

# DECENTRALISED CLINICAL TRIALS IN THE EU

STRATEGIES AND DIGITAL SOLUTIONS FOR  
NAVIGATING THE REGULATORY LANDSCAPE

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# Introduction

## What is a decentralised clinical trial (DCT)?

DCTs can take a variety of forms depending on patients' needs, study protocol, drug company preferences, or regulatory requirements. Trials may be remote and decentralised from start to finish—with no physical contact between participants and investigators—or they may rely on hybrid designs that incorporate only certain elements of decentralisation (e.g., direct-to-

patient investigational medicinal product (IMP) distribution and remote collection of routine blood tests). Although many US-based pharmaceutical companies have been employing some features of DCTs for years, the COVID-19 pandemic demonstrated the potential of fully remote recruitment, study administration, and data collection. Truly decentralised studies became more than a pipe dream, cementing the utility and benefit of some of these approaches in the clinical trial repertoire.

### Characteristics that are common to most DCTs include:



Flexible locations, geographically distributed mini-hubs, or non-site-centric study schedules



Reduced travel burden for patients via decreased or total elimination of site-based visits, to increase convenience for participants and their families



Digital/remote monitoring capabilities and virtual data reporting options



Telehealth, virtual visits or other remote visit and participant communication strategies







Distribution of IMP, often directly to patient homes or via pharmacies nearer to patients



Extended vendor networks for laboratory testing, home nursing, data management, and other study elements, to make visits and study requirements less burdensome for participants

## Benefits of DCTs

Some of the top benefits reported by sponsors that have completed DCTs include:<sup>1</sup>

-  **Faster and simpler patient recruitment**, especially for rare diseases, since patient location, distance to study site, and qualified site location become less important
-  **Increased participant adherence and retention** due to improved communication, greater patient convenience, and enhanced monitoring
-  **Faster speed to trial completion**
-  **Reduction in travel-, site- and time-related budget overruns**

Collectively, these benefits can translate to a significant return on investment. New data from the Tufts Center for the Study of Drug Development indicate that DCTs deliver a higher expected net present value (eNPV) than traditional trials. The eNPV metric integrates trial cycle time, cost, revenue, and risk into a summary measure. Based on an analysis of more than 150 DCTs, the eNPV reported in this study translates to an approximately \$10 million return on a \$2 million investment for phase 2 trials and an estimated \$39 million return on a \$3 million investment for phase 3 studies.<sup>2</sup>

In addition, companies that have completed remote and decentralised studies reported a significant financial benefit and time savings, due in part to more streamlined recruitment and fewer patients being noncompliant or lost to follow-up.<sup>1</sup>



**75%**  
saw cost savings



**70%**  
saw their studies move faster



**50%**  
said patient recruitment was made easier

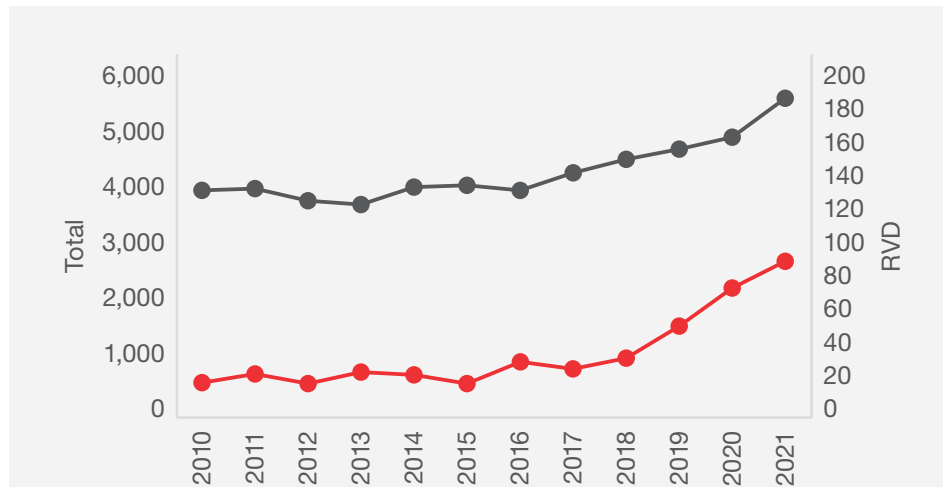
## Practical adoption of DCTs

Just as with conventional clinical trials, no two decentralised trials are the same. Country-specific adaptations must be made to meet localised regulatory requirements. Vendor and supplier networks must be re-evaluated and updated to ensure that each partner in the chain has the capabilities to deliver and monitor the selected digital and remote activities. Training must be adapted to familiarise study staff with new techniques. Furthermore, each company must ensure that the decision to pursue a DCT is accepted by its stakeholders and investigators.

