Bringing data to life

Document development is our business

Document development for drug makers is time-consuming and resource intensive.

Acumen focuses on building solutions to the myriad challenges associated with writing regulatory documents, including those critical submissions, such as INDs and NDAs/BLAs.

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The brains behind the software

Acumen is a team of industry-experienced medical writers and clinical developers who provide top-tier support to drug makers.

We have harnessed our collective industry experience to develop the Smart Document Solution.

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What is the Smart Document Solution?

It’s a suite of software modules that integrate with Microsoft Word.

The modules include:

- **eCTD Templates (integrates with Stylus)**
- **Stylus (document formatter)**
- **Electronic Style Guide**
- **Quality Control Module**

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What Does the Smart Document Solution Achieve?

Bring together novel technology to assist drug developers in writing and submitting compliant, professional documents

Increase the speed and efficiency of writing and publishing teams

Automate time- and labor-intensive writing and editing tasks to maximize resources and minimize cost.

Templates

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The Challenges

The document burden is immense for pharma companies.

Smart organizations look for strategies to streamline the process of writing and submitting documents.

Operating without templates leads to wasted hours and impacts the quality of submissions.

Acquiring a full set of eCTD templates addresses these critical issues.

The Problem

There are a few sets of eCTD templates available on the market.

But are the templates any good? Who developed them? How often are they updated? Do they come with tools that make formatting easier? Are they stable or will they crash repeatedly when deployed? Are they easy to access?

The Solution – Acumen's eCTD Templates

Our eCTD templates are in a class of their own.

Designed by a team of experienced medical writers and editors, they offer features not available in other templates.

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Acumen's eCTD Templates

- ✓ Meet required eCTD structure
- ✓ Are enriched and continually updated with the latest regulatory guidance
- ✓ Include writing tips from Acumen's medical writers and editors
- ✓ Integrate with Stylus, a powerful and intuitive MS Word add-in to ensure crisp and consistent formatting and styling
- ✓ Stylus tool written in C# coding language, leading to greater stability when deployed
- ✓ Downloadable on-demand

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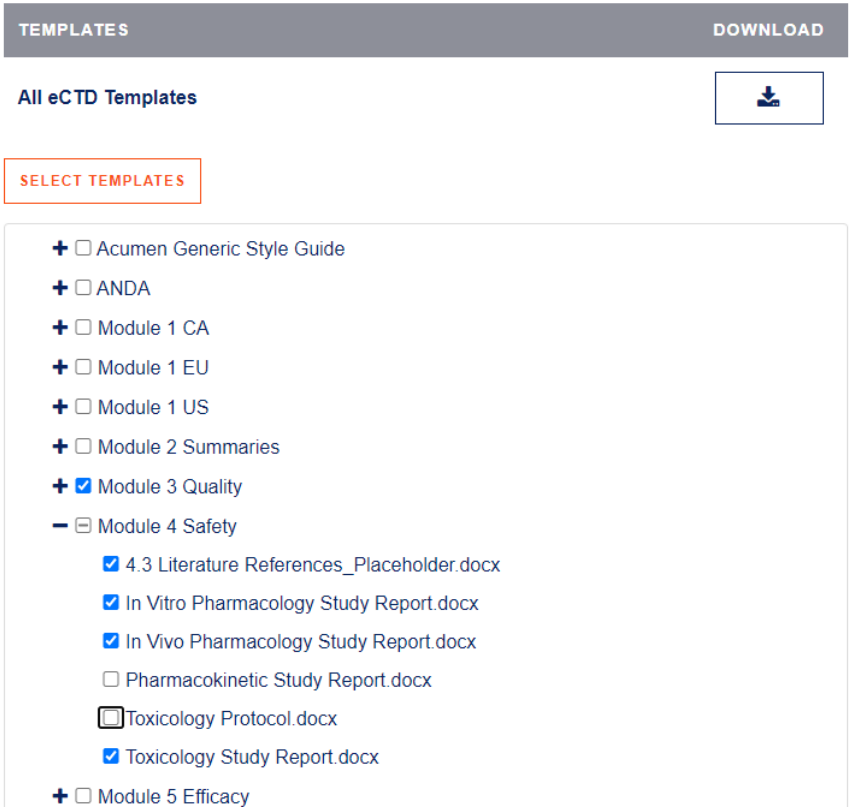
Accessibility

