

Optimized Data Capture and Data Management

EDC systems built for data capture and used with manual data entry methods cannot handle the volume and variety of today's many new types of data sources. This frustrates data managers, cripples data governance, and results in not having a single source of truth for downstream data consumers. What if there was an easy way to clean and manage all data sources, while meeting the needs of data managers and consumers?

An EDC System for Today

As data sources expand, demands on data managers are increasing. Yet, there has never been a system that meets their specific needs, as well as those of the entire study team, until now. Oracle Health Sciences InForm coupled with Oracle Health Sciences Data Management Workbench (DMW) provide the only end-to-end, automated, data capture and management solution that can be used to generate submission-ready artifacts. These combined solutions do this at a substantially lower cost for all trial stakeholders via on-demand, downstream, data visibility processes, including medical monitoring and analytics.

- Incorporate data from any of the multiple data sources now available
- Provide real time data access
- Create a trustworthy, single source of truth

Recognizing the Needs of Data Managers and Consumers

As the number of data sources rise and their volumes/frequency/velocity grow, manual data management methods -- like spreadsheets, statistical programs, etc. -- become impractical as they can't scale to the challenges of our new multi-source data management world. Teams need faster, easier ways to make newer data sources usable alongside traditional data sources. They need to spend less time on low value data wrangling activities (aggregating, cleaning, aligning, and transforming) and more time on high value pursuits like data science, medical monitoring, analytics, etc.



"For 95% of respondents, manual effort is involved in aggregating, cleaning, and transforming clinical trial data and two out of three respondents experience issues with this process."

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Inform and DMW automate and simplify the entire data capture process. Further, DMW provides a purpose-built tool to clean data and transform it into submission-ready, STDM-formatted outputs.

- Data validation and automatic reconciliation for data discrepancies
- Complete traceability for compliance and reduced study risks
- Immediate visibility into errors for real time action

InForm and DMW provide the industry's leading, end-to-end, combined data capture and management solution with the strongest capability to manage your clinical trial workloads in our new multi-data-source, data management world.

InForm provides an optimized site user experience:

- Highly responsive user interface including rapid page turns
- Real-time study data capture
- Discrepancy management
- Data viewer optimized for data freezing, source data verification, etc.
- Study reporting
- Dynamic grid for streamlined safety processes
- Self-service mid-study changes with no database migration

DMW provides a high volume computation platform for:

- High volume file loading for the new world of multi-source data management
- Data aggregation
- Data review & validations
- Data transformations
- Cross data source data and discrepancy management
- Querying trial sites for EDC corrections
- Raising queries with third-party data sources
- Centralized, real-time, status tracking on all queries





Managing data from mHealth sources such as wearables, smartphones and other sources – and finding resources that know how to manage and clean new forms of data – will be the most urgent clinical trial data challenges five years from now.

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