Project Onboarding Guide

IDMP-O: Project Onboarding Guide

Authors: Pawel Garbacz, Heiner Oberkampf
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Overview
The following overview should help you get started. There is more to explore after you are on-boarded to the IDMP Ontology project.

Public Project Information

Key Project Contacts

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Lead</td>
<td>Gerhard Noelken, Pistoia Alliance</td>
<td><a href="mailto:gerhard.noelken@pistoiaalliance.org">gerhard.noelken@pistoiaalliance.org</a></td>
</tr>
<tr>
<td>Project Manager</td>
<td>Melih Tuzunoglu, Pistoia Alliance</td>
<td><a href="mailto:melih.tuzunoglu@pistoiaalliance.org">melih.tuzunoglu@pistoiaalliance.org</a></td>
</tr>
<tr>
<td>Project Champion</td>
<td>Sheila Elz, Bayer</td>
<td><a href="mailto:sheila.elz@bayer.com">sheila.elz@bayer.com</a></td>
</tr>
<tr>
<td>Project Champion</td>
<td>Jean-Gonzague Fontaine, GSK</td>
<td><a href="mailto:jean-gonzague.x.fontaine@gsk.com">jean-gonzague.x.fontaine@gsk.com</a></td>
</tr>
<tr>
<td>Project Co-Lead + Demo Implementations</td>
<td>Heiner Oberkampf, Accurids</td>
<td><a href="mailto:heiner.oberkampf@accurids.com">heiner.oberkampf@accurids.com</a></td>
</tr>
<tr>
<td>Project Co-Lead + Use Case Specification</td>
<td>Ivana Miljkovic/Rafael Kasapis, OSTHUS</td>
<td><a href="mailto:Ivana.miljkovic@osthus.com">Ivana.miljkovic@osthus.com</a></td>
</tr>
<tr>
<td>Project Co-Lead</td>
<td>Jan Kroh, EDM Council</td>
<td><a href="mailto:jkroh@edmcouncil.org">jkroh@edmcouncil.org</a></td>
</tr>
<tr>
<td>Governance Infrastructure</td>
<td>Pawel Garbacz, EDM Council</td>
<td><a href="mailto:pawel.garbacz@makolab.com">pawel.garbacz@makolab.com</a></td>
</tr>
<tr>
<td>Ontology Lead Engineer</td>
<td>Elisa Kendall, EDM Council</td>
<td><a href="mailto:ekendall@thematix.com">ekendall@thematix.com</a></td>
</tr>
<tr>
<td>Value Capture Lead</td>
<td>Torsten Osthus</td>
<td><a href="mailto:torsten.osthus@osthus.com">torsten.osthus@osthus.com</a></td>
</tr>
</tbody>
</table>

Reoccurring Meetings

<table>
<thead>
<tr>
<th>What</th>
<th>Purpose</th>
<th>When</th>
<th>Organizers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Advisory Board</td>
<td>Strategic guidance on long term roadmap</td>
<td>Every 6-8 weeks</td>
<td>Gerhard, Sheila</td>
</tr>
<tr>
<td>Project Steering Team Meeting</td>
<td>Project-level guidance and decision making</td>
<td>On as-need basis</td>
<td>Gerhard, Sheila</td>
</tr>
<tr>
<td>Project Management</td>
<td>Project coordination &amp; reporting</td>
<td>Weekly Wed 13:00-13:45 CET</td>
<td>Gerhard, Heiner</td>
</tr>
<tr>
<td>Sprint Review &amp; Planning</td>
<td>Sprint results review and priority setting for next sprint</td>
<td>Bi-weekly Fri 15:00-15:30 CET</td>
<td>Heiner, Jan</td>
</tr>
<tr>
<td>Project Core Team</td>
<td>Project status reporting and general alignment</td>
<td>Bi-weekly Fri 15:30-17:00</td>
<td>Gerhard, Heiner</td>
</tr>
<tr>
<td>Value Capture</td>
<td>Identification of business cases for IDMP-O adoption</td>
<td>Ad-hoc</td>
<td>Torsten, Ivana</td>
</tr>
<tr>
<td>Use Cases Specification</td>
<td>Identification and description of use cases and competency questions</td>
<td>Weekly Wed 16-17:00 CET</td>
<td>Ivana, Elisa</td>
</tr>
</tbody>
</table>
Definitions & Terminology
Clarification of definitions for important ontology concepts with pharma SMEs
Weekly Mon 16-17:00 CET
Elisa

