

# Registry Meeting Minutes

2015, EACTS Amsterdam

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Members present: De Kerchove Laurent, Mangini Andrea, Bardia Arabkhani, Patrick Yiu, Antona Carlo, Jose Aramendi, Kong Ye, Zheng Yue, Jaroslav Hlubocky, Aicher Diana, El Hamamsy Ismail, Frederiek De Heer, Hanneke Takkenberg, Jolanda Kluin, Emmanuel Lansac, Stéphanie Lejeune.

## Agenda

### 1. Project update

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The new database is ready, and you can start data entry. If you are not yet a participant to Aviator you need to complete the participation agreement available online: <http://heartvalvesociety.org/working-groups.cgi>. Participation is free to the registry but at least one member of the team should become a member of the HVS. All agreements should be returned via email to the Heart Valve Society at [AVIATOR@HeartValveSociety.org](mailto:AVIATOR@HeartValveSociety.org).

*Regarding the export of data in the previous database:*

If you have entered your clinical data in Julius Center database before, the extraction will be done automatically. We will inform all users when the actual transition will take place. We will freeze the old database and upload these data in the new database. This process will take some days. You then receive your new access code.

If you have entered your data in another local database and if you want to include your database into the Aviator project, please contact us (Frederiek De Heer ([F.deHeer@umcutrecht.nl](mailto:F.deHeer@umcutrecht.nl)) and/or Stéphanie Lejeune ([stephanie.lejeune@imm.fr](mailto:stephanie.lejeune@imm.fr)). We need to do mapping with your local data manager in order to transfer the data correctly.

### 2. Presentation of the finalized AVIATOR database components

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This database is composed of:

- A summary on patient level, which could be used as a clinical tool: you can search each patient by his name and visualize directly his medical history by clicking on "summary". It is possible to consult it online or to print it as pdf form.
- AVIATOR registry : this is the main database and the name of the entire project common to every team
- Dedicated studies: If you want to create your own study, you can add dedicated items that are not in the main registry. These items are only visible for your center. For example, in France (at the institute of Emmanuel Lansac) they decided to register the aortic diameters as well in diastole as in systole. Furthermore they added a CRF with a Health Survey. To create some new dedicated items,

you need to send a request. We will also provide a list of all additional modules, so each center can decide if it will participate only in the main registry or it will join specific side branches. You will find a procedure online very soon.

- Online data extraction and Friendly Surgical Report (see paragraph below)

Data ownership: You have entire access to your own data which remains the property of each center and you will not see data of other centers. Publication of your own data is possible without any restrictions. Please, do mention you participate in the Aviator project and send a copy of the paper to the HVS scientific committee (AVIATOR@HeartValveSociety.org). For multicenter analysis, you need to make a request to the HVS scientific committee, who will also review the paper before sending for publication.

Filters: It's possible to create your own filters. In the database these are called 'dashboards'. With these dashboards it is possible to generate some frequently used patients list to select specific groups of patients (without consulting a data manager) such as bicuspid valve, valve sparing root replacement, reoperated patient, Residual AI >2 etc.....

Encrypted data: It is possible to enter the name of the patient (this is optional). The patient name is only visible for your own center.. The identifying data (patient name) is encrypted and stored in a separate database to meet the required safety US and European regulations The name of the patient will not be extracted in exported datasets.

Extraction: Online extraction is possible for your own center data. In the extraction module you can select two file types: CSV or Text. These file types can be opened in all other applications, like Excel, SPSS etc.

### 3. Comments and suggestions of database

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- Intention to repair: if during the preoperative, the intention to repair is "yes" but "no" during the operation, we should have an item below "if no, reason". This suggestion will be transferred to the provider, to do the modification.
- Inclusion criteria: It is important that we do not only include the valve repairs. We do need to have a control group like valve replacement. Pure stenosis is excluded. To make the inclusion criteria more clear "mixed AV disease" should be added as option in the question 'Main reason for referral'. It was not clear if every group present at the meeting did enter the same population. Some do not enter the dissected patients,.
- ECHO part: You can enter echo data whatever the chronological order. You can sort echo chronically by clicking on "moment" in the column headings. This applies also for the other columns in the table.

- The question was raised if it is possible to add specific pediatric items as a dedicated study . The pediatric database could be a spate project like AIDA registry as it required some different items. Besides it must respect the authorities regulations regarding children from each country.
- Do we register CT-measurements? At this moment it is not incorporated in the main registry. It is off course possible to develop a side branch with a specific CT-CRF.
- Is there a minimum of patients per center? In the protocol it is stated that each center should have at least 10 patients per year. This number was discussed. Conclusion?

## 4. Surgical Report

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It permits to have online statistics with a quickly feedback. Your own data are compared to data from all centers. The idea is that the aggregated data from all centers are updated once a year, so that it can be validated properly. The data of your own center can be updated by yourself, when you agree it is complete and valid.

The surgical report should be filtered not only by repair and replacement, but with type of valve and phenotype too, to have a better overview. The same was suggested for the echo measurements. It is not meaningful to summarize these parameters over a very heterogeneous group. In the future it is perhaps possible to develop a dynamic tool as a separate project. These development are ongoing but rather complex and need to time to be finalize.

## 5. AIDA Registry

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this is the sub-database with the medical information. This side branch is not available yet, a working group including mostly cardiologist needs to finalize.

The group (mostly surgeon) re expressed clearly that inclusion criteria need to be in coherence with the surgical registry as defined in Monaco inclusion criteria ( AI>1(mild) and/or ascending aorta >40mm at sinus or tubular level).

AIDA registry will be host by telemedicine (cleanweb) in order to be link to AVIATOR registry. For practical feasibility due to differences in pathology and physician involved, it was suggested in a small AIDA meeting (David Messika Zeitoun, Guillaume Jondeau, Alain Berrebi) at London ESC 2015 to have two main branches in AIDA registry, one for AI and one for aneurysm.

AIDA could have a common data set for patient characteristics and will have to branches one for AI and one for Aneurysm with specific items for each one. This organization needs to be validated by the scientific committee as well as Working group for AI branches and Aneurysm branches.

## 6. Data monitoring

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Today, there is no financial issue for monitoring. This point should be discussed again in the next meeting.

Finally, data completeness is very important. The STS audit committee discovered recently that 10-20% of the data was not uploaded. We would like to emphasize here that the Aviator project will only get meaningful answers when all patients that meet the inclusion criteria are uploaded in each center. Thank you very much for all the effort.

*Kind regards,*

*Frederiek Heer, Stephanie Lejeune, Hanneke Takkenberg and Emmanuel Lansac*

*On behalf of the Aviator working group and scientific committee*