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 data and supporting clinical trial documents through multi-sponsor data sharing platform, Vivli.org. By enabling responsible data sharing to the qualified researchers, we aim to enhance scientific research, increase understanding of new and current medicines, and ultimately advance patient care.

Studies listed

ViiV sponsored interventional trials, ranging from phase 1 to 4, are made available for data sharing once a medicine or vaccine is either approved by regulators or its development is terminated for all indications.

- This includes global interventional trials initiated in or after 2009.
- Exceptions to data sharing include trials involving rare diseases, or documents not in English, and trials prematurely terminated due to insufficient enrolment.

Timeframe

Data sharing occurs within six months of specific events, including:

- Product approval by both the US and EU Health Authorities, or approval by either when regulatory submissions are not planned for both regions, or when development is terminated across all indications.
- Publication of the primary endpoints, key secondary endpoints, and safety endpoints.

Requesting data

Consistent with the PhRMA-EFPIA Principles for Responsible Data Sharing and good scientific practices, researchers can request access to ViiV studies by submitting a research proposal that includes a commitment to publish their findings.

Requests are reviewed by an independent panel, and upon approval, researchers are granted access to anonymised data in a secure environment after signing a Data Sharing Agreement (DSA).

ViiV studies listed on CSDR platform (www.clinicalstudydatarequest.com) span the period from January 2014 to December 2022. Starting in 2023, all new data requests are directed to the Vivli platform (www.vivli.org) for further assessment and data sharing.

Vivli

ViiV studies listed since January 2023

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

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, legal limitations, 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

Access to ViiV data is provided only for a period of 12 months. Where available, the following information is provided for each clinical study.

- Raw dataset (anonymised)
- Analysis-ready dataset (anonymised)
- Protocol with any amendments (redacted)
- Annotated case report form (redacted)
- Reporting and analysis plan (redacted)
- Dataset specifications (redacted)
- Study Report Synopsis (redacted)

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

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