Making Every Connection Count: IQVIA Connected Devices Power Clinical Trials with Better Data

How connected devices in clinical research provide better data and solutions for customized clinical trials.

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OVERVIEW

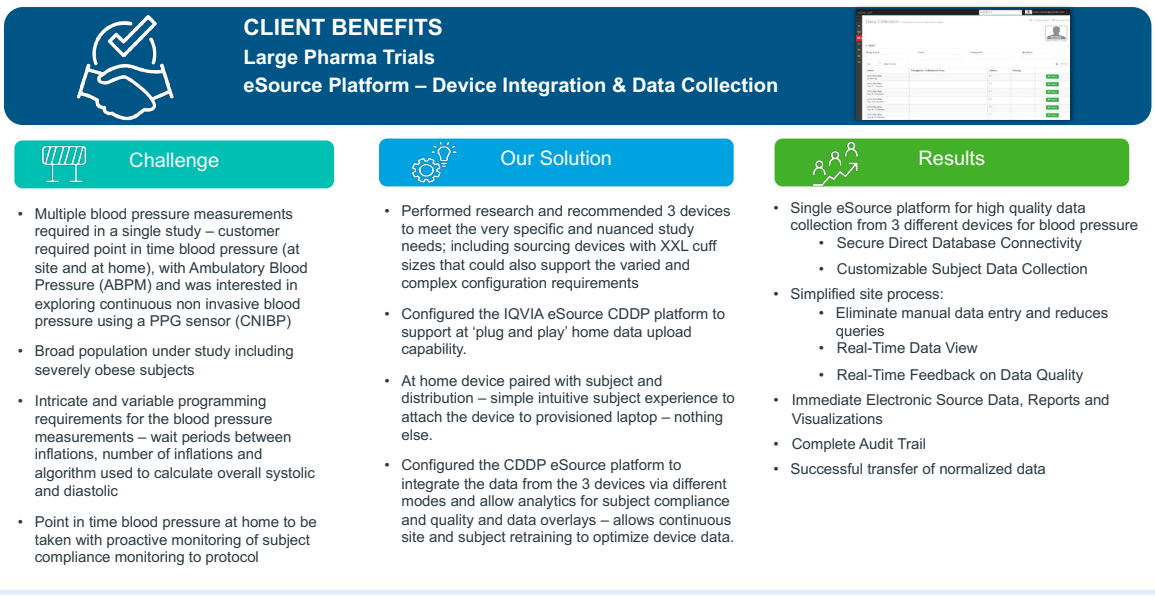
As drug developers are under increasing pressure to accelerate the pace of bringing new treatments to market, the use of connected digital medical devices in clinical research is taking a larger role. This paper explores how sponsors can work with experts in medical-device selection to simplify and accelerate data collection as well as refine a smart data management strategy. Taking those steps produces more trustworthy and timely data that accelerates insights from a clinical trial.

NEED: BETTER DEVICES IN CLINICAL RESEARCH

Today's clinical trials accumulate a large amount of data, as well as more diverse types of data collected across wider geographic areas. With an immense increase in the number of devices that are being shipped globally and used in trials, how do we keep track of that data effectively? And what are the logistical and regulatory challenges to such global data capture and analysis?

The right type of devices must be selected and incorporated in a platform that meets a wide range of needs (**FIGURE 1**). For instance, devices for clinical trials must be extremely patient friendly in design and support. Patient centricity becomes even more important as trials evolve from the traditional centralized model to hybrid trials, meaning patients must be able to provide important data to the study team from their homes. So, the best devices must accommodate those trial designs. Plus, the selection of these devices must consider the impact on the sponsors, patients, and sites, which will result in better engagement, transparency, and outcomes.

FIGURE 1: Better Devices: Multiple medical devices for blood pressure integrated into a single study for respective end point evaluations



In reviewing potential devices, the best options meet several criteria:

- **Accessibility:** Connected devices should be familiar to patients.
- **Engaging:** Devices should be engaging and include reminders, chat features, and a call center for help.
- **Easy to use:** Devices must be easy to use and the instructions for a trial must be easy to understand, including being multi-lingual as necessary.

After selecting the devices that will be used in a clinical trial, the sponsors must be able to get them, which can be complicated with some import/export limitations and meeting regulatory compliance. Sponsors must also be able to easily manage the inventory and real-time data and analytics. In the field, devices only benefit a trial when combined with appropriate project management, site and patient support, and technical support.

