

GlaxoSmithKline

Data Management Summary



This guide summarises the data management and sharing requirements for research funded by GlaxoSmithKline (GSK). Please visit their website for further details.

Resource types covered:

Research findings obtained from completed & abandoned projects.

Data Plan:

A data management Plan is not required for grant applications. However, data issues must be addressed in trial protocols and other documents.

Data-related funds:

Not stated

Retention:

Established in contract

Data standards:

Domain-specific standards

Documentation:

Domain-specific standards should be used for data documentation.

Data hosting:

Clinical trials and related research must be disclosed through appropriate national/regional regulatory authorities as part of the medicine development and approval process. GSK post protocol summaries on ClinicalTrials.gov and Clinical Study Register (<http://www.gsk-clinicalstudyregister.com/>) on study initiation.

Sharing timescales:

Summaries of study results are published on Clinical Study Register within 8-12 months of study completion.

A sharing waiver is allowed in circumstances where patents are sought. Ethical and legal requirements related to participant confidentiality apply.

Rights:

Subject to contract. Patents for 'radical' and 'incremental' research may be obtained. GSK support the use of clinical data in conformance to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), when it does not undermine Regulatory Data Protection (RDP).

Monitoring:

Technology issues should be addressed when reporting clinical trials progress.

References:

- Clinical Study Data Request
<https://clinicalstudydatarequest.com/>
- GSK Clinical Study Register
<https://www.gsk-clinicalstudyregister.com/>
- All Trials Registered
<http://www.alltrials.net/>