

Preparation of Clinical Documents for Public Disclosure

Background and Scope

In line with <u>our transparency commitments</u>, we register protocols of all studies of our products and provide a summary of the results once the study has completed on the GSK Study Register. We disclose full Protocols, Statistical Analysis Plans and Clinical Study Report (CSR) Synopses, and list studies for data sharing. All documents that are released for public disclosure have Personally Identifiable Information (PII) removed or redacted to protect data privacy.

Since our commitment to sharing clinical documents pre-dated the release of the European Medicines Agency's (EMA) external guidance on the implementation of the EMA's policy on the publication of clinical data in 2016, ^[i] our documents were historically prepared for public disclosure based on redacting direct and indirect personal identifiers as described in the Health Insurance Portability and Accountability Act [HIPAA] ^[ii] and Safe Harbor principles. Documents which were prepared for public disclosure in accordance with this procedure are still accessible and have not been subject to further redaction or review following the revisions to GSK's procedures described below.

Over the years GSK's approach to preparing clinical documents to ensure their suitability for public disclosure has been adapted based on evolving requirements on patient privacy and regulatory recommendations such as guidance on clinical data publication (as published by EMA under its Policy 0070 in November 2018), and with the recommendations in Health Canada's Public Release of Clinical Information initiative in March 2019. GSK considers that the principles applied by these bodies facilitate a common understanding of data privacy.

This document provides an overview of our current approach to preparation of clinical documents for public disclosure, covering protection of personal data, third-party copyright information and redaction of commercially confidential information.

Protection of Personal Privacy

Personally identifiable information is excluded through a combination of removing sections from a clinical document or irreversibly masking information from view with a solid blue box using a technique called redaction.

Where required, risk-based approaches may be implemented to strike an optimal balance between patient privacy and data utility. These approaches include using additional anonymization techniques like randomization, generalization, offset, and/or recoding of patient data. Additional steps may be taken to protect privacy in some circumstances, for example for patients with a rare disease.

Protection of Third-party Copyright Information

Non-consented third-party copyright information, such as clinical outcome assessments / measures and publications, is either removed or irreversibly redacted with a solid black box in the clinical documents prior to public disclosure.

Redaction of Commercially Confidential Information

Commercially Confidential Information is defined by the EMA as 'any information contained in the clinical documents submitted to the Agency by the applicant/Marketing Authorization Holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH. This information is either removed or irreversibly redacted with a solid black box in the clinical documents prior to public disclosure.

DISCLAIMER: The information presented herein is for informational purpose only and is subject to change without notice. No materials may be copied, reproduced, broadcasted, transferred, or transmitted in any way without GSK's permission.

[[]i]. EMA; https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data en-3.pdf

[[]ii]. HIPAA 2000; https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/prdecember2000all8parts.pdf