April 2025

Opportunity for Improvement:

Performance of Clinical Trials Programs at Academic Medical Centers

A Report from the Center for Connected Medicine

Center for Connected Medicine

KLAS RESEARCH

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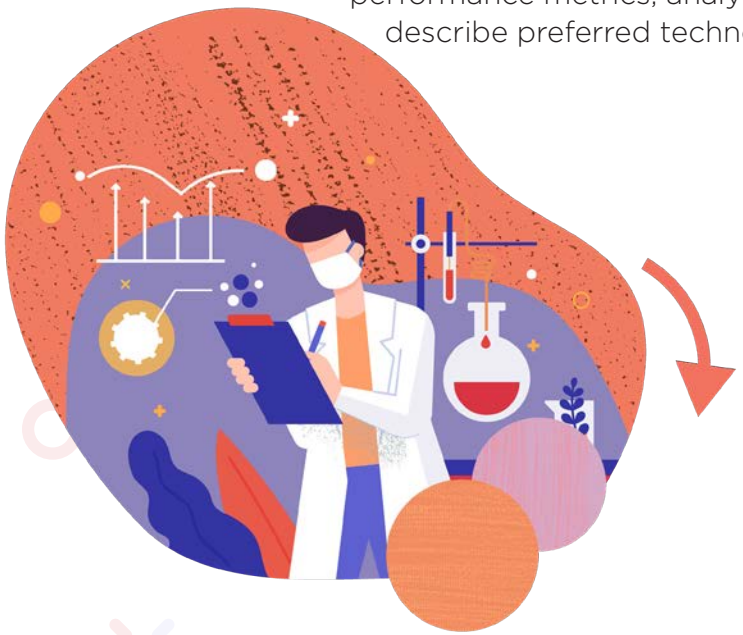
Introduction: AMCs Play an Essential Role in Advancing New Medicines

Clinical trials are essential for advancing medical knowledge, bringing new treatments to market, and ultimately improving patient care and outcomes. Conducting these trials is a complex, time-consuming, and expensive endeavor for the pharmaceutical and biotechnology companies that are typically the sponsors of this research.

Academic Medical Centers (AMCs) across the United States have traditionally hosted most clinical trials as they are epicenters for physician-researchers and patients. Despite these strengths, there are challenges for AMCs, including study approval times, ability to recruit and retain study subjects, and provide timely and complete data. These challenges have created opportunities for AMCs to deliver greater value to sponsors and cement their position as leading centers for studies.

With these opportunities in mind, The Center for Connected Medicine worked with KLAS Research to examine clinical trial programs at 17 AMCs to learn more about their organizational structures, technologies, performance, and finances. The three primary objectives of the survey of AMC sponsored clinical trial programs were to evaluate performance metrics, analyze financial performance, and describe preferred technology and automation.



There are some key takeaways and unified themes that came out of this research:

- **While most organizations have adopted a centralized approach to the management and oversight of clinical trials, their areas of responsibility vary widely with few clear functions that all AMCs perform.**
- **Times to study approval and full enrollment are slow, and technology adoption, which could aid in making operations more efficient, is uneven.**
- **Few AMCs are seeing growth in the number of trials they are able to secure and approve.**
- **A dearth of growth likely impacts profitability, which was low among the handful of organizations that shared financial information.**

