



ACUMEN

MEDICAL COMMUNICATIONS

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.

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.

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

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.



Stylus





The Challenges

Success in the pharmaceutical industry depends on document development – IND and NDA/BLA submissions may include hundreds or even thousands of documents.

Ensuring consistent and clean document sets at this scale is difficult.



The Challenges

Historically document alignment has been done by teams of writers and editors using general tools not specific designed to address this task.

This inefficiency spread over so many documents adds up to a mountain of lost time and money.



The Solution – Acumen’s Stylus

A Microsoft Word Add-in that integrates with Acumen eCTD Templates and includes:

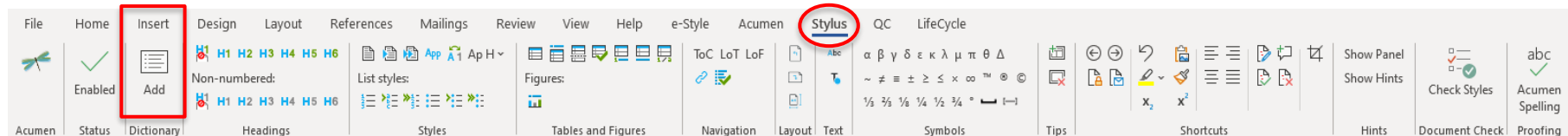
- ✓ **Tools for formatting headings, tables, footnotes, appendices, cross-references and more**
- ✓ **A dictionary of over 25,000 medical and scientific terms not found in the native MS Word dictionary**
- ✓ **Integration with our eCTD Templates**
- ✓ **Quick access to frequently-used features buried in MS Word**



Acumen's Stylus Toolbar

Once downloaded, the Stylus tab appears in the user's Microsoft Word ribbon.

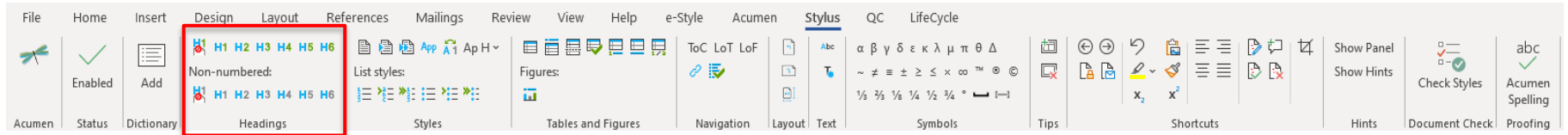
The Stylus dictionary is connected to Acumen's cloud which is continually updated with additional scientific and medical terms.





Document Headings

Styled with a click.



8. STUDY POPULATION

Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, is not permitted.

8.1. INCLUSION CRITERIA

Participants are eligible to be included in the study only if all of the following criteria apply:

Age

1. Participant must be [18] to [X] years of age inclusive, at the time of signing the informed consent.



Lists and Appendices

Consistent formatting is easily managed.

