DIA Regulatory Information Management Reference Model V2.0 User Guide

DIA RIM Reference Model Working Group

2026

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1.0 Introduction

Over the past decade, the regulatory affairs function within the life sciences industry has undergone a fundamental transformation from a primarily document-centric discipline to one that is increasingly data-driven. Historically, organizations managed registrations, submissions, health authority interactions, release requirements, variation assessments, and other critical regulatory activities through spreadsheets, home-grown tools and systems, or manually compiled documentation. As global marketing and regulatory requirements continue to expand in both scope and complexity, traditional methods are no longer sustainable.

Regulatory Information Management (RIM) has emerged as a strategic capability to streamline and modernize the regulatory value chain. Built on foundations of standardized processes, structured data, enabling technologies, and defined organizational roles, RIM helps life sciences companies manage regulatory activities with precision and transparency. Beyond its regulatory focus, modern RIM also enables integrated data exchange across key functions, eg, clinical, manufacturing, quality, safety, nonclinical, and commercial, supporting a seamless flow of regulatory and product information throughout the product lifecycle.

However, as RIM practices have evolved across organizations, so too has the diversity of definitions, data models, and terminology. This inconsistency has made collaboration, interoperability, and system integration challenging across the industry. To address this fragmentation, the DIA RIM Working Group developed the DIA RIM Reference Model, a unified framework designed to harmonize terminology, data structures, and process definitions across the regulatory landscape.

1.1 What is the DIA RIM Reference Model?

The DIA RIM Reference Model V2.0 provides a foundational framework for understanding Regulatory Information Management (RIM) processes, information management, business entities and data elements, and relationships between them. The model offers an abstract, yet practical, structure that can be adopted across organizations and regulatory systems to foster consistency, interoperability, and shared understanding.

The model is designed to capture and standardize the information needed to manage regulatory operations, product registrations, labeling, and health authority interactions

and other regulatory activities effectively. It defines a common taxonomy and a detailed set of business entities (or “objects”), each with attributes, definitions, relationships, and usage contexts, organized around regulatory business processes. The model is presented as a spreadsheet workbook with an associated Entity-Relationship (E-R) diagram of data objects/entities, defining a taxonomy and a comprehensive data dictionary pertaining to RIM. Each “object” (traditionally viewed as a data table) in the model includes the “attributes” (field names), along with definitions, data types, cardinality, relationships to other objects, typical values, etc.

The model can be used by pharmaceutical sponsors, technology vendors, and system integrators as a foundational “starter kit” to design and architect RIM system implementations and data harmonization projects.

It should also be noted that unlike industry and agency standards, such as Identification of Medicinal Products (IDMP), eCTD, etc., this is designed around sponsor processes, not just the compliance requirements for agency submissions. Where applicable, we have included FHIR definitions to leverage work that is already underway with IDMP implementation.

1.2 Goals and Objectives

The DIA RIM Working Group established this reference model with the following objectives:

- **Define a Common Framework**: Establish a unified data and information structure that supports all key regulatory activities.
- **Enable Standardization**: Promote consistent terminology, processes, and relationships across organizations and systems.
- **Support Integration**: Facilitate data interoperability across regulatory, clinical, manufacturing, quality, and other related systems.
- **Accelerate** Mergers and Acquisitions **(M&A) Harmonization**: Provide a foundation for rapid and thorough alignment of data models and systems during M&A.
- **Improve Visibility and Traceability**: Enable cross-functional teams to access accurate and consistent product and registration data.
- **Enhance Compliance**: Align with international data standards, such as ISO IDMP and EMA SPOR, to improve data accuracy and regulatory reporting.
- **Improve Usability**: Define commonly occurring objects/concepts, relationships, and related data in a simple and user-friendly manner.

While not a formal standard, the DIA RIM Reference Model serves as an industry-aligned framework that encourages convergence toward best practices and shared understanding across diverse regulatory ecosystems.

Unlike the Submission Electronic Document Management (EDM) and Trial Master File (TMF) Reference Models, which are based on artifacts such as documents and their meta-data, the DIA RIM Reference Model is about RIM processes, data objects and attributes, and their relationships. Therefore, the DIA RIM Reference Model is process- and data-centric, while the other DIA EDM and TMF Reference Models are document/metadata-centric. Just as the TMF model started out as a DIA-led initiative and has now become part of CDISC standards, there is opportunity for the DIA RIM Reference Model to become a globally accepted standard in the future.

