Decentralized Clinical Trials Technology Stack in 2026

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Executive Summary

The decentralized clinical trial (DCT) technology stack has matured from a pandemic-era improvisation into a regulated, multi-vendor software category as of August 2026. A **decentralized clinical trial** is one that moves some or all trial activities away from a traditional investigator site using telehealth visits, in-home visits, or visits with local health care providers, per the U.S. Food and Drug Administration's (FDA) definition (Source: fda.gov). FDA finalized its guidance on "Conducting Clinical Trials With Decentralized Elements" on September 18, 2024, mandated by Section 3606(a) of the Consolidated Appropriations Act, 2023 (Source: govinfo.gov), and the European Commission published an updated Recommendation Paper on decentralised elements in clinical trials, endorsed October 15, 2025 and published October 29, 2025 (Source: health.ec.europa.eu). The International Council for Harmonisation's (ICH) revised Good Clinical Practice guideline, E6(R3), was adopted January 6, 2025 and took legal effect in the European Union on July 23, 2025, while its Annex 2 covering decentralized and pragmatic trial designs reached Step 4 in June 2026 and becomes EU law on January 15, 2027 (Source: ema.europa.eu).

Vendor product materials show that several platform vendors offer bundled electronic informed consent (eConsent), electronic patient-reported outcomes (ePRO), electronic clinical outcome assessments (eCOA), televisit, and connected-device capabilities, sometimes through a single login. This vendor positioning does not establish that all sponsors use a converged stack rather than integrated point tools. **Medable**, **Signant Health**, **Castor**, **THREAD**, **Veeva Systems**, **Medidata**, **IQVIA**, and **ICON plc** are the most cited platform providers, alongside device-and-nursing specialists such as **Illingworth Research Group**, **Cardinal Health**, **ActiGraph**, and **VivoSense**. Medable signed a four-year enterprise contract with GSK covering its global product portfolio (Source: medable.com), while Sanofi named THREAD its sole DCT technology provider under a five-year, 2023 enterprise agreement (Source: prnewswire.com). The category has also consolidated through acquisition: Science 37, an early decentralized-trial pioneer, agreed in January 2024 to be acquired by telehealth firm eMed in a deal valued at approximately $38 million in equity value; eMed completed its tender offer in March 2024 (Source: globenewswire.com) (Source: prnewswire.com), and wearable-sensor firm ActiGraph acquired Biofourmis's life-science business in January 2025 to combine hardware with an AI-driven digital trial platform (Source: prnewswire.com).

Market-size estimates for the DCT category vary sharply by definition and research firm. BCC Research sizes the DCT market at $8.8 billion in 2024, growing to $18.8 billion by 2030 at a 13.7% compound annual growth rate (CAGR) (Source: bccresearch.com), while P&S Intelligence estimates the DCT market at $10.2 billion in 2026 and $21.4 billion by 2032 (a 13.0% CAGR for 2026–2032) (P&S Intelligence, and Grand View Research sizes the broader clinical trial technology and services market at $25.7 billion in 2024, growing to $60.8 billion by 2030 (Source: grandviewresearch.com). Adoption itself remains uneven: a February 2023 IQVIA assessment found only 1% of industry-sponsored trial starts were using DCT solutions (Source: appliedclinicaltrialsonline.com), while a November 2025 Tufts University Center for the Study of Drug Development (CSDD) review of more than 16,500 published articles since 2022 found only 6% contained empirical performance data (Source: csdd.tufts.edu). Where rigorous data exists, the returns are notable: Tufts CSDD's peer-reviewed economic model found DCT methods increase expected net present value by roughly $20 million per drug entering Phase II with a seven-fold return on investment (Source: pmc.ncbi.nlm.nih.gov), and IQVIA's internal analysis of 12 DCTs found a 78% reduction in time to first patient in versus conventional trials (Source: iqvia.com). This report examines the vendor landscape, the 2024 to 2026 regulatory framework, remote patient monitoring and risk-based quality management (RBQM) practices, the underlying market and adoption data, and named case studies from Pfizer, Novartis, Sanofi, Eli Lilly, and Signant Health that illustrate what a working DCT technology stack looks like in practice.

Introduction and Background

Clinical trials have historically required participants to travel repeatedly to a physical investigator site for screening, dosing, and follow-up assessments, a model that concentrates enrollment near academic medical centers and excludes patients who cannot easily travel. The **decentralized clinical trial** concept, which shifts some or all of those activities to a participant's home, a local pharmacy, or a community health care provider, dates to at least 2011, when Pfizer ran what it described as an entirely web-based randomized trial for the overactive-bladder drug tolterodine, allowing patients "to participate in the clinical trial regardless of their proximity to clinical sites" (Source: pfizer.com). The concept remained a niche pilot for the following decade; it was the operational disruption of the COVID-19 pandemic, when site visits became impossible for months at a time, that forced sponsors, contract research organizations (CROs), and technology vendors to build production-grade remote trial infrastructure at scale.

That crisis-driven build-out has since been formalized into a distinct **technology stack**: a set of interoperating software and hardware components that together let a sponsor run trial activities outside a physical site while still meeting Good Clinical Practice (GCP) and data-integrity obligations. The core layers are electronic informed consent (eConsent) for enrolling and re-consenting participants remotely, electronic patient-reported outcomes (ePRO) and electronic clinical outcome assessments (eCOA) for symptom and quality-of-life data, telehealth or televisit modules for clinician contact, connected devices and wearable sensors for objective physiological data, direct-to-patient (DtP) drug shipment and home-nursing logistics, and a randomization and trial supply management (RTSM) layer that ties it together with the sponsor's clinical trial management system (CTMS) and electronic data capture (EDC) platform. By 2026, several major vendors market converged suites alongside interoperable modules. For example, Medable markets "eCOA, eConsent, TeleVisit, devices, and agents all in one login, with one view" (Source: medable.com).

Two forces have reshaped the category since the pandemic-era surge. First, regulators moved from tolerating decentralized elements as an emergency accommodation to codifying them as a standard trial-design option, culminating in FDA's September 2024 final guidance and the EU's revised 2025 recommendation paper, both discussed in detail below. Second, the market corrected from inflated pandemic-era adoption expectations toward a more measured "**hybrid**" model, in which sponsors combine limited decentralized elements (typically eCOA and televisits) with a still-substantial site-based backbone, rather than running fully virtual, site-less trials. A 2021 Veeva survey found that "during the pandemic, 87% of sponsors and CROs surveyed rapidly deployed decentralized trials to manage clinical studies (compared with 28% pre-COVID)," a difference of roughly 59 percentage points (Source: veeva.com), yet the same survey found only 56% believed the shift had actually improved the patient experience (Source: veeva.com), a gap between enthusiasm and measured benefit that continues to shape purchasing decisions as of August 2026. This report surveys the vendor landscape, the regulatory framework governing it, the remote-monitoring and quality-management practices layered on top, the underlying market data, and named real-world deployments to give life-sciences technology buyers a current picture of the DCT stack.

Key Changes

The Technology Stack: From Point Solutions to Unified Platforms

The defining shift in the DCT technology stack between 2020 and 2026 has been consolidation: vendors that once sold a single module, such as eConsent or ePRO, now sell converged platforms, and platform vendors have absorbed or partnered with adjacent specialists rather than leaving sponsors to integrate disparate systems themselves.

