ORACLE HEALTH SCIENCES INFORM: COMPREHENSIVE CLINICAL DATA CAPTURE AND MANAGEMENT CLOUD

The Oracle Health Sciences InForm integrated clinical data capture and management cloud platform reduces clinical trial timelines, cost and risk through advanced data capture and query management, real-time actionable visibility to data and standards-based, integrated workflows. With InForm you can build a trial in as little as a few days and auto-deploy rapidly to a choice of 100,000 InForm-ready sites worldwide … assess and lock a site or an entire study in minutes … know if and when a patient took your drug … and easily collect, clean and transform data from different sources for faster, more accurate analysis and submission.

KEY BENEFITS

- Accelerate clinical trial timelines while reducing trial cost and risk
- Collect and deliver higher-quality data to biostats faster
- Easily consolidate and transform data from multiple sources – clinical, genomic, EMR, and more
- Assess, review, and lock a site or entire study in minutes
- Maximize security and data integrity and minimize risk of business disruption
- Identify in real-time potential risks to trial timelines and data quality
- Facilitate risk-based monitoring and adaptive trials

KEY FEATURES

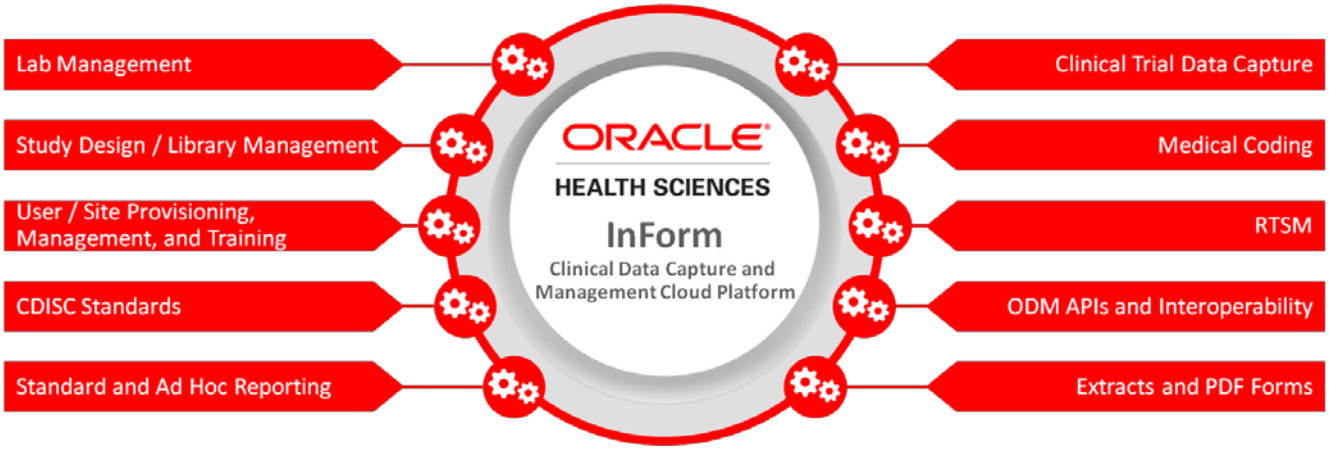
- Comprehensive, proven open standards-based data capture cloud with automated and integrated workflows
- Complete core data capture capabilities: advanced query management, study design, coding, IRT, and more
- Growing, extended ecosystem of value-added solutions such as measuring medication adherence, managing clinical biomarkers, and ePRO/eCOA
- Full self-service deployment capabilities including mid-study changes, with no data migration required

Integrated, Open Standards-Based Cloud Platform Delivers High-Quality Data and Drives Efficiencies

Increasingly complex and global clinical trials, shrinking R&D resources and budgets, and a more competitive environment have fueled new demands for more efficient clinical data management solutions. Sponsors, CROs, and sites need an integrated data capture and management solution that can consistently speed study design and deployment, while scaling to global trials with large patient populations and complex protocols.

Oracle Health Sciences InForm provides an integrated and market-leading solution with trial design and build, site and user management, patient randomization and trial supply, data capture and management, and medical coding. Together with its intuitive user interface, multi-language capabilities, and extensive software modules, the solution delivers a more streamlined workflow with more accurate and timely information driving clinical trial decision-making – accelerating clinical trials while reducing cost and risk.

The integrated InForm provides comprehensive data capture capabilities and automated workflows for more accurate and efficient data capture and management.

