



**OFSEP**

**Observatoire Français  
de la Sclérose en Plaques**

Access to a powerful  
epidemiological tool  
dedicated to Multiple Sclerosis

The French  
MS registry,

Observatoire Français  
de la Sclérose  
en Plaques.



Hospices Civils de Lyon  
Lyon University Hospital



ANR

[www.ofsep.org](http://www.ofsep.org)

# OFSEP, from care to research and from research to patient care, increasing knowledge about Multiple Sclerosis

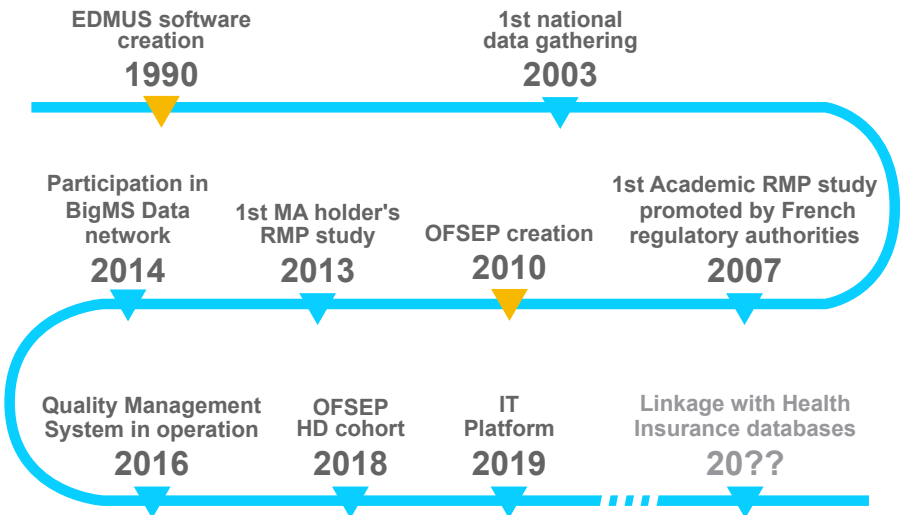
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OFSEP, the French Multiple Sclerosis registry, is a joint project between French neurologists, neuroradiologists and biologists working on Multiple Sclerosis (MS).

This huge database aims at being a key epidemiological tool to serve the scientific community, encouraging research on MS and allowing to improve patient care.

- ✓ A powerful tool built by the medical and scientific community
- ✓ The biggest national MS registry in the world with more than 60,000 patients to date, representing half of French MS patients
- ✓ A standardized collection over years
- ✓ Available real-world data
- ✓ More than 400 committed experts working together, involved in patients' care

