



OFSEP

**Observatoire Français
de la Sclérose en Plaques**

FROM LIFE TO SCIENCE

MS DATA IS OUR COMMITMENT



OFSEP

Observatoire Français
de la Sclérose en Plaques

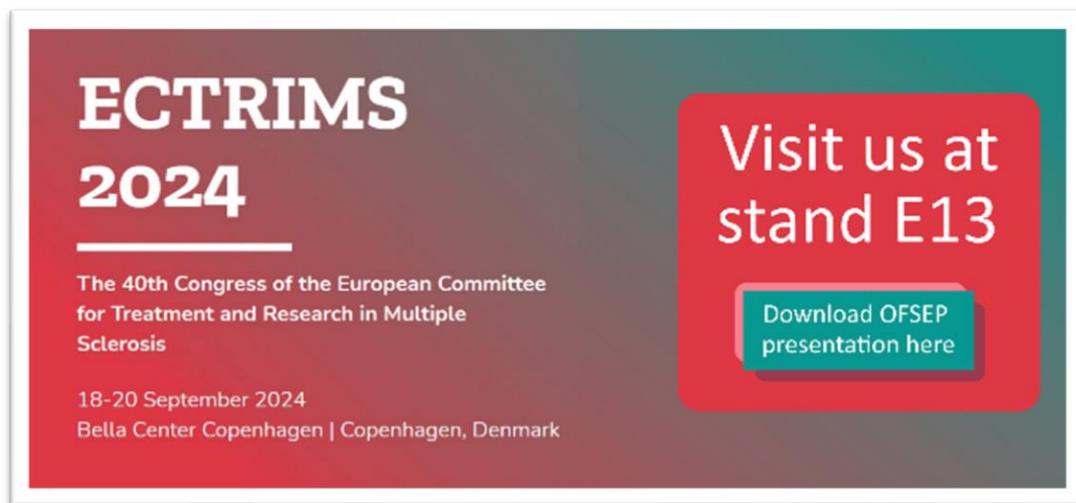
OFSEP, the French MS registry

ECTRIMS 2024



OFSEP

Scientific presentations at ECTRIMS 2024



**ECTRIMS
2024**

The 40th Congress of the European Committee
for Treatment and Research in Multiple
Sclerosis

18-20 September 2024
Bella Center Copenhagen | Copenhagen, Denmark

Visit us at
stand E13

Download OFSEP
presentation here



Wednesday 18 September

Poster session 1

🕒 16:15 - 18:15 - Room D3

P018 The NOMADMUS French Cohort: Unveiling the Evolving Landscape of NMOSD and MOGAD Diagnosis and Treatment (2010-2023). Thomas Roux.

P034 Analysis of health care utilization before the diagnosis of radiologically isolated syndrome does not support the existence of a prodromal phase in multiple sclerosis. Christine Lebrun-Frenay.

P286 From Big Data to PRIMUS: a precision medicine platform supporting neurologists in selecting treatments for multiple sclerosis with explainable-by-design analytics. Stanislas Demuth.

P339 Time to multiple sclerosis reactivation after anti-CD20 treatment discontinuation: a retrospective observational study from 4 large French MS Reference centers in the OFSEP national Database. Hugo Viguier.

Thursday 19 September

Scientific Session 10: Treating MS - real-world evidence

🕒 15:27 - 15:34 - Room D3

O089 - Is there therapeutic inertia in women with MS?

Antoine Gavaille

Poster session 2

🕒 16:45 - 18:45 - Room D3

P508 Evaluation of the frequency of oligoclonal bands restricted to the CSF and its predictive value on residual disability and risk of relapse, in MOGAD adult patients – The MOGADOC study. Julie Pique.

P577 Acute clinical events identified as relapses but with stable MRI in multiple sclerosis. Antoine Gavaille.

P713 Evaluation of an automatic segmentation tool to help radiologists and neurologists detect spinal cord lesions from T2 and STIR acquisitions in patients with MS. Baptiste Lodé.

P844 Anti-CD20 therapies in drug-naïve primary progressive multiple sclerosis patients: A multicenter real-life study. Marion Hay.