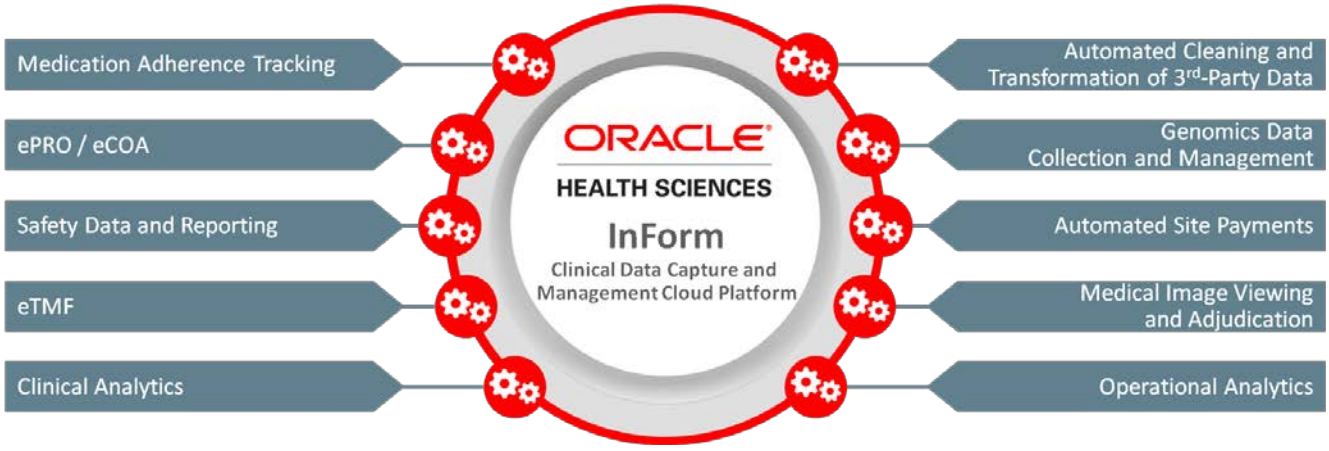


Expanding Ecosystem of Integrated, Best-in-Class Oracle and Partner Solutions Help Drive Improved Clinical Trial Data Quality and Efficiencies

Oracle Health Sciences has significantly increased and accelerated our investment in internal solutions and integrations, as well as greatly expanding our partner ecosystem for InForm and other Oracle solutions. The solutions help life sciences organizations easily add capabilities to the core InForm platform scale in order to effectively manage the data challenges presented by today's clinical trials.

New, critical capabilities offered range from automated collection, measurement, and management of medication adherence, genomic, and ePRO data produced in a clinical trial, to automating site payments directly from InForm as well as streamlining the cleaning and transformation of trial data for faster delivery to biostatistics for analysis.

InForm customers can easily add modular capabilities that provide even greater added value to accelerate trials, improve data quality, increase trial success, improve efficiency and reduce costs.



Strong, Long-Term Commitment to Continuous R&D and InForm Innovation

Oracle Health Sciences offers the most comprehensive and broadly integrated clinical R&D cloud platform in the industry, from planning and study startup, through trial conduct and management, through analysis and submission to post-marketing. Our unwavering commitment and strong investment in life sciences R&D and InForm has resulted in more than eight major InForm releases and integrations over the most recent 24 months alone. Your organization thus benefits from software that is continually updated to reflect rapidly evolving business requirements.

"InForm allows USAMRMC to more efficiently develop, conduct and manage electronic data capture-based clinical trials. Utilizing Oracle's Central Designer software, USAMRMC is able to accelerate trial development, increase trial efficiency, and more readily share clinical data with external partners, collaborators, and the Food and Drug Administration (FDA)."

-U.S. Army Medical Research and Materiel Command (USAMRMC)

