

Do you need to author IND documents in a consistent style and format but don't know where to start?

Are you planning to submit an eCTD IND for your compound but lack the resources?

Are you considering electronic data capture (EDC) for your Phase I Study but think it's too costly?



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.**

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



Breakthrough Outsourcing World-Class Consulting Game-Changing Software

Octagon's Early Development Package

IND Authoring • Templates • eCTD IND Compilation • Phase I EDC

If you answered yes to those questions, you are probably faced with the daily challenges of trying to rapidly guide a product (or products) through early development with minimal resources while constantly trying to control costs. Small companies face the same struggles as large organizations when it comes to drug development processes. Yet they carry the additional burden of bringing products to market with smaller resource pools, tighter budgets and limited access to enabling technologies.

The Octagon team understands the hurdles that small organizations face in bringing a new product to market. We also understand the value of leveraging standards, automating technologies, practical experience and innovative outsourcing strategies to overcome those hurdles and successfully move through development phases in the most efficient manner possible.

That is why we are introducing our **Early Development Package**. This package offers vital early stage capabilities at an attractive price that enables small organizations to have access to the same technologies, expertise and standards that help larger organizations decrease time to market.

The Early Development Package includes:

- A comprehensive collection of over 150 IND related eCTD Authoring Templates selected from Octagon's **StartingPoint**® submission document authoring template suite
- Expert compilation services supporting an original IND application in eCTD format, provided by Octagon's experienced Regulatory Services Team
- Complete EDC capabilities for a Phase I Study utilizing ViewPoint FUSE that includes submission compliant deliverables

This offering enables small companies to leverage our game-changing technologies and breakthrough outsourcing model to increase capabilities and quickly expand capacity. Utilizing Octagon's practical expertise from electronic data collection to regulatory submission provides small organizations with big capabilities based on deep domain knowledge, cross-functional eSub expertise, a holistic process approach and integrated solutions.

Highlights of the Early Development Package include:

- Value of working with industry experts
- Use of enabling technologies to decrease costs
- Increased efficiency and reduced time to market

Octagon's submission-compliant deliverables remove the need for rework and redundancies. Industry standards (eCTD and CDISC SDTM) are the foundation for our refined processes and innovative software, ensuring speedy and compliant deliverables.

In conjunction with Octagon's Early Development Package, small companies may also choose to take advantage of discounted pricing on **ViewPoint**® for Document Management. ViewPoint provides a secure and collaborative environment that supports content creation, development and management across organizations and their partners. Delivered through a hosted model, **ViewPoint** offers robust document management features with minimal maintenance or IT infrastructure required.

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

www.octagonresearch.com

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