OntDev + Demo Implementation Weekly
Alignment on Ontology Engineering questions and tasks + discussion and planning of public demo implementations
Weekly Wed 17-18:00 CET
Heiner, Elisa

OntDev + Demo: Sprint Grooming
Clarify tasks and scope for the next sprint regarding ontology development and demo implementation
Bi-Weekly Thu 18-19:00 CET
Heiner

Pharma Implementation Consulting
Individual pharma implementation sessions to align on plans and implementation progress
Individually
Ivana, Heiner

Community of Interest
Increasing awareness with public presentations and demos
Every 6 weeks
Gerhard, Sheila, Heiner

Exchange with Regulators
Exchange with GIDWG (FDA, EMA, WHO)
Monthly 3rd Tue 16-17:00 CET
Sheila, Jean-Gonzague

Exchange with Accumulus
Exchange with Accumulus project for alignment and identification of synergies
Monthly 3rd Tue 17-18:00 CET
Sheila, Jean-Gonzague

Communications
Plan and coordinate communications activities
Bi-weekly Fri 17:00-17:30
Gerhard, Heiner

Participation Roles
The following table provides high-level role description for pharma participation in the project. Detailed governance roles are not covered here.

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma Business Expert</td>
<td>A subject matter expert that knows the IDMP related data sources and processes.</td>
</tr>
<tr>
<td>Pharma Implementation Contact</td>
<td>A technical contact for the use case realization at a specific pharma company.</td>
</tr>
<tr>
<td>Pharma Ontology and Governance Expert</td>
<td>A expert of semantics and ontologies and/or governance topics.</td>
</tr>
</tbody>
</table>

Collaboration Environments: General
The participants in the IDMP project have at their disposal six platforms:

<table>
<thead>
<tr>
<th>System</th>
<th>Usage</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pistoia Website</td>
<td>Official communication page</td>
<td><a href="mailto:gerhard.noelken@pistoiaalliance.org">gerhard.noelken@pistoiaalliance.org</a></td>
</tr>
<tr>
<td>MS Teams</td>
<td>General info and communication materials</td>
<td><a href="mailto:gerhard.noelken@pistoiaalliance.org">gerhard.noelken@pistoiaalliance.org</a></td>
</tr>
<tr>
<td>Confluence Wiki</td>
<td>Documentation of ontology development</td>
<td><a href="mailto:pawel.garbcz@makolab.com">pawel.garbcz@makolab.com</a></td>
</tr>
<tr>
<td>JIRA project</td>
<td>Task Management</td>
<td><a href="mailto:pawel.garbcz@makolab.com">pawel.garbcz@makolab.com</a></td>
</tr>
<tr>
<td>Git Repository</td>
<td>Ontology master files</td>
<td><a href="mailto:pawel.garbcz@makolab.com">pawel.garbcz@makolab.com</a></td>
</tr>
<tr>
<td>onto-viewer</td>
<td>Ontology lookup</td>
<td><a href="mailto:pawel.garbcz@makolab.com">pawel.garbcz@makolab.com</a></td>
</tr>
<tr>
<td>Accurids</td>
<td>Ontology lookup and use case implementation</td>
<td><a href="mailto:support@accurids.com">support@accurids.com</a></td>
</tr>
<tr>
<td>Shared Miro Board</td>
<td>Use case collection and prioritization</td>
<td><a href="mailto:ivana.miljkovic@osthus.com">ivana.miljkovic@osthus.com</a></td>
</tr>
</tbody>
</table>

Collaboration Environments: for Individual Pharma Implementation Support
With RESTRICTED access to corresponding pharma team members only

