CHIESI FARMACEUTICI S.p.A.

CLINICAL TRIAL TRANSPARENCY AND DATA SHARING POLICY

Running clinical studies and obtaining results is what clinical development is all about. Sharing results is very important too. Therefore, Chiesi Farmaceutici S.p.A. (Chiesi) is committed to **Clinical Trial Transparency and Data Sharing**.

As a member of the *European Federation of Pharmaceutical Industries and Associations* (EFPIA), Chiesi undertakes to set up policies and procedures to implement the *EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing*.

Clinical Study Registration and Posting of Summary Results

In accordance with the local legislative and applicable requirements on clinical studies, Chiesi discloses in public registries (e.g. *ClinicalTrials.gov*, *EU Clinical Trials Register*), the **Clinical Protocol** and **Study-related Information** and the **Summary Results** of those clinical studies sponsored by Chiesi Farmaceutici S.p.A.

Furthermore, Chiesi commits to making available information regarding any phase 2-4 clinical trial, non-interventional study and clinical investigation on medical devices, sponsored by Chiesi Farmaceutici S.p.A., which is not subject to a mandatory disclosure requirement in any Primary Registry part of the World Health Organization (WHO) Registry Network and which is initiated on or after *1st June 2018*. This information is provided by means of the public registration in *ClinicalTrials.gov* and disclosure of Summary Results (e.g. posting on *ClinicalTrials.gov*, CSR synopses, structured summary data, etc.), within 12 months from completion of the study.

All clinical studies sponsored by Chiesi Farmaceutici S.p.A. and their study-related and results-related information publicly disclosed are made available on the ***Chiesi Clinical Study Register***.

Sharing Clinical Study Report Synopses

Chiesi commits to sharing the **Clinical Study Report (CSR) Synopses** of those clinical studies sponsored by Chiesi Farmaceutici S.p.A., submitted to Food and Drug Administration (FDA), European Medicines Agency (EMA) or National Competent Authorities of European Union Member States for any new medicine or indication approved for the first time in the United States and/or European Union after *1st January 2015*, within 12 months after the approval.

Chiesi provides the CSR Synopses consistently with the need to protect patient privacy, publication rights, and commercially confidential information, through appropriate redaction.

The CSR Synopses are made available on the ***Chiesi Clinical Study Register***.

Publication of Clinical study Results in Scientific Literature Journals

Chiesi encourages and supports the submission for publication in **Scientific Literature Journals** of results from at least all phase 3 clinical trials sponsored by Chiesi Farmaceutici S.p.A. and any clinical study results of significant medical importance regardless of the outcome.

References to the peer-reviewed journals publications of Chiesi Farmaceutici S.p.A. clinical studies results are made available on the ***Chiesi Clinical Study Register***.

Sharing Lay Summary Results

Chiesi, as member of EFPIA, is working with regulators to adopt mechanisms through which companies may share clinical trial information with subjects who participated in a particular clinical trial, consistently with applicable laws.

Therefore, in support of this principle, Chiesi commits to developing an internal approach to provide research participants with **Lay Summary Results**.

Sharing Clinical Trial Data with Qualified Researchers

Chiesi commits to sharing with qualified scientific and medical Researchers, conducting legitimate research, **Patient-level Data**, **Study-level Data**, the **Clinical Protocol** and the full **CSR** of Chiesi Farmaceutici S.p.A.-sponsored interventional clinical trials in patients for medicines and indications approved by EMA and/or FDA after *1st January 2015*.

Chiesi provides access to clinical trial information consistently with the principle of safeguarding commercially confidential information and patient privacy. Any shared Patient-level Data is anonymized to protect personally identifiable information.

Fundamental conditions for providing the requested clinical trial data are that qualified Researchers agree to sign a *Data Sharing Agreement*, to use the data only for non-commercial purposes and to seek publication of their research results.

Nevertheless, the access to clinical trial data is not be granted if any of the following apply:

- There is a reasonable likelihood that individual patients could be re-identified: for example, clinical trials of rare diseases, single-centre clinical trials, or clinical trials with a very small number of subjects (< 50 subjects);
- The external research has the purpose of re-evaluating safety and efficacy issues already addressed in the product labelling;
- There are substantial practical and/or technical constraints to provide data access;
- There are contractual or legal or patients' informed consent provisions that prohibit the transfer of clinical trial data to third parties;
- There is a potential conflict of interest or an actual or potential competitive risk;
- Lack of necessary documentation related to the request.

Clinical Trial Data Request Process

1) Preliminary Identification

Preliminary information on the identity of the Lead Researcher and on the Research Proposal must be submitted using ***Preliminary Identification Form*** on the ***Chiesi Clinical Trial Data Request Portal***.

Chiesi conduct an initial evaluation of the submitted information and, based on this assessment, the Researcher may be granted with the access to the password-protected and reserved area of the ***Chiesi Clinical Trial Data Request Portal***.

2) Submission of the Research Proposal

Upon registration and login into the reserved area of the ***Chiesi Clinical Trial Data Request Portal***, the Researcher can submit the request for clinical trial data through the *Research Proposal Form*.

A complete and valid Research Proposal must contain:

- Detailed description of the data being requested;
- Detailed description of the rationale of the proposed research with bibliographic references and copy of the cited papers;
- Details explanation of the hypothesis to be tested;
- Detailed research design and objectives;
- Statistical Analysis Plan that will be used for the analysis;
- Proof of Ethics Committee or Institutional Review Board approval or commitment to provide proof of approval before any data is accessed (if necessary);
- Publication and posting plan;
- Description of any potential competitive use of the data;
- Detailed and documented description of the source of any research funding;
- CV of every member of the research team;
- Description of any potential conflict of interest.

Step 3) Review of the Research Proposal

Once received the *Research Proposal Form*, Chiesi assesses and ensures that the Researcher's request is complete and valid as per the above requirements. If and when the request is deemed valid and complete for formal acceptance, an appointed Chiesi Evaluation Committee starts the assessment of the Research Proposal.

In case of a positive evaluation, Chiesi formally approves the research proposal.

In case of a negative evaluation, but no direct competition is envisaged, Chiesi forwards the assessment to a Scientific Review Board, composed by qualified researchers who are not Chiesi employees. For more details about the Scientific Review Board, please contact clinicaldatasharing@chiesi.com.

Within 180 working days from Research Proposal acceptance, Chiesi commits to informing the Researcher of the final decision and of any condition for collaboration.

Step 4) Access to the requested clinical trial data

Following the Research Proposal approval, signing of the *Data Sharing Agreement* between Chiesi and the Researcher or related Institution is the condition for granting the access to the required clinical data via a password-protected environment.

Within 90 working days from the *Data Sharing Agreement* signature, Chiesi commits to making available the requested clinical trial data.