Friday 20 September

Scientific Session 20: Aging with MS - implications for treatment

🕒 11:19 - 11:26 - Room A1

O129 - Comparison of High Efficacy Treatment Discontinuation and Continuation among Stable Multiple Sclerosis Patients after 50.

Guillaume Jouvenot

The French MS registry

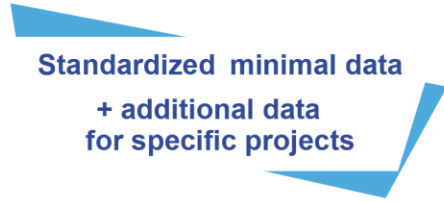
Collected data

Clinical data collection

FROM LIFE ...



- Data reconciliation
- Control
- Queries
- Statistical analyses
- Reports



... TO SCIENCE

MS DATA IS OUR COMMITMENT

- Clinical data collected during routine follow-up visits, usually at least once a year, retrospectively at the first visit and prospectively thereafter
- Minimal mandatory data set:
 - demographic and socioeconomic characteristics
 - neurological episodes
 - disability
 - brain and spinal cord MRI reports
 - disease-modifying treatments
 - serious adverse events
- Patients with RIS, CIS, MS, NMOSD or MOGAD followed up in a participating centre are eligible
- All French MS expert centers and several peripheral centers participate in data collection

