



# 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

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



## 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.