## Our success story in a few dates

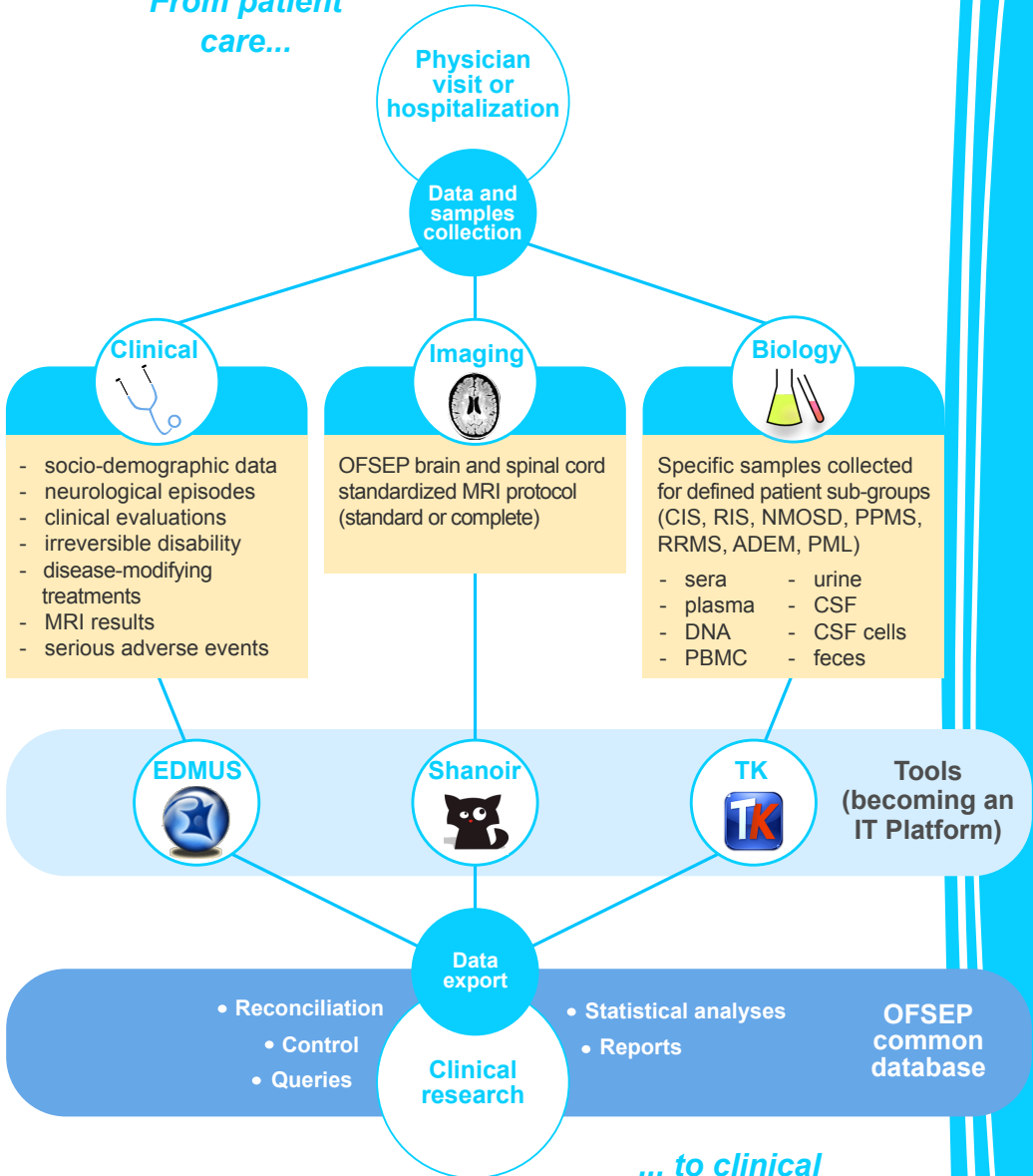


RMP = Risk Management Plan  
MA = Marketing authorization

# Data collection

- Standardized disease description since 1990
- Minimal set of data implemented since 2013
- Tools and guidelines have constantly evolved ever since, always complying with the latest international recommendations

