

**Addressing the clinical burden of
Clostridium difficile infection (CDI):
Evaluation of the burden, current
practices and set up of a European
Research Platform**

Need for public-private collaboration

A collaborative approach to develop a robust assessment of the burden of CDI, various stakeholders are key.

- To understand current practices and to make gap analysis on existing data in Europe
- To generate evidence to support effective control and prevention strategies.
- To ensure that different perspectives and a broad range of diverse evidence sources are gathered and synthesised.

Objectives of the full project

To develop a detailed understanding of the epidemiology and clinical impact of CDI

- Align and understand the unmet public health needs relating to CDI
- Identify the direct and long term burden on healthcare systems
- Set up a EU research platform that will provide support for potential proof of concept studies of new prevention and treatment strategies

Pre-competitive nature

Need combined expertise, sharing of knowledge

- **Public Health:** Establish priority and burden associated with CDI, identify data sources to track epidemiology and surveillance.
- **Industry:** Conduct research to identifying patients and populations at risk of CDI and develop new preventive and treatment approaches
- **Clinical societies:** Provide the clinical description of the need for surveillance, diagnostic, prevention and treatment of CDI
- **Government and payers:** Assess preventative and curative approaches and establish the burden of CDI
- **Patients/Society:** Develop and communicate the societal impact of CDI

Expected impact on the R&D process

- Synthesize all efforts made at EU level so far to understand the epidemiology and clinical impact of CDI
 - at multinational, national and local level
- Identify and fill key remaining gaps that are key to support effective control and prevention strategies
- Develop a research platform to help the development of alternative prevention and treatment approaches

Suggested architecture of the project

Work Package 1: Epidemiology of C. difficile

Work Package 2: Disease detection and management

Work Package 3: Build a Research Network and Platform

**Work Package 4:
Coordination and project
management**

Expected contributions of the applicants

- Access to **healthcare databases and surveillance data** (including molecular data);
- Understanding of the **limitations of historical datasets and approaches to minimise these issues**;
- Experience of **handling and analysing complex and large data sets from multiple sources**;
- Infectious **disease modelling** expertise;
- Expertise on **cost analysis**;

- Expertise on **testing practice, treatment approach**;
- **Public health program** evaluation expertise;

Expected contributions of the applicants

- Experience with **prospective data collection**;
- Experience in **developing proof of concept** for new prevention and treatment approach;
- Ability to **attract external funding**;

- Ability to **coordinate large research initiatives and to create a scientific network**;
- Proven **project management** skills;
- Ability to **assemble and coordinate multi-stakeholder discussions** form both the public and the private sector and resolve blocks;
- Experience with **public health issue management** and communication of key public health messages.

Expected contributions of the applicants

- The applicant should include in their proposal their suggestions for **creating the full proposal architecture**
- To avoid any duplicate **work the applicants should take into consideration existing projects/initiatives and establish potential collaboration.**
- To translate project outputs into regulatory, clinical and healthcare practices **interactions with Regulatory Agencies/health technology assessment bodies should be proposed**
- A plan for aspects related to **sustainability and facilitating continuation beyond the duration of the project** should also be proposed.

Expected contributions of EFPIA members

- Expertise from pharmaceutical partners:
 - Epidemiology
 - Health Economics
 - Data collection methodology
 - Statistical analysis
 - Disease transmission model
 - Healthcare database analysis
 - Data and project management

- Indicative in-kind budget: EUR 3.0 MM

What's in it for you?

- To be **actor** in a pan-European multidisciplinary based research platform.
- To improve **knowledge** and to **disseminate** evidence based data on *Clostridium difficile* in Europe
- To develop **interaction** between public and private sectors and to improve **transparency** and **communication**.
- To answer *Clostridium difficile* unmet medical needs in Europe.

Key deliverables of the full project

- Create and communicate a multifaceted understanding of CDI epidemiology across the European region.
- Provide insights in the differences in incidence, strain prevalence, reporting and testing practices, current control measures, diagnosis and treatment variations within and between countries.
- Quantify the burden of disease and outcomes related to the disease in different settings.
- Identify potential reservoirs of CDI spread (community paediatrics, food/agriculture, and environment) and the drivers for transmission between and within community and healthcare setting.
- Identify opportunities for innovative prevention and treatment strategies.



Questions?

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