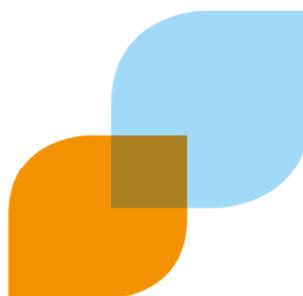


TERMS AND CONDITIONS ACCESS
PHARMO DATABASE NETWORK



PHARMO Institute

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Terms and conditions access PHARMO Database Network

Before granting access to data from the PHARMO Database Network the applicant should consent to the 'Terms and conditions for access to data from the PHARMO Database Network' as described below. Access to the data from the PHARMO Database Network is exclusively granted to researchers employed by universities and research institutes for scientific research. The applicant will complete the application form 'Access to the PHARMO Database Network' and share the study protocol.

The PHARMO Institute ("PHARMO") may, as responsible party for the PHARMO Database Network, institute additional requirements for access to the PHARMO Database Network. When the Compliance Committee approves the data request without additional requirements, the 'general terms and conditions for access to data from the PHARMO Database Network' are effective. In case it is not possible to honour the data request with the PHARMO Database Network and additional data have to be retrieved by STIZON, additional requirements may be set (including permission healthcare institution/provider, informed consent from the patient).

Stichting Informatievoorziening voor Zorg en Onderzoek ("STIZON") collects and maintains identifiable patient data retrieved from general practitioners, clinical laboratories and community and hospital pharmacies. STIZON is a non-profit foundation authorised by data providers (i.e. healthcare providers) to manage and process identifiable patient data. STIZON links the identifiable patient data on a patient-level for scientific research. The PHARMO Database Network is created by STIZON and is shared with PHARMO for research purposes after identifiable patient data is deleted.

Terms and conditions for access to data from the PHARMO Database Network

1. PHARMO only provides access to anonymous data to the applicant that cannot be traced directly or indirectly to a person and/or healthcare providers/institutions.
2. STIZON only provides patient identifiable information when written consent from the patients is obtained (informed consent), in accordance with the Personal Data Protection Act. The informed consents are checked by STIZON for completeness.
3. Applicants must strictly abstain from actions by which the identity of persons and/or healthcare providers/institutions whose access to the data was provided could be traced back, unless the patient has explicitly given permission (including for example linking to or comparison with other data).
4. Until PHARMO has developed a remote access no complete datasets are delivered. PHARMO will deliver a random sample of the data to enable development of the analyses. The complete datasets are available at PHARMO. The applicant can run the analyses on the complete datasets at location (i.e. PHARMO's office).
5. The applicant is obliged to mention all funders of the research on the application form. In situations where a conflict of interest exists or threatens to occur with respect to one or more of these funders, PHARMO may refrain from providing access to the requested data, or revoke a right to use this data provided to the applicant. If there is remuneration in the context of scientific research this financial information must be publicly available in order to indicate the risk of potential conflicts of interest.
6. The data and the obtained study results will not be used and published by the applicant for any other purpose than indicated in the application form and the study protocol.
7. Only the researcher mentioned on the application form has permission to access the data provided. It is not permitted to deliver the data to the other parties involved as mentioned on the application form. Only the aggregated results obtained after analysis of the data may be shared with the other parties involved. The applicant must ask PHARMO in advance for permission to deliver the data to the other parties involved as mentioned on the application form.
8. Without prior written permission of PHARMO, the applicant is not permitted to deliver the data and/or the therefrom obtained results to third parties (parties not involved with this research, as described in the application form)
9. Applicants must request prior permission from PHARMO for any re-use or further use of the data, such as for additional research, for research that deviates from the research as indicated in the application form, or with a different question arising from the first research. Patient traceable data may not be re-used unless explicitly authorized by the patient.

10. An exception to the previous article is the allow access to the data for scientific verification or other evaluation of the quality of the research and the publications (peer review). As far as relevant, the legal regulations for the protection of personal data are taken into account. PHARMO will be informed of such a request for peer review.

11. Applicants must take care of a careful organizational, procedural and technical security of the data. To this end, provisions should be made to prevent:

- a. negligence or willful misuse of the data
- b. loss of data supplied, and
- c. unauthorized access to or inspection of the data provided.

12. The applicant will store the research data for 10 years in accordance with the Dutch Code of Conduct for Scientific Practice. The data obtained by the PHARMO applicant shall be destroyed by the applicant after the expiry of this period or stored in an adequately secured manner that prevents access to the data or re-use by the applicant or a third party without prior permission from PHARMO. After this period has expired, the applicant will proceed to annulment and submit a declaration of destruction to PHARMO.

13. The applicant meets the legal requirements regarding the protection of personal data and certifies to work in accordance with the Code of Conduct for Health Research (FMWV/Federa).

14. All statements relating to the data for which access has been granted (such as reports, abstracts for conferences, (poster) presentations, manuscripts and theses, referred to as publications below) are submitted to PHARMO for assessment before being offered for publication.

15. When publishing the study results based on the supplied data, the source should be mentioned as "PHARMO Database Network" including the databases used (see www.pharmo.nl for the correct naming of these databases). The PHARMO Institute endorses the guidelines of the ICMJE as a basis for authorship (<http://www.icmje.org/recommendations>).

16. The applicant commits himself during the conduct of the study, when requested by PHARMO, to provide insight into the methodology of analysis of the data to a PHARMO employee in order to prevent the data being used in an irresponsible manner and thereby inflict damage to PHARMO and/or the original supplier of the data.

17. In the event of violation of the above conditions, PHARMO may, without prior notice, terminate access to the data and/or revoke the right to use data already provided, and the user, when summoned by PHARMO, must stop the use of this data and destroy the already provided and processed data and will provide a written and dated declaration of destruction to PHARMO. In such a case, the applicant will be liable for any direct and indirect damage suffered by PHARMO.