Medable offers a unified platform spanning eCOA, eConsent, televisit, connected devices, and, as of 2026, AI agents, all accessible from a single login (Source: medable.com). The company's AI-assisted "Study Studio" tool claims to cut eCOA study build times from 16 to 20 weeks down to 4 to 6 weeks (Source: medable.com), and the company entered a four-year enterprise contract with GSK to power decentralized and hybrid trials across GSK's global portfolio (Source: medable.com). **Signant Health**'s SmartSignals platform likewise bundles ePRO with more complex clinician-reported outcome (ClinRO) collection, noting that "ePRO systems are a type of eCOA" rather than a separate category (Source: signanthealth.com) and that its offering covers "ePRO, complex ClinRO, as well as the tools and reporting" sponsors need (Source: signanthealth.com). **Castor**, historically an electronic data capture (EDC) vendor, now markets a "5-in-1" model combining EDC, ePRO, eCOA, eConsent, and eRecruitment "natively, with no middleware required" (Source: castoredc.com), directly targeting the integration overhead that plagued earlier point-solution stacks.

THREAD has focused on complex, multi-arm trial designs; in July 2026 it launched a platform update enabling research teams "to manage multiple participant pathways, indications, and workflows within a single study" for basket, umbrella, and adaptive designs (Source: threadresearch.com), and the company was named a "Major Contender" in Everest Group's 2025 Life Sciences eCOA Products PEAK Matrix Assessment (Source: threadresearch.com). THREAD also holds government-funded work: in October 2024 it partnered with CRO Allucent on BARDA-funded decentralized COVID-19 research programs (Source: threadresearch.com).

Among the enterprise clinical-data incumbents, **Veeva Systems** entered the category with MyVeeva for Patients in May 2020, offering "virtual visits, patient adherence, ePRO, eConsent, eSource and an easy to use" interface built on its existing Vault Clinical suite (Source: veeva.com), positioning DCT features as an extension of a sponsor's existing Veeva CRM and Vault investment rather than a separate purchase. **Medidata** (a Dassault Systèmes brand) built its DCT program around Medidata Consent, eCOA, and Sensors modules, and its RTSM module "features robust DtP capabilities that offer high flexibility for decentralized and hybrid trials" (Source: medidata.com); the company also partners with Circuit Clinical to provide a pre-trained, turnkey network of decentralized-ready trial sites (Source: medidata.com).

Oracle Health and Life Sciences has pursued integration over in-house build: in February 2026, patient-engagement vendor **ObvioHealth**'s ObvioGo platform became directly integrated with Oracle's Clinical One Data Collection product, "extend[ing] Oracle Health and Life Sciences Clinical R&D portfolio with ObvioGo's enterprise-grade ePRO, eConsent, and eCOA capabilities" (Source: prnewswire.com). ObvioHealth describes its own platform as one that "simplifies study design, boosts participant engagement, and delivers cleaner, faster data" (Source: obviohealth.com). Smaller

specialist **Curavit** completed a fully remote trial for Sana Health's investigational PTSD wearable in February 2024 using "a technology platform including ePROs, eCOA, telehealth, device training, and randomization" delivered entirely off-site (Source: curavit.io), with study coordination "managed [through] all aspects of participation with remote-based clinical research coordinators" (Source: curavit.io).

Category consolidation has also happened through acquisition. **Science 37**, one of the earliest fully virtual-trial companies and a partner in Novartis's and Sanofi's initial DCT programs (discussed further below), agreed in January 2024 to be acquired by telehealth and diagnostics company eMed, in a transaction valued at approximately $38 million in equity value (Source: globenewswire.com) (Source: fiercebiotech.com). The large global CROs have built or bought their way into the same layer: **IQVIA**'s platform page reports "500+ Decentralized Trials" across "75+ Countries" (Source: iqvia.com) (Source: iqvia.com), and states that "IQVIA is the first and only DCT Program to achieve GDPR Validation Compliance" (Source: iqvia.com), while **ICON plc**'s Digital Platform bundles a "Televisit capability that enables scheduling and virtual one-on-one patient visits securely via an internet connection" (Source: iconplc.com) with an eCOA module pre-loaded with the validated Mapi Research Trust instrument library to shorten study start-up (Source: iconplc.com).

Beyond the software layer, physical logistics remain a distinct sub-category. **Illingworth Research Group** provides Good Clinical Practice trained "Mobile Research Nurses that travel to visit patients" in their homes in place of site visits (Source: illingworthresearch.com), coordinating sample and investigational medicinal product (IMP) shipments through global medical logistics partners (Source: illingworthresearch.com). **Cardinal Health**'s Sonexus Access and Patient Support business, used for specialty and direct-to-patient drug programs, combines "hub and pharmacy operations, clinical expertise and digital tools such as our AI-powered chat solution" (cardinalhealth.com. One legal barrier persists across this whole stack: Parexel's regulatory analysis notes that "many countries have no regulations in place that would enable e-signatures and eConsent," citing China, Taiwan, Hong Kong, and South Africa as jurisdictions where eConsent still lacks explicit legal footing (Source: parexel.com), meaning global platform vendors must still build country-specific consent workflows rather than a single universal one.

Table 1 below compares the core capabilities and notable market activity of the leading DCT technology vendors as of August 2026.

VENDOR	CORE STACK COMPONENTS	NOTABLE CAPABILITY OR DIFFERENTIATOR	NOTABLE 2024 TO 2026 ACTIVITY
Medable	eConsent, eCOA, TeleVisit, connected devices, AI agents	AI-assisted "Study Studio" build tool; single-login unified platform (Source: medable.com)	Four-year enterprise contract with GSK (Source: medable.com)
Signant Health	eCOA, ePRO, ClinRO, RBQM (SmartSignals suite)	Positions ePRO as a subtype of the broader eCOA category (Source: signanthealth.com)	Shionogi COVID-19 trial supported across 90+ sites in four countries (Source: signanthealth.com)
Castor	EDC, ePRO, eCOA, eConsent, eRecruitment	"5-in-1" native suite with no middleware required (Source: castoredc.com)	Continued EDC-to-DCT platform expansion
THREAD	eCOA, ePRO, adaptive/multi-arm trial workflows	Everest Group "Major Contender" in 2025 eCOA PEAK Matrix (Source: threadresearch.com)	Sole DCT provider for Sanofi's global platform since 2023 (Source: prnewswire.com)
Veeva Systems	eConsent, ePRO, eSource, virtual visits (MyVeeva)	DCT features layered onto existing Vault Clinical/CRM investment (Source: veeva.com)	Continued Vault Clinical Cloud expansion
Medidata (Dassault Systèmes)	Consent, eCOA, Sensors, RTSM/DtP	RTSM offers flexible direct-to-patient shipping for hybrid trials (Source: medidata.com)	Circuit Clinical turnkey site network partnership (Source: medidata.com); expanded Sanofi Vaccines eCOA collaboration (2024)
IQVIA	Full-service DCT program plus CRO operations	First DCT provider with TRUSTArc GDPR validation (Source: iqvia.com)	500+ decentralized trials across 75+ countries as of platform disclosure (Source: iqvia.com)
ICON plc	eCOA (Mapi-preloaded), TeleVisit, digital platform	Pre-validated instrument library shortens study start-up (Source: iconplc.com)	85% eConsent adoption case study with Medable in a U.S. menopause trial (Source: medable.com)
Oracle Health and Life Sciences / ObvioHealth	ePRO, eConsent, eCOA (via ObvioGo integration)	Direct integration into Oracle Clinical One Data Collection since February 2026 (Source: prnewswire.com)	Extends Oracle's Clinical R&D portfolio without a native rebuild (Source: prnewswire.com)

