Our Commitment to Data Sharing

The ViiV Healthcare is committed to provide access to anonymised patient-level data that sit behind the results of our clinical trials. External researchers can request access to anonymised patient-level clinical trial data and supporting clinical trial documents through either of two multi-sponsor data sharing portals. It is hoped that sharing these data with researchers will help to further scientific research, increase understanding of new and current medicines and ultimately improve patient care.

Studies listed

ViiV sponsored interventional phase 1-4 trials are listed for data sharing once a medicine or vaccine has been approved by regulators or terminated from development across all indications.

- All Interventional trials starting in or after 2009.
- Exceptions include studies of rare diseases, or with non-English documents as well as prematurely terminated trials.

Timeframe

Within 6 months of:

Product approval by both the US and EU Health Authorities; or approved by either of them when regulatory submissions are not planned in both regions; or where development is terminated across all indications.

and

Publication of the primary endpoints, key secondary endpoints, and safety endpoints.

Requesting data

Consistent with the PhRMA-EFPIA Principles for Responsible Data Sharing and with expectations of good scientific practice, researchers can request access to our studies by providing a research proposal with a commitment to publish their findings.

Researchers whose requests are approved by an independent panel and accepted by ViiV are provided access to data in a secure environment upon signing a Data Sharing Agreement (DSA).

Appropriate measures are taken to protect data privacy and ensure that further research is legitimate and done by qualified researchers.

Vivli

ViiV studies listed since January 2023

To request data visit: **www.Vivli.org**

Click here
to request DSA template

CSDR

ViiV studies listed since January 2014 until December 2022.

To request data visit:
ClinicalStudyDataRequest.com

Click here
to request DSA template

Review Criteria

- The scientific rationale and relevance of the proposed research to medical science or patient care.
- The ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives.
- The qualifications and experience of the research team to conduct the proposed research review.
- Whether the proposal has potential to produce information that may increase the risk of identification of individual research participants
- Any real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest.
- The publication plan for the research.

Additional Conditions for Access

Patients give permission through informed consent form to use their data for original studies. Further research must therefore study the medicine or disease that was researched in the original studies.

Data will not be provided to requesters where there is a potential conflict of interest, data is to be used for a commercial purpose or there is an actual or potential competitive risk.

Interim data from clinical trials will generally not be shared by default, although efforts will be made to share such data in long-term, event-driven trials (such as oncology).

Researchers are required to sign a Data Sharing Agreement. This includes requirements to publish results of the analysis in a scientific journal or pre-print option and open-source release of any software or models.

Data and Documents shared

Where available, the following information is provided for each clinical study. Access is provided for an initial period of 12 months but an extension may be granted, when justified, for up to 6 months.

- Raw dataset (anonymised)
- Analysis-ready dataset (anonymised)
- Protocol with any amendments
- Annotated case report form
- Reporting and analysis plan
- Dataset specifications
- Clinical study report

For any queries, please contact :
ww.share-support@gsk.com **or**
viivhc.globalcoms@viivhealthcare.com

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