EuRoD (European Robotic Database)

EuRoD is a multicentric international databaseproject established and designed by the French Robotic Group (CRG) for the Society of European Robotic Gynaecological Surgery (SERGS) and also for the use ofthe national societies of member countries (i.e.CRG, BIARGS etc.).

How to participate in EuRoD?

Definition of a EuRoD member

All gynae robotic surgeons who want to share their data through a European platform and who accept the guidelines of the EuRoD.

All EuRoD members must be at least a member of SERGS or a national gynae robotic societythat is participating in EuRoD or an affiliated society toSERGS.

Definition of a EuRoD Centre

A EuRoD Centre is a single institution where multiple members may be working.

Definition of a EuRoD Group

A EuRoD Group is a collection of Members or Centres who form collaborative group (e.g.: a National Society).

How can a National Society be member of EuRoD?

If the Council of the society has accepted the guidelines of EuRoD

How to apply to be a member EuRoD?

A request must be sent to the SERGS Secretariat at info@sergsmail.org and/or Data Management and Analysis Centre in charge of the EuRoD (DMAC, Paoli Calmettes Institute in Marseille, France (The Data managers are: martinv@ipc.unicancer.fr, labordel@ipc.unicancer.fr).

Once the guidelines are accepted and signed by the candidate, then a personal login and password are sent to the candidate for access to the Database.

Description, Mission and Organisation of the Data Management and Analysis Centre (DMAC)

The Datacentre for EuRoD is the Data Management and Analysis Centre (DMAC) at the Paoli Calmettes Institute (IPC) in Marseille, France. IPC is a recognised French Centre of Control Against Cancer (CRLCC) and is a recognised private, non-profitmaking, publicly recognised, organisation whose mission is to support the public interest in oncology according to French Governance and Laws.

Mission

To ensure that data entered is accurate, complete and consistent with the project database.

Skills

e-CRF Design, data entry and cleaning, data tracking and security, CDISC data standards, web data management.

Staff

3 biostatisticians, 3 data managers, staff DMAC 2 clinical research Technicians.

Tools

DMAC use Clinsight (Clinical Data management system), which is CFR part 11 compliant, and ORACLE database (version 11G).

Certification of DMAC

DMAC is ISO 9001 certified (Quality Management) by Bureau Veritas meaning that itconsistently provide products and services that meet the needs of their customers and other relevant stakeholders.

DMAC is also endorsed by the French National Cancer Institute (INCa), which is the preeminent health and science agency in charge of cancer control in France. Created under the Public Health Act of 9th August 2004, it is attached to both Ministries of Health and Research.

DMAC is also the regional platform for clinical research performed by La Ligue Contre Le Cancer.

Informed Consent Form–ICF

The ICF should be reviewed and validated by the lead group.

Each group adapts the ICF according to their local requirements and the name of the EuRoD group has to be present on the ICF

If parts of the ICF are amended by the non-leading groupthis has to be approved by the leading group.

electronic Case Report Form –e-CRF

The e-CRF is managed by the Data Management and Analysis Centre.

Certification of EuRoD

The French Robotic Group (CRG) has designed the e-CRF. The EuRoD Project and the e-CRF have received the agreement of the following French authorities via DMAC in order to allow theanonymous collection of patient data in a Registry:

1. Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS - Advisory Committee on Information Processing in Material Research in the Field of Health)

2. Commission Nationale de l'Informatique et des Libertés (CNIL)

Design

After accessing EuRoD, the e-CRFis available online (or from national group websites or the SERGS website)andcan be used if EuRoD members have accepted EuRoD's guidelines as described above.
Four different topics are available: oncological indications, myomectomy, sacrocolpopexy and deep infiltrating endometriosis.

The format is the same for all centres and online access is via a personal login and password that cannot give access to the data of others centres.

The e-CRF structure can be modified on demand with the agreement of the data manager.
Individual centres will have access to their own patient data automatically. Only the data manager will have access to the data of all the centres for use if a EuRoD multicentric trial is planned and approved by SERGS.

Are National Groups or Societies controlled by SERGS?

No, national groups or national societies are independent entities. If they want to manage a study between two or more EuRoD members within their own country, then they can request their own national data. Thestudy must be agreed by the National Group, which must obtain the consent of all national centres and members involved. The SERGS Council must also be informed of national studiesand they will inform others European centres. If other European centres are interested to be

involved, the national group running the study is free to decide if it wishes to allow other European groups or centres to join.

Who is the owner of the data?

Each centre or member of the EuRoD is the owner of its own data.

Each centre can use its own data in isolation for clinical evaluation but cannot call it a EuRoD study.

Each EuRoD member can choose whether they wish to share their data in a EuRoD trial.

What about retrospective data?

Anyretrospective data collected prior to joining EuRoD can be included by the data manager into the online database (e.g. in EXCEL Spread sheet format).

Utilisation of the Database and EuRoD Studies.