Table 1 summarizes vendor-described capabilities and selected activity; component availability, integration depth, instrument libraries, implementation support, and pricing should be verified against a sponsor's protocol and existing systems. The table is not an independent measure of feature parity or sponsor purchasing preferences. Buyers evaluating this list should weigh existing enterprise software commitments (a Veeva CRM shop has a different total cost of ownership than a Castor or Medidata shop) alongside the vendor's regulatory-compliance track record, since, as IntuitionLabs (a life-sciences and AI consultancy that holds Veeva Vault CRM X-Pages Partner status (Source: intuitionlabs.ai) notes in its own technology-assessment advisory work, evaluating a sponsor's current stack and making recommendations for optimization is a distinct exercise from simply comparing vendor feature lists (Source: intuitionlabs.ai).

Regulatory Foundations Take Shape

The single most consequential change to the DCT technology stack since 2023 has been regulatory: agencies moved from informal, pandemic-era tolerance of remote trial conduct to final guidance describing FDA's current recommendations for decentralized trial conduct, alongside applicable binding statutes and regulations that technology vendors must address.

FDA's centerpiece document is "Conducting Clinical Trials With Decentralized Elements," jointly issued by the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (Source: fda.gov). The guidance defines decentralized elements to include "telehealth visits with trial personnel, in-home visits with remote trial personnel, or visits with local health care providers" (Source: fda.gov). FDA announced the final version in the Federal Register on September 18, 2024, finalizing the draft guidance first issued May 3, 2023 (Source: govinfo.gov), under a Congressional mandate in Section 3606(a) of the Consolidated Appropriations Act, 2023 (Source: govinfo.gov). The guidance covers nine distinct areas, including "use of digital health technologies in DCTs" and "the roles of sponsors and investigators in DCTs" (Source: govinfo.gov), and it makes explicit that decentralization changes trial logistics, not regulatory standards: "FDA's regulatory requirements are the same for trials that include decentralized elements" as for conventional site-based trials (Source: govinfo.gov). Compared with the 2023 draft, the final text notably dropped a requirement that sponsors maintain a task log of local health care providers involved in a trial, a compliance burden industry had flagged as impractical (Source: govinfo.gov).

FDA supplemented the DCT guidance with two related final documents that directly govern the technology stack. First, "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations," finalizing a December 2021 draft, was announced in the Federal Register on December 22, 2023 under a mandate from Section 3607(a) of the Food and Drug Omnibus Reform Act of 2022 (Source: govinfo.gov), and it governs the selection of digital health technologies (DHTs) suitable for use in clinical investigations, as well as validation, endpoint use, and data-retention obligations (Source: govinfo.gov). Second, FDA finalized its 21 CFR Part 11 electronic records and electronic signatures guidance for clinical investigations on October 1, 2024, covering 29 questions and answers on how existing electronic-records rules apply to modern trial software (Source: cooley.com). That guidance clarified electronic health records are not subject to Part 11 compliance until entered into a sponsor's own electronic data capture system (Source: cooley.com), and it requires that each electronic data element be linked to an authorized "data originator" for audit-trail attribution, a requirement that directly shapes how ePRO and eCOA vendors architect their databases (Source: cooley.com).

Europe moved on a parallel but distinct track. The European Commission's original Recommendation Paper on decentralised elements in clinical trials, published December 2022 as part of the Accelerating Clinical Trials in the EU (ACT EU) initiative, defined qualifying elements to include "home health visits, remote monitoring and diagnostics, direct-to-patient shipment of study drugs and electronic informed consent" (Source: ema.europa.eu), aiming to facilitate DCT conduct "while safeguarding" participant protections and data quality (Source: ema.europa.eu). That paper was superseded by a version 2, endorsed by the Clinical Trials Coordination Group on October 15, 2025 and published October 29, 2025 (Source: health.ec.europa.eu). The updated paper frames decentralization explicitly as extending the trial site itself, treating the introduction of decentralised elements as an extension of the clinical trial site rather than a wholly separate mode of conduct (Source: health.ec.europa.eu), and it instructs sponsors to take a risk-proportionate approach adapted to participant risk when a decentralized element is deemed critical-to-quality under ICH E8 (Source: health.ec.europa.eu). Computerised systems and electronic data used in decentralized elements must separately comply with EMA's dedicated guideline on computerised systems and electronic data in clinical trials (Source: health.ec.europa.eu), an added compliance layer platform vendors must engineer to directly.

The most structurally important 2024 to 2026 development, though, is the revision of ICH's foundational Good Clinical Practice guideline, **E6(R3)**, which for the first time explicitly accommodates the DCT model rather than treating it as an exception. The core Principles and Annex 1 of E6(R3) were adopted by the ICH Assembly under Step 4 on January 6, 2025 (Source: database.ich.org), and they explicitly note that technologies such as wearables and sensors may expand the possible approaches to trial conduct (Source: database.ich.org). The EU brought E6(R3)'s Principles and Annex 1 into legal effect on July 23, 2025 (Source: ema.europa.eu), while FDA published the same guideline in the Federal Register on September 9, 2025 but had not, as of that publication, set a formal U.S. compliance date, according to trade-press coverage (Source: acrpnet.org), a divergence the same coverage notes explicitly: "Unlike the European Medicines Agency, which made E6(R3) effective on July 23, 2025" (Source: acrpnet.org). The specific decentralized-trial content lives in a separate Annex 2, covering "designs such as pragmatic clinical trials and decentralized clinical trials" (Source: ema.europa.eu), which reached Step 4 through ICH adoption on June 3, 2026 and Committee for Medicinal Products for Human Use (CHMP) adoption on June 25, 2026, but does not become legally effective in the EU until January 15, 2027 (Source: ema.europa.eu). FDA describes E6(R3) overall as one that "incorporates flexible, risk-based approaches and embraces innovations in trial design, conduct, and technology" (Source: fda.gov), and among its stated updates is "advancing quality by design and risk-based quality management in trial conduct and oversight" (Source: fda.gov), a theme this report returns to below. Trade coverage of the FDA publication summarizes the practical shift concisely: "E6(R3) opens the door for decentralized elements, digital technologies, and the use of real-world data" where scientifically and ethically justified (Source: acrpnet.org).

The United Kingdom regulates DCTs through its Health Research Authority (HRA), whose "Decentralised trial methods position statement," last updated April 28, 2026, "aims to confirm the current UK position on the use of decentralised trial" methods for clinical trials of investigational medicinal products (Source: hra.nhs.uk). UK trials must comply with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 alongside ICH GCP principles (Source: hra.nhs.uk), and the HRA places direct verification burden on sponsors, requiring that they "assess, verify and validate the technology, methodology and usability of any novel digital" tool used to collect data directly from participants (Source: hra.nhs.uk). *Table 2*, in the Implementation Considerations section below, summarizes the full regulatory timeline across these jurisdictions.

