Welcome to the PHUSE Advance Hub



PHUSE is an independent, not-for-profit organisation run by a worldwide team of volunteers. We are a global community and platform for the discussion of topics encompassing the work of data managers, biostatisticians, statistical programmers, data scientists and eClinical IT professionals. PHUSE has become the industry voice to regulatory agencies and standards organisations such as the FDA, EMA & CDISC.

Welcome to the PHUSE Advance Hub, the home for all things Working Groups. To help you navigate through this website, we have created a 'how to' video.

This provides an overview of the where to find the Working Groups Projects, useful information such as templates, projects that are calling for volunteers and all the latest news under our 'Hot Topics' section.

This website has been produced for you and we welcome feedback. If there is anything you would like to share, please email workinggroups@phuse.global



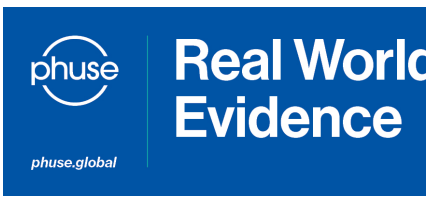
















Our Working Groups Mission

To provide an open, transparent and collaborative forum in a non-competitive environment in which academia, regulators, industry, technology providers and others can address computational science needs in support of health product development and regulatory review, ultimately bringing safe and effective medical products to those who need them.

Our Working Groups Goals

The collaboration was initially formed between PHUSE, the FDA and industry and has been extended across other regulatory agencies and stakeholders with the following goals:

- To facilitate discussions among regulatory agencies, industry and other stakeholders that inform and improve computational science, to support product development and review.
- To bring together experts in specific areas to collaborate on computational science, describe best practices in challenging areas, and propose methods for addressing knowledge gaps.
- To support ongoing collaborative Working Groups and Projects throughout the year by aligning Working Groups objectives, reviewing project requests, and deliverables, and providing direction for project issues and gaps.
- To establish an infrastructure and operational processes to support the collaboration.

Our Projects

PHUSE collaborations are organised into a number of Working Groups, each with a broad topic area. Each Working Group has specific projects designed to achieve a set of specific objectives.

Working Groups include volunteers from major stakeholders including academia, the pharmaceutical industry, biologics industry, device industry, contract research organisations, core laboratory organisations, technology vendors, SDOs and interested regulatory agencies. Participation is open to anyone who wants to contribute. Reach out to workinggroups@phuse.global.