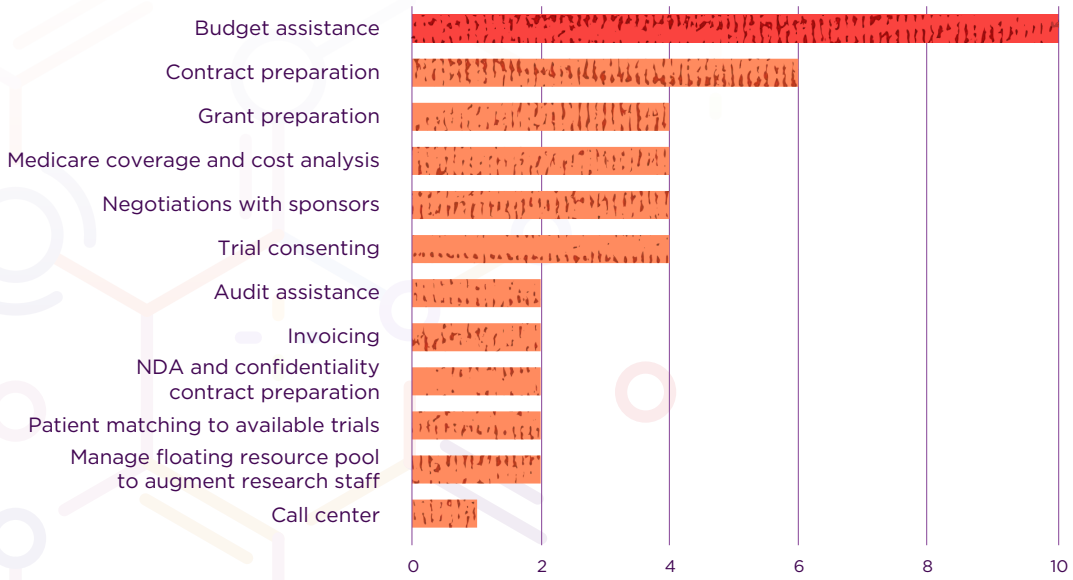
All of which adds up to significant opportunities for AMCs to improve and offer stronger service to study sponsors, which could lead to more trials that ultimately benefit patients.

Most AMCs Utilize a Centralized Clinical Trial Office

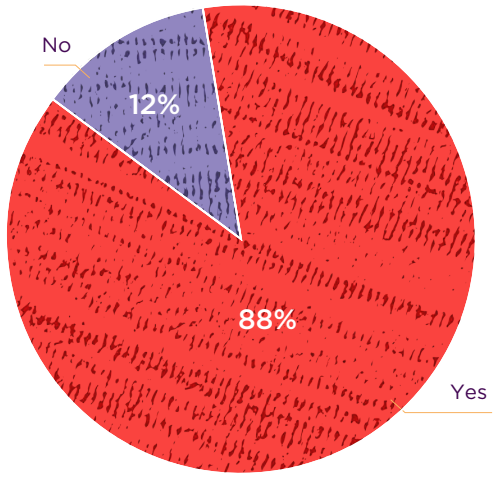
Nearly all 17 organizations surveyed for this report use a centralized clinical trial office to manage and oversee sponsored clinical trials. While these offices can play a crucial role in managing research studies through their full life cycle, from feasibility assessment to study closure, the scope of responsibility can vary greatly from organization to organization. Thirteen functions were cited by respondents as being handled by their clinical trials office, with only budget assistance being performed by the central office at more than half of organizations.

Ideally, the central office handles contracts, budgets, and compliance to ensure that all necessary protocols and regulations are followed. The centralized approach also can help maintain consistency and efficiency across various departments, giving sponsors a predictable and consistent experience with the AMC. To this end, some organizations have implemented concierge services to help investigators design and manage clinical trials. These services provide support in areas such as protocol development, budgeting, and compliance, further enhancing the efficiency of the clinical trial process. The integration of these services with the central office ensures that investigators receive comprehensive support throughout the trial.

What functions does your centralized clinical trial office perform? (select all that apply)



Does your organization use a centralized clinical trial office? (N=17)



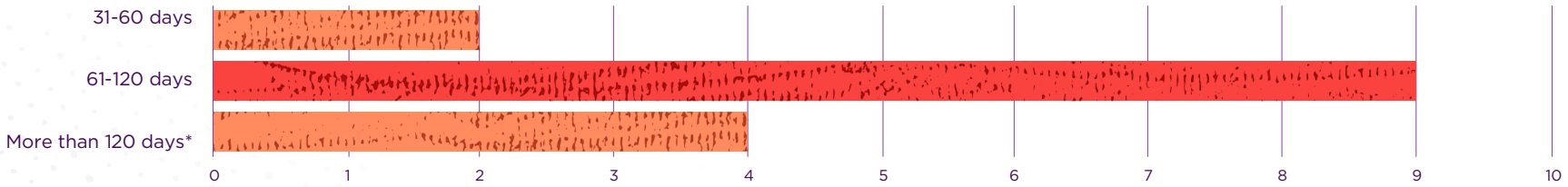
Contract Approval and Subject Enrollment Times are Frequently Delayed