Remote Patient Monitoring and Digital Biomarkers Mature

The connected-device layer of the DCT stack, commonly described as **remote patient monitoring (RPM)**, includes devices and data platforms used in clinical investigations. FDA clearance, where applicable, is specific to an individual device and its intended use; “medical-grade” is not an FDA regulatory classification. FDA's Digital Health Technologies guidance recommends that sponsors select DHTs suitable for their clinical-investigation use and evaluate them for the intended endpoint, rather than assuming consumer fitness trackers are qualified for that purpose. Applicable statutes and regulations—not the guidance itself—supply any binding obligations (Source: hhs.gov).

Device consolidation mirrors the platform consolidation described above. **ActiGraph**, whose wearable devices have been used in nearly 250 industry-sponsored clinical trials and cited in over 25,000 published scientific papers (Source: prnewswire.com), acquired Biofourmis's life-science business in January 2025, combining "ActiGraph's leading-edge, medical-grade LEAP wearable technology" with additional device categories including "ECG, pulse oximetry, spirometry, and blood pressure" monitors under one AI-driven digital trial platform (Source: prnewswire.com). Medidata built a comparable multi-device ingestion layer earlier, launching Sensor Cloud in February 2021 to standardize data intake from devices "that includes BioStamp, ActiGraph, and BioIntellisense" (Source: 3ds.com), a company executive projecting at the time that sensor usage in clinical trials would "surge up to 70% by 2025" (Source: 3ds.com), a forecast that should be read as a vendor projection made in 2021 rather than an independently confirmed 2025 outcome.

Regulatory precedent for using sensor data as a primary trial endpoint predates the pandemic. In a 2019 agreement, FDA endorsed actigraphy-measured moderate-to-vigorous physical activity as the primary endpoint in Bellerophon's pivotal trial for pulmonary hypertension associated with interstitial lung disease (Source: globenewswire.com), an early example of FDA treating wearable-derived data as regulatory-grade evidence rather than supportive-only information. More recent operational data corroborates that sensors can now match or exceed traditional data-collection reliability: a Phase 3B cystic fibrosis study managed by wearable-sensor specialist VivoSense achieved "99% data availability and 94% wear compliance," a result strong enough that "no further patient recruitment was required" to compensate for missing data (Source: dimesociety.org) across 200 devices deployed at 18 global sites. A separate peer-reviewed case study describes the FDA-cleared Current Health wearable platform serving as "a continuous remote patient monitoring technology that supports hospital-at-home care and is used as a data collection tool" in a fully virtual COVID-19 clinical study (Source: formative.jmir.org).

Sponsor-side adoption data reinforces that RPM is being used to reduce trial burden, not merely to collect novel data types. AstraZeneca's review of 91 clinical trial protocols found that "74 to 85% of trial assessments could be successfully collected remotely using clinically validated devices," which the company estimated "could reduce the number of physical visits to the clinic by up to 40%" (Source: astrazeneca.com). Applied to a chronic obstructive pulmonary disease (COPD) trial using at-home spirometry, AstraZeneca's "Unify" digital platform is projected to "reduce treatment duration and the number of in-person visits by 50%, and lead to a 15% reduction in overall trial duration, a 32% reduction in costs" (Source: astrazeneca.com), figures the company presents as projections rather than completed, independently audited outcomes. Sanofi, for its part, reports having "implemented digital components across 100% of their trials" (Source: clinicalleader.com), and defines the resulting digital biomarkers as "objective, quantifiable measures of physiology and/or behavior used as indicators of biological, pathological processes or responses to exposures or interventions" derived from those devices (Source: clinicalleader.com).

Risk-Based Quality Management Becomes the Operating Model

Running trial oversight across dozens of remote sites, home visits, and device streams is only tractable if sponsors abandon the older model of verifying essentially all trial data on-site, in person. That is the function of **risk-based quality management (RBQM)**, sometimes called risk-based monitoring (RBM): a set of centralized, statistically driven techniques for identifying which sites, participants, or data points most warrant scrutiny, rather than exhaustively checking everything.

The industry consortium **TransCelerate BioPharma** pioneered the modern RBM approach, establishing its Risk-Based Monitoring Initiative in 2012 "as one of TransCelerate's five initial projects designed to create efficient and effective solutions in the R&D industry" (Source: transceleratebiopharmainc.com). Its foundational 2013 position paper undercut the industry's prior reliance on exhaustive source data verification (SDV), reporting that critical-data queries generated through SDV amounted to only a small fraction, about 2.4%, of the total query volume (cqaf.org, meaning nearly all of the effort spent on manual SDV was catching very little that mattered. That data underpinned TransCelerate's recommendation to shift "monitoring processes from an excessive concentration on Source Data Verification to comprehensive risk-driven monitoring" using centralized statistical indicators instead (cqaf.org. TransCelerate's current DCT-adjacent effort, the Modernizing Clinical Trial Conduct initiative, extends that logic to hybrid designs, explicitly "supporting efforts to blend patient-friendly decentralized methods with traditional methods to make participation more accessible and flexible" (Source: transceleratebiopharmainc.com).

RBQM has since been incorporated into ICH E6(R3): as noted above, the guideline lists "advancing quality by design and risk-based quality management in trial conduct and oversight" among its core updates (Source: fda.gov). This reinforces RBQM as an internationally harmonized GCP approach, while its legal status depends on how each jurisdiction implements the guideline and on applicable laws and regulations. Software vendors have built dedicated RBQM modules to operationalize it: **Signant Health**'s Study Oversight and RBQM product lets sponsors "select, define, and track quality indicators to drive targeted study monitoring and central monitoring activity based on TransCelerate, MCC [Metrics Champion Consortium], or in-house risk indices" (Source: signanthealth.com). RBQM specialist **CluePoints** cites Tufts CSDD data to argue the underlying problem has only worsened, pointing to "a 68% rise in procedures per patient, an 88% surge in data volume, and twice as many countries involved per study" between 2005 and 2015 as trial complexity outpaced traditional monitoring capacity (Source: cluepoints.com). CluePoints also cites an analysis of FDA marketing-submission first-cycle review failures between 2000 and 2012 finding that "one-third (32%) of all first-cycle review failures, representing 16% of submissions overall, were due to quality issues" (Source: cluepoints.com), and reports that sites using its own RBQM platform "show a 46% improvement in data quality compared to comparator studies, consistently across all therapeutic areas and phases" (Source: cluepoints.com), a figure that, as a vendor-published result, should be read alongside independently audited benchmarks where available rather than taken as an industry-wide norm.

The practical link between RBQM and DCTs is direct: once trial activities are dispersed across patients' homes, local pharmacies, and remote nurses rather than concentrated at a handful of investigator sites, centralized, indicator-driven oversight is often important for effective oversight because traditional on-site SDV may be impractical at scale. The appropriate monitoring approach remains subject to the protocol, risk assessment, and applicable legal and regulatory requirements. This is why nearly every major eCOA and eConsent platform reviewed in this report, including Signant Health, Medidata, and CluePoints, now bundles or partners for RBQM functionality rather than treating it as an optional add-on.

