ProtocolBuilder™ White Paper

Why Clinical Research Protocol Templates Don't Work

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Why Clinical Research Protocol Templates Don't Work

Abstract

Writing investigator-initiated clinical research protocols can be a time-intensive and daunting effort. Investigators agree that writing protocols is difficult (Figure 1) and time consuming (Figure 2), according to a survey by BRANY, a national organization providing support services to sponsors and investigators involved in research in a wide variety of therapeutic areas, medical devices, biologic and diagnostic trials. The biggest hurdles are the ability to provide all information needed and the ability to write a protocol that meets IRB standards. Busy investigators are having difficulty finding time to write comprehensive trial protocols, even if their institutions provide training and templates.

Writing Protocols Can Be Daunting

A well-written clinical trial research protocol is important for the success of any clinical trial; it can also speed up the process of department head, regulatory and IRB approval. The quality and completeness of clinical trial research protocols are often inadequate. On average, about one in every three clinical trials fails to meet its primary goals due to poor design, faulty statistical strategy, lower recruitment, poor management of resources, and regulatory issues. Most of these causes of failure can be mitigated by a well-designed clinical trial protocol.

For first-time or even experienced users, the tools available, such as training courses, institutional templates, or checklists do not necessarily improve the quality, completeness or amount of time it takes to write and approve a clinical trial research protocol.

In an independent market research survey of over 100 research professionals and investigators on protocol writing, the biggest hurdles cited were the challenges of providing all the information needed in the first iteration, meeting the IRB standards and finding time for writing research protocols.

Figure 1 Both decision-makers (for example, clinical research directors, IRB directors or clinical department chairs) and investigators felt the process of writing a protocol was difficult.

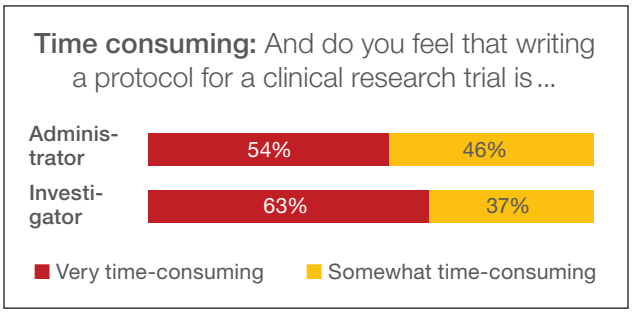

Figure 2 The majority of research professionals and investigators said that writing a protocol is time-consuming.

Current Solutions Aren't Working

Most institutions offer a variety of protocol-writing solutions to investigators (Figure 3). Just over half of institutions offer training, and nearly half offer templates. Of those that offer software programs, some are purchased enterprise-level software solutions and others are "home grown" online solutions, developed by internal IT departments. These products or services can take three to six months to implement, be costly, and are not always easy to navigate. Current software solutions generally do not provide expert advice or resources to users to help streamline the protocol writing process.

Training courses, either classroom-based or online webinars, to prepare investigators to write a clinical

trial protocol, can take more time than actually writing the protocol. Other tools available – checklists, guides and templates – can be overwhelming and are not always applicable to the type of research protocol investigators are about to write.

While many investigators are satisfied with these tools, about 40 percent expressed frustration with them (Figure 4).

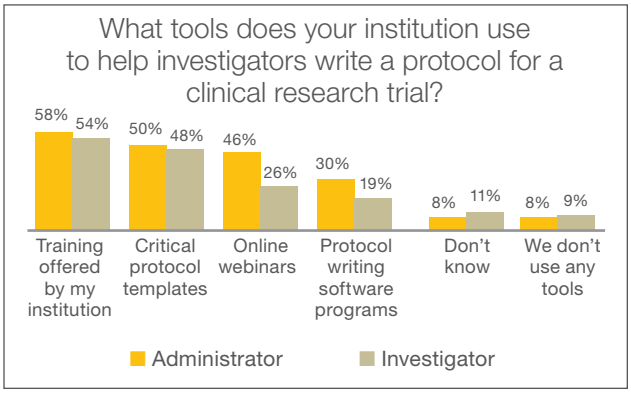

Figure 3 Many institutions offer some kind of training, either in person or online, but very few offer any software that helps investigators in the actual writing of the protocol.

In general, how satisfied are you with the tools that your institution provides for protocol writing support in clinical research trial processes?

Satisfaction with Tools	Administrator		Investigator	
	N	Somewhat + very satisfied	N	Somewhat + very satisfied
Training offered by my institution	29	69%	29	59%
Online webinars	23	61%	14	64%
Critical protocol templates	25	56%	26	65%
Protocol writing software programs	15	60%	10	70%

Figure 4 While a majority of users expressed satisfaction with their institutions tools, about 40 percent were dissatisfied.

Guided expertise can save time and ensure completeness

Investigators said a tool with the following attributes would be most appealing.

- **Hands-on, guided expert guidance.** Investigators most often desired a solution that walks users through the steps of building a clinical trial protocol – much like tax preparation software would walk a user through a tax return – starting with a pre-work checklist through the research framework and the research design and methodology. No matter how complicated the protocol, the experience of using an application with this feature would provide a higher sense of confidence.
- **Time-savings.** Both investigators and research professionals sought to save time with any protocol-writing tool. They also wanted to be assured that protocols would be completed without any omissions to ensure a smooth IRB review and approval.
- **Flexibility.** Investigators interested in specialized projects were interested in an application that is flexible enough to accommodate the special needs of their research.

Conclusion

Investigators and research professionals are seeking easy-to-understand solutions that offer comprehensive guidance for writing protocols. Organizations are looking for practical teaching tools that not only facilitate the ability for investigators to write research protocols well, but also enhance the quality of the research that is conducted throughout the organization. Solutions that save time, ensure completeness and offer flexibility are keys to the success.

To learn more about Protocol Builder:
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Website: www.statref.com