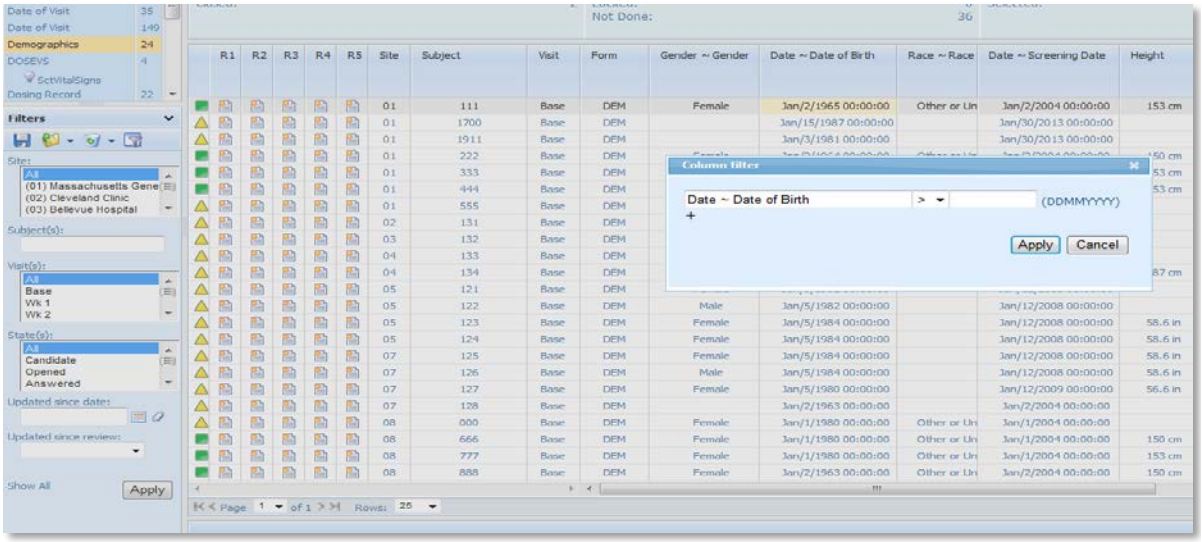
How InForm Delivers Greater Speed and Accuracy through Process Efficiencies

Thanks to ongoing innovation, Oracle Health Sciences InForm helps our customers greatly increase trial speed and efficiency. Some of these key supporting capabilities are listed below.

InForm's Data Viewer feature gives you real-time, 24/7 actionable visibility into trial data with a single click, for internal or outsourced trials. You can instantly review and manage clinical data across visits and sites with built-in export to Excel on every screen, easily filter by site, subject, visit, and data status, and immediately identify and filter on data that is new or updated since a previous review. There's no waiting for reports to be generated, and no need to rely on someone with programming expertise to mine the data.

With Data Viewer, you get to database lock much faster and with far less manual effort by assessing and locking a site, multiple sites, or even an entire trial in a matter of minutes – simply by selecting, locking, and confirming. Free staff up for high-priority tasks. Significantly reduce trial cost by accelerating study closeout, eliminating redundant queries and saving time and effort checking the system against multiple spreadsheets. And lower trial risk through real-time, actionable visibility to trial data and by minimizing data errors.

InForm also provides **Customizable Review Workflows** so you can track review progress with definable CRF states. Seamlessly integrated with Data Viewer, this feature allows you to create custom workflows to track the review progress for the study such as "Medical Review." You automate the review process to track and take direct action, such as locking the data marked "Medical Review " that has been reviewed , and simplify collaboration and communication between sponsors and CROs – significantly improving productivity and efficiency.



InForm's Data Viewer lets you assess and lock a site, multiple sites, or even an entire trial in a matter of minutes – so you get to database lock faster and with far less manual effort.

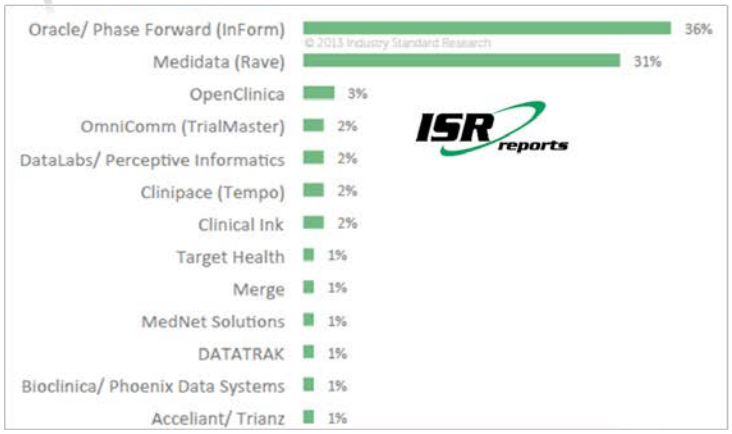
Streamlined Workflows offer a single location for designing, deploying, versioning and maintaining changes to an InForm trial, while a **Self-Service Deployment Model** including mid-study changes provides you with complete control over InForm trial deployment.

In-Place Revisions let you design and deploy revisions to an existing study version to any trial type in days or even hours with the click of a button – *without migrating previously entered data* into new forms and visit structures and applying new edit checks as required by many other EDC solutions.

You thus avoid the added risk to data integrity as well as the increased downtime, delays, manual effort and cost of migrating trial data every time there is a protocol amendment or updated study requirements.

Two different independent studies, in 2013 and 2014, stated that InForm is the preferred EDC system of sites worldwide.

