INSIGHTS FOR INSIDERS

adaptive clinical SYSTEMS

A curated list of articles from the world of clinincal data integration

LIVING IN AN eSOURCE WORLD

The clinical trial world used to be simple.

Black and white simple. As in we wrote everything on paper simple!

And for the new generation of clinical trial professionals who grew up as digital natives, you may not understand just how simple the world was before you, but that doesn't matter now.

We're here.

It's 2020 and with that comes a revolution of sorts, one that requires we change our business processes from outdated EDC plus paper-driven procedures to the eSource world. To clarify, in this paper the concept of eSource means that now we electronically capture data at the point of visit instead of manually capturing it. And even though many of us are using EDCs and such, it is no longer enough.

It's the digital age — why not digitize our data capture processes? Here are 5 things you need to consider if you want to live in an eSource world:

1. Go eSource if you want information flow modernization

At SCDM 2019, we were involved in the eSource conversation among our peers. We agreed that eSource makes sense and has many advantages, including cost savings; better access to data which leads to better information and better decisions; higher data quality; and safety improvement now that data is better and more reliable.

Adaptive Clinical Systems CEO Sina Adibi advises “If you want well-designed, well- run clinical trials, you need to keep up with new sources of data and integrate it with a vendor neutral platform enabling the full realization of eSource; utilization of measurable and accurate real-world data and allow information flow modernization in your clinical trials.”

2. Tread carefully, make the business case

Recently there has been discussion that despite the benefits of eSource, there has to be a thoughtful plan to socialize and sell within an organization. To make the business case, one must assess the current situation, show what eSource is and how it is different, enumerate benefits, and demonstrate its effectiveness. It’s important to be specific and create a use case. Recognize that change can be hard and threatening as new procedures and processes have to be learned.

Implementation also requires equal — if not greater and even more thoughtful planning. Be keenly aware that by recommending eSource, the impact to a complex process with a number of involved parties — each with its own embedded behaviors — must be anticipated.

And, changes need to be well understood. One of the panelists shared a a real life situation where a tablet device intended for eSource data capture at sites required constant, slow page reloading. Directions on how to use the device and correct issues were not clear, and other issues that arose were not foreseen due to inadequate pre-rollout testing. The project was quickly abandoned.

Here are some good suggestions to ease into eSource:

- Avoid large, complex global/multi-national studies
- Consider smaller phase I or phase II
- Employ fewer sites rather than more
- Shy away from EMR's
- Use a strong study team
- Consider doing just part of a study to minimize risk and more easily manage unforeseen issues.

3. Wake up to new technologies and small advancement

According to PRA Health's CSO, Ken Thoelke sponsors and CROs need to "re- define, re-imagine and re-engineer the drug development paradigm through the use of real-world data, patient level data, machine learning and AI. To improve drug development we need to do all of this – and break out of an existing mold." Basically we are still developing drugs based on approaches that were established in 1938, revised in the early 1960s and then again in the 80s. Our industry often blame regulations for the lack of innovation, but former FDA chief Scott Gottlieb said "the guidelines are there – it is the antiquated business models within Pharma that are the hindrance now."

Could that be true? In some cases absolutely.

Does your organization employ antiquated business models? If so, now is the time to wake up and reconsider the reality that paper based studies are slow and in some cases flat-out impractical when you take into account the data deluge that we face. Always expect the 4 V's when thinking about your data: Volume, Velocity, Variety and Veracity. Clearly there is no room for slow pace processes any more.

4. Stay on top of trending trials

If fully vrtual trials are too much of a change or impractical for your organization, then consider hybrid trials instead of fully virtual trials. It's all about ePRO and mobile technology. Maybe you've already encountered these types of clinical trials. If so, you may have faced or will face these challenges:

- Not everything can be virtual – for example, home healthcare nurses can manage visits but what about lab work?
- Planning and setup cost more up front in virtual or hybrid but pay back later. (This makes justifications more difficult.)
- There will be IRB challenges so plan for them.
- We can't assume that data is always perfect so you will need to allow for some monitoring – take a good look at RBM.

5. Be aware of others misconceptions surrounding eSource solutions trending

As you assess eSource options, understand that a number of new and emerging vendors are not often clear on Part 11 compliance and what it demands from your users and staff. For these often disparate systems, integration compatibility is also a challenge because if integration does not take place, site data will be subject to the very risks and errors that you are trying to avoid by moving away from paper and manual data entry.

When leveraged and utilized properly, e-source is a solution that saves time, money, and leaves little room for error. Talk to your peers and get their thoughts on the topic before socializing in your organization. Look for best-in-class partnerships and integrations – this is how you can tell one has a unique competitive advantage.

Read Gartner's Market Guide for Life Science E-Clinical Platforms Published June 21, 2019 for more on eSource and recommendations on integrated platform specialists.

Adaptive-Clinical Systems created the only proven technology platform that lets you quickly go from integration to interoperability across all eClinical tools, leveraging a re-usable connector library and intelligent middleware. Our clinical rules engine not only moves, but can also transform data, all on a fully validated platform compliant with CFR 21 Part 11. The proven cloud-based Adaptive eClinical BusR solution helps increase efficiency, enhance collaboration, and improve trial performance and is modernizing data flow from any data source, now and in the future.

For more information, go to adaptive-clinical.com, email info@adaptive-clinical.com or call 856-452-0864.