*From patient care...*



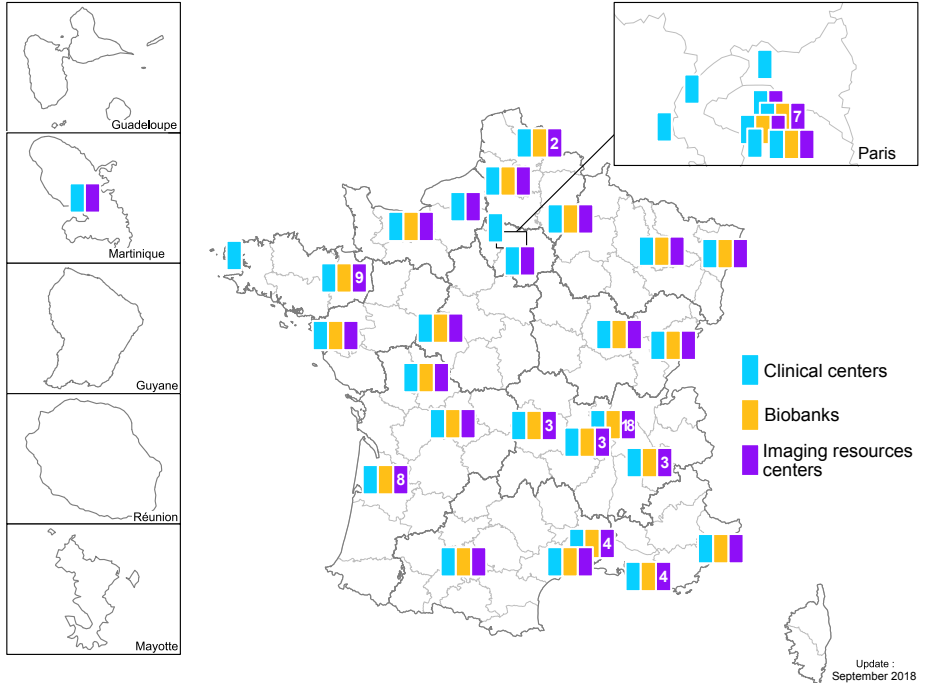
*... to clinical research*

CSF = Cerebrospinal fluid  
 DNA = Deoxyribonucleic acid  
 PBMC = Peripheral blood mononuclear cells

# OFSEP Participating expert centers

Data is mainly collected by French MS reference clinical centers (CRC SEP), nominated by the regional health authorities. They are familiar with the quality requirements of data collection.

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- ✓ MS expertise (diagnosis, follow-up, treatment management)
- ✓ Certifications (Good clinical practice, Neurostatus)
- ✓ Knowledge of important outcomes
- ✓ Multi-disciplinary approach (MRI, biology, quality of life...)
- ✓ Fully conversant with regulatory requirements and quality control
- ✓ Close collaboration with other clinical centers
- ✓ Research, teaching and training

# Introducing a new cohort: OFSEP High Definition (HD)



OFSEP entered a new phase by implementing a new project, the OFSEP HD cohort.

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- ✓ **Promoter:** *EDMUS Foundation (OFSEP)*
- ✓ **Funder:** *ANR (French national research agency)*
- ✓ **Scientific coordinators:** *Profs Sandra Vukusic & Francis Guillemin*
- ✓ **Status:** *Ongoing*
- ✓ **Start date:** *July, the 1st 2018*
- ✓ **Expected inclusions:** *5,000 patients from MS reference clinical centers*
- ✓ **Collected data:** *Clinical, socio-demographical, patient-reported outcomes (PRO), treatments, safety data, MRI exams and biological samples (incl. neurofilament dosage and biobanking)*

## A new cohort, for which purpose?

- Evaluating the impact of MS on multimodal dimensions of disability and identifying causal factors of disease progression through different key moments of the disease course.
- Thereby making it possible to develop personalized predictive tools to help in making decision to start, maintain or adapt care management.

## Why is this project innovating?

- ✓ A regular yearly follow-up with specific additional data
- ✓ A combined utilization of clinical, biological, MRI and PRO
- ✓ A focus on key moments over the disease course
- ✓ A step forward in personalized medicine



## A quality management strategy in line with our practice

Quality is one of our main concerns. Therefore, we built an ISO-9001 based Quality Management System, including a continuous improvement approach. To guarantee our biological samples quality, all our biobanks are certified according with the French NF S96-90 norm. In addition, numerous actions are undertaken to assure our data quality.

### ✓ EDMUS data quality control



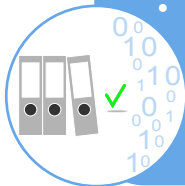
- Control of aberrant data at entry, alert messages
- Integrated data verification tool generating queries on missing or incoherent minimal data
- Additional queries sent by our coordination team twice a year for more specific or complex tests

### ✓ Support to centers



- Documents, tools, users' guides, regular training provided
- Center-based quality reports
- Regular instruction reminders
- Internal newsletter

### ✓ Center audits



- Audit of data collection's organization
- Data quality control
- Action plan defined and follow-up of the actions
- Audit of all MS reference clinical centers

