

## Harmonize Objectives

Harmonize will build on EurFMT activities to support implementation of the new EU SoHO Regulation. The achievement of this goal is based on the sub-objectives listed below.

### 1) Expert forum:

- Create a pool of experts from different entities

### 2) Guideline development:

- Guidelines on manufacturing standards of FMT
- Guidelines to comply with oversight requirements
- An approach for the future update of these Guidelines

### 3) Training program:

- Development and Implementation of training programs for stool banks

### 4) Gap Analysis in FMT-related procedures

- Harmonizing data from different EurFMT partners in the EurFMT registry

### 5) Setting up a dialogue with industry stakeholder and regulators

## Work packages

### WP 1

#### Consortium Management

WP leader: European Helicobacter & Microbiota Study Group

### WP 2

#### Guideline Development

WP leader: Leiden University Medical Center, Netherlands

### WP 3

#### Training

WP leader: Aarhus University Hospital, Denmark

### WP 4

#### Gap Analyses and Management

WP leader: Aarhus University Hospital, Denmark and Goethe University Frankfurt, Germany

Join the EurFMT network and get ready for the SoHO regulation!



To prepare for the implementation of the new SoHO regulation, we invite academic experts to join the EurFMT network.



Harmonize

#### The Harmonize Beneficiaries



#### Expert network



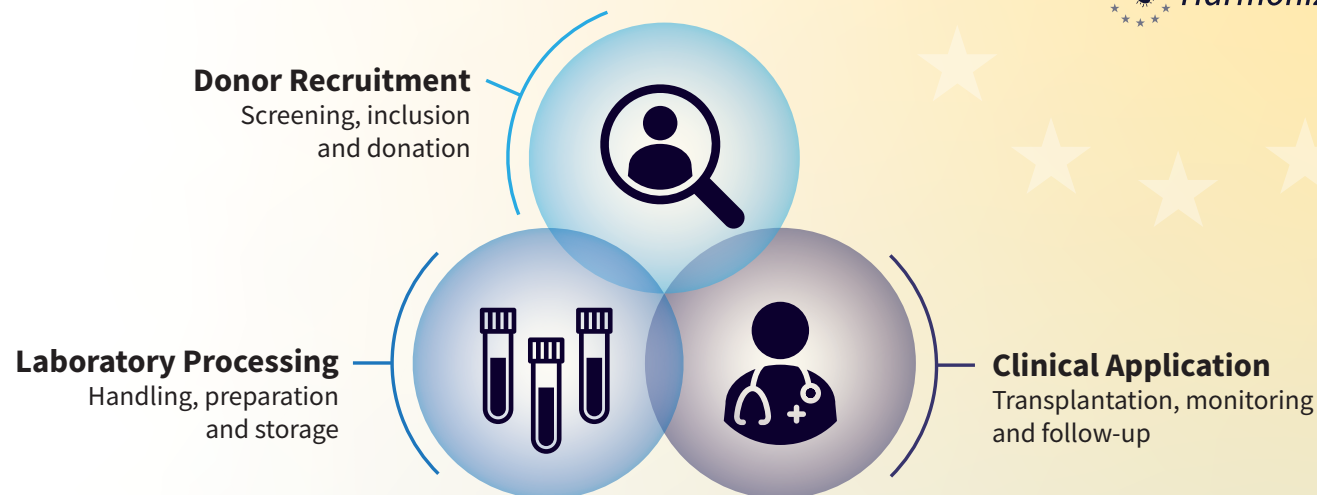
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# Harmonize

The Harmonize project is dedicated to support the implementation of the new substances of human origin (SoHO) regulation by the development of expert groups, training program and guidelines that secure the preparation, distribution and application of safe and effective Faecal Microbiota Transplantation (FMT) preparation in the European Union (EU).



Start Date  
**01.01.2025**



Estimated Project Costs  
**€ 666,401.75**

Duration  
**18 Months**



Beneficiaries  
**Five**

## The SOHO Regulation

In July 2024, a new EU regulation on standards of quality and safety for SoHO intended for human application was published. With an expanded definition and scope, intestinal microbiota is now included in this regulatory framework. This marks a major milestone for the microbiome field, as it is the first time in Europe that microbiota is recognized within a comprehensive legislative text.

## About Faecal Microbiota Transplantation (FMT)

FMT is a therapeutic approach that restores a disrupted gut microbiota by transferring fecal microbiota from a healthy donor to a patient. With success rates of up to 90%, FMT has become the standard treatment and has been integrated into clinical guidelines for recurrent, refractory or fulminant *Clostridioides difficile* infection (CDI), a potentially life-threatening condition.

## Stool banks and EurFMT Network

Safety concerns, including the risk of pathogen transfer, have led to the creation of guidelines to standardize safe FMT preparation. These efforts have been reinforced by inclusion of a chapter on “Intestinal microbiota” in the 5th edition of Guide to the Quality and Safety of Human Cells and Tissues for Human Application by the European Directorate for the Quality of Medicines & Health-Care (EDQM).

In parallel, healthcare institutions have established stool banks for donor screening, processing, storage, and distribution. Academic FMT stool banks have built a network, the EurFMT Network, with the aim to:

- Unite relevant European academic expertise on FMT
- Implement harmonized quality control measures
- Develop a European FMT Registry

With its structured governance and expert network, EurFMT is well-positioned to support these new regulatory developments and ensure high standards for FMT across Europe.