Clinical data collection

About



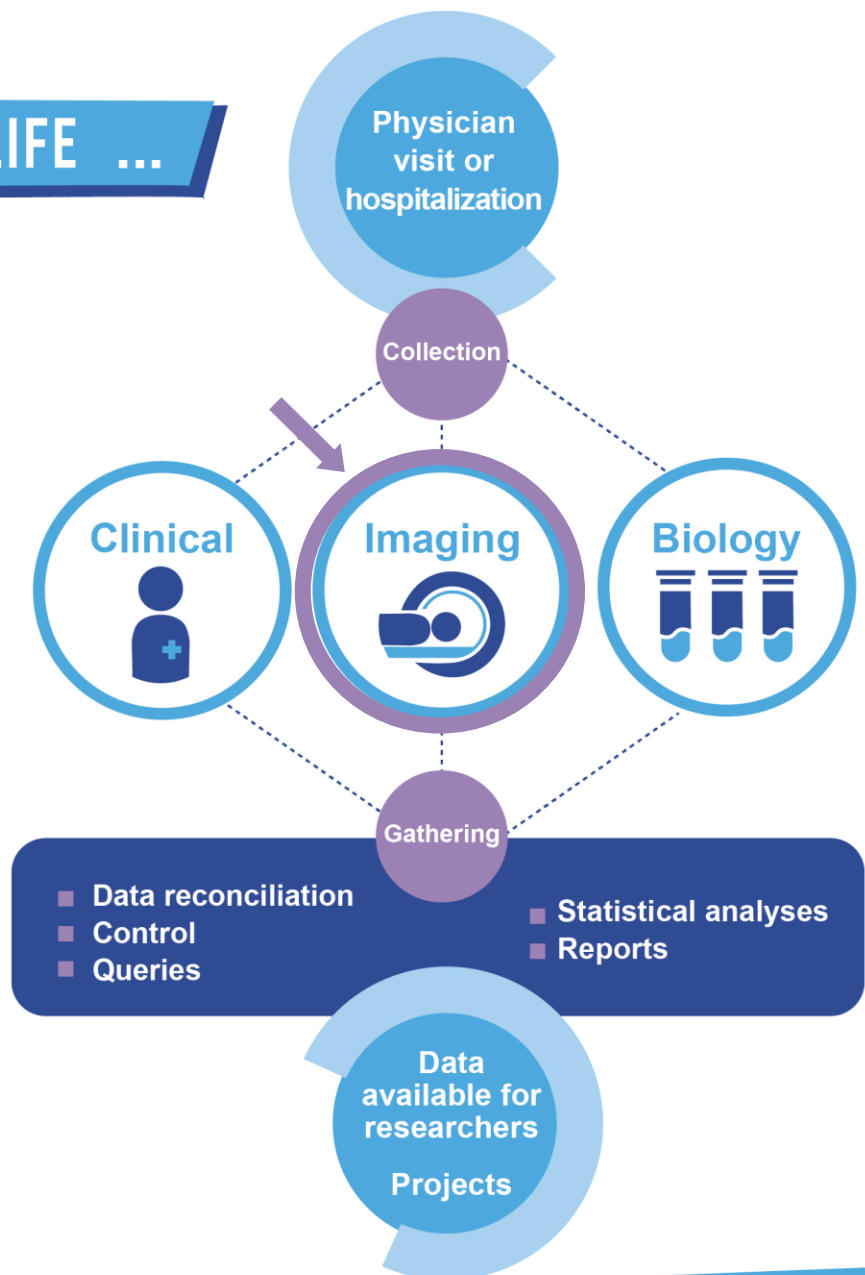
20,000
patients
followed-up
every year

1,100,000 person-years of disease

> 500,000 person-years of prospective follow-up

Imaging data collection (MRI)

FROM LIFE ...



Data collection during patient visit

Standardized minimal data + additional data for specific projects

Data gathered in the OFSEP common database

... TO SCIENCE

MS DATA IS OUR COMMITMENT



OFSEP cerebral and spinal cord MRI acquisition protocol*,

a consensus within the scientific community, feasible on all equipment and compatible with clinical acquisition times

Recommended sequences:

- **Brain:** 3D FLAIR, 3D T1, DWI, 3D T1 gado (*if necessary*)
- **Spine:** T2 SAG, T1 gado SAG (*if necessary*)

DICOM files stored on a centralized neuroimaging platform

* Brisset JC, Kremer S, Hannoun S, et al. New OFSEP recommendations for MRI assessment of multiple sclerosis patients: special consideration for gadolinium deposition and frequent acquisitions. *J Neuroradiol.* 2020;47(4):250-258.