1 *2013 ISR Reports: "Which of the following EDC applications do you prefer to use?"*



2 *Top 3 CRO - 2014 Survey*

- Independent, global customer EDC feedback survey
- Leading CRO polled 50+ sponsors

Oracle Health Sciences InForm the preferred EDC choice by sponsors and sites worldwide

Targeted Source Data Verification (SDV) down to the item level provides flexibility to set targeted source verification strategies that allow for increase or decrease of the source verification workload based on the data quality. It offers automatic updates, remote online source verification, easy batch loading of external source data, and user-driven filters and reports that simplify preparation for source verification and data review. With InForm targeted SDV, you significantly reduce the time and cost of verifying data, accelerating trial timelines without adding risk.

Rich Reporting and Easy Ad-hoc Reporting provides the comprehensive visibility required to manage a trial and its data effectively. The solution offers real-time, Web-based, on-demand, user-driven dashboard-style reports, immediate access to reports on trial go-live date, standard reports for reviewing operational data, and simple, non-technical, ad hoc reporting for reports, graphs, and charts – all without impacting transactional performance at site or sponsor locations. You can establish and track key performance and operational metrics such as data entry, enrollment, aging and cycle times to quickly identify underperforming sites and develop corrective action, ensuring that trials stay on track.

Multi-Language and Multi-Regional Functionality in a Single Environment delivers a standard process for trial development, deployment, and management across sites, regions, and languages. You accelerate trial setup and deployment while simplifying trial management, minimizing errors and reducing training and support costs.

InForm offer a global network of more than 100,000 sites and tens of thousands of trained investigators.

InForm Single Sign-On (SSO) offers a cloud-based identity management platform that enables centralized user authentication for InForm. Each application user can log in to their authorized applications and trials with their own username and password, streamlining the user experience and providing improved user management and security.

Site and Sponsor Preference for InForm means you can quickly deploy your trial regardless of the number of sites or different regions. InForm is deployed to more than 100,000 sites worldwide, offers tens of thousands of trained investigators, and according to two independent studies is the preferred EDC system by sites.

Global, 24/7/365 Support by Oracle Employees helps ensure that trial setup, deployment, and management stay on track and on schedule. Support is offered 24/7/365 globally in English, with local language and time zone support in Japanese, French, German, Spanish, and Italian – provided entirely by Oracle employees rather than an outsourced or temporary labor pool.

Worldwide Services by Domain Experts increases your productivity and accelerates timelines by augmenting your own resources when needed. This global team of life sciences professionals has extensive domain expertise and experience designing, deploying, and managing InForm trials across therapeutic areas.

Comprehensive Support for Industry Standards

Oracle Health Sciences InForm provides comprehensive support for industry standards such as CDISC to speed trial setup, increase efficiency and data quality, and help ensure compliance. As an active member and participant in groups including the CDISC Advisory Council, European CDISC Coordination Committee (E3C), and CDISC technical teams such as Define-XML and Protocol Representation, Oracle Health Sciences stays at the forefront of standards and their impact on clinical development.

Oracle Health Sciences is CDISC ODM certified, offers ODM-based APIs as well as ODM-based clinical data and study design metadata exchanges, and is a CDISC Registered Solutions Provider for:

- ADaM
- CDASH
- Define-XML
- ODM
- Study/Trial Design Model
- LAB
- SDTM

Is Your Data Safe?

Unlike EDC systems which require you to migrate trial data to new forms and visit structures and apply new edit checks every time there is a protocol amendment or updated study requirements – adding risk, time, and cost to your trial – InForm pre-validates your data and does not migrate it. You can make updates and deploy them in a matter of hours with the click of a button –with no impact on your data or queries.

Proven Performance, Scalability, and Security Reduce Data and Business Risk

With over 5,000 successful trials, InForm has proven its effectiveness in small, simple trials to the world's largest and most complex global mega trials featuring thousands of sites and tens of thousands of patients. In addition to the Oracle Health Sciences Cloud, InForm is available as an on-premise or hybrid offering – aligning software delivery with your IT standards and business processes and increasing user acceptance, productivity, and efficiency.

And with security and data integrity becoming ever more critical, it's important to carefully examine a vendor's resources to apply and maintain deep and broad security practices. Oracle applies the latest security best practices, governance, and process controls across the organization from physical security down to the software coding level – applying stringent security controls to Oracle vendors and continually updating these practices.

In addition, unlike cloud-based EDC systems which are dependent on a single hosting facility and rent space for your trial data on 3rd-party clouds, the Oracle Health Sciences Cloud offers multiple hosting centers and is owned and managed completely by Oracle – drawing on Oracle's extensive capabilities and experience helping companies manage "big data" effectively and securely. You get a reliable and secure life sciences R&D cloud that is HIPAA-certified and supports 21 CFR Part 11.

