iADRG Template (PHUSE)

German CDISC User Network F2F / 14-Mar-2024

www.mainanalytics.de

Abbreviations

Term	Translation
PHUSE	Pharmaceutical Users Software Exchange (Global Healthcare Data Science Community, a non-for-profit organization run by industry volunteers)
RG	Reviewer‘s guide
ADRG	Analysis dataset reviewer‘s guide
iADRG	Integrated analysis dataset reviewer‘s guide
LDCP	Legacy data conversion plan

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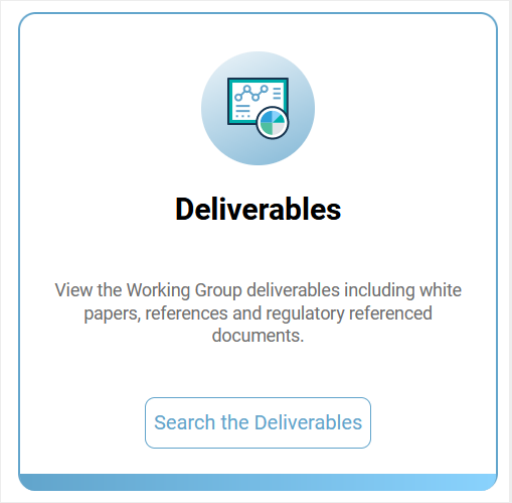
PHUSE Deliverables

https://phuse.global/

- PHUSE Deliverables



- Reviewer's Guides (RGs)

RG Packages

Year	Working Group	Deliverable Types	Deliverable Format	Title	Links
2023	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	BDRG V3.0 Package	BDRG+V3.0+Package.zip
2023	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	iADRG	iADRG V1 Package.zip
2022	Nonclinical Topics	Regulatory Referenced Deliverable	Template	nSDRG v1.2	nSDRG+v1.2.zip
2019	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	ADRG Packages V1.2 18-Jul-2019	ADRG Packages V1.2.zip
2019	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	Clinical SDRG V1.3, 2-Nov-2018	Clinical SDRG.zip

iADRG Package

Content of zip-file

- iADRG template, incl. LDCP (.docx)
- iADRG Completion Guidelines (.pdf)
- Two iADRG examples (.pdf)

Purpose of RGs

- Provide regulatory reviewers with additional context for datasets received as part of a regulatory submission.
- Duplicate limited information found in other submission documentation to provide regulatory reviewers with a single point of orientation to the datasets.
- Avoid redundancy between RG and Define-XML
  > Best Practices for Documenting Dataset Metadata-Define-XML Versus RG (PHUSE)

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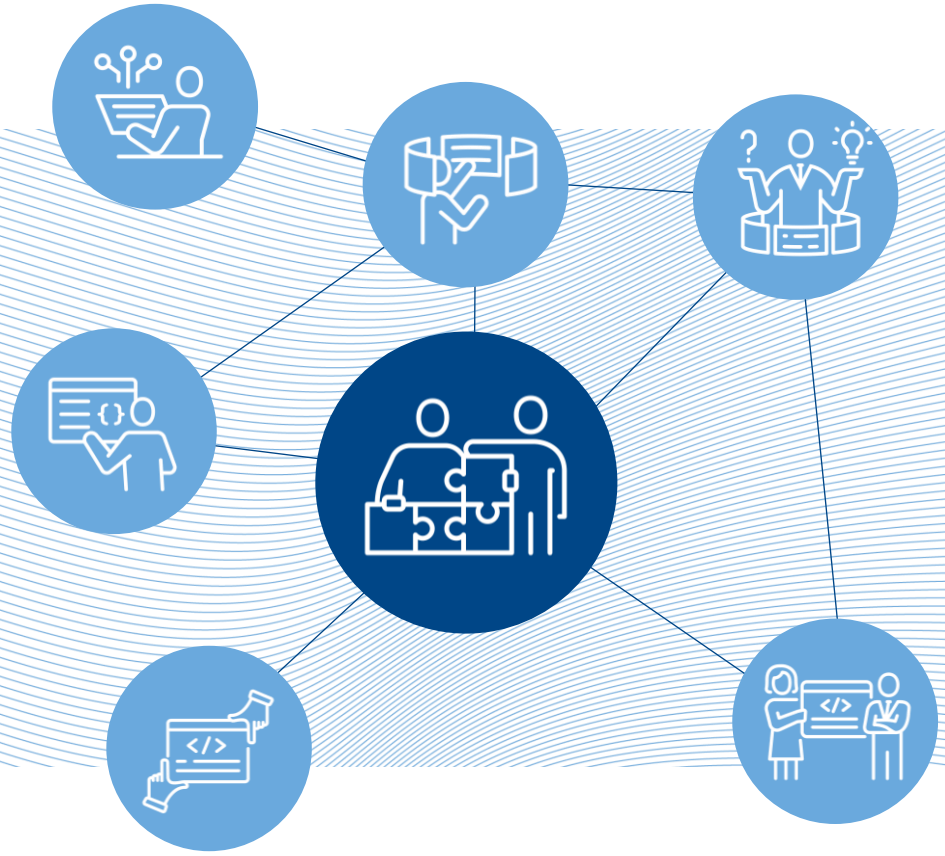
Integrated Analyses

