Stakeholders' Deliverables Review

Project Scope

This project reviews on a regular basis a number of deliverables produced by other key stakeholders in the form of guidance, policies and articles. In particular, the PHUSE Data Transparency Working Group was invited to the EMA Policy 0070 Stakeholders meetings to comment on earlier version of the External Guidance.

In addition, the Working Group has had a collaboration with TransCelerate on the topic and the 2 organisations provided each other comments on respective deliverables.

The Working Group also provided comments to Health Canada on their respective policy and guidance that were available for public review. The Working Group had an opportunity to provide feedback to the Cochrane organisation on their paper 'Interim guidance on how to decide whether to include clinical study reports and other regulatory documents into Cochrane reviews'.

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Objectives and Deliverables	Timelines
Approaching British Data Privacy Agency to participate in the development of a guidance	Ongoing
Continue to monitor for new opportunities to comment on relevant topics.	Ongoing

Project Members
For each deliverable to be reviewed, different Working Group members volunteer based on their interest. We do not try to align all the comments, although all comments are discussed within the group of reviewers, and we provide all comments that are received from different experts so that the authors can receive and assess different opinions.

CURRENT STATUS **Q3/42021**

Identification of volunteers to provide feedback on the UK Information Commissioner's Office anonymisation, pseudonymisation and privacy-enhancing technologies draft guidance. Work will begin Q3. There will be 7 chapters released on a monthly basis until the end of the year and this Working Group will provide feedback on behalf of PHUSE for each chapter.

Published Deliverables	
PHUSE Comments to EMA 'Publication and access to clinical-trial data', 2013 - Stakeholder 107, pages 87-92	PHUSE DT WG - FDA Pilot Review Comments - v1.0.pdf: "PHUSE Data Transparency Working Group's Comments on FDA's Clinical Data Summary Report Pilot Program - Federal Register / Vol. 84, No. 124 of Thursday, June 27, 2019"
PHUSE Data Transparency Working Group's Comments on Canada's Gazette, Part 1 of 9. December 2017	PHUSE re-start of EMA Policy 0070 Suggestions_20200117.pdf – "PHUSE Data Transparency Working Group's Suggestions to EMA Policy 0070 Re-start – 17 January 2020
PHUSE Data Transparency Working Group's Comments on Health Canada's DraftGuidance for the Implementation of the Public Release of Clinical Information of 10 April 2018.	When to include clinical study reports and regulatory documents in systematic reviews