Preparation of Clinical Documents for Public Disclosure

Background

Clinical Study Reports (CSRs) are formal study reports that provide details of the study design, methods, and results of clinical trials. CSRs are provided to regulators when a medicine is submitted for approval.

We have published CSRs for clinical trials for our approved medicines dating back to when GSK was formed in December 2000. The CSRs are disclosed alongside other study information on our GSK Clinical Study Register.

In addition, we are publishing Clinical Study Reports (CSRs) for new studies starting from the beginning of 2013 for both medicines that are approved by regulators and those that are terminated from development. CSRs for these studies are disclosed after the results are published in the scientific literature.

Protection of Personal Privacy

It is important that the privacy of those involved in our studies is protected. We follow regulatory and industry standards in preparing clinical documents such as CSRs for public disclosure. Personally identifiable information is excluded through a combination of removing sections from a clinical document or masking information from view with a solid black/blue box using a technique called redaction.

Details of the GSK approach is summarised in Tables 1-3 below. These tables show how we have adapted our approach based on experience and external guidelines.

We may take additional steps to protect privacy in some circumstances, for example for patients with a rare disease.

CSRs in English or mainly English language are redacted for disclosure. Non-English text is redacted / removed. CSRs in languages other than English are not disclosed on the GSK Clinical Study Register.

Table 1: Subject Information Redacted from Clinical Documents to Protect Personal Privacy

Person	Information type	Previous approach	New approach *March 2017 onwards**
Subject (e.g. Patient, Healthy Volunteer)	Individual identifiers (IDs) *(e.g. Subject ID, Case ID, Randomisation Number)*	Redact.	
	Date of birth / death	Redact.	Redact day/month, retain year.
	Age	Retain any age that is 89yrs or less. Redact any age that is >89yrs and replace with 'age 90yrs or older'.	
	Subject event / assessment date	Redact.	Redact where study day is present otherwise retain. *(Study day is calculated as the number of days from start of treatment phase.)*
	Investigator name / geographic location of investigator site	Redact except for country, when associated with an individual subject.	
	Facial photographs or other identifiable images	Redact.	

***Note:** CSRs prepared for public disclosure according to our previous approach may be disclosed after March 2017.

Table 2: Study Personnel Information Redacted from Clinical Documents to Protect Personal Privacy

Person	Information	Previous approach	New approach *March 2017 onwards**
Signatories	Sponsor and Investigator* **This relates only to where individuals are stated as being a signatory. Rules below apply where individuals perform other roles*	Redacted to rules defined in **Sponsor Staff** and **Investigator and site staff** below.	Retain name and initials. Redact other details according to sponsor staff / investigator rules detailed below.
Sponsor Staff	GSK, vendor and other company personnel	Redact name, initials, signature, email, phone / fax number, staff ID.	
Investigators & site staff	Interventional studies started from 1st January 2013 onwards.	Redact signature, email, phone / fax number, site / investigator identifier. Remove curriculum vitae.	
	Interventional studies started before 2013 and Non-interventional / Observational studies	Redact signature, email, phone / fax number, site / investigator identifier, name, initials, organizational title & department, institutional website URL, name & address (except country). Remove curriculum vitae.	
Other individuals	Study consultants and committee members	Redact signature, email, phone / fax number and name, initials, organisational title & department, institutional website URL, name & address (except country)	

***Note:** .CSRs prepared for public disclosure according to our previous approach may be disclosed after March 2017.

Table 3: Redaction Rules Applied to Specific Information

Type of information	Previous approach	New approach *March 2017 onwards**
Subject level data / information, which contain multiple specific data points that may risk identification of a patient *(e.g. verbatim text, textual summaries, narratives)*	Redact / remove.	Redact identifier types as in Table 1. Specific sensitive events redacted more fully or in full, on a case by case basis.
Listings	Redact / remove.	Patient listings removed, except for following listings: • Randomisation listings. • Listing of deaths, other serious & significant adverse events. For the above listings identifier types as in Table 1 and Table 2 are redacted.
Figures and plots	Redact subject data lines and subject identified outlier points Retain pharmacokinetic figures.	
Patient Case Report Forms	Remove.	

***Note:** CSRs prepared for public disclosure according to our previous approach may be disclosed after March 2017.

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Redaction of Commercially Confidential Information (CCI)

Commercially Confidential Information (CCI) is defined by the European Medicines Agency (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.’

At the point of market authorisation, we do not regard information contained within CSRs and associated documents (such as protocols and analysis plans) as containing CCI.

Third party copyright redaction

Prior to public disclosure of clinical documents, we are required to remove third-party copyright information, such as clinical outcome assessments / measures and publications, for which we do not have permission to disclose.