The process of approving a study on average can take 61–120 days, or longer, from the initiation of the contracting process, according to the AMCs who participated in this research. Only two respondents stated that 60 days or less was their estimated average approval time. Also of note, about two-thirds of respondents (10 out of 16) stated that a study feasibility assessment is required as part of the approval process, and 70% (7 out of 10) said they include a sample size estimation.

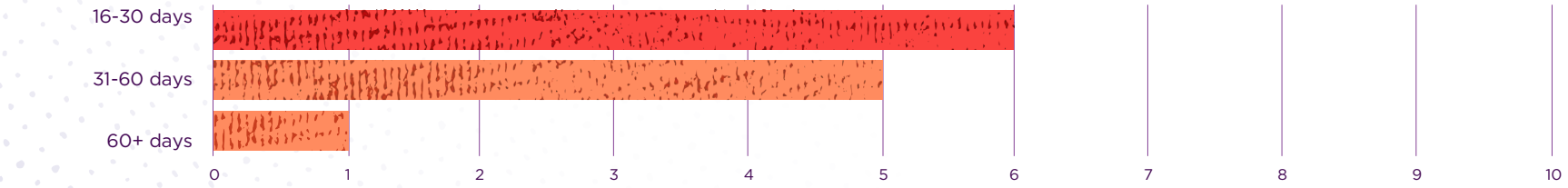
Most respondents (11 out of 12) said enrollment of the first subject into a study after approval takes an average of 60 days or less. But when asked if the enrollment times met expectations, more than half (9 out of 15) said that achieving full enrollment generally takes longer than they expected. While these delays can be due to the complexity of the trials, the specific patient populations being targeted for enrollment, the variability in study preparedness, and a challenging patient recruitment process, it is clear that improvement is needed in enrollment of study subjects.

Not only can enrollment take longer than expected but sometimes AMCs fail to enroll any patients, even a year following study approval, according to some organizations who participated in this research. This is particularly common with oncology studies, where the targeted patient population can be very specific and difficult to recruit. Even with patient recruitment platforms and real-world data platforms to identify and engage potential participants, the enrollment process remains a bottleneck for many clinical trials, highlighting the need for innovative solutions and processes in this area.

Estimated average number of days from initiation of study contracting process to approval of study (n=15)



Estimated average number of days from approval of study to enrollment of first patient (n=12)



Half of Organizations Reported Small Increase in Number of Studies in 2023

Of the eight AMCs that provided exact numbers or estimates, half experienced an increase in the number of trials submitted for approval at their organizations from 2022 to 2023. The other half held steady or declined. Many respondents reported a high approval rate for the studies submitted, however it should be mentioned that many of these numbers were estimates. It is further interesting to note that two of the organizations that reported a decline in studies submitted between 2022 and 2023 also did not have high approval rates in 2022.

Number of studies

Organization	2022		2023	
	Submitted	Approved	Submitted	Approved
Respondent 1	3	3	5	5
Respondent 2	40	40	52	51
Respondent 3	52	52	31	30
Respondent 4	91	78	68	49
Respondent 5	200	200	200	200
Respondent 6	265	237	292	264
Respondent 7	300	200	325	225
Respondent 8	300	300	300	300

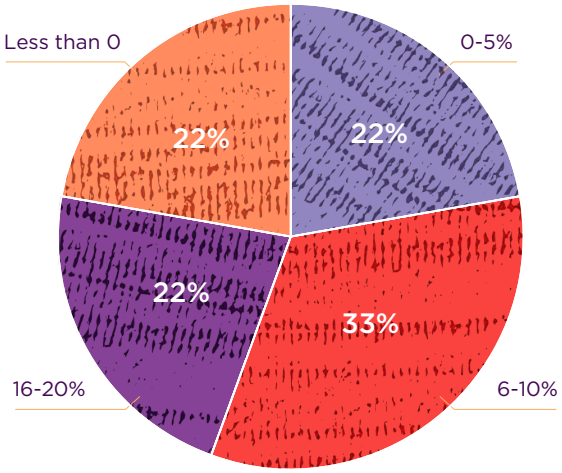
Note: The goal of this question was to assess overall clinical trial office approval volume; details including why studies were not approved, frequency of study withdrawals, types and phases of studies, and other information was not collected.

