Principles on

Clinical Study Transparency

Sharing Clinical Data

Sanofi believes that the sharing of clinical study information and data can improve medical science and holds the promise of accelerating development of and access to new treatments for the people who need them. Accordingly, we are committed to sharing clinical study data with external researchers, guided by the framework laid out in Pharmaceutical Research and Manufacturers of America (PhRMA) / European Federation of Pharmaceutical Industries and Associations (EFPIA) Principles for Responsible Clinical Trial Data Sharing) and as required by regulatory bodies. Sanofi also supports and engages in the sharing of participant-level clinical trial data through public-private partnerships and collaborations.

Sanofi data from interventional phase II - IV clinical studies will be made available for request through the clinical trial data sharing portal, www.Vivli.org. for Sanofi products approved on or after January 1, 2010 by both the US and EU Health Authorities, or by the US or EU Health Authorities when regulatory submissions are not planned in both regions; and for products for which development has been terminated on or after January 1, 2010.

Trials, for which the data may be requested, will be listed on the portal when the trial has been completed (or was terminated after participants were enrolled) and the primary trial results have been accepted for publication. In exceptional circumstances, listing will occur only after key additional results have been accepted for publication. In the absence of a publication, the trial will be listed once the results have been made publicly available. Researchers can enquire about access to clinical study documents without patient-level data such as the Clinical Study Report by completing the online enquiry form.

Sanofi will not list studies when

- Sanofi believes that the privacy and confidentiality of research participants cannot be protected through anonymization,
- there are legal or contractual agreements in place that would limit our ability to list the study and share the data with a third party,
- there are substantial practical/technical constraints to providing the data,
- the data file and/or supporting documents are not in English.

Only under exceptional circumstances would access to data be declined by the study sponsor, for example, where there is an actual or potential competitive risk.

Researchers may enquire about the availability of data from any Sanofi clinical trials that is not listed on the site by completing the online enquiry form at CSDR. This includes: 1) enquiries for access to data of

- trials of products approved prior to January 1, 2010;
- Phase I trials;
- unlisted trials for products for which development has been terminated; and
- trials for co-developed products and access to study documents without patient-level data.

For all enquiries received, Sanofi will conduct a feasibility assessment based upon the criteria described above. All enquiries will be considered on a case-by-case basis.

In making its data available, Sanofi will respect participant autonomy. Historically, when participants agreed to take part in Sanofi clinical trials they gave Sanofi permission, through informed consent, to use their data to study the medicine or disease being researched. Therefore, in making data available Sanofi will require that any use by a researcher must address a scientific question in the same disease area as the original trial. However, for Sanofi clinical trials initiated in 2014 and onward, Sanofi participants have been asked to give permission for broader research beyond the original trial intent, so research on other disease areas may be possible with data from these trials.

Our commitment to clinical study transparency is based on high ethical standards and norms and is consistent with all relevant national and regional regulations and laws. In making data available, Sanofi goes above and beyond such regulations to ensure that our clinical trial data is shared with researchers around the world to advance medical knowledge.

Study Registration and Results Reporting

Sanofi believes that the registration of clinical studies and the reporting of the results of such studies are essential to the advancement of medical science and public health. Transparency about clinical studies helps to develop trust between the public and the sponsors of clinical studies, reinforces the public's confidence in the process of pharmaceutical development and encourages greater participation in the studies themselves.

Above and beyond such regulations and where feasible, all Sanofi-sponsored studies, whether interventional Phase I-IV or observational, will be registered and summary results will be posted on a public clinical study registry, such as the NIH clinical trials registry, http://www.clinicaltrials.gov/ and the EU clinical trials register: http://www.clinicaltrialsregister.eu/.

Where the results of Sanofi-sponsored clinical studies are not made available through posting on a public registry website, we commit to publicly posting the results summary of the relevant Clinical Study Reports, or comparable documents, on our company website, https://www.sanofi.com/en/our-science/clinical-trials-and-results/our-data-sharing-commitments .

Publication of the Results

The presentation of the results of our clinical studies at scientific conferences or the publication of such results in peer-reviewed scientific journals helps to ensure transparency, enables critical review by the scientific community and advances medical knowledge. Sanofi is committed to presenting the results of such studies at scientific conferences and submitting such results for publication in peer-reviewed journals.

Sanofi's publication commitment includes clinical studies associated with marketed products, products in development and discontinued programs, regardless of whether the outcomes of the study were positive or negative. When the results of a clinical study are not published in a peer-reviewed journal, we commit to publicly posting the results summary of the relevant clinical study report, or comparable document, on our company website.

Providing Lay Summaries Study Participants

Returning aggregate clinical trial (interventional study) results to study participants, both healthy volunteers and participants, in the form of a layperson summary is recognized as an important emerging practice by both industry and non-industry sponsors and regulators and health authorities, as well as by researchers and participants themselves.

Lay summaries will be easily understandable and non-promotional and will provide a high-level summary of the key (primary) results of a clinical trial. This will ensure that the most pertinent results of a trial are made available, both to trial participants and to the public.

Lay summaries for Sanofi trials, submitted in accordance with the EU Trial Regulation, will be made available in Europe using the European Medicines Agency (EMA) portal (when available), and consistent with the company commitment to transparency.

Principles on Clinical Study Transparency approved by Sanofi Bioethics Committee (first approval in June 2019 - last review in 2024)