InForm Core Platform: Key Capabilities and Benefits

Oracle Health Sciences InForm offers comprehensive core capabilities to enable fast study startup, efficient and accurate data collection, and effective data management:

Advanced Query Management

InForm provides comprehensive online edit checks and an online query process to easily assess and capture trial data and rapidly reconcile discrepancies – delivering data transparency, reduced backend cleaning of data, and faster data extracts to minimize data-entry errors and quickly resolve data discrepancies. The result? You obtain higher-quality data faster and get to database lock more quickly.

Comprehensive Trial Design and Library Management Environment

Central Designer, InForm's sophisticated web-based study design application, improves reuse of trial component groups, simplifies creation of new trial components, and lets non-technical clinical users quickly and easily define trial workflow and customizable review states. It enables you to easily transform protocols to EDC trials through simultaneous global collaboration, designing trials in as little as three days and auto-deploying even highly complex trials in less than four weeks.

Randomization and Trial Supply Management

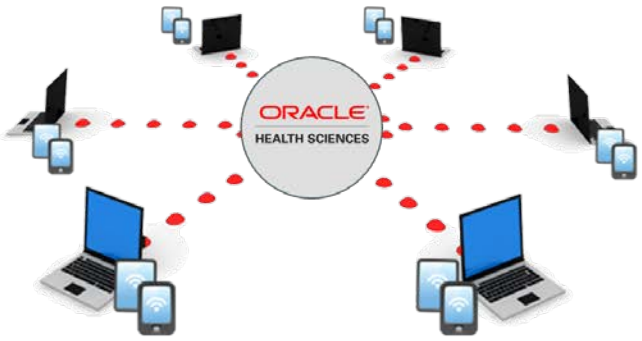
InForm is fully integrated with Oracle Health Sciences IRT, giving you the ability to randomize subjects, dispense medication and capture eCRF data through the InForm application. You can access real-time subject and supply information, conduct drug reconciliation as well as self-service data edits with no support desk required. The InForm-IRT integration enhances operational and user efficiencies through one workflow, eliminating duplicate data entry, simplifying the site experience, and gaining a more efficient and accountable delivery process.

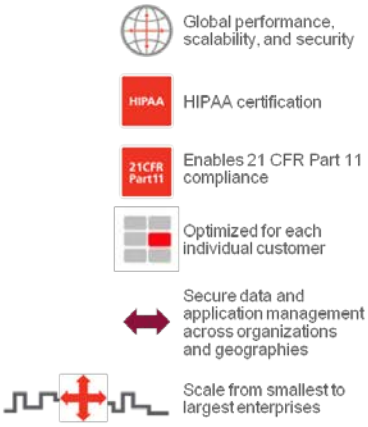
Centralized Coding of AEs and Con Meds

Comprehensive, integrated, multi-trial medical coding and dictionary support for drug and adverse event terms is integrated seamlessly within InForm and applies across trials globally. You can raise queries and send back to InForm for a comprehensive workflow, and code medical terms within the application and consistently across multiple trials in a single environment. In addition, the application enables mid-trial dictionary upgrades with full impact analysis capabilities and support – reducing manual coding and data errors and increasing efficiency.

Application of Lab Normal Ranges

InForm provides integrated, multi-trial lab normal range management support for seamless integration of lab ranges within InForm and across trials globally. You can manage lab vendors and lab test normal ranges, and send them back to InForm for a comprehensive workflow. The solution also lets you match lab test normal ranges by subject characteristics within the application and consistently across multiple trials in a single environment, and identify missing lab ranges or deterministic subject characteristics – reducing manual reconciliation and data errors.





Cloud services built for life sciences applications. Owned and managed by Oracle.

InForm is part of the Oracle Health Sciences Cloud, which offers multiple hosting centers and is owned and managed completely by Oracle – and subject to Oracle's stringent security and privacy best practices and governance. Many EDC systems are dependent on a single hosting facility and rent space for your trial data on 3rd-party clouds.

Single-Sign-On and User/Site Management

InForm's User Management Tool (UMT) enables our customers to manage easily sites, users, rights and roles for InForm trials. The application provides a centralized repository for InForm trial site, user and role assignments, and an online user interface for entering and updating trial sites, roles and users as well as import templates and an auto-import feature for trial setup. InForm UMT also enables single sign-on for InForm trials by setting up sponsor and site user unique identities in the HSGBU Identity and Access Management Services (IAMS) as well as deploying single user identities to InForm trials.

Extracts and PDF forms

InForm automatically generates purpose-specific (archival/submission), fully-compliant PDF output of InForm clinical content, and provides a wide range of options for PDF content. Its scalable architecture supports the ability to produce content from megatrials with millions of data points, and layout of both blank forms and clinical data forms – letting you generate PDF output for submission and archival purposes quickly and easily.