Note that sponsors often forget about the time it takes to create agreements with device partners. Having an appropriate strategy and an awareness of that process can reduce start-up time. Pre-qualifying partners can accelerate such timelines.

CASE STUDY 1: BETTER DEVICES = BETTER TRACKING OF BLOOD PRESSURE IN A CLINICAL STUDY

In this study, the sponsor collected various blood-pressure measurements in a hybrid clinical trial design in which data was collected at sites and by patients at home. Data included several endpoints, different types of blood pressure, and different measurement inflations and wait periods between inflations (depending on whether data were collected at home or at sites). Given the hybrid nature of the study, the sponsor needed to confirm that patients followed a very specific protocol for data collection.

The sponsor also wanted to introduce some exploratory endpoint review using photoplethysmography sensors, which could provide continuous non-invasive blood pressure data to compare with the more traditional ways of collecting blood pressure data. In addition, the study had a diverse patient population, including severely obese subjects.

To address these challenges, IQVIA's Connected Devices team developed a solution, which included three kinds of devices to meet the very specific and nuanced needs of the study (e.g.,

source devices with XXL cuffs). Each device was configured for the IQVIA eSource Connected Devices Digital Platform (CDDP) to support "plug and play" home data uploads. This combination of devices and control simplified the processes at the site and the homes. For example, the platform controlled how to take the measurements and when. In fact, connecting the device started the required measurements, which reduced the burden on the participants. They only needed to work with plug-and-play methods on a small laptop.

To simplify oversight of this clinical trial, real-time dashboards and reporting were available for site monitors and the sponsor. That allowed for corrections as needed during the trial.

Overall, this case study—built on IQVIA's eSource CDDP—provided real-time collection of data from various types of devices without manual entry from the participants, all while supplying real-time data transfers and oversight, plus a complete audit trail. As shown in **FIGURE 2**, IQVIA's connected devices provide better data that benefits patients, sites, and sponsors.

NEED: BETTER DATA IN CLINICAL RESEARCH

How do we get better data when it comes to device-related trials? A comprehensive eSource strategy is a major part of the answer. Connected devices on a capable platform can:

- **Reduce manual input of data.** This is important because up to 30% of data received from sites contain data entry errors in demographics, visit number/sequence, and procedure results.
- **Improve data quality.** Inexperienced sites need help to collect quality procedure data that standalone devices often can't provide.
- **Support timely, expert analysis.**
- **Provide better access to (enriched) data.** Enriched, cleaner data drives proactive decision making, increases efficiency, and supports regulatory compliance (**FIGURE 3**).

CASE STUDY 2: MULTIPLE MEDICAL DEVICES SOLVE DATA COLLECTION CHALLENGES IN PARKINSON'S STUDY

A second case study came from a project with a large pharmaceutical company interested in using multiple devices to measure the effects of an experimental drug on cognition and motor function in patients with Parkinson's Disease Dementia (PDD). The client wanted to measure multiple parameters: sleep patterns, mobility, various metrics relayed to motion, blood pressure, and ECG data. Plus, the sponsor wanted to collect the data at a trial site and at home.

In addition to collecting a wide variety of data, this project involved a patient population that does not necessarily use

FIGURE 2: Benefits of enriched data.

