Market Guide for Life Science E-Clinical Platforms

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Initiatives: Healthcare and Life Science Digital Optimization and Modernization

E-clinical platform vendors bundle applications and services into a single, integrated offering for running clinical trials. Life science CIOs seeking to improve trial speed, quality and resource utilization use should use this research to help with e-clinical platform selection decisions.

Overview

Key Findings

- E-clinical platforms support a wide range of point solution integrations that are focused on the clinical trial process, and offer a practical alternative to managing and integrating multiple clinical trial point solutions.
- E-clinical platforms vary greatly in level of integration, point solution types, deployment options, functionality and architecture maturity. As partners, platform vendors offer varying strengths with a wide range of service capabilities, competencies and solution components.
- Inconsistent quality, performance and features across various e-clinical solution offerings often complicate the CIO's decision to select a platform instead of licensing best-of-breed solutions individually.
- Contract research organizations (CROs) continue to acquire other CROs, site networks and software companies — expanding their e-clinical managed services and solutions into differentiating software as a service (SaaS) platforms.

Recommendations

Life science (LS) CIOs advancing healthcare and life science digital optimization and modernization should:

- Assess potential e-clinical platform vendors by ascertaining their strengths, weaknesses and overall fitness as a business partner. Look for vendors who are actively building enhancements and new features as signs of life, indicating the vendor's overall trajectory and fitness.
- Evaluate breadth and depth of clinical trial solutions, cost of upkeep, licensing and hosting options, and roadmap for future expansion by performing a thorough RFP process with business leaders. Consider both completeness of vision and ability to execute as indicators of vendor commitment to the space.
- Build an e-clinical platform assessment approach by seeking vendors that include the requisite architecture enabling ready integration with solutions both within trial operations and in adjacent clinical partner ecosystems. Ensure this strategy also supports composable architectures, ready-made data integrations and plug-in analytics solutions.

Market Definition

E-Clinical Platforms Enable Interoperative Trial Management

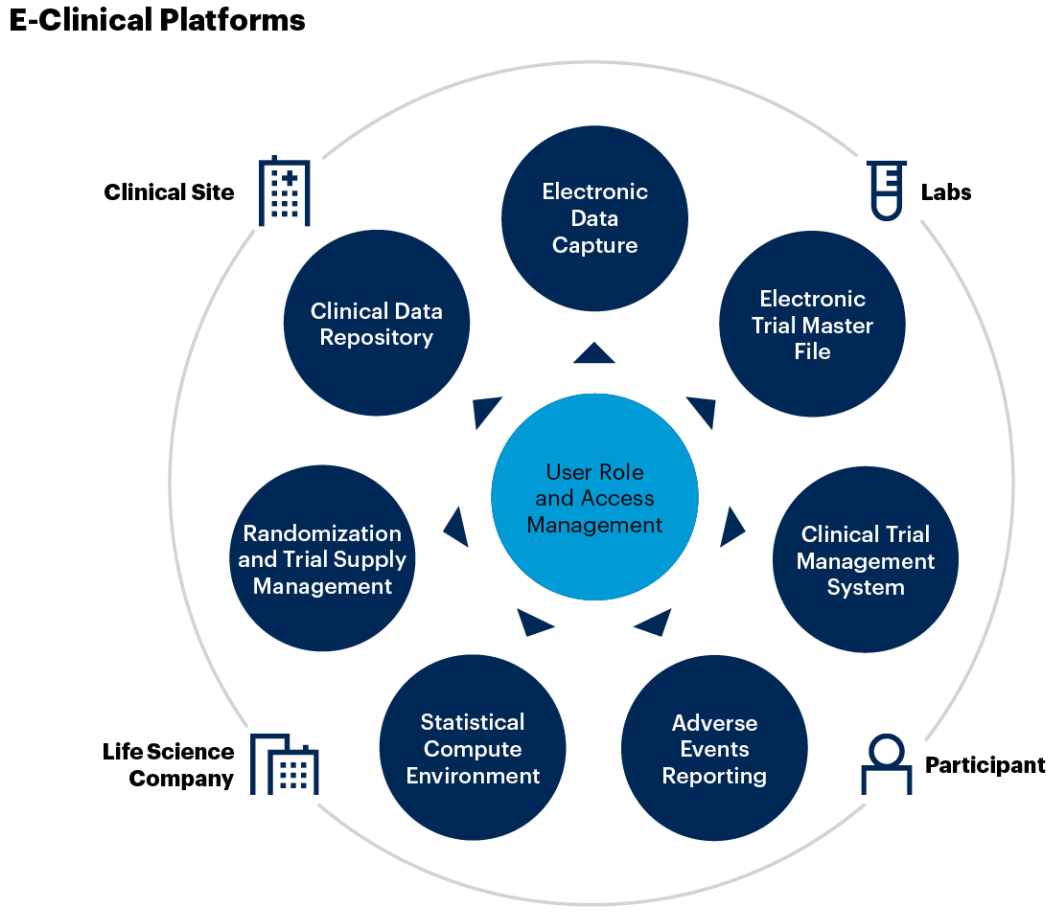
Gartner defines an e-clinical platform as an integrated suite of technologies connected in a platform architecture that provides services and solutions to manage clinical trial planning and execution. Modern e-clinical platforms are typically cloud-native environments, built either as SaaS, application platform as a service (aPaaS) or a combination. Integrated suites of point solutions exist primarily to support the setup and conduct of clinical trials (see Hype Cycle for Life Science Research and Development, 2021). These capabilities consist of integrated solutions used for:

- Trial planning, forecasting and feasibility
- Protocol design
- Electronic data capture (EDC)
- eConsent
- Clinical trial management systems (CTMS)
- Randomization and trial supply management systems (RTSM)
- Risk-based and centralized monitoring (RBM)
- Clinical data repository (CDR)

- Electronic Clinical outcomes assessment (eCOA)
- Statistical Compute Environment (SCE)
- Trial analytics and Reports
- Other capabilities that support trial operations

We define the primary components and solutions of the e-clinical platform in Figure 1.

Figure 1: E-Clinical Platforms



Source: Gartner
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Gartner

Market Description

E-Clinical Platforms Are Growing in Market Share and Feature Depth

The COVID-19 pandemic sent shock waves throughout the clinical trials community, with many canceled, delayed and challenged trials. As a result, LS companies are pursuing more effective digital technologies that enable trials to run unimpeded. The global clinical trials market is projected to have an annual compound growth rate (CAGR) of 5.1% through 2027, with this growth fueled by increasing prevalence of chronic disease and a growing market in developing countries. [1] E-clinical platforms and solutions supporting clinical trials should see a 14% CAGR over the next five years. [2] This growth will likely drive increased competition, innovation and solution optimization. Gartner expects that e-clinical platforms will continue to play a central role in LS development organizations.

For several years now, major e-clinical software vendors and large CROs continue to:

- Build out their platforms, both more deeply with expert features and more broadly, with new software services.
- Integrate the various clinical systems, selecting integrated data flows that solve client problems or further optimize trial execution.
- Develop service and support models to manage many varying customer scenarios.
- Expand services organically, and in some cases, partnering to extend capabilities.

With the ascendency of the cloud, existing vendors and service providers face an “adapt or perish” situation. The increased capabilities and features available in SaaS cloud systems, as well as the greater market share, have become particularly pronounced in the past several years, when compared to on-premises solutions. Cloud-native vendors such as Veeva Systems differentiate by offering a multitenant deployment option, while other vendors maintain an on-premises deployment option for clients not yet comfortable with cloud systems or hosted cloud environments. Vendors have made these decisions as part of a strategic approach toward cloud adoption and are not looking back (see Note 1).

An e-clinical platform will typically be broad enough to conduct the bulk of trial activities, including point solutions such as EDC, CTMS, and RTSM or interactive response technology (IRT) solution types. Other "narrower" platforms may have deeper capabilities in EDC and data management, including site-based and mobile solutions, such as electronic clinical outcome assessment (eCOA) and electronic patient reported outcomes (ePRO). Similarly, companies that specialize in trial operations may have CTMS, RBM and electronic trial master file (eTMF) solutions, with deeper capabilities in logistics involved in management of trials. This year, we have broadened our definition and included many vendors that have other application areas of focus, with EDC considered the primary clinical solution in scope (see Note 2).