Last year

> 2,200
new patients

> 17,000
exams

> 100,000
sequences

11,348
patients with
at least one
MRI scan

44,742
brain exams

391,973
brain sequences

18,811
spinal cord exams

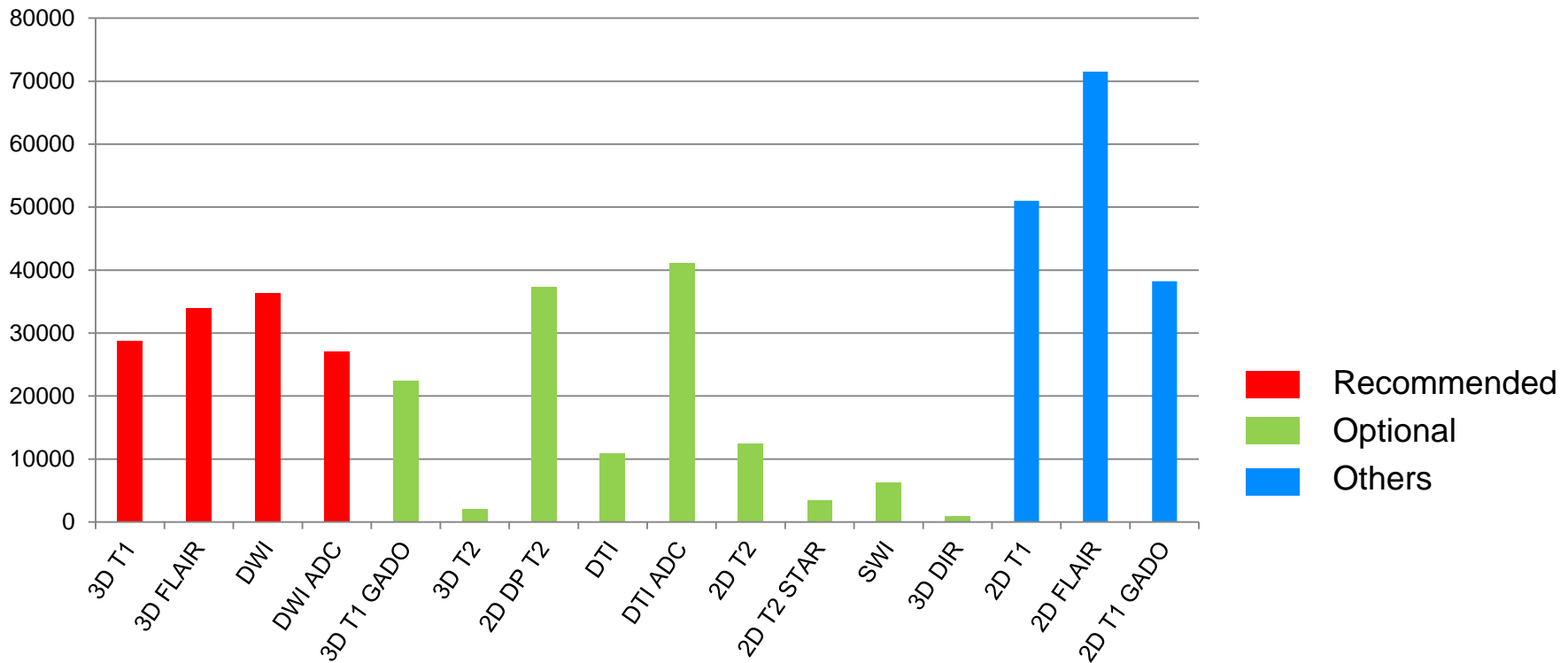
101,607
spinal cord sequences

Brain MRI

Main sequences

44,742
brain exams

391,973
brain sequences



Siemens: 54%
Philips: 23%
GE: 22%

1.5T: 46%
3T: 54%

44,742
brain exams

391,973
brain sequences

	Number of patients					
	1 TP*	2 TP	3 TP	4 TP	5-10 TP	> 10 TP
Brain IRM	2,532	1,670	1,156	959	2,206	339

* Time point

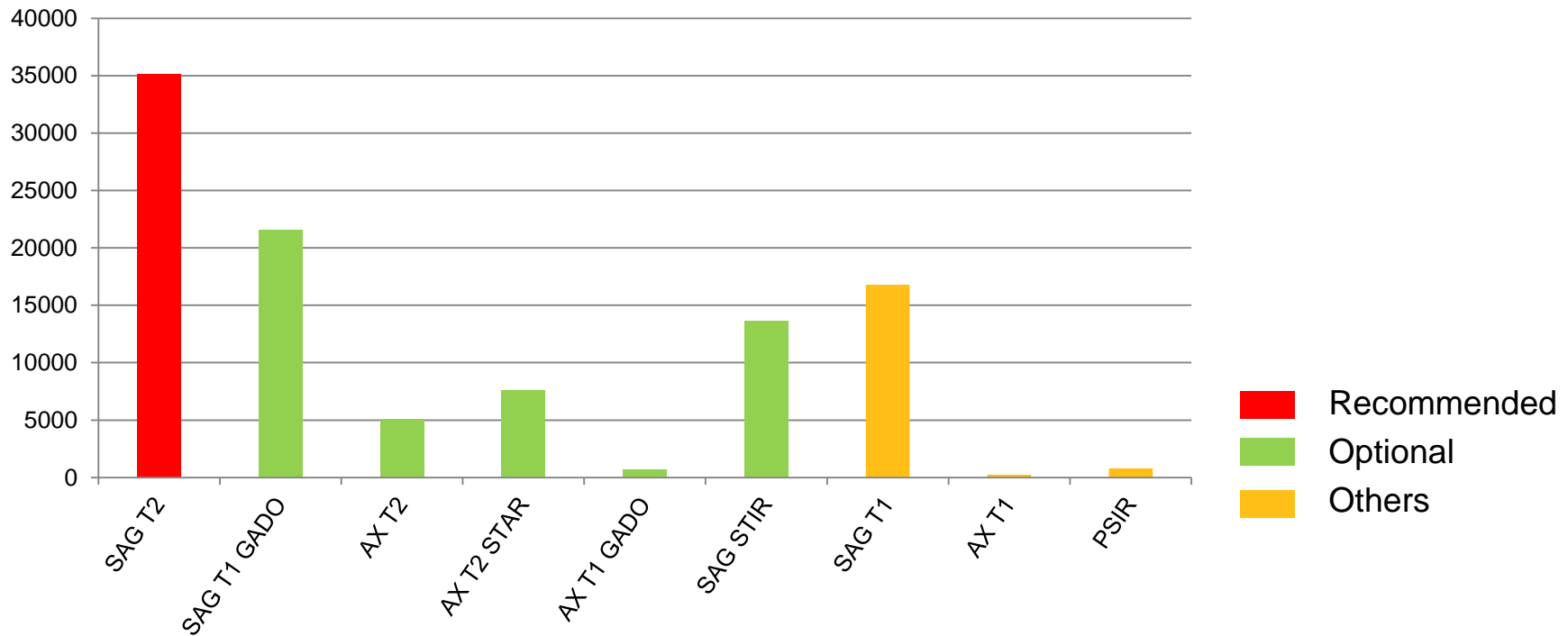
Disease form at the first MRI	N
RIS	155
First attack	3,070
RRMS	5,344
SPMS	993
PPMS	837
NMOSD	257
MOGAD	293
Not currently identified	168

