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Enhancing the Data Journey in Oncology Clinical Trials

Clinical trials are the springboard for progress in modern healthcare, guiding the development and evaluation of new treatments and next-generation therapies for patients. Trials exist at the critical juncture where scientific innovation meets real-world patient care and offer the promise of improved health outcomes and an enhanced quality of life. Yet as innovative as clinical trials are, the industry itself is still ripe for innovation from within. The structure and setup of clinical trials, coupled with the technologies that facilitate them, play a pivotal role in shaping their success or failure.

The choices made in trial setup – from patient recruitment strategies to data collection methods – directly impact the success and cost of a trial. Efficiency is crucial at every point in the drug development process. The industry has moved from paper-based data collection methods to the use of electronic data capture (EDC) systems and healthcare providers have moved to electronic health records (EHRs). While these EHRs and EDC systems are digital, the connection between them mainly is not digital, but analogue. This non-digital connection creates an opportunity for innovative approaches using technology to better streamline trial processes, enhancing data accuracy, reducing cost, and expediting the development of new therapies.

Data Transformation in Clinical Trials

The transformation from paper-based to electronic-based records has expanded exponentially. Clinical research has not been immune to this. More than 3.6 million datapoints were collected in a 2021 Phase III clinical trial, which is three times the amount collected in similar protocols ten years prior.[1] As medical records transitioned to EHRs and clinical data moved from paper to electronic clinical forms in EDCs, electronic information has become more standard across the clinical research industry. If EDC is managed well, costs and errors should decrease. But this digital transformation has not been without hurdles, including adoption and technological.

In this white paper, we delve into the implications of EHR to EDC technology, dissecting its role in enhancing the efficiency, accuracy, and integrity of clinical trials, as well as the roadblocks keeping this technology from becoming standard at scale. We also share our perspectives on the future of EHR to EDC technology to innovate design and deliver better trials.

Undertaking EHR to EDC Integration

In July 2018 the U.S. Food and Drug Administration (FDA) published its guidance to "modernise and streamline clinical investigations through the use of EHR data"[2] with motivation for clinical researchers to work toward "interoperable or fully integrated" EHR and EDC systems.[3]

Although EHRs and EDCs are standard practice for clinical trials, the systems are distinct and often noninteroperable. Even today someone at a treatment site manually transcribes data from one system into another. As the industry has grown in complexity, the volume of data being analysed in clinical trials has increased. Clearly this task is ripe for innovation. Despite the technological challenges and regulatory intricacies that come with innovation in healthcare technology, the benefits of automating the flow of data from EHR to EDC for clinical trials are undeniable.

Streamlining data collection, enhancing accuracy, enabling real-time monitoring, and facilitating seamless collaboration from patient data and sites to clinical trial teams for analysis and reporting through to regulators are compelling reasons for successfully integrating EHR to EDC. There are powerful benefits to EHR to EDC interoperability from site, clinical research organization (CRO), and sponsor perspectives, as well as some challenges as to why interoperability has yet to become universal at sites.

Decreasing Site Burden and Error

Clinical trial sites prioritise their mission to serve patients and help uncover new drug therapies. Treating patients and keeping them active and engaged in the clinical trial process while also complying with Good Clinical Practice (GCP) and study protocols are more than enough work for clinical research staff to handle. Requiring staff to manually transcribe data from EHR or other electronic forms into EDC requires significant site resources that could be better focused on patient care.[4] Repetitive, human-led data transfer also comes with the potential for human error. In a literature comparison, an observational study mapping between EHR to EDC found that efforts for manual data entry "could have resulted in over 300 data queries" versus 30 times fewer with direct linkage from EHR to EDC.[5] Once properly mapped, interoperability of EHR to EDC can reduce transcription errors to nearly zero, which helps to keep trials on track while using accurate data. Reducing site burden is a significant benefit of EHR to EDC technologies and is something we as an industry should adopt so site resources can be better focused on patient care.

Increasing Data Flow

Speed and efficiency in clinical trials are pivotal. On average, drug development takes 10 to 15 years from start to finish,[6] and a significant portion of that development time happens at the clinical trial stage. Within a clinical trial, data from a recent patient visit with a physician may exist in the EHR system. In our experience, particularly at larger academic cancer research centres, to transcribe a visit into EDC can take up to four weeks.

Instead, if patient data transfers instantaneously, sponsors have access to their data sooner to analyse it and act upon it. Faster data access leads to faster trials, faster drug development, faster approvals, and faster patient access to life-changing drug therapies.

With so many clear benefits, interoperability of EHR to EDC seems a significant approach that sites should consider. While paper-based records and manual transcription may still be functional, technology ensures sites are more efficient and effective while saving multiple resources. Unfortunately, many clinical trial sites are still reluctant to adopt EHR to EDC systems. Technology and industry leaders continue to work to minimise or remove challenges that keep sites from realising benefits of EDC. Some of the challenges include noninteroperable systems, potential privacy concerns, and the addition of another system to the portfolio of technologies sites are already using.