- Which studies should be included?
- Which data should be selected?
  (study design, indication, treatment, planned analysis)
- Which data standards serve as basis?
  (legacy, SDTM, ADaM)
- Coding Information, CDISC CT
  (up-versioning)
- Traceability



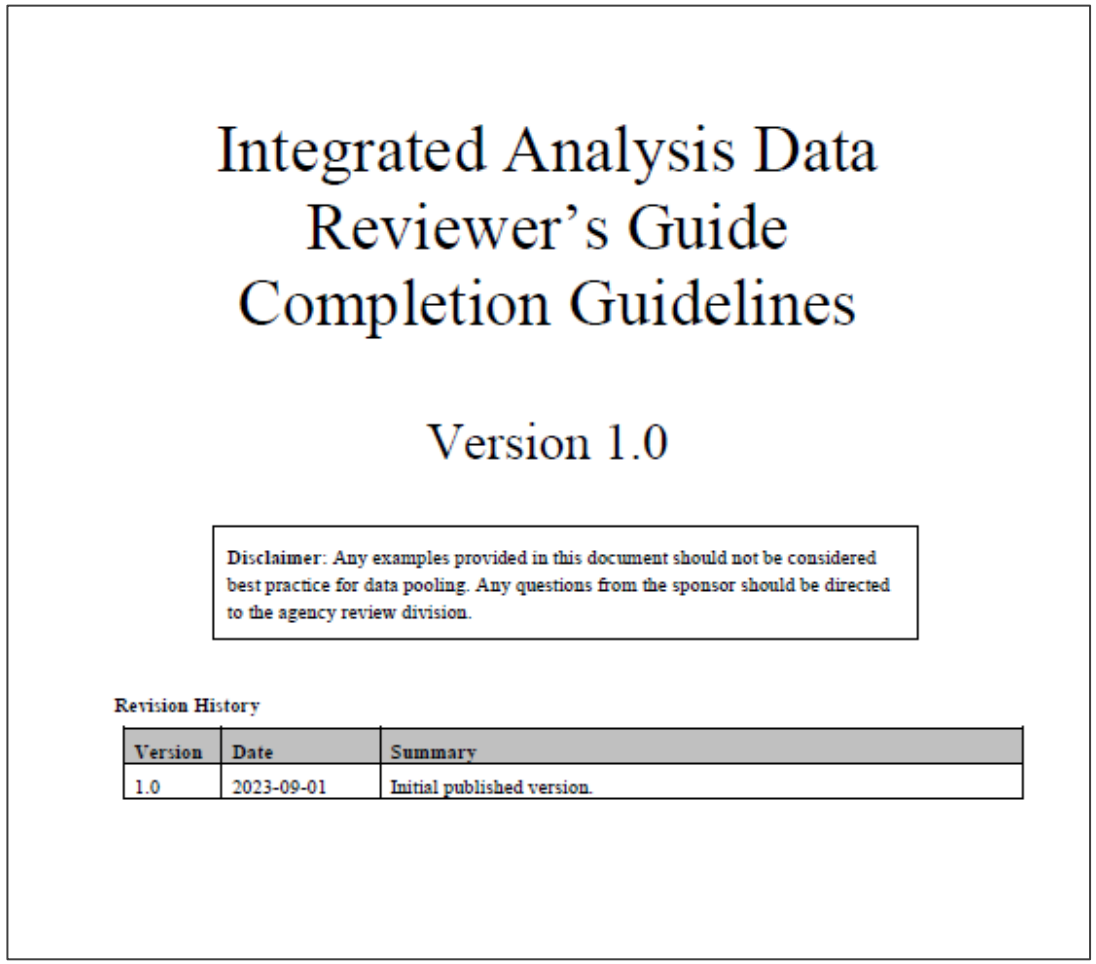
iADRG vs. ADRG

- Almost identical table of contents
- Section „Traceability Flow Diagram“ moved
- Completion Guidelines:
  - examples
  - points to be considered