Spinal cord MRI

Main sequences

18,811
spinal cord exams

101,607
spinal cord sequences



Siemens: 64%

Philips: 17%

GE: 18%

1.5T: 67%

3T: 33%

18,811
spinal cord exams

101,607
spinal cord sequences

Number of patients						
	1 TP*	2 TP	3 TP	4 TP	5-10 TP	> 10 TP
Spinal cord MRI	2,464	1,234	671	395	515	20

* Time point

Disease form at the first MRI	N
RIS	155
First attack	3,070
RRMS	5,344
SPMS	993
PPMS	837
NMOSD	257
MOGAD	293
Not currently identified	168

Biology samples collection

FROM LIFE ...

Physician
visit or
hospitalization

Data collection
during patient visit

Collection

Clinical

Imaging

Biology

Standardized minimal data
+ additional data
for specific projects

Gathering

- Data reconciliation
- Control
- Queries

- Statistical analyses
- Reports

Data gathered in the
OFSEP
common database

Data
available for
researchers
Projects

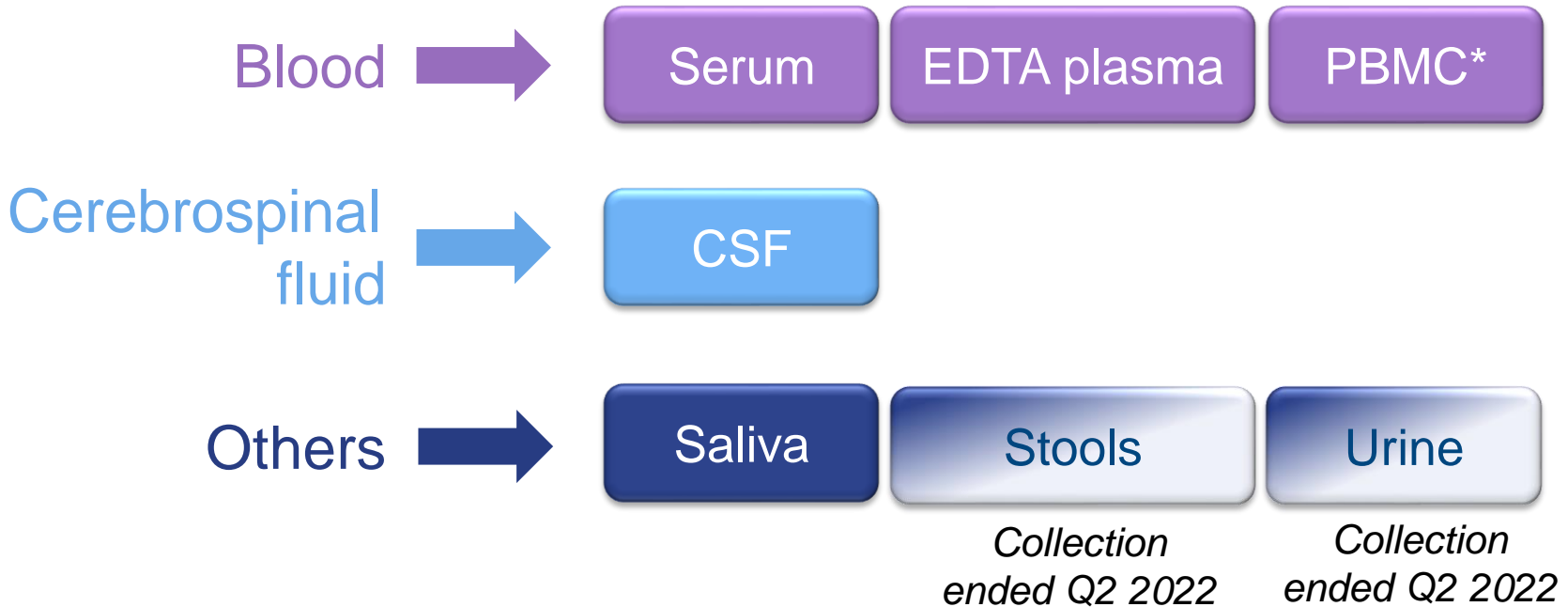
... TO SCIENCE

MS DATA IS OUR COMMITMENT

Integrated cohorts with biological samples

Cohort	Iterative sample
Radiologically isolated syndromes (RIS)	Every year until conversion
Clinical isolated syndromes and relapsing-remitting MS (CIS / RRMS) 'First Attack' - Sample at less than 6 months of the first inflammatory event of the central nervous system - DMT naive at first sample	At year 1, 3 and 5 and during a relapse
Primary progressive multiple sclerosis (PPMS) - Less than 6 years disease duration - Untreated patient	At year 3 and 6
Neuromyelitis optical spectrum disorders (NMOSD) and Myelin oligodendrocyte glycoprotein-IgG (MOG-IgG) associated disorder (MOGAD) – NOMADMUS cohort	At year 1, 3 and 5 for patients included after the first relapse and before the second one. Additional sample during a relapse.
Acute Disseminated EncephaloMyelitis (ADEM)	No
Progressive Multifocal Leukoencephalopathy (PML)	No
Covid-19 - Sampling within 3 months after biological confirmation of the diagnosis by PCR or onset of symptoms	No
MS patients included in High Definition (HD) cohort	Every 2 years

Biological samples



*Peripheral blood mononuclear cells

7,318 biological samples collected among 5,016 patients.

Patients‡	N. of patients	Blood*	PBMC	CSF**	Saliva	Urine***	Stools***	N iterative
RIS	207	207	201	81	47	134	6	32