1.3 Benefits

Adoption of the DIA RIM Reference Model offers a broad range of strategic and operational benefits, helping organizations transform regulatory information into a trusted, enterprise-level asset that drives efficiency, compliance, and innovation.

Strategic Benefits

- **Accelerated Speed to Market**: Standardized data structures streamline submission preparation, review, and approval processes, reducing cycle times and enabling faster product launches.
- **Enhanced Data Analytics and Insights**: The model provides a structured foundation for advanced analytics, forecasting, and regulatory intelligence, empowering organizations to make proactive, data-driven decisions.
- **Improved Accuracy, Quality, and Compliance**: Consistent data definitions and alignment with international standards, such as IDMP, SPOR, and HL7 FHIR, minimize errors, strengthen regulatory submissions, and ensure global compliance.
- **Cross-Functional Interoperability**: By establishing common data semantics, the model facilitates seamless information exchange across key functions, e.g., regulatory, clinical, quality, manufacturing, and safety, enabling a unified view of product and registration data.
- **Harmonized M&A Integration**: The model serves as a blueprint for aligning data across merging organizations, simplifying integration, reducing redundancy, and accelerating post-merger system harmonization.

Operational Benefits

- **Process Automation and Digitization**: Structured, high-quality data supports the deployment of Robotic Process Automation (RPA) and Artificial Intelligence/Machine Learning (AI/ML) solutions, enabling intelligent automation of regulatory workflows and submissions.

- **Efficiency and Cost Optimization**: Reduced manual reconciliation, rework, and data cleansing efforts lead to measurable gains in operational efficiency and cost savings across the regulatory function.
- **Foundation for Master Data Management (MDM):** The model defines core regulatory master data entities, such as products, submissions, and licenses, supporting enterprise-wide governance and improved data stewardship.
- **Improved Collaboration and Visibility**: Shared terminology and consistent data structures enhance collaboration among internal teams, affiliates, and vendors, while providing clearer visibility into regulatory activities and product status across global markets.

Cross-Functional Data Needs

In addition, regulatory information is exchanged for operational data needs of other functions and systems within R&D and manufacturing. For example:

- **Quality Management System** exchanges information related to change control, commitments, manufacturing sites, certifications, IDMP data, etc.
- **Pharmacovigilance** exchanges information regarding international birth date, labeling change requests, clinical particulars, etc.
- **Manufacturing** exchanges information related to packaging, artwork, marketing status, manufacturing sites, etc.
- **Clinical Systems** such as CTMS and TMF supply clinical trial metadata, protocol approvals, etc.
- **Clinical Trial Management System** supplies clinical trial metadata, protocol approvals, etc.
- **Pharmacology and Toxicology Systems** supply non-clinical trial metadata.
- **Promotional Material System** exchanges meta-data associated with labeling, promotional material, etc.

In essence, the DIA RIM Reference Model elevates regulatory information from an administrative necessity to a strategic enabler. It promotes transparency, operational excellence, and digital transformation, helping organizations achieve compliance with greater speed, precision, and confidence.

1.4 Scope

The DIA RIM Reference Model focuses primarily on regulatory activities related to drugs and biologics, with future extensions planned for medical devices and combination products. The model defines the key entities, relationships, and processes needed to

manage the full regulatory lifecycle, from investigational products to marketing product registration and submissions to labeling and post-approval commitments.

1.5 History of the DIA RIM Reference Model

The DIA RIM Reference Model originated from an “Ask the Experts” panel at the May 2015 DIA eRegulatory and Intelligence Conference. The panel discussed the success of the DIA TMF Reference Model, highlighting parallels between TMF’s early lack of structure and the fragmented state of RIM. Both were critical to regulatory efficiency yet lacked common definitions and frameworks.

Inspired by TMF’s collaborative model, several participants formed a new working group to bring similar structure and consistency to RIM.

Initially, the group drafted a charter and explored affiliation options, including the IRISS Forum, but determined its submissions-centric focus was too narrow. In late 2015, the members voted to align with the Drug Information Association (DIA) under its Regulatory Affairs Community (RAC). DIA’s broad membership, proven reference-model governance, and alignment with related groups (such as Regulatory Intelligence and Labeling) made it the ideal home for the initiative.