Market Direction

E-Clinical Platforms Trend Toward Greater Integration

Technology has advanced considerably since many of the clinical point solutions that make up e-clinical platforms were first developed. Vendors built these first-generation solutions within the boundaries of various clinical departments, such as data management and trial operations, and these solutions were often designed based on paper-based workflow processes that transitioned to electronic systems. Today, the boundaries and capability of these point solutions can be limited by these origins in paper processes. The e-clinical platform provides an opportunity for IT leaders to rethink traditional solution boundaries, optimize trial processes by leveraging prebuilt integrations between various product types and build a platform that is greater than the sum of its parts. To meet these new optimization demands, e-clinical platform vendors are building next-generation solutions, with prebuilt integrations between platform components, such as:

- Integrating eTMF and CTMS data for a true voice of the customer (VoC) view for the clinical research associate (CRA).
- Autopopulating monitoring visit report data from multiple systems, including EDC.
- Mass intake of laboratory and electrocardiography (ECG) results using direct API data links or AI-assisted intelligent document processing (IDP) and PDF scraping technologies.
- Using protocol and trial design data to autoconfigure RTSM/IRT setup.
- Triaging of adverse events automatically from electronic case report forms (eCRFs) into PV systems, and autogenerating investigator notification letters for distribution on receipt of an adverse event from safety vigilance systems.

- Pulling field data from monitoring visit reports into trial analytics and risk-based monitoring systems.
- Integrating RTSM or IRT data with EDC to autocreate subjects, and with CTMS to record subject visit data.

We expect these new vendor platform-driven solution integrations to continue. These solution integrations provide new pathways to further optimize trial approaches, and enable discovery of key metrics to measure trial performance and quality. In addition to business value, CIOs must also consider the profound effect that e-clinical platforms have on their IT organization. This includes both reducing IT infrastructure needs and changing the way clinical IT supports trials, with many former IT support functions being migrated to business operation teams.

Market Analysis

E-Clinical Platform Benefits Continue to Expand

The cloud has been a fundamental enabler in the emergence of the e-clinical platform, facilitating the modernization of software features, convergence of point solutions and specialization of resources at platform vendors. Platform vendors that include only a few solution components will build out their platforms to provide the full suite of tools needed to support clinical trials (see Note 3). Platform vendors will offer new products such as data as a service, data insights as a service and machine learning (ML) with the aggregate lessons from multiple clients, among other offerings. We expect these new benefits to eventually exert more influence over LS CIO licensing decisions, as these accumulated platform benefits become impossible for IT and business leaders to ignore.

LS companies are increasingly adopting modern e-clinical platforms because they deliver value across a range of benefits, including:

- Single sign-on point of entry into the application platform, ensuring secure transactions and coordination among sponsors, investigators and other trial participants.
- E-clinical solutions (for example, CTMS, EDC, RTSM/IRT and eTMF) with prebuilt API connections, allowing transfer of data process signals and alerts between logically separated application environments.

- Clinical data repositories and reporting environments that access data from multiple systems, providing improved reports and dashboards that require very little coding to deploy from study to study.
- Study planning and study build environments that feed design elements into trial conduct environments, logically separating development, test and production phases, yet making study deployment a low-code process of a few mouse clicks.
- E-clinical data used as an asset, in which the platform vendors use anonymized data from many LS companies and trials to provide common insights, key performance indicators (KPIs), and standard metrics and benchmarks on trial performance.
- Master data management and investigator database solutions that provide common point of reference and "the golden record" for physician and site organization information and metrics, simplifying the task of trial investigator collection, maintenance and management.
- Prebuilt APIs and data gateways that enable faster and stronger connections with external entities such as clinical sites, regulatory authorities, clinical research organizations, central labs and other partner systems and services.
- Multitenant public cloud environments that enable faster global access of trial data, secure cloud architecture, improved uptime, scalable application and database resources, and robust system recovery.

Because of these enhancements, there are many choices when it comes to technology deployments, and the decision to go with a platform, composed of many solutions, runs contrary to the standard practice in clinical IT of selecting point solutions. This best-in-breed approach, defined as the selection of the best solution within a traditionally defined capability area, typically along department boundary lines, is the traditional upgrade strategy. However, as e-clinical platforms continue to mature and individual point solution capabilities within these platforms improve, Gartner expects the industry to reach an inflection point in several years. At that time companies select e-clinical vendors based on platform capabilities and utilize several solutions from each vendor. CIOs and their clinical leaders will make this multilayered decision in favor of e-clinical platforms based on the following benefits:

- **Reduced integration costs:** Platform vendors will continue to drive value by implementing new integrations, reducing middleware and paper-based handoffs within clinical development and with adjoining departments.