Financial Performance is Uneven at AMCs

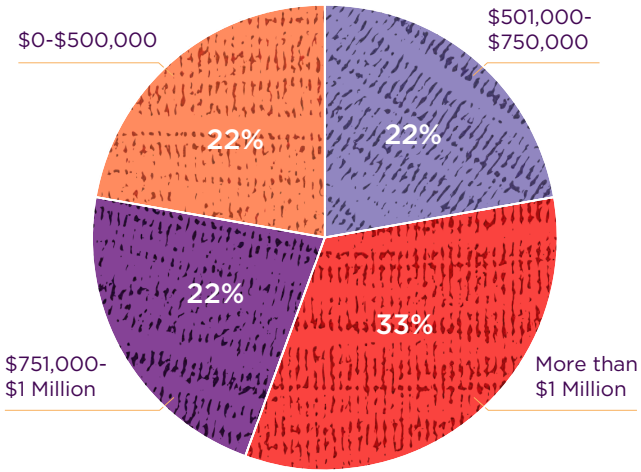
A handful of AMCs participating in this research agreed to share information about the financial performance of their sponsored clinical trial programs, providing ranges for total revenue, costs, and profit margin. While most respondents (9 out of 12) said their organizations are generating $50 million or less in annual revenue from clinical trials, program costs and profit margins were highly variable. Most respondents reported breaking even or earning a small margin on clinical trials, while two said their organizations lose money (see charts below).

Most respondents (12 out of 16) said their organizations do not offer investigators financial or other incentives. Of the four respondents who said yes to offering financial incentives, the offers were described as small, department-dependent amounts or portions of residuals accruing to development accounts. Half of respondents (5 out of 10) described the financial success of sponsored clinical trials programs as "neutral" and the other half as "moderately profitable."

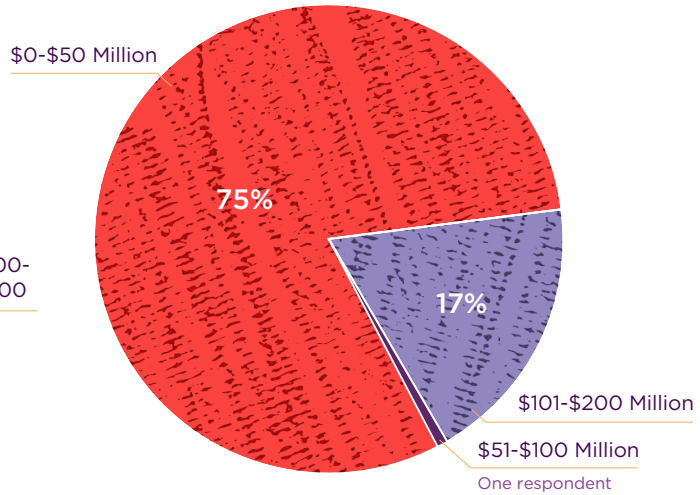
Estimated Profit Margin in 2023 (n=9)



Estimated Operating Costs of Central Contracting Office in 2023 (n=9)



Estimated Total Revenue from Sponsored Trials in 2023 (n=12)