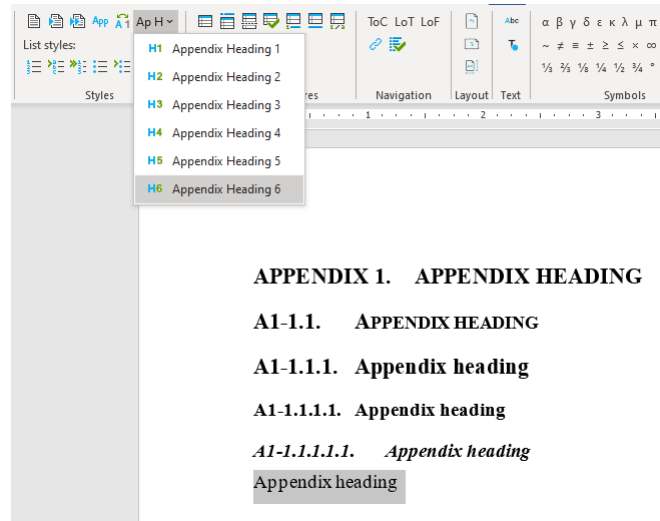
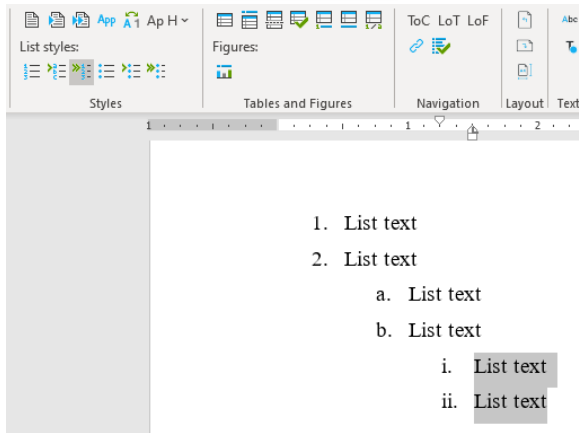
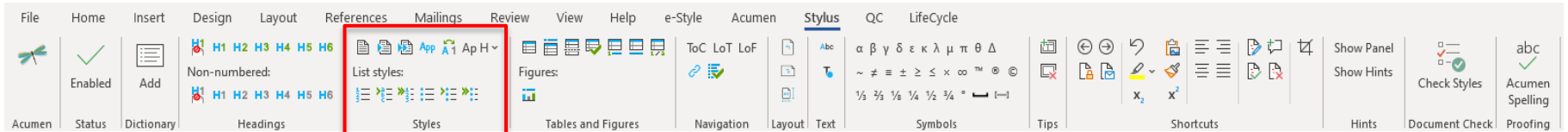
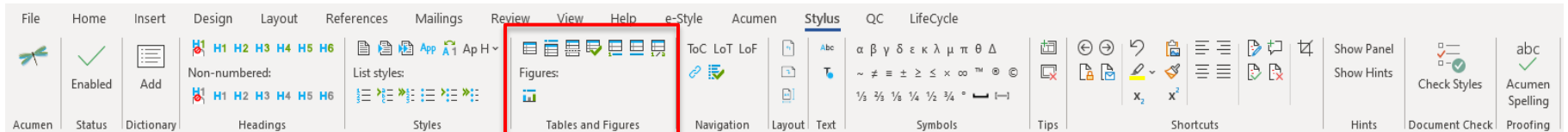




Table Formatting

Styling tables, footnotes, and figures is easy.



Insert Formatted Table

Enter Title for Table:
Sample Table

Number of Header Rows: 1
Number of Table Rows: 3
Number of Table Columns: 3

OK Cancel

Table Footnote

Type footnote text and click 'Add new footnote' to insert new footnote.

Footnote

Add new footnote

Select an existing table footnote to insert or delete.

Insert Delete

Cancel

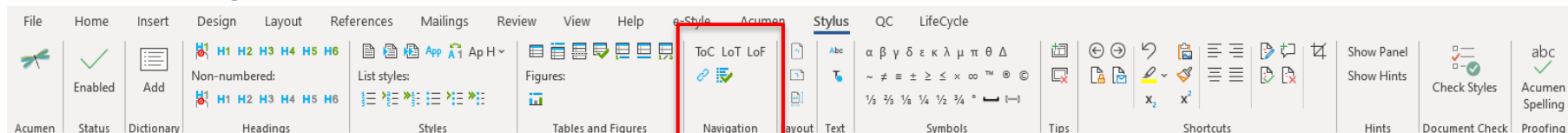
Table 1: Sample Table

Header	Header	Header



Table of Contents

Insert TOCs, LOTs, LOFs and cross-references right from the Stylus.



LIST OF TABLES

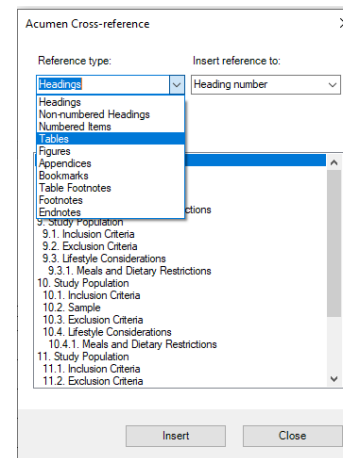
Table 1: Sample Table	12
Table 2: Sample Table	15