- **Reduced complexity:** The platform vendors manage the complexity of integrating multiple systems, simplifying the work IT must do in-house to connect systems and processes.
- **Ease of system support:** As platform vendors integrate and support various clinical systems, LS companies can reduce IT level support by a corresponding amount, often allowing these activities to be managed within business operations teams.
- **Cost advantage:** Maintaining on-premises infrastructure, managing multiple cloud vendors, purchasing middleware and building integrations can be costly for LS companies. These costs can be alleviated by use of platforms, which gain efficiencies of scale by managing systems for many clients.
- **Simplified management:** Platform vendors help to pool the risks for LS companies, as their systems support the operations for many companies — and their robustness and reliability is a primary business concern. Also, managing one or two platform vendors becomes simpler for IT than multiple internal systems or multiple e-clinical SaaS vendors.

This change will take several years as there are many differentiating features and capabilities of these vendors. Often platforms include weaker solutions that are bundled with the others, serving as an obstacle to overall platform adoption.

CROs Use eClinical Platforms as a Competitive Advantage

Gartner expects clinical research organizations (CROs) to continue to grow and take on more trial work, with some estimates indicating CRO growth doubling in size from 2019 through 2027. [3] The largest CROs are building their own clinical development platforms (see Table 2) that often consist of both clinical services and acquired vendor solutions. For example, the CRO IQVIA has made a number of acquisitions with the intent of building its own platform, IQVIA, including ACUTA, DrugDev, Foresight Group, Linguamatics, Pilgrim Quality Solutions, among others. CROs increasingly apply technology to the complex problem of trial optimization, and sell a combination of technology and services to help their clients run their trials. In contrast, last year Parexel made headlines by breaking off its technology division into a new software company, Calyx. [4] Other CROs choose instead to build their own best-in-breed platforms for trial operations, building market share and reputation based on their ability to conduct trials.

Many different shades of gray exist, with technology services vendors and consultancies, such as Accenture Life Sciences and Octalsoft, leveraging their own e-clinical platforms, made up of individual products that they own, and from partnerships with, other software vendors. These vendor platforms offer managed IT services to support LS companies in the conduct of their own trials, effectively offering the IT platform but not the CRO services, which must be managed internally by the sponsor. Similarly, many large consultancies, such as Cognizant, Tech Mahindra and Wipro, offer flexible staffing provider (FSP) services that provide a subset of trial services, although few provide a full platform for trial conduct.

The variations in solutions, CRO services, IT services, FSPs and managed cloud services that are available in e-clinical platforms create a dizzying market for buyers. When assessing these vendors, ensure there is clarity around the solution provided, such as who owns and updates the software, who is integrating these solutions into a platform and who is delivering the services, as applicable. For example, a major consultant shop may provide a platform that includes an amalgam of different solutions, integrating a vendor's RTSM, another vendor's EDC and a third vendor's CTMS with systems linked together using middleware, or an underlying low-code platform. Often the separate vendor applications are white-labeled by the CRO, with the end user unaware of the underlying application architecture.

Representative Vendors

The vendors listed in this Market Guide do not imply an exhaustive list. This section is intended to provide more understanding of the market and its offerings.

Market Introduction

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Table 1: Representative E-Clinical Platform Vendors — Software

(Enlarged table in Appendix)

Vendor	Solution Name
Advarra	Advarra EDC, OnCore, Clinical Conductor
Anju Software	eClinical Suite
ArisGlobal	LifeSphere Clinical
Axiom Real-Time Metrics	Fusion eClinical Suite
Calyx	Calyx
Castor	Castor EDC
Clario	Clario
Cloudbyz	Cloudbyz
CRScube	CRScube
Crucial Data Solutions	TrialKit Platform
Dacima	Dacima Products
Dassault Systèmes (Medidata Solutions)	Medidata Clinical Cloud
Datatrak	Datatrak Enterprise Cloud
DSG	eCaseLink
eClinical Solutions	elluminate
Ennov	Ennov Clinical Suite
Evado	Evado Clinical Trials
Flex Databases	Flex Databases
IBM Watson Health	IBM Clinical Development
Mednet	iMedNet
Medrio	Medrio
Oracle Life Sciences	Oracle Clinical One
Prelude Dynamics	VISION
Signant Health	Signant SmartSignals
SureClinical	SurePlatform
Veeva	Vault Clinical Suite
Viedoc	Viedoc Solutions
Vsoft Infoware	Clinical Trial Management

