# HEAL ITALIA Foundation

# SPOKE 7 - Prevention Strategies

## Tema 1- Support for patient data activities

# Clinical Validation from Biopharmaceutical Findings (CVBF)

The Clinical Validation from Biopharmaceutical Findings (CVBF) is a non-profit research organization that provides clinical research support services to all types of sponsors and participates as a leader and partner in numerous national and international research projects.

Currently, CVBF is registered as a non-profit clinical trial sponsor with the European Medicines Agency (EMA) and has been self-certified as a Contract Research Organization (CRO) with the Italian Medicines Agency (AIFA) since 2009.

# Project Details

## Project Title

Clinical Trial Coordination and Management Hub

## Affiliate Spoke

SPOKE N.7 Prevention Strategies

## Objective of the Project

Reduce administrative and bureaucratic burdens in clinical research, enhancing researchers' efficiency through:

- Data Management: Optimization of data collection and management processes
- Clinical Studies: Simplification and reduction of the investigator's burden in authorization procedures for observational and interventional studies
- Costs and Timelines: Reduction of costs and acceleration of study implementation

## Tools and Services Offered:

Support infrastructure for conducting clinical trials.

Advanced technologies for data management.

Training and technical support for researchers.

# Contribution to the Spoke Research Program

## Specific Objectives

- Provide comprehensive and integrated support for clinical research, contributing to meaningful outcomes in health and precision medicine.
- Generate high-quality evidence for innovative diagnostic and therapeutic pathways
- Reduce disparities in the management of clinical studies between Northern and Southern Italy

# Contribution to the HEAL ITALIA Program and Precision Medicine

**The objectives of SPOKE 7 will be achieved through:**

- Development of advanced systems for clinical research management, such as the adoption of a Clinical Trial Management System (CTMS) or validated platforms for the creation of study-specific eCRFs
- Support from experts in all areas of clinical research, tailored to the identification of study-specific needs
- Documentary Support:
  - Implementation and dissemination of guidelines and quality standards
  - Assistance in drafting and reviewing regulatory documents (protocols, consent forms, Clinical Study Reports)
- Authorization Management:
  - Support throughout the entire study authorization process
- Study Monitoring:
  - Continuous monitoring activities
- Data Management:
  - Collection, management, and analysis of data to ensure quality

# Contribution to the HEAL ITALIA Program and Precision Medicine

## Expected Benefits

- Acceleration and specialization of research activities
- Efficient coordination of Precision Medicine projects
- Improved data management and ethical approval for clinical studies