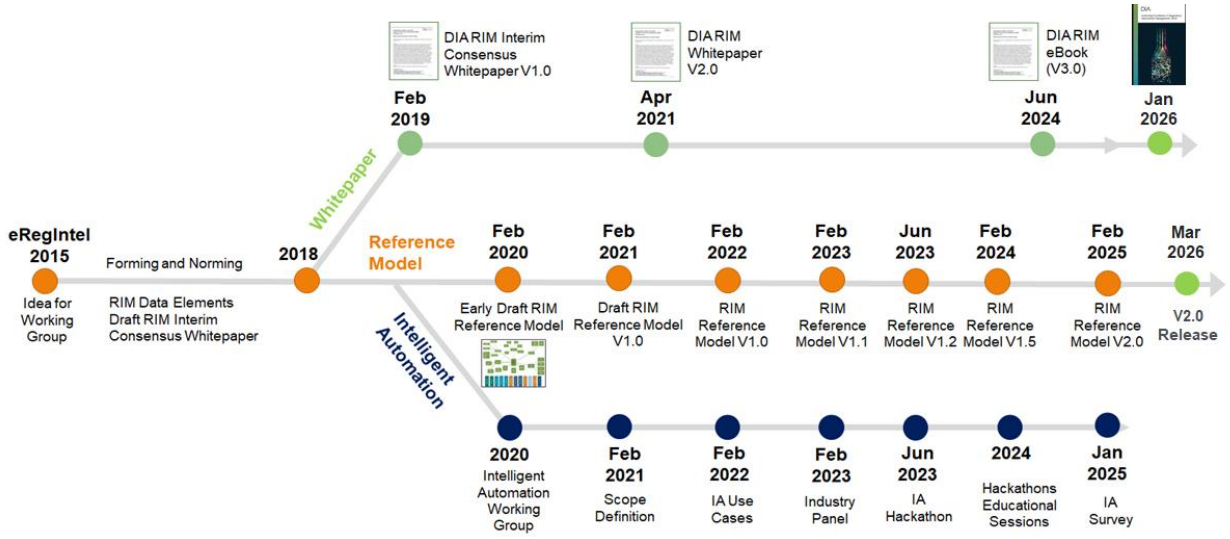

Figure 1. Workstreams and accomplishment within the DIA RIM Working Group

Over time, the RIM Working Group (RIMWG) evolved to include multiple workstreams focused on:

1. Development of a foundational RIM White Paper (Versions 1.0 and 2,0) and subsequently Version 3.0, published as a book titled “Achieving Excellence with Regulatory Information Management”, available as eBook on Amazon
2. Definition and validation of the RIM Reference Model

3. Exploration of RIM Intelligent Automation and Artificial Intelligence practices

Figure 1 depicts the timeline of the activities of the workstreams since their inception.

Since its formation, the RIMWG has received participation and feedback from a global community of sponsors, service providers, and vendors. The model continues to evolve through industry collaboration and alignment with standards such as IDMP, SPOR, and HL7 FHIR, reinforcing its goal of establishing a unified, data-centric foundation for RIM.

1.6 Industry Engagement

The RIMWG continues to engage with regulatory professionals, sponsors, solution providers, and health authorities worldwide. Industry feedback remains central to refining the model, ensuring it reflects real-world use cases and emerging regulatory expectations. Contributions from the broader community help maintain the model's relevance, accuracy, and practical applicability and determine the governance of the model.

Future updates will expand coverage beyond pharmaceuticals and biologics to include medical devices, combination products, and advanced therapy medicinal products and different regulatory pathways, reinforcing its position as a universal reference framework for global regulatory information management.

1.7 Governance

The governance of the DIA RIM Reference Model will be performed by standing members of the DIA RIM Reference Model Working Group.

The following parameters are under development, but will be critical to the ongoing maintenance and development of the model:

- Requests for changes can be sent to a DIA mailbox which will be monitored by the DIA and the RIM Working Group.
- The RIM Working Group will review the requests and categorize changes as major, minor, or clarification. For example, a major change could be the introduction of a whole new object or relationship or deletion of an object or significant changes to an existing object with more than one third of the attributes currently associated with that object.
- Team members of the RIM Working Group will vote on the requested changes - voting on changes must be done with due consideration for impact. Two-thirds of the working group must review the changes in a meeting and approve the changes to be included in a newer version of the model.
- The Working Group will meet on a quarterly basis to review requests for changes, assess impact, and approve changes for release. Changes will be

made every six months based on type of change requests, along with Version History.

