

Rules for regulation of the European Association for the Study of the Liver-

VAscular Liver Diseases Interest Group (EASL-VALDIG)

Preamble:

The EASL-VALDIG is a network of investigators with a common interest in vascular liver disorders, aiming at promoting research in such field. The EASL governing board has endorsed the EASL-VALDIG and this interest group develops according to EASL rules.

The following Rules of the EASL-VALDIG Governance aim at setting up a governance framework with the objective of enhancing the progress and development of the EASL-VALDIG, the effective monitoring of the activities of the EASL-VALDIG and the accountability of the governing structure of the EASL-VALDIG to the participating members, the Assembly and where applicable to the EASL.

Aim of the EASL-VALDIG

The aim of the EASL-VALDIG is to perform large multicentre epidemiological, pathophysiological and particularly interventional studies within the field of interest and to stimulate research for vascular liver disorders.

Vascular liver disorders (VALDI) is a heterogeneous entity of conditions which are not as frequent as other liver disorders (e.g. hepatitis, cirrhosis, liver failure) and therefore need a large network of collaborating centres to be studied in a sufficient sample size. Portal vein thrombosis, Budd-Chiari-syndrome, idiopathic portal hypertension, and further disorders, which are primary initiated in the tributary and hepatic vessels might form part of VALDI. These disorders may lead to life threatening complications including acute liver failure or complications of portal hypertension. The management of these disorders is not yet standardized. The standardization of the management of VALDI is one aim of this Interest Group.

The EASL-VALDIG intends to operate through a variety of initiatives including:

1. Identifying new relevant topics on VALDI and establishing synergies between groups (basics and clinics) within and outside the EASL-VALDIG.
2. Designing a multi-annual coordinated research program based on these features to which members participating in the EASL-VALDIG can adhere
3. Supporting specific research proposals raised by the members participating in EASL-VALDIG
4. Raising the awareness of VALDI in specialized and general areas of investigation and patients care.
5. Stimulating the formation of new research groups, providing opportunities for young investigators to enter the field, and establishing exchange and interaction with patients associations.
6. Fostering fund raising to support the research activities within the Interest Group and possible areas of cooperation with industry.

II

Members of the EASL-VALDIG

1. The EASL-VALDIG consists of members mainly affiliated to Departments of Academic Clinical Medicine, but also of interested translational and basic science research groups and foundations, in which studies and research within the aim of the Interest Group may be developed and/or performed.

2. Applicants may be members of the EASL-VALDIG after individual application and acceptance by the Steering Committee. The application should include:

- a. A formal letter communicating the interest to be part of the EASL-VALDIG
- b. A document reflecting the characteristics of the affiliation centre of the applicant, including a detailed description of clinical and research facilities
- c. Brief CV of the applicant together with a list of his/her main publications on VALDI, or their willingness to contribute in studies in this field

3. The Steering Committee of the EASL-VALDIG shall evaluate the application. The applicant shall become a member of the EASL-VALDIG once the Steering Committee approves the application.

4. In case that in one affiliated institution there are more than one member of VALDIG, for the coordination of studies within EASL-VALDIG, each institution shall designate one Coordinator. An affiliated single centre may have more than one coordinator if the scientific production of this centre on VALDI is very relevant and provided they belong to different departments or areas within the centre (e.g. hepatologist, internist, basic or translational science) or groups with long-term successful well-differentiated research activity within the centre (e.g. participation in multi-centre studies). The coordinator should be hepatologist or equivalent physician (gastroenterologist, internist) or basic/translational scientist with the main interest within VALDI.

III

The Assembly

1. All members of the EASL-VALDIG compose the Assembly of the EASL-VALDIG.
2. The Assembly is responsible for:
 - a. Approving the overall policy of EASL-VALDIG
 - b. Proposing amendments, deletions or additions to these Rules
 - c. Proposing candidates for the Steering Committee. These candidates should be affiliated to centres provided with infrastructures for clinical and basic/translational research.
 - d. Approving possible Annual Accounts of the EASL-VALDIG
3. The Assembly shall meet at least once a year, during the Annual Meeting to be held at the location and on the date designated by the Chair and notified to the members of EASL-VALDIG with a lead time of at least one (1) month. The location and date shall coincide with the EASL International Liver Congress (ILC).

