EoE Connect: European Registry of Clinical, Environmental and Genetic Determinants in Eosinophilic Esophagitis

Scientific Exploitation and Management Rules

The project aims to promote clinical and epidemiological studies from a large number of patients with EoE and provide a common working tool for the European community of researchers and physicians interested on EoE and EUREOS members. The key element of a database will be complemented in the future with a biobank.

The database has been developed by a committee of experts by consensus, presented and discussed at several meetings of the UEG Link Award researchers group and sponsored by UEG funds.

The database includes different sections, that besides contributing to the Ha-EoE-EU project, can be used locally, such as registration of patient, though it will evolved in order to get selected variables on different aspects of the disease (epidemiological, clinical, drug safety, etc.) for further exploitation common scientific and translational purpose.

The EoE connect registry will allow the exploitation of information for conducting clinical studies. To this end the EoE connect project will be approved by the Clinical Research Ethics Committees prescriptive, and registration will be done in agreement with the Data Protection Agency, whereby the use of collected information will meet all legal requirements.

To participate in the Ha-EoE-EU database project and benefit both the scientific production thereof and their usefulness locally, the establishments concerned must get approval from the local ethics committee and sign the contract/agreement with EUREOS. This will send the center codes needed to access the website database.

European EoE Connect Scientific Committee

The Scientific Committee consensual will emerge from among the members who had contributed to the creation of the patients' database. The organization of the Committee will be set out under the complete transparency of the project, its objectives and the establishment of its operation.

Since the EoE connect, as a part of the Ha-EoE.EU project, is participated with EUREOS and the SEPD, within four components of the Committee must belong to the board of EUREOS. The remaining four members of the Committee shall be selected by vote (after presenting his candidacy) mid-term of each board

EUREOS coinciding with its annual meeting; thus renewing the Committee entail the replacement of all members at once but by halves every two years.

Optimally one or two of the Committee members must be knowledgeable of basic sciences (e.g. biologists, geneticists, immunologists) and epidemiology. Having been a member of the Committee on one occasion does not prevent the same person to be again, but renewal is recommended in the charges.

The main function of EoE Connect Scientific Committee is to evaluate the projects submitted for exploitation of clinical/epidemiologial/genetic data base, and approve its implementation if the evaluation is positive. Therefore, the Committee members have access to all data (anonymized) of the central database. This privilege is lost when a member leaves the Committee. No other researcher will have access to the central database. The Committee is responsible for ensuring the proper functioning of the EoE Connect registry, including inter alia the management of data and policy authorship of the works that are generated from it.

Committee members cannot evaluate projects that come from their own center whether or not they IP project.

The Committee meets in person at the annual meeting of EUREOS and UEG; also has a frequent conference system for decision-making.

How to participate in the Ha-EoE-EU database

To use the EoE connect database in a center is necessary to have a signed written "RESPONSIBLE FOR THE FILE" by the manager (or legal person responsible) of each hospital. This requires completing the document according to the data processing complies strictly with the Data Protection regulation. A suggested document containing the information for the manager or head of the Hospital will be downloaded from the link at the project webpage.

The data controller (manager or legal person) retains the exclusive right to ownership and use thereof as well as all processes of renovation and requests the provision of services by the DATA TREATMENT MANAGER (EUREOS) ensuring that all conditions are met according to regulatory rule. A company can be subcontracted by EUREOS to manage the database and analyze statistical data.

To participate in the EoE connect database project and benefit both the scientific production thereof and their usefulness locally, the institutions concerned shall notify the secretariat of the Scientific Committee of their intention to participate and sign the contract with EUREOS. Once this is done, a number will be provided for identifying the center and researcher.

A model of Informed consent for the patients will be provided, as well as other related documents, which will be downloadable from the database webpage:

- Patient informed consent (in PDF and Word format)
- Authorization management document (in PDF and Word format)
- Instructions for filling database forms.

Proposing and presenting studies

Every center that provide EoE cases to the EoE Connect registry may request the exploitation of the information collected. To request the proposal of a study, researcher should be a member of EUREOS and submit a specific form to the Secretariat of the Scientific Committee.

They will be some prerequisites for the application to access the data in the central database:

1. - Having at least 30 cases included in the database.

2. - Having approved the study requested by the Ethics Committee of the Hospital to which it belongs and attaches it to the request.

3. - The main objective of the study should contribute to improving the knowledge of a field unexplored or under-explored. The relevance of it with literature support must be clarified before listing the main objective.

4. - If the similarity between two projects is high, the applicant who did first will be assessed. In exceptional cases a meeting of the two research teams will be proposed.

5. - The results of the projects approved in the previous year will be presented at the UEG Annual Congresses and the maximum scientific dissemination will be given to them.

Policy authorship for projects supported on the Ha-EoE-EU database

The effort by the contribution of any institution participating in the project must be rewarded in the scientific production resulting therefrom. To this end, the politics of authorship of the EoE Connect projects will aim to benefit the maximum number of researchers.

To do this, the principal investigators (PIs) of each project awarded will be responsible for proposing the list of authors for approval by the EoE Connect Scientific committee. In the list of authors will try to give maximum

representation, including the maximum number of authors, who have made a significant contribution to the project and allow the publication of a paper. The order of authorship will be established considering the relative contribution of each of the researchers to the project both in terms of the number of cases brought. Contribution to the study design, analysis of results and drafting the manuscript will be also assessed. In all items the list will be included with all IP project (as an addendum), a fact which amounts to being author of the article at curricular level.

In those journals or conferences that the limited number of authors should be added after the last signatory "EUREOS representing the project"

The IP of each EoE Connect are required to:

1. Notify the Committee each scientific congresses and meetings that the study results are presented.
2. Submit to the Committee the manuscript/s of the study with proposed authors before submission for publication.
3. Submit to the Committee an explanatory document on the relative contribution of each author.
4. Contact each of the signatories centers in the list of authors to notify the author that should be his/her centre representative.
5. Present the final results of the study at the UEG Annual Congress.

Failure to comply with these regulations by the IP of a project may make it impossible to apply for new projects if the Committee so will consider.