Completion Guidelines iADRG

Three sections:

- Purpose and overview
- **Template completion instructions (per section)**
- Finalisation instructions



Integrated Analysis Data Reviewer's Guide Completion Guidelines

Version 1.0

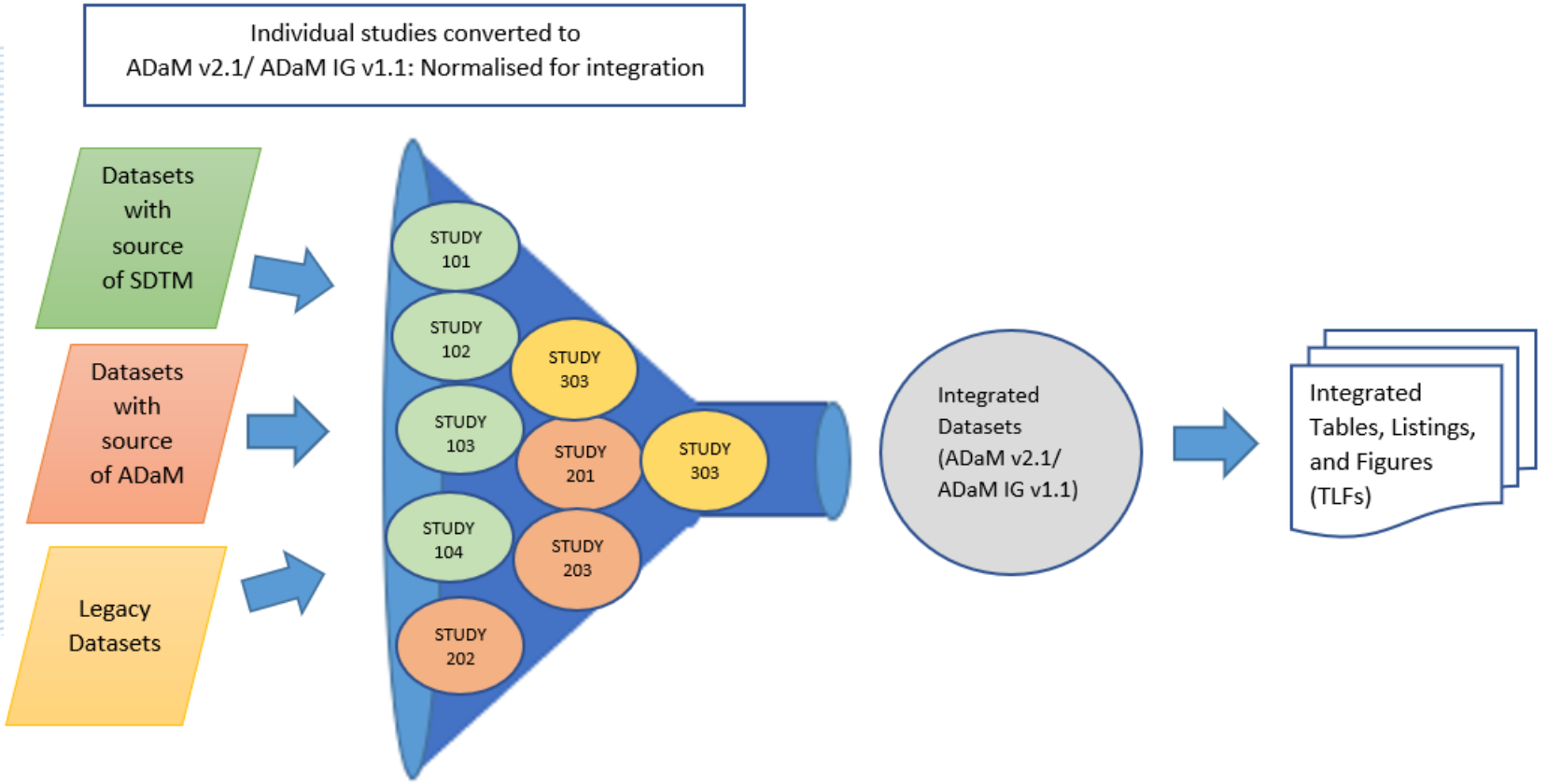
Disclaimer: Any examples provided in this document should not be considered best practice for data pooling. Any questions from the sponsor should be directed to the agency review division.

