

Octagon- CLINICAL INFORMATION MANAGEMENT

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

From Data Collection to Submission



Q: Is your CRO providing
submission-ready
deliverables?

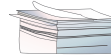
Don't **Compromise.**



From Data Collection to Submission



Compile



Validate



View



Octagon's eCTD Suite (ViewPoint® eCTD Compiler, eCTD Viewer and eCTD Validator)

As the industry continues to move toward global standards for regulatory submissions, you must position your organization to be ready for the intricacies of implementing the eCTD. You'll have to make decisions that align with your organization's eCTD strategy, position yourself with adequate capabilities and learn the rules of the game. In order to be successful you'll need refined processes, educated resources and tools that provide value and visibility.

There are three critical tools needed to support any eCTD strategy:

- **eCTD Compiler** – The eCTD Compiler allows users to create eCTD submissions in concert with ICH and regional specifications, and guidance. This includes the creation of all XML “backbone” files.
- **eCTD Validator** – The eCTD Validator allows users to confirm that their submissions are meeting the expectations set forth within ICH and regional specifications, guidance and industry best practices.
- **eCTD Viewer** – The eCTD Viewer allows users to view a single submission as well as the lifecycle of the dossier.

Octagon's eCTD Suite was developed to support the global need for flexible, enabling technologies that facilitate the eCTD submission process. These solutions were developed with critical business input from Octagon's experienced Regulatory Operations and Regulatory Affairs professionals.

The **ViewPoint eCTD Compiler** manages the compilation of each submission in the context of the lifecycle of the dossier. The eCTD compiler coupled with ViewPoint's robust process engine offers a unique blend of compilation and process management capability.

Octagon's eCTD Viewer provides practical viewing functionality that supports the entire eCTD submission lifecycle. Octagon's eCTD Viewer also facilitates searches across instances and displays leaf lifecycles including leaves in related dossiers.

Octagon's eCTD Validator automates the tedious verification of critical folder, file and meta data information. It validates submission XML files for compliance with technical specifications as well as industry best practices. Octagon understands the eCTD process. We have designed the eCTD Validator as a flexible tool that supports speedy and thorough checking of a submission so last minute details don't go unnoticed.

This innovative suite offers comprehensive viewing and validation capabilities, limiting the risk of missing a submission date or filing an incomplete or noncompliant eCTD submission.