



STATISTICAL SUB COMMITTEE

Minutes of the meeting held on 27th March 2007, EBMT meeting in Lyon

Participants: Myriam Labopin, Antonella Santucci, Simona Iacobelli, Ronald Brand, Emmanuelle Polge, Carmen Canals, Irina Ionescu, Roberto Crocchiolo, A Latouche, Alessandra Carobbio, Alessandra Spagnoli, Henk Jan van der Wijk

Absent persons: Richard Szydlo, Stefan Suciuc, Vanderson Rocha, Sandrine Katsahian, Jean-Yves Mary, Marie Lorraine Balere.

1. Statistical courses:

a. Content of the course: Antonella Santucci presented first the proposal from Richard to give a series of courses ie every EBMT meeting. His plan is then to begin with "basic" statistics such as comparison of groups, t-test, regression, etc... and to go on with survival analysis / Cox.

However, it does not seem realistic since:

- the majority of the DM and MD interested in the course would like to get information on Kaplan Meier and maybe competing risk calculations
- the main issue is to start and to adapt the course according to the feedback after the first one. We cannot plan the further years at this time.
- Ronald suggested to go through the statistical guidelines and to point out the principal issues during the course.
- A questionnaire will be sent out to all persons who have answered the survey and were interested in such course asking for:
 1. their possible participation
 2. What they would like we go through within the different issues of the statistical guidelines already published in the web site.
 3. What software they are using

The final content will be defined after, but the idea is to perform a first simple course going through the different steps of a statistical analysis, the definition of the endpoints, the survival curves. Simona said that it would be important to include competing risk calculation, at least on the principle.

b. Antonella can get a licence for SPSS for these courses, but we must verify that the participants will be able to use it when coming back "home". This will be also decided after the feedback of the questionnaire. At this moment it seems that SPSS (or NCSS) are the most friendly used softwares, and it could be appealing to propose a practical session. Ronald & Simona informed us that a macro in SPSS will be probably available in order to perform CI curves and competing risk comparison.

c. Practical issues:

- Henk Jan inform us that it will be difficult to get a computer room ready on Saturday, but this is the best time to organize such course.
- The computer room contains 16 computers
- No fee will be asked.
- Participant will have to register
- The duration of the courses will be about 3 hours (including 1 or 2 breaks).

Actions

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| <ul style="list-style-type: none">- contact Fiona (and AKM) to ask for organising such course on Saturday afternoon (computer room, registration...)- send out a questionnaire to interested people to define more precisely the content of the course- exchange the courses support that each of us could have (slides, material...in English) |
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2. **CLINT:** (Establishment of the Infrastructure to Support International Prospective CLINical Trials in Stem Cell Transplantation). Myriam inform the participant that the official date for the beginning of this project whose aim is to improve the quality of prospective clinical trial has been fixed to April 1. Aurtélien Latouche will take the post doc position (2 days a week) for 2 years.

3. **Statistical symposium in Firenze:**

Three speakers will present complementary talks on Design, Analysis and methodology for clinical trials.

- Stefan Suciú will thus present "Design and analysis of EORTC clinical trials: theory and practice".
- Hein Putter will provide a general introduction to multi-state models with a focus on Splus/R package, he developed. It will supplement the talk of Marta Fiocco (Stat symposium 2007).
- Aurélien Latouche will focus his talk on statistical planning of clinical trial, with an emphasis on sample size determination (in the presence of competing risks). Abstract of the talks can be found in the statistical portal of the EBMT <http://test.ebmt.org/dnn>

Aurélien made a proposal for inviting 1 or 2 speaker at the next EBMT meeting, that collaborate on methodology with application to BMT :

- J.P. Fine (Department of Biostatistics , University of Wisconsin, Madison)
- J Beyersmann, University of Freiburg

It would be desirable to have statisticians invited in regular session, for exposing new methodology (outside the Stat Symposium. Notably, both researchers presented talks in late 2006 and early 2007 in biostatistics seminar at Hopital Saint-Louis (France) with financial support of the EBMT. J. Beyersmann on "A competing risks analysis of bloodstream infection after transplantation", JP Fine on "Modelling the Effect of Prednisone on Graft Versus Host Disease".

Action:

Aurélien and Myriam will contact chairpersons in order to define clinical applications. The EBMT will be asked to invite one or two speakers.

4. **Portal:**

The portal has been implemented for one month and nobody had comments... Ronald concluded that everything is OK.

Myriam asked for a short manual. Henk Jan will distribute such a manual (one page maximum) to the participants.

Ronald rise the issue of maintaining the portal . Aurélien does agree to be in charge of that maintenance and this will be discussed again during the next statistical subcommittee meeting. The first step will be to remove what is in the actual EBMT website and to select what will be implemented into the portal (in order to avoid double information).

In order to increase communication via the portal, Myriam propose to make a reminder of the existence of the portal to all the EBMT members and to point out at the same time specific information (document or FAQs of interest for MD) that need to be implemented first onto the portal. Each participant is asked to think about some questions that have been asked to them in the past and some question that they think are interested.

Actions:

Henk Jan will distribute a short manual for the use of the portal Ronald will check for statistical documents to be removed from the website and implemented into the portal and communicate the list to Aurélien Aurélien will be in charge of the maintenance of the portal Everyone is invited to think one or two question of interest for clinicians and/or datamanagers.

5. **Next meeting:**

The next statistical Committee meeting is scheduled to take place in Paris in November. The date need to be confirmed.