Source: Gartner (April 2022)

Table 2: Representative E-Clinical Platform Vendors — CRO and IT Service

(Enlarged table in Appendix)

Vendor	Solution Name
Accenture Life Sciences	INTIENT
Clinipace	Clarity
Fortress Medical Systems	Clindex
ICON	ICONIK
IQVIA	IQVIA Technologies
Labcorp Drug Development	Xcellerate Technology Suite
Medpace	ClinTrak
Octalsoft	Clinical Trial Management System
Prosoft Clinical	Prosoft Clinical Technology
Thermo Fisher Scientific (PPD)	PPD Technology

Source: Gartner (April 2022)

Market Recommendations

Adopt E-Clinical Platforms as Technology Partners

Consider the following recommendations when selecting e-clinical platform vendors:

- Assess the maturity of the e-clinical platform vendors' integrations between their point solution offerings. Your team should individually review each integration to fairly assess the business-level impact and change requirements of each enhanced feature. Ask these questions during vendor selection:
  - What types of integrations that add significant value, either by reducing trial cycle time or the full-time equivalent (FTE) effort, are required for trial tasks?
  - What integrations between point solutions are requested by business teams?

- Take stock of the platform's capabilities for interoperability, including APIs, services and the platform vendors' reliability as a partner. Platform interoperability with solution and service vendors in the LS ecosystem is a clear differentiator. For example, the ability of a platform to integrate with a third-party medical imaging vendor can save time and effort for trial support teams.
- Determine the platforms' weak points and frailties, both from a technology and functional perspective:
  - Your team should work with the business to assess each capability in consideration to determine the minimum features required by each corresponding platform solution to be considered for selection.
  - Your team should also work with the business to assess which platform features set it apart from the competition. It could be a specific "must-have" feature (or service) that differentiates the vendor from others. The business teams should consider solutions based on feature depth and breadth, and the IT teams should focus on vendor, deployment and composite value of the overall solution.
  - Ensure the platform vendor can be a responsible partner you can work with to help achieve multiyear objectives. You will want a partner that is willing to align their product roadmap to help meet your long-term goals.
- Collaborate with your IT team to move beyond best-in-breed approaches as the sole strategy for software selection by broadening your vendor selection process to include adjacent systems and adopting a more holistic platform strategy approach to selection.

- Partner with business teams to discuss when the use of a CRO platform or functional service provider platform might be considered, as this impacts longer-term IT strategy.
    - With more services available, due to the expansion of offerings from FSPs, the decision to augment existing capabilities can be an attractive option, allowing tighter control of spend during slack periods and faster expansion of capabilities when trial demand rises. Work closely with your business colleagues to anticipate opportunities as they typically will also have an IT component.
    - Remain open to considering CRO-owned solution vendors, as the combination of services and solutions can lead to business efficiencies that are often hard to quantify.

Evidence

[1] Clinical Trials Market Size, Share and Trends Analysis Report by Phase (Phase I, Phase II, Phase III, Phase IV), by Study Design (Interventional, Observational, Expanded Access), by Indication, and Segment Forecasts, 2020-2027, Grand View Research.

[2] Global eClinical Solutions Market to Witness 14.0% CAGR During 2020-2025, Attaining the Market Size of USD 13.4 Billion by 2025, VynZ Research.

[3] U.S. CRO Market Tipped to Double in Size, Outsourcing-Pharma.

[4] Parexel Completes Separation of Parexel Informatics and Medical Imaging Business, Parexel.

Note 1:
Representative Vendor Selection

The vendors named in this Market Guide were selected to represent capabilities within the core categories of e-clinical systems as discussed in the Market Description section. We list representative vendors in this Market Guide that were identified through secondary Gartner research and vendor briefings to Gartner analysts, or were vendors in which Gartner has received client interest (such as searches on gartner.com and inquiries).

Note 2:
Gartner's Initial Market Coverage

This Market Guide provides Gartner's coverage of the market and focuses on the market definition, rationale for the market and market dynamics.

