LeishMan consortium agreement

Version 8-5-2023

Contents

General aim and scope

- LeishMan is short for <u>Leishman</u>iasis <u>man</u>agement.
- 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 leishmaniases 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 leishmaniases.
- These objectives the scope of application can be expanded depending on possibilities and requirements.

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.
- A distinction is made between “contributing” and “corresponding” centres (detailed further).
- Non-European membership applications will be considered by the steering committee, and if included, they will be “corresponding” but not “contributing”.
- The LeishMan consortium consists of two task groups: the clinical and the diagnostic group (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 and is renewed every 5 years
- 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 the Website LeishMan.eu or LeishMan.science
- The steering committee appoints one of its members as the network coordinator for 5 years.
- 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)

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 restricted access to network-intern confidential data on the condition that they do not share confidential information to non-members/third-parties.
- 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, LeishMan data are captured via a web-accessible database sponsored by ***WHO:***. 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 pierre.buffet@pasteur.fr and clea.melenotte@pasteur.fr
(In PDF reader: More tools → Certificates → Digitally sign → Follow instructions).