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Are you hiding from rework  
at submission time?

From **Clinical Data Collection**  
to **Regulatory Submission**

Breakthrough Outsourcing

World-Class Consulting

Game-Changing Software



**Octagon**  
Research Solutions, Inc.<sup>®</sup>  
Don't **Compromise.**

# From Clinical Data Collection to Regulatory Submission

Breakthrough Outsourcing   World-Class Consulting   Game-Changing Software



## Process Consulting

Preparing data, documents and submissions in a manner to minimize rework at submission time requires sponsors to have well documented procedures centered upon the use of data and submissions standards. These standards and processes must be implemented in the context of supporting technologies to ensure regulatory compliance and to maximize efficiencies and throughput.

### CDISC Data Standards

Impact on the clinical data lifecycle

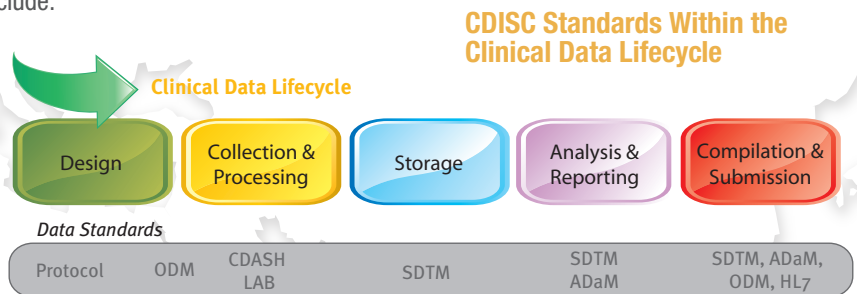
Octagon's **Process Consultants** specialize in assisting clients with the planning and development of CDISC-based data and electronic submission capabilities in order to achieve regulatory compliance and maximize operating efficiencies.

## Clinical Data Lifecycle

A CDISC standards-based clinical architecture streamlines data flow from trial design to submission. Organizations seeking to leverage this type of architecture can rely on **Octagon's Clinical Data Strategies Consultants** to provide initial strategy development, conceptual and functional design, and standards metadata development. Our Clinical Data Strategies Consultants possess the standards expertise required to effectively implement change and are invaluable partners throughout your clinical data lifecycle.

Octagon's Clinical Data Strategies consulting services include:

- CDISC Strategy Development
- Data Lifecycle Conceptual/Functional Design
- Data Standards Governance
- eClinical Technology Implementations
- Metadata Registry Design

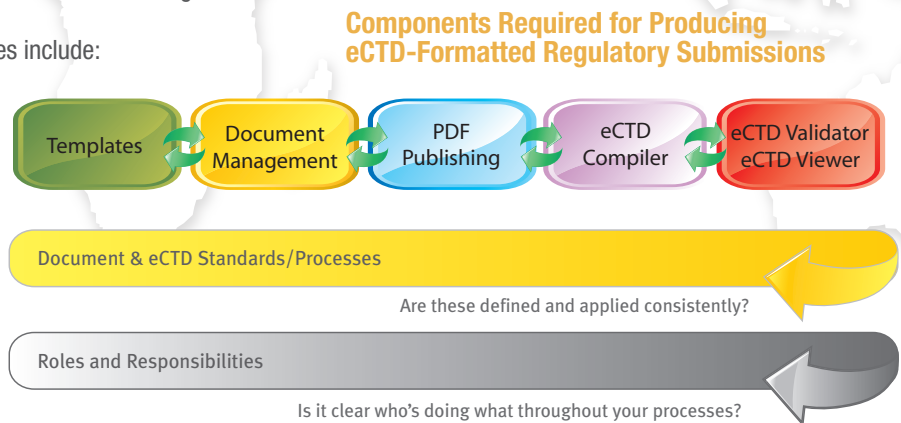


## Regulatory Submissions

When preparing an electronic submission, many organizations seek to minimize the rework required on functional area contributions. Octagon has a proven methodology to enable organizations to move eCTD-specific standards and processes into the "up-stream" areas to ensure that submission contributions can readily be included by Regulatory. Our experience with leading document management and publishing software enables our consultants to provide leadership and guidance on technology implementation projects and ensure that both regulatory compliance and process efficiencies are achieved on "go-live."

Our eSub Process and Technology consulting services include:

- eCTD Transition Strategy
- eCTD-ready Standards Development
- Document and Data Process Development
- Technology Implementations
- Organizational Design



For more information, please visit [www.octagonresearch.com](http://www.octagonresearch.com) or **contact us** at 610.535.6500.

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