## Simplified regulatory aspects for you

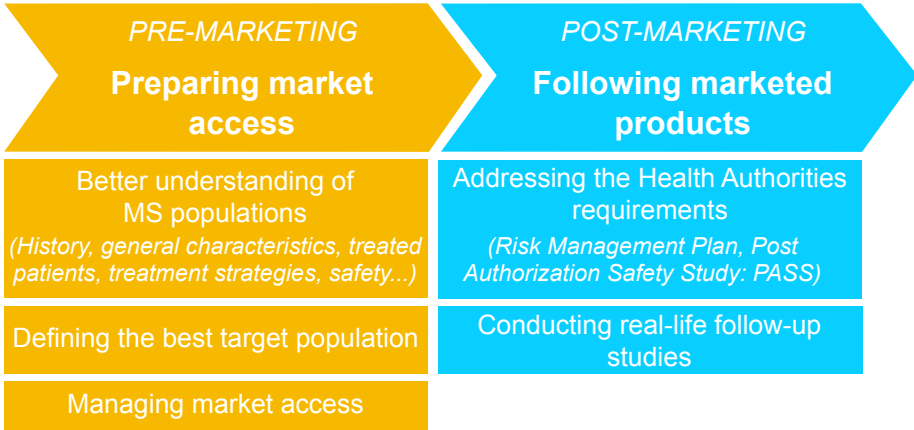
OFSEP cohorts have been authorized in France. Our authorization covers data collection, anonymized export by participating centers, pooling and statistical analysis by the OFSEP National Coordination team.

For other data circuits, please contact us.

# Benefit from our expertise in observational studies

## What you may need

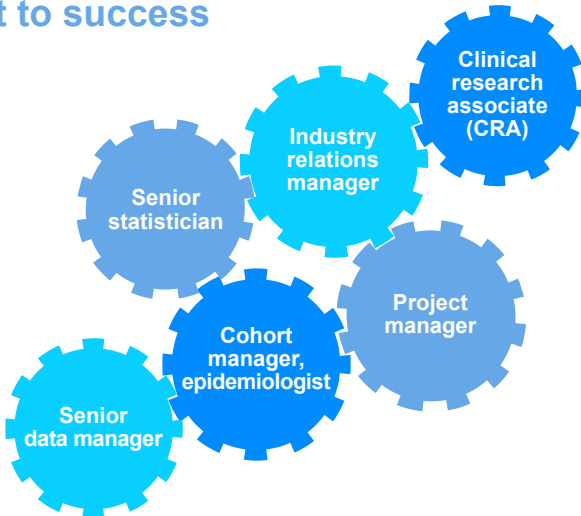
Accurate data can help you fulfill some of your requirements, such as:



## What OFSEP can do for you

OFSEP is collecting data (minimal or project-specific) to respond to your issues. Our dedicated team will use all their MS expertise to assist you in setting your projects up, from global support to a totally "à la carte" service, always anticipating the next steps of our collaboration.

## Meet our expert dedicated team and drive your project to success



# Different types of projects addressing each of your questions

Whatever the project, OFSEP has a solution to answer your question. Contact us to find which type of project would be the most suitable for you.

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Counting	Scientific project on available data	Scientific project on data to be collected
Data collected routinely and present in the centralized database* (using OFSEP minimal form)		Specific additional data if needed
Simple counting without comparisons	Advanced statistical analyzes with comparisons	
<i>Example: How many people switched from drug A to drug B?</i>	<i>Example: What is the safety profile of drug B in real-life conditions?</i>	<i>Example: PASS of drug C, including patient-reported outcomes and pregnancy.</i>

*\*data present at the time of project submission*

## Some examples of the services we offer

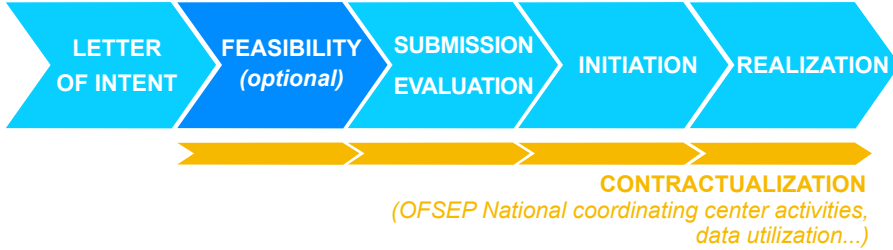
- ✓ **Project management**, center coordination, according to the regulation requirements and to our quality management system
- ✓ **Data management**, standard or project-specific data clarifications, SAS database generation, programming of aggregated tables for data transfer
- ✓ **Statistical analyses**, number needed of subjects, statistical analysis plan, basic or complex statistical analyses
- ✓ **Scientific publication support**, epidemiology, statistical methodology, bibliography



# How to begin a collaboration?

You can request access to the data and biological samples collected by OFSEP by submitting a research project, following the steps described below.