Cloud-based interface where the templates can be selected and downloaded on demand



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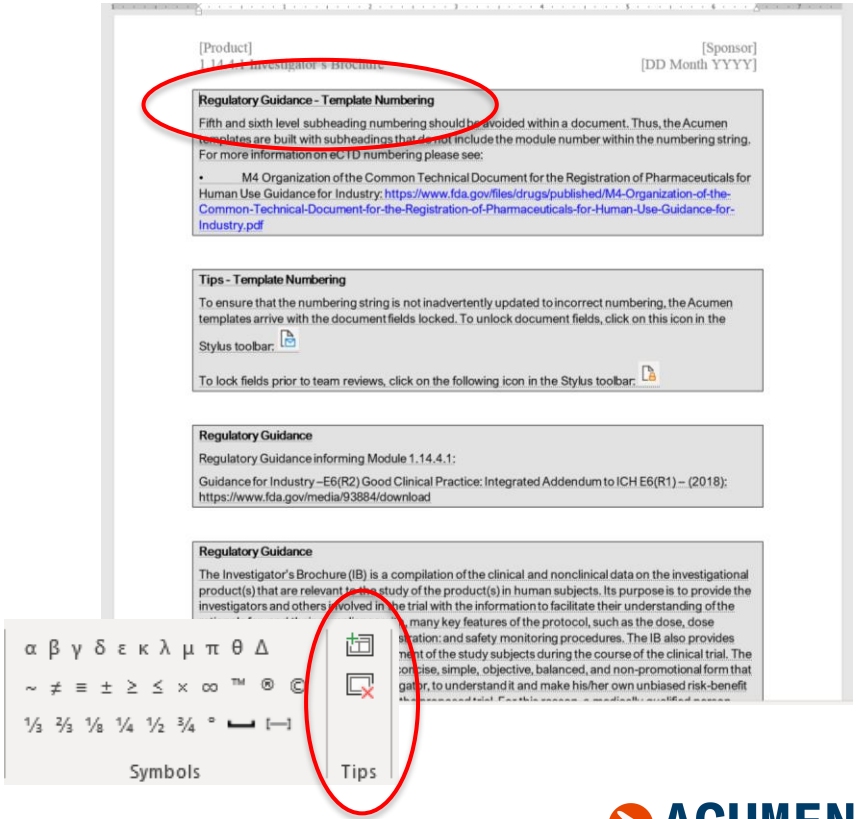
Regulatory Guidance

Each template has a summary of the applicable regulatory guidance.

Links to the specific guidance ensure authors maintain compliance.

Guidance and Tips can be hidden or even completely removed with the push of a button.



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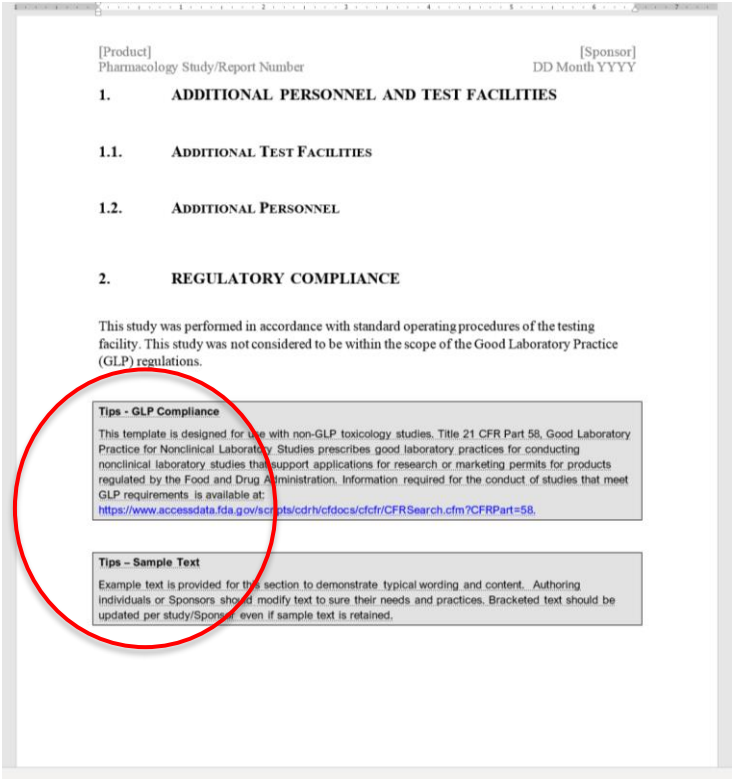
Writing Tips

