propharma

CASE STUDY

Defining and Implementing Global Data Standards & Governance

ProPharma has played a pivotal role in the implementation of scientific data standards and significantly contributed to the R&D-wide Data Standards & Governance program for a global biopharma with over 20,000 employees.

While the company already had processes in place to manage the key clinical data standards used, there was no overall coordination between the different functional areas of R&D on other standard terminology and no standardisation of scientific terminology in the early R&D space.

Previous engagements with the company as part of our Digital Blueprint methodology had identified that the implementation of a global set of data standards and related governance structures were key to the successful implementation of new software systems, and would help increase the value of their data; treating R&D data as a key asset.

What Process was Followed?

ProPharma used our Data Standards & Governance project methodology, which leverages our knowledge of existing industry data standards and related organisations (e.g. ISO, Allotrope, Pistoia, ISA-88 etc) and our experience of delivering similar projects. This focuses on the three key pillars of data standards and governance: Defining Standards, Implementing Governance and Implementing Supporting Tools.

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From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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Successful Data Standards & Governance

Define Standards

- Define scope for standards (entities & attributes)
- Identify existing standard terminology
- Agree on future standard reference data/terminology

Also consider:

- Identify external ontologies
- & standards to leverage
- Define standard naming rules for identifiers

Implement Governance

- Build a team to own the data standards
- Define a governance structure
- Implement a process (SOP) for managing change control

Also consider:

- Define Data Stewards for all relevant systems
- Identify metrics/KPIs to measure performance

Implement Supporting Tools

- Evaluate capabilities of existing systems to manage data standards
- Create single source of truth for data standards (Data Standards Catalog)
- Integrate or align end user systems with published data standards

Also consider:

- Evaluation/vendor selection of dedicated data standards system (ontology management or RMDM system)

Our structured approach ensures that the data model, standards and required governance elements are delivered iteratively, easing the complexity for scientific subject matter experts (SMEs) who may be new to this topic.

Through a series of workshops involving representatives across the business, and access to existing data standards sources, we identified the key entities and attributes that the customer needed to standardise. ProPharma then worked with the business to provide clear and unambiguous definitions for these and defined the business ownership and existing systems that were being used to manage data relating to them.

What were the Key Outputs?

Following the workshops, ProPharma modelled the data to create a Master Entity Model, which defined the scope and ownership of data standards across the three key functional areas of Scientific, Clinical and Business. This model also provided a useful communication tool to use within the business to help promote the goals to senior management.

A governance structure was proposed and implemented, with each functional team moving forwards with their own standards definition under the umbrella of a coordinating and escalation team. This included the definition of key roles and responsibilities within the scientific domain and the identification of data stewards, who were responsible for the standard terminology used in specific data management systems.

ProPharma led the Scientific Data Standards team and coordinated the identification of existing lists of terms used within the organisation, identified external ontologies that could be leveraged to provide standards in areas where they were not already defined, and defined and documented the standards governance and change control process in both formal SOPs and working operational models.

In tandem with these activities, we also identified and documented the use cases required for a system to support the maintenance and change control of the standards, assisted with the demonstration and evaluation of potential solutions from a variety of software vendors, and provided input to the selection process leveraging our years of collective industry experience.

One of the primary solutions selected was a centralised ontology management solution. ProPharma assisted with the implementation of this tool, defining local business rules for the creation of new ontologies, and supported the training and roll-out of the system to all users.

A custom ontology for scientific data standards was then designed and built by ProPharma consultants using the data standards identified in the earlier phase of the project.

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What Specific Problems were Solved?

The company had previously managed independent lists of metadata terms in different end user applications, with little or no coordination between systems and variables approaches to change control.

The scientific data standards ontology now acts as the single source of truth for the standards and is available across the entire organisation to query and use as standard metadata in all experimental processes. The ontology management solution also provides API access to the standards for any system to integrate with directly.

The new governance team and processes ensure that new terminology or updates to existing terms can be added to the standards in a controlled manner, and updates to the ontology are published to all users on a regular basis.

What Next?

ProPharma has continued to provide ongoing support for the governance of scientific data standards, coordinating the regular governance meetings, processing change requests, publishing status updates and metrics, and drafting new guidelines to encourage the use of standards across the scientific domain.

We are also working with individual application teams and other groups to help identify business use cases for the use of the new centralised ontologies, and provide support for integrating end-user systems with the ontology management tool to access the data standards directly, further benefiting from the centralisation of these data standards.

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