

Clinical Integrated Study Data & Analysis Data Reviewer's Guide



Project Scope
The cSDRG and ADRG apply to a single study. Sponsors have used these templates when creating a reviewer's guide for integrated Study Data and reviewer's guide for integrated Analysis Data. The template has to be changed in order to document the information for multiple studies. There is an opportunity to create a template for integrated Study Data and integrated Analyses Data. The project team will determine if this can be accomplished in one reviewer's guide or if there should be two separate reviewer's guide. Deliverables include a template, completion guidelines and example documents.

Project Leads	Email	Objectives & Deliverables	Timelines
Kiran Kunderapu, <i>Loxo Oncology</i>	kkunderapu@loxooncology.com	iADRG template, completion guidelines and 2 examples	Q2 2023
Satheesh Avvaru, <i>Alexion AstraZeneca Rare Disease</i>	satheesh.avvaru@alexion.com	icSDRG project: integrated clinical Study Data Reviewer's Guide (icSDRG) Template, Completion Guidelines and Example	Q2 2024
Nicola Newton, <i>PHUSE Project Assistant</i>	nicky@phuse.global		

CURRENT STATUS Q1 2024
- Incorporating PHUSE CSS 2023 comments into the icSRDG draft template - Started draft icSDRG example document