

Internal Clinical Study Data Sharing Process



Project Scope

This project will gather feedback across industry on internal data sharing in order to provide a white paper summarising the results. The white paper will provide recommendations surrounding guidance on Internal Data Sharing Process, as well as identify similarities/differences between external and internal data sharing process. As many functions request for data internally, this could impact Statisticians, programmers, Clinicians, software developers and IT.

Project Leads	Email
Arlene Coleman	arlene.coleman@pfizer.com
Cathal Gallagher	cathal.gallagher@d-wise.com
Lauren White (PHUSE Project Coordinator)	lauren@phuse.global

Objectives and Deliverables	Timelines
Finalise survey	Q2 2021
Send survey out cross-industry	Q2 2021
Review and summarise survey results	Q2 2021
Draft White Paper	Q2 2021
Final White Paper	Q3 2021

Project Members	Organisation
Alex Hughes	Roche
Andreas Schwalm	CSL Behring
Ashwini Weber	Amgen
Barbara Rusin	SBC Global Alliance
Benjamin C Shim	Eli Lilly
Bhavna Nanda	Kinapse
Darcy Hille	Merck
Gregory Campbell	Gilead
Hannah Sharp	Gilead
James Stef	AstraZeneca
Jennie Mcguirk	ICON
Jennifer Alf	Astellas Pharma

Project Members	Organisation
Lisa Moorehead	Gilead Sciences
Lukasz Kniola	Biogen
Margi Sheth	AstraZeneca
Mats Knutsson	Micro Focus
Megan Schmidt	UCB
Mekhala Acharya	Takeda
Niamh McGuinness	Privacy Analytics
Renee Entzminger	Industry
Rohit Bajaj	GCE Solutions
Sanjay Bagani	Xogene
Santha Ramakrishnan	Sanofi
Shannon Lefavre	Roche
Srinivas Veeragoni	Bayer
Tamsin Sargood	Janssen Research & Development

CURRENT STATUS Q3/42021

Gathered additional feedback on potential gaps through the PHUSE CSS Working Group. Reviewing current draft white paper to determine if gaps need to be filled.