

REGULATION FOR EASL CONSORTIA

1. Meaning

A Consortium is a network of individual research groups or centres with a common interest in a specific research area of hepatology with an organizational structure that facilitates the development of common research projects and fosters the acquisition of financial resources to support the activity of the consortium.

2. Aim

- a) To establish multidisciplinary European-based research networks to address important issues on the pathophysiology, diagnosis and treatment in specific fields of Hepatology.
- b) To facilitate the interaction and integration between basic and clinical research activity.
- c) To identify new relevant topics in a field, to establish synergies between groups within and outside the network, and areas of cooperation with biotech and pharmaceutical European industry.
- d) To design a multi-annual coordinated research program of the network based on these features.
- e) To select, through peer review, research proposals from the Consortium Centers, and facilitate the interaction between potentially interested centers to engage in these projects.
- f) Based on the above, to make calls on specific research projects, to which the Centers participating to the Consortium can adhere on a voluntary basis.
- g) To foster fund raising from external sources (e.g., public agencies, foundations and industry) to support approved research projects.
- h) To stimulate the formation of new research groups in that field and to provide opportunities for young investigators to enter in the field.

3. Governing structure

- a) A Consortium is constituted by Research groups, Centers or Institutions (from now on “Centers”), represented by their Coordinators.

- b) Investigators belonging to Centers are the Members of the Consortium. Membership of the Consortium does not preclude participation to other research networks.
- c) The Coordinators of the participating Centers meet in an Assembly on a yearly basis minimum.
- d) A Consortium is coordinated by a designated Chair and, if deemed necessary, other governing bodies, such a Steering Committee (SC) and a Data Management Center (DMC) will be implemented.
- e) Members of the governing bodies of a Consortium should also be EASL members.

4. Centers

- a) The participating Centers join the Consortium on a voluntary basis.
- b) They should consist in clinical and/or biomedical research units devoted to Hepatology and based at Institutions with facilities for clinical and/or biomedical research.
- c) They join the research programs proposed by the Consortium on a voluntary basis, if they meet the requirements of a specific program.

5. Assembly

- a) It is composed of all the Coordinators of the Centers of the Consortium.
- b) It proposes candidates for the Chair and other governing bodies if existing. These candidates should belong to Centers provided with infrastructures for clinical and translational research.
- c) It approves the overall policy of the Consortium.
- d) It can propose amendments, deletions or additions to the statutes of the Consortium.

6. Steering Committee (if existing)

- a) The SC is composed of Consortium Members, whose number depends on the complexity of the research area. The Members of the SC are approved by the EASL Governing Board (GB) following nominations from the Assembly through the Consortium.

- b) The period during which the SC remains in charge is variable, depending on the indication by the Assembly.
- c) It shall coordinate and organize the selection of research topics proposed by Centers to elaborate the research program of the Consortium in a coordinated manner.
- d) The SC will look for financial resources from public agencies, foundations and industry.
- e) The SC will report to the assembly on overall policy, direction, promotion and activities.

7. The Chair

- a) The Chair is designated by the EASL Governing Board based on nominations from the Assembly.
- b) The period during which the Chair remains in charge is variable, depending on the indication by the Assembly.
- c) The Chair is responsible for the conduct and quality of the scientific activities and the finances of the network and represents the Consortium in its business with other organizations.
- d) The Chair reports to the EASL Governing Board on the activities of the consortium and may be requested to report to the EASL Business Meeting upon request from the EASL Governing Board.
- e) In the absence of a SC, the Chair will carry out the functions reported under 6.c-f.

8. Data Management Centre (DMC) (if existing)

- a) The DMC shall support and be involved in the scientific, logistic and statistical aspects of the network studies (protocol and manual of operations development, data collection and management, data safety and confidentiality, quality assurance, data entry, data analysis, electronic communications, interim and final reports and writing manuscript assistance).
- b) The DMC will also be responsible for the management of data from special and laboratory studies.
- c) The DMC is nominated by the Assembly or the SC and may include a biostatistician.

- d) Centers belonging to the Consortium should have access to data gathered by the DMC through institutional data transfer agreements and relevant national research ethics clearances. Access to data is granted upon presentation of studies ancillary to the core studies of the Consortium.

9. Other governing structures

Once clinical trials are implemented by a Consortium, then Data Safety and Monitoring Boards, external Contract Research Organizations and other Boards required to run the trial according to the rules dictated by the laws regulating the Good Clinical Practice will be activated. These Boards remain in charge for the time needed to complete the study.

10. Financial structure

- a) The financial structure of a Consortium must be not-for-profit.
- b) The Chair and the SC (if existing) will look for financial support by third parties (see 7.e and 6.d).
- c) The transfer of financial support to the Centers of the Consortium is related to their participation to the core studies of the research program of the Consortium. The financial support to ancillary studies will be regulated on an individual basis.

11. Statutes of the Consortium

- a) Upon its foundation, the Consortium must implement a set of statutes.
- b) The Chair and the SC (if existing) are responsible for implementing the statutes.
- c) The statutes should set the rules for:
 - I. the governing structure of the Consortium;
 - II. the rotation of governing bodies of the Consortium;
 - III. financial management and fund assignment of Centers;

- IV. authorship rules for publications arising from the research activity of the Consortium.

12. Benefits for the Consortium

- a) Use of the EASL brand in consortium denomination.
- b) Utilization of EASL communication channels for dissemination and communication purposes.
- c) Meeting room to host an annual Assembly during the EASL ILC.
- d) Involvement in EASL ILC programming as defined by the EASL Governing Board.
- e) Proposing EASL monothematic conferences and other EASL programming components.

13. Methodology for starting the consortium

- a) EASL GB receives the proposal for a Consortium by a group of EASL members.
- b) EASL GB approves the proposal.
- c) EASL facilitates the consortium to provide a call, inviting Centers that present the features reported under 4.b. to express their intention to participate to the Consortium.
- d) Interested groups summon the Assembly during the next EASL ILC; this first meeting is moderated by the initiators and an EASL GB member.
- e) The Assembly nominates candidates for Chair and, if needed, Members of the SC.
- f) The EASL GB approves the Chair.
- g) The EASL GB and the Chair approves the Members of the SC.
- h) The Chair and SC (if existing) establish other governing bodies of the Consortium as needed.