



LeishMan consortium agreement

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Contents

General aim and scope.....	2
Structure of the consortium.....	2
Steering committee.....	3
Clinical group.....	3
Diagnostic group.....	4
Corresponding centres and members.....	4
Contributing centres and members	5
Databases and terms of use	6
Meetings.....	7
Logo	7
Signature section.....	7

General aim and scope

- LeishMan is short for Leishmaniasis management.
- The aim of the consortium is
 - to harmonize clinical case management of leishmaniasis patients in Europe;
 - to optimize detection and identification of the *Leishmania* parasite;
 - to contribute to monitoring and surveillance of the leishmaniasis in Europe.
- All forms of imported and autochthonous leishmaniasis are studied: (muco-) cutaneous, visceral, and all derived clinical presentations.
- The network aims at fostering exchange at the level of clinical cases, technical issues, and scientific research with regard to diagnosis, treatment, and epidemiology of the leishmaniasis.
- These aims and scope can be extended in function of opportunities and needs.

Structure of the consortium

- LeishMan is an informal exchange network, composed of clinicians and clinical laboratory scientists active in leishmaniasis management.
- The consortium has no legal status, and receives no structural funding.
- The steering committee (see further) takes care of the daily management.
- In principle all interested parties working on leishmaniasis management in European centres can join, after *pro forma* approval from the steering committee.
- Non-European membership applications will be considered by the steering committee, but will not be approved automatically.
- The LeishMan consortium consists of two task groups: the clinical and the diagnostic group (detailed further).
- A distinction is made between “contributing” and “corresponding” centres (detailed further).
- The list of affiliated centres and members is kept updated on a SharePoint site accessible for each member: <https://itgitm.sharepoint.com/sites/Leishman>.

Steering committee

- The steering committee is responsible for the daily management of the consortium.
- The steering committee is appointed by the members of the network. Each member can request a change of steering committee at any time.
- The actual steering committee composition can be consulted on [SharePoint](#).
- The steering committee appoints one of its members as the network coordinator.
- In principle, the steering committee consists of at least 5 members, preferably from different European countries, and equally distributed between the clinical and diagnostic task groups (see further).
- The steering committee coordinates and communicates (non-exhaustive list):
 - joint publications resulting from network initiatives
 - joint conference abstracts from network activities
 - grant proposals covering network activities
 - studies using data from the network databases (see further)
 - the consortium website
 - the consortium databases
 - the consortium profile on academic platforms (e.g. [ResearchGate](#))
 - the consortium [SharePoint site](#)

Clinical group

- Members of the clinical group exchange information on clinical case management, including clinical diagnosis, treatment, and patient follow-up.
- Members of contributing centres add clinical patient information to the LeishMan databases, and aid in defining the captured variables.
- The clinical group disseminates information relevant for clinical management of leishmaniasis patients via scientific papers, conferences, or other types of publications.

Diagnostic group

- Members of the diagnostic group exchange information on development, validation, and quality control of laboratory procedures for diagnosing leishmaniasis and characterizing the causative parasite.
- Members of contributing centres add diagnostic information to the LeishMan databases, and aid in defining the captured variables.
- The diagnostic group disseminates information relevant for diagnosis of leishmaniasis via scientific papers, conferences, or other types of publications.

Corresponding centres and members

- Definition: corresponding centres do not add leishmaniasis case data to the LeishMan databases. As a consequence, they have no access to the case data shared by the contributing centres.
- Corresponding members, *i.e.* LeishMan members affiliated to a corresponding centre, are kept informed of all LeishMan activities, and are invited to the meetings.
- Corresponding members gain access to the confidential [SharePoint site](#) of the consortium, on the condition that they do not share confidential information to non-members.
- Corresponding members must seek approval from the steering committee for all third-party disclosures mentioning LeishMan prior to dissemination. This applies to printed, oral, and electronic information for publications, patent applications, funding applications, *etc.*

Contributing centres and members

- Definition: Contributing centres share diagnostic, clinical, treatment, and epidemiological data about their patients in the LeishMan databases.
- In principle, a contributing centre is represented by at least two members: one being part of the diagnostic group, the other of the clinical group.
- Contributing members, *i.e.* LeishMan members affiliated to a contributing centre, are responsible for timely and complete data entry in the LeishMan databases.
- Contributing members have access to the case data entered by all LeishMan members, but are bound to the terms of use as specified in the database section of this agreement.
- Per contributing centre, one or several members receive a password for accessing the LeishMan databases. If needed, this password can be shared with other colleagues from the same centre for practical reasons (*e.g.* data entry), provided that the password holder ensures that all persons who are given a copy of the password respect this consortium agreement and sign a copy of it.
- Each request to become a contributing centre must be approved by the steering committee. Equally so, the steering committee can decide to end a contributing membership in case the terms of use (see database section further) are violated.
- Apart from database contribution and access, all privileges and restrictions apply as outlined for the corresponding members.

Databases and terms of use

- Currently, 2 databases are capturing LeishMan data:
 - **EpiConcept**: Data from **2012-2019**. As this database comes with a cost and the LeishMan network has no funds of its own, this database is discontinued as from 2020. Access: <https://epidemiopasteur.fr/leishmaniasis/>
 - **WHO**: Data **from 2020**. This database captures basic clinical and diagnostic information from leishmaniasis cases on the [DHIS2](#) system (District Health Information Software 2), in the frame of surveillance. In exchange for providing these data to WHO, LeishMan can freely use it for additional, LeishMan-specific data capturing. Access: <https://extranet.who.int/dhis2>
- After signing the consortium agreement, at least one member of each contributing centre receives a login to access the LeishMan databases. He/she ensures that everyone in his/her centre with whom this login is shared complies with the terms of use outlined here.
- Contributing centres ensure ethical clearance from their respective Institutional Review Boards and Ethical Committees for sharing their data.
- Contributing members are responsible for timely and complete data entry in the LeishMan databases. For the [WHO-DHIS2 platform](#) this applies to all leishmaniasis cases diagnosed in their respective centres, even if the data are incomplete.
- All contributing LeishMan centres have access to the data entered by other LeishMan centres. Equally so, upon a motivated request the steering committee can grant access to specific corresponding members.
- WHO is entitled to use aggregated and anonymized data captured in their generic variables, as outlined in their policy: <https://www.who.int/about/policies/publishing/data-policy>. WHO will not use the data captured in the specific LeishMan variables.
- All contributing centres remain owner of their own data.
- Any LeishMan member wanting to use data from other members for any publication (written, oral, or electronic) or disclosure to third parties (*e.g.* patent or grant applications), must seek consent from all centres who contributed the respective data, and from the steering committee.

Meetings

- In principle, at least one consortium meeting is organized each year by one of the member centres.
- The place and venue of the meeting is decided by the steering committee, after consulting with the members.
- LeishMan does not cover any cost of meeting participation.
- All members are invited to the consortium meetings, and can be asked to contribute to the costs of the meeting venue, if applicable (if so this will be clearly communicated).
- Meeting reports are shared via the [SharePoint](#) site.

Logo



Signature section

By signing the consortium agreement, I declare to comply with the conditions for being member of a contributing LeishMan centre, and to have obtained ethical clearance for sharing case data in the LeishMan databases.

Please insert your digital signature here and send the signed document to gvdauwera@itg.be.
(In PDF reader: More tools → Certificates → Digitally sign → Follow instructions).