

Addressing the Clinical Data Tsunami

Where are we now, and where are we heading with clinical data management?

Financial pressures that require R&D to deliver new therapies have never been more intense, and the pace of technological change is accelerating faster, well beyond the current regulatory framework.

The swell of the clinical data tsunami, created by pushing the current research frontier, is more and more prevalent as the industry seeks to consolidate and exploit voluminous legacy and ballooning clinical data repositories. The challenge and opportunity lies with the data and how it can be optimally 'commercialized' more efficiently and effectively by the greater enterprise.

Over the last year, a variety of emerging technologies have shown promise, with the goal of streamlining the flow of raw, clinical data, and eventually delivering submission-ready clinical data sets.

Trends and Observations

- **Data:** The definition of clinical 'data' has expanded to include operational, unstructured scientific, and real-world evidence data. Clinical analytics and decision making now require a wider range of data types and sources, with greater granularity, and at a scale *many* times larger than what the industry has previously known. Collaboration and integration drives a desire to explore peer-to-peer data exchange mechanisms, such as blockchain, to increase data transparency and traceability.
- **Artificial Intelligence:** The emergence of AI, and, in particular, the use of machine learning, to support the collection and analysis of unstructured data at scale and at levels of accuracy suitable for production use.
- **mHealth:** As the prevalence of mobility and mHealth devices and sensors increases in the clinical domain, we now have a business



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Oracle Health Sciences Data Management Workbench provides real-time access to complete and trustworthy trial data to make critical decisions fast.

need to aggregate and process hundreds of millions of streaming data points into the clinical data funnel. The emergence of mHealth creates new opportunities to establish secondary and exploratory uses of new data *types*, which requires a new *data science*-driven analytical approach.

- **Analytics:** Business intelligence and analytics have evolved to support faster and easier methods of ad-hoc data analysis across a larger, varied set of data sources. Organizations want to provide a greater variety of stakeholders access to relevant, high-quality data quickly and more securely. Providing stakeholders with access to high quality data, thus giving them the ability to respond critically and quickly, is the ultimate goal in data analytics.
- **Metadata:** As organizations understand their data, it is apparent that the organized management of metadata has the potential to streamline the clinical data flow. Metadata-driven transformation, intelligent data flow, and the use of data standards are given renewed focus as organizations look to enhance business processes with automated data validation and data structuring to drive clinical study design through clinical submission.

The Evolution of Clinical Data Management

As the industry evolves and data types, structures, and volume continue to increase, technology must also evolve. To support the challenges and opportunities that come from these developments, data management strategy must align with the following guiding principles:

- **Ensure regulatory compliance and patient safety** is maximized through the collection, processing, and distribution of clinical data across the enterprise and wider value chain.
- **Maximize the utility of data to drive value** by providing a trustworthy, single source of truth for all trial data that is validated, reconciled, and completely traceable.
- **Optimize clinical data flow** by consolidating data sources, and enabling data review, cleaning, and generation of standards-based, submission-ready clinical data sets with actionable insights.

Oracle Health Sciences Data Management Workbench enables our industry partners by offering a process-driven approach to simplify end-to-end clinical data flow, resulting in lower costs, increased quality, and lower risk.



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