Connected Technologies:
Optimising Data Management in the Era of Wearable Technology

On average, a clinical trial generates up to three million data points. These data points provide extensive insights into the health status of study participants – they can highlight their health status, responses and potential risks, enabling researchers to monitor patient safety and efficacy continuously, as well as enable the successful advancement of therapies.

At the same time, the increasing use of mobile devices (wearables) and apps to collect patient data is leading to the data becoming more and more heterogeneous. The influx of data from multiple devices, each with different formats, frequencies and parameters, presents challenges for researchers as it can be more difficult to standardise and integrate these inputs into one cohesive dataset. This is leading to challenges with creating consistent and complete data sets.

In the UK, the government plans to introduce more wearable health technology in a bid to reform and digitise the NHS. It means more people will soon be able to monitor their blood pressure, glucose levels, and cancer treatment responses from the comfort of their own home. It also highlights that this challenge with data is only set to become more complex.

Many biopharmaceutical companies are faced with the challenge of addressing this situation in order to create a complete data set. With it, effective data management is becoming critical to the success of research, and ensuring data quality and consistency is integral.

Data workbenches play a key role here as they enable access, control, transmission, monitoring and presentation of data in dashboards. In clinical trials, a data workbench serves as a central platform that enables researchers to manage, standardise, and analyse vast amounts of data collected from multiple sources. Working as a single source of truth, it allows researchers to seamlessly merge data from diverse sources, providing a unified source for monitoring study progress, enhancing patient safety and optimising efficiency.

To realise the possibilities of a unified data foundation, the heterogeneous data sets must first be structured and standardised. The background to this is the unification of data structures in a standardised format to facilitate comprehensive analyses including new data points. Only with the help of these analyses is it possible to draw comprehensive and evidence-based conclusions regarding the potential of therapeutic innovations.

Here, we explore the challenges that biopharmaceutical companies face in today's increasingly digitised world, and the vital role that data workbenches play in supporting them.

Removing Barriers with a Unified Data Foundation

In practice, clinical data is collected in both structured and unstructured formats. This presents two key challenges for data controllers in clinical trials. On one hand, they must ensure that wearables and apps for collecting patient data meet the requirements of clinical research.

On the other hand, the data from these sources must be merged for further processing. This requires standardised application programming interfaces (APIs) to transfer the data between the different systems and to ensure a uniform standard of data.

While compliance with guidelines is primarily the responsibility of the wearables' manufacturers and app providers, integration into clinical databases is the responsibility of the data controllers. Data workbenches enable them to combine and process data from electronic data capture (EDC) systems and external data from apps and wearables. Data aggregation systems combine them in a database.

This means that all data is available to the study managers in a single database, the data workbench, and can be accessed and processed. This creates a central, unified data source and allows managers to monitor data quality, identify trends as well as improve trial efficacy and patient safety.

For those involved in research and development (R&D), the focus is now more than ever on increasing efficiency and cost-effectiveness while improving the patient experience.

Clinical data workbenches can overcome some of the obstacles and enable a reduction

in costs and administrative burdens for contract research organisations (CROs) and trial sites. For example, study workflows and data collection technologies can be linked, accelerating the time to market for therapies across a range of indications. Patients can share information directly through apps while participating in the study, meaning a timely analysis of information and more robust results overall.

Single Source of Truth: More Efficient Studies

By combining clinical data from diverse sources – such as electronic health records, wearable devices, mobile health apps, and lab results – into a central database, contract research organisations gain a comprehensive and real-time view of study progress. This approach enables them to monitor data trends across multiple sites, track patient engagement, and detect inconsistencies or anomalies early on. With all data consolidated, they can better evaluate the accuracy and quality of findings, streamline reporting processes, and make any adjustments as needed. This ultimately supports more effective studies.

Monitoring data quality in near real time helps to ensure data quality and provides an opportunity to identify potential risks at participating investigative sites and among other study stakeholders. Other aspects include gaining comprehensive insights into data patterns, reducing response times and enabling a more transparent exchange of information between study sponsors, contract research organisations, study sites and investigators. This allows adverse developments that could potentially jeopardise patient safety or data integrity to be detected early on and appropriate measures to be taken.

Clinical Data Workbench: The Key to Efficiency

Starting a clinical trial still requires a significant investment of resources, especially when sponsors manage and share data in traditional spreadsheets, emails, or other forms of storage that are not designed with structured data requirements in mind.

Our experience shows that sponsors can achieve greater efficiency in their studies by optimising their data management in the following phases of the study lifecycle:

1. **Preparation:**
   A clinical data workbench can be used to merge data from different sources more quickly. Data managers can use proven industry and technology standards, APIs and procedures such as the Study Data Tabulation Model (STDM). Standardisation makes it possible to build the entire data infrastructure faster, implement interface programmes more easily and exchange data between different databases. The one-time integration at the beginning of the project saves resources.

2. **Implementation:**
   The uniform formatting of the data and standardised databases makes it easier to create and review reports and to carry out interim analyses quicker and more efficiently.

3. **Completion:**
   A standardised, STDM-compatible database significantly increases the efficiency of the analysis and/or the provision of data for the sponsor, since the data is already available in a predefined structure. This makes it easier to transfer the metadata (including audit trails) to study sponsors and to subsequently archive the data structures in the standardised format.

The following applies throughout: Ensuring the security and integrity of study data is a joint task for study sponsors, trial centres, and clinical research organisations (CROs). To comply with the risk-based approach according to Good Clinical Practice GCP E6(R2), a clinical database including the workbench must meet all data protection and security requirements. One of its essential functions is therefore to create study-specific reports that can be used for quality management monitoring and compliance.

Conclusion

The constant increase in data volumes in the context of global, multi-site studies with new digital tools requires the development of methods for effective data management. Only in this way can the necessary quality, compliance with requirements and informative analysis of study data be guaranteed in equal measure.

The growing importance of apps and wearables for collecting patient data presents CROs with data management challenges. Clinical data workbenches have proven to be an effective tool for managing the increasing volume of heterogeneous and isolated digital data, working as a single source of truth. Networked systems that enable the uniform integration of data and insights into study progress in near real-time help study managers to monitor data trends and quickly answer emerging questions.

As clinical trials continue to evolve in complexity and scale, and the use of wearable technology continues to expand, the role of advanced data management tools will only grow in importance. Not only will they ensure clinical research organisations are able to manage this data, but ultimately, it will pave the way for delivering faster, safer and more effective therapies to people worldwide.

REFERENCES

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