Additional writing guidance from Acumen's writing team is provided in many templates.

These tips are based on years of experience and best practices in preparing submissions.

Helps writers of all experience levels to get things right the first time.


[Product]
Pharmacology Study/Report Number

[Sponsor]
DD Month YYYY

1. ADDITIONAL PERSONNEL AND TEST FACILITIES

1.1. ADDITIONAL TEST FACILITIES

1.2. ADDITIONAL PERSONNEL

2. REGULATORY COMPLIANCE

This study was performed in accordance with standard operating procedures of the testing facility. This study was not considered to be within the scope of the Good Laboratory Practice (GLP) regulations.

Tips - GLP Compliance

This template is designed for use with non-GLP toxicology studies. Title 21 CFR Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies prescribes good laboratory practices for conducting nonclinical laboratory studies that support applications for research or marketing permits for products regulated by the Food and Drug Administration. Information required for the conduct of studies that meet GLP requirements is available at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58.

Tips – Sample Text

Example text is provided for this section to demonstrate typical wording and content. Authoring individuals or Sponsors should modify text to sure their needs and practices. Bracketed text should be updated per study/Sponsor even if sample text is retained.

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Ease of Use

Acumen's eCTD templates integrate with the Stylus toolbar which makes formatting fast and simple.

With the Stylus, those annoying and time-consuming formatting issues are resolved with a click:

- Harmonizing numbering
- Fixing messy tables
- Adding hyperlinks to headings, table, or figures

Our writers and editors have thrown everything they know into this toolbar to save you time and make work easier.

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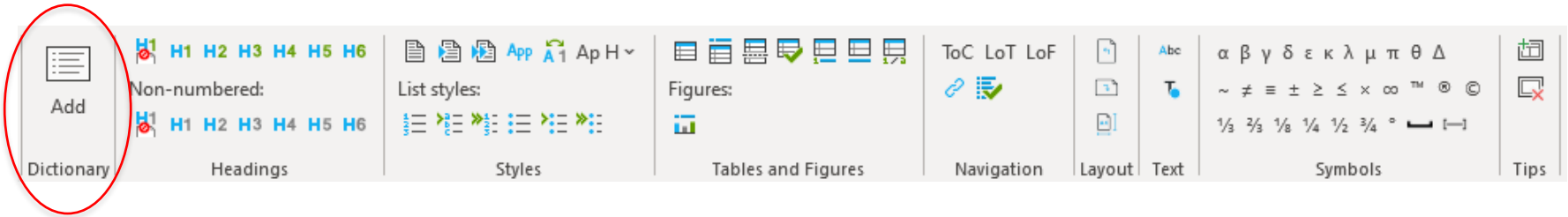
Enhanced Dictionary

Don’t let spelling errors diminish your message.

Our Templates come with an imbedded dictionary to capture and correct medical and scientific terms that Microsoft Word does not recognize.



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Templates Key Takeaways

- ✓ Align with current eCTD structure
- ✓ Enriched with valuable authoring tips from Acumen's experienced medical writers and editors
- ✓ Frequently updated as guidance changes
- ✓ Downloadable from a web interface at any time
- ✓ Integrates with the Acumen Stylus, a Microsoft Word add-in for clean formatting
- ✓ Equipped with a robust medical dictionary

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Pricing

Monthly or yearly subscriptions are available.

Pricing designed to match your company's size and budget.

Discounts are available when bundled with other Smart Document Solutions Modules.

To purchase, contact us via our website or email us at solutions@acumenmedcom.com

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