First attack	1,215	1,215	829	595	93	683	33	304
RRMS	2,201	2,201	302	171	27	220	29	1,098
SPMS	413	413	24	13	2	22	2	183
PPMS	417	417	277	185	16	224	13	160
PML	10	10	10	2	0	9	0	0
NMOSD	369	369	363	28	56	224	3	56
MOGAD	285	285	279	17	52	168	4	57
ADEM	21	21	21	4	0	15	0	1
Covid-19***	66	66	65	0	0	21	0	0

‡ some patients could be counted several times if they enter an new cohort during the follow-up (ex : RIS => FA)

* serum, EDTA plasma, DNA

** cerebrospinal fluid

*** closed collection

Merging with medico- administrative database

French National Insurance database

Merging with medico-administrative database

- **French National Insurance database (SNDS)**
 - Reimbursements made by all health insurance plans (consulting, drug dispensing, medical procedures, biological exams, issuance of technical aids, long-term disease)
 - Hospital medical activity (hospitalizations, diagnoses, medical procedures, external consultations)
 - Death causes
- **Allows to access non-specific MS data** including comorbidities, co-prescriptions, recourse to care...

Merging with medico-administrative database



SNDS extraction

2009 ~ 2019 (planned until 2024)

85%
successfully
merged

>40,000
merged patient files

The French MS registry

Projects and nested cohorts

FROM LIFE ...

Physician
visit or
hospitalization

Data collection
during patient visit

Collection

Clinical



Imaging



Biology



Standardized minimal data
+ additional data
for specific projects

Gathering

- Data reconciliation
- Control
- Queries

- Statistical analyses
- Reports

Data gathered in the
OFSEP
common database

Data
available for
researchers
Projects

... TO SCIENCE

MS DATA IS OUR COMMITMENT

OFSEP HD cohort

OFSEP HD cohort Inclusion criteria

- **Diagnosis of multiple sclerosis** according to the most recent criteria
 - Age \geq 15 years
 - **Irreversible disability \leq 7.0 (permanent use of a wheelchair) on EDSS**
 - Followed up in one **MS expert center**
 - New cases diagnosed after the beginning of the study
- or
- For patients diagnosed before the beginning of the study, **regular follow-up** (at least one visit every two years since the date of the first EDSS assessment) with **prospective collection of minimal dataset in EDMUS since 2011**

