ARTICLE

FINALLY: GLOBAL CLINICAL RESEARCH TECHNOLOGY STANDARDIZATION IS WITHIN REACH

Clinical trials have increasingly complex protocols. According to an analysis performed by Tufts Center for the Study of Drug Development, the number of protocol deviations and significant amendments for the average trial in the reviewed period has increased by almost 4% when compared to previous years.[1] Trials are also becoming more and more decentralized, with the use of decentralized elements such as digital data collection, remote monitoring, and ePRO and eCOA rapidly accelerating since 2020.[2] Complex protocols and decentralized clinical trials share the same goal: getting better treatments to patients faster. Unfortunately, they also make clinical trial management and clinical data management much harder.

With the increase in trial complexity and decentralization, the research industry is also seeing an uptick in unplanned time and costs, with sites often bearing the brunt of these difficulties. Sites are facing more administrative tasks and spend countless hours on manual processes. They are also dealing with staffing shortages and low patient enrollment rates, taking up an increasing amount of time and requiring them to get even more creative with the resources they do have.

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IS CLINICAL TRIAL TECHNOLOGY THE ANSWER?

Solutions such as clinical research technology, digital platforms, and other tools aimed at increasing efficiency at clinical research sites can go a long way toward easing these difficulties. Such technology offers benefits for sites, sponsors, and patients alike. Take, for example, eSource digital data collection tools.

Before the advent of eSource, the research industry relied on source data review, source data verification (SDV), and other on-site monitoring. As such, clinical research associates had to conduct site visits every one to two months to do SDV, using precious time and resources better spent on other aspects of research. In fact, Pharma IT states the industry spends about $8 billion every year on SDV.[3] But with eSource, trial data are directly added to sponsor databases without extra verification, saving significant time and money.

But has clinical trial technology gone too far? Has the sheer number of new research platforms and tools transformed them from solutions into problems?

TOO MUCH TECHNOLOGY, TOO LITTLE TIME

The rapid expansion of new clinical trial technology isn't making research easier on sites, it's making it harder.

Sponsors require certain trial platforms and systems for each study with the hope of making protocol, data collection, and analysis easier. But just because one sponsor uses one platform for their study doesn't mean another sponsor will use it for theirs. Sponsors want to standardize technology and data capture across all the sites for each of their studies, so they push their specific solutions for each study onto their sites. What happens if a site is running 10 studies with 10 different sponsors?

As reported by Pharma IT, a May Sites NOW survey from the Society for Clinical Research Sites (SCRS) found 60% of surveyed sites use a minimum of 20 different research systems every day. The same survey discovered that each of these different systems necessitates at least 17 hours of training per month. What's more, the sheer number of platforms sites are forced to use is creating an unsustainable environment of immense research personnel burnout and turnover. Pharma IT also reported research site staff turnover rates have gone up from about 37% pre-pandemic to almost 61%.[3]

The tools intended to make clinical trials more efficient are creating significant challenges for sites and staff, resulting in slower studies, blown budgets, and longer journeys to market for potentially life-saving products.

IntElligo can get lifesaving therapies, devices, and products to patients faster.

ONE STANDARDIZED SOLUTION

A consistent clinical trial technology used across all sites and studies would alleviate the additional burdens multiple platforms create for research sites and staff, ultimately accelerating clinical trials and better serving patients. Luckily, such standardized technology already exists.

Elligo Health Research® seeks to increase access to clinical trial participation, and one essential way we're achieving that goal is by making research easier for sponsors and sites through our IntElligo® Research Stack technology. IntElligo is a healthcare-enabling workflow tool designed to enhance trials from feasibility through submission. It facilitates simple, standard, and efficient patient source data collection, real-time data updates and analytics, and streamlined study operations, supporting everything from patient identification and recruitment to data interoperability so studies can go from protocol to system ready in just 72 hours.

IntElligo is also the only clinical research system that works in a real-world healthcare environment, collecting data at the point of care in CDISC global research data standard and automatically using it for regulatory compliance and study operational management. By automating administrative tasks, alerting for any quality issues, and streamlining data output, it also accelerates studies to save time, money, and resources.

Since every site and study powered by Elligo has access to IntElligo, our sites only have one platform to use, saving time and resources and freeing up their focus for patient care. Our sponsor partners also gain standardization of technology and data capture across all sites, leading to clean, coherent, and usable data as well as faster study startups, reduced spending, and a shorter journey to market.

IS GLOBAL STANDARDIZATION POSSIBLE?

Traditionally, sponsors contract a variety of research sites in a range of locations and networks to run a study because spreading a wide net is the only way to enroll the required number of patients. However, with a variety of sites comes a variety of trial technologies, necessitating the sponsor to mandate the use of their provided or chosen system. The need to contract such a range of sites to enroll patients is a large roadblock on the path to global trial technology standardization. But Elligo offers a solution.

Our Patient*Select* service model offers access to 150 million patients and counting, serving as a one-stop enrollment shop. We can easily provide all the patients, and therefore sites, necessary for any given study. And, since all Elligo-enabled sites used in our Patient*Select* service model are already using IntElligo, standardization is once again achievable.

WHAT CAN INTELLIGO DO FOR YOUR STUDY?

Despite increasing complexity and decentralization, there is a faster path to market: standardization with Elligo and our IntElligo Research Stack technology.

Instead of spending 340+ hours per month training and using different research platforms, sites using IntElligo can spend that time running studies and caring for their patients. Rather than getting bogged down in SVD or mandating technologies, sponsors using IntElligo can get lifesaving therapies, devices, and products to patients faster.

Finally, global research technology standardization is within reach.

REFERENCES

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2. Hillman, A., et al. Who and what is at the crest of the clinical trial decentralisation wave? Clinical Trials Arena. Published 2022 Feb. 3.
3. Munda, J. Line of "site" to better drug development: Site-centric clinical trial tech. Pharma IT, First Analysis. Published 2022 Sept. 28.

ABOUT ELLIGO HEALTH RESEARCH®

Elligo Health Research accelerates clinical trials through healthcare with access to over 150 million known patients and their HIPAA-compliant healthcare data, our IntElligo® Research Stack technology, and our Patient*Select* identification and engagement model. Coupled with the largest Known Patient Access Network, Elligo's Site Solutions enable healthcare practices and research sites to participate in clinical trials. By adaptive engagement of known patients and physicians, we accelerate the development of new pharmaceutical, biotechnology, and medical device and diagnostic products.