IV

The Steering Committee

1. The EASL-VALDIG shall be managed by a Steering Committee composed of ten members.
2. Members of the Steering Committee should belong to the staff of a liver unit or equivalent clinical unit with facilities for clinical and/or basic/translational research and significant experience on VALDI research.
3. Proposals and applications to be a member of the steering committee must be sent to the steering committee at latest two months before the annual meeting.
4. The EASL Governing Board approves the Steering Committee members selected by the Assembly. In case of disagreement, this would be discussed with the VALDIG Chair and Secretary.
5. The members of the Steering Committee shall be appointed for a two (2) year term, which may be extended once for an additional two (2) year subsequent term (a maximum of 4 years). Upon expiration of any such term, the appointment shall be valid until a resolution by the EASL Governing Board is adopted.
6. In order to provide flexibility but avoid discontinuity on the direction of the VALDIG, the elections should be held every two years for five members of the

Steering Committee. Five of the ten members of the first elected steering committee (EASL 2014) are allowed to be extended twice (a maximum of 6 years).

7. The Steering Committee is the governing body of the EASL-VALDIG and it is responsible for:

- a. Governing the EASL-VALDIG defining its strategy and the scientific direction of the EASL-VALDIG, setting performance objectives; and monitoring implementation.
- b. Identifying important research topics to elaborate the research program of the EASL-VALDIG.
- c. Reviewing, selecting and approving research proposals to be incorporated into the research program or to be performed by or with the support of the EASL-VALDIG. These proposals may be presented by any member of the EASL-VALDIG or by individuals or entities not pertaining to EASL-VALDIG.
- d. Designating the Centres and the individuals who shall participate in the studies included in the research program of the EASL-VALDIG and monitoring performance of such Centres and individuals.
- e. Establishing such Sub-Committees and Working Groups as the Steering Committee may deem appropriate for carrying out specific activities.
- f. Looking for financial resources from public agencies, foundations, and industry and adopting measures to promote visibility of the EASL-VALDIG.
- g. Approving any third party agreement with any non-member of the EASL-VALDIG by any individual who shall participate in the studies included in the research program of the EASL-VALDIG, which may involve in any way the exploitation of any result of any studies included in the research program of the EASL-VALDIG.
- h. Reporting to the assembly on overall policy, direction, promotion and activities.

8. The Steering Committee shall meet at least two (2) times a year, at the location and on the date designated by the Chair, preferentially in Europe, and notified to the members of the Steering Committee with a lead-time of at least one (1) month. In the event that the Chair deems it necessary to hold any extraordinary

meeting, it may issue a notice calling for such meeting with a lead-time of at least five (5) calendar days.

9. The members of the Steering Committee shall not receive any compensation. The EASL-VALDIG shall not cover travelling nor accommodation expenses for the members of the Steering Committee if the meeting is held at the same location and on the same dates of any major international liver meeting in Europe. In other cases, reasonable travel expenses in coach or economy class and reasonable accommodation expenses may be covered by EASL-VALDIG, if possible.

10. All members of the Steering Committee shall exercise their duties on a fully informed basis, in good faith, with due to diligence and care, in a manner which they reasonably believe to be in the best interest of the EASL-VALDIG, and with such care as an ordinarily prudent person in a like position would use under similar circumstances. In order to allow and facilitate the members of the Steering Committee to exercise their duty of loyalty and of care, the following rules and principles shall be observed:

- a. Before a meeting of the Steering Committee, the Chair (or another person to whom the Chair delegates the responsibility) shall establish an agenda and gather materials related to the topics to be discussed.
- b. The members of the Steering Committee shall be provided with all material information, which could reasonably be made available to them in order to make a decision. This information shall be delivered to the members of the Steering Committee with sufficient lead-time prior to each meeting so that they have time to review it.
- c. The members of the Steering Committee may request any information to be validated by external experts.
- d. Discussions at the meetings of the Steering Committee shall be open and frank, allowing all members of the Steering Committee to consider alternatives and consequences. The members of the Steering Committee shall respect a duty of candour. When seeking or recommending action, the members of the Steering Committee shall disclose all information material to the action and shall provide a balanced, truthful account of all matters disclosed in their communications.
- e. Any contract or other transaction where a potential conflict of interest may appear shall be concluded through fair dealing. The negotiations

leading to such contract or transaction shall only begin if a legitimate interest on the part of the EASL-VALDIG exists and the terms of the contract or transaction shall be at arms length.

f. The minutes of the meeting of the Steering Committee (to be taken by the secretary of the EASL-VALDIG and distributed to all Steering committee members for final approval) shall reflect the contents of the discussion without prejudice to the non-disclosure of any confidential information. The approved minutes will be forwarded to the EASL Governing Board (through the EASL office) as information.

11. The members of the Steering Committee shall seek to obtain a consensus on all matters, which may be presented to them. In the event that voting is required, the Steering Committee may adopt valid decisions when a majority of its members, present or represented at the meeting, vote in favour of such adoption.

12. The EASL Governing Board may also exclude any Member from the Steering Committee, but for such exclusion to be effective, the decision must be endorsed by at least three quarters (3/4) of the members of the Steering Committee other than the Member or Members whose separation is sought, at a special meeting to be held for such purposes.

V

The Chair and the Secretary

1. The Steering Committee shall propose an individual to act as Chair of the EASL-VALDIG and an individual to act as Secretary of the EASL-VALDIG among the members of the Steering Committee. The Chair and the Secretary corresponds with the EASL Governing Board.

2. The Chair and the Secretary will remain in charge for two (2) years, and can be confirmed in the position once.

3. The Chair and the Secretary should be senior investigators of sufficient scientific status and advanced enough in their careers to have authoritative presence at the Steering Committee and assembly of the EASL-VALDIG.

4. The Chair is responsible for the conduct and quality of the scientific activities and the finances of the EASL-VALDIG, and represents the EASL-VALDIG in its business with other organizations.

5. The Chair reports to the Steering Committee and to the EASL Governing Board on the activities of the EASL-VALDIG at least once a year or upon request.

6. The Chair and Secretary shall not receive compensation from the EASL-VALDIG.

7. The Secretary is the official substitute of the Chair at every situation, when unavailable.

VI

Financing of the EASL-VALDIG

1. The EASL-VALDIG shall obtain funds from public agencies, foundations and industry, preferably, but not limited to, in the form of unrestricted grant for specific projects and purposes.

2. The funds of an EASL-VALDIG project shall be administrated by a the Principal Investigator of the specific EASL-VALDIG-endorsed project

3. In case of funds donated directly to the EASL-VALDIG the secretary shall administrate these funds.

4. Any disposal of funds from the EASL-VALDIG shall require prior generic or specific approval from the Steering Committee or the Chair of the EASL-VALDIG. Generic approval is deemed to have been given for payments coming under the budget, which may have been established for any project. Specific approval is required for ad hoc payments not covered by any such budget.

VII

Exploitation of results

1. For the purpose of these Rules, "Results" shall mean any and all assets such as, but not limited to, data, information, findings, samples, interim results and results, documents, know-how, formulas, ideas, inventions, patents, patent applications, discoveries, technology, processes, procedures, devices, products, utility models, copyrights, and improvements as well as trade secrets, designs, and any other intellectual property analogous to the same, whether protectable or not, an any existing or future rights therein, directly or indirectly derived or arising from any studies included in the research program of the EASL-VALDIG.

2. The members of the EASL-VALDIG, by entering into the EASL-VALDIG, agree that the exploitation of any Results shall be regulated in each specific project endorsed by EASL-VALDIG between participants before hand.