Central to any DCT is the focus on patients: study participants come first. This prioritisation dictates that services and study visits come to the patient as much as possible, rather than the other way around. There are, however,

natural limits to what can and should be done remotely. For example, DCTs are less suitable for certain activities, such as surgical procedure trials, and for some types of follow-up, such as specialised imaging to track cancer metastasis. There are also regulatory challenges that can complicate decentralised management of some studies.

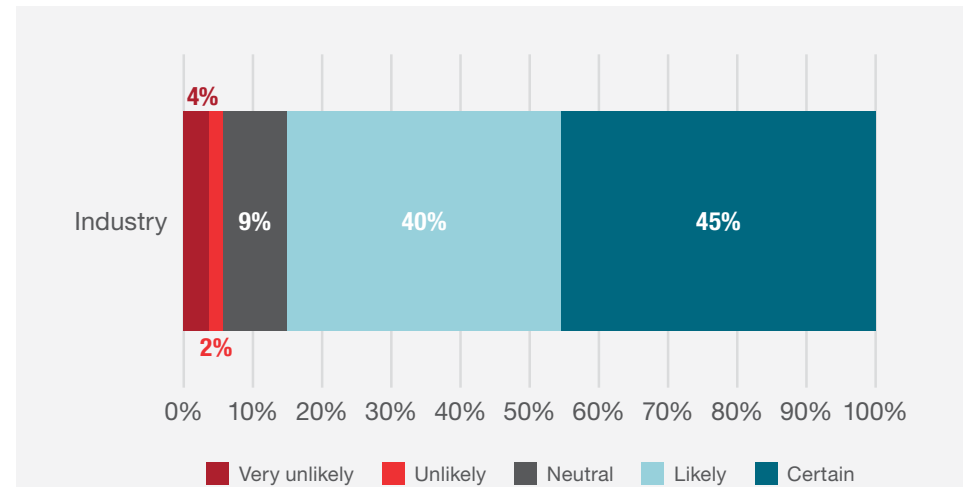
By better understanding these limitations and taking proactive steps to address them, many trials can successfully incorporate patient-friendly, cost- and time-saving decentralised elements into their studies. Indeed, most US-based companies that have adopted decentralised and remote monitoring options, or that embraced these types of trial administration activities during the pandemic, plan to keep these innovations in place or use them more frequently moving forward.<sup>1</sup>



### Trial starts for all trials vs. remote, virtual, or decentralised (RVD) trials show a major uptick in RVDs

- RVDs more than doubled from 2015 to 2019
- RVD trials approximately tripled from 2018 to 2021 as a result of the COVID-19 pandemic

IQVIA. [Global Trends in R&D 2022: Overview through 2021](#). IQVIA Institute. 10 February 2022. Accessed online 13 October 2022.



### Significant likelihood of increase in DCTs within the next two years

- Digital technologies and enablers are shifting the point of care into the patient's home
- More than 80% of respondents expect it is likely or very likely that COVID-19 will catalyse increased adoption of DCTs in the long term

PharmaIntelligence, Informa. [Decentralized and Hybrid Trials 2020: A Global Survey](#). 21 July 2020. Accessed online 20 July 2022.

While this robust acceptance of DCTs has facilitated adoption of these technologies in the United States, companies conducting research in the EU have faced significant barriers to the deployment of available remote monitoring options. In part, this is because EU regulatory bodies and individual nations have been slow to generate new guidance and requirements specific to remote monitoring and decentralised trial activities.

Despite this hesitancy and delay, many pharmaceutical and biotechnology companies in the EU have expressed their intention to move towards remote and decentralised trials in the coming years.<sup>1</sup> Unfortunately, uncertainty surrounding the EU regulatory landscape may slow their progress. Furthermore, lack of familiarity with the digital and remote monitoring solutions available for decentralised trial activities may cause some companies to believe that not enough assurance is available to help meet regulatory requirements while also executing the simplified trials.