InForm Ecosystem: Key Solutions and Benefits

Oracle Health Sciences InForm provides a rapidly expanding set of value-added capabilities through integrations with best-in-class Oracle and partner solutions.

These solutions include but are not limited to:

"Oracle Health Sciences InForm helped us to accelerate the entire trial process, from design and data input, to management and analysis—and it has improved transparency. The solution is the key to our ability to deliver comprehensive and efficient clinical trial services."

-SGS Life Sciences Services

True End-to-End Clinical Data Capture and Management

The integration of InForm with Oracle Health Sciences Data Management Workbench lets you automate the cleaning and transforming of trial data, as well as data from 3rd-party data sources, alongside and in conjunction with InForm – ensuring that all data across the entire trial is cleaned to the same rigor throughout the entire process.

This integration:

- Significantly reduces the time-consuming and resource-intensive manual processes and custom programming required to load, transform, and clean trial data by as much as 80%.
- Enables the quick and accurate setup of data models, transformations, validation checks, and discrepancy workflows in a single environment.
- Facilitates the implementation of reusable processes (workflows, transformations, validation checks) and improves traceability by creating and administering standards from one location.

The result? You increase data collection speed and accuracy, deliver cleaner, traceable data to biostats much more quickly, improve control, and facilitate adaptive trials.

Automated Transfer of S/AE data to Oracle Argus Safety

InForm is integrated with the market-leading safety solution, Oracle Argus. This solution enables the transfer of time-critical S/AE data from InForm to Argus within minutes of entry in InForm and returns the case ID to InForm, saving manual efforts in both safety systems, and providing pertinent and accurate information for safety reporting more quickly. You eliminate the need to create complex safety reports and for InForm sites to manually complete SAE fax forms, and reduce or eliminate the need for reconciliation between InForm data and safety data for SAEs – saving time and effort and increasing accuracy.

Medication Adherence Tracking

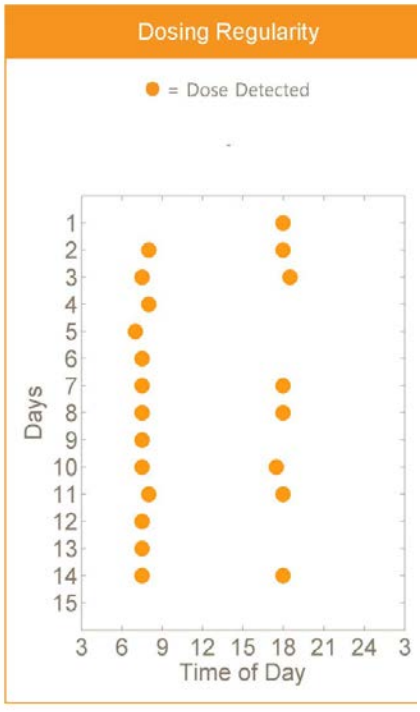
Highly engaged patients that consistently take their prescribed medications as directed are the cornerstone of a successful clinical trial. Yet, researchers have long struggled to effectively and efficiently validate adherence – relying on an arduous and often inaccurate combination of self-reporting and lab tests.

InForm Medication Adherence Insights, the result of a groundbreaking strategic partnership between Oracle and Proteus Digital Health, addresses this challenge by automatically capturing and viewing medication adherence data directly from InForm.

By generating standard charts, graphs, and ingestion profiles, as well as being able to easily create ad hoc reports, users can track adherence by subject and time of ingestions – providing deep and actionable insights which reduce monitoring costs while enabling critical distinctions between non-adherence and non-response.

When used in clinical studies, this insight enables study managers and researchers to answer critical questions including:

- Which patients are dose and timing adherent and which are not?
- Is our trial performance at risk of being undermined by poor adherence?
- Will our data be of sufficient quality for analysis?
- Which patients are problems for us?
- Are there sites with overall patient adherence trending below the average for the trial?