Hybrid Trial Design Becomes the Default

Perhaps the clearest technology-strategy trend of 2024 to 2026 is that sponsors have converged on **hybrid trial models**, meaning some decentralized elements layered onto a still-substantial site-based structure, rather than fully virtual, site-less trials of the kind Pfizer and Science 37 originally pioneered. P&S Intelligence estimates that hybrid trials hold a 60% share of the DCT market in its 2026 market analysis (P&S Intelligence; this is a market-research estimate, not a registry-based count of all trial designs.

Pfizer, whose 2011 REMOTE trial was among the first fully virtual pilots, has since repositioned around a deliberately hybrid "Clinical Trial Anywhere" strategy, stating plainly, "We want to bring the clinical trial to participants" through a mix of remote sample collection, local pharmacies, home health visits, and mobile units rather than a single all-remote design (Source: pfizer.com). The company reports that "about 90% of Pfizer's participants complete a clinical trial, compared to the industry average of about 75%" under this hybrid approach (Source: pfizer.com), though as a company-reported figure without a cited independent comparator study, it should be treated as a directional claim rather than a peer-reviewed benchmark.

Industry surveys corroborate that hybrid, not fully virtual, has become the operative model. GlobalData's clinical trials database was tracking 16,076 decentralized clinical trials worldwide "at various stages, from planned to completed," spanning 9,291 drugs and 9,108 companies at the time of a late-2024 trade-press analysis (Source: medicaldevice-network.com), and a companion GlobalData survey found 74% of respondents believed decentralized elements "will be most frequently used in the next one to four years" (Source: medicaldevice-network.com), a forward-looking figure consistent with hybrid rather than fully decentralized adoption. Persistence Market Research similarly reports that "industry surveys show that 79% of decentralized studies utilize eCOA/ePRO technologies" (Source: persistencemarketresearch.com), underscoring that eCOA and ePRO, rather than fully remote site elimination, remain the most commonly adopted decentralized components. Not every hybrid pilot succeeds: Novartis, at the request of Sweden's Medical Products Agency, ran a hybrid DCT for an alpelisib/fulvestrant advanced breast cancer trial but "made the decision to stop this trial early after 2 participants had joined," attributing the failure to a "lack of awareness among hospital staff and researchers regarding the benefits of this hybrid DCT" (Source: novctrd.com) (Source: novctrd.com), a case discussed further below that illustrates hybrid design is not a guaranteed operational fix.

Implementation Considerations and Process Changes

Sponsors evaluating or expanding a DCT technology stack face a distinct set of implementation questions beyond simple vendor selection. First is **integration scope**: whether to adopt a single converged platform (Medable, Castor, THREAD) or layer specialist point tools onto an existing CTMS and EDC investment (as Veeva and Medidata customers typically do). Point-solution stacks generally carry higher integration overhead but preserve flexibility to swap individual components; converged platforms reduce integration risk but increase vendor lock-in, a tradeoff sponsors must weigh against their existing enterprise software commitments.

Second is **regulatory jurisdiction planning**. Because eConsent legality is not uniform globally, with Parexel's analysis flagging China, Taiwan, Hong Kong, and South Africa as jurisdictions currently lacking enabling e-signature regulations (Source: parexel.com), global multi-region trials cannot assume a uniform DCT technology configuration across all countries. Sponsors running trials spanning the United States, European Union, and United Kingdom must additionally reconcile several only partially aligned compliance timelines, summarized in *Table 2* below.

Table 2 below summarizes the current status of the principal regulatory documents governing decentralized trial conduct in the United States, European Union, and United Kingdom as of August 2026.

DOCUMENT	ISSUING BODY	KEY DATE(S)	STATUS AS OF AUGUST 2026
Digital Health Technologies for Remote Data Acquisition in Clinical Investigations	FDA	Final: December 22, 2023 (Source: hhs.gov)	Final FDA guidance; nonbinding recommendations
Conducting Clinical Trials With Decentralized Elements	FDA	Final: September 18, 2024 (Source: govinfo.gov)	Final FDA guidance; nonbinding recommendations
Part 11 Electronic Systems, Records, and Signatures in Clinical Investigations	FDA	Final: October 1, 2024 (Source: cooley.com)	Final FDA guidance; nonbinding recommendations. 21 CFR Part 11 itself is binding where applicable.
ICH E6(R3) Principles and Annex 1	ICH / EMA / FDA	Adopted January 6, 2025 (Source: database.ich.org); EU effective July 23, 2025 (Source: ema.europa.eu)	In effect in EU; no formal US compliance date as of September 2025 (Source: acrpnet.org)
Recommendation Paper on Decentralised Elements in Clinical Trials (version 2)	European Commission / CTAG	Endorsed October 15, 2025; published October 29, 2025 (Source: health.ec.europa.eu)	In effect
ICH E6(R3) Annex 2 (decentralized and pragmatic trial designs)	ICH / EMA	Step 4: June 3 to 25, 2026 (Source: ema.europa.eu)	Not yet legally effective in the EU; legal effective date: January 15, 2027
Decentralised Trial Methods Position Statement	UK Health Research Authority	Updated April 28, 2026 (Source: hra.nhs.uk)	In effect

As *Table 2* shows, the United States and European Union have each finalized core decentralized-trial guidance, but the EU's decentralized-specific ICH E6(R3) Annex 2 will not become legally effective until January 15, 2027, and FDA has yet to publish a formal compliance date for E6(R3) overall. Sponsors running concurrent US, EU, and UK trials should identify the applicable statutes, regulations, and jurisdiction-specific requirements for their trials, and use final agency guidance as the agency's current recommended approach, rather than assuming a single global compliance date.

Third is **device and endpoint validation**. FDA's Digital Health Technologies guidance recommends that sponsors select and evaluate DHTs for their specific intended trial use rather than assume off-the-shelf suitability (Source: hhs.gov), while the UK HRA position statement describes UK expectations that sponsors "assess, verify and validate the technology, methodology and usability of any novel digital" tool before deployment (Source: hra.nhs.uk). Sponsors should plan for evaluation and validation activities appropriate to the device, endpoint, trial, and applicable legal requirements.

Fourth is **data-architecture planning for RBQM**. Since decentralized trial data arrives from dispersed, heterogeneous sources (home devices, local labs, telehealth visits, mobile ePRO entries) rather than a handful of investigator sites, sponsors must build or buy centralized data-aggregation and risk-indicator infrastructure before, not after, decentralizing trial conduct; retrofitting RBQM onto an already-running decentralized trial is considerably harder than designing it in from protocol development. Finally, sponsors should budget realistically for build timelines: even with AI-assisted tooling

that vendors claim can compress build cycles, such as Medable's claimed 4 to 6 week eCOA study build versus a historical 16 to 20 weeks (Source: medable.com), validation, translation, and regulatory review of decentralized elements still add meaningful lead time relative to a conventional, purely site-based protocol.

Data Analysis and Evidence

Quantitative data on the DCT market splits into two distinct categories that are frequently conflated in industry commentary: market-size and growth forecasts from research firms, and empirical adoption or performance data from academic and CRO analyses. The two categories tell different, and sometimes contradictory, stories, and this report presents them separately.