The Most-Used Technology Solutions in Clinical Trials Programs

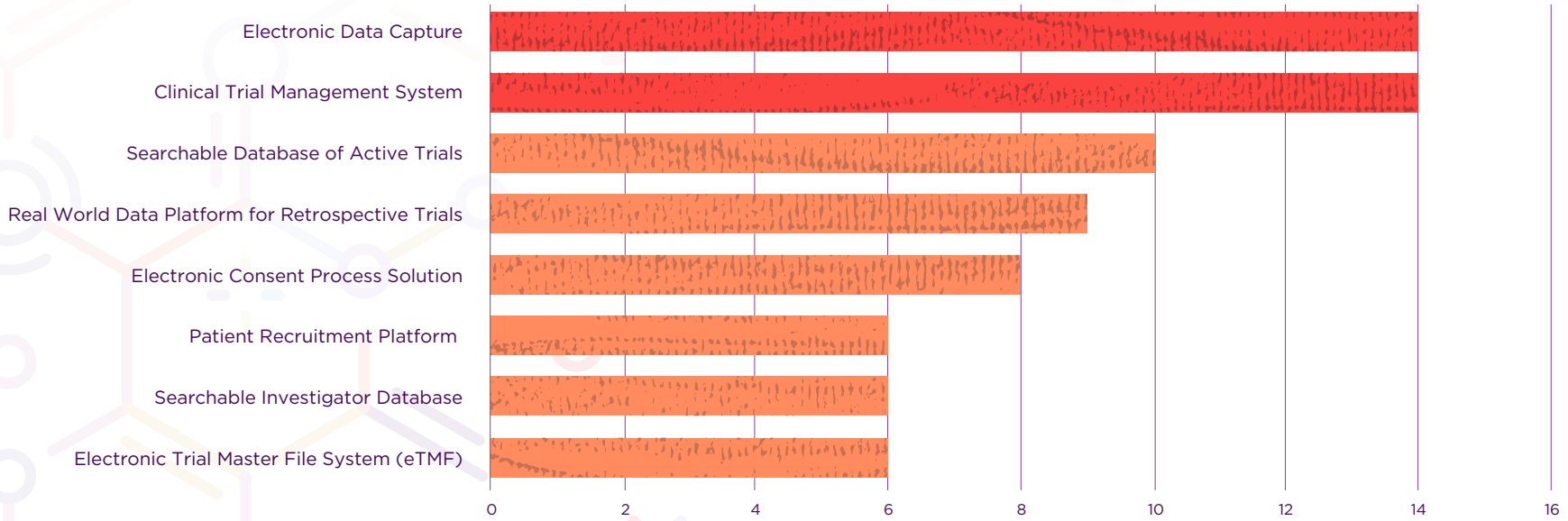
Electronic Data Capture (EDC) and Clinical Trial Management Systems (CTMS) were the two most commonly cited technology solutions used by AMCs participating in this research. Electronic Data Capture allows study managers to save time and money by streamlining data collection in a single system, increasing accuracy, security, and access. A Clinical Trial Management System maintains and manages planning and reporting functions over the life of a clinical trial, including participant contacts, deadlines, and milestones.

Respondents said these two technologies are especially critical to running clinical trials sponsored by pharmaceutical companies or federal agencies.

Respondents highlighted the elevated benefits of using a CTMS in conjunction with an EDC solution and noted the importance of having both systems well integrated with their electronic health record (EHR) research management solution. Such integration allows organizations to manage clinical trial workflows within their EHR, enables seamless data transfer, and reduces the need for manual data entry, thereby improving data quality.

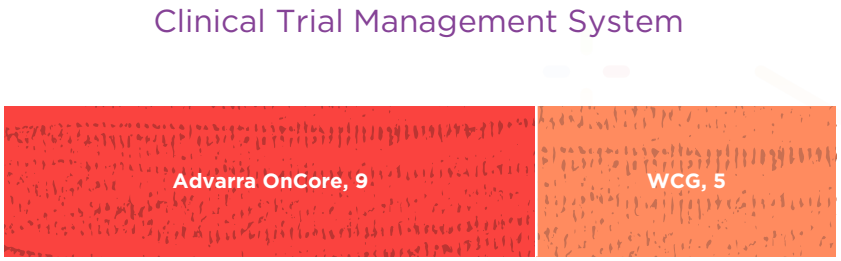
Other systems that can be helpful in improving trials, including searchable databases, real-world data platforms, patient recruitment platforms, and others are less uniformly adopted by AMCs.

