Pierre Fabre's Clinical trial and Real-World Evidence Data Transparency Policy

Pierre FABRE take care of life by designing and developing innovative solutions inspired by consumers and patients and contributing to the well-being of everyone from health to beauty.
We achieve this by cooperating with health-care professionals, our trusted partners worldwide, by drawing relentless inspiration from nature and plants, and by placing pharmaceutical ethics at the very heart of our operations.

"Every time we care for a single person, we make the whole world better"

WHAT IS CLINICAL DATA TRANSPARENCY FOR PIERRE FABRE?

Pierre Fabre invests in 4 lines of pharmaceutical research, oncology, dermatology, rare diseases and over the counter medicines to devise innovative solutions and provide therapeutic options for unmet needs. Our company conducts clinical trials worldwide to evaluate the safety and efficacy of its products. These trials are fundamental to the development of innovative medicines that treat and prevent illness in humans.
We strongly believe that sharing clinical trial information is in the best interests of patients and their caregivers, clinicians, health authorities and medical research.

Pierre Fabre, thus offers access to the data gathered in company-sponsored clinical trials, while protecting patient privacy, in the belief that greater openness may accelerate medical progress and benefit patient outcomes and public health.

Information about clinical trials and real-world evidence studies (RWEs) is shared on our dedicated website: https://clinicaltrials.pierre-fabre.com
Pierre Fabre's data transparency policy is resting on 5 pillars:

PILLAR 1 **<u>We register all Pierre Fabre Sponsored clinical trials and real word evidence studies on Public Registries and post online related information on our website</u>**

- Basic information about Pierre Fabre sponsored clinical trials and real-world evidence studies (RWEs) are published in European data base (EudraCT) https://www.clinicaltrialsregister.eu and/or Clinical Trial Information System (CTIS portal): https://euclinicaltrials.eu or worldwide database (CT.gov) https://clinicaltrials.gov and for RWEs in European Union electronic Register of Post-Authorisation Studies (EU PAS Register) http://www.encepp.eu.

  All information is also available on our clinical transparency website:
  - ➢ *Access to: page "Pierre Fabre Clinical study index"*

- For on-going studies, in addition to basic information, easy to understand summaries of the trial's protocol (lay Protocol summaries) are made available on our website to ensure any reader can understand the trial of interest as quickly, , and completely as possible.
  - ➢ *Access to: page "Pierre Fabre Current studies"*

PILLAR 2 **<u>We enhance public access to clinical trial results</u>**

- **For completed trials or trials with intermediate results,**
  - ➢ We disclose on our website Summaries results for clinical trials and RWEs studies in scientific/technical language (synopses) and/or summaries in easy-to-understand words and graphics (lay summaries results).

PILLAR 3 **<u>We commit to publish Pierre Fabre sponsored clinical trial results in scientific and medical journals</u>**

- ➢ Results from all Pierre Fabre Sponsored clinical trials are considered for publication in peer reviewed medical journals. These articles share the results of Pierre Fabre research that are reviewed by independent scientists before publication.

PILLAR 4 **<u>We disclose on our website and/or on https://clinicaldata.ema.europa.eu/ all clinical study reports (CSRs) and certain associated documents used in the submission for approval of medicinal products in the EU after January 2014</u>**

- For clinical trials submitted to the EMA (European Medicines Agency), or national competent authorities following approval of a new medicine or new indication for an approved medicine in the EU on or after January 1, 2014. Others clinical trial documents could be made available to researchers for additional analyses via voluntary data sharing policies (Pillar V)

PILLAR 5 **We enhance responsible data sharing with researchers**

- Pierre Fabre provides qualified researchers with the detailed data (patient level data, study level data such as clinical study report and protocols) from completed studies upon request on the Vivli Platform (a central place for researchers to search for studies available for clinical data sharing provided by numerous sponsor). Study participants' personal information is protected before these data are shared. Responsibly sharing data from our studies allows other researchers to conduct additional research that could help patient

We have established policies and procedures to implement these five data sharing commitments.

PIERRE FABRE'S TRIALS AND STUDIES TRANSPARENCY DETAILED PILLARS

Strengthening clinical trial transparency positively and directly benefits patient outcomes, improves the allocation of scarce medical research and healthcare resources but also facilitates and accelerates the development of new treatments and cures.
Pierre Fabre Transparency Policy and practices meet the five transparency principles endorsed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA). These principles were tackled in a manner that safeguard patient privacy, respect regulatory processes and oversight but also maintain incentives to invest in biomedical research.
Here is how our transparency policy meet the five EFPIA/PhRMA principles [1] in anticipated accordance with the EU Clinical Trials Regulation (EU 536/2014) [2] and the EMA policy 0070 [3].

