

**Report on the
1st ESF-ENSAT workshop on the ACC database
February 21, 2013
14:00 - 19:30 pm
Paris, France**

Venue

Hospital Cochin, Paris

Organizing committee

Martin Fassnacht, Felix Beuschlein, Eric Baudin, Harm Haak, Rossella Libe, Anthony Stell, Massimo Terzolo

1) Summary

In the last 10 years the European Network for the Study of Adrenal Tumors ENS@T has established a network and infrastructure that allowed significant progress in clinical care for patients with adrenocortical carcinoma (ACC). One key instrument is the ENSAT ACC database, which was finally launched in 2011 and includes clinical data of more than 1600 patients.

The ESF-supported workshop held in Paris at February 21, 2013 allowed us to make great progress to standardize the database.

Seven experts presented the current version of the database and proposed detailed definitions for each item of the database. After an extensive discussion with all 25 participants, we finally found a consensus for the vast majority of items. However, the time was too short to discuss all items and some definitions are still under debate.

Therefore, the organizing committee of the meeting is currently in process to find an agreement on each of the open items using email exchanges and telephone conferences.

Furthermore, the meeting was a great opportunity to share hands-on experience with the database of the attendees from 15 different centers from 6 different countries. During this discussions, it became clear which parts of the database need special attention (e.g. the "follow-up" form).

In the meantime, the IT manager of the database, Anthony Stell, who was also attending the workshop, has already implemented several of the proposed modifications in the online-database and a detailed "how to use..." guideline is in preparation.

In conclusion, this 6-hours intensive workshop led to a major additional improvement of the ACC database, which now can even better serve as template for the other three ENSAT databases.

2) Description of the scientific content of and discussion at the event

Adrenocortical carcinoma (ACC) is a rare but highly malignant tumor with poor prognosis. In different patient series the five-year-survival ranged between 16 and 44 %. The disease is highly heterogeneous and shows a bimodal incidence with a first peak during childhood and a second peak between the fourth and fifth decade. Patients not only suffer from the reduced life expectancy but also from concomitant hormonal dysregulation with hypersecretion of cortisol and/or androgens leading to Cushing's syndrome and virilisation.

The recently established national and European networks for adrenal disorders and the first three International Adrenal Cancer Symposia in 2003 and 2008 in Ann Arbor and 2011 in Würzburg have stimulated international collaboration in the field of ACC, which has led to significant advances.

One if not the main player in this concert is the European Network for the Study of Adrenal Tumors ENS@T. The establishment of this network successfully fostered strong collaborations between many European centers. A key idea of ENSAT is to share clinical data and biomaterial between the centers. For this purpose the different ENSAT databases have been established and are in the meantime an important tool for the different ENSAT projects.

The ACC Registry was finally launched in October 2010 and within 2 years more than 1600 ACC patients have been registered by 31 European centers (status 30.04.2013: 1670 patients). The ACC Registry is collecting far more than 100 items per patient on 10 different sub-topics: Diagnostic work-up, Surgery, Pathology, Mitotane, Chemotherapy, Radiotherapy, Chemoembolisation, Radiofrequency, Biomaterial, and Follow-up. Thus, this database is probably by far the largest database on this rare disease with detailed clinical annotation.

However, over the time, it was realized that several items are straight forward to enter in the database, but for some different investigators had a slightly different interpretation what exactly should be entered in the database. Thus, it is time now to find unanimous definitions for all main parameter in the database and to train all people who are entering data. And this was the idea of this half-day workshop.

In the first session, Anthony Stell and Martin Fassnacht presented the current version of the database for the sections "patient identification" and "diagnostic workup" and made several suggestions about standardizations of the data entry in general. Since the definition of several items in the "diagnostic workup" were not 100% clear to all participants, the discussion to find unanimous definitions was quite lively, but very productive.

The second session, led by Rossella Libe focused on "surgery" and "pathology" and the third chaired by Massimo Terzolo on "mitotane" and "chemotherapy". Especially, during these later topics, it was realized that a modification of the follow-up form might be necessary to make the database even more user-friendly. Therefore, the discussion on "follow-up" was chosen as next topic. Harm Haak presented his suggestions and after an intensive discussion it was decided that the "follow-up" form should be extended to gather all key information during his later disease, but also to guide the user to the other forms.

After the coffee break, Felix Beuschlein presented the "biomaterial" form and made some suggestions for standardization. Furthermore, he explained how to use this form and the database to structure the local biomaterial bank in a sufficient manner.

In the last session, we shortly discussed "radiotherapy", "chemoembolisation" and "radiofrequency", chaired by Eric Baudin. However, due to time restriction the final decisions on several questions had to be postponed and are currently solved within the members of the organizing committee by email exchange and telephone discussion.

During the entire meeting, all participants had the chance to ask specific questions to the database and to share their personal experience with the database. This feedback was certainly not only appreciated by the IT manager of the database, Anthony Stell, but also by the other leaders of the ACC Registry.