Which solutions is your organization using to support clinical trials? (select all that apply)



Clinical Trial Management System — Vendors and Ratings

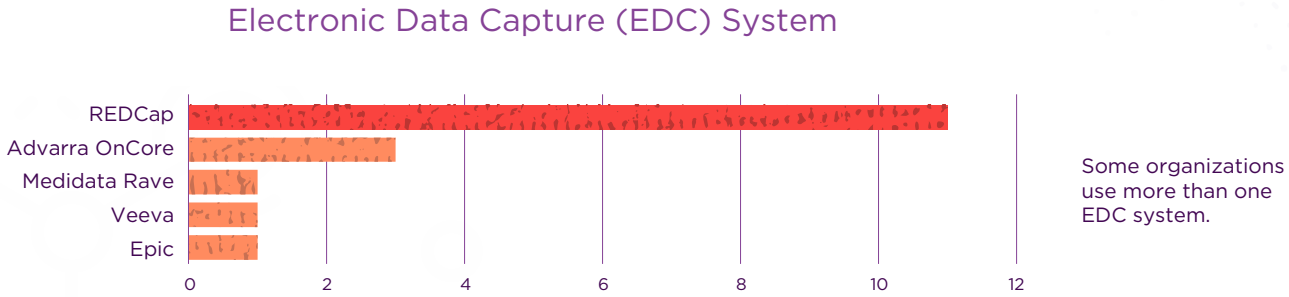
Advarra's OnCore system was the most-used Clinical Trial Management System, with WCG the second most-used. Both received a moderate satisfaction rating from users.



Vendor	Satisfaction Rating (1–5, 5 is very satisfied and 1 is very dissatisfied)	Comments
Advarra OnCore	3.3	• Broader suite of tools and integrations with Advarra acquisition of OnCore. • Reported issues with CCPay, solution used to compensate patients. • Growing pains from Advarra acquisition of OnCore. • Multiple respondents indicate opportunity to improve reporting.
WCG	3.5	• User friendly. • Vendor support responsiveness could be improved. • Frustrating EHR integration issues.

Electronic Data Capture — Vendors and Ratings

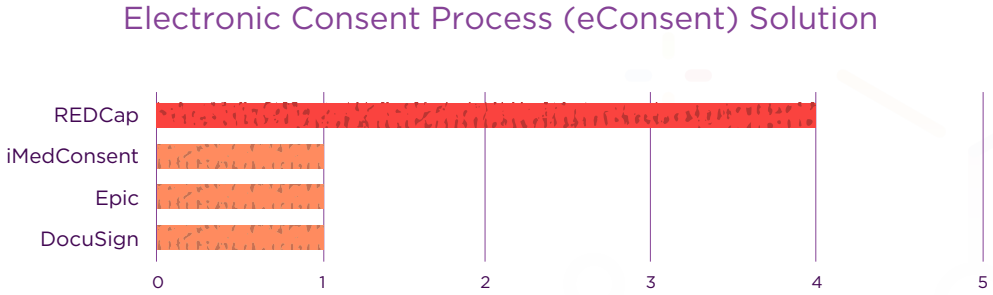
REDCap and Advarra's OnCore were the two most-used EDC systems by respondents' organizations. Both received higher satisfaction ratings than the most popular CTMS systems.



Vendor (Ordered most mentioned)	Satisfaction Rating (1–5, 5 is very satisfied and 1 is very dissatisfied)	Comments
REDCap	3.9	• Respondents split on ease of use, some report it is easy to use and some say product could more user friendly, especially when building new products. • Training could be improved. • "The customization can be more complex, which I think is typical for something that you are going to use in some ways off the shelf. You are not going to get your own sort of personalized, built-out, someone designed it for you EDC." • Customers wish it was 21 CFR compliant.
Advarra OnCore	4.3	• "Easy to use service." • Dissatisfaction with lack of direct interface between Epic and system. • Request for more automation. • One respondent indicated feeling nickel and dimed.

