

Policy 0070 Interpretations



Project Scope

The PHUSE Data Transparency Working Group has been reviewing very closely Policy 0070 and its External Guidance. The Working Group is looking further into different aspects of the policy and aim at providing further guidance and interpretations where needed. The Working Group has been working on 4 topics:

- Policy 0070 Submission Reviews
- Handling of Narratives
- Data Utility
- Risk Assessment in CSR

Project Leads	Email
Jean-Marc Ferran	jean-marc.ferran@phuse.global
Lukasz Kniola	lukasz.kniola@biogen.com
Rashmi Dodia	rdodia@mms Holdings.com
Sarah Nevitt	sarah.nevitt@liverpool.ac.uk
Lauren White (PHUSE Project Coordinator)	lauren@phuse.global

Resources

[A review of the first 47 EMA policy 0070 submissions](#) was conducted and presented during the 2017 EMA TAG meeting.

The White Paper on "Handling of Narratives" has been completed and published on the [PHUSE Website](#).

[Analysis of CSRs already published \(PHUSE review\), 2017](#)

CURRENT STATUS

Project concluded.

Recent Activities

- EU CSS 2018 - Review of Data Utility and Handling of Narratives drafts and discussion with FDA officers around their Data Sharing initiative
- EU CSS 2017 - Review of initial deliverables and discussion with EMA Policy 0070 officers after 1 year of Policy 0070 submissions.
- US CSS 2016 - Initial Workshop to define the different subtopics of the "Policy 0070 Interpretations" project
- EU CSS 2016 - Follow-up from US CSS 2016 and planning of tasks