And yet, solutions exist. DCT success in the EU relies in part on engaging valuable consultant relationships, proactive regulatory outreach, and an innovative approach to meeting the likely challenges specific to trial needs. By preparing and working with experts in direct-to-patient studies, companies can proactively address regulatory concerns and overcome traditional objections posed by members of regulatory bodies, or even internal industry colleagues who maintain some reservations about the suitability of remote or decentralised trials.

Numerous companies have successfully executed fully decentralised trials in the EU. Many more have the capability to do so. What is essential for all of them, however, is adoption of digital technologies to ease the challenges associated with DCTs, which pharmaceutical companies that are experienced in DCTs identify as key to their success and to future efforts.<sup>3</sup>



# Navigating the EU regulatory landscape

There is no quick and easy way to guarantee acceptability of a DCT by EU regulatory bodies. Many countries within the EU employ unique requirements and regulations on top of EU-wide requirements. Examples of some of the regulations that vary within countries include e-consent options, acceptability of home health nursing, requirements for direct-to-patient IMP solutions, and data privacy regulations.

In addition, there are some overarching EU regulations that must be considered regardless of how digital or decentralised your trial may be. These regulations have been slow to incorporate guidance for new technology and decentralised techniques, but compliance with the regulations is vital to achieving regulatory approval both for study execution and for new drug applications. In all situations, trials must meet the minimum standards for patient safety, data privacy, safety and oversight monitoring, and other factors.

**ICH E6.** All trials conducted in the EU must comply with **International Council for Harmonisation (ICH) E6 Good Clinical Practice (GCP)** guidance. In 2021, the European Medicines Agency (EMA) released a draft update to these principles that reflects increased utilisation of digital technologies in clinical research.<sup>4</sup> If the updates are included in the final guidance, technology and digital approaches that offer all stakeholders a practical way to collect necessary data, enable protection of participant privacy and safety, and maintain trial quality and data rigour are acceptable.

The EMA's draft update of the document stresses that guidance is intended to be "media neutral" to enable selection among a variety of technologies for documentation purposes. It also highlights the importance of greater inclusivity and representativeness in clinical trials together with minimised burden and complexity, which can be effectively achieved with greater uptake of technology. It specifically allows room for digital involvement in informed consent practices and data capture, management and analysis. However, all data collection methods and study protocol decisions must be fit-for-purpose, designed with quality and reliability in mind, and enable true data integrity, privacy, and traceability.

**In general, the GDPR's intention is to protect trial participants' identities and personal information, minimise unnecessary data collection, facilitate personal control over collected data, and hold companies accountable to stringent requirements for data collection, security, storage, and transmission.**

**GDPR.** The **General Data Protection Regulation (GDPR)**<sup>5</sup> was updated in 2018 and is intended to offer EU-wide acceptable data privacy practices and requirements. However, Article 89 of the GDPR does allow member states to depart from certain requirements if they make the conduct of scientific research impossible or impractical. This flexibility allows different countries to exercise different laws regarding privacy and data protection for clinical research efforts.

In general, the GDPR's intention is to protect trial participants' identities and personal information, minimise unnecessary data collection, facilitate personal control over collected data, and hold companies accountable to stringent requirements for data collection, security, storage, and transmission. When interpreted for clinical trials, these principles are consistent with ICH E6 in that they emphasise personal rights and privacy, minimal necessary data collection, deidentification when possible, and strict data handling requirements to protect data integrity and privacy.

**OTHER REGULATORY GUIDANCE.** The EMA offers scientific advice and guidelines for companies pursuing pharmaceutical research and product approval. The agency also offers parallel guidance with the European Network for Health Technology Assessment (EUnetHTA), which helps evaluate evidence-generation plans and facilitate efforts related to health technology laws and technology-related trial methodology across the EU. The EMA's Heads of Medicines Agencies' joint goals for 2025 also report an interest in innovative trial designs and increased use of digital technologies for implementation of clinical trials, within parameters that safeguard data privacy and participant safety.<sup>6</sup>

Other organisations are emerging to grapple with and promote the evolution of digital solutions in the field of medicine and research, as well. These include Trials@Home (supported via an Innovative Medicines Initiative as an EU and European Federation of Pharmaceutical Industries and Associations joint undertaking), Sweden's Medical Products Agency's feasibility study on DCTs (which reported no formal obstacles to virtual trials), and more.<sup>7</sup>

Because of the complex regulatory environment for clinical research in the EU, entire consulting organisations exist to help ease the way through planning and implementation of RVD studies. Specialty consulting from companies with networks and regulatory experts in the countries of interest can identify inconsistencies in country-specific policies and acceptable procedures and provide key guidance for moving forward. They can also help sponsors proactively reach out to local regulatory bodies to obtain consent or approval for study tactics that may not yet have a history of approval.

