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The Decentralized Clinical Trial Playbook



About this playbook

Decentralized Clinical Trials (DCTs) are getting much attention due to recent global events. The need for trial continuity in a world of restricted movement and distancing has disrupted the traditional location-centric clinical trial model, and DCT technology is the enabler. Though DCT technologies have existed for several years, they are now at the forefront.

This playbook is a tool for sponsors and CROs who want to leverage DCT technology to support remote interactions in their clinical studies. We hope this playbook helps your selection, planning, and prioritization as you move into the exciting world of DCTs.

In this playbook

- **Learn which study areas leverage DCT technology**
- **Identify key DCT tools**
- **Learn why Castor is your DCT technology solution**
- **Other DCT considerations including support, training, communications, and IRB approvals**
- **Seven steps to getting started with a DCT technology partner**

Study areas that leverage DCT technology

If you are reading this, you likely already understand the high-level benefits that DCTs can provide. But certain study areas benefit more directly from DCT technology. You don't need to apply technology to each area, especially when just starting, but understanding which areas are an option is helpful.



- **Enrollment –** Recruitment and enrollment are significant challenges for clinical trials and are often the cause of delays and unexpected extra expense. Using digital methods to recruit, enroll, and get consent can increase the chances of success for a trial by saving time and money; and can provide other benefits such as reaching a broader and more diverse participant group. eConsent is a pivotal technology for remote enrollment because it lets participants use their own devices from home, further reducing the need for sharing and sanitizing. In today's world of rapid changes, seeking remote re-consents for participants in ongoing studies is another benefit that eConsent can offer.

- **Patient experience -** Ensuring that the participant and patient experience in a trial are as burden-free and straightforward as possible is a goal that contributes to trial success. When a participant's experience is optimized, they are more likely to stay in a trial. A key enabling technology that enhances participant experience is electronic patient-reported outcomes (ePROs), which can be completed using a participant's computer or smartphone and has robust reminders and notifications to keep participants in compliance with timely trial task completion.

- **Trial visibility –** A critical trial success factor is the ability to focus on the study's operational oversight. Trial activity dashboards keep the study team in sync with study activities and help keep study conduct on track. When every study activity is captured and presented on role-based dashboards, study activities stay top-of-mind and are more likely to get done. This oversight helps keep trial timelines on track and can even increase the chances that they can be accelerated.

- **Data capture –** Clinical technology offers new and powerful ways of collecting data. For DCTs, the ability to capture data in real-time continuously from multiple sources while managing a substantial amount of data is of primary importance. Having a robust data model and data capture technology improves data quality in many different ways. Remote electronic data collection on an enterprise-grade platform that includes regulatory considerations for in-home data collection is critical.

- **Monitoring -** Purpose-built remote trial monitoring solutions enable CRAs to review documents and conduct oversight activities without being in the physical site. CRAs can spot problems and trends more efficiently to improve quality with direct access to regulatory and source content. Besides, higher-level metrics, such as safety issues or turnaround times, can be more easily identified. A combination of processes and tools provide the optimum level of remote monitoring. CRAs can perform remote monitoring activities and support the site monitoring plan. Deploy centralized monitoring resources to assist where needed.

- **Compliance -** Regulatory considerations for applying remote technologies in DCTs are not unique compared to traditional trials. Still, there is a need to use existing regulations in a new environment. Those considerations will vary based on the disease area, the type of investigational drug, and the types of trial activities that are decentralized. In the context of a virtual or decentralized clinical trial, the Health Insurance Portability and Accountability Act (HIPAA) covers all data collected during the trial, including from mobile devices.

DCT Tools

The specific digital technologies used for data collection vary by study and include telemedicine, wearable/sensor devices, eConsent, electronic clinical outcome assessments (eCOA), and electronic health records (EHRs). Mobile technologies include data collection vehicles such as electronic diaries and wearable sensor devices. In-home services allow the collection of vitals such as blood pressure and blood samples. Let's look at how Castor's DCT tools align across DCT technology-ready areas of a trial.

Enrollment

Castor strives to set the standard for the industry by enabling our customers to recruit, screen, and consent participants through a customizable digital enrollment workflow. Participants sign up through a study-specific recruitment landing page and receive an invitation to Castor eConsent. Once registered, they can provide additional information to help with the study team's screening activities and review and sign their Informed Consent form. The consent process can include ICF comprehension questionnaires and/or be followed by an automated ePRO survey. Castor eConsent can be integrated directly with Castor EDC for each research project minimizing administrative overhead and ensuring visibility over the study progress.

- Flexible enrollment flow with optional comprehension and screening questionnaires. Integrated with Castor EDC for real-time subject and study progress
- Maintain face to face engagement with fully remote consent using secure video calling
- Custom recruitment landing page per research project
- 21 CFR Part 11 compliant
- Reduced administrative burden and nonconformance/compliance risk/ adherence to ICF process at sites
- Castor's enrollment portal makes the entire process, from recruitment to electronic informed consent, straightforward and automated.