- Changes will be communicated as follows: Initially, there will be an acknowledgement of request for change. Reviewed and approved changes will then be notified to people who requested the changes along with notifications to those who have downloaded the model or expressed interest. Change announcements will be made on the DIA page.
- Lastly, the RIM Working Group needs to have appropriate representation from the sponsors, industry, product vendors, and consulting organizations to seek, incorporate and balance different perspectives. For group members to vote on changes, minimum participation time is required. There will be limits on the number of votes per organization.

2.0 DIA RIM Reference Model V2.0: Objects, Key Attributes, and Key Relationships

This section provides a comprehensive, technical description of the DIA RIM Reference Model structure. It expands on each domain, outlining core objects, key attributes, and interrelationships. The content is intended for system architects, regulatory operations experts, and data governance professionals designing or validating RIM implementations.

The DIA RIM Reference model is a catalog of data objects, attributes, and relationships between them to support various business processes and information needs related to Regulatory Information Management. The model organizes information into key domains: Product, Regulatory and Commercial, Manufacturing, Process and Interaction, and Organizational Objects, which are explored in detail below. The model contains 56 different objects and relationships among them. For the purposes of brevity, this User Guide does not cover all the objects and relationships among them but covers a significant portion of them at a high level. The details of the Model can be found in the accompanying Excel Workbook.

There are two artifacts related to the DIA RIM Reference Model V2.0 in addition to this User Guide:

1. A Conceptual Entity-Relationship (E-R) Diagram showing objects and relationships, available in PDF. Some objects are shown as container objects containing other objects. For example, Clinical Particulars tab shown in the E-R diagram contains other objects such as Indication, Contraindications, Other Therapy, Population, Undesirable Effects, Interactions, and Interactant.

2. An accompanying Excel Workbook, containing tabs for each of the objects depicted in the E-R diagram above, along with their attributes and relationships with other objects.

2.1 Foundational Concepts

- **General Object:** A high-level entity representing a real-world item, such as a Product, Submission, Organization.
- **General Attribute:** A data element that provides a single piece of information about an object (eg, a name, a date, a status).
- **Key Relationships:** Objects are connected to each other through various types of links:
    - **Parent Object:** A higher-level object that contains or groups a child object.
    - **Child Object:** A lower-level object that is part of a parent object.
    - **Peer Object:** An object that is related to another object but not a parent or child, but as a peer.
    - **Inherited Attribute:** An attribute that is automatically inherited from a parent object.

2.2 Product Objects

This section describes the core objects related to a medicinal product, from a high-level product family down to its individual components and clinical data. Most of these product objects align closely with industry standards such as IDMP, HL7 FHIR, the electronic Common Technical Document (eCTD), etc., with additional features such as Product Family that support sponsor/manufacturer activities not relevant to the agencies or submissions.

The current model is aligned with drug products – expansion is planned to support combination and device products which may not have the concept of active ingredients.

Product Family

This is a top-level object that groups related products, often encompassing multiple therapeutic areas and indications. The usage of Product Family is often very sponsor-specific, grouping products by marketing categories, active ingredients, etc., however many RIM systems use this to mean all products based on the same active ingredient(s).

- **Key Attributes:** *Product Family Name, Product Family Code, Sponsor, Active Ingredient, and Therapeutic Area.* For more information on other attributes, please look at the Product Family tab in the Excel Workbook.
- **Key Relationships:** Acts as a **parent** to *Global Product* object and is linked to an *Organization* object via the Sponsor attribute, meaning the product family's regulatory sponsor and to *Ingredient* object via the Active Ingredient attribute.
- **Challenges:** This object is focused on drug products and does not support medical device or combination therapy products.

Global Product

This object represents a product in a specific dosage form. for a specific therapeutic area and indication for all countries in which it is marketed or intended to be marketed.