LIST OF FIGURES

Figure 1: 11

TABLE OF CONTENTS

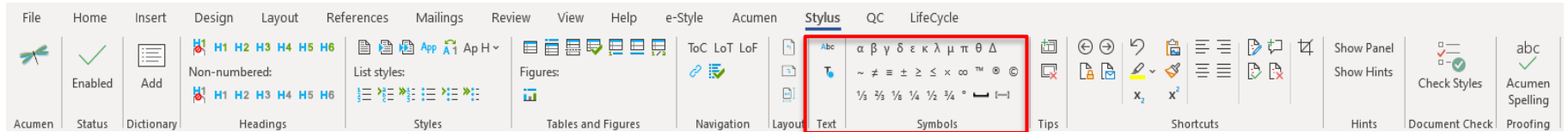
8. STUDY POPULATION.....	1
8.1. Inclusion Criteria	1
8.2. Exclusion Criteria	2
8.3. Lifestyle Considerations.....	2
8.3.1. Meals and Dietary Restrictions.....	2





Text and Symbols

Styling title case, hyperlinks, and inserting symbols are a breeze.



Title Case

Aβγ

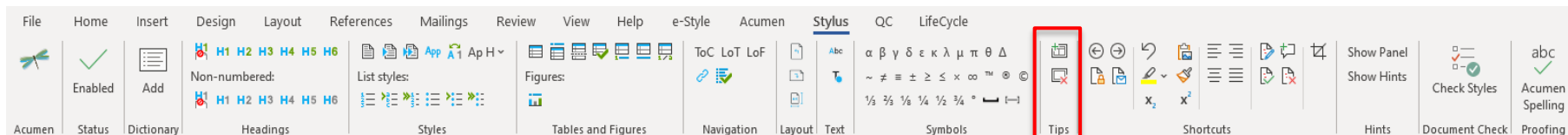
Hyperlink

½ ¼ ¼ ¼ ¼ °



Managing Guidance

Showing, hiding, and removing Template Guidance and Tips is simple.



[Product]
1.14.4.1 Investigator's Brochure

[Sponsor]
[DD Month YYYY]

3. PHYSICAL, CHEMICAL, AND PHARMACEUTICAL PROPERTIES AND FORMULATIONS

Regulatory Guidance

A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified, if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

Any structural similarities to other known compounds should be mentioned.

3.1. PHYSICAL PROPERTIES

3.2. CHEMICAL PROPERTIES

3.2.1. Chemical Name

[Product]
Pharmacology Study/Report Number

[Sponsor]
DD Month YYYY

7. EXPERIMENTAL PROCEDURES

7.1. STUDY DESIGN

Tips - Study Design Tables

Inclusion of tables is not required, but is recommended to help readers visualize important parameters of the Study Design. The table setup is flexible, and each should be customized as needed to best demonstrate the critical Study Design elements.

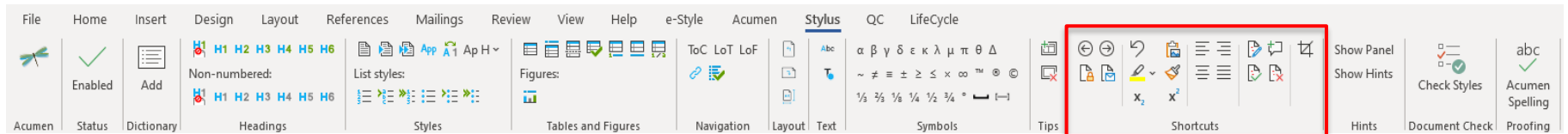
Tips - Appendix Information

Bioanalytical reports and methods validations should be provided as appendices.