## Solutions that enable DCTs

Many of the digital technologies that enable DCTs actually increase the reliability and availability of data in a study. They provide increased monitoring and oversight opportunities, and they enable the collection of more accurate adherence and compliance data. Furthermore, they can actually help sponsors demonstrate enhanced safety and data quality by ensuring that all IMP has remained within acceptable temperature ranges, enhancing blinding, and much more.

For any trial in the EU, but especially for DCTs, regulatory consultants can be valuable strategic partners. Experienced consultants can provide guidance in selecting the appropriate technologies to support a DCT's regulatory compliance and streamline its execution, recommending the best digital solutions to address data oversight, safety monitoring, and other trial-specific elements in applicable EU regulations. A robust range of digital solutions exists that can facilitate DCTs and their acceptability to regulatory bodies, even in a geographically variable and challenging regulatory environment.

**“Patient adherence is critical for any clinical trial. A significant amount of money is lost due to the patients not adhering to the protocols they were given.”**

*Sr. Director, Clinical Operations,  
small and emerging biotechnology company*



# Digital solutions for innovative, regulatory-friendly and data-savvy DCTs

Digital technologies and remote monitoring applications make it possible to document and uphold typical trial monitoring activities while also maintaining the rigour required by regulatory bodies. They have the added benefit of often being more patient-friendly, faster, and even less expensive than traditional procedures. Although not all of these technologies may be available in all EU countries, some form or adaptation of them will likely be acceptable in most study locations.

**Based on a breadth of experience facilitating remote studies around the world, we propose five key digital strategies to help overcome EU regulatory challenges in the utilisation of DCTs.**

These five key solutions represent the core ways many companies can begin incorporating digital tools into the launch of DCTs, but they are just the tip of the iceberg; myriad solutions also exist at the prelaunch and post-trial analysis phases that can further facilitate remote trial activities.

## 1. E-consent and virtual visits

One of the most direct and cost-effective ways to implement a DCT is to remove required visits at a brick-and-mortar study site. The more that can be done in patient homes or at decentralised study hubs, such as local physician clinics or pharmacies, the more convenient the study becomes for patients and the more affordable the study often becomes for sponsors.

E-consent is a challenge in some EU nations, but temporary adaptations made for research during the pandemic may serve as an opening to gain approval for continued use of these technologies moving forward. In most cases, local regulatory bodies are concerned about adequate patient education and true informed consent surrounding procedures when they do not take place face to face.



Others are concerned about the data privacy and security issues surrounding data collection over the internet or remote video sessions. Despite these concerns, draft updates to ICH E6 encourage member states to facilitate digital options for this process, provided quality of consent can be adequately documented and privacy can be maintained.






Many vendors exist with the capability of building high-quality virtual patient education for informed consent processes and trial education experiences. Options also exist to engage in virtual meetings during which staff explain the trial, potentially with the use of on-screen educational assets to further enhance engagement and understanding. Numerous groups have emerged that also specialise in meeting EU guidelines for virtual data security, which allows acceptable digital documentation and transmission of consent.

Virtual visits and home health visits by nonphysician study staff may also raise regulatory concerns. In some cases, a physician is required to sign off on or evaluate certain elements of clinical trial medical visits, such as



adverse event assessments. There are creative ways to address these concerns, such as home health nurses who facilitate a virtual visit with the study physician while present at the patient's house. The nurse can conduct physical examinations while the physician observes remotely, carrying out standard clinical assessments and evaluations with the guidance of the physician. For study visits that do not require a physical examination, remote (unchaperoned) virtual sessions or even telephone calls may suffice to maintain connectivity and provide the required data collection.

