

# **QALIFF - Prospective observational study on the quality of life of patients with Clostridium difficile infection**

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General	
Identification	
Detailed name	Prospective observational study on the quality of life of patients with Clostridium difficile infection
Sign or acronym	QALIFF
General Aspects	
Medical area	Infectious diseases
Pathology (details)	Clostridium difficile infection
Health determinants	Others (specify)
Others (details)	quality of life, sociodemographic and clinical characteristics of patients, therapeutic management
Keywords	Clostridium difficile infection, quality of life
Scientific investigator(s) (Contact)	
Name of the director	Levy Bachelot
Surname	Laurie
Address	34 avenue Léonard de Vinci 92418 Courbevoie cedex
Organization	MSD
Collaborations	
Participation in projects, networks and consortia	No
Funding	
Funding status	Private
Details	MSD France

Governance of the database	
Sponsor(s) or organisation(s) responsible	MSD France
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
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	Evaluate the consequences of a Clostridium difficile infection (CDI) on the quality of life of the patients through the progression of the EQ-5D profile before/during the episode
Inclusion criteria	<p>Inclusion criteria</p> <ul style="list-style-type: none"> <li>- Adult patient with CDI, regardless of the reason for hospitalisation,</li> <li>- Patient having given informed consent.</li> </ul> <p>Exclusion criteria</p> <ul style="list-style-type: none"> <li>- Patient under 18 years of age.</li> <li>- Patient without telephone.</li> <li>- Patient unable to answer questionnaire (language barrier, cognitive deficits).</li> <li>- Patient refusing to participate.</li> <li>- Patient with chronic Inflammatory Bowel Disease (IBD).</li> <li>- Patient included in a therapeutic trial at the time of the study</li> </ul>
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

Pathology

XI - Diseases of the digestive system

Gender

Male  
Woman

Geography area

National

Detail of the geography area

place of hospitalisation

## Data collection

Dates

Size of the database

Size of the database (number of individuals)

< 500 individuals

Details of the number of individuals

250 theoretical patients

## Data

Database activity

Current data collection

Type of data collected

Clinical data  
Declarative data  
Administrative data  
Utility / preference data

Clinical data (detail)

Direct physical measures  
Medical registration

Declarative data (detail)

Face to face interview  
Phone interview

Presence of a biobank

No

## Procedures

Participant monitoring

Yes

Monitoring procedures

Monitoring by contact with the participant (mail, e-mail, telephone etc.)

Links to administrative sources      No

## Promotion and access

### Promotion

### Access

Terms of data access (charter for data provision, format of data, availability delay)	No data access charter
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Access to aggregated data	Access not yet planned
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Access to individual data	No access
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