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“Small” Research Projects Pave the Way for the Future of Clinical Research Operations

E-sourcing of EHR data for clinical trials is the future, but industry-wide adoption is not today’s reality. Application in small research projects not only delivers value for life science companies as the industry transitions, it is how we can build the network of tomorrow

Recent USDCI interoperability standards and gains in technology enable the ability to e-source patient data from medical records into sponsored clinical research. While we have seen some adoption of the approach to acquire data through USCDI, there are challenges scaling it across the industry. We are recommending that sponsors start with smaller retrospective studies or surveillance studies with sites that have deployed e-sourcing interfaces as a way to bootstrap their way into e-sourcing or EHR to EDC.

For sponsors, a number of factors stand in the way of e-sourcing for clinical trials. While a growing number of health system sites are set up to e-source, others are not yet connected. As a result site networks that are ready in time for the study are incomplete or only a small fraction of the sites to be included in the study have live interfaces ready for the first patient. Clinical trials have complex data requirements and high risk from the large investment in the product being tested. Use of established methods of data collection in manual EDC would have to be combined with e-sourcing in order to avoid the risk that the change to a novel data collection process could jeopardize the success of the product in the study.

Further, adoption of new technology and associated changes in workflow requires effort and cost that is hard to budget into a single study. It will take time for value to be fully realized and likely that the first clinical trials to transition into sourcing this way will be more learning how to operate successfully with new approaches than a way to achieve a positive ROI for that trial. Ultimately the shift from the current practice of 100% reliance on EDC into either limited e-sourcing or broad e-sourcing involves significant risk and change management. Most if not all life science companies have yet to take the leap and many are only cautiously running pilots to test feasibility.

Until there is broad adoption at scale, good opportunities for becoming a leader in e-sourcing still are readily available. Through recent work with client sponsors and health systems, the team at Graticule have learned that e-sourcing can also be a very valuable tool for small-scale research projects. These might include a 100 to 200 patient study for a rare disease, or a data feasibility project in support of an advanced piece of future research, or a protocol design project to understand the available data and clinical workflow that the study will fit into.

Data sets through e-sourcing are rich and granular and almost always provide better clinical insight than an EDC project to curate a small set of variables. Direct access to source data in the EHR can be a key to success in research projects of any size and scope. Small projects are an ideal place to start. Why? Typically the requirements for small projects look different than those of a clinical trial. For example a single-site research network or very small research network may suffice for the study. This allows for rapid contracting and low technical burden vs. multi-site data sourcing across multiple geographies and requirements for IT maturity needed for a clinical trial. Small projects are simply less complex, helping with management of adoption, implementation and risk. They are a very useful way to build a foundation of capabilities. Also these projects can be directed toward sites that are already actively engaged in other e-sourcing projects and can shortcut the long first stages of setting-up software, contracting, governance, and FHIR interfaces.

Starting small helps life science companies grow competency with e-sourcing. And do so with less risk and disruption. Once the e-sourcing IT infrastructure are established at a site and the processes can be trusted then it is ready for use for more complex projects such as clinical trials. When new sites go live with e-sourcing to support small projects, it also contributes to the greater opportunity of a more mature network to build from. The network grows to include more patient records, more diversity and more geographies available to support future research efforts.

An example use case is a small-scale natural research study. This type of study will typically require a targeted data set on a limited number of patients with a rare disease. Researchers will want a deep understanding of the patients' clinical profile, the diagnostic process and milestones in the care journey.

But getting quality data for something like this can be quite difficult. A licensing contract with a big national Real World Data aggregator often requires a high cost, contracting that is hard to reconcile with research plans, and the resulting data can be limited by upstream contracts or interfaces with source health systems. For example, we may seek long term surveillance of data on a set of patients, whereas the aggregator's terms are established to allow use of data for a single year of licensing and no further refreshes in the future without additional annual licensing. With e-sourcing, we can work directly and efficiently with sites to establish an agreement that matches the data needs and to collaborate with the site regarding any gaps in knowledge or interfaces that we have on their workflow and documentation process.

We are actively piloting e-sourcing projects using our CLEHR EHR-to-sponsor e-sourcing solution with a client sponsor and participating health systems. We have learned that e-sourcing can solve gaps in how we have tried to work in the past. For example, a natural history study that we are working on will establish a target population of patients where a standard FHIR interface pulls a detailed medical record for the small target population with a rare disease. All

outputs are deidentified and made available to the sponsor. The data is granular so researchers can better see trends in individual values such as lab results, vital signs, and flexibly generate other insights. By working with a health system we are able to do long-term surveillance on the patients in the study through the live interface for as long as the research collaboration maintains an active protocol and research agreement.

At Graticule we have done this type of data access project without FHIR interfaces before but with significant limits and challenges. Before FHIR we would work with health system teams to generate data extracts from the participating hospital's research warehouses. Historically, the process often involved quite a challenging back and forth between sponsor and sites to define the exact data needed and how to write each query for every element delivered. Things had to be very clearly, explicitly specified, including the output format and concepts to be shared. The data then had to be extracted and formatted often through custom queries and pipelines for the research data set through the IT team that often had limited available resources. This then was sent to us for quality control where errors might be identified.

E-sourcing the FHIR record for the target patient population eliminates the back and forth of creating a complex data specification for the desired output data for the study. The study instead handles the downstream processing and formatting from the domains and date ranges requested from the FHIR resource APIs. We leverage a data use agreement to allow us to pull only the minimum data resources needed on the patients for the study. If there were subsets of the FHIR records that are not specified, this is written into the protocol. Using the new approach, the effort to define and extract data is completed at a low cost, within a relatively short time frame vs. the formal data warehouse request and data set specification and delivery process.

Where to Start

We recommend working with Graticule start with sourcing a small study that requires a single site that is already linked through FHIR through CLEHR. The process would establish a protocol for analysis of a few hundred patients or less and have analysis objectives that can be achieved within 3 months. We would love to get started and can help select a site that is also interested in establishing better integration with you!

Interested in learning more?

Reach out to us at info@graticule.life