- **Key Attributes:** *Global Product Name, Global Product Trade Name, Dosage Form, and Therapeutic Area.* For more information on other attributes, please look at the Global Product tab in the Excel Workbook.
- **Key Relationships:** It is a **child** of *Product Family* and **parent** to both *Medicinal Product* and *Global Label*. It also inherits attributes from *Product Family*.
- **Challenges:** This object is focused on drug products and does not support medical device or combination therapy products. Attributes such as Therapeutic Area and Dosage Form are currently region-specific – this is a challenge for the entire industry beyond the scope of this model.

Global Label

This object represents labeling information that is common across countries and regions, such as the Company Core Data Sheet and similar documents.

- **Key Attributes:** *Global Label Name, Global Label Type, Global Label Version Number, Global Label Status, Global Label Status Date, Language, Change Summary, Content.* For more information on other attributes, please look at the Global tab in the Excel Workbook.
- **Key Relationships:** It is a **child** of *Product Family* and **peer** to both *Medicinal Product* and *Global Label*. It is the **parent** to the *Responsible Department* and *Responsible Person*

Medicinal Product

This object represents the specific medicinal product licensed or intended to be licensed in a particular country or region, including its strength and dosage form.

- **Key Attributes:** *Medicinal Product Name, Medicinal Product Dosage Form, and Medicinal Product Strength.* For more information on other attributes, please look at the Medicinal Product tab in the Excel Workbook.
- **Key Relationships:** It is a **child** of *Global Product* and a **peer** to *License-Registration* and *Market Status*. It serves as a central hub, connecting to *Clinical Particulars* objects below.
- **Challenges:** This object is focused on drug products and does not support medical device or combination therapy products. *Note that at the Medicinal Product Level, attributes such as Dosage Form are necessarily in* ***regional-specific*** *terminology.*

Pharmaceutical Product Details

This object represents the specific product *as administered* to the patient or subject, including its Dose Form. Unit of Presentation, and Route of Administration.

- **Key Attributes:** *Name, Description, Route of Administration, Unit of Presentation,* and *Dose Form.* For more information on other attributes, please look at the Pharmaceutical Product Detail tab in the Excel Workbook.
- **Key Relationships:** It is a **child** of *Medicinal Product* and a **parent** to *Medicinal Product Component*.
- **Challenges:** This object is focused on drug products and does not support medical device or combination therapy products.

Clinical Particulars

These objects contain the clinical details associated with a *Medicinal Product*.

- **Indications:** Describes the proposed or authorized use of the product
  - **Key attributes:** *Disease/Symptom/Procedure* (including *severity, comorbidities* and other categories which would limit the usage of the product), *Target Population*, and *Duration*.
  - **Key Relationships:** It is a **child** of Medicinal Product
  - **Challenges:** Coding to meet both the textual descriptions in labels, as well as the individual terms needed for registration submissions, including IDMP, can be difficult.
- **Contraindications:** Defines conditions where the product should not be used.
  - **Key attributes:** Identical to Indications: *Disease/Symptom/Procedure Target Population*, and *Duration*.
  - **Key Relationships:** It is a **child** of Medicinal Product
  - **Challenges:** Coding to meet both the textual descriptions in labels, as well as the individual terms needed for registration submissions, including IDMP, can be difficult.
- **Undesirable Effects:** Captures unwanted side effects (i.e., Adverse Experiences).
  - **Key attributes:** *Disease/Symptom/Procedure, Frequency of Occurrence, Classification*
  - **Key Relationships:** It is a **child** of Medicinal Product
  - **Challenges:** Coding to meet both the textual descriptions in labels, as well as the individual terms needed for pharmacovigilance and registration submissions can be difficult.
- **Interactions:** Captures known interactions with other substances or products.
  - **Key attributes:** *Interaction Type* (eg, Drug, Food, Clinical Test)*, Interactant, Effect, Incidence*
  - **Key Relationships:** It is a **child** of Medicinal Product
  - **Challenges:** Coding to meet both the textual descriptions in labels, as well as the individual terms needed for pharmacovigilance and registration submissions can be difficult.

Product Components

These objects detail the physical, manufacturing, and chemical makeup of a product.

