WHITE PAPER

IQVIA TECHNOLOGIES

Beyond Integration: Flexible Orchestration of IRT and eCOA Solutions

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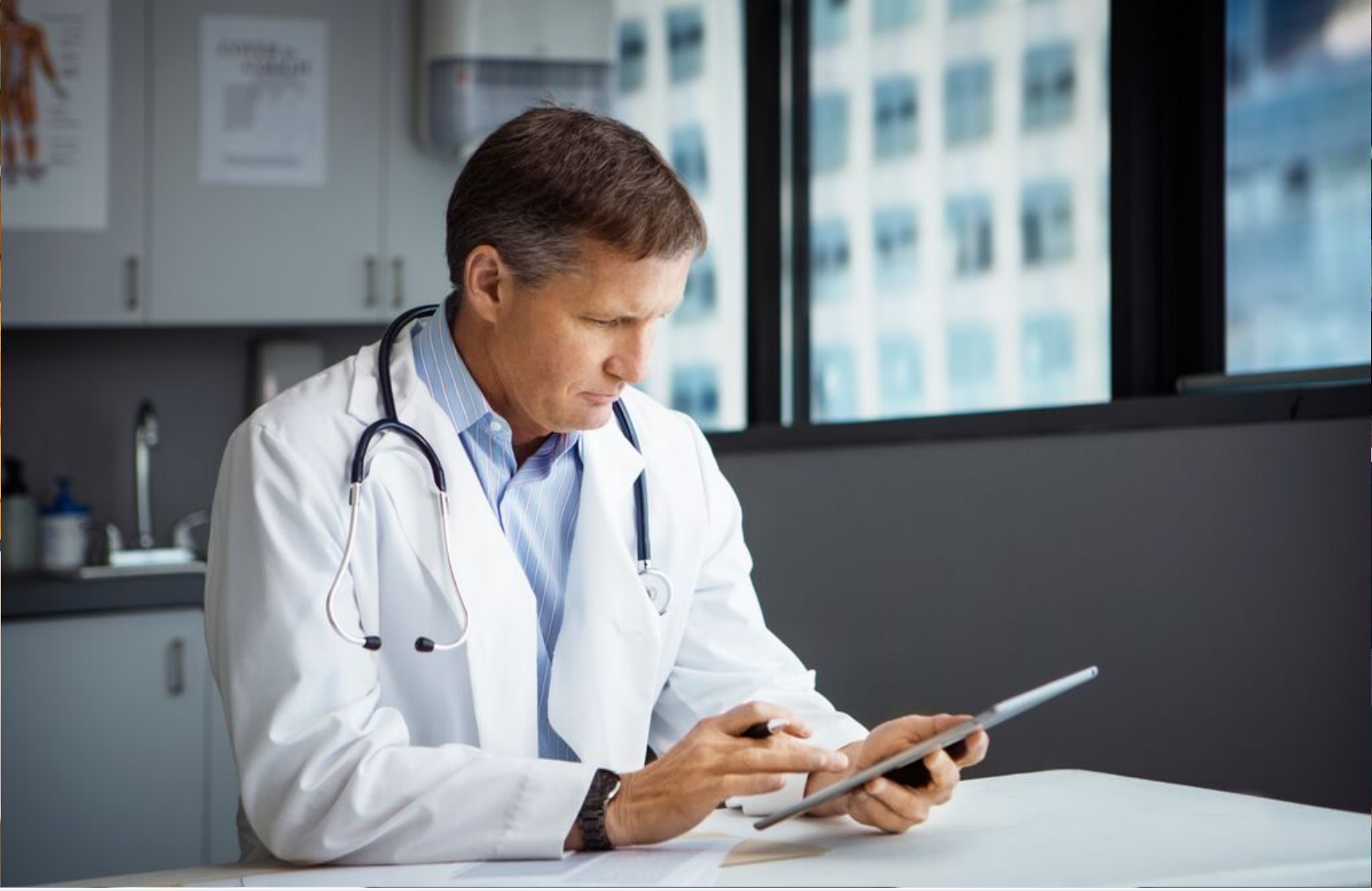

Clinical trials have grown increasingly complex over the past decade. Mobile devices, sensors and wearables are now commonplace in research, enabling us to collect larger volumes of data in more settings and glean greater insights than ever before. These advancements have also made an impact within the regulatory sphere, with the FDA recently publishing draft guidance on proper implementation of Digital Health Technologies (DHT)[1]. In the past two years, we have also seen an acceleration in patient-centric Decentralized Trials (DCT) as well as a variety of technologies that support the benefits of these studies, such as more patient diversity and convenience. These factors, in turn, support patient enrollment, retention and satisfaction in research participation.[2]

While these advancements in technology and data gathering are beneficial, they have added a level of complexity that often burdens site staff with the time-consuming work of collating large amounts of data, entering redundant data into multiple systems and then reconciling that data across systems. How do we balance the use of multiple technologies and increased data volume with the need to streamline and simplify clinical research?

The answer lies in integrating both technology and process through orchestrated solution build, delivery, and management. API-driven, deep integrations produce systematic integrations that are validated and built for configurability, rapid study start-up and flexible mid-study changes. Solution orchestration requires a more powerful build than point-to-point integrations – delivering on rapid configuration to accelerate design, coordinated User Acceptance Testing (UAT), and unified study management. In this paper, we will consider how the orchestration of Integrated Response Technologies (IRT) for Randomization and Trial Supply Management (RTSM) and electronic Clinical Outcomes Assessments (eCOA) – key features of IQVIA's Orchestrated Clinical Trials (OCT) tech suite – improves these processes.

Goals of IRT eCOA Orchestration

Powered by real-time data, IRT and eCOA systems are critical to supporting patients and site personnel throughout a study. For IRT, up-to-the-minute information on the patient, drug supply, and other factors are essential to ensuring every patient is properly randomized and receives the correct medication and dosage at each visit. For eCOA, patients must respond to the protocol-specified assessments according to their study progress at that moment. Randomization, dose titration and other IRT functions may depend on eCOA responses, and eCOA assessments may depend on IRT factors such as the particular cohort or study arm to which a patient is randomized. The linkage of these functions means that data must be accurate and up to date, which poses a major administrative burden, as well as risk of improper entry, when done manually.

With these factors in mind, the main goals of IRT eCOA orchestration are:

- Simplify clinical trial processes, from planning through close-out
- Eliminate redundant, duplicative activities
- Reduce overall timelines and the time it takes to complete each task
- Reduce the burden for all participants and stakeholders (site, sponsor and patient)
- Accelerate time to database lock
- Achieve the above goals using best-of-breed, integrated platforms – validated and built for configurability, rapid study start-up and flexible mid-study changes

ACHIEVING THE GOALS

To meet the goals of building a streamlined, integrated IRT eCOA platform, the IQVIA team used best practices for product management and built a thorough analysis of dozens of studies conducted over a number of years. The analysis included a role-based study as well as a critical look at each step involved in the clinical trial process, from planning through close-out and archiving. In doing so, several key questions were asked:

- What are the consistent workflows?
- Where has there been a need for customization?
- What are the possible permutations in building configurable workflows and what parameters govern these?
- How have DCTs affected these workflows and variations - e.g., Direct-to-Patient (DtP) IP shipment or Bring Your Own Device (BYOD) for eCOA?
- What are the pain points for sponsor, site and patients and how can these be eliminated?

In addition to retrospective study reviews, the team worked directly with a sponsor and interviewed key clinical research stakeholders to further identify the pain points and to gain additional insights on the questions used in the analysis.

Equipped with the detailed workflows and information on inefficiencies, the development team created user requirements that led to functional system requirements for the orchestrated solution. The team then worked through many sprint cycles to unify the two systems and to implement the full functional specification. Product Owners paid particular attention to the integrated workflows for each user role to eliminate any possible redundancies and ensure that the configuration options allowed for maximum flexibility.

Once the solution was developed, the study build team rebuilt a previous study that had been run without integration in order to test and refine the joint platform. Full solution integration benefits included:

Sponsor

- One Project Manager from planning through close-out simplifies all sponsor-vendor communications.
- The study specification process is streamlined and integrated and the User Acceptance Testing (UAT) is completely unified, effectively leading to testing one system rather than two. Since the platform is validated and configurable, UAT is much simpler than for a bespoke integration.
- Creation of a site for IRT automatically creates the site for eCOA.
- Device Inventory Management is delivered through the strength of the IRT; there is no need for a separate device management system. Device provisioning is also handled through the core capabilities of the IRT, much as study medications and other supplies are managed. Sponsors can track the movement of provisioned devices through the full chain of custody.
- Unified dashboards and reports enable rapid access of necessary data and lead to faster, better decisions.

- Streamlined data flows save time and more importantly, enhance quality by eliminating redundant entries and the potential for human error. The need to reconcile data between the solutions is therefore reduced, and time to database lock is reached faster.

Site

- With a single login for most roles, site users can perform many IRT and eCOA tasks and view all data, dashboards, and reports in one place.
- Many duplicative tasks between solutions, often performed by sites, have been eliminated. For example, enrolling a patient in the IRT automatically creates that patient in the eCOA system.
- Patient status changes automatically flow between eCOA and IRT. For example, if the patient is discontinued via the IRT, the assessment schedule automatically reflects it.

This step allows the preservation of patient rights, especially when consent is withdrawn.

- Sites appreciate the integrated training and fewer steps required to accomplish their workflows. The study guides are also simplified and unified.
- Global, integrated help desks are available to sites 24x7 to fully support IRT and eCOA.

Patient

- The improved workflow allows site personnel to spend more time with patients and less with technology.
- When eCOA scores are used for screening, randomization, titration, or other IRT purposes, the integration ensures complete accuracy in a timely manner.
- eCOA setup for each patient is simplified, whether it performed at site or remotely (e.g., through BYOD.)

Results: Time savings realized by IRT eCOA Orchestration

As mentioned before, IQVIA selected a current study in which unintegrated IRT and eCOA solutions has been applied, then built an integrated platform using the same study protocol. For this Phase II study that was modelled for the sponsor, the total estimated savings was between 600 and 800 hours.[3]

The figure below shows the estimated work reductions in four important areas based on the study that was rebuilt using the integrated solution. Additional details on time savings, along with the model assumptions, are shown below in the subsequent visualization and chart.[3]

... in effort during user acceptance for the clinical team during User Acceptance Testing

... of redundant data entries for site activation and more updated visit scheduling from source systems

... in sponsor effort during site/user creation by having a single source of data

... in efforts for clinical teams during the start-up and maintenance phases of the trial

The study parameters for the Phase II model study are:

- 48-week treatment period
- 80 sites, 260 patients
- 40 treatments delivered per patient
- 12 site visits
- 40 electronic patient-reported outcomes assessments

The assumptions used for the modelled study were determined based on several completed studies and they are summarized below. As noted above, using conservative estimates on the number of times each of the events below typically occurs, typical time savings is in the range of 600-800 hours. Other benefits include enhanced data quality, streamlined workflows and faster time to database lock.

Estimated time saved (minutes) per task	Activity
10	IRT activation automatically creates site users in IRT and eCOA (eliminates second patient setup in eCOA)
10	eCOA device assignment and setup automated via IRT onboarding (Eliminates login to eCOA to perform device assignment)
5	IRT events affecting eCOA status automatically sent to eCOA (e.g. dose change triggers assessment) (no need to re-enter data in eCOA)
3	eCOA events affecting IRT status are automated (e.g. eCOA score as stratification factor) (no need to lookup values and re-enter in IRT)
3	Unexpected study events automatically change patient status in eCOA (e.g. patient discontinued via IRT) (no need to login to eCOA to change patient status)
5	Login to one system (IRT) to view all reports eliminates login to eCOA (note: eCOA compliance reports are frequently referenced)
5	eHelpdesk / support calls via one point of contact

Conclusion

In this paper, we have explored how orchestration is far superior to back-end data integrations or bespoke system integrations. The objective of the OCT framework is truly unify systems, creating configurable solutions that are designed for rapid study builds and mid-study changes. Since these orchestrations are validated platforms, processes for study design, planning and testing are also greatly simplified and UAT takes place on one solution rather than two. Additionally, as was demonstrated with the orchestrated IRT eCOA solution, an intelligently integrated IRT eCOA platform streamlines user workflows and enhances the quality of a clinical trial by removing error-prone manual steps and redundant activities. Other advantages to an orchestrated IRT eCOA solution include a unified service delivery team and one Project Manager who is the single point of contact for the integrated solution as well as simplified training procedures and materials, automated device management and access to dashboards, reports and data in one place.

The IQVIA team continues to invest significant effort into enhancing integrations among OCT solutions like IRT eCOA. For more information on any OCT solution, including the IRT eCOA integrated solution, please contact your IQVIA representative or reach out to us at OrchestratedYourTrials@IQVIA.com.

References

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2. Shaw K., Sanford K., Mentzer M. “Patient Centricity by Design – Improving Patient Engagement and Retention While Reducing Burden with Scalable, Adaptable Decentralized Trials”, August 2020. https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/patient-centricity-by-design-for-web.pdf

3. IQVIA internal metrics. Derived from a use case comparison of single study with both an integrated IRT eCOA solution and an unintegrated solution applied to a study protocol with a sponsor on a study that had been awarded to IQVIA for both IQVIA eCOA and Cenduit IRT.

About the author

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Helen brings over 17 years of deep expertise from the clinical research industry and significant global experience working with various CROs, supporting clinical operations teams across, Asia, Middle East, Europe and US. Her expertise includes Clinical monitoring, Project management, Regulatory affairs, and Clinical technologies such as IRT and eCOA. Helen has been a part of IQVIA/Cenduit leadership team since 2015, She has recently taken on responsibility as IRT eCOA customer success lead and supporting North America Project Management team at Cenduit. Prior to her stint at IQVIA, Helen held several positions across various global CROs. Helen is based out of IQVIA headquarters in Durham, North Carolina.

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