Note 3: Clinical Trial Technology Categories

Table 3: Clinical Trial Technology Categories

(Enlarged table in Appendix)

Document Revision History

Market Guide for Life Science E-Clinical Platforms - 28 October 2020

Market Guide for Life Science E-Clinical Platforms - 21 June 2019

Recommended by the Author

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Hype Cycle for Life Science Research and Development, 2021

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Quick Answer: How Can Life Science CIOs Accelerate Remote Audit Adoption?

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

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Cloudbyz	Cloudbyz
CRScube	CRScube
Crucial Data Solutions	TrialKit Platform
Dacima	Dacima Products
Dassault Systèmes (Medidata Solutions)	Medidata Clinical Cloud
Datatrak	Datatrak Enterprise Cloud
DSG	eCaseLink
eClinical Solutions	elluminate

Ennov	Ennov Clinical Suite
Evado	Evado Clinical Trials
Flex Databases	Flex Databases
IBM Watson Health	IBM Clinical Development
Mednet	iMedNet
Medrio	Medrio
Oracle Life Sciences	Oracle Clinical One
Prelude Dynamics	VISION
Signant Health	Signant SmartSignals
SureClinical	SurePlatform
Veeva	Vault Clinical Suite
Viedoc	Viedoc Solutions
Vsoft Infoware	Clinical Trial Management

Source: Gartner (April 2022)

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Thermo Fisher Scientific (PPD)	PPD Technology

Source: Gartner (April 2022)

Table 3: Clinical Trial Technology Categories

Perspective	Capabilities	Application Categories
Trial Strategy and Planning	■ **Clinical trial portfolio management** assists in analyzing and reporting clinical trial opportunities and performance across the enterprise so that investment decisions can be made objectively. It includes dashboards that offer a view of decision variables (such as risk, opportunity, resource allocation, cost, potential revenue performance and market acceptance) for all clinical trial efforts. It may incorporate simulation and project management functions natively or through integration with third-party software. ■ **Clinical trial resource planning and simulation** provides the ability to model various clinical trial scenarios to shape the protocol and determine the preferred approach for conducting a clinical trial. Simulations may examine scientific or operational options, along with their cost and timing implications. ■ **Protocol design and documentation development** refers to the creation of the study plan and associated documentation governing the conduct of clinical trials.	■ EDC ■ CTMS ■ Trial Simulation ■ Protocol Feasibility ■ Patient Curation

	■ **eCRF and CRF development** involves the design and development of the paper or electronic record used to capture clinical trial observations and other information required by the study protocol. It allows for feedback and lessons learned from previous protocols to be incorporated into improving protocol design. ■ **Study feasibility and recruitment planning** includes verifying trial subject availability using internal or third-party investigator databases, and trial enrollment planning and analysis tools. Recently, this has been better-informed by the availability of real-world data, enabling more promising investigators, locations and subjects to be selected for a particular protocol.	
Trial Resource Management	■ **Project management** components provide integrated support for defining and tracking clinical trial stages and milestones. It supports planning schedules, budgets and resources required to complete clinical trial programs, according to specified cost and time constraints. ■ **Trial performance** involves the collection and reporting of key performance metrics and detailed activity metrics during the course of	■ CTMS ■ Business Planning ■ CRO Performance ■ CTSM

clinical trials. It provides real-time or near-real-time visibility into project status and indications of potential problems (such as low site or subject enrollment and incomplete subject reporting). It allows for feedback and lessons learned from previous efforts to be incorporated into improving trial performance.

- **Financial management** refers to budget development and monitoring, and includes detailed cost simulations (as needed), as well as the allocation of infrastructure costs across clinical trials. It also involves collecting and reporting information on individual investigator reimbursement for clinical trial activities.
- **Investigator relationship management** provides a 360-degree view of investigators' relationships with trial sponsors. It includes collaboration with investigators to design trials, information on their performance during clinical trials and insight into their participation in other activities, such as key opinion leader forums or responses to direct marketing campaigns. It also includes e-learning tools for site coordinators and patients, and investigator portals for information sharing.
- **Clinical supply and tracking** processes involve the status, location and tracking of information

