

Brochure

IQVIA Clinical eSource Platform

Better devices, better data, better solutions.





As clinical trial sponsors strive to bring treatments to market faster, the pressure is on to collect high-quality data in a timely fashion. However, older devices and systems can make this a daunting task. These stand-alone devices lack the connectivity and intelligent programming needed for study management at the device level or any 21 CFR part 11 compliance, resulting in data entry errors and extended timelines.

Challenges in Clinical Trial Data Collection

Manual data entry

Up to 30% of data received from sites can contain data entry errors within: Demographics Visit number/sequence Procedure results



Inexperienced sites need help to collect quality procedure data that stand alone devices often can't provide.



Up to 50% of ECG machine measurements don't agree with cardiologists. Timely expert analysis can be crucial in screening decisions.



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Less than 50% of devices used on trials in the past had any meansto capture users or limit their actions to ensure data integrity.

To help conquer these limitations, sponsors have begun to embrace more modern digital health technologies to improve the way that sites acquire data and the efficiency with which sponsors can gain insight on treatment effect.

eSource data collection is revolutionizing the clinical trial process, providing an efficient and modernized approach for sponsors to conduct research. With bi-directional communication between devices and applications linking to a central database/study management platform, sponsors are now able to compile comprehensive data that includes not only objective physiological parameters, but also subjective feedback from patients.

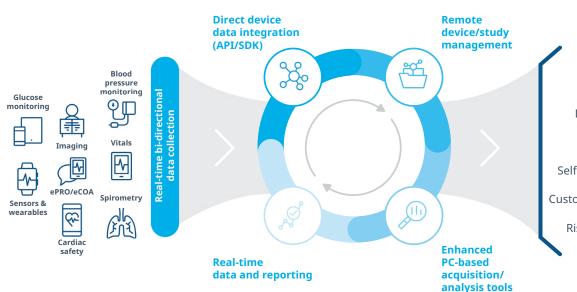
This intelligent approach to data collection guides sites and patients efficiently through the process, with built in data integrity checks and computerized workflow enhancements not seen within clinical trials until now.

IQVIA Clinical eSource Platform: Leveraging data and insights for smarter trials

IQVIA's device data acquisition solution is powered by our proprietary Clinical eSource Platform which provides a streamlined solution for data collection, integration, and analysis. Stakeholders can leverage the full power of connected devices to optimize clinical trials and deliver new treatments to market faster.

Device manufacturers have traditionally provided post-procedure data in a cloud-based repository for later synchronization with other procedure data. However, these systems can be viewed as a "black box" repository, with no integration to devices at the site level to provide procedure guidance or rulesbased assistance to help sites collect compliant data. Furthermore, there are no quality checks prior to data landing in the cloud-based repository.

In contrast, our Clinical eSource Platform is device agnostic, allowing for integration of data from any device. Electronic data is captured directly from subjects or sites in near real-time providing transparency and accessibility, which is crucial for compliance reporting as well as keeping your trials safe.



Connected devices data acquisition strategy A robust eSource study management solution that meets the new demands of the markets

Integrated processes:

Decentralized trials Statistical analysis Self-serve data availability Custom reporting & analytics Risk-based monitoring

Eliminate poor () data quality



Our Clinical eSource Platform is the answer to tedious, manual data entry and high-quality procedure data. Connected directly to a central database, personnel can easily select patient and visit schedules instead of manually entering them and in addition be guided through all procedure workflow steps to ensure compliance.

Rules-based data selection allows for the removal of previous visits from the list presented to sites, which eliminates a major source of errors. What's more, large screen tablets or laptops connected to the IQVIA database allows for rules-based data selection, rather than data entry. As a result, our Clinical eSource Platform significantly reduces or eliminates site queries and data correction forms, associated with meta data collected prior to procedure data.

Intelligent design within the acquisition software hosted on tablets or laptops allows for protocol specific device data collection rules to be pushed to the device and, in addition, provides sites with a clear view of the data being acquired. Finally, machine assisted tools allow sites to select optimized patient data based on study criteria, even if they are not experts in the field of ECG, Spirometry, Actigraphy, etc.





As electronic data is collected at investigator sites via tablets or laptops, the direct connection between our Clinical eSource Platform being used and the device means the source data is saved directly into the eSource database as quickly as the site is satisfied. This eliminates scanning paper or converting data prior to sending it for analysis. It also results in faster inclusion/exclusion decisions around the endpoint being collected. Physicians with the proper eSource credentials can access and analyze data while the patient is still at the site, and ensure enrollment is not slowed unnecessarily. With the Clinical eSource Platform, state-of-the-art digital analysis tools are integrated directly into the platform so that no source data leaves the audit trail controlled 21 CFR part 11 compliant environment. This also allows physicians to provide their expert analysis from anywhere in the world when they log in to the platform. Putting timely data with powerful built-in tools into the hands of experts produces the insights required in today's fast paced drug development environment.

Improve analysis time and quantity

Clinical research sponsors no longer need to spend their time sending and waiting for emails or faxes to get the latest data – now it's available on demand. With one click, sponsors can log in at any time to check their study status on a site or macro study level. All open queries and out of range values are available within a dashboard landing page, and the underlying data can be viewed with a click. The data transparency available within the platform means that an engaged sponsor never has to initiate a request for a report. Since IQVIA's Clinical eSource Platform is the single source for all data and is continually online and accessible, with the proper role-based credentials, no tedious back and forth communication is required.

Conclusion

With increased pressure to quickly bring new treatments to market, connected digital health technologies have become critical in helping clinical trial sponsors meet these demands.

At IQVIA, we understand that the value of devices directly correlates to the value of the data they produce. That's why we're dedicated to providing a platform that reduces patient burden and increases compliance, while also helping you expand the diversity of your trials. Our Clinical eSource Platform streamlines data collection, integration, and analysis, unlocking valuable insights that lead to better healthcare outcomes.

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