<table>
<thead>
<tr>
<th>Miro Board Name</th>
<th>Miro Board Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen IDMP-O</td>
<td><a href="https://miro.com/app/board/oXiVP88ChRk=/">https://miro.com/app/board/oXiVP88ChRk=/</a></td>
</tr>
<tr>
<td>Novartis IDMP-O</td>
<td><a href="https://miro.com/app/board/oXiVP833oMz=/">https://miro.com/app/board/oXiVP833oMz=/</a></td>
</tr>
<tr>
<td>Roche IDMP-O</td>
<td><a href="https://miro.com/app/board/oXiVPD8htEw=/">https://miro.com/app/board/oXiVPD8htEw=/</a></td>
</tr>
<tr>
<td>GSK IDMP-O</td>
<td><a href="https://miro.com/app/board/oXiVPYMDkAc=/">https://miro.com/app/board/oXiVPYMDkAc=/</a></td>
</tr>
</tbody>
</table>
This guide provides the basic explanations on when and how to use these platforms – the links to more comprehensive tutorials are given in the respective sections below.

**Access Provisioning**
**MS Teams**
Will be granted at onboarding.

**JIRA & Confluence**
Note that you have the same login credential for Confluence and JIRA. If you have a GitHub account, you can log in to Confluence and JIRA using its credentials instead:

![Login form](image)

*Figure 1 Accessing GitHub repository*

**OntoViewer**
https://spec.edmcouncil.org/idmp/ontology
“Quick”, i.e., merged versions of IDMP ontology, can be obtained from:
http://spec.edmcouncil.org/idmp/ontology/dev.idmp-quickstart.ttl
http://spec.edmcouncil.org/idmp/ontology/prod.idmp-quickstart.ttl

**Git**
Only relevant for the implementation team for now

**Accurids**
Sign-up at https://pistoiaalliance.dev.accurids.com/

**IDMP Ontology Releases**
https://wiki.edmcouncil.org/display/IDMP/IDMP+Ontology+Releases

**Confluence Wiki**
https://www.atlassian.com/software/confluence/guides

The IDMP Confluence space documents the process of ontology development – this includes documenting project meetings, recording discussions, explaining design choices, etc.
The Confluence pages are organized in the hierarchical structure – more or less like the file system on your computer. The current structure is shown below – we believe that top pages have self-explanatory names.

Once logged in you can create and/or edit pages, upload attachments, and add comments.

**Create Page**

In order to create a page click on the orange ‘Create’ button at the top of the page:

Note that the page will be created “under” the page you are currently in, i.e., the parent of the created page will be the current page – in the case of the example [https://wiki.edmcouncil.org/display/IDMP/Test+Page](https://wiki.edmcouncil.org/display/IDMP/Test+Page) was created “under” [https://wiki.edmcouncil.org/display/IDMP/Pistoia+Alliance+IDMP+Ontology+-+Phase+1+Home](https://wiki.edmcouncil.org/display/IDMP/Pistoia+Alliance+IDMP+Ontology+-+Phase+1+Home).

When you create a page, you need to add its title – which needs to be unique within the space. After you are happy with the contents you need to publish the changes:
Confluence has an in-built version control mechanism, called ‘Page History’, so you can see all versions of your page and you may roll back to any earlier version if needed.
When you add content to the page, you may wish to use a macro, e.g., to add an image or list all attachments to a page. The list of all macros is available through the ‘plus’ button when you are editing the page:

![Figure 6 How to find a macro](image)

**Add Comment**

We use comments to engage in a discussion related to specific issue. Confluence offers two options here.

**Page Comments**

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3: None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semantic Accuracy</td>
<td>ok as long as we don't consider the physical world</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Realization of OVs</td>
<td>simple</td>
<td>more complicated</td>
<td></td>
</tr>
<tr>
<td>Extensibility</td>
<td>Possible to add further subclasses of substances to allow groupings.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Proposal**

Go with Option 1 for now (for MVP) and only switch to option 2 if:
1. there are competency questions that require more sophisticated reasoning.
2. the texts and added value justify the increased complexity.

**11 Comments**

**Pawel Garbacz**

One can follow option 1 without excluding the physical world.

**Thomas Weber**

We can define an Ambidipine instance like this, but is it useful? What can you assert about it?

