Management of ODS Regulatory Referenced Deliverables

Project Scope

The scope of this project is to identify a primary and back-up representative for each PHUSE regulatory referenced deliverable that will:

- review updates to regulatory documents where PHUSE deliverables are referenced to ensure they are in alignment
- identify any updates that are required due to updated regulatory documents
- organise the updates, including addressing feedback from PHUSE members
- discuss the updates with the ODS Working Group Leads to agree on the updates
- oversee the updates and publishing of PHUSE deliverables
- commit to serving as a representative for two years.

The project team will meet quarterly with the ODS Working Group Leads to discuss potential updates and their timing to avoid burdening the project team members and the regulatory authorities in reviewing the updated deliverables.

Problem Statement

The Optimizing the Use of Data Standards Working Group is responsible for the maintenance of four regulatory referenced deliverables (the cSDRG, ADRG, SDSP and BDRG) as well as three that will be published in the future. There is no regular maintenance process for updating these deliverables due to updates to binding and non-binding guidance from regulatory authorities. The project teams that were formed to create the documents no longer meet on a regular basis. This project will address the issue of implementing scheduled updates to these deliverables.

Problem Impact

Regulatory authorities reference the deliverables within their guidance documents and the deliverables must be in alignment with the guidance documents. Stakeholders include regulatory authorities and organisations that create the regulatory referenced deliverables. The FDA expects sponsors to submit the deliverables using the templates that PHUSE creates. Included in the PHUSE deliverables are the templates, example documents and completion guidelines.

Project Leads	Email
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CURRENT STATUS **Q1 2024**

- Q1 meetings accomplished

Regulatory Referenced Deliverables	Representatives
ADRG	Sumit Pradhan, *Syneos Health* and Pradnya Bharambe, *Fortrea*
BDRG	Dipen Kachhiapatel, *Syndax* and Mathura P Ramanathan
cSDRG	Zhaojuan Meng, *Sanofi* and Suresh Yenishetty, *IQVIA*
iADRG	Christine Rossin and Kiran Kundarapu, *Loxooncology*
SDSP	Venkat Rajesh Datla, *Genmab* and Priyanka Pollarine, *Biogen*

Regulatory Referenced Deliverables	Representatives	Email
ADRG	Sumit Pradhan, *Syneos Health* and Pradnya Bharambe, *Fortrea*	sumit.pradhan@syneoshealth.com pradnya.bharambe@fortrea.com

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iADRG	Christine Rossin and Kiran Kundarapu, *Loxooncology*	cjrossin@gmail.com kkundarapu@loxooncology.com
SDSP	Venkat Rajesh Datla, *Genmab* and Priyanka Pollarine, *Biogen*	veda@genmab.com priyanka.pollarine@biogen.com