ACUTA announces the release of version 1.0 of the ACUTA Regulatory Intelligent Documents (ARID) Template System

Marlborough MA – September 28, 2017 – ACUTA announced the release of ACUTA Regulatory Intelligent Documents (ARID) version 1.0 – a system of templates and productivity and quality automation for Microsoft® Office Word. ARID includes over 250 shell documents designed to provide a starting point for the regulatory content needed for the Common Technical Document (CTD)- and Clinical Trial Authorisation (CTA)-based submissions sent to regulatory agencies. It also provides a focused ACUTA toolbar tab in Word that combines the most commonly used features from Word's other tabs with new features specific to regulatory documents. ARID arrives at a great time for bio/pharma companies, when the number of vendors supporting regulatory templates has been dwindling.

Shy Kumar, ACUTA's Founder, President and CEO had this to say about ARID:

> *"Our customers using ARIM (ACUTA Regulatory Information Management) for publishing and registration tracking have asked for a way to create the content they will compile into submissions. With our regulatory publishing expertise, we distilled down the common parts of documents used in those types of submissions, and our development team rapidly created the tools authors need to fill them back in."*

The over 250 shell documents include clinical and market application content for the US, European and Canadian submissions for marketing applications and clinical study registration. Each shell contains the appropriate metadata fields, automating the process of inserting information such as the product name and manufacturer throughout the document. With a system of profiles, customers can configure the page layout to their specific requirements of margins, and which metadata information appears in the header and footer.

The automation features include quick access to the most commonly used styles to help authors keep their documents well-structured, and a means of reporting the page layout and styles used. Other tools include inserting landscape pages, palettes of over 100 commonly-used symbols, and assistance in inserting and formatting tables, figures, and the table of contents. Joel Finkle, ACUTA's Director of Regulatory Innovation had this to say: "Too many of the tools provided out-of-the-box in Word Processors are designed for either very simple documents, or to demonstrate features that are only used once or twice a year. ARID concentrates the most useful features of Word in one place – while still leaving the full functionality at your fingertips -- and fills in the gaps to make regulatory authoring more consistent and straightforward."

ARID is built using Microsoft's Visual Studio Tools for Office, providing a clean and safe integration with the Word environment, supporting Microsoft Office Word version 2010, 2013, 2015 and 2016.

Other features of ARID 1.0 include:

- Numbered and Unnumbered headings, and configuration of heading numbering to include prefixes for the Common Technical Document structure

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- Four levels of numbered and bulleted lists, that can be configured for a particular document's needs
- A simple tool to split a table across multiple pages, optionally repeating the caption as "continued"
- Insertion of the Table of Contents, and lists of Tables, Figures and Appendices
- Quick access to features that Microsoft Word "buries" such as Hypertext Links, internal Cross References, and Page Breaks
- Instructional and Guidance text that can be removed in a single step before publishing

For more information on ARID, please visit www.acutallc.com/arid.html

About ACUTA, LLC

ACUTA was founded in November 2012 to assist life science companies in complying with ever changing regulatory requirements that guide the product lifecycle through approval and maintenance. ACUTA's founder Shy Kumar, and his team members are well known in the industry, with over 20 years of experience. They have successfully deployed state-of-the-art solutions that were well received by industry and users.

ACUTA's vision is to develop innovative solutions to assist life sciences and related companies with their regulatory information management, which ultimately benefit everyone and specifically the needs of patients around the world.

ACUTA is headquartered in the Marlborough, MA, with offices in Bensalem, PA, and Bangalore India. For more information, visit www.acutallc.com.

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