OFSEP, the French MS Registry

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Nadine Debard, OFSEP Clinical project manager
Overview:

- **OFSEP project**
- **OFSEP tools**
- **Scientific added value**
- **Planned improvements**
<table>
<thead>
<tr>
<th><strong>NAME</strong></th>
<th>OFSEP</th>
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<tr>
<td><strong>Nationality</strong></td>
<td>French</td>
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<td><strong>Scientific domain</strong></td>
<td>Multiple sclerosis (Neurology)</td>
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<td><strong>Date of birth</strong></td>
<td>2011</td>
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<td><strong>Structure</strong></td>
<td>Consortium of 3 entities: Lyon University Hospital, Lyon 1 University and EDMUS Foundation</td>
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<td><strong>Main funding</strong></td>
<td>French State call for projects « cohorts », 10 years</td>
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<td><strong>Other fundings</strong></td>
<td>ARSEP foundation, private projects</td>
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Operational objectives

1. To maintain and expand the nationwide cohort of patients with MS in France

2. To enrich the existing clinical data with imaging and medico-economic data and with biological samples

3. To allow all researchers worldwide to access the collected data and biological samples
   (research project submitted to OFSEP)
1. To describe MS population included in the cohort

2. To conduct research on priority projects (nested cohorts) on specific populations:
   Clinically Isolated Syndrome (CIS), Radiologically Isolated Syndrome (RIS),
   Primary Progressive MS course (PPMS) and Devic’s disease.

3. To set a minimal amount of data for the clinical, imaging, therapeutic,
   medico-economic data and biological samples
   = to harmonize data collection
Data provided twice a year by an automatic and anonymised extraction:

47,438 patients files
+ 4,845 files in 2014
+ 3 new centres in 2015

Estimated number of french MS patients : 80,000 to 120,000
Overview:

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A database dedicated to MS: what for?

1. (Harmonised) computerised single medical file (dedicated for care)
2. Local or regional database (dedicated for care and research)
3. Multicentric study (research)
4. National cohort/registry (research and public health)
5. International studies (meta- and big data)
Le protocole IRM cérébrale

**Recommandé**
- 3D T1
- DWI Axiale avec carte ADC
- IDP/T2 Axiale
- Injection de Gadolinium (0.1 mmol/kg)
- 3D FLAIR (ou 2D FLAIR Axiale si la 3D FLAIR n’est pas disponible sur la machine)

*Standardized samples for priority cohorts*

**Centralised storage infrastructure**

« Shanoir-Ofsep »

https://shanoir-ofsep.irisa.fr
OFSEP tools

IMAGING
Shanoir® web platform for neuroimaging

CLINIC
EDMUS® database

BIOLOGY
Tumorotek® samples management system

Separate anonymised databases linked by a national unique identifier
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First example of institutional Risk Management Plan (RMP) based on clinical data collected by EDMUS users, before OFSEP

**National multicentric phase IV RMP**
- ANSM promotor (french regulatory authority)
- **French patients** having natalizumab
  - 4061 patients recruited in 5 years
  - 115 250 infusions

**Primary Objective**
- To establish the **safety profile** of natalizumab (short to long term) in real life settings

**Secondary objectives**
- To describe the **clinical evolution** of patients treated with natalizumab
- To determine the **conditions of use** of Tysabri® in real life settings
TYSEDMUS example

- PML (Progressive multifocal leukoencephalopathy) surveillance (N=25)
- Other serious adverse events surveillance (7% SAE)
- Pregnancies (N=131)
  - Confirmed treatment tolerance
  - Confirmed treatment efficacy in real life settings (82% reduction of annual relapse rate on 1st year)

✓ Proved that french neurologists were able to conduct huge post-marketing studies
✓ Favoured OFSEP creation by the same neurologists
A huge cohort describing MS patients in >30 hospitals (university or not) in the whole french territory

Data are available for the scientific community: 19 projects submitted by researchers and assessed by OFSEP in 2014-2015: 15 accepted.

Allows regulatory authorities to give recommendations to improve healthcare

Dissemination of results
Special interest for:

- Special populations
- New drugs evaluation (Risk management plans, PASS, ...)
- Natural history (some patients followed-up >30 years)
- Added value of imaging, biology and medico-economics
Overview:

- OFSEP project
- OFSEP as an epidemiological tool
- Scientific added value
- Planned improvements
Planned improvements

- **Quality processes** (OFSEP structure and data collection)
  Quality of data is a priority and will affect financial support given to participating centres

- **A unique web-based platform**
  Implementation of a unique file for each patient (manage the doubles, secure facilities, audit trails, immediate access to the data...). In progress.

- **Linkage to the French Health Insurance medico-administrative database** (SNIIRAM database): regulatory issues are not yet answered. This database contains medical consumption from all French people.

- To implement a **multi-drug pharmaco-epidemiological surveillance system**
Towards a generalized MS treatment registry?

Why?

- **Increase in the therapeutic arsenal** means an increase in the number of Risk Management Plans
- **Need to evaluate treatment switches**
- **Need to evaluate succession/association of DMTs**

- The accumulation of phase IV studies is more and more difficult to manage for investigators
- Neurologists need to think of a **proactive and systematic approach**, always challenged with benefits, in order to **optimize the benefit/risk balance of the drugs**, all along the patient’s life
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Dr. Anne CASTOT (ANSM, chair)
Dr. Fanny ROCHER (CRPV)
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With the support of:

ANSM
Société Française de Neurologie
Fédération Française de Neurologie
Biogen-Idec France
This work has been supported by a grant provided by the French State and handled by the "Agence Nationale de la Recherche," within the framework of the "Investments for the Future" programme, under the reference ANR-10-COHO-002

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Acknowledgements
We would like to thank all participating centres, neurologists, radiologists, biologists, CRA, engineers, and every person taking part into the project.