC for study designers
- RDC for system administrators
- RDC for end users

Compared to other systems that require dual environments to support non-production use and testing, the embedded nature of OC's test capability significantly **reduces** the overall time and effort required to test and deploy new and amended studies as well as the various costs associated with maintaining separate, multiple environments.

#### Proven Scalability

Using a time-tested and sophisticated data model built on powerful Oracle technology, customers have successfully run studies using OC/RDC for the past 15 years. Studies range across all development phases and many have included vast patient populations, with submissions approved across therapeutic areas.

#### Contact Us

For more information about Oracle Clinical / Oracle Remote Data Capture Onsite, please visit <http://www.oracle.com/healthsciences> or call +1.800.ORACLE1 to speak with an Oracle representative.



Oracle is committed to developing practices and products that help protect the environment

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