



PROTOCOL BUILDER

CLOUD-BASED CLINICAL
PROTOCOL PROCESS
EFFICIENCY SOLUTION



Protocol Builder is a cloud-based software solution that changes the way clinical protocols are built. It was designed to eliminate the process inefficiencies: version control issues, time-consuming formatting, collaboration breakdowns and more.

AUTOMATIC FORMATTING

Protocol Builder eliminates time-consuming tasks that face any protocol author by:



- ▶ Automatically formatting input from all collaborators
- ▶ Automatically number and format references, footnotes, list of tables and appendices
- ▶ Automatically track all changes and pre-load them into the Summary of Changes - all that is needed is the rationale for the changes.

SPEEDS UP COLLABORATION

The protocol process is often held up by breakdowns and missed between collaborators on the project. With Protocol Builder you can:

- ▶ Ensure everyone is working on the same version of the protocol
- ▶ See all the changes you need to review in one place





- ▶ Compare revisions in a before and after format
- ▶ Distribute same template or pre-written protocols to groups of collaborators or investigators
- ▶ Receive notifications when changes are made.

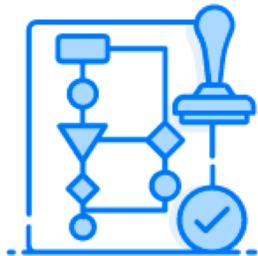
INCREASE TRANSPARENCY AND ACCOUNTABILITY

It can be time consuming to keep track of comments and changes, including who made them and when. Protocol Builder makes that easy with:

- ▶ Needs Review List: a worklist, organized by date and by section, showing what changes need to be reviewed and which ones have been completed/accepted
- ▶ Audit Trail: go when level deeper to see all changes made to any section of the protocol
- ▶ Protocol Dashboard: at-a-glance quickly assess protocol development progress.



CREATE A PROCESS THAT WORKS LIKE YOU WANT IT TO



Protocol Builder provides companies with the tools to customize and manage the protocol development process:

- ▶ Customizable templates to fit your clinical needs.
- ▶ Cloud-based hub centralizes protocol development efforts
- ▶ Administrative reporting on users and protocols

ENTERPRISE-STRENGTH APPLICATION

Protocol Builder is the only protocol-writing application designed to support large quantities of individuals involved in research and compliance at any organization.





KEY FEATURES

GUIDANCE	<ul style="list-style-type: none">▪ Step by step guided experience▪ Templates by study type (drug, device, observational, etc.)▪ Expert guidance for each topic▪ Easy to navigate contents menu▪ Collaborate with instructor
WRITE	<ul style="list-style-type: none">▪ Automatic protocol set up▪ 17 protocol templates (incl. SBER and NIH IND/IDE)▪ Easy-to-navigate contents menu▪ Protocol completeness indicators▪ Protocol cloning▪ Advanced editing tools▪ Compare revisions/tracked changes▪ Protocol preview▪ References Library▪ Resource Center▪ Protocol Archive
COLLABORATE	<ul style="list-style-type: none">▪ Compare revisions/tracked changes▪ Needs review alerts and review list▪ Email notification of changes▪ Protocol sharing▪ Invite collaborators (inside/outside institution)▪ Research administration access
REVIEW	<ul style="list-style-type: none">▪ Professionally-styled PDF or Word Output▪ Automatic Summary of Changes▪ Sponsor/Research administration specific access
MANAGE	<ul style="list-style-type: none">▪ Template set up flexibility▪ User management and reporting▪ Corporate Branding▪ Standard Confidentiality Statement



PRE-LOADED STANDARD TEMPLATES

INTERVENTIONAL

- NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
- Interventional FDA Approved Drug/Biologic
- Interventional Investigational New Drug/Biologic
- Interventional Non-Significant Risk Device
- Interventional Significant Risk Device
- Interventional Combination
- Behavioral Intervention (incl. benign behavioral intervention)

OBSERVATIONAL

- Chart Review
- QA/QI
- Repository with the use of Broad Consent
- Repository without the use of Broad Consent
- Observational study of a FDA regulated product
- Observational study of individual or group characteristics or behavior, or human factor evaluation

SOCIAL BEHAVIORAL

- NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans
- Social Behavioral

BACKED BY AN INDUSTRY LEADER

Protocol Builder is powered by the BRANY, a leader in providing hospitals and academic medical centers IRB, research ethics consulting and training, and end-to-end clinical trial support services.