The following technologies enable increased contact, improved follow-up, and enhanced oversight and monitoring capabilities for virtual visits and e-consent processes:

-  **Study apps and platforms** designed explicitly for virtual consent technology, which proactively remove privacy and data security concerns
-  **Study-provided, secure tools for digital contact**, such as iPads and other tablets or mobile devices
-  **Regular check-ins** via scheduled telemedicine sessions, for routine questionnaires, patient-reported outcomes (PRO) data, and non-invasive examinations
-  **Mobile sites and home health nurses**, which let the study staff come to the patient for in-person assessment
-  **Expansion of study site networks** to include pharmacies, laboratories, and local physician (or dialysis, chemotherapy, etc.) clinics to help supplement options for local and in-person follow-up, especially for emergencies or lab procedures

Together, these technologies offer several options for a dramatic reduction in required study site visits and travel on behalf of patients. When coupled with thoughtful criteria to identify circumstances in which an adverse event or safety issue may require an in-person evaluation at a study site, many studies can significantly limit or even eliminate all other on-site visit requirements.

## 2. Site-agnostic IMP delivery and tracking

**1500+**

direct-to-patient  
clinical shipments  
delivered

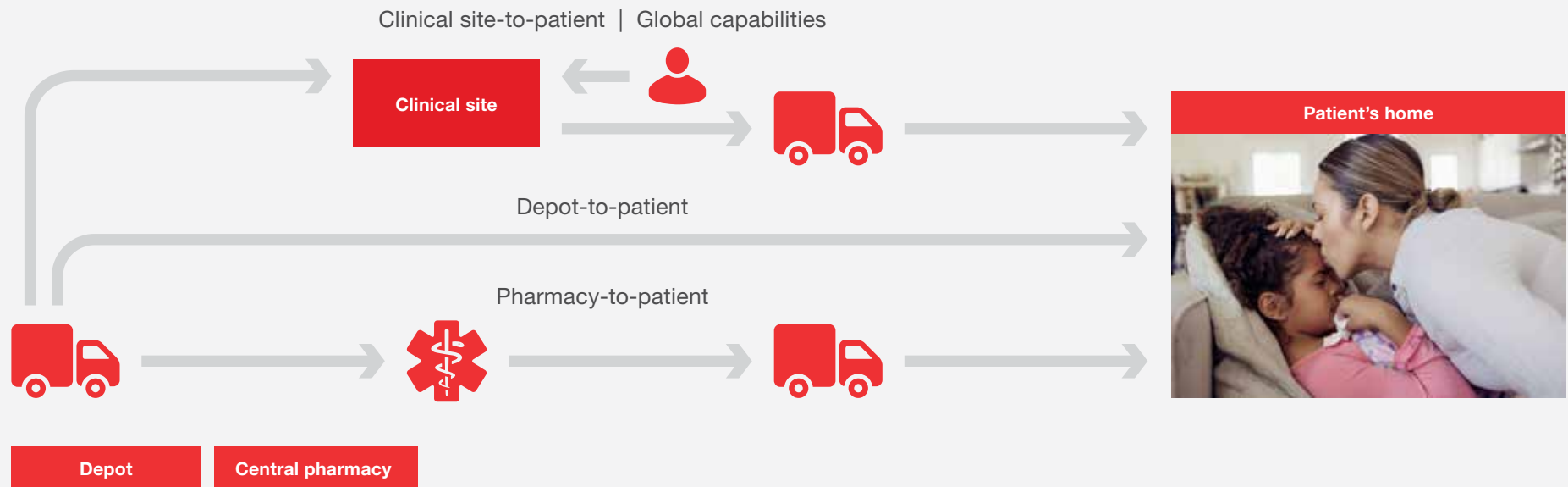
Delivery of pharmaceutical products in DCTs has seen a dramatic evolution over the past decade. Even the most stringent regulatory environments often allow local pharmacy-based distribution or direct-to-patient courier shipment to the patient's home. More flexible environments may allow alternative arrangements, such as shipping from a depot directly to patients, with no clinician touchpoint in between. This can reduce travel

time and expense on behalf of patients and families and reduce burden on sites and study investigators. When coupled with robust platforms for

storing and monitoring these data, flexible arrangements for IMP delivery and tracking can offer improved data trails and safety awareness information.

In traditional trials, once the patient leaves a site with the study medication, the only knowledge about product temperature control or usage is patient reported. In contrast, with direct-to-patient or other non-site-based IMP shipment options, highly sensitive instruments can collect temperature and location information and transmit it to a centralised monitoring platform. This allows sponsors or sites to monitor study drug details in near-real time. It also allows immediate intervention if a drug becomes unsuitable for use due to unacceptable temperature excursions, uncertain chain of custody, or delays in receipt. This enhanced data and safety oversight is unique to decentralised and innovative trials and undeniably improves data for regulatory agencies.

