

# Registry Meeting Minutes

7-8 May 2015, HVS Monaco

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Members present: Arsène Basmadjian, Ismail El-Hamamsy, David Messika-Zeitoun, Yan Tolpisky, Thierry Le Tourneau, Jaroslav Hlublocky, Juan P. Umana, Jean-louis Vanoverschelde, Rita Milewski, Hector Michelena, Maurice Sarano, Arash Khamooshian, Hanneke Takkenberg, Marta Stiges, Raphael Rosenhek, Luciana Young, Bart Loeys, Frederiek de Heer, Jolanda Kluin, Emmanuel Lansac, Monica Contino, Alain Berrebi, Stéphanie Lejeune, Rakesh Suri, Jan Vojacek, Igor Rudez

## Agenda

The aortic valve repair Group had a very productive meeting. It started with 2 very good news. The first one is that Frederiek Heer from UMC Utrecht who is already deeply involved on the registry will be officially 2 days full time working on the aviator data base which will be also the subject of her PhD. The second one is the allocation of a 100 000 Euros grant from the Association of operated patients ADETEC promoting research in Cardiac surgery.

### 1. Presentation of the new database CleanWeb

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The new database is still under construction and the pre-existing data from the older database (Julius Center) are not yet transferred to CleanWeb database. We still are waiting for minor modifications and construction of the medical registry. The aviator surgical registry will be launched at the end of June and a mail will inform you on time.

Current centers (with data in the old database) could go on with data entry in the old database. At a certain moment we will freeze the old database and transfer the data to the new database. We will inform you when this will take place. After transmission we will ask you to check some records (randomly) to be sure the data transfer was successful. After the test phase you can include new patients in the new database. We will inform you when all the lights are on green.

New participants (without data in the old database) could start with patient enrollment in the new database as soon as it is ready. New centers do not have to wait when the old data is transferred. We advise you to wait till this moment and not start including patients in the old database.

### 2. Organizational issues

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A legal advice will be provided by the HVS (Stan Alger) and telemedicine regarding database security and legal responsibility in case of problem (if the data base is hacked for example or if the company closes).

Regarding the Aviator participation agreement. It will be added in the letter of understanding that "participants agree that their data can be used for multicenter studies".

Multicenter studies must submit a protocol to the scientific committee as well as the paper prior to publication. If not, the authors will be automatically excluded from the HVS. (modifications of protocol and letter of understanding, Frederiek de Heer, Stéphanie Lejeune)

Monocenter studies should inform the scientific committee by sending a copy of the paper. Moreover, they must mention the Aviator registry from the Heart Valve Society as the database in the paper.

### 3. Construction of the Medical Registry

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Inclusion criteria: AI > 1 (mild), ascending aorta  $\geq$  40 mm at sinus or tubular level

The design of medical registry forms is under construction. A new CRF form will be send very soon to add comments and modifications. David Messika Zeitoun and Jean-louis Vanoverschelde volunteered to coordinate the medical registry. As soon as the form is finished, the link with telemedicine will be made straight away for the online set up.

### 4. Election of the first scientific committee

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7 members including at least 2 cardiologists, 2 surgeons, 2 scientists. The following scientific committee agreed for 2 years is :

- 2 scientist: Frederiek De Heer (secretary) / Hanneke Takkenberg (co-chair)
- 2 surgeons: Emmanuel Lansac (co-chair) / Jochen Schafers
- 3 Cardiologists: Jean-Louis Vanoverschelde / Guillaume Jondeau / Maurice Sarano

It will be a co-chaired (avoiding two people from the same specialty), 1 secretary and 4 members Member of the committee will serve for 2 years not renewable straight away. After another term of 2 years, it is possible to be candidate again.

They are in charge of reviewing :

- Research proposals
- Papers originating from the registry
- Financial issue (do you mean initiation of grants?)
- Relation with other working group of HVS and advisory function HVS board.

Of course any personal or collective initiative to improve group action and visibility of the group are more than welcome and will be supported.