Patient experience

Capture data at the source: the patient. Wearable devices open a whole new world of patient data capture convenient for the patient and allows you to collect more data. These wearables also allow real-time data capture, which can provide you with more frequent, and earlier indications for patient safety issues and other insights that can allow you to adjust work on the trial in flight if needed.

You can capture another type of patient data with electronic patient-reported outcome (ePRO) technology. Design, edit, and send ePROs with Castor's intuitive platform, seamlessly tracking survey distribution and retrieving responses.
Save valuable time spent integrating data from multiple sources by connecting all clinician, patient, and device data at an individual record level. Castor ePRO provides a complete overview of all data, including granular audit logging.
Build ePRO surveys with Castor's form builder, or import them from our Form Exchange. You can bundle surveys into packages to share with recipients via email. Develop ePRO and Patient Dictionary mobile apps to support more specific study needs (eCOA). Send individual or multiple invitations either immediately, at a later date, "yet to be defined," or at a scheduled date and time. Check the progress of your requests, send survey reminders, or analyze responses as they come in.

- Streamlined patient communication
- Reduced barriers to participation such as inconvenience and costs of traveling to sites facilitated by telehealth visits, eConsent, and ePRO
- Participant platform with integrated questionnaires
- Wearable and connected devices for patient data capture are more convenient for the patient and allow sponsors to collect more data.
- Intuitive, user-friendly multilingual interface
- A growing suite of apps including a COVID-19 Symptom Tracker

Castor's ePRO solution and ability to integrate with multiple devices, wearables, and apps make it easy to collect and continuously update research data for your decentralised and hybrid trials.

Visit website



Trial visibility

Effortlessly monitor and manage your research participants throughout the study lifecycle. Progress dashboards enable you to identify issues rapidly and trigger actions on time.

- Participant monitoring and management throughout the study lifecycle
- Real-time reporting
- Patient progress dashboards
- Document management
- Study health dashboards
- Milestone tracking
- Amendment tracking

Data capture

- Easily collect and store data from diverse sources with Castor EDC. Our robust API enables data collection directly from other systems and IoT enabled devices.
- Import lab data and EHR/EMR data using HL7 FHIR messaging.
- Take periodic measurements
- Connect devices and wearables like scales, home pulse oximeters, and thermometers through our API
- Capture survey data from ePRO, eCOA, ePerfO, Elinor, and eObsRO forms

Monitoring

Castor supports onsite, remote, and centralized monitoring practices with its cloud-based platform and a robust suite of automation tools designed for hybrid and decentralized trials. Automatically generate queries with our automation engine, perform source data verification (SDV), view subject progress dashboards, and create custom data review and verification types.

- Cloud-based system accessible from anywhere
- Granular user permissions for flexible user rights set up
- Submit and track amendments
- Manage study team documentation and track eTMF progress.

Compliance

Castor software is compliant with all relevant regulations, including Good Clinical Practice (GCP), FDA 21 CFR Part 11, and Annex 11. Collect data for decentralized and hybrid trials with confidence, knowing you're doing so in a secure and compliant manner.

- Compliant with ICH-GCP E6, FDA 21 CFR Part 11, and EU GMP Annex 11
- ISO 27001 and ISO 9001 certified
- Enables ISO-14155 compliant data management
- Supports GDPR compliant studies at European sites
- HIPAA-compliant servers in the US
- Global servers allow compliance with local privacy and security regulations.

Castor is your DCT technology solution.

To run a DCT, you need modern enterprise-grade technology. Castor is the top-rated Electronic Data Capture (EDC) system. Castor's EDC, ePRO, eCOA, eConsent, eSource, and eTMF solutions enable researchers to easily capture and integrate data from any source and decentralize their trials. Highlights: Build studies within hours leveraging pre-built templates; Integrate EMR/EHR, patient, clinical, and device data; we find that clients build and pass UAT for 90% of studies in Castor in less than four weeks, significantly faster than the industry benchmark.

Castor at a glance

- The top-rated EDC system
- User-friendly technology
- Reduce study build time
- Decentralize your trials
- Capture data from any source
- Run efficient multi-center studies
- World-class support and professional studies
- FDA 21 CFR Part 11 compliant

Castor has clinical experience.