On market sizing, estimates diverge substantially depending on how narrowly "decentralized clinical trials" is defined. **BCC Research** sizes the DCT market specifically at $8.8 billion in a 2024 base year, forecasting growth to $18.8 billion by 2030 at a 13.7% CAGR for the 2025 to 2030 period (Source: bccresearch.com). **P&S Intelligence** estimates the DCT market at $9.1 billion in 2025 and $10.2 billion in 2026, growing at a 13.0% CAGR during 2026–2032 to $21.4 billion by 2032; it also estimates hybrid trials at 60% share (P&S Intelligence. These are the firm's market-research estimates, with scope and methodology distinct from registry-based adoption measures. **The Business Research Company**'s DCT-specific report projects growth "from $8.77 billion in 2025 to $10.31 billion in 2026 at a compound annual growth rate (CAGR) of 17.7%" (Source: researchandmarkets.com), broadly consistent with BCC Research and P&S Intelligence despite different absolute figures. Using a broader definition, **Grand View Research** sizes the entire clinical trial technology and services market, spanning EDC, CTMS, and DCT tools together, at $25,723.9 million in 2024, projected to reach $60,813.8 million by 2030 at a 15.5% CAGR (Source: grandviewresearch.com), and the broader overall global clinical trials market (encompassing all trial services, not just technology) at $84.54 billion in 2024, rising to $158.41 billion by 2033 at a 7.5% CAGR (Source: grandviewresearch.com). At the narrower software-category level, **Mordor Intelligence** sizes the global eCOA solutions market specifically at $2.18 billion in 2025, growing to $2.52 billion in 2026 and $5.15 billion by 2031 at a 15.42% CAGR, with North America holding a 41.76% share and Asia-Pacific the fastest-growing region at a 16.29% CAGR (Source: mordorintelligence.com), while **Persistence Market Research** sizes the combined ePRO, e-patient diary, and eCOA market at $2.9 billion in 2026, growing to $7.9 billion by 2033 at a 15.3% CAGR (Source: persistencemarketresearch.com). Using a still broader definition that bundles eCOA with eSource and general clinical trial technology, **The Business Research Company** reports the combined market "has reached $51.15 billion in 2025" (Source: thebusinessresearchcompany.com), growing toward $81.46 billion by 2030 at a 9.8% CAGR. Readers should treat these figures as directionally consistent, DCT- and eCOA-adjacent markets are all growing at low-double-digit to mid-teens CAGRs, but not directly comparable, since each firm scopes its market boundary differently.

Table 3 below summarizes these divergent market-size estimates side by side.

RESEARCH FIRM	MARKET DEFINITION	BASE ESTIMATE	FORECAST	CAGR
BCC Research	Decentralized clinical trials (DCT), specific	$8.8B (2024)	$18.8B (2030)	13.7% (2025 to 2030) (Source: bccresearch.com)
P&S Intelligence	Decentralized clinical trials (DCT), specific	$9.1B (2025)	$21.4B (2032)	13% (2026 to 2032) (P&S Intelligence
The Business Research Company	Decentralized clinical trials (DCT), specific	$8.77B (2025)	$10.31B (2026) then $19.55B (2030)	17.7% then 17.3% (Source: researchandmarkets.com)
Grand View Research	Broad clinical trial technology and services (EDC, CTMS, DCT combined)	$25,723.9M (2024)	$60,813.8M (2030)	15.5% (Source: grandviewresearch.com)
Mordor Intelligence	eCOA solutions, specific	$2.18B (2025)	$5.15B (2031)	15.42% (Source: mordorintelligence.com)
Persistence Market Research	ePRO, e-patient diaries, and eCOA combined	$2.9B (2026)	$7.9B (2033)	15.3% (Source: persistencemarketresearch.com)
The Business Research Company	eCOA, eSource, and clinical trials technology combined	$51.15B (2025)	$81.46B (2030)	9.8% (Source: thebusinessresearchcompany.com)

As *Table 3* makes clear, buyers and analysts should always confirm a cited DCT market figure's precise scope before comparing it against another source; a headline "$50 billion market" figure and a headline "$9 billion market" figure can both be accurate simultaneously because they are measuring different boundaries of the same broader technology ecosystem.

Turning to adoption and performance data, the picture is more cautious than market-growth forecasts alone suggest. Tufts CSDD's February 2023 assessment, cited by industry researcher Kenneth Getz, found that "only 1% of industry-sponsored clinical trial starts are using DCT solutions" based on an IQVIA review of ClinicalTrials.gov listings (Source: appliedclinicaltrialsonline.com), a strikingly low figure relative to survey-based sentiment data. A 2021 Industry Standard Research survey, cited by IQVIA, found 83% of sponsors expected to increase DCT use within three years (Source: iqvia.com), and a 2022 ACRP survey of 291 clinical research site professionals found that "almost one-half of sites currently have no trials using DCT elements, with most others using such elements for only a small proportion of their trials" (Source: acrpnet.org), meaning intent to adopt DCT technology has consistently outpaced actual site-level deployment. More recent data suggests site-level readiness has since improved: a Tufts CSDD and Evinova global site survey, fielded in mid-2025 across 387 investigative site professionals representing roughly 275 distinct sites, found that "nearly 40% of sites have made investments in digital data capture tools and remote visit technologies" (Source: evinova.com), and a related trade-press write-up of the same survey found "75%+ of sites have experience using digital and remote trial solutions" (Source: appliedclinicaltrialsonline.com).

Where DCT elements are actually deployed, the measured operational impact is favorable. IQVIA's analysis of 12 DCTs compared with matched conventional trials found "average 78% reduction in time to first patient in, 54% reduction in protocol deviations, and a 26% reduction of non-enrolling trial sites" (Source: iqvia.com). Tufts CSDD's peer-reviewed economic model, published in Therapeutic Innovation & Regulatory Science, found that applying DCT methods across Phase II and Phase III development "the increase in value is $20 million per drug that enters phase II, with a seven-fold ROI" (Source: pmc.ncbi.nlm.nih.gov), driven substantially by reduced screen-failure rates and fewer costly protocol amendments; the underlying Tufts CSDD white paper details "a reduction of 27% in substantial protocol amendment filings for Phase II trials and a reduction of 6% for Phase III trials" (Source: dtra.org). Among specific decentralized components, "electronic outcome assessments (EOAs) were the most used DCT solutions supporting study visits, representing nearly 73% of clinical trials" in a July 2025 Tufts CSDD/PACT Consortium analysis of 69 global trials across 14 member organizations (Source: clinicalleader.com), confirming that eCOA remains the leading and most mature decentralized technology component in actual practice.

Despite this growing evidence base, Tufts CSDD's November 2025 review of the peer-reviewed literature found a persistent evidence gap: of "more than 16,500 articles published since 2022 on clinical trials executed with DCT component support, only 6% included qualitative or quantitative data" from surveys or actual trial performance (Source: csdd.tufts.edu). Tufts founded its PACT (Partnership for Advancing Clinical Trials) Consortium in 2024, "with funding from the Reagan Udall Foundation, Medable, and member companies," specifically to close that gap by gathering empirical evidence directly from member trials rather than relying on published literature alone (Source: csdd.tufts.edu). This gap between abundant vendor-published claims and scarce independently audited performance data is a recurring theme across the DCT technology stack and should inform how buyers weigh vendor marketing claims against academic or regulator-sourced evidence. Regional growth data outside the United States and Europe remains comparatively thin: P&S Intelligence's market report cites China's Center for Drug Evaluation figures showing 4,900 clinical trials registered in China in 2024, alongside a figure showing India's national telemedicine service eSanjeevani recorded over 400 million patient consultations by 2025, both offered as adjacent infrastructure indicators rather than DCT-specific counts.