Cumulative Adherence, by Site and Subject

GREEN = Excellent YELLOW=Average RED = Below Average

Site Mnemonic	Subject Number	Cumulative Doses Ingested	Cumulative Doses Expected	Adherence %
001	001-001	25	28	89.3
	001-002	8	14	57.1
	001-003	10	12	83.3
002	002-001	29	56	51.8
	002-002	13	16	81.2
	002-003	9	14	64.3
	002-004	125	146	85.6
	002-005	2	32	6.2
003	003-001	400	658	60.8
	003-002	345	696	49.6
	003-003	13	18	72.2
	003-004	30	68	44.1
	003-005	94	140	67.1
	003-006	77	138	55.8
	003-007	12	18	66.7
004	004-001	27	58	46.6
	004-002	10	14	71.4
005	005-001	51	56	91.1
	005-002	7	8	87.5
006	006-001	37	58	63.8

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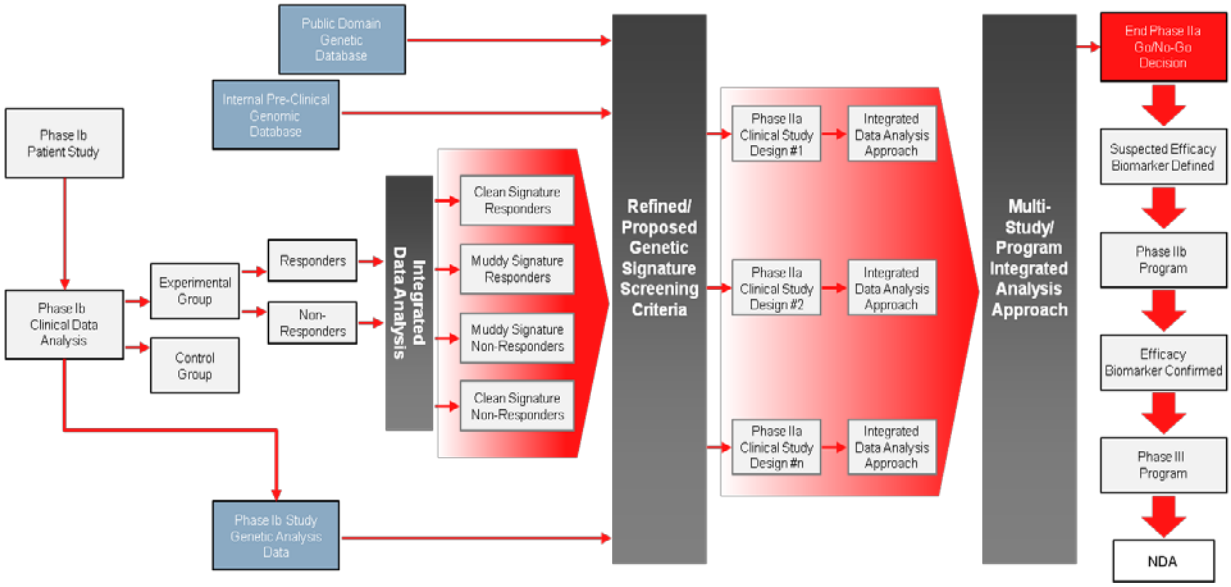
InForm provides accurate and timely insight into medication adherence patterns and trends during a clinical trial, enabling better dosing decisions, improved product lifecycle management, and earlier detection and correction of adherence problems per the trial protocol.

Collect, Store and Analyze Genomic Data in Clinical Trials

As the industry moves aggressively forward to expand the effective application of personalized medicine, biomarkers are becoming a key component of clinical development programs. InForm Advanced Molecular Analytics (AMA) is the first commercially available cloud-delivery solution to incorporate genomics into the clinical data capture and management process. Study managers and clinical researchers can thus effectively capture, aggregate and analyze molecular data along with clinical data, providing the information needed to identify new predictive biomarkers.

Oracle Health Sciences InForm AMA facilitates the prospective dynamic randomization of patients with or without "omics" signatures into respective treatment arms to optimize study conduct. Leveraging this seamless process enables improved trial efficiency by reducing the sample sizes and potentially the treatment duration required to demonstrate statistical and clinical outcomes. The solution leverages proven technology from Oracle Health Sciences cloud-based Translation Research Center to deliver the first "molecular-aware" clinical data capture and management solution.



With InForm, you can analyze the correlation between efficacy and safety data with patient-specific molecular data to optimize study design and strengthen the evidence for regulatory approval.

Device-Independent ePRO/eCOA

InForm offers seamless integration of site- and patient-captured clinical data, with both EDC and ePRO data captured in InForm. This multi-modal data capture encompasses a wide variety of devices including laptops, tablets, smartphones, and supports a Bring Your Own Device (BYOD) strategy. You receive a complete data capture solution for both clinical and post-marketing studies, eliminating the need for site data entry of patient-reported outcomes – delivering improved patient retention, compliance, and overall study quality.

Clinical & Operational Analytics

Comprehensive, real-time analytics form the linchpin of trial monitoring and management to ensure trials stay on track. InForm's integration with Oracle Health Sciences Clinical Development Analytics (CDA) provides consolidated reporting across all InForm studies and delivers roll-up from clinical sites through programs. You can combine data from multiple transactional systems in a single report and obtain accurate, consolidated views across multiple InForm studies for rapid cross-study comparisons – enabling access to usable data in real time to identify problems and take corrective action more quickly.

