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Are you ready for your next electronic submission?

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



*The traditional approach to producing submissions is one of institutionalized chaos, where domain experts and technical professionals work in silos of information, never realizing the gains that can be achieved through an integrated, cross-functional submission methodology.*

## **Octagon Provides Unsurpassed Submission Management**

In alignment with our next generation outsourcing methodologies, Octagon provides unsurpassed, global leadership in the submission management process through collaborative content planning, evaluation of cross-functional deliverables, thorough quality assurance/control, state of the art training and effective agency interactions. We have the largest electronic submission team in the industry, encompassing both Operations and Affairs personnel. We are the trusted submission partner to over eighty companies. Our methodology integrates Regulatory Affairs and Regulatory Operations expertise in optimized cross-functional processes. We manage and control every aspect of the submission compilation process through **ViewPoint®**, our global enterprise submission process management solution.

Octagon's Regulatory Services contribute practical expertise and an in-depth understanding of the intricacies of the submission lifecycle. Every engagement includes an element of training because knowledge transfer is part of every deliverable we produce. We are networked throughout Europe to provide quality, local and pan-European advice dedicated to delivery.

## **Regulatory Affairs Consulting**

Our Regulatory Affairs experts provide a thorough understanding of the changing regulatory landscape that is founded in practical experience compiling submissions and interacting with global regulatory authorities. We will act as a U.S. Agent for global companies seeking regulatory approval in the United States.

## **Submission Compilation**

Our optimized business process outsourcing model offers document publishing, metadata compilation and complete electronic submission capabilities to our clients. A cross-functional team of Regulatory Operations, Regulatory Affairs and Quality Assurance professionals focus on every submission we produce.

## **Submission Stewardship Program**

Our **Submission Stewardship Program™** delivers complete eCTD capabilities that span the submission lifecycle. Our Regulatory and technical teams will provide quality and consistency reviews, electronic publishing, metadata and lifecycle management and complete compilation capabilities from investigational application to marketing authorization and beyond.

## **SPL Stewardship Program**

Our **SPL Stewardship Program** offers complete SPL submission capabilities including SPL Training, Capability Consulting, Conversion Services and Submission Compilation.

## **Electronic Submission Training**

Our expert Regulatory resources conduct multiple training programs that focus on key electronic submission topics. Our training strategy is built on a foundation of practical expertise combined with a solid understanding of the current regulatory landscape, networked for knowledge transfer of strategic initiatives and a vision for the future of electronic submissions.

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

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