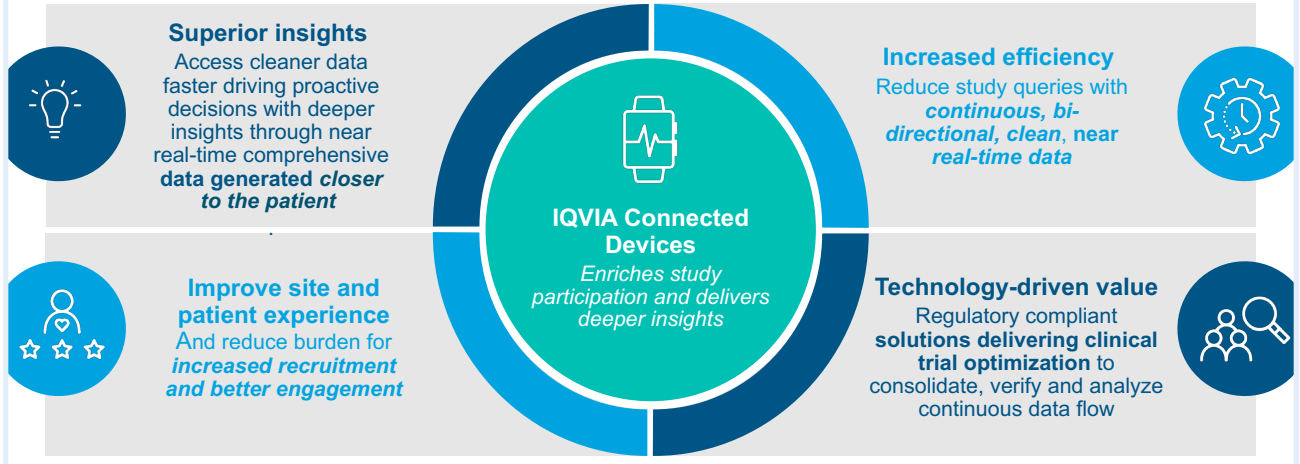


FIGURE 3: Better Data: Multiple medical devices for study in Parkinson's Disease Dementia (PDD) with population with data collection challenges

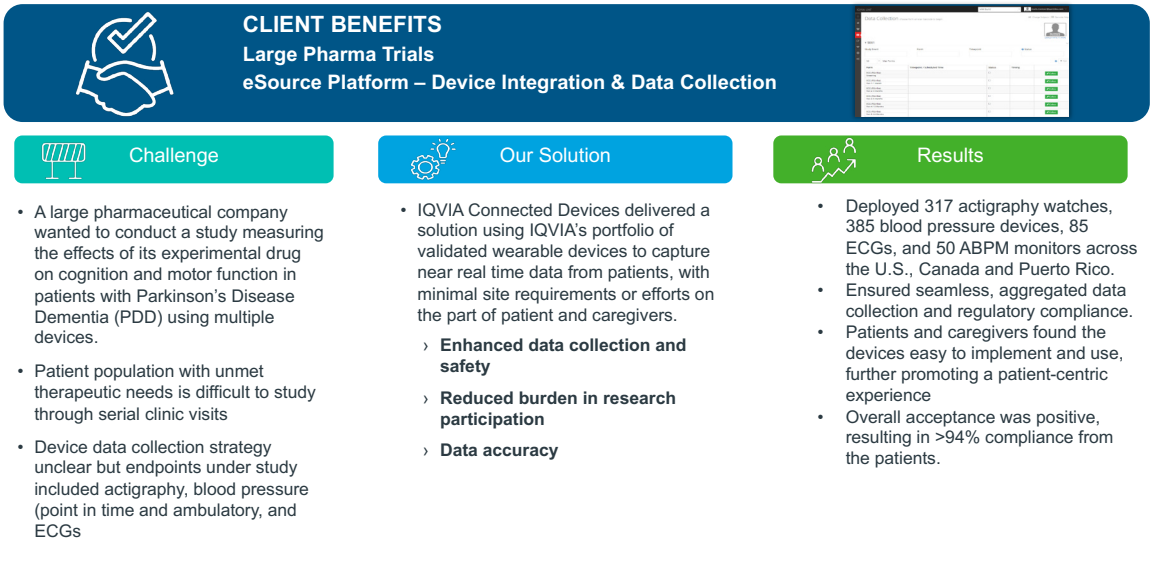
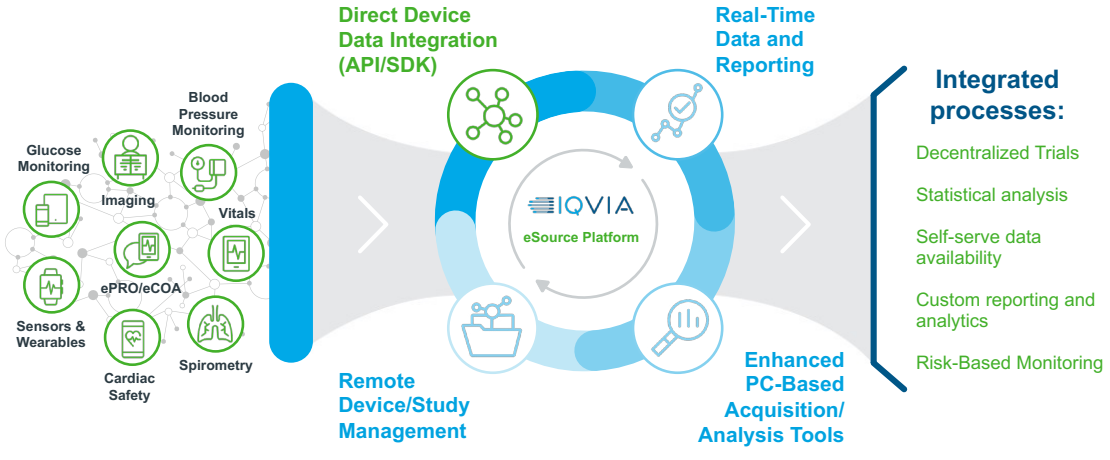