Configurable, Automatic Site Payments

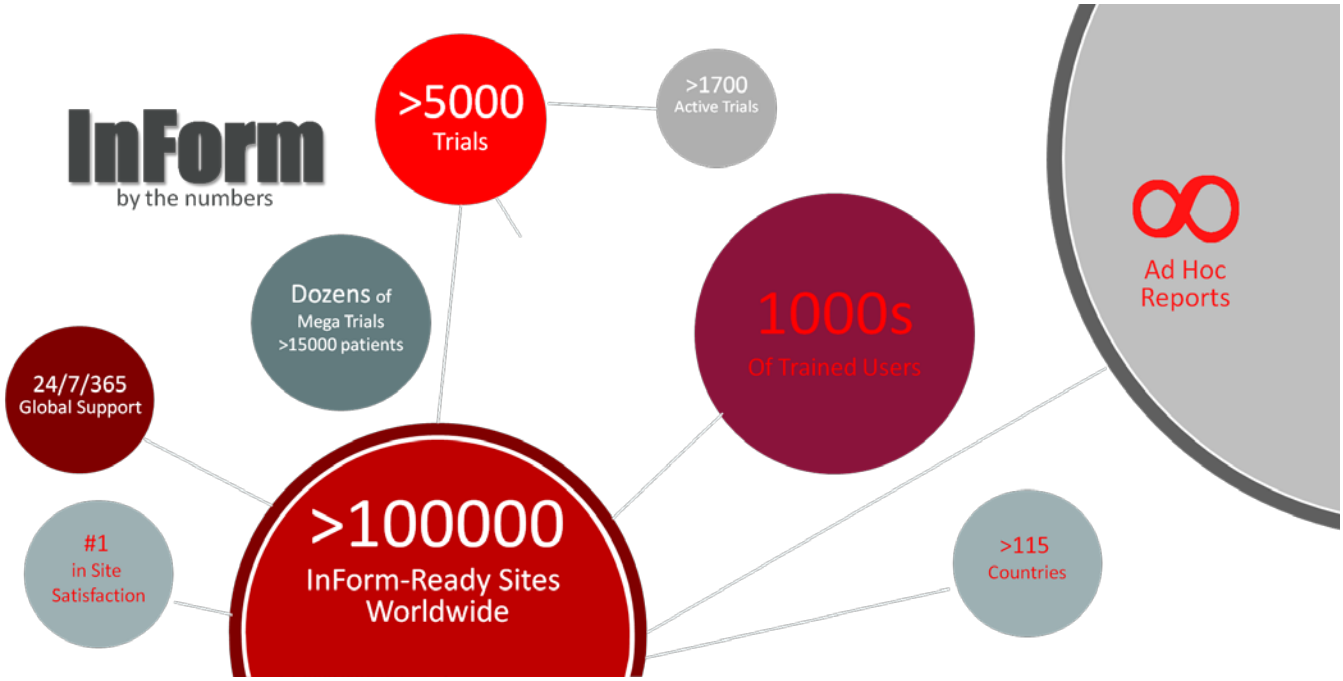
With InForm, you can set up configurable triggers to generate automatic payments to sites, with site payment history and other payment metrics available to InForm users for reporting and analysis. You reduce costs and manual effort, and increase site satisfaction through faster payments and increased transparency.

Medical Image Viewing and Adjudication

InForm supports the viewing and management of medical image information at the patient level using the AG Mednet Cloud – providing fast reconciliation of imaging submissions, reducing time and cost associated with transporting images between clinical sites and central reviewers, and eliminating many typical causes for errors.

eTMF

InForm supports the population of the eTMF reference model with InForm eCRFs, offering compliant document and virtual document lifecycle management for greater efficiency.



Why Oracle Health Sciences

Backed by the resources of the largest business software company in the world, Oracle Health Sciences delivers advanced transformative value for clinical R&D in a modular, integrated and scalable cloud environment. We enable you to:

- **Optimize operations** with technology that helps you maximize efficiency across your clinical life cycle
- **Gain actionable insights** from aggregated clinical and healthcare data
- **Innovate** by incorporating genomics, biomarkers and real-world patient data
- **Future-proof** your business with a significant and ongoing commitment to research and development that evolves and grows with you and the industry

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 InForm, visit oracle.com, e-mail healthsciences_ww_grp@oracle.com, or call +1.800.633.0643 to speak to an Oracle representative.

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

Hardware and Software, Engineered to Work Together

ORACLE