After concluding this productive meeting, all participants joined the official FISAC Welcome Reception.

3) Assessment of the results and impact of the event on the future direction of the field

As pointed out above, this meeting with all core members of the ACC working group that are heavily involved in the ACC database allowed us to improve significantly the database of the ACC Registry.

The following points can be judged as key points of the meeting:

- Agreement on unanimous definitions for all main parameters in the database. This major task was achieved for about three quarter of topics. The outstanding issues are currently addressed by email and telephone discussions.
- Adaptation of the database to the needs of the user. Although the database was already an extremely good tool for the ACC researcher in Europe, the face-to-face discussion during this workshop was a good opportunity to discuss about further improvements.
- Preparation of a "how to use..." guideline. It was judged as important that each item of the database is clear to all users of the database (not only the key investigators, but also the research associates that enter frequently the data). Therefore, such an online tool should help future users to enter all important data in a correct manner. As soon as all definitions are finally agreed on, these definitions will be implemented as "pop-ups" in the online database.

In conclusion, this half-day workshop led to a major additional improvement of the ACC database by increase the consistency of the data entries in the futures. Thus, the ACC Registry can even better serve as template for the other three ENSAT databases, which are a major goal of the ESF-ENSAT project.

4) Final programme of the meeting

see pdf file attached.

**1st ESF-ENSAT workshop on the ACC Registry
February 21, 2013
Paris, France**



Venue: Cochin Hospital
27 rue du Faubourg Saint Jacques-75014 Paris
DUSSEY room-PNEUMOLOGY
Pavillon CORNIL-BRISSAUD
Floor -2

The exclusive aim of this workshop is to further improve the ENSAT ACC Registry and to standardize the data entry by the local investigators. Thus, the agenda follows the structure of the database and it is the key goal of this meeting to find unanimous definitions for all main parameter in the database.

14:00	Welcome	Xavier Bertagna, Martin Fassnacht
14:10 - 15:00	Identification + Diagnostic workup	Anthony Stell, Martin Fassnacht
15:00 - 15:30	Surgery+ Pathology	Rossella Libe
15:30 - 16:00	Coffee break	
16:00 - 16:45	Mitotane + Chemotherapy	Massimo Terzolo
16:45 - 17:30	Biomaterial	Felix Beuschlein
17:30 - 18:00	Radiotherapy, Chemoembolisation, Radiofrequency	Eric Baudin
18:00 - 18:15	Follow-up	Harm Haak
18:15 - 18:45	Additional measures for quality assurance	Anthony Stell
18:45 - 19:00	General discussion	
19:30-21:30	FISAC Welcome Reception	

Supported by



PARTICIPANTS
ESF-ENSAT ACC REGISTRY WORKSHOP
PARIS FEB 21, 2013

Name	Center	email
Anthony Stell	Melbourne	anthony.stell@unimelb.edu.au
Rossella Libe	Paris	rossella.libe@cch.aphp.fr
Massimo Terzolo	Orbassano	terzolo@usa.net
Felix Beuschlein	Munich	Felix.Beuschlein@med.uni-muenchen.de
Eric Baudin	IGR	baudin@igr.fr
Harm Haak	Eindhoven	H.Haak@mmc.nl
Michaela Haaf	Würzburg	Haaf_M@medizin.uni-wuerzburg.de
Katharina Lang	Würzburg	Lang_K@medizin.uni-wuerzburg.de
Ilse Hermsen	Eindhoven	I.Hermsen@mmc.nl
Thomas Kerkhofs	Eindhoven	T.Kerkhofs@mmc.nl
Paolo Dalino Ciaramella	Milano	pdalino@libero.it
Maria Verena Cicala	Padua	mariaverena.cicala@unipd.it
Salvatore Grisanti	Brescia	salvatore.grisanti@tin.it
Cristina Ronchi	Würzburg	Ronchi_C@medizin.uni-wuerzburg.de
Letizia Canu	Firenze	letiziacanu@yahoo.it
Maria Candida Barisson Villares Fragoso	Birmingham	mariafragoso@uol.com.br
Vitoria Basile	Orbassano	basile_vittoria@libero.it
Margaritha Bala	Würzburg	Bala_M@medizin.uni-wuerzburg.de
Martin Fassnacht	Munich	Martin.fassnacht@med.uni-muenchen.de
Xavier Bertagna	Cochin	xavier.bertagna@cch.ap-hop-paris.fr
Thomas Papathomas	Rotterdam	t.papathomas@erasmusmc.nl
Stephan Glöckner	Dresden	Stephan.Gloeckner@uniklinikum-dresden.de
Barbara Altieri	Roma	<altieri.barbara@gmail.com>
Tracy McLean	Birmingham	TAM146@bham.ac.uk
Irina Banco	Birmingham	i.bancos@bham.ac.uk