FIGURE 4: Better solutions meet the new demands of the market



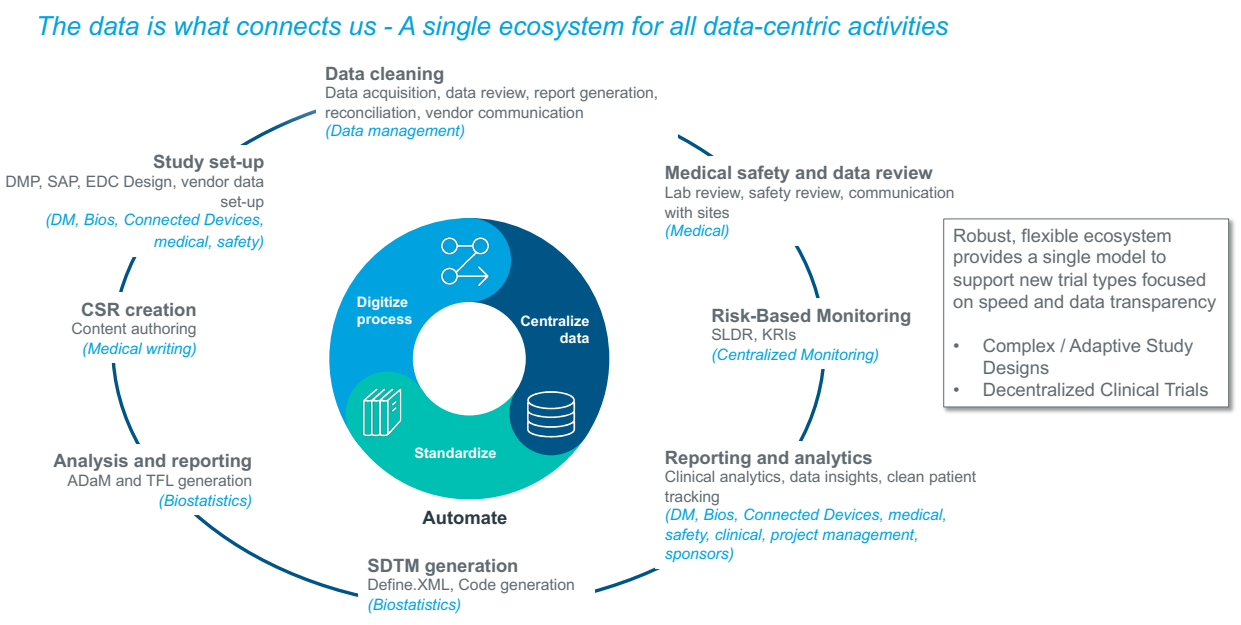
a lot of technology. Thus, ease of use mattered more than ever for the devices. Using its validated, wearable devices and point-in-time devices, the IQVIA Connected Devices team developed a solution that collected nearly real-time data from the patients with minimal site requirements and some light caregiver requirements. The devices included 317 actigraphy watches, 385 at-home blood pressure monitors, 85 ECG devices, and more than 50 ambulatory blood pressure monitors.

The patients and caregivers found the devices easy to use, which indicated a successful patient-centric experience. That contributed to the greater than 94% compliance in data collection (**FIGURE 3**).

NEED: BETTER, MORE ROBUST SOLUTIONS FOR CLINICAL TRIALS

Pairing the right devices with the right digital platform creates a better solution. As shown in **FIGURE 4**, however, the definition of a "better solution" is complex.

FIGURE 5: A single ecosystem for all data-centric activities.



