

ENTIS

EUROPEAN NETWORK OF TERATOLOGY INFORMATION SERVICES Constitution and Bylaws

1. Name

European Network of Teratology Information Services (ENTIS)

2. Domicile

ENTIS has taken domicile at the Netherlands Pharmacovigilance Centre Lareb in 's-Hertogenbosch, The Netherlands, where the ENTIS Foundation registered.

3. Characteristics

ENTIS is a voluntary, non-profit organisation.

4. Objectives and functions

a) The main task of ENTIS is to recognize and to detect risk factors with the objective of preventing birth defects.

The general purpose of ENTIS is to increase the efficiency of each Teratology Information Service (TIS) and to contribute to the primary prevention of birth defects and developmental disorders.

b) ENTIS shall stimulate and facilitate the exchange of experience of the different TIS. The task of a TIS is to counsel individual cases of exposure to drugs and other exogenous agents during pregnancy with respect to the risk of reproductive toxicity. Callers who request information are generally from medical and paramedical professions as well as the general public.

c) ENTIS shall promote the skills of counselling in risk assessment in pregnancy. Counselling is based on literature searches as well as the individual experience of the TIS of previous cases, including pregnancy outcome and follow up. To increase the number of cases and to acquire a sufficient amount of information to make solid conclusions an international follow up system for data pooling will improve the weight and impact of the human teratology experience.

d) ENTIS shall provide training in counselling. ENTIS shall help the individual service to get an overview of substantial scientific literature and to train new staff members by developing quality and quality control guidelines, and by providing facilities for staff exchange.

5. Membership

a) General

Members are programs or institutions engaged in counselling pregnancies at risk and evaluating and following up pregnancy outcome. In addition, individuals scientifically engaged in clinical teratology and/or drug risk assessment in pregnancy can be an associate member.

Each member will designate a program director to be its principle liaison with ENTIS. The representation of each TIS/member during meetings of ENTIS will be through its program director or representative. Each member TIS will have one vote. Observers and associate members have no vote.

b) Qualifications

Candidate for membership/associate member can be every TIS/specialist with practical experience in counselling and follow up procedure. Candidates have to submit a description of structure, means (method and finances) and activity of their TIS/individual. The program director should have a medical, medical biology, pharmaceutical Ph.D. or equivalent degree and should have experience in running a TIS. Candidate TIS/associate member can be affiliated to universities, hospitals, public or other health institutions and should offer information and/or advice on a non-profit basis and should be free of charge.

c) Admission procedures

All applications will be reviewed by the ENTIS board. The application shall be circulated with opinions from at least three members of the Board of ENTIS to all members for review at least 30 days before the annual meeting. The absence of conflict of interests should be clearly stated by the candidate applying for member and associate member applicants. At that meeting, members will vote on whether the applicant is eligible. A majority vote is required for admission.

d) Obligations

Members should take part in the annual meeting as well as in other joint activities. Members are expected to respond within one week to information requests and other personal (email-) communications within ENTIS. Each member has to pay an annual membership fee, the amount to be established at the Annual meeting. Members get free access to Reprotox database. Membership will be cancelled if the fee is not paid in two successive years. Furthermore, membership can be cancelled if a member repeatedly violates basic rules of the constitution and/or a TIS has not participated for three successive years in the annual meeting without written notice.

e) Observers

Representatives of institutes planning to establish a TIS can apply for the status of observers. The Board can decide about the admittance of non-members as observers. These observers could also be invited to the Annual meetings and collaborative activities of ENTIS. The Board must report to the Annual Meeting for its decision regarding observers. The observer status is limited to a time of 3 years at maximum. Latest after 3 years the board has to decide upon full membership or cancel the observer status. Observers pay one third of the annual fee of ENTIS members. This include free access to Reprotox database.

Members with voting rights of the Organization of Teratology Information Services Specialists (OTIS) in the North-Americas are reciprocally accepted as observers in ENTIS without time limit. All members of ENTIS will have a corresponding nonvoting membership in OTIS. This entitles them to attend annual OTIS meetings, to receive all OTIS mailings and to participate in consensus votes at general meetings. ENTIS members will have the opportunity to join as voting, dues-paying members of OTIS. ENTIS and OTIS support a mutual exchange of information to strengthen the link among TIS on an international basis.

f) Honorary Members

Individual members who are no longer officially associated with a TIS, but who have given distinguished service to ENTIS, may be elected at the Business meeting as

Honorary Members, who will not pay a membership fee, but will have the right to attend meetings of ENTIS.

g) Associate Members

Individuals scientifically engaged in clinical teratology and/or drug risk assessment in pregnancy can apply for the status of an associate member. The application should be sent to ENTIS board and SC that can decide about the eligibility of non-members as associate members. Associate members are invited to the Annual meetings and collaborative activities of ENTIS. Associate members pay the reduced annual fee that does not include access to Reprotox database. However, they may pay the full annual membership fee to get access to REPROTOX. All other obligations of ENTIS members are valid for associate members as well.