### Direct-to-patient options: At a glance



Automated sensors and digital pathways associated with direct-to-patient and similar shipping options offer unsurpassed richness in data trails by digitising and streamlining all of the following:



**Remote tracking of temperature and location**



**Changes in the chain of custody**



**Patient-friendly advanced delivery scheduling**



**Customised selection of IMP handoff** based on selected patient preference (pick-up, delivery, etc.)



**Near-real time, centralised monitoring of IMP for usability and safety**, with immediate alarms to indicate temperature excursions, lost products, and so on



### 3. Smart packaging

Going one step further than transportation and temperature tracking, smart packaging offers a unique and appealing option for regulatory agencies to enhance monitoring of medication adherence. **Smart packaging can provide digital logs of when medication containers are opened; correct dosing; whether a dose is late, missed, or even overdosed; as well as ongoing storage conditions and temperature information.**

Smart packaging solutions require up-front materials and shipping investment on behalf of the sponsor, but the quality and reliability of data make up for these costs via improved awareness of actual compliance and reduced patient recruitment- and retention-related expenses. Knowing whether and how patients are taking their medication offers sites the valuable opportunity to contact patients who are missing doses or are not following dosing instructions. Early intervention allows sponsors to fix problems before they create retention concerns or unreliable data. Improved documentation also demonstrates how drugs work under *known* use, and results in cleaner and more robust data sets that rely less on estimations and truncations.

Additional options for smart packaging can make participation easier for patients who live in geographically remote locations, improving recruitment and enabling participation among populations that may not have been able to participate otherwise. For example, smart packaging can be shipped virtually anywhere, in equipment or packaging that maintains proper temperatures. Upon arrival at the patient's home, the package itself can be plugged into a standard wall outlet. From there, it continues to maintain the proper temperature and transmit data on usage and temperature to the central study monitoring platform.

Smart packaging offers sponsors the following advantages:



**Digital compliance data** that surpass the detail, quality, and reliability of standard adherence tracking methods



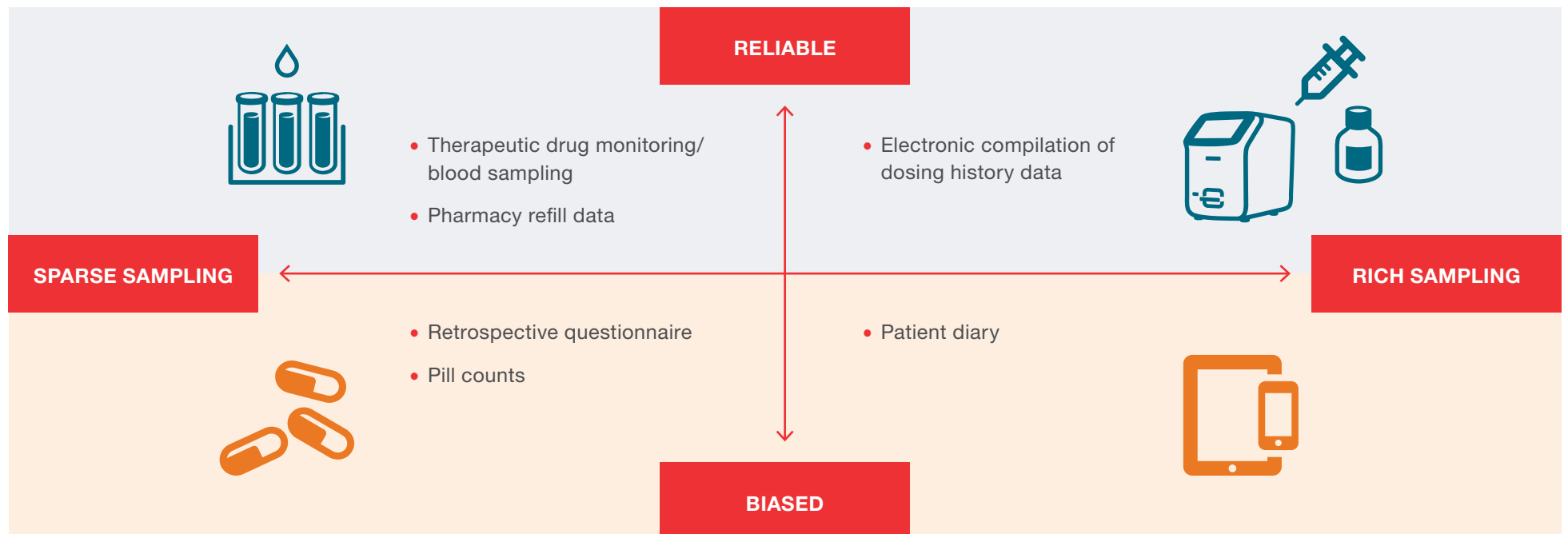
**Increased geographic diversity** in patient populations