Revision History

Version	Date	Summary
1.0	2023-09-01	Initial published version.

Traceabillity Flow Diagram

(Example from Completion Guidelines)



Outlook

Optimizing the Use of Data Standards

Created by , last modified by Nicola Newton on Feb 13, 2024

Working Group Scope

The development and adoption of data standards over the last decade has shown significant promise in improving efficient delivery of data to support drug product and device submissions as well as the review process. However, there have also been gaps, issues and challenges in the interpretation and use of data standards. This Working Group will identify specific gaps that prevent FDA and industry from Optimising the Use of Data Standards. This Working Group will collaborate to close those gaps.

Current Projects

Best Practices in Data Standards Implementation Governance

Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum

Clinical Integrated Study Data and Analysis Data Reviewer's Guide

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Questions?

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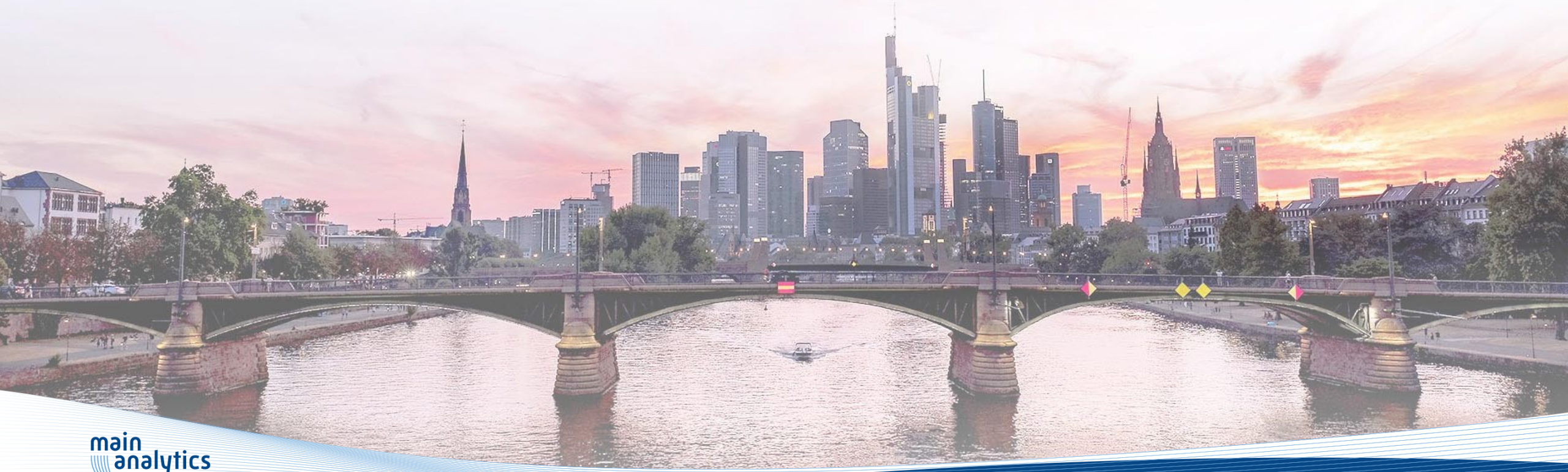
Thank You!



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