Case Studies and Real-World Examples

Pfizer's REMOTE Trial (2011) and the Clinical Trial Anywhere Model

Pfizer's REMOTE trial for tolterodine extended release, an overactive-bladder medication, launched in June 2011 as what the company described as an entirely web-based randomized trial conducted under an FDA Investigational New Drug application, "allow[ing] patients to participate in the clinical trial regardless of their proximity to clinical sites" (Source: pfizer.com). Then-FDA official Janet Woodcock publicly commended "Pfizer's progress on the REMOTE pilot" and encouraged other manufacturers to explore similar approaches (Source: pfizer.com). The peer-reviewed results, published in 2014, illustrate both the promise and the recruitment challenge of a fully virtual model: against "a goal of 283 randomized participants, 5157 registered on the trial website" (Source: pubmed.ncbi.nlm.nih.gov), but "only 18 passed e-diary assessments and were randomized to treatment" (Source: pubmed.ncbi.nlm.nih.gov), a funnel drop-off of roughly 99.6% from registration to randomization. That early result helps explain why Pfizer's current strategy, branded "Clinical Trial Anywhere," is explicitly hybrid rather than fully virtual: "We want to bring the clinical trial to participants" through remote sample collection, local pharmacies, home health visits, and mobile units combined with a still-present site backbone (Source: pfizer.com), and the company now reports a roughly 90% participant completion rate compared with an industry average near 75% (Source: pfizer.com).

Novartis and Science 37: Expansion and a Cautionary Pilot

Novartis was among the earliest large pharmaceutical adopters of the fully virtual model, having "already initiated virtual trials for cluster headache, acne and nonalcoholic steatohepatitis (NASH)" with partner Science 37 before expanding the relationship in March 2018 to "initiate up to 10 new clinical trials over the next three years" (Source: novartis.com) (Source: novartis.com), positioning the company toward what it described at the time as a "site-less" model. That early enthusiasm was later tempered by a more sobering result: a subsequent Novartis hybrid DCT pilot for alpelisib combined with fulvestrant in advanced breast cancer, run in Sweden at the specific request of the Swedish Medical Products Agency, ended early after only two participants had enrolled, with Novartis's own sponsor results summary attributing the shortfall to "lack of awareness among hospital staff and researchers regarding the benefits of this hybrid DCT" (Source: novctrd.com). Read together, these two Novartis cases, one an expanding multi-trial program and the other an early-terminated single pilot, illustrate that decentralized and hybrid technology alone does not guarantee successful trial execution; site and staff change-management is as consequential as the technology stack itself.

Sanofi's Multi-Vendor Decentralized Trial Strategy

Sanofi has pursued decentralized trial technology through a succession of vendor partnerships spanning nearly a decade. In March 2017, shortly after Sanofi's venture arm had "helped raise $31 million for LA-based clinical research company Science 37" (Source: fiercebiotech.com), the two companies launched a virtual-trials offering intended to "reduce the time required for a typical trial by at least 30%" (Source: fiercebiotech.com). By January 2023, Sanofi had consolidated its DCT technology strategy around a single provider, announcing "its five-year collaboration with innovative global health care company, Sanofi," naming THREAD the sole DCT and eCOA technology provider for its global "Act4Patients" patient platform (Source: prnewswire.com). In parallel, Sanofi's vaccines division extended a separate collaboration with Medidata in February 2024 to expand eCOA and eDiary technology across its vaccine trial pipeline, following pilot results in which "pilots of eCOA were performed in six vaccine studies and demonstrated high levels" of feasibility (Source: businesswire.com). Sanofi's own digital-technologies group separately reports having "implemented digital components across 100% of their trials" (Source: clinicalleader.com), making it one of the more thoroughly documented multi-vendor DCT deployments among large pharmaceutical sponsors.

Curebase and the FDA Clearance of Regulora for IBS

Decentralized trial technology has directly supported at least one named FDA regulatory milestone. Decentralized-trial platform Curebase's technology was described as key to metaMe Health's FDA clearance of Regulora, characterized in trade coverage as "the first FDA-authorized treatment of any kind specifically for abdominal pain" related to irritable bowel syndrome (IBS), cleared in December 2021 (Source: clinicalresearchnewsonline.com). The supporting trial, run across 362 evaluable subjects using Curebase's remote infrastructure, reported that "68% of subjects assigned to Regulora reported overall satisfaction with the treatment" (Source: clinicalresearchnewsonline.com) alongside a minimal reported adverse-event rate, making this one of the clearer examples of decentralized trial infrastructure supporting an actual product authorization rather than only accelerating an intermediate trial milestone.

Signant Health and Shionogi's Pandemic-Era COVID-19 Trials

During the COVID-19 pandemic, Signant Health's SmartSignals eCOA platform supported Shionogi Pharmaceuticals' Phase II/III therapeutic trials across more than 90 sites in four countries, enabling "real-time tracking of patient-reported symptoms, blood oxygenation levels, and body temperatures" from participants' homes (Source: signanthealth.com). The remote infrastructure also compressed enrollment timelines during a rapid trial expansion, with Signant reporting new-country enrollment beginning within "only six weeks in South Korea following trial expansion" (Source: signanthealth.com). This case remains a frequently cited foundational example in current DCT vendor materials because it demonstrates eCOA infrastructure operating at true multi-country, multi-site scale under acute time pressure, a stress test few peacetime deployments have replicated since.

Eli Lilly and Care Access: Bringing a Trial Directly to Nursing Homes

In 2020, Eli Lilly partnered with decentralized-trial site network Care Access on what trade press described as a "first-of-its-kind decentralized, mobile trial to safeguard the health of patients in nursing homes" during the COVID-19 pandemic, testing a monoclonal antibody for COVID-19 prevention among a population unable to travel to conventional trial sites (Source: clinicalleader.com). Using a "Sites-On-Demand" model, the companies were able to "deploy this trial directly to a long-term care facility in late July," roughly six weeks after planning began (Source: clinicalleader.com), an operational speed that would have been effectively impossible for a conventional site-activation timeline and illustrates the mobile-deployment end of the decentralized technology spectrum, distinct from the software-only eConsent and eCOA examples discussed elsewhere in this report.

Implications and Future Directions

The regulatory picture through 2026 and into 2027 is one of incomplete but converging harmonization. FDA's core DCT, digital health technology, and Part 11 guidances are final, nonbinding guidance that states FDA's current recommendations; applicable statutes and regulations, including 21 CFR Part 11 where applicable, remain binding. The EU's Principles and Annex 1 of ICH E6(R3) are already in force, but the EU's decentralized-trial-specific Annex 2 does not become binding until January 15, 2027 (Source: ema.europa.eu), and FDA itself had not set a formal U.S. compliance date for E6(R3) as of the most recent trade-press coverage available (Source: acrpnet.org). Sponsors and technology vendors operating across US, EU, and UK jurisdictions should therefore expect a multi-year window in which country-specific compliance requirements diverge, rather than a single uniform global DCT standard, through at least early 2027.