**Reduced recruitment costs** due to the ability to intervene earlier with at-risk participants, preventing dropout and noncompliance



### Adherence monitoring techniques have a direct impact on data quantity and quality



Comparison of current adherence measurement methods. Modified from Vrijens B, Urquhart J, (2005). *J Antimicrob Chemother.* 55(5):616–627. DOI: 10.1093/jac/dki066.

## 4. Digital communication platforms

A common concern raised with DCTs and remote monitoring is that patients and study staff will not be able to communicate as effectively as they could during regular in-person visits, potentially leading to missed adverse events, unattributed side effects, or unobserved advancement of health problems requiring intervention.

In reality, properly implemented remote studies often increase touchpoints and communication between participants and study staff. High-quality and tech-savvy clinical research organisations (CROs) and their vendors can offer customisable, study-specific applications and computer programs that facilitate communication. Solutions such as digital visits and webinars, video documentation submissions, patient-focused apps for regular check-ins, study-provided patient tablets and e-diaries, and wearable devices allow participants in remote trials to be in near-constant connection and communication with their study team. Wearables, monitoring devices, and home health equipment such as remotely monitored dialysis machines, for example, also enable direct reporting and warning systems to flag study physicians in case of changes in vital signs, potential adverse events, or disease management.

For studies that may not require frequent touchpoints with patients, digital solutions to improve communication and avoid patient disengagement include virtual symptom assessors and PRO questionnaires. In cases where adherence is paramount, some trials have patients record a short video as they take their medication, which is then submitted to the study team for compliance monitoring. Research indicates these tactics can effectively maintain patient engagement while preserving the perks of remote participation. Around-the-clock telephone contact numbers can be maintained for all medical needs or study questions that require urgent personal communication, as well.



Of course, these virtual tools require training above and beyond typical patient education to ensure an optimal communication dynamic. The educational component to digital patient communication tools can be delivered at the time of consent or prior to the study via training videos that can be accessed and repeated as needed during the course of the study. It can also be done at an initial site visit, to ensure that participants and their families feel comfortable using the technology. Investigators and study staff should also be educated on how to use and get the most value out of the digital tools. This training may include how to manage the digital platforms, flag potential concerns, follow-up as needed, and implement protocols for virtual visits or other remote assessment techniques.

Virtual communication platforms and wearables can provide far more data and interactivity than traditional trials, ultimately improving the quantity and robustness of the data available for review. From a regulatory standpoint, however, management of data security and patient privacy is paramount. Careful study design can ensure that only appropriate data are obtained, while selection of vetted, experienced technology vendors can help sponsors address regulatory concerns regarding data privacy and security. Vendor platforms and wearables should meet or surpass all data access, audit, storage, transmission, and integrity guidelines laid out in existing regulations, as well as 2021 draft guidance proposed by the EMA regarding computerised systems and electronic clinical trial data.<sup>8</sup> Study staff will also have to be trained for appropriate digital data access, management, certification, and protection protocols related to their use of the systems.

Overall, study-specific digital platforms offer simplified, direct, secure communication options that can:



**Increase the number of touchpoints with participants while reducing the burden of those touchpoints** in terms of time, travel, expense, and duration



**Reduce the cost of frequent patient outreach**, health monitoring, interactive discussion, and impromptu evaluations or assessments



**Enable digitisation of PROs and other questionnaires** that can then be done at the patient's leisure, without the presence of study staff



**Facilitate nonurgent communication** regarding prescription refills, diary details, symptom monitoring, and even changes in contact information



**Improve the availability of site staff** by opening a new avenue for contact, engagement, and information sharing, other than a direct telephone call or site visit



**50+**

**countries approved and vetted by Thermo Fisher Scientific regulatory experts for our clinical site-to-patient service**

## 5. Centralised monitoring dashboards

The array of new digital capabilities for conducting decentralised trials presents opportunities for deeper data collection, but it also introduces challenges related to how the large volumes of data will be ingested, stored, analysed, monitored, and reported in an accurate and meaningful way. Centralised data monitoring platforms, such as those that collect IMP data and those that allow centralised access to study site electronic case reports and medical records, allow sponsors and site investigators to have constant access to aggregated and up-to-date study data. The centralised platforms use advanced statistical and analytical tools to test the data for consistency and coherence. This functionality allows sponsors and medical review boards to quickly identify data patterns, gaps, abnormal trends, safety signals, and site performance issues that may lead to trial delays or protocol adjustments.

