

# Defining Communication Quality Standards for Your Clinical Research Reports

*Learn how to effectively convey instructions, key messages,  
and data in clinical documentation*

## Webinar Description

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<b>Webinar Audience:</b>	Entry through senior-level authors and reviewers of clinical protocols, study reports, and annual updates
<b>Webinar Purposes:</b>	To learn best practice methods to help improve the underlying logic and communication quality of clinical research documents and reduce the time spent crafting these documents
<b>Webinar Duration:</b>	One hour
<b>Webinar Design:</b>	Facilitator-lead with 90% presentation and 10% discussion utilizing an exhibit-rich user manual and presentation slides
<b>Webinar Date:</b>	Various dates are available. Check current list here: <a href="http://www.mcculley-cuppan.com/webbasedlearning.html">http://www.mcculley-cuppan.com/webbasedlearning.html</a>

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*Clinical research is complex and resource-intensive work involving large and scientifically demanding documentation. Both individual careers and organizational success depend on high-quality documents that effectively capture and communicate the development work. Establishing quality and document standards is a difficult process. This webinar highlights the communication quality standards that distinguish clinical research writing from other forms of technical writing. In particular we discuss utilization of a well-characterized set of document standards that authors and reviewers can apply to determine the communication quality of clinical study protocols and ICH-compliant research reports.*

## Webinar Outline

### **Understanding why document standards are critical for creating high-quality documents**

This section discusses how writing is a transaction between the writer and the reader, with the principal obligation for effectively conveying the message belonging to the writer. It is the writer's responsibility to reduce the amount of "interpretive space" available to the reader to construct alternate meanings. Therefore to ensure communication success, effective writers of complex clinical research material know they must work to well-defined standards.

### **Applying document standards to clinical study protocols**

This section of the webinar introduces the McCulley/Cuppan document standards that measure the quality of the chain of logic in a protocol and address why a clear logic trail is essential to make a protocol coherent and reduce the likelihood of investigator error. We also discuss standards related to effective document organization. Particular attention is given to the importance of how similar types of information, such as actions, explanations, definitions, or assignment of decision-making should be grouped together in a manner that is most meaningful to the reader and to different types of list structures that are best suited for use in protocols. Lastly, this section considers standards for

writing clear and precise instructions and using correct word choice to avoid ambiguity that could lead to delays and even errors.

## **Applying document standards to clinical study reports**

In clinical research, the study report describing research findings is situated within complex scientific, organizational, regulatory, and legal contexts. This section of the webinar discusses the document standards that effectively measure the rhetorical moves that must be accomplished within established places of argument in an ICH-compliant clinical study report. We also consider the standards that measure whether a study report provides sufficient detail regarding the purpose of the work; the relationships to be studied; the reasons for the study; and the specifics of study design, conduct, and analysis. Effective representation of these details enables readers to critically evaluate and determine whether the characteristics of an adequate and well-controlled study are present. Additionally, we focus on the standards needed to measure quality of logic, because most high-quality clinical research reports require effective integration and discussion of two interdependent tasks: 1) generalizing observations from few to many (statistical reasoning); and 2) integrating empirical data with theory-based and practice-based knowledge (clinical reasoning).

## **About your speaker**

### **Gregory Cuppan**

Greg is the Managing Principal of McCulley/Cuppan LLC, a group he co-founded. He has spent 16 years providing consulting and training services to pharmaceutical and medical device companies and research enterprises. Greg has personally interviewed dozens of regulatory agency staffers regarding the task of reading and using the documents submitted by drug and device sponsors.

## **How to register for the webinar**

1. Visit our website <http://www.mcculley-cuppan.com/webinarregistration.html>.
2. Complete the registration form for each registrant and click Submit.
3. A member of our E-Learning Program staff will contact you to complete registration and process payment.
4. Following your registration, you will receive an emailed confirmation that includes connection instructions for the webinar and a copy of the webinar manual.

## **About McCulley/Cuppan**

McCulley/Cuppan provides a full range of consulting, training, and writing support to the pharmaceutical R&D industry.

- We have worked with over 60 pharmaceutical and biotech companies worldwide.
- We interviewed, trained, and worked with the FDA to help medical officers improve the quality of their documents and document development processes.
- We have developed and conducted customized training programs and workshops for over 4000 scientists worldwide.



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