Electronic Consent Process — Vendors and Ratings

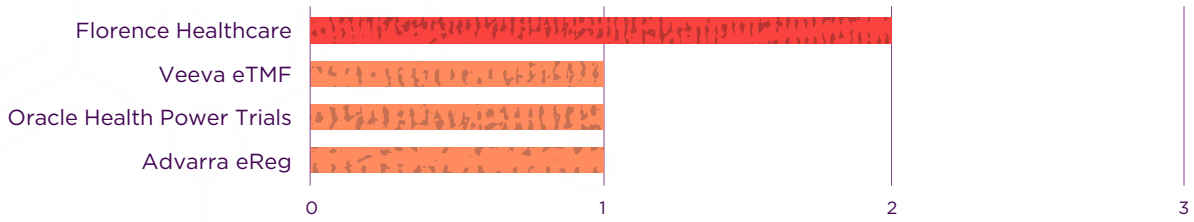
REDCap was the most popular eConsent solution, with a good satisfaction rating.



Vendor (Ordered most mentioned)	Satisfaction Rating (1–5, 5 is very satisfied and 1 is very dissatisfied)	Comments
REDCap	4.0	• Respondents appreciate the product flexibility and ability to create different templates that researchers can utilize to best fit study. • It performs necessary function of capturing/validating/timestamping signature well.
Epic	4.0	• Reported challenges with their eConsent tool in general.
iMedConsent	2.0	• Difficulty with audit process, customer indicated moving to Epic once they enhance offering.

Electronic Trial Master File — Vendors and Ratings

There was no strong consensus on the most popular solution for Electronic Trial Master File, with five respondents using four different solutions.



Vendor (Ordered most mentioned)	Satisfaction Rating (1–5, 5 is very satisfied and 1 is very dissatisfied)	Comments
Florence Healthcare	5.0	• Strong integration and available partnerships, they are the "Switzerland" of eTMF. • Savvy organization, strong implementation.
Advarra eReg	4.0	• User-friendly and meets needs of customer.
Oracle Health Power Trials	4.0	• EHR integration driving satisfaction.

Other Technology Solutions

Below are other vendors solutions that were cited in the categories of searchable trials database, patient recruitment platforms, real-world data platforms, other solutions.

Category	Vendor	Satisfaction Rating (1–5, 5 is very satisfied and 1 is very dissatisfied)	Comments
Searchable Database Containing All Active SCT	Advarra OnCore (3 mentions)	4.0	• Training is necessary for reporting and search functionality to get consistent and accurate results from system.
Patient Recruitment Platform	Epic (3 mentions)	4.0	• Granular controls and functionality. • Additional customization control requested by customers.
Searchable Database Containing All Active SCT	Epic (3 mentions)	3.7	• Training necessary to be able to extract historic data accurately.
Patient Recruitment Platform	TriNetX (4 mentions)	4.0	• Strong customer support. • Lots of available training resources.

Methodology

The Center for Connected Medicine contracted with KLAS Research to survey clinical trials leaders at academic medical centers (AMCs) about their organization's sponsored clinical trial (SCT) operations and administration. KLAS Research, which conducts regular survey research with health system leadership across the U.S., conducted a prospective telephone survey of clinical trial executives representing 17 AMCs from May through August 2024. The organizations ranged in size from one hospital to 51 hospitals. The leaders who participated had titles ranging from manager-level through C-suite executive, with nine respondents being vice president or C-Suite.

About the Center for Connected Medicine

The Center for Connected Medicine (CCM) at UPMC is defining the future of the modern health system through programming that informs, connects, and inspires leaders and innovators in health care. Collaborating with a network of experts from across the health care ecosystem, the CCM focuses its research and events on consumer-centered solutions, digital transformation, and scientific and medical innovation.

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About KLAS

Driven by a mission to improve the world's healthcare, KLAS is a healthcare–focused research firm whose data helps provider, payer, and employer organizations make informed software and services decisions. Powered by insights and experiences discovered in the 26,000+ interviews with healthcare organization leaders and end users that KLAS conducts each year, KLAS' work creates transparency in the healthcare market and acts as a catalyst for software vendors and services firms to improve their offerings.

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