Clinical Trial Templates – Meet the New Guidance

The NIH and FDA have teamed up to create a clinical trial template to ensure accuracy and quality while also expediting review processes, but how can organizations meet the new guidance?

Last week, the National Institutes of Health (NIH) and Food and Drug Administration (FDA) announced that they have joined forces to create a protocol template to expedite review processes for clinical trials. Many companies welcome a formalized template to follow, but how can they best prepare to adopt this protocol format? The answer lies in creating structure for the information so that the content required can lend itself both to meeting requirements and eventual re-use.

What the template contains

The template, which is still in its draft phase, provides both instructional and sample texts for clinical investigators writing trial protocols involving investigational new drug (NDA), or device exemption (IDE) applications.

In an FDA Voice blog post announcing the partnership and template, Peter Marks, the Director of FDA's Center for Biologics Evaluation and Research, explained how the product can help investigators follow the trial guidelines set by the Internal Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use E6 Good Clinical Practice: Consolidated Guidance. The current guideline requirements outline trial elements like objectives, methodology and organization but not a standardized format. Unfortunately, when the documentation is submitted for review, clinical investigators are forced to spend extra time determining that all required information has been included, potentially delaying the start of a trial, and ultimately preventing new and important medical treatments from reaching patients.

The NIH and FDA felt that the industry could benefit from a standardized template with the aim of making it easier for companies to create consistently organized and ICH E6 guideline-abiding protocol documentation. Then, more trials can go through quick, proper review processes by the FDA and NIH. Both organizations stress that the point of the template is to guide trials, not dictate them.

"Our goal is to provide an organized way for creative investigators to describe their plans so that others can understand them," said Dr. Pamela McInnes of NIH in the blog post on FDA Voice.

Marks noted the similar efforts by the non-profit organization TransCelerate, which has also created a protocol template for clinical trials intended for eventual release in electronic form. While TransCelerate focuses on patient population and therapeutic areas of clinical research, the NIH and FDA plan to work with the organization and other similar projects to ensure consistency throughout the medical community.

There is a better way...

To be able to align with either protocol template, organizations need to create information in a way that will enable them to compile and submit it whatever format is needed. The best way to accomplish this task is through a structured authoring process. By taking a structured approach, companies will find that they will be better able to create and place the right information in the right place. The benefit beyond adopting one of these protocol standards is that this structured information can ultimately be re-purposed into other documents that come out of the clinical trial process – statistical analysis plans, clinical study reports and more.

Structured authoring solutions allow organizations to author components of documents that can be individually developed and approved enabling teams to create content that is discoverable, reusable, reconfigurable and adaptable, making the information needed to match differing protocols much more flexible.

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