**Laurent Lelubre**

Hello all,

- not an expert in this type of modelling but adding some insights on the substance itself:
  - There are much more "physical objects" than just the product on the shelf
  - Ambidipine besylate is actually a crystallized substance used as a powder in the manufacturing of the tablet (ODM Manufactured Item) which is ultimately going into a blister (Package Item) going into the box finally delivered to the patient (Packaged Medicinal Product)
  - The "ambidipine" active moiety is indeed not existing as a real physical form in your tablet or medicine, it will only appear in the body after being administered to the patient and absorbed, this dissolution will separate it from the "baselike" salt which is mostly here to stabilize the substance and being able to crystallize it as a powder.
  - It is important to have the "active moiety" relationship as this would be the way to link together different dosage form / formulation that still contain ambidipine (e.g. you may have Ambidipine sodium...)

![Figure 7 How to add a comment](image)
The IDMP JIRA project helps manage project development by organizing work flow by mean of tasks, epics, and sprints.

**Issue Types**

We use two issue types:

1. Tasks - these are genuine tasks to be performed within the IDMP project
2. Epics – these are “container” for tasks, which related all issues related to a single deliverable in the project

**Boards**

The current sprint [1] can be accessed in the [IDMP Sprints Board](#):

There is also the [Kanban board] [2] that shows all tasks, irrespective of sprints:
Create Issue

To create an issue click on ‘Create’ button at the top of any JIRA page:
Most of the fields there are self-explanatory – perhaps except for labels, which we used in the MVP stage to indicate the workstream to which a given issue belongs to.

**Issue Lifecycle**

The diagram above shows the lifecycle of IDMP issues. When an issue is created, it gets the ‘TO DO’ statues. When someone starts working on it, it goes to ‘IN PROGRESS’ etc. One can change the issue either dragging and dropping it in the Spring or Kanban board or using the progress buttons – for instance when an issue in in progress, one can move to in review stage clicking on the ‘Ask For Review’.

**GitHub Integration**

Note that you can access the git repository directly from the JIRA project:
Confluence JIRA Integration

You can integrate your JIRA tasks with Confluence pages using the JIRA macro in the Confluence page:

This will link the issue and the page both ways.
We use the **EDMC GitHub repository** to store, master, and version the IDMP suite of ontologies. As of now these ontologies are stored in 5 folders whose names are UPPERCASED – etc folder contains auxiliary metadata used by the Ontology DevOps infrastructure:
Figure 18 GitHub IDMP repository

The proper way of using this platform is described in the guide on how to contribute to the development of FIBO:
Issues and Pull Requests

The FIBO sources are kept in this repository on GitHub. As is customary with GitHub, changes to FIBO can be proposed via the issues or can be made in a fork of this repository, and then proposed directly to the FIBO Community Group through a pull request.

You will need a GitHub user name to participate in the development process.

Issues

Create an issue if you would like to report a problem or a bug concerning FIBO.

Discussions

Create a new discussion if you would like to

- announce your FIBO Content Team to get more attendees,
- ask a question about FIBO,
- suggest an idea for FIBO extension or FIBO documentation.

Pull Requests

If you want to extend the content of FIBO through pull requests, you'll need to do the following things:

1. Make sure you have java installed; see https://www.oracle.com/technetwork/java/javase/downloads/index.html, if you need to download java.
2. Install a git client.
   - In FIBO, we recommend SourceTree from Atlassian
3. Make a "fork" of the "fibo" repository. Clone your fork to your local repository.
4. Install FIBO serialization tools. This is important so that your code can be compared and merged with code from other contributors.
   - You cannot submit a pull request to the fibo repository without this step.
5. Install the local testing tools. This will allow you to process FIBO with the most common semantic web editing tools.
6. Edit FIBO using the RDF/OWL editor of your choice (Protégé, TopBraid, MagicDraw CCM, VOM, Cognitum Fluent Editor, etc.).
7. Submit a pull request to the EDM Council’s "fibo" repository. Please add "(WIP)" sufif to the title of your pull request.

You only have to do steps 1-5 once. Once you have begun contributing, you just repeat steps 6 and 7.

To have your contribution considered by the maintainers

- Follow all instructions in the template.
- Follow the principles of best practices.
- Add "(WIP)" sufif to the title of your pull request.

Figure 19 How to raise an issue

You may use the GitHub repository to get the latest version of the ontology or a specific release:
Figure 20 How to get the latest version of the IDMP ontology

Figure 21 How to get a release version of the IDMP ontology

To find out more about Kanban boards see https://www.atlassian.com/en/agile/kanban/boards.