ENTIS members will vote at the annual meeting on whether the applicant is eligible. A majority vote is required for admission.

6. Board

The Board of ENTIS consists of an odd number of members, numbering at least three. The Board consists of a chairperson, a vice-chairperson secretary, a treasurer and council members, one of the Board members will serve as liaison officer with other organizations engaged in clinical teratology, such as OTIS. The board can also appoint a member outside the board as a liaison officer. Board members are elected at the annual meeting. The governing period should be at least two years but no longer than three years. A re-election is possible. The Board can arrange standing or not-standing committees, e.g. membership committee, financial committee, scientific advisory committee etc. The Board can arrange additional meetings, workshops or working groups apart from the annual meeting. At least two Board meetings are to be held each year. At least one Board meeting requires the physical presence of the majority of the Board members. Remaining meetings may be realized by telecommunication.

7. Meetings

It is obligatory for ENTIS to organize at least one annual meeting. Such meeting have to be prepared by the Board and/or by the meeting-organizing TIS. All ENTIS members have to be invited at least three months in advance of the meeting. Minutes of the meeting are to be distributed within two months. Applications for extra meetings, workshops and working groups can be made by each member. They have to be submitted to the Board.

8. Resources and accounting

An ENTIS Foundation has been established in 1991. The Board of this foundation shall consist of the treasurer and at least two other members of the Board of ENTIS. The Board of the foundation can decide to give financial support for organizing annual meetings, workshops or other activities. The Board of the foundation has to prepare an annual budget for approval at the Annual meeting. The Board undertakes commitments and makes disbursements in accordance with the budget approved by the Annual Meeting of ENTIS members. Details of financial support to members or projects have to be circulated in a written form by the board to all members.

9. Independence

a) General

Each TIS is autonomous and is responsible for its own scientific and financial organisation. However, ENTIS members are expected to work in line with the code of ethics of ENTIS. These specify that information given to clients about the safety and risks of medicines and other exposures, should conform to the highest standards of scientific and medical integrity and objectivity. Statements should be free from any conflicts of interest. Recommendations and guidelines made (under contract) by an ENTIS member should not be influenced by specific interests of the requesting party (e.g. pharmaceutical industry).

Case reports collected by a TIS are the property of that TIS and should not be sold to pharmaceutical industry. The TIS has the responsibility for independent evaluation of these data. To prevent misinterpretation and misuse of the case data, these should not be handed over to institutions or persons not experienced in evaluating clinical teratology data.

In any collaboration with the pharmaceutical, or other relevant industries, care has to be taken to preserve the final rights relating to interpretation and publication of the results. This applies to work undertaken by individual TISs as well as ENTIS collaborative studies.

The TIS should be aware of (inter)national regulations regarding privacy and confidentiality of data related to their users or clients.

b) Research

- Objectives of research have to be defined by the ENTIS members willing to collaborate in a study. Design, outcome parameters, methodology of a study, interpretation and publication of results are exclusively decided by the collaborating ENTIS centres.
- Research priorities in ENTIS should consider the primary goal of ENTIS to prevent damage to the unborn AND optimize treatment of the pregnant mother.
- Research projects should normally focus on drugs that are already frequently used by women of reproductive age and/or belong to evidence based medicines or good therapeutic practice or follow established therapy guidelines.
- If a pharmaceutical company asks ENTIS (members) to investigate their products (i.e. contract research), such a project should only be performed when in accordance with the research ethics of ENTIS.
- The ENTIS mission of independent research has to be published on the ENTIS website and in a scientific journal. Every publication of an ENTIS study should refer to this mission statement.
- Collaborative ENTIS studies should be approved by the ENTIS Scientific Committee (SC). In case of research grants (from industry) for collaborative ENTIS studies the SC must provide transparency and account of received grants and supported studies.
- ENTIS members should primarily check other financial sources (than industry) for research projects, e.g. grants from health ministries, universities, European Union sources, insurance companies, other research organizations and foundations.

10. Official language

The official language of ENTIS is English.

11. Adoption of Bylaws

These bylaws originally accepted by the majority of votes cast after the fifth annual meeting of ENTIS in Crete, Greece in March 1994 were modified during and after the 18th annual meeting in Helsinki, Finland June 2007. These modifications of the bylaws were accepted by the majority of ENTIS members (16 of 20 of the valid poll) during the 19th annual meeting in Edinburgh, Scotland September 2008.

The modifications on membership were accepted by the majority of ENTIS members during the 24 annual meeting in Amsterdam, Netherlands, April 2013.