Clarifying Ownership of Clinical Trial IRT Data: Site vs. Sponsor

Craig Mooney
Vice President, Scientific eTech-Enabled Services, Calyx

A change in the landscape regarding the clarity around IRT data is ripe for industry discussion

Recently, MHRA posted, "Is your eSystem actually an eCRF?" (https://bit.ly/3CHzVMw), which identified an equivalency between IRT and eCRF as it relates to the investigative site's ownership of the data. While reading this blog, an experience I previously had as a trial sponsor came to mind. During an MHRA inspection, a clarity in perspective about IRT data ownership was being communicated. The inspectors made sure we (the sponsor) weren't as integrated into the data change process as is typical (i.e., site requests change, sponsor approves). The message was the investigative site was responsible for the validity of its IRT data and sponsors need to understand the implications.

Since entering the industry in the mid-90's, my perspective has been that IRT data is seen more as transactional for the purpose of randomization and drug assignment. It's not the same as eCRF data and shouldn't be treated as such. But my perspective somewhat changed after this inspection and was reinforced upon reading MHRA's blog.

In the blog, MHRA reminds us what a CRF is, defined as ICH GCP E6 R2 (2016), 1.11: A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. So, basically any system that is designed to record the data of the protocol and report to a sponsor on each trial.

They drive home some key points, including:

- "…regardless of what you call your system, if it is recording protocol-required information and providing this to the sponsor, then it is also a CRF and needs to have the required functionality of an eCRF."
- "The functionalities of such systems should permit data changes and authorizations by the investigator with a clear audit trail to verify the integrity of the trial data and to explain why the data was amended."
- "As per ICH GCP, this data belongs to the investigator and therefore should be available to, and under the control of the investigator (and not under the direct control of the sponsor)."

So, between my inspection experience and MHRA's blog, it is clear to me that regulators are taking a closer look at how IRT data meets requirements to ensure data integrity, including data ownership. Equally clear is that the industry was not prepared to act on this and will benefit from best practices in light of the implications.

I've since spoken with different trial stakeholders (sponsors, CROs, solution providers) and can suggest several questions that need to be addressed as best practices are established. The overarching question is, as IRT data belongs to the investigative site, do sponsors currently have too much input on data changes?

Additional questions centered around what happens at the end of a study include:

- What data should be included?
  - ◊ Data changes? Audit trails? Who made each change?
- What process changes need to occur from a sponsor, provider, and site perspective?
  - ◊ Should data go directly to sites rather than via sponsors to ensure data integrity?
  - ◊ Will sites need to go through a culture shift to look at the data as more than just transactional?
- How is the data to be transferred/what format?
  - ◊ Shouldn't we be using modern data archive and delivery methodologies?
- How will investigative sites respond to this clarity in IRT data stewardship?
  - ◊ What will investigative sites do with the data?

A change in the landscape regarding the clarity around who owns and is responsible for IRT data is ripe for industry discussion. As we come to a level set on what is expected and when, the challenge will be to look at this clarity in expectations and understand it not only as a change for trial sponsors, but one the whole industry is affected by, requiring input from different industry stakeholders to ensure effective implementation.

CALYX™
Contact **hello@calyx.ai** for more information.

© 2021 MultiMedia Pharma Sciences, LLC. Reprinted from AppliedClinicalTrialsOnline.com AN MJH life sciences BRAND