PILLAR 1. Clinical Trial Registration: Inform the public about the designs of our clinical trials
We register and disclose all relevant clinical trial information of all Pierre Fabre-Sponsored/co-Sponsored interventional trials conducted in subjects (Phase I–IV) since 2004, prior to their initiation on EudraCT and/or CT.gov, and comply with other international and national clinical trial disclosure requirements.
Posting takes place following approval of the final protocol and prior to the first subject consenting to participate in the trial. Posted information is reviewed periodically to ensure it remains up to date.

For interventional trials initiated after January 1rst 2020, a trial synopsis is also made available in easy-to read language (Lay Protocol Synopsis) on Pierre Fabre clinical trial transparency website and will be disclosed in the CTIS portal for trials transitioned or initiated to new EU regulation.

We also register and disclose relevant information of all Pierre FABRE-sponsored non interventional trials that evaluate the safety and/or efficacy of a Pierre Fabre product on the European Union electronic Register of Post-Authorisation Studies (EU PAS Register) and CT.gov, since 2020.

- *Access to "Pierre Fabre Clinical Study Index"*

PILLAR 2. Clinical Trial Results Summaries

Study Phase I-IV intermediate and final headline results summaries for Pierre Fabre-(co)sponsored clinical trials are disclosed on Pierre Fabre website and local websites or registries in compliance with international and national clinical trial disclosure requirements and in alignment with the timing and modality set forth by the European Medicines Agency and/or in compliance with applicable laws and regulations:

- Pierre Fabre submits results for all Phase I-IV interventional clinical studies in subjects on the EU Clinical Trial Register (EudraCT) or Clinical Trial Information System (*Clinical Trials in the European Union - EMA (euclinicaltrials.eu)*)
    - within 12 months after the intermediate analyses or study has ended, if the study included only participants 18 years old or older.
    - within 6 months after the study has ended, if the study included any participants under 18 years old.
    - results of studies seeking deferrals [If the trial is studying an unapproved product or indication, in rare circumstances, a deferral may be requested], voluntary postings, and triggered studies will be submitted within 30 days of first marketing approval.
- Pierre Fabre submits results for all Phase II-IV interventional clinical studies conducted outside Europe in patients including Protocol and statistical analysis plan (SAP) on CT.gov.

Non-interventional post-authorization safety studies are posted in accordance with Guideline on Good Pharmacovigilance Practices EMA Guidance - Guideline on Good Pharmacovigilance Practices - module VIII 09-Oct-2017, on the European Union Post Authorization Safety Study register, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance and on our website within 18 months after the study ends.

Clinical Trial Summaries in lay language

Pierre Fabre posts lay summaries of clinical study synopses and results to its website and provide them to study participants via trials investigators and/or patients organisations. For each lay summary, we include feedback from a panel that includes a patient, a medical professional, a lay expert, and members of the general public.

Currently, lay protocol summaries are available for all Pierre Fabre sponsored trials or real-world evidence studies that ended or were on going as of 1st of January 2020.

For Studies that began after the 1rst January 2020 or still ongoing at that time, we post on our website and in the CTIS portal (for studies initiated or transitioned to the EU Clinical Trial Regulation Pierre Fabre) the intermediate (when applicable) and final results in plain language of all Phase I-IV interventional clinical studies and observational studies.

- Within 12 months after the Primary completion/study has ended, if the study included only participants 18 years old or older.
- Within 6 months after the study has ended, if the study included any participants under 18 years old.

- Results of studies seeking deferrals [If the trial is studying an unapproved product or indication, in rare circumstances, a deferral may be requested], voluntary postings, and triggered studies will be submitted within 30 days of first marketing approval in Europe.
- For observational studies, lay summaries will be posted voluntary on our website within 18 months of study completion.

For interventional and observational studies, all lay summaries will be provided at least in English and French.

➢ *Access to Pierre Fabre clinical study index*

PILLAR 3. Medical Publications of clinical trial data:

All Pierre Fabre-sponsored clinical trials are considered for publication in a peer-reviewed irrespective of whether the results of the clinical trials are positive or negative e.g. an article submitted to a peer-reviewed journal or an abstract, resulting in a poster or talk presented at a medical/scientific congress or international or local meetings.
Pierre Fabre follows established guidelines in medical and scientific publishing including the International Committee of Medical Journal Editors Recommendations and Good Publication Practice [3.]