## Project life cycle



- i** You will find the submission form on our website, [www.ofsep.org](http://www.ofsep.org), section "Data and samples access".

## Why do we propose a feasibility phase?

A feasibility analysis can help you facilitate your project initiation by giving you accurate information and expert advice:

- Providing you with knowledge about our database to help you define your project (what do we have, what could we collect, etc.)
- Writing a short counting report describing the requested available data
- Helping you to strengthen your study protocol before you submit it to the Healthcare Authorities thanks to our scientific and methodological expertise on real-world data

Should you need further information or if you want to talk with our industry or academic relations manager, please contact us at [projects@ofsep.org](mailto:projects@ofsep.org)



## Acknowledgements

We would like to thank the patients and all the neurologists, radiologists, biobanks, CRAs, engineers, technicians, nurses, secretaries involved in data collection and cleaning, and the hospitals, healthcare networks and universities involved in the project.

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List of centers by center size, investigators (neuroradiologist):

Lyon, Prof Sandra VUKUSIC (Prof François COTTON). Nancy, Prof Marc DEBOUVERIE, Prof Francis GUILLEMIN (Prof René ANXIONNAT). Rennes, Prof Gilles EDAN (Dr Jean-Christophe FERRE). Toulouse, Prof David BRASSAT, Prof Michel CLANET (Prof Isabelle BERRY). Bordeaux, Prof Bruno BROCHET (Prof Vincent DOUSSET). Strasbourg, Prof Jérôme DE SEZE (Dr Stéphane KREMER). Lille, Prof Patrick VERMERSCH. Paris Salpêtrière, Prof Catherine LUBETZKI (Prof Damien GALANAUD). Nice, Dr Christine LEBRUN-FRENAY (Dr Lydiane MONDOT). Caen, Prof Gilles DEFER. Montpellier, Prof Pierre LABAUGE (Dr Nicolas MENJOT DE CHAMPFLEUR). Dijon, Prof Thibault MOREAU (Dr Frédéric RICOLFI). Nantes, Prof David LAPLAUD (Dr Hubert DESAL). Besançon, Dr Eric BERGER. Clermont-Ferrand, Prof Pierre CLAVELOU (Dr Béatrice CLAUSE). Marseille, Prof Jean PELLETIER (Hervé BRUNEL). Nîmes, Dr Giovanni CASTELNOVO, Prof Eric THOUVENOT. Paris Saint-Antoine, Prof Bruno STANKOFF. Poissy, Dr Olivier HEINZLEF. Rouen, Dr Bertrand BOURRE (Dr Emmanuel GERARDIN). Amiens, Dr Abdullatif AL KHEDR (Dr Jean-Marc CONSTANS). Paris Rothschild, Dr Olivier GOUT (Dr Julien SAVATOVSKY). Fort-de-France, Prof Philippe CABRE. Limoges, Prof Laurent MAGY (Dr Marie-Paule BONCOEUR-MARTEL). Grenoble, Dr Olivier CASEZ (Dr Sylvie GRAND). Saint Etienne, Prof Jean-Philippe CAMDESSANCHE (Dr Claire BOUTET). Tours, Dr Anne-Marie GUENNNOC (Prof Jean-Philippe COTTIER). Créteil, Prof Alain CREANGE. Pontoise, Dr Corinne POTTIER. Poitiers, Prof Jean-Philippe NEAU (Dr Rémy GUILLEVIN). Kremlin-Bicêtre, Dr Céline LABEYRIE. Corbeil-Essonnes, Dr Ivania PATRY (Dr Sylvie GONIN). Versailles, Dr Chantal NIFLE. Saint Denis, Dr Thomas DE BROUCKER. Reims, Prof Ayman TOURBAH (Dr Laurent PIEROT).

## ✓ Entrust us with your project management

- ✓ A massive standardized database, enhanced by the medical and scientific community since 1990
- ✓ Benefit from our MS epidemiological and methodological skills
- ✓ Different types of projects according to your needs
- ✓ "À la carte" or global services provided by our expert dedicated team
- ✓ A permanent involvement in quality management including a continuous improvement approach

OFSEP is the best partner for your projects, from simple counts to complex post-authorisation safety studies.

## ✓ These little things that make a great difference



For further information, please contact us.



## Contact information

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