Helpful Shortcuts

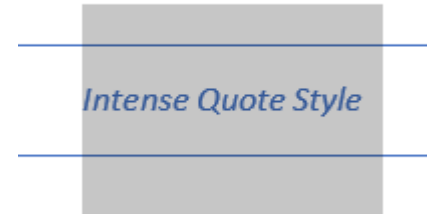
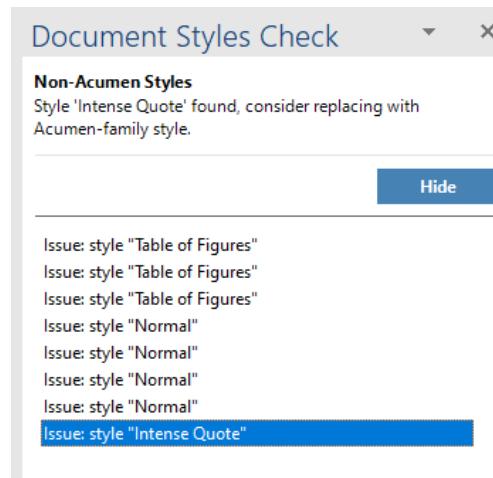
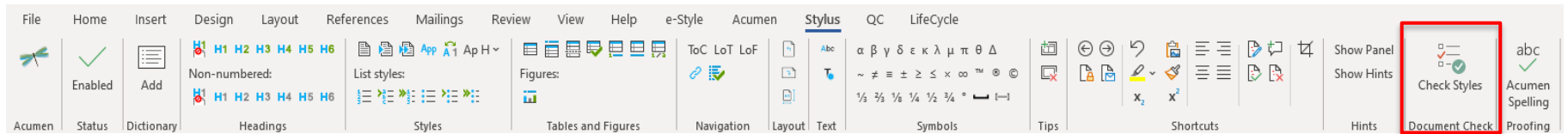
Shortcuts to common Word functions are conveniently grouped.





Style Scanner

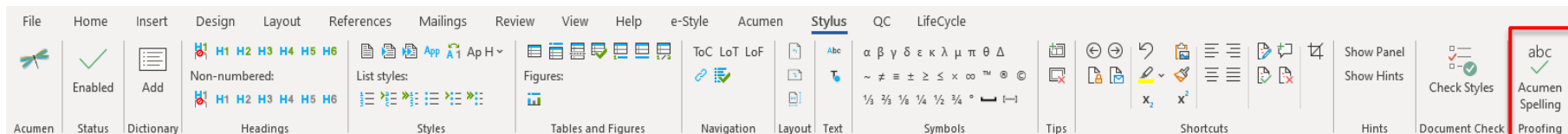
Check the document for rogue styles with this button.





Enhanced Spellcheck

Access to Acumen's scientific and medical dictionary is a click away.

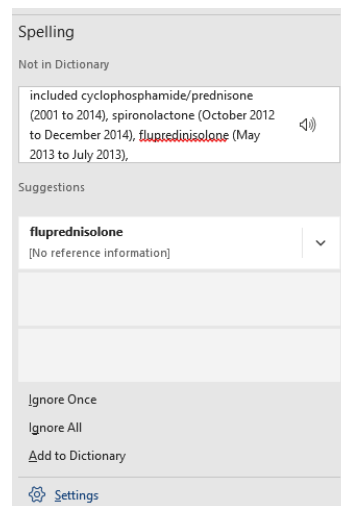


The patient was an 47-year-old male (race not reported) who was diagnosed with Cancer on 24 May 2001. The International Prognostic Scoring System (IPSS) stage at initial diagnosis was not specified. The stage at study entry was IPSS-Cancer was intermediate risk.

Prior therapies for treatment of Cancer included cyclophosphamide/prednisone (2001 to 2014), spironolactone (October 2012 to December 2014), fluprednisolone (May 2013 to July 2013), cyclophosphamide/prednisone (December 2014 to December 2014), chloroquine (January 2017 to June 2017), and methylidopate hydrochloride (August 2018 to June 2019).

The patient's past medical history included rheumatic fever, diabetes, cerebrovascular accident, hip fracture, head injury, H3N2 influenza, pneumonia, and heart failure. The patient's ongoing medical history included hair loss and macular degeneration.

On DD Month 2020, the patient received the first dose of study drug 160 mg (once daily).





Stylus Key Takeaways

- ✓ Integrates with Microsoft Word and the Acumen Templates
- ✓ MS Word-based ribbon makes consistent styling easy
- ✓ Consolidates hidden MS Word features, saving time
- ✓ Includes Acumen's 25,000+ medical and scientific terms
- ✓ Automates scanning for noncompliant styles
- ✓ A COM-based MS Word add-in written in C#



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