Meet the game changer for writing investigator-initiated clinical research protocols

Introducing Protocol Builder ®

Protocol Builder is cloud-based protocol writing technology that makes it faster and easier to develop investigator-initiated clinical research protocols that meet IRB and regulatory standards.

This robust yet simple to use application is available to individuals or institutions, and can be accessed conveniently on laptops, desktops, and iPads.

Key Benefits

▶ **Save significant time and effort developing protocols**

▶ **Improve adherence to IRB and regulatory standards**

▶ **Enable collaboration among contributors**

▶ **Advance the ability to publish research**

▶ **Strengthen research programs and increase study pipelines**

Protocol Builder is based on in-depth research and interviews that identified the needs of protocol writers:

▶ **94%** wanted a guided experience
▶ **89%** asked for expert advice and examples
▶ **84%** requested quick access to regulatory forms

Plus, it's enhanced on an ongoing basis with the guidance of user feedback.

Protocol Builder has formed a strategic partnership with STAT!Ref for institutional sales. For more information, visit www.statref.com or call 800-901-5494.

Designed with your needs in mind

Protocol Builder offers specific benefits to meet the needs and priorities of individuals with various roles in the clinical research process.

Research Investigators

Whether you are an experienced or new research investigator, doctor, medical resident, or medical student, Protocol Builder can help you develop better protocols in less time with less effort—even if you are new to protocol writing. It's easy to get started and simple to use. It also enables collaboration and helps avoid multiple rounds of revisions, so you can get your research up and running faster.

Research Administrators

Protocol Builder can help you enforce protocol standardization with pre-set templates and a guided experience that includes simple instructions and expert tips. It also allows institutions to add specific guidelines and use their own templates in the application. Plus, it offers features to easily, compare, track, and summarize protocol revisions. It can be implemented easily in less than 30 days, and can be integrated with your IRB, CTMS, or single sign on platforms.

Research Librarians

This technology can be a valuable addition to your e-resource collection. It streamlines the protocol writing process and promotes learning to support your research, research education, and health science programs. It also helps advance research publication with automated citation/reference functionality and the ability to reference management libraries, such as Endnote, RefWorks, Mendeley, and PubMed.

Residency Programs

Protocol Builder not only helps residents develop consistent protocols more easily, it also helps them learn as they go. It offers a guided experience developed by protocol writing experts and can bolster your program's efforts to meet or exceed ACGME research requirements. In addition, it enables communication and collaboration to help foster mentorship.

Backed by an industry leader

BRANY

Protocol Builder is powered by the Biomedical Research Alliance of New York (BRANY), a leader in providing hospitals and medical schools IRB and clinical research support services.

Much more than just a time saving tool

Protocol Builder excels at saving time and reducing hassle for protocol writers, but it goes above and beyond those benefits.

▸ **Saves significant time and effort for protocol writers**

Automatically sets up the table of contents to help ensure the right topics are included

Automates time consuming tasks, such as creating the References and Glossary sections

Eliminates the need to copy/paste content or rely on templates that may be missing sections

▸ **Helps protocol writers work more efficiently**

Protocol duplication allows users to repurpose existing protocol contents and references

Advanced editing tools enable users insert citations, abbreviations, glossary terms, and more

Helps check for accuracy and completeness to avoid multiple rounds of revisions

▸ **Boosts the quality and consistency of protocols**

Features including expert tips and resources improve adherence to IRB and regulatory standards

Templates and relevant instructions promote standardization for easier development and review

Tools are available to help determine protocol type and whether an IND/IDE is needed

▸ **Enables communication and collaboration**

Users can invite colleagues and supervisors to comment on or revise protocol topics

Revisions can be tracked, compared, and accepted/rejected

Protocol writers can message reviewers directly about specific changes

▸ **Promotes learning and the ability to publish research**

Best practices, expert tips, and a robust resource center help users learn as they go

Automated citation/reference functionality makes it easier to insert references correctly

Reference search tools, including EndNote and RefWorks, can be pulled into the application

▸ **Strengthens institutional research programs**

Helps increase study pipelines by improving the quality of protocols

Frees up resources to focus on other tasks like getting approved research off the ground

Assists residency programs in meeting ACGME research requirements

Protocol Builder is secure with SSL encryption as well as password and firewall protection. It can be implemented in as little as 30 days with no time consuming or costly set up or training needed.

Robust features streamline the process

Protocol Builder offers easy to use features developed by protocol writing and usability experts.

Key Features List

Automatic Set Up	Enter basic information and appropriate protocol sections are set up automatically based on protocol type.
	Protocol Builder can help you determine the type of study and whether or not you need an IND or IDE application.
Protocol Duplication	Instead of creating a new protocol, you can duplicate an existing protocol to repurpose the contents and references.
Advanced Editing Tools	Insert references, tables, appendices, abbreviations and glossary terms easily as you write.
	Those sections are then set up automatically at the end of the document.
Easy to Navigate Contents Menu	Go step-by-step through the writing process or use the menu to navigate to any section.
	Switch to the preview mode to read through it more easily.
Expert Guidance	Refer to relevant instructions and expert tips as you go through the protocol.
	You'll also find sample protocols in the Resource Center that you can use for reference or as a template.
Resource Center	Access well-written samples as well as links to important educational and regulatory information. A list of commonly used forms is also available for download.
Share and Review	Invite others to review and add comments directly into the appropriate sections.
	You can also download and email PDF versions.
Compare Revisions	Compare revisions made to a particular section and accept or disregard them.
	You can also send a message to users about the changes.
Summary of Changes	Review all recent changes to a protocol and enter a rationale for each one.
	This information will be used to create a Summary of Changes page, which can be included if a protocol needs to be resubmitted.
Reference Management Software Integration	Pull in reference management libraries, such as Endnote, RefWorks, Mendeley, and PubMed.

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