The constant and steady stream of data being aggregated and processed by these platforms simplifies safety reporting, compliance monitoring, lab result review, and other case-related reporting. This improved visibility and data trail can alleviate some regulatory concerns. It can also accelerate data monitoring sessions and analysis for crucial study decision-making stages, and it can make it easier to identify and prepare the most relevant and impactful data for eventual publication.

Some centralised monitoring dashboards automatically analyse data and provide data summaries to help identify areas of concern. For example, IMP dashboards may automatically generate reports regarding the percentage of shipments that had unacceptable temperature excursions and require shipment of new product. Similarly, lab value and electronic case report dashboards may be able to automatically provide what percentage of participants had bloodwork results that fell outside acceptable limits after the initial dose of the study drug.





While the degree of central monitoring and the desired features of the dashboard may vary significantly from study to study, programs that provide investigators and sponsors a centralised view of study data offer demonstrable benefits, including:



**Quicker access to study data**, which can enable earlier data-driven decision-making



**Enhanced visibility of data across sites**, which enables faster analysis of site-based variations



**Improved site-specific monitoring** for data quality and protocol adherence



**Uniformity of data** together with universal alarms for errors, excursions, warning signs, or trial safety signals



**More immediate ability to intervene** when site trends, specimen integrity, or other data show alarming results



**Stronger data trail and easier data access** for regulatory reporting



# Conclusion

The COVID-19 pandemic accelerated the adoption of DCTs worldwide, but the rate of uptake has not been consistent globally. Some early implementation barriers, including immature digital infrastructures and sponsors' limited experience with the approach, have been steadily receding as enabling technologies become more prevalent and knowledge of benefits grows. Other obstacles, such as the perception of regulatory barriers, are more challenging to navigate, especially in the EU, where EMA recommendations are not interpreted consistently across countries.

While the complexity of the regulatory landscape in the EU is real, it is navigable with the right guidance and resources. In particular, digital solutions that support enhanced communication with patients, improved data reliability, adherence oversight, and centralised data monitoring and analysis are among the key enabling technologies that help sponsors meet regulatory requirements for data quality, data security, and patient safety. There is also a growing body of evidence demonstrating that the trials enabled by these tools are better suited to the needs of patients and improve the return on investment for sponsors.

As regulatory bodies continue to issue guidance on emerging digital and DCT concepts, the success of these enabling technologies, both during the pandemic and in its wake in US-based trials, points to their value for future clinical research and provides ample support for addressing EU regulatory requirements.

Because regulations can vary from country to country and sometimes region to region, for each step of a DCT—from study approval to clinical deployment to post-study follow-up—careful planning is essential. This includes paying close attention to the areas of greatest regulatory concern, such as data gathering, data management and storage, quality control, clinical supply transportation, and, most importantly, protection of patients' rights.

Pharmaceutical and biotechnology companies considering conducting DCTs in the EU should work with experienced partners and consultants who can

help them navigate the regulatory landscape. Doing so will help them realise all the benefits associated with DCTs while minimising the risk of regulatory pushback or procedural delays.

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## Additional resources

- View our webinar, [“The future of decentralized clinical trials in an evolving EU regulatory landscape”](#)
- Learn more about smart packaging via our brochure, [“Increase confidence in clinical trial outcomes with digital adherence measurement solutions”](#)
- Explore the options for direct-to-patient services in [“Solved with solutions & support”](#)
- Check out our eBook on DCTs: [“No place like home: How to make decentralized clinical trials a win for patients, sponsors & investigators”](#)

# About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. Built on a reputation for scientific and technical excellence, we provide pharma and biotech companies of all sizes instant access to a global network of facilities and experts across the Americas, Europe, Asia and Australia. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. Our Quick to Clinic™ programs for large and small molecules help you balance speed and risk during early development so you can file your IND quickly and successfully. Digital innovations such as our mysupply Platform and Pharma 4.0 enablement offer real-time data and a streamlined experience. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

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