

**Euro Histo Net Meeting**  
**Paris**  
**December 18th 19th 20th, 2008**

**Thursday 18th**

2 PM Opening of the meeting and Welcome  
Organisation of the sessions, Practical aims of the meeting

2 15 PM: General organisation of the project – Agenda

3 PM: Aim of the session:  
To validate the frame of a consortium agreement including regulations concerning web portal and web data base

Consortium agreement:

- Presentation of a draft of the contract that has been sent out in advance (draft of table of contents: see second file)
- Discussion

Specific topics to address:

- Who are the partners and who may become a new partner (partners from EU and partners from outside EU)? – Obligation and rights
- What subjects need to be regulated in particular? – Mandatory and subsidiary decisions. (What is important, what is secondary?)
- Web portal and web data base:
  - General decision rules
  - Property of software, table structure and data – Who will be the owner? (A community of owners?)
  - Data safety and confidentiality, data inclusion, modification and amendment, data maintenance and access regulation
  - Decision rules to exchange data

6 PM End of the session – first conclusion

7 PM Free evening

**Friday 19th**

Aims of the day:

- To agree on the frame of a data base
- To agree on the minimal data that needs to be collected

10 AM

Data base – The state of the art

- A) Regulation issues in EU
- B) Recall: What data has to be collected for which purpose?
  - a. Epidemiology
  - b. Description of the natural history
  - c. Therapeutic trial

- C) Frames of the available data bases (working document will be sent out in advance) – What data fulfil the needs of transferability/merging, consent and quality control?
- D) Presentation of the CRF of LCH IV – others possibilities
- E) What is the present situation and will a consensus be possible?
- F) How to optimise the existent systems – Does Euro Histo Net need to be a new system or may Euro Histo Net be a spin-off of existing systems?

12 30 PM Lunch

13 30 PM

What are the minimal data to collect and how to organise them?

Demographic

Familial history

Disease extension

Follow up

Sequels

Standard information about therapy

Standard information about MRI, CT scan and biology

Tissue banking

Consensus about the definition of variables and their codification

16 30 PM Break

17-19 PM First conclusions about the data base – Fixation of the results to be translated in IT solutions, according to GCP, integrating a module for transfer of imaging materials

20 PM Dinner in town

## **Saturday 20th**

Aim of the day:

To agree on the web portal and web data base regulations

To agree on the consortium agreement

To allocate tasks

9 to 12 PM

Discussion of open questions and remarks

Web data base – Final conclusion

Web portal – Define the items for the selection of a subcontractor

Consortium agreement – Conclude the outline for required modifications

Future plans – Allocation of tasks