



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?

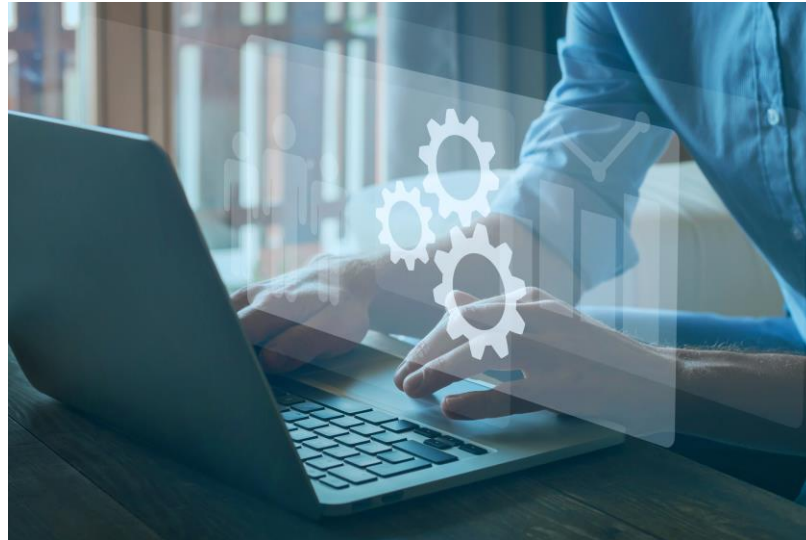
Assists drug developers in writing and submitting compliant professional-level documents

Increases the speed and efficiency of writing and publishing teams

Automates time- and labor-intensive editing tasks



Electronic Style Guide





The Challenge

Regulatory submissions contain thousands of pages and hundreds of terms and standards to keep aligned.

To address this, companies create **style guides**. Paper documents between 30 and 100 pages that define a program's nomenclature, right down to the last hyphen.



The Problem

It takes a team of dedicated editors endless hours to check all those documents against your paper style guide (assuming you have one) and against gold-standard dictionaries and manuals.

There limits to what a human can find.

Couldn't technology do this task much faster?



The Solution – Acumen’s E-Style Guide

A cloud-based electronic reader that scans documents in seconds to highlight potential errors and inconsistencies.

Key features:

- ✓ Scans documents in seconds
- ✓ Fully configurable, allowing clients to add/modify terms whenever they want
- ✓ Built on a backbone of standard scientific and medical nomenclature
- ✓ Conforms to scientific editorial gold standards, such as AMA Manual of Style
- ✓ Significantly reduces time and cost
- ✓ Automates key aspects of style guide review
- ✓ Helps teams produce consistent and professional documents fast



The Solution – Acumen’s E-Style Guide

Some of the items it searches for:

- ✓ **Defined program nomenclature**
- ✓ **Standard scientific nomenclature**
- ✓ **Standard medical and clinical nomenclature**
- ✓ **Punctuation, including spacing and capitalized terms**
- ✓ **Italics, such as genes and species**
- ✓ **Consistent hyphenation**
- ✓ **Generic and commercial drug names**
- ✓ **Acronyms**
- ✓ **Units of measure**
- ✓ **Numerical presentation**
- ✓ **MedDRA terms (American to British English)**



A web interface allows you to update specific nomenclature

Generic Client Backbone E-Style Guide

COPY FROM

E-STYLE GUIDE MODULE			LAST UPDATED
Nomenclature	Add Terms	Run Settings	15 May 2020
Acronyms	Add Terms	Run Settings	05 Jun 2020
Punctuation	Add Terms	Run Settings	15 May 2020