Recent transactions and integrations indicate continued interest in combining DCT capabilities, but the available vendor announcements and market reports do not establish a market-wide preference for single-login platforms or predict further acquisitions. Sponsors should assess whether a converged suite or integrated specialist tools best fit their protocol, systems, jurisdictions, and operating model.

The evidence gap identified by Tufts CSDD, in which fewer than 6% of published DCT-related articles since 2022 contain empirical performance data (Source: csdd.tufts.edu), is likely to remain the single largest obstacle to broader adoption for at least the near term. Efforts such as the Tufts CSDD PACT Consortium, founded in 2024 specifically to gather empirical, cross-sponsor evidence directly from member trials rather than relying on vendor case studies or published literature alone (Source: csdd.tufts.edu), represent the most likely near-term source of independently credible adoption and performance benchmarks, and sponsors evaluating DCT technology investment should watch its output closely rather than relying solely on vendor-published case studies of the kind cited throughout this report.

Risk-based quality management is likely to become increasingly important as decentralized elements expand. ICH E6(R3) incorporates quality-by-design and RBQM principles, but its legal effect depends on jurisdictional implementation and applicable laws and regulations; it does not itself establish a universal obligation for every decentralized trial to use one particular monitoring model. Sponsors should assess whether centralized, indicator-driven monitoring is appropriate to their protocol, data sources, and risk assessment. Finally, P&S Intelligence's 2026 market analysis

estimates hybrid trials at 60% share (P&S Intelligence, while Tufts CSDD's ClinicalTrials.gov analysis found a still-low single-digit share of industry-sponsored trial starts using DCT solutions. Because these measures differ in scope and methodology, they should not be read as directly comparable. Together, they support a cautious expectation of continued growth in hybrid, eCOA-and-televisit-centric designs rather than a wholesale shift toward fully site-less trials of the kind Pfizer and Science 37 originally pioneered in 2011.

Frequently Asked Questions (FAQs)

What is a decentralized clinical trial? A decentralized clinical trial is a study in which some or all trial activities take place away from a traditional investigator site, using mechanisms FDA defines as "telehealth visits with trial personnel, in-home visits with remote trial personnel, or visits with local health care providers" (Source: fda.gov). FDA's regulatory expectations do not change based on this design choice (Source: govinfo.gov).

Which decentralized clinical trial software vendors lead the market as of 2026? Medable, Signant Health, Castor, THREAD, Veeva Systems, Medidata, IQVIA, and ICON plc are the most frequently cited platform vendors, alongside device and logistics specialists such as ActiGraph, VivoSense, Illingworth Research Group, and Cardinal Health, as detailed in *Table 1* above.

What regulatory guidance governs decentralized clinical trials in the US and EU as of 2026? In the US, FDA's final "Conducting Clinical Trials With Decentralized Elements," Digital Health Technologies, and electronic-systems guidances state FDA's current nonbinding recommendations. Sponsors must separately comply with applicable statutes and regulations, including 21 CFR Part 11 where applicable. The EU relies on the European Commission's updated Recommendation Paper on decentralised elements (October 29, 2025) and ICH E6(R3), whose decentralized-specific Annex 2 will become legally effective in the EU on January 15, 2027 (Source: ema.europa.eu). *Table 2* above summarizes the full timeline.

What is the difference between eConsent, ePRO, and eCOA? eConsent is the electronic collection of informed consent. eCOA (electronic clinical outcome assessment) is the broader category of digitally captured outcome data, and ePRO (electronic patient-reported outcomes) is one subtype within it, since "ePRO systems are a type of eCOA" (Source: signanthealth.com).

How common are hybrid clinical trial models among pharma sponsors? Hybrid designs, combining decentralized elements with a site-based backbone, are a leading model. P&S Intelligence estimates that hybrid trials hold 60% of the DCT market in its 2026 market analysis (P&S Intelligence; this is a market-research estimate rather than a count of all sponsor trials. Persistence Market Research also cites industry surveys reporting that 79% of decentralized studies use eCOA/ePRO technology specifically (Source: persistencemarketresearch.com).

Is remote patient monitoring data acceptable to regulators as a clinical trial endpoint? Yes, with validation. FDA endorsed actigraphy-measured physical activity as a primary trial endpoint as early as 2019 (Source: globenewswire.com), and FDA's Digital Health Technologies guidance formalizes selection and validation expectations for such devices (Source: hhs.gov).

What is risk-based quality management in the context of decentralized trials? RBQM is a centralized, statistically driven approach to trial oversight that replaces near-total on-site source data verification with targeted, indicator-driven monitoring, a shift TransCelerate began advocating in 2013 (cqaf.org and which ICH E6(R3) has since incorporated directly into the global GCP standard (Source: fda.gov).

Conclusion

The decentralized clinical trial technology stack has, over roughly fifteen years and one global pandemic, moved from an experimental pilot format to a codified, regulator-endorsed component of standard clinical trial design. As of August 2026, the technology layer includes converged platforms and interoperable specialist tools, with Medable, Signant Health, Castor, THREAD, Veeva Systems, Medidata, IQVIA, and ICON plc among the prominent vendors. Across these vendors, capabilities include eConsent, eCOA and ePRO, telehealth, and connected-device data; the components and degree of integration vary by vendor rather than forming one uniform unified system. The regulatory framework governing that stack has simultaneously matured: FDA's DCT, digital health technology, and Part 11 guidances are final statements of the agency's current, nonbinding recommendations, while applicable statutes and regulations—including 21 CFR Part 11 where applicable—supply binding US obligations. The EU has adopted both an updated recommendation paper and the core of ICH E6(R3), and the UK's HRA has issued its own position statement, although Annex 2 will become legally effective in the EU on January 15, 2027; that date alone does not establish full jurisdictional harmonization.

What the data makes clear, however, is that adoption remains more cautious than the technology's availability or the market's growth projections might suggest. Actual fully decentralized trial starts remain a small minority of overall trial activity, hybrid designs anchored around eCOA and televisit dominate real-world deployment, and rigorous, independently sourced performance evidence remains scarce relative to the volume of vendor-published case studies. Sponsors evaluating this stack should weigh vendor claims against the smaller but growing body of peer-reviewed and consortium-based evidence, including Tufts CSDD's ongoing PACT Consortium research, budget for jurisdiction-specific compliance timelines that will not fully converge before 2027, and assess whether risk-based quality management and centralized, indicator-driven monitoring are appropriate for

the protocol, data sources, risk assessment, and applicable requirements. Named deployments from Pfizer, Novartis, Sanofi, Curebase, Signant Health, and Eli Lilly, spanning both clear successes and at least one instructive early termination, illustrate that the technology stack itself is now mature and regulator-endorsed; the harder remaining work lies in change management, site readiness, and building the independent evidence base that has so far lagged the pace of vendor innovation.

Tags: decentralized clinical trials, dct technology stack, econsent, epro, ecoa, remote patient monitoring, risk-based quality management, clinical trial software, hybrid clinical trials, fda dct guidance

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