A study can be a formalised EuRoD study if:

There is collaboration between at least two EuRoD members, centres or groups. EuRoD, via SERGS Council, will always encourage the lead Member, Centre or Group of a proposed study to include other EuRoD members, centres or groups if it fits with the remit of the study.

Is it possible for non-EuRoD groups (either European or rest of world) to join a study?

It is possible for individuals, centres or groups who are not part of the EuRoD collaboration to join a EuRoD study if the national society where theyare based is in agreement.

Selection of the centres and feasibility

The EuRoD study group must assess the feasibility of running the study at sites in its area and then be responsible for their selection (this can be done with the mutual agreement of an industry partner if necessary).

Can a company choose to run a national studywithout cooperation of thenational EuRoD group and local EuRoD centres and members concerned?

In principle it will not be possible to run a study without the cooperation of the relevant nationalEuRoD group and local centres and members in one of the countries represented by EuRoD. However, if isolated centres affiliated to the local EuRoD group want to do the study, and there is approval of the nationalEuRoD group,then this might be possible.

Can a EuRoD study be lead by a non-EuRoD Principal Investigator?

In principle, the leader of an institution of aEuRoD group should be the principal investigator. However, in exceptional circumstances EuRoD can decide to accept a principal investigator whom does not belong to EuRoD.

Study Protocols

In case of « National » EuRoD Study (including at least 2 national members of EuRoD and sanctioned by the relevant national group)

One protocol should be produced and agreed by the lead study group and the industry partner (if there is one). This should then be reviewed and approved by ethical and the scientific committee of the National group.

In case of « European » EuRoD Study (including at least 2 members from 2 different countries of EuRoD and sanctioned by SERGS)

One protocol should be produced and agreed by the lead study group and the industry partner (if there is one). This should then be reviewed and approved by the ethical and the scientific committee of SERGS.

Guidelines for Authorship for Studies run within EuRoD

General.

a. Authorships and Co-authorships are not to be decided by individual members or centres. They will be mutually decided by the relevant groups and study centres involved in the study and agreed upfront.
b. Calculations regarding the number and position of co-authorships will generally be based upon the numbers of recruited patients by potential authors.
c. Once a subgroup in a study has been allocated the number and position of authorship places it is entitled to, then they are completely free and independent to decide themselveswhich of their subgroup authors occupy

which allocated positions(the sub-group may even appoint persons whom havenot recruited patients if appropriate).

d. The following "rules" should help to guide authorship position consultation and give a fair template to ensure benefit for all participants involved.

Fixed authorship positions.

a. All co-authorship positions generally depend upon the recruitment numbers by groups except the authorship position of the International Principal Coordinator (The IPC will beappointed by the leading group in the study) and one for the statistician of the study (usually 4th position).

b. The International Principal Coordinator is the first author or last author (senior author) depending on the pre-study authorship agreement.

c. Co-authorship positions of a potential industrial sponsor (not a study group) can be settled on a case-by-case basis, however, this should be stated in the agreement upfront and would be rather the exception than the rule.

Number of authors per group

a. Each group will be allowed one author for every 4% of recruitment that they contribute to the study (i.e. 4% = 1 author, 8% = 2 authors etc. up to 4 authors).

b. From then on, additional author places will by awarded for every 5% of recruitment instead of 4% to avoid the overrepresentation of very strong groups.

The percentage numbers are a general guideline and might be adapted to each specific protocol and will depend on the population size of the study and the number of participating groups (e.g. 5 and 6% instead of 4 and 5 %)

Position of the authors

The specific place of the group's representative is defined by the overall recruitment by the group; e.g. if group A has the highest recruitment number, group B the 2nd highest recruitment number, group C the 3rd highest, and group D the lowest then the 2nd author would be appointed by group A, 3rd author by group B etc.

Example: Study of 1000 patients:

Group A: 220 patients =   22% =   5 authorship positions
Group B: 210 patients =   21% =   5 authorship positions
Group C: 120 patients =   12% =   3 authorship positions
Group D: 65 patients =   6.5% =   1 authorship position
Group E: 40 patients =   4% =   1 authorship position

Resulting positions:

A1 (if IPC), B1, C1, Statistician, D,E,A2,B2,C2,A3,B3,C3,A4,B4,B5, A5 (if senior author or IPC)

The IPC will usually will usually either be A1 or A5 unless they come from a group other than A and then, if agreed, they would supersede A1 and A5 in the order and choose to be either first or last author.

Each Subgroup would usually have a Principal Investigator for their site whom will occupy position one in their subgroup (i.e. A1, B1 etc.)

Remark

In all the publications the DMAC will be mentioned, as well as the national societies who have participated in the recruitment,and the European Society (SERGS).

I accept the above guidelines for use of EuRoD and confirm that I am either a member of SERGS or am a member of a National Society that has affiliate membership to SERGS.

Signature of Applicant………………………………………………………………………………

Name of Applicant………………………………………………………………………………………

Centre of Applicant………………………………………………………………………………………

Country of Applicant……………………………………………………………………………………

Date………………………………………………………………………………………………………