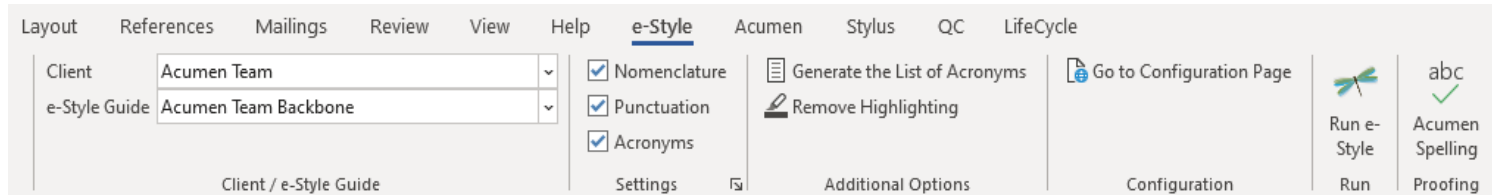
BACK

Program Specific Terms	▼
Preferred English Usage	▼
Hyphenated and Non-Hyphenated Words	▼
MedDRA Terms	▼
Drug Names	▲
Drug Names	
Italicized Terms	▼
Capitalized Terms	▼
Clinical Terms	▼
Scientific Terms	▼

Drug Names	
Avoid	Preferred
<input type="text" value="Tekamlo"/>	<input type="text" value="amlodipine"/>
<input type="text" value="Tekamlo®"/>	<input type="text" value="amlodipine"/>
<input type="text" value="Eliquis"/>	<input type="text" value="Apixaban"/>
<input type="text" value="Abilify"/>	<input type="text" value="aripiprazole"/>
<input type="text" value="Abilify Maintena Kit"/>	<input type="text" value="aripiprazole"/>
<input type="text" value="Abilify Mycite Kit"/>	<input type="text" value="aripiprazole"/>
<input type="text" value="A.P.L."/>	<input type="text" value="chorionic gonadotropin"/>



Easily integrates with Microsoft Word





Scans by category to focus in on specific areas

The writer or editor can target specific areas of interest to streamline the review.

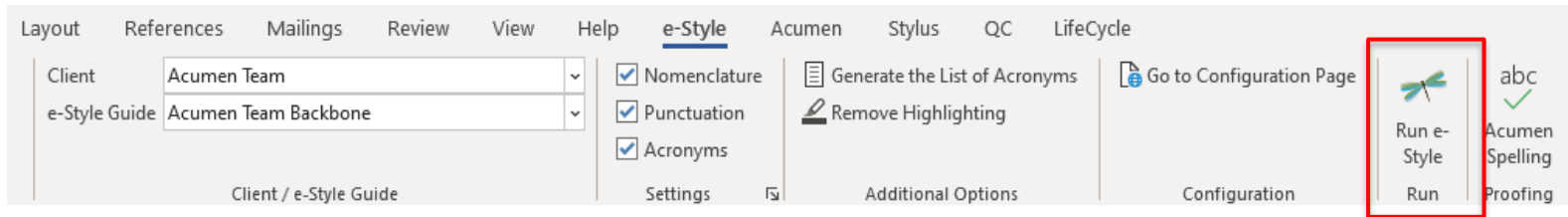
The screenshot shows the e-Style software interface. The 'e-Style' ribbon is active, and the 'Settings' button is highlighted with an orange box. A dialog box titled 'Categories and Subcategories Settings' is open, showing three columns: Nomenclature, Punctuation, and Acronyms. The 'Program Specific Terms' checkbox under Nomenclature is selected. The 'Abbreviations' checkbox under Punctuation is also selected. The 'Acronyms' checkbox under Acronyms is not selected. The 'OK' and 'Cancel' buttons are visible at the bottom of the dialog box.

