

Oracle Health Sciences Clinical Development Analytics



Oracle Health Sciences Clinical Development Analytics (CDA) is a comprehensive analytics solution that provides sponsors and CROs with timely, fact-based insight into clinical programs. CDA helps users to make more informed business decisions, increase R&D productivity, and develop drugs more effectively. With Oracle Health Sciences CDA, executives, data managers, clinical monitors, and project managers can easily obtain personalized, relevant, and actionable views of clinical development program, get more timely access to business-critical information, improve site/staff productivity, increase clinical effectiveness, and consolidate information across system.

IMPROVE DRUG DEVELOPMENT,
SPEED, AND EFFICIENCY WITH
TIMELY, FACT-BASED INSIGHT INTO
CLINICAL PROGRAMS

KEY FEATURES

Achieve faster implementation, reduced costs/risks, and obtain better business results from prebuilt components:

- Comprehensive data models
- Extract, transform, and load programs sourcing from Oracle Health Sciences InForm, Oracle Clinical, Oracle Remote Data Capture, and Oracle's Siebel Clinical Trial Management System
- More than 1,200 business attributes covering performance management metrics and associated descriptive terms about clinical trial progress
- More than 230 prebuilt reports and nine dashboards designed for specific user roles

Make Important Decisions Faster

Oracle Health Sciences CDA provides executives and clinical managers with rapid visibility into their clinical data, helping them to identify issues sooner and make better-informed decisions.



Figure 1: Oracle Health Sciences Clinical Development Analytics provides insight into key performance indicators (KPIs), identifying trends and tracking progress over time.

CDA provides a comprehensive view of clinical program and study activity across all levels of the organization. Clinical study managers can quickly see enrollment progress and identify any screen failure trends that are impacting the time to complete

KEY BENEFITS

- Make key business decisions earlier by reviewing and managing all clinical programs across the organization.
- Accelerate progress, improve overall performance, and reduce study costs with better visibility into site and partner performance.
- Gain insight into the completeness and cleanliness of study data for proactive data management.
- Increase operational efficiency with more-focused resource optimization.
- Proactively manage study and site risks throughout the study lifecycle.
- Gain actionable insights for effective monitoring with risk based monitoring (RBM).
- Identify trends in key performance indicators (KPIs). Obtain insights at portfolio, regional, study and site level.

enrollments. Clinical monitors can prioritize site visits and proactively communicate with sites using the dashboards to guide their conversations. Clinical data managers can obtain insight into how complete and clean study data is, enabling more-proactive data management to drive rapid database lock. Executives can view performance trends across therapeutic areas to identify opportunities for performance improvement.

Improve Staff and Site Productivity

Enabling sponsors and CROs to review and manage all studies holistically in their clinical portfolios, CDA identifies nonperforming sites and targets resources to reduce study costs and time.

The solution provides greater insight into subject enrollment and site performance, optimizing clinical staffing and site productivity. It empowers managers and clinical monitors to focus resources, balance workloads, and plan for/manage site visits in a superior manner.

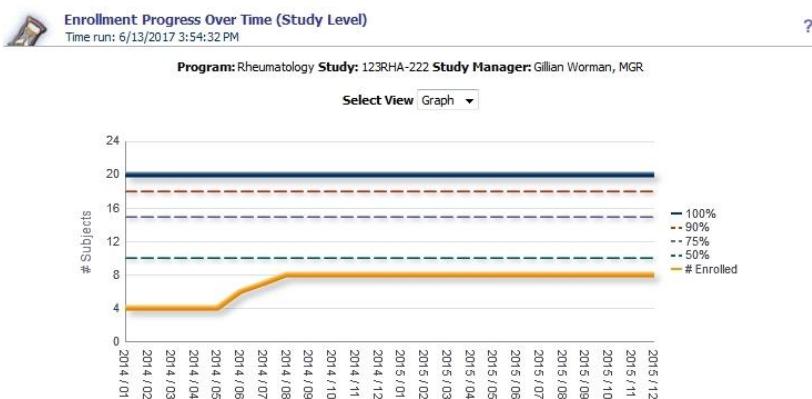


Figure 2: Oracle Health Sciences Clinical Development Analytics enrollment reports provide at-a-glance insight into enrollment progress, as compared to initial planning. This helps to optimize timelines for current and future studies.

CDA facilitates proactive monitoring to address site issues prior to site visits and to oversee risks throughout the clinical trial lifecycle. In addition, project managers can easily compare and contrast site performance within and across studies to help identify and manage nonperforming sites sooner.

CDA enables:

- Regional managers to gain insight into cross-study progress in their region.
- Program managers to compare regional performances easily to determine where clinical resources will provide the greatest impact
- Data managers and clinical monitors to gain an easy understanding of current data processing workloads and discrepancy/query volumes
- Study managers and CRAs to examine planned and actual data trends to facilitate risk-based monitoring
- Users to explore performance management information through a simple and intuitive user interface. This empowers them to address data capture backlog, reduce the number of discrepancies or queries, or optimize processes.