An efficient solution provides: 100% automated data uptake from a wide range of devices and locations; data-driven standardized processes that capture and review the data; real-time data cleaning that includes centralization and harmonization; and real-time flow and access that integrates decentralized clinical trials, as well as providing risk-based monitoring, self-serve data availability, reporting and analytics, and statistical analysis and reporting.

Such a solution sits in the center of a data ecosystem, which is depicted in **FIGURE 5**. The eight steps in this ecosystem go from study set-up through the creation of a clinical study report (CSR)—all of which run more smoothly and easily because of the better solution in the hub of this clinical-trial wheel. Plus, this ecosystem allows a clinical trial to run faster, which accelerates the delivery of value to sponsors—and ultimately patients. Not only does this data ecosystem reduce the timeline of a clinical trial, but it also helps sponsors consider using other types of trials.

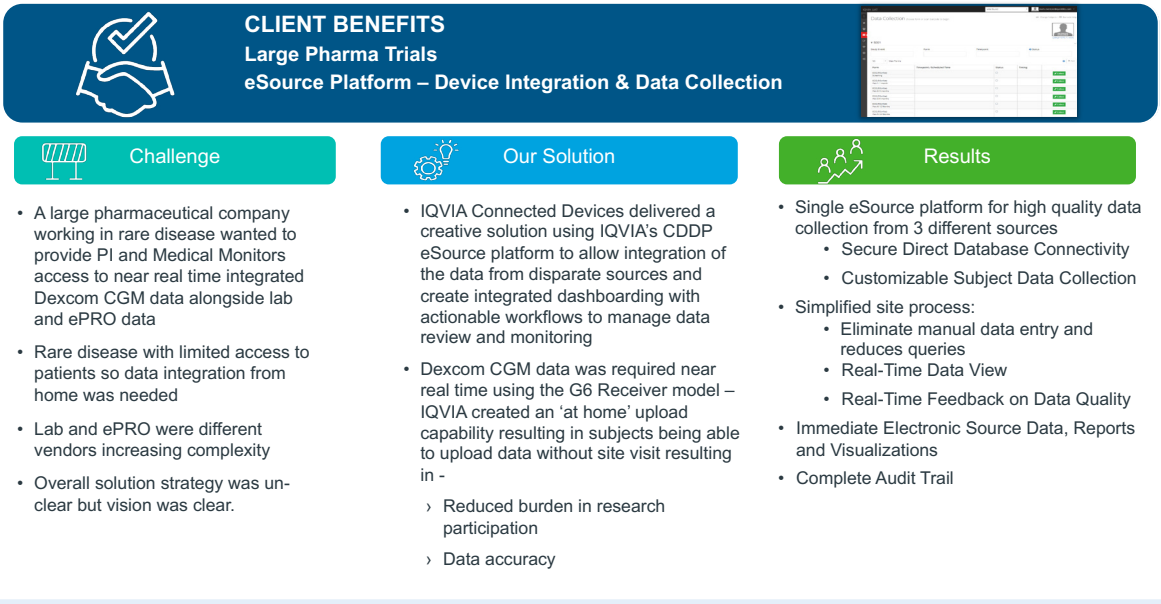
CASE STUDY 3: BETTER SOLUTIONS SUPPORT INTEGRATING EPRO AND LAB DATA FOR IMPROVED PATIENT OVERSIGHT AND MONITORING

In the final case study considered here, the clinical-trial sponsor wanted to integrate electronic patient-reported outcome (ePRO) data and lab data. In this rare-disease study, the collected information included continuous glucose data, as well as ePRO data from food diaries, and lab data.

Here, near real-time lab data from glucose monitoring and ePRO data from the homes of patients were integrated in IQVIA's Connected Devices digital platform. Every night, a patient would plug into the platform to provide data.

This solution combined data from devices, ePRO, and a lab. Consequently, data could be reviewed as needed at the trial site to simplify working with patients and caregivers (**FIGURE 6**).

FIGURE 6: Better Solutions: More than just connected device data – integrating ePRO and Lab data for improved patient oversight and monitoring.



CONCLUSION

Today's increasingly decentralized clinical-trial environment requires the use of various connected devices, and better ones improve outcomes. More specifically, better devices produce better data, which is more easily collected and compliant.

Next, using better devices and data on an advanced digital platform creates a better solution in an evolving data ecosystem. In combination, these tools and techniques allow clinical trials to be more patient-centric and faster at developing new treatments.