

VISION - Longitudinal study on patients with severe Crohn's disease that did not respond to treatment and who are initiating treatment with anti-TNF alpha

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General

Identification

Detailed name	Longitudinal study on patients with severe Crohn's disease that did not respond to treatment and who are initiating treatment with anti-TNF alpha
Sign or acronym	VISION
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1379382

General Aspects

Medical area	Gastroenterology et hepatology
Keywords	psychometric validation, questionnaire, satisfaction, patients, anti-TNF alpha

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Private
Details	Abbott France

Governance of the database

Sponsor(s) or organisation(s) responsible	Abbott 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 made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Random selection of 30 gastroenterologists from a list of French gastroenterologists who follow and treat patients for their Crohn's disease
Database objective	
Main objective	Validate a new satisfaction questionnaire for patients with regards to their treatment with Anti TNF in Crohn's disease at a severe and evolving stage
Inclusion criteria	Patients suffering from severe and evolving Crohn's disease and who have not responded to the treatments despite a complete and adapted protocol of corticotherapy and/or an immunosuppressant or intolerant to such treatments or that have medical contraindications and who move to an anti TNF treatment
Population type	
Age	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 National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2010

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 300

Data

Database activity Current data collection

Type of data collected Clinical data
Declarative data

Clinical data (detail) Direct physical measures

Declarative data (detail) Paper self-questionnaire

Presence of a biobank No

Health parameters studied Others

Other (detail) Satisfaction questionnaire

Procedures

Classifications used CIM 10

Participant monitoring Yes

Details on monitoring of participants 3 months of follow-up starting from patient inclusion

Links to administrative sources No

Promotion and access

Promotion

Link to the document <http://tinyurl.com/Pubmed-VISION>

Description List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay) Publications

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only