65k
users

4k
live studies

600k
surveys sent

250m
data points



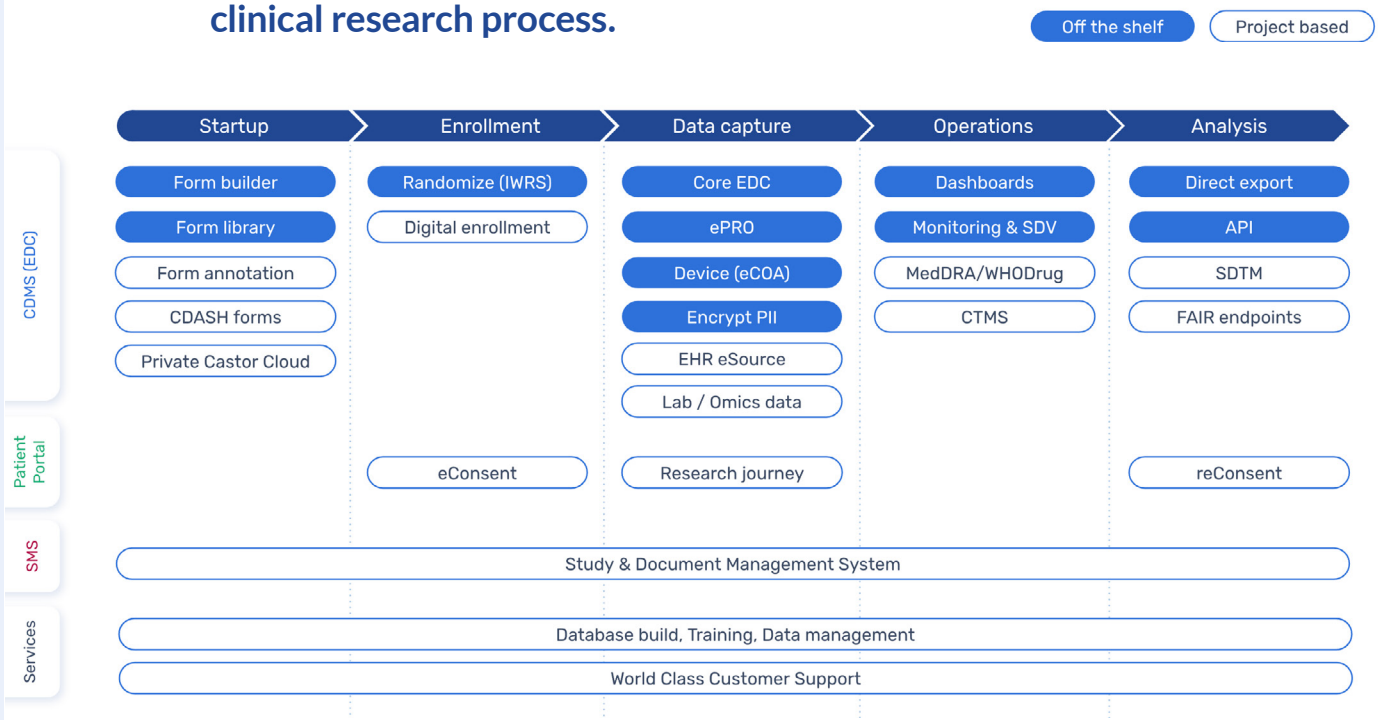
4.6 ★
Avg rating

Castor contains the core EDC functionality you need

- Standard features of the base EDC -

- Unscheduled forms
- Real time edit checks
- Automatic data saving
- Unlimited fields and data points
- File attachments up to 5MB
- Form Builder
- Form Exchange
- Advanced calculations
- Repeated measurements
- Dependencies (skip logic)
- 21 field types
- Export and import of the study structure
- Email surveys (ePRO)
- Coding metadata
- Print eCRFs and forms
- Export data to SPSS, Excel, CSV and R
- Bulk import data
- Statistics dashboard
- Audit trail
- Multicenter collaboration
- Role-based form visibility
- Automation Engine
- Query management
- Source data verification (SDV)
- Electronic signing
- Randomization
- Advanced user management
- RESTful API
- Online manual
- Video tutorials
- Email support

Castor supports the entire clinical research process.



Castor has happy clients



“It was impossible to conduct this type of trial without an API integration.”

- Peter Christian Gaarde, Software Development Engineer at RSP Systems

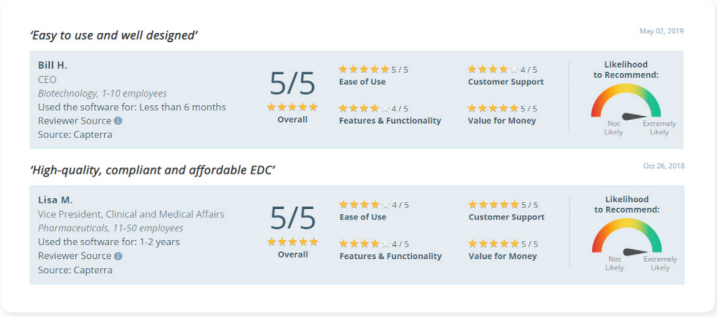
RSP Systems solved the problem of disparate clinical data capture with a single, centralized EDC platform. Using Castor EDC, they are now able to seamlessly capture clinician, patient, device, and any other external data and get a complete overview of all the data linked to an individual patient.

