Your data platform

Hybrid decentralized trials can have multiple sources of data–for example, greater Electronic Patient Reported Outcomes (ePRO) or Electronic Clinical Outcome Assessments (eCOA), medical devices, Electronic Health Records (EHRs), third party labs, telemedicine services, Interactive Response Technology (IRT), etc. To keep your study running smoothly, it's imperative that these streams of data are available and actionable in real time. As a result, your EDC system needs to be able to orchestrate this entire data collection process in a precise and reliable manner. It's the platform in which all this data ends up, is reviewed, cleaned, and prepared for analysis. It's important to make sure that this foundational system has the right set of capabilities to address needs across your hybrid/virtualized study's lifecycle.

Here are key capabilities to look for in an electronic data capture (EDC) platform to support virtualization of your trials:

- ☐ Ability to incorporate disparate data sources seamlessly and in real time (e.g., from EHRs, labs, devices, etc.).
- ☐ Adaptability to different, unpredictable usage environments. The system should be usable on any device, screen size, and browser (both by participants as well as study team members).
- ☐ High quality end-user experience: little to no training required, real-time edit checks, calculations, and dynamic logic, automatic saving of data. Support for collaboration. Different teams in charge of different aspects of the trial should be able to work together asynchronously.
- ☐ Robust change management to ensure data integrity across changes and a smooth user experience.
- ☐ Flexibility to adapt to changing virtualization. You should be able to launch your study with certain parts virtualized and change this as time goes on.
- ☐ Flexible notifications and messaging. With more parties to coordinate, your system should be smart about prompting users about what they need to do and when.
- ☐ Unfettered analytics. The increased number of digital moving parts in your virtualized study produce data that you can use to enhance the study itself. You can use this data to measure compliance rates, look for bottlenecks/breakdowns in process, and identify unintended consequences before they become real problems.
- ☐ Ease of configuration. Can your team be self-sufficient in building out their hybrid trial? Can they easily make changes and iterate quickly? How easily can they take a change from design, to test, and finally to production?
- ☐ Targeted review and verification of data. As more of your study becomes eSource, there's less data to review and verify. Thus, the ability to granularly define what needs to be reviewed can help monitors save time.
- ☐ Ability to incorporate best-of-breed point solutions. You never know when you'll find that one piece of technology you really want to use to do something very specific in your study. Your EDC platform should be able to play well with others via a robust web services API.
- ☐ Remote data monitoring. Access to data within the EDC so that monitors can ensure source data follows ALCOA principles (attributable, legible, contemporaneous, original, and accurate).

Don't forget - the whole idea behind EDC should be that the people involved in your clinical study are less burdened and more empowered, especially when conducting research virtually.

Check out OpenClinica's EDC platform ⟶

EDC benefits by stakeholder

Sites

Whether you are using virtual or physical sites, EDCs should give sites an easy and intuitive way to provide accurate study data, auto-notify users with actions required, auto-manage study calendars, and apply electronic signatures.

- Let sites leverage data they already have (e.g., from the EHR)
- Make it easy for them to support their patients (don't force your sites to be in the tech support business)

Participants

Allow patients to provide data anytime, anywhere from their own device. Think frictionless.

- Don't tie participants to a particular device, let them use the device already in their pocket
- Configure automatic push notifications to send participants text messages and emails when data is required
- Let participants leverage data they already have (e.g., Apple HealthKit)

Sponsors

Keep up to date with study progress. Save time and money. Maintain regulatory compliance. Rest well knowing your data is secure and clean.

- Cast a wider net with regard to recruitment
- Accelerate study timelines (less wrangling with sites, less cleaning) while obtaining higher quality, more timely data
- Obtain real-time insight into study progress

Data Managers & Study Admins

Data managers should be able to build, test, and push studies in a collaborative manner while ensuring strict change control. They should also have a good toolset for provisioning sites and users, resolving queries, and creating datasets.

- Make it easy to build and change case report forms (CRFs)
- Data review should be highly efficient to ensure that data is flowing smoothly and at maximum quality

Providing business intelligence to different stakeholders should be easy and flexible. Data from external sources should be available in real time for optimal decision making

Monitors

Your EDC system should do the heavy lifting for monitors and direct their focus to the highest areas of risk. Hybrid trials require less source data verification, allowing monitors to focus on higher value activities.