Reducing Trial Costs

Drug development is expensive with each treatment therapy estimated to cost billions of dollars.[7] The adage that "time is money" rings true in the clinical trial ecosystem. Most trials run on incredibly tight budgets, with research and development necessitating the majority of spending. Yet, manual data transfer is labour intensive, costly, and prone to errors, as discussed above. While an EHR to EDC linkage carries initial setup costs, it can ultimately save money over time. Approximately 20% of total study cost is apportioned to replicating and substantiating data.[8]

Sites would realise cost savings via a reduction in time for site staff to enter data, which could ultimately translate to reduced site budgets for sponsors. Eliminating human error in data transcription results in fewer data queries, which also saves sponsors money. One estimate puts the cost at $28 to $225 per data query.[9] Perhaps most impactful, any automatic data flow would not need to be source verified. Instead, some quality checks or perhaps just verification for a trial's most critical data would be needed, significantly reducing the need and cost for on-site source document verification (SDV). Combining all three benefits with the adoption of EHR to EDC interoperability can provide significant cost savings over the course of a clinical trial.

Noninteroperable Ecosystems

The benefits of EHR to EDC outweigh many of the hurdles for adoption.

Site Challenges

Across healthcare, EHR systems are inconsistent and disparate. While Fast Healthcare Interoperability Resources (HL7 FHIR) standards have made a minimum level of interoperability achievable, digital records, including those that predate 2014, are not user-friendly and cannot speak to each other or share data easily. In the clinical trial sector, this lack of interoperability causes challenges in site adoption. Data mapping and transformation tools help smooth the process, but interoperability must be frictionless, affordable, and easy to manage for EHR to EDC technology to appeal to clinical researchers and sites.

Technology Fatigue

One of the issues trial sites face today is too much technology. Because healthcare systems were not built on interoperability, sites may use a different system for each trial function: scheduling, televisits, eConsent, EHRs, trial management, and more. There is resistance to EHR to EDC solutions because it's another login, another area of change, and another unlinked technology adding to site burden instead of reducing the burden.

Enhancing Data Capture

CROs aim to ease site burden and reduce costs while offering technology systems that integrate seamlessly, lead to better and more accurate data, promote data currency, and improve data flow outcomes. Trial sites have individual infrastructures and preferences, which leads to preferred specific technologies, including EHR to EDC systems. CROs may also recommend EHR to EDC systems, which helps to benefit sponsors and sites on oncology full-service trials. Our approach is flexible and technology-agnostic in that we develop processes to partner with multiple validated, industry-leading EHR to EDC technologies, all to help lower barriers and increase adoption by administrators and technology providers.

CROs should use their expertise to help companies navigate the operational complexities of running trials, including the challenges that come with data transfer. As with many aspects of trial operations, we know that solutions and technologies are not a one-size-fits-all approach.

Technology Integration Benefits

Sites and sponsors benefit from a CRO-managed technology integration approach.

Site Benefits

With our technology-agnostic approach, Catalyst can support a site or site network with whichever EHR platform or EHR to EDC technology preference is currently used. Our experience has been to work across client trials using multiple platforms, using the strong, established partnerships we have with technology providers, including EHR to EDC tools. We help sites leverage these existing partnerships, providing guidance and assistance to strengthen choices. Our method helps sites streamline their technology, while reducing operational costs they shoulder. When this technology replaces manual transcription of data from EHR to the EDC, sites are then enabled to save costs and time.

Sponsor Benefits

With EHR to EDC integrated, sponsors benefit from the speed of data capture to the increased speed in accessing data. Normally data processing time is reduced and transferred to the EDC in near real-time – with cleaner data. With faster access to data directly from EHR without risks of transcription errors, sponsors can act and analyse the data sooner. Combining that with the promise of reduced SDV, this translates to faster trials and increased cost savings.

Keeping Pace with Technology

With any growing area of technology, change takes time. We will continue to recommend EHR to EDC as part of full-service trial operations. We believe within five years, EHR to EDC technology is expected to be a tool most research centers – even smaller trial sites—leverage to streamline and speed their trial process. In fact, we have experienced site networks requesting specific EHR to EDC technologies during our clinical management process.

When EHR to EDC technology is used as a standardised tool applied across multiple sites, trial networks see clear value from a cost perspective and with staff familiarity of the technology. It's exciting to see this momentum, and we believe these value-added approaches make the benefits of EHR to EDC more accessible to any site network.

As EHR to EDC tools progress and become more interoperable with other data sources in the healthcare system, such as wearable devices and remote patient monitors, healthcare providers and clinical trial operations can equally benefit from better insights into patient health and clinical trial outcomes. This directly impacts other key issues in the trial ecosystem, such as patient safety, trial accessibility, patient engagement, and patient recruitment.

