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

Visit www.tetondata.com or call 800-901-5494 to request a demo.
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.

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**KEY FEATURES**

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<th>GUIDANCE</th>
<th>WRITE</th>
<th>COLLABORATE</th>
<th>REVIEW</th>
<th>MANAGE</th>
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<td>• Step by step guided experience</td>
<td>• Automatic protocol set up</td>
<td>• Compare revisions/tracked changes</td>
<td>• Professionally-styled PDF or Word Output</td>
<td>• Template set up flexibility</td>
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<td>• Templates by study type (drug, device, observational, etc.)</td>
<td>• 17 protocol templates (incl. SBER and NIH IND/IDE)</td>
<td>• Needs review alerts and review list</td>
<td>• Automatic Summary of Changes</td>
<td>• User management and reporting</td>
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<td>• Expert guidance for each topic</td>
<td>• Easy-to-navigate contents menu</td>
<td>• Email notification of changes</td>
<td>• Sponsor/Research administration specific access</td>
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<td>• Easy to navigate contents menu</td>
<td>• Protocol completeness indicators</td>
<td>• Protocol sharing</td>
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<td>• Standard Confidentiality Statement</td>
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<td>• Collaborate with instructor</td>
<td>• Protocol cloning</td>
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<td>• Advanced editing tools</td>
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PRE-LOADED STANDARD TEMPLATES

**INTERVENTIONAL**
- NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
- Intervventional FDA Approved Drug/Biologic
- Intervventional Investigational New Drug/Biologic
- Intervventional Non-Significant Risk Device
- Intervventional Significant Risk Device
- Intervventional 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.

Visit www.tetonda.com or call 800-901-5494 to request a demo.