Aligned with the 'Joint Position on the Publication of Clinical Trial Results in the Scientific Literature' from IFPMA (2010), we commit to submit the results of all Pierre Fabre Sponsored Phase III clinical trials and any investigational clinical trial results of significant medical importance for publication in a peer-reviewed journal or presentation at a congress wherever possible within 12 months and no later than 18 months of:

- In the case of already marketed medicinal products, the completion of clinical trials,
- In the case of investigational medicinal products,
- The regulatory approval of the new medicine or
- The decision to discontinue development.

For a comprehensive overview of our medical publication by clinical trial:

➢ *Access to Pierre Fabre clinical study index*

PILLAR 4: Clinical Study Reports and documents disclosure:

Clinical Study Report (CSRs) are the formal study reports that we prepare, to provide more detail on the design, methods and results of our clinical trials. They form the basis of the information we provide to regulators such as EMA or FDA when a medicine is submitted to them for approval for use in patients.

Our commitment to Clinical Trial Transparency continues through the EMA Policy 0070 (4) and EU CTR 516/2014 (5) which require all CSRs and certain associated documents used in the submission for approval of medicinal products in the EU be publicly disclosed. Personal protected data and commercial confidential information may be redacted in these documents, consistent with the need to protect privacy, publication rights, and confidential commercial information. We have implemented a procedure to comply with the process for publication of redacted clinical documents as per EMA policy 0070.
For Studies that are part of an EU or US marketing submission after the application of the EU Clinical trial regulation, redacted CSRs will be posted on our website and CTIS portal, 30 days after the marketing authorisation decision (authorisation or refusal of MA application) or 30 days after withdrawal of the application by the Applicant.

Study Reports of observational studies will be shared within 18 months after the study ends.

PILLAR 5. Enhancing Data Sharing with Researchers:
Pierre Fabre commits to share patient-level data, study-level data, redacted CSRs, and protocols with qualified scientific and medical researchers. Pierre Fabre has established a process for researchers to request access to such data from PF-sponsored interventional clinical trials conducted in patients (Phase II-IV) for products and indications part of an approved marketing application in the European Union and or US or a global discontinuation of development has occurred by Pierre Fabre, since January 2015. Data will be provided to the researchers pending approval of a research proposal and a Data Use/Sharing Agreement signed by the data requestor. Data from these trials will be made available within 6 months after the regulatory review of the dossier and the primary manuscript describing the results has been accepted for publication.
The research proposal may include enquiries for clinical trials outside of the scope of this Policy. In these instances, PF will assess feasibility of sharing the data as part of the review process.

Exceptions to Pierre Fabre's Data Sharing Policy:

- Clinical trials where there is a reasonable likelihood that the study participant could be re-identified, such as with trials of rare diseases and single-centre studies.
- Clinical trials where data sharing is prohibited by the informed consent; or where regulatory, legal, contractual, or other limitations exist and do not allow such data sharing.
- Clinical trials where data/documents are not in English.
- Clinical trials where there are ongoing regulatory activities or publication plans.

Where Pierre Fabre has a co-research, co-development or co-marketing/co-promotion agreement or where the product has been out-licensed, it is recognized that disclosure may be dependent on the agreement between parties. Under these circumstances, Pierre Fabre will endeavour to gain agreement to share data in response to requests.

We generally do not share imaging data (e.g. DICOM files of images from x-rays, ultrasounds, MRI scans, etc.) and we will only share genomic data with explicit consent.

For information on the process for submitting a scientific or medical research proposal that includes a request for access to data from Pierre Fabre -sponsored clinical research, please visit Vivli (https://vivli.org/).

Certify Procedures for Sharing Clinical Trial Information
You may review Pierre Fabre's full policy, including descriptions of our procedures, https://clinicaltrials.pierre-fabre.com that also publish metrics on adherence.

References

1. PhRMA/EFPIA, Principles for Responsible Clinical Trial Data Sharing, accessed at: https://www.efpia.eu/media/25189/principles-for-responsible-clinical-trial-data-sharing.pdf

2. EMA Clinical Data, Online access to clinical data for medicinal products for human use, accessed at https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-datapublication (last accessed 03 February 2022)

3. IFPMA, EFPIA, JPMA & PhRMA Joint Industry Position on the Publication of Clinical Trial Results in the Scientific Literature, 10 June 2010

4. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

5. EMA Policy 0070 (EMA/240810/2013)