Category	Subcategory	Setting
Nomenclature	Program Specific Terms	<input checked="" type="checkbox"/>
	Preferred English Usage	<input type="checkbox"/>
	Hyphenated and Non-Hyphenated Words	<input type="checkbox"/>
	MedDRA Terms	<input type="checkbox"/>
	Drug Names	<input type="checkbox"/>
	Italicized Terms	<input type="checkbox"/>
	Capitalized Terms	<input type="checkbox"/>
	Clinical Terms	<input type="checkbox"/>
	Scientific Terms	<input type="checkbox"/>
	AMA	<input type="checkbox"/>
Punctuation	Spacing	<input type="checkbox"/>
	Units of Measure	<input type="checkbox"/>
	Numerals	<input type="checkbox"/>
Acronyms	Abbreviations	<input checked="" type="checkbox"/>
Acronyms	Acronyms	<input type="checkbox"/>



Scans documents with the push of a button

From the E-Style Guide ribbon a writer or editor can initiate a document scan.





View findings

The E-Style Guide scans the document and identifies items that may need replacement.

This multicenter, multinational study, sponsored by sponsor company, enrolled subjects at 202 sites across 17 countries (including, the US and EU).	
Publications (reference): Doctor et al, "Results from the Phase 3 Trial: A Randomized Comparison of <u>Druggamab</u> vs Comparison Agent in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma," Oral Presentation presented at the 100 th Annual Meeting of American Society of Hematology (ASH), 14 March 2016	
Studied period (years): Data cutoff for this report: June 19, 2018 As of 19 May 2019 , 6 patients remain on <u>druggemab</u> and no patients remain on comparison agent	Phase of development: 3
<i>Primary Objective</i> <ul style="list-style-type: none">Examine the efficacy of <u>druggamab</u> monotherapy versus comparison agent monotherapy in subjects with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma	

Acumen Team Backbone

chronic lymphocytic leu → CLL

Suggestions:

Acronyms: CLL

Apply Ignore Add Comment

- relapsed or refractory → R/R
- chronic lymphocytic leukemia → CLL
- small lymphocytic lymphoma → SLL
- quality of life → QoL
- pharmacodynamic → PDn, PD
- relapsed/refractory → R/R
- orally → PO
- twice daily → BID, BID
- mg → mg
- Complete blood count → CBC
- physical examination → PE
- performance status → PS



Apply or ignore findings

The user manages these replacements through a side panel, accepting or ignoring as appropriate.

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Generate a list of acronyms from the document in seconds

Generate a table of acronyms with a click of a button

List of Acronyms

Acronyms	Definitions
ABC	activated B-cell
ABC123	
AE	adverse event
AIHA	
ASH	American Society of Hematology
AT	
BID	twice daily
BRANDNAME	
BTK	Brutons tyrosine kinase
CBC	complete blood count
CLL	chronic lymphocytic leukemia
CR	complete response
CRi	complete response with incomplete recovery
CT	computed tomography
CTCAE	Common Terminology Criteria for Adverse Events
DOR	duration of response
ECOG	Eastern Cooperative Oncology Group
ESMO	European Society for Medical Oncology
EU	European Union

The screenshot shows the Acumen software interface with the 'e-Style' menu open. The 'Generate the List of Acronyms' option is highlighted with a red box. A red arrow points from this button to the 'List of Acronyms' table on the left. The interface includes a menu bar with 'Layout', 'References', 'Mailings', 'Review', 'View', 'Help', 'e-Style', 'Acumen', 'Stylus', 'QC', and 'LifeCycle'. The 'e-Style' menu has options for 'Nomenclature', 'Punctuation', and 'Acronyms'. The 'Acumen' menu has options for 'Run e-Style' and 'Acumen Spelling'. The 'QC' menu has a 'Go to Configuration Page' option. The 'LifeCycle' menu has 'Run' and 'Proofing' options. The 'e-Style' menu also has a 'Settings' option. The 'Acumen' menu has a 'Client / e-Style Guide' option. The 'e-Style' menu has a 'Remove Highlighting' option. The 'Acumen' menu has a 'Run e-Style' option. The 'Acumen' menu has an 'Acumen Spelling' option. The 'QC' menu has a 'Go to Configuration Page' option. The 'LifeCycle' menu has a 'Run' option. The 'LifeCycle' menu has a 'Proofing' option.