- **Substance:** Describes an active pharmaceutical ingredient (API) or other chemical substances,
  - **Key attributes:** *INN (generic name)*, *CAS Number, Molecular Formula, Substance Class* (Small Molecule, Peptide, Nucleic Acid, Polymer, etc.)
  - **Key Relationships:** A substance is a **child** of the Ingredient and Interactant objects.
  - **Challenges:** Substances may have synonyms local to a particular market or region
- **Ingredient:** Describes a substance in the context of its Role within a product
  - **Key attributes:** *Role* (eg, *API, Adjuvant, Excipient*), *Manufacturing Source*.
  - **Key Relationships:** An ingredient is a **child** object of a *Pharmaceutical Product Detail***,** and a **Parent** of a *Substance*
- **Medicinal Product Components:** Represents the physical components of a product *as sold or marketed*, such as a *powder or liquid in a vial, a tablet or capsule*, and *administration devices such as syringes or* spoons,
  - **Key attributes:** *Component Name, Quantity, Dose Form, Unit of Presentation,* and Physical Characteristics
  - **Key Relationships:** This is a **child** of the Medicinal Product
- **Shelf Life/Storage:** Defines the shelf life and storage conditions.
  - **Key attributes:** *Shelf Life Name, Shelf Life Region, Storage Conditions (temperature, humidity, etc.), and Shelf Life Time and Period.*
  - **Key Relationships:** This is a **child** of the Medicinal Product Component and Packaging objects.
- **Physical Characteristics:** Documents physical properties
  - **Key attributes:** *Height, Width, Length, Nominal Volume, Weight, External Diameter, Shape, Color, Imprint, Scoring, Image*
  - **Key Relationships:** This is a child of the Medicinal Product Component and Packaging objects

2.3 Regulatory & Commercial Objects

This section covers objects related to regulatory submissions, licenses, and commercial activities.

Application

This is a key object for a regulatory application with a given Health Authority.

- **Key Attributes:** *Application Name, Application Number, Application Type (eg, IND, NDA, BLA), Application Status, and Legal Basis for Approval*. For more information on other attributes, please look at the Application tab in the Excel Workbook.
- **Key Relationships:** It is a **parent** to Submission and a **peer** to *License*, *Studies (Clinical and Nonclinical)*, *HA Correspondence*, and *Process Objective*.

License-Registration

This object contains information about the formal marketing license or registration for a product in a specific country.

- **Key Attributes***: License Name, License Number, License Type, License Status, and Country/Region of License*. For more information on other attributes, please look at the License-Registration tab in the Excel Workbook.
- **Key Relationships:** It is a **peer** to *Application, Health Authority*, and *Process Objective*.

Submission

This object tracks a specific dossier or submission sent to a Health Authority.

- **Key Attributes:** *Submission Number, Submission Format (eg, eCTD), Submission Type, Submission Status, and Submission Country*. For more information on other attributes, please look at the Submission tab in the Excel Workbook.
- **Key Relationships:** It is a **child** to *Application* and a **parent** to *Submission Content Plan*.

Submission Content Plan & Submission Content

This hierarchy organizes the documents within a submission and has program management capabilities.

- **Submission Content Plan:** A high-level plan.
  - **Key Attributes:** *Status, Status Date, and Plan Coordinator*. For more information on other attributes, please look at the Submission Content Plan tab in the Excel Workbook.
  - **Key Relationships:** It is a **parent** to Submission Content and a **child** to *Submission*.
- **Submission Content:** Represents a file or section within the plan
  - **Key Attributes:** *Status*, *Status Date*, and *Context of Use*. For more information on other attributes, please look at the Submission Content tab in the Excel Workbook.
  - **Key Relationships:** It is a **child** to *Submission Content Plan*.

Labeling and Packaging

These objects manage product labeling, artwork, and packaging.

- **Labeling:** Describes a specific product label, including its Language and Countries of application.
  - **Key Attributes:** *Language and Version Number*. For more information on other attributes, please look at the Labeling tab in the Excel Workbook.
  - **Key Relationships:** It is a **parent** of *Artwork* and is a **peer** to *Packaging*.

- **Artwork:** Represents the visual artwork for a product label or package.
    - **Key Attributes:** *Language, Version Number*, and Status Date. For more information on other attributes, please look at the Artwork tab in the Excel Workbook.
    - **Key Relationships:** It is a **child** to *Labeling* and a **peer** to *Packaging*.
- **Packaging:** Describes the physical packaging.
    - **Key Attributes:** *Type, Material, and Quantity*. For more information on other attributes, please look at the Packaging tab in the Excel Workbook.
    - **Key Relationships:** It is a **peer** to *Artwork*, *Labeling*, and *Packaged Product*.