While regulatory receptivity toward finding EHR to EDC solutions may be strong, technological acceleration for more advanced use

cases of EHR to EDC at sites may cause some to stumble. At this stage, industry partnerships and problem-solving are solid catalysts toward adoption and growth at scale of EHRs to EDCs within clinical trials.

Adoption of EHR to EDC technology will significantly influence a trial several times over through reducing site burden, increasing cost savings, and improving data accuracy. As we continue to evaluate and recommend EHR to EDC system partners and platforms, we will see increased adoption and acceptance.

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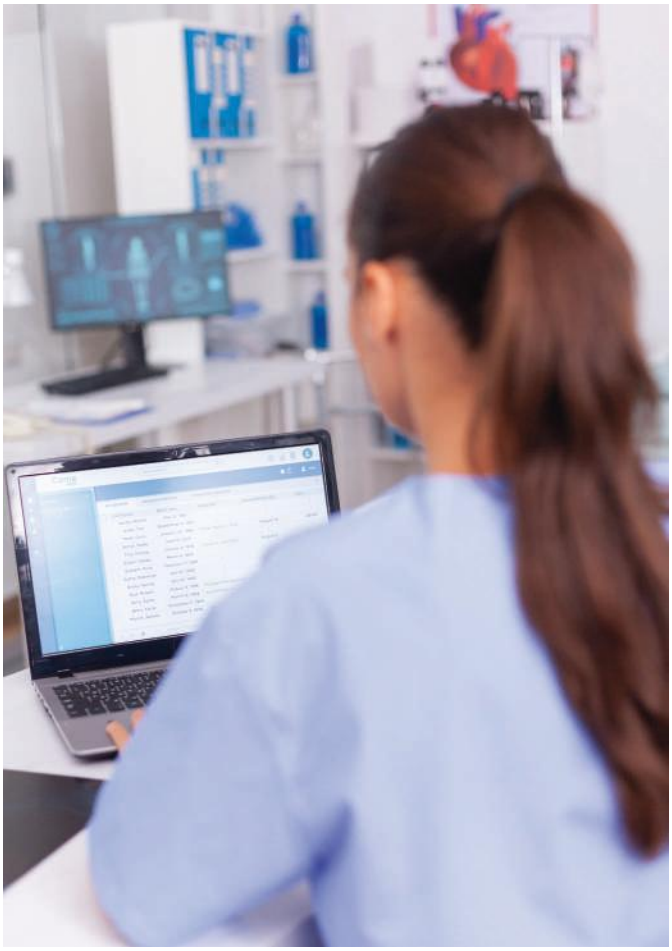

Andrew Zupnick

Andrew Zupnick, PhD, Vice President, Oncology Drug Development, Catalyst Oncology, has focused exclusively on oncology for over 20 years and serves as the vice president, Oncology Drug Development for Catalyst. He leads Catalyst's full-service oncology solution, supporting study optimisation, delivery oversight, training, and new initiatives across the commercial and operational teams to keep Catalyst at the forefront of industry trends and cutting-edge oncology therapies. Andrew is a cell and molecular biologist with a Ph.D. from Columbia University and a B.S. from MIT. He brings a broad base of oncology experience to Catalyst. Andrew began his professional career at Prologue Research, a niche oncology CRO, which was founded out of what became the James Cancer Center at The Ohio State University and acquired in 2010 by Novella Clinical. At Novella, Andrew led the growth of the organization's oncology division into a market-leading oncology specialty CRO. After the acquisition of Novella by Quintiles, Andrew spent nearly seven years working within the standalone CRO subsequently rebranded to IQVIA Biotech in 2019.

Craig McIlloney

Craig McIlloney, CStat, MSc, BSc Hons, Vice President, Data Sciences, Catalyst Flex, brings 25 years of experience with large and small CROs to his role with Catalyst. As vice president of data sciences, he is responsible for global data management, biostatistics, statistical programming, and medical writing teams. He's held various roles across biostatistics and programming functions, including project, program, local, regional, and global management of more than 800 staff. As the previous vice president of biostatistics and programming for a large CRO, Craig drove the company's expansion into Asia. His work has focused on various therapeutic areas, including oncology, infectious diseases, dermatology, endocrine/metabolic disease, hematology, nervous system disorders, circulatory conditions, respiratory disease, digestive system diseases, genitourinary disease, and musculoskeletal disease. Craig's leadership experience spans activities across various delivery models, including FSP, full-service, and hybrid models. He earned a B.S. (Hons) degree in statistics from the University of Glasgow, U.K. in 1994 and an M.S. in applied statistics from Napier University, Edinburgh, U.K., in 2000. He is a chartered statistician (Cstat) with the Royal Statistical Society and was previously a director of the Statisticians in the Pharmaceutical Industry (PSI).