Follow-up

- Annual follow-up (\pm 2 months) with rebaseline at the first disease activity
- Continuation of the study at least until the end of 2026

Specific data every year

- PRO : sociodemographic data, medical background, quality of life (EQ5D-5L, SF-12, MusiQoL), tobacco, cannabis and alcohol consumption
- Walk test (T25FW), test of upper extremity function (9HPT), test for the detection of information processing speed (CSCT)
- MRI (post-processing) : T2 and new T2 lesions, cerebral volume and atrophy

Population

- 2842 patients included between July 2018 and September 2020.
- At inclusion
 - 73% ♀
 - age = 43 years (\pm 12)
 - disease duration = 11 years (\pm 9)
 - prospective follow-up = 8 years (\pm 7)
 - 80% RRMS, 14% SPMS, 6% PPMS
 - untreated patients or all types of ongoing treatments

Biocollection

- Blood sample and dosages (at inclusion and every two years) :
NF-L, GFAP, vitamin D

NOMADMUS cohort

- **Inclusion criteria**

- Patients meeting the international NMOSD criteria (Wingerchuk criteria 1999 and 2006, IPND 2015) including Aquaporin 4 – IgG positive patients (AQP4+)

- or Isolated, recurrent or not, acute extensive transverse myelitis

- or Isolated atypical optic neuritis

- or Myelin Oligodendrocyte Glycoprotein – IgG positive patients associated disease (MOGAD)

- or MOGAD-like patients (MOG-IgG negative patients presenting clinical and/or radiological MOGAD features)

- The **NOMADMUS expert group** validates inclusions with a focus on double seronegative (AQP4 and MOG) patients and MOGAD-like patients

- **Minimal mandatory data** set specific to NMOSD/MOGAD

- 2369 patients included
- 1184 patients with biological samples (serum, plasma, PBMC, CSF...) in a dedicated biobank or in the OFSEP biobank
- 1444 patients with at least one MRI in a dedicated imaging bank or in the OFSEP imaging bank

RIS cohort

Inclusion criteria

- MRI lesions suggestive of multiple sclerosis according to 2005 and 2017 MS DIS criteria
- EDSS=0
- Index MRI indication not consistent with demyelinating disease

Exclusion criteria

- Any focal neurological manifestation prior to the acquisition of the MRI

Mandatory data set specific to RIS and RIS conversion

- The **RIS expert group** validates all inclusions
- The RIS expert group is member of the Radiologically Isolated Syndrome Consortium (RISC)
- **714** RIS 2023 patients including 245 MS conversion

Publications

Reference publications

Confavreux C et Al. **EDMUS, a European database for multiple sclerosis.** J Neurol Neurosurg Psychiatry 1992; 55: 671-676

Vukusic S et Al. **Observatoire Français de la Sclérose en Plaques (OFSEP): A unique multimodal nationwide MS registry in France.** Mult Scler. 2020;26(1):118–22

Brisset JC et Al. **New OFSEP recommendations for MRI assessment of multiple sclerosis patients: Special consideration for gadolinium deposition and frequent acquisitions.** J Neuroradiol. 2020;47(4):250-258. doi:10.1016/j.neurad.2020.01.083

Brocard G et Al. **The biological sample collection of the OFSEP French MS registry: An essential tool dedicated to researchers.** Multiple Sclerosis and Related Disorders. 2023 Sep;77:104872

All publications

OFSEP publications are available on our website:

<https://www.ofsep.org/en/publications-en>

Acknowledgement



This work was done within the framework of OFSEP, the French multiple sclerosis registry

Data collection 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 "France 2030" programme, under the reference ANR-10-COHO-002 OFSEP; and the support of the "Eugène Devic EDMUS Foundation against multiple sclerosis"





OFSEP

**Observatoire Français
de la Sclérose en Plaques**

FROM LIFE TO SCIENCE

MS DATA IS OUR COMMITMENT