



Q ■ Does managing global metadata sometimes feel like herding cats?

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

Breakthrough Outsourcing

World-Class Consulting

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



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ViewPoint® Metadata Registry

Global pharmaceutical and biotechnology companies continue to struggle with the complexity of managing standards for clinical data collection and processing. It is not only critical to define, collect, and maintain the data itself, but also the information about the clinical data: metadata. In the clinical data lifecycle, there are multiple types of metadata that are relevant at any given point in time. Data metadata, standards metadata, systems metadata and study metadata are all types of metadata that require management and tracking throughout the lifecycle.

To complicate the situation further, the metadata itself has a lifecycle. For example, data collection standards change over time. The status of a particular standard may change from “active” to “archived” over a period of time. As examples, the approval date, implementation date and archive date may be relevant to a discussion of the use of a particular data standard.

Mature organizations are now being challenged to manage the resulting chaos. Most organizations don't have a standard way to describe how data is collected and transformed over time. They have no mechanism for managing and communicating standards metadata. There is no governance process and no global standard to convey. As a result, study teams “reinvent the wheel” with each new study. It becomes increasingly burdensome to maintain a set of standards with conventional technologies and tools.

The **ViewPoint® Metadata Registry (MDR)** provides a centralized registry that is user-friendly and simple to maintain, while offering a powerful set of features that assure global standards are easily accessible and reusable.

Highlights of the ViewPoint Metadata Registry include:

- **Standards Management** - Provides a functional registry for creation and maintenance of standards metadata for data elements and supports flexible metadata describing collection, processing, transformation and lineage.
- **Process Management** - Supports key standards governance activities including planning and execution, communication, issue management and reporting.
- **Content Management** - Facilitates creation of supporting documentation as well as storage and versioning of study and supporting documents.
- **Standards Communication** - Supports machine-readable communication of standards metadata and study definition metadata between the registry and clinical systems across the clinical data lifecycle.

The ViewPoint Metadata Registry offers a scalable technology platform on which a global standards governance process can be built, deployed and maintained. It offers the sophisticated management functionality required to address the complex challenges of managing the lifecycle of metadata across the R&D organization.

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

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