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

Head :Levy Bachelot Laurie

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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)<br>(Contact)              |   |
| Name of the director                                 | Levy Bachelot   |
| Surname  | Laurie  |
| Address  | 34 avenue Léonard de Vinci<br>92418 Courbevoie cedex  |
| Organization   | MSD   |
| Collaborations                                       |   |
| Participation in projects,<br>networks and consortia | No  |
| Funding  |   |
| Funding status                                       | Private   |
| Details  | MSD France  |

| Governance of the database   |   |
|--|---|
| Sponsor(s) or organisation(s)<br>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<br>out as part of an interventional<br>study | No  |
| Database objective   |   |
| Main objective   | Evaluate the consequences of a Clostridium difficile<br>infection (CDI) on the quality of life of the patients<br>through the progression of the EQ-5D profile<br>before/during the episode   |
| Inclusion criteria   | <ul> <li>Inclusion criteria</li> <li>Adult patient with CDI, regardless of the reason<br/>for hospitalisation,</li> <li>Patient having given informed consent.</li> <li>Exclusion criteria</li> <li>Patient under 18 years of age.</li> <li>Patient without telephone.</li> <li>Patient unable to answer questionnaire (language<br/>barrier, cognitive deficits).</li> <li>Patient refusing to participate.</li> <li>Patient with chronic Inflammatory Bowel Disease<br/>(IBD).</li> <li>Patient included in a therapeutic trial at the time of<br/>the study</li> </ul> |
| Population type  |   |

|  | Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
|--|---|
| Population covered                           | Sick population   |
| Pathology                                    | XI - Diseases of the digestive system   |
| Gender                                       | Male<br>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<br>Declarative data<br>Administrative data<br>Utility / preference data                                 |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration  |
| Declarative data (detail)                    | Face to face interview<br>Phone interview   |
| Presence of a biobank                        | No  |
| Procedures                                   |   |
| Participant monitoring                       | Yes   |
| Monitoring procedures                        | Monitoring by contact with the participant (mail, e-<br>mail, telephone etc.)   |
|  |   |

| Promotion and access  |                        |
|---|------------------------|
| Promotion   |                        |
| Access  |                        |
| Terms of data access (charter<br>for data provision, format of<br>data, availability delay) | No data access charter |
| Access to aggregated data   | Access not yet planned |
| Access to individual data   | No access              |