	on medications in the supply chain. CTSM systems cover activities such as distribution from depots to investigational sites, dispensing to subjects, inventory levels, and confirmation of return and destruction. Trial logistics and sample management is also included in this category. This is often managed by interactive response technology (includes interactive voice response system [IVRS]/interactive web response system [IWRS], RTSM, and trial logistics and sample tracking solutions).	
Trial Execution and Site Engagement	■ **Investigator recruitment** includes the creation of materials and the execution of campaigns to alert physician investigators about impending clinical trial programs. Awareness options include advertising, internet, email, phone and integration with electronic health records (EHRs). ■ **Subject recruitment and retention** involves the creation of materials and the execution of campaigns to alert subjects about impending clinical trials. Awareness options include advertising, internet, email, phone and integration with EHRs.	■ EDC ■ IRT/RTSM ■ eCOA and ePRO ■ Study Startup ■ eTMF ■ AERs ■ eTMF

- **Study and site startup** includes the processes involved in startup for a site such as contracts, study and site mandatory documents, site personnel identity management, training, and system setup tasks.
- **Subject enrollment and visit scheduling** is the screening and qualification of individuals to determine whether they are qualified to participate in the clinical trial and, if so, scheduling visits for participation.
- **Site monitoring** involves the monitoring of clinical study sites and site processes to ensure adherence to the study protocol, and the development of on-site and off-site visit reports, action items, issues, and deviation tracking to ensure compliant site operations and recording of trial data.
- **RTSM** processes involve the assignment of patients to control groups or treatment groups to remove bias and to coordinate trial supply kits and materials. This is often managed by IRT, IVRS, IWRS, and RTSM systems.
- **Subject activity monitoring** means tracking, analysis and reporting of subject activity during clinical trials, such as visit completion and reporting of patient-recorded outcomes.

	■ **EDC** involves the collection and validation of clinical trial information that is received from any combination of electronic sources, such as IRT, web interfaces, eCRF and remote data entry applications, and eCOA and ePRO. ■ **Safety reporting** is the ability to detect adverse events (AEs) and serious adverse events (SAEs) when they occur during the course of clinical trials, and to notify the appropriate personnel. Usually, this information is passed to a safety case processing system. ■ **Trial records management and archival** processes involve the tracking and management of site documents, site correspondence, monitoring visit reports, and other study records required to be retained as evidence of trial conduct in the eTMF system.	
Data Management and Analysis	■ **Clinical data management** is the input, storage, organization, quality control, compliance, search and access of content created during the course of clinical trials. It includes electronic and manual data entry, normalization, edit checking, query resolution, and auditing of trial data.	■ EDC ■ Clinical Data Repository (CDR) ■ Clinical Warehouse (CDW) ■ Statistical Compute Environment (SCE)

- **Clinical data review** involves the standardization and review of clinical trial data into submission-ready format, as well as making this data available for analysis and review to biostatisticians and clinical research managers.
- **Clinical study report development** involves the preparation of the report that summarizes the results and findings of a clinical trial.
- **Clinical trial statistical analysis** involves the preparation of the tables, graphs and reports by statisticians that enable clinicians to review the results of a clinical trial, usually prepared in an SCE.
- **Data warehousing and analytics** involves storing and accessing large volumes of clinical trial data and operations information, which may include data, documents and images, and making the data available in on-demand reports and interactive dashboards.
- **Application integration** is the transfer of information across the applications and tools used during clinical trials. Among other things, it includes alternative clinical trial data capture mechanisms (such as phone-based subject enrollment and laboratory systems),

	connections to EHR applications, and lab and ECG data imports.	
Other Support Systems	■ **Clinical trial collaboration tools** are the infrastructure that provides partners in the clinical trial network (including trial sponsors, CROs, investigator sites and labs) with the ability to communicate, find and share disparate types of information, and perform process steps that run the gamut of clinical trials. ■ **Clinical Data Interchange Standard Consortium (CDISC) standards support** is the adherence to CDISC models that define protocol, laboratory, analysis and submission datasets, as well as the exchange of clinical trial data. ■ **Training management** involves the creation and management of integrated online training (e-learning) for site personnel, investigators and trial subjects, and training certification, tracking and management. ■ **Portals for access and communications** are used for information exchange with partners, investigator sites and regulatory agencies.	■ E-Portals ■ CDISC Validator ■ LMS

Source: Gartner (April 2022)