Studies

These objects track details related to clinical or nonclinical studies.

- **Key Attributes:** Study Number, Study Type and Subtype, Study Description, and Study *Sponsor*. For more information on other attributes, please look at the Clinical and Nonclinical Study tabs in the Excel Workbook.
- **Key Relationships:** Both study objects are **peer** to Application that link to the *Product* object.

2.4 Manufacturing Objects

This group defines information about the manufacturing processes and related activities associated with the production of drug substances and products at different manufacturing establishments.

Manufacturing Business Operation

The object describes the type of manufacturing operation at each site, e.g. manufacturing of API, testing, validation, labeling, re-packaging

- **Key Attributes:** *Manufacturing Operation Type, Confidentiality Indicator, Effective Start Date, Effective End Date*. For more information and examples, please look at the Manufacturing Business Operation tab in the Excel Workbook.
- **Key Relationships:** It is a **peer** object to *Manufacturing Organization Site, License, Medicinal Product & Manufacturing Process*.

Manufacturing Process

The object describes the manufacturing process performed at a site as part of the overall drug-manufacturing process, e.g. cell-line development, chemical synthesis, isolation, purification, drying.

- **Key Attributes:** *Manufacturing Process Name, Manufacturing Process Type, Manufacturing Process Organization, and Manufacturing Process Organization Site*. For more information and examples, please look at the Manufacturing Process tab in the Excel Workbook.

- **Key Relationships:** It is a **child** object to *Manufacturing Business Operations*.

Manufacturing Process Step

Describes the manufacturing process step performed at a site as part of a drug-manufacturing process, e.g. cell banking, centrifugation, filtration, distillation

- **Key Attributes:** *Manufacturing Process Step Name, Manufacturing Process Step*. For more information and examples, please look at the Manufacturing Process tab in the Excel Workbook.
- **Key Relationships:** It is a **child** object to *Manufacturing Process*.

Manufacturing Process Step Material

Describes the material(s) associated with a manufacturing process step performed at a site as part of a drug-manufacturing process, e.g. raw (starting) materials, reagents, solvents, excipients, adjuvants,

- **Key Attributes:** *Manufacturing Process Step Material Name, Manufacturing Process Step Type*. For more information and examples, please look at the Manufacturing Process tab in the Excel Workbook.
- **Key Relationships:** It is a **child** object to *Manufacturing Process Step*.

2.5 Process & Interaction Objects

This group defines the processes and interactions a company has with Health Authorities.

Process Objectives

This hierarchy defines the overall strategic goals and plans.

- **Process Objective Group:** A group of related process objectives.
  - **Key Attributes***: Process Objective Group Name (for example, Tylenol Global Rollout), Process Objective Group Description*.
  - **Key Relationships:** It is **a parent** to *Process Objective*

- **Process Objective**: A single, defined objective (eg, "CMC Variation," "Marketing Approval").
  - **Key Attributes:** *Process Objective Name, Process Objective Description, Process Objective Type (such as CMC Variation), Process Objective Planned Start Date, Process Objective Planned End Date, etc.*
  - **Key Relationships:** It is a **child** of *Process Objective Group* and **parent** of *Process Plan Template*. Process objectives could be related to other process objectives, thus having a self-referencing relationship.

- **Process Plan Template:** A reusable template for a process plan.
  - **Key Attributes:** *Process Plan Template Name, Process Plan Template Type, Process Plan Template Category, etc.*

    - **Key Relationships:** It is a **child** of *Process Objective and Country* and **parent** of *Process Plan*.

- **Process Plan:** A specific, planned sequence of steps to achieve an objective, generated from a process plan template. It is a **child** of *Process Objective*.
    - **Key Attributes:** *Process Plan Name, Process Plan Type, Process Plan Planned Start Date, Process Plan Planned End Date, etc.*
    - **Key Relationships:** It is a **child** of *Process Objective* and *Process Plan Template*.

- **Process Step Template:** A reusable template for a process step.
    - **Key Attributes:** *Process Step Template Name, Process Step Template Type, Process Plan Template Category, etc.*
    - **Key Relationships:** It is a **child** of *Process Plan Template* and **parent** of *Process Step*.

