

Q ■ The Global eCTD Guidance Interpretation: What's in it for you?



Unifying **Clinical Data** and **Submission Strategy**
for the **Global Life Sciences Industry**

Breakthrough Outsourcing

World-Class Consulting

Game-Changing Software

Octagon
Research Solutions, Inc.[®]
Don't **Compromise.**

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Octagon's Commitment to eCTD Excellence

A critical component in defining an organization's approach to eCTD is the development of an eCTD Guidance Interpretation that contains the organization's strategy and details the relevant standards of practice that support the creation of compliant eCTD submissions. There are a substantial number of guidances and specifications that define the format and approach for electronic submissions. Within these guidances, there are areas requiring further clarifications or interpretation before a sponsor can put them into practice.

In response to these issues, Octagon's Regulatory Affairs, Regulatory Operations and Process experts have combined their expertise to develop the **Global eCTD Guidance Interpretation**. The Global eCTD Guidance Interpretation enables sponsors to quickly locate critical standards information and is the result of over 500 hours of expert effort spanning over 35 different guidance documents and specifications.

The Global eCTD Guidance Interpretation facilitates communication of cross-departmental standards throughout a research and development organization and provides an easier means to generate department specific quality related checklists. It promotes improved consistency within and across departments, which leads to improved submission format quality and provides clarity where guidances are not detailed or specific enough.

The Global eCTD Guidance Interpretation provides a common framework and establishes your organizational approach to eCTD submissions. It offers consistency across therapeutic or functional areas and can be used as a training tool to ensure common understanding of strategy and standards across your organization.

The Global eCTD Guidance Interpretation includes an optional annual subscription for guidance updates to ensure that everyone in your organization is accessing the most current interpretation and moving in a common direction. The Global eCTD Guidance Interpretation provides a common foundation for the "fuzzy gray areas", where most guidances lack clarity or where sponsors need to make company specific decisions.

Global eCTD Guidance Interpretation includes:

- Detailed documentation of current electronic submission guidances and specifications including Octagon's expert interpretation of these documents
- Available for US based interpretation or combined EU (with focus on Centralized Procedure) and Canadian interpretation
- Computer-based training supporting the implementation of the Guidance Interpretation
- Options for customization to the interpretation and customized training to support your specific organization requirements

The Global eCTD Guidance Interpretation compliments Octagon's other solutions designed to support the development of electronic submissions including:

- **StartingPoint®** - Octagon's Global eCTD Template Suite which is a collection of over 240 submission authoring templates to simplify the authoring process and enable authors to work at the granular level required to support eCTD.
- **ViewPoint® eCTD Complete** - A package of unique services and products that provide the four essential capabilities required to create and maintain an eCTD submission: compilation, issue management, validation and viewing.

For more information, please visit www.octagonresearch.com or **contact us** at 610.535.6500.



**Global
eCTD Guidance
Interpretation**

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