

OPISEP - Profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment

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General	
Identification	
Detailed name	Profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment
Sign or acronym	OPISEP
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Numéro CNIL 908245, CPP = NA, AFSSAPS = NA
General Aspects	
Medical area	Neurology
Others (details)	multiple sclerosis MS-RR (Relapsing - Remitting)
Keywords	central nervous system, first attack under IMD treatment
Scientific investigator(s) (Contact)	
Name of the director	VIGNAL
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Unit	Sanofi Aventis
Collaborations	
Funding	
Funding status	Private

Details	Sanofi-aventis France
Governance of the database	
Sponsor(s) or organisation(s) responsible	Sanofi-aventis France
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Describe the profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment.
Inclusion criteria	? Patient of legal age (? 18 years) ? Patient suffering from MS-RR ? Patient having, after initiation the first immunomodulator treatment, a recent first attack (less than 10 days) ? Patient accepting to participate in the survey Criteria for non-inclusion ? Patient participating in clinical research (pre-market authorization)
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population

Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2011
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	Less than 500 individuals
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Face to face interview
Paraclinical data (detail)	MRI
Biological data (detail)	Search for IFN neutralizing antibodies
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Others
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Other (detail)	EDSS scale
Procedures	
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	methods for accessing the database are currently being defined
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only