- **Process Step:** The most granular level, representing a single action or task. It is a **child** of *Process Plan*.
    - **Key Attributes:** *Process Step Name, Process Step Type, Process Step Planned Start Date, Process Step Planned End Date, etc.*
    - **Key Relationships:** It is a **child** of *Process Plan* and *Process Step Template*. Process steps could be related to other process steps, thus having a self-referencing relationship.

Health Authority Interactions

These objects capture different types of correspondence and events with regulatory bodies. They are all **peer** objects related to *Process Step*, *Application,* and *Submission*.

- **HA Correspondence:** Tracks official communication, including Correspondence Type (eg, Approval Letter, RFI).
    - **Key Attributes:** *Correspondence Name, Correspondence Type, Correspondence Date, Correspondence Action, etc.*
    - **Key Relationships:** It is a **child** of *Process Step* and is a **peer** to *Correspondence Content* object*, Application* object and *Submission* Object.

- **HA Q&A:** Specifically tracks questions and answers received from or sent to a Health Authority.
    - **Key Attributes:** *Question Topic, Question Type, Question Date, Question Text, Question Response, Response Lead, etc.*
    - **Key Relationships:** It is a **child** of *HA Correspondence*. It can contain many questions and answers, and hence a self-referencing relationship.

- **Meeting:** Documents regulatory meetings, including Meeting Type and Attendees.
    - **Key Attributes:** *Meeting Subject, Meeting Type, Meeting Date, Meeting Status, Meeting Material, Meeting Owner, etc.*

- **Key Relationships:** It is a **child** of *Process Step and Process Step Template and is a* **peer** *to Submission Object.*

- **Commitment:** Tracks specific commitments made to a Health Authority.
  - **Key Attributes:** *Commitment Subject, Commitment Title, Commitment Type, Commitment Date, Commitment Status, Commitment Owner, etc.*
  - **Key Relationships:** It must be related to an *Application* and a *License* as a condition of approval and may have a **peer** relationship to *Process Step*, *Meeting*, *Submission*. It can contain other commitments and hence a self-referencing relationship.

- **Inspection:** Captures details of regulatory inspections.
  - **Key Attributes:** *Inspection Subject, Inspection Title, Inspection Type, Inspection Date, Inspection Status, Inspection Owner, etc.*
  - **Key Relationships:** It is related to a *Health Authority* and has a **peer** relationship with *Process Step*. It can be related to other inspections and hence a self-referencing relationship.

2.6 Organizational & Study Objects

This section describes the entities and studies involved in the model.

Organizations & Contacts

- **Organization:** Represents a legal entity or organization, such as a Sponsor or Health Authority.
  - **Key Attributes:** *Organization Name, Organization Type, Organization Status, etc.*
  - **Key Relationships:** It is the parent of *Organization Site* and has **peer** relationship to *Application*, *Packaged Product*, *HA Correspondence*, *Ingredient* and *Packaging*.

- **Organization Site:** Represents a physical location or site for an organization.
  - **Key Attributes:** *Organization Site Name, Organization Site Type, Organization Site Status, etc.*
  - **Key Relationships:** It is a **child** of *Organization,* **parent** *of Contact* and has peer relationship to *License*.

- **Contact:** Represents a person within an organization,
  - **Key Attributes:** *Contact First Name, Contact Last Name, Contact Title, and Contact Role, etc.*
  - **Key Relationships:** It is a **child** of *Organization* and *Organization Site* and a **peer** to *Country*.

3.0 How to Contribute

Over the past seven years, the DIA RIM Working Group has invested substantial effort in developing, refining, and validating the RIM Reference Model. The model continues to evolve through ongoing industry collaboration and feedback. It has been shared and discussed at multiple stages of its maturity across various professional forums, most notably during successive DIA RSIDM conferences, where its practical applications were demonstrated — including examples of its use in regulatory data hub implementations and small-company RIM initiatives.

Looking ahead, continued advancement of the model depends on broader participation across the industry. We invite more sponsor organizations to adopt and validate the model in their environments, and to contribute real-world insights that help strengthen its relevance and accuracy. Likewise, solution providers and technology vendors are encouraged to review, align, and incorporate its structure into their products and services. Finally, we welcome new volunteers to join the Working Group and help drive the next phase of innovation, harmonization, and adoption within the global RIM community.

4.0 Acknowledgements

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