Increase Clinical Effectiveness

CDA fulfills a critical need in life science organizations for clinical systems that help improve the quality/timeliness of clinical information and enhance the effectiveness of their clinical programs. The solution delivers a rich set of prebuilt reports and role-based dashboards providing detailed performance management metrics across programs, studies, regions, and sites.

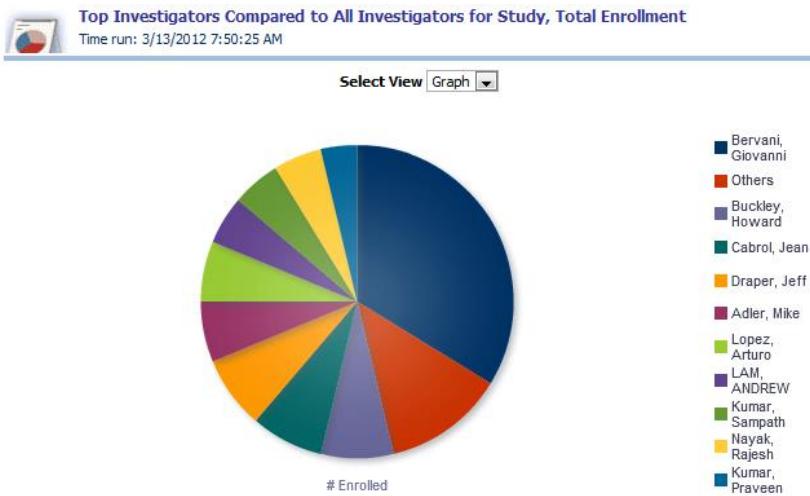


Figure 3: Oracle Health Sciences Clinical Development Analytics provides the identification of top-performing investigators within a study, region, or program —even across the entire organization. This helps focus resources on the sites that provide the most value.

Clinical monitors can observe how their sites are performing against defined milestones and targets. They can quickly and easily identify issues -- such as site delays in submitting key documents and outlying query rates -- before these issues impact study timelines. By proactively monitoring these performance metrics, clinical monitors can target the sites that should be prioritized for visits based on study progress, activity since last monitoring visit, data volume, and quality.

Support for Risk Based Monitoring Strategies

CDA provides support for risk based monitoring (RBM) processes throughout the study lifecycle. Dashboards are included out of the box to view analytics related to RACT assessments and Key Risk Indicators (KRIs) at the study and study-site level. These measures are aligned with TransCelerate guidelines for risk assessment and KRIs. Additionally, RBM issues and resolutions can be visualized to provide a single source for the reporting of all actions taken throughout the study. CDA can be configured easily to provide links from KRIs or other RBM-related dashboards directly to RBM issue management tracking in the Oracle Health Sciences Siebel Clinical Trial Management system.



Figure 4: The Risk Profile dashboard in Oracle Health Sciences Clinical Development Analytics provides at a glance insight into key risk indicators (KRIs) at the study and site level, enabling risk based monitoring (RBM).

Mobile Access to Insight When and Where You Need It

CDA offers a powerful Web client that facilitates access to dashboards, reports, and ad hoc reporting through a simple web browser. The Oracle Business Intelligence Mobile app for the Apple iPhone and iPad gives mobile users access to the latest performance management information when on the road. Integration with Microsoft Office enables users to consume rich datasets in the tool of their choice.



Figure 5: Oracle Business Intelligence Mobile provides instant access to clinical operations data from your mobile device.

Prebuilt Components Offer Faster Implementation, Reduced Costs/Risk, and Better Business Results

CDA's prebuilt components enable rapid, time-to-business value through fast, lower-cost, and lower-risk deployment. The software facilitates this by providing:

- Prebuilt data models
- Prebuilt extract, transform, and load (ETL) programs sourcing from Oracle Health Sciences applications including:
 - Oracle Health Sciences InForm
 - Oracle Clinical & Oracle Remote Data Capture
 - Oracle Health Sciences Siebel Clinical Trial Management System
- More than 1,200 business attributes covering performance management metrics and associated descriptive terms about clinical trial progress
- More than 230 prebuilt reports and ten dashboards designed for specific user roles

This prebuilt platform combined with a highly intuitive, ad hoc report builder enables users to customize and extend dashboards and reports quickly and easily, without burdening IT organizations.

Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences provides the industry's most comprehensive set of software solutions addressing every aspect of the health value chain from discovery to care delivery. With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization's goals today and in the future.

CONTACT US

For more information about Oracle Health Sciences Clinical Development Analytics, visit oracle.com/healthsciences, email healthsciences_www_grp@oracle.com or call +1.800.633.0643 to speak to an Oracle representative.



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Integrated Cloud Applications & Platform Services

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