HEAL ITALIA Foundation

SPOKE 8 Clinical Exploitation

Theme 3- New strategies for faster clinical protocol development, more effective study coordination and data management

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.8 Clinical Exploitation

Objective of the Project

The project aligns with the objectives of the HEAL ITALIA Research Program by generating evidence for innovative therapeutic approaches and reducing regional disparities in clinical research. It aims to facilitate the achievement of the outputs and outcomes of the Spoke.

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 support in the following activities:

- Drafting and/or revision of key documents required by regulatory authorities:
    1. Study Protocol
    2. Informed Consent/Assent and Data Protection Form
    3. Investigator's Brochure (IB)
    4. Patient Information Material
    5. Study-specific Procedures and Manuals
    6. Clinical Study Report (CSR)
- Management of the study authorization process from submission to final approval:
    1. Preparation of the main submission package and its adaptation to national/local requirements
    2. Oversight of the study authorization process from submission to final approval

Contribution to the Spoke Research Program (2)

Specific Objectives

- Monitoring of activities conducted within the studies of interest
    1. Monitoring Plan
    2. Site Initiation Visit
    3. Monitoring Visit
    4. Study Close-Out Visit

- Collection, management, and analysis of study data to ensure integrity and quality