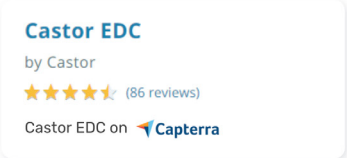
The ability to send data directly from a patient’s home into the Castor EDC database enables RSP Systems to not only accomplish a lot more in a short time but also provides them with controlled access to their study data.

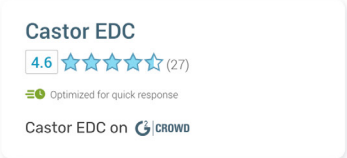
Read the full success story here | **Other success stories**

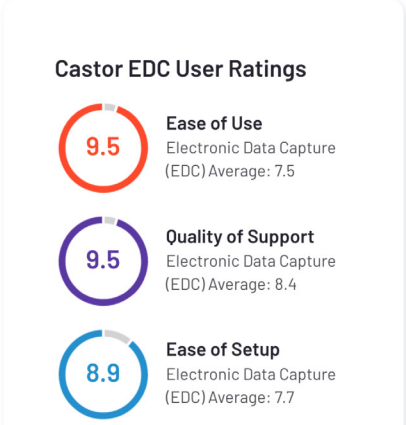
Castor is the best-reviewed platform in the industry.

Mark Twain famously said, “I can live for two months on a good compliment.” We believe in that sentiment and are grateful for all of the great feedback we’ve gotten from our clients. [Check it out here.]









Other DCT considerations

Of course, DCT planning goes beyond technology. Other factors to consider:

- **Support** participants and site staff throughout the clinical research journey to ensure your DCT's success. Sites need help with participant identification, engagement, recruitment, and associated study and site activities. Participants need to have the comfort of knowing they can get advice with trial activities and with technology.

- **Training -** Investigators should articulate procedures and train staff on processes unique to DCTs. For example, trial participants must know what to do in the case of experiencing an adverse event. For study startup, remote SIV and IM training is key to DCT success – as well as the ability to maintain automated role-based assignments and compliance tracking.

- **Communication –** Having tools to connect with site staff remotely to meet training and support needs without removing collaboration is a critical consideration. Planning for communications processes in trial planning will also help to ensure success.

- **IRB Approval –** DCTs are not held to a different standard than traditional clinical trials with regard to investigator delegation and oversight. But DCTs may require additional considerations for potentially enrolling increased participant populations, and for participants that may be geographically distant from the investigator and research team. The study protocol should clearly identify the trial team's roles and responsibilities in accordance with applicable FDA regulations such a 21 CFR parts 11, 50, 54, 56, 312, and 812.

It is essential that sponsors partner with CROs and technology vendors with proven experience in running successful DCTs to help them navigate their DCT journey.

Don't forget about support, training, communication, and regulatory guidance. The right technology partner can guide you through this planning as well.

Seven steps to getting started with a DCT technology partner

Your flow may be slightly different, but these are the general steps to start your engagement with a DCT technology vendor:

1. Share your research, business/operational goals with your vendor.

2. Assess their tooling and support to help you achieve your goals

3. What is their experience in the DCT space, and

4. Ability to adapt when the inevitable bumps occur during implementation.

5. Agree on timelines and dependencies on definitive requirements, implementation, and onboarding.

6. Establish an engagement framework for support, account management, and product feedback.

Recap

- The time is now to incorporate DCT technology into your clinical research.
- The critical areas of DCTs are enrollment, patient experience, trial visibility, data capture, monitoring, and compliance.
- Technology enables DCTs, so you need a reliable technology partner to execute a successful DCT.
- Castor is your DCT technology solution.
- Consider support, training, and communication.
- Follow the seven steps to getting started.



About Castor

A global health tech company, Castor enables manufacturers and research organizations to maximize the impact of data through clinical trial automation and data reuse, while supporting a patient-centric, decentralized approach to research.

Castor's platform has supported more than 4,100 commercial and academic studies that cover a broad range of disease areas including oncology, diabetes, cardiovascular disease, central nervous system, rare diseases, and infectious diseases.

Castor's capabilities include:

Electronic Data Capture (EDC) to maximize productivity in clinical studies and integrate data from different sources

Electronic Patient Reported Outcome (ePRO) forms to administer surveys and collect clinical data into a centralized platform

Integrations to capture data directly from multiple sources, including patients, clinicians, devices, wearables, and EHR systems

eConsent to facilitate and automate patient enrollment processes

Services for study set up and study conduct to help reduce study build time, capture higher quality data, and get to market faster



65k users

4k studies

90+ countries

250m data points

2.2m patients

600k surveys sent

98% satisfaction