Enhanced spelling of medical and scientific words - as you type or via scan

Leverages Acumen's 25,000+ term medical and scientific dictionary

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 hip fracture, her medical history

On DD Month

On DD Month

Bad event second

onset was taken

up to 60 days prior

to afibercept, ps

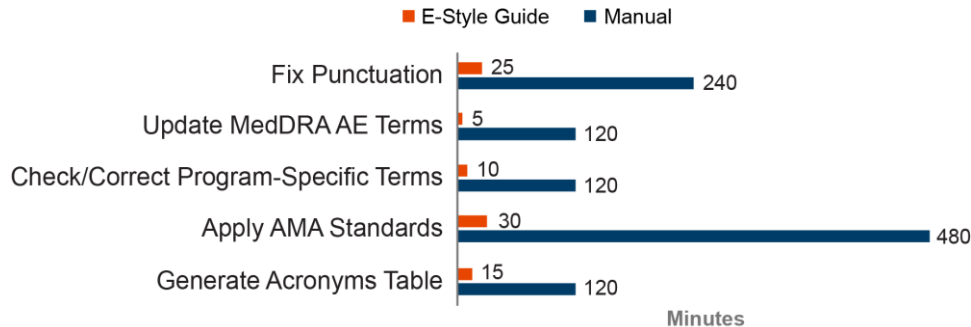
potassium.

Concomitant medications up to 30 days prior to start of the SAE of Grade 3 **Asthma** included pantoprazole, larondase, ofloxacin, alectninib hydrochloride, pantoprazole sodium sesquihydrate, copanlasib dihydrochloride, paracetamol, alogloptin benzoate, azithromycin, cefepime, carglemic acid, and enoxaparin sodium.



Acumen's E-Style Guide Saves Valuable Time and Money

Editing Time: ESG vs. Manual by Task on 150-page Doc



Use of the ESG can lead to significant reductions in editing time.

Multiplied across hundreds of documents, this added efficiency allows your team to:

- ✓ **Focus on science and strategy**
- ✓ **Decrease overall spend**
- ✓ **Complete quality submissions faster**
- ✓ **Achieve document consistency and quality that matches your science**



Acumen's E-Style Guide Drives Document Quality

The depth of the ESG's database and search speed results in significantly more meaningful findings than a human editor working unaided.

The remaining editing hours can be refocused on document readability and flow, and refining key elements for the end users, such as FDA or clinical sites.

The screenshot displays the Acumen E-Style Guide interface. At the top, the search term 'pharmacokinetics' is entered, with a dropdown arrow pointing to 'PK'. Below this, a 'Suggestions:' section shows 'Acronyms: PK' highlighted in blue. A control bar contains three buttons: 'Apply' (green), 'Ignore' (red), and 'Add Comment' (blue). A scrollable list of suggestions follows, each with a colored dot and a text change: 'placebo → PBO' (red), 'pharmacokinetics → PK' (blue), 'healthy volunteer → HV' (red), 'due to → because of' (green), 'clinically significant → CS' (red), 'tumors → tumours' (green), 'clinically significant → CS' (red), '> → >' (cyan), 'mg → mg' (cyan), '< → <' (cyan), 'higher → greater, larger' (green), and 'mg → mg' (cyan). At the bottom, a red-bordered box contains the text: 'The number of detected errors: 956' and 'Time spent: 2 min, 12 sec.'



The E-Style Guide Key Takeaways

- ✓ Industry's first scientific/medically oriented electronic editing system
- ✓ Integrates with Microsoft Word
- ✓ Users can add program-specific terms through an intuitive web interface
- ✓ Side panel allows rejection or acceptance of suggestions with the click of a button
- ✓ Comes with Acumen's gold-standard backbone based on AMA Manual of Style
- ✓ Acronym scan and generation of table of all acronyms
- ✓ As-you-type and scan-based spell check
- ✓ 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
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or email us at
solutions@acumenmedcom.com