RATIO - Research Axed on Tolerance of BIOtherapies

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General	
Identification	
Detailed name	Research Axed on Tolerance of BIOtherapies
Sign or acronym	RATIO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL
General Aspects	
Medical area	Endocrinology and metabolism Infectious diseases
Pathology (details)	Infections
Health determinants	latrogenic Medicine
Keywords	Anti-TNF-alpha, tolerance
Scientific investigator(s) (Contact)	
Name of the director	Mariette
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Organization	AP-HP Hôpital
Collaborations	
Funding	
Funding status	Mixed

Details

- Institut National pour la Santé et la Recherche Médicale- Laboratoire Abbott- Laboratoire Schering Plough- Laboratoire Wyeth

Governance of the database	
Sponsor(s) or organisation(s) responsible	AP-HP Hôpital Bicêtre
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Institut National de la Santé et de la Recherche Médicale
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Agence Française de Sécurité Sanitaire des Produits de Santé
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Additional information regarding sample selection.	Patients enrolled at time opportunistic infection occurs and subsequently monitored over a prolonged period.
Database objective	
Main objective	To describe cases of opportunistic infection, severe bacterial infection and lymphoma in patients who are receiving or have received anti-TNF-alpha therapy.
Inclusion criteria	- Men or women - receiving or have received anti- TNF? therapy
Population type	
Age	Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
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)	02/2004
Date of last collection (YYYY or MM/YYYY)	01/2007
Size of the database	
Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	57 711 par an / by year
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Capture-recapture system used to control and improve recorded data for each case.
Participant monitoring	Yes
Details on monitoring of participants	3-year observational follow-up

Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	<u>http://rheumatology.oxfordjournals.org/content/50/</u> <u>1/222.long</u>
Link to the document	http://tinyurl.com/HAL-RATIO
Description	Liste des publications dans HAL
Link to the document	http://tinyurl.com/PUBMED-RATIO
Description	Liste des publications dans Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only