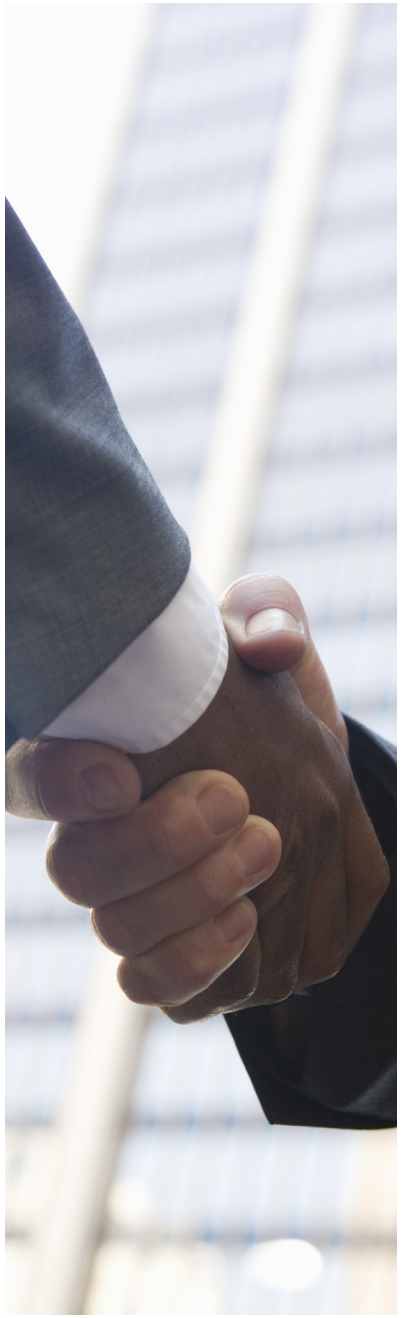
- Help monitors identify issues before they become problems (dashboards and notifications looking at key risk indicators)
- Reduce monitor effort (less travel, less SDV), allow for upload of source documents to support remote monitoring
- Target SDV to only necessary portions of data

Developers and Partners

Make it easy for developers and third parties to get your data from their systems (e.g., from EHRs, devices, a mobile phlebotomy service, etc.). To do this, your EDC system would have an extensive, reliable, and well documented web services API based on the industry CDISC standards. This is the technical toolset developers can use to get external data into your study database in real time.

How to pick the right partner for your hybrid trial

There are 4 key factors to consider when evaluating technology partners for your decentralized clinical trial.



Software

Write down and prioritize your requirements to serve as a "shopping list." But keep in mind that while it's important to check off a certain number of requirement boxes, it's also important to realize that the toolset itself isn't the sole determinant of a successful trial. Just because you have a box full of hammers, saws, and wrenches, doesn't mean you'll be able to build a house. How reliable is the system? Can the features you need sufficiently scale and adapt? Evaluating ease-of-use is particularly difficult to distill into written requirements. Ask the vendor you're considering to provide a sandbox where you and your team members can get hands-on with the software.

Support

Every clinical study requires a certain level of support when it comes to onboarding new technology. How long does implementation take? What skills and resources are required? What does training look like? You'll need more than just responsive tech support. Your vendor should also make it easy to demonstrate ongoing compliance with regulations such as ICH GCP, 21 CFR Part 11, HIPAA, and GDPR.

Professional Services

Most technology companies offer a variety of professional services, but make sure you investigate the availability and expertise of the support personnel that will be the key to your success. Believe it or not, some vendors hire and train people with very little industry experience. Search for a partner that hires people with field experience, such as former clinical data managers or clinical research coordinators. You're bound to have a much better experience by working with a company whose people understand what it's like to be in your shoes.

Cost

Cost is always a critical factor. Consider not just the direct cost of the software, but how other costs may be impacted as well (such as data entry/cleaning costs, monitoring costs, site payments, etc.). The correct way to assess costs is to look at them holistically.

The partner you can count on to drive the future of your digital clinical trials

OpenClinica is available to help you with all your decentralized clinical trial needs. We pride ourselves on making the complex easy. Our eClinical platform is the product of more than 15 years of refinement and input from our community of clinical data managers, researchers, study participants, and other clinical trial stakeholders.

We obsess over user experience. We believe that electronic data capture shouldn't be difficult or require specialized expertise to implement. For these reasons, we've worked hard to make our platform easy to adopt so that you can stay focused on what matters most: your clinical research and the advancement of healthcare for patients that live happier, healthier lives. Plus, our support staff is here to help you in whatever ways you need.

In today's increasingly virtual world, we can help you bring innovative, immersive experiences to life for your clinical research. The end result? Better data, faster.

Ready to talk about your decentralized clinical trials?

Contact Us

OpenClinica

About OpenClinica

OpenClinica is transforming healthcare through innovative cloud technology that simplifies running clinical trials. Proven in over 10,000 trials worldwide, the OpenClinica platform is trusted by leading biopharmaceutical companies, contract research organizations, academic institutions, and government agencies.

OpenClinica is used across a wide spectrum of clinical research, including drug, device, and diagnostic trials, global health studies involving over 2 million patients, adaptive platform trials, and clinical trials for some of the first gene therapies to be approved for market. Hundreds of small, midsize, and large research teams leverage OpenClinica to capture better clinical data faster, and to do so in a way that meets the highest standards for security and regulatory compliance (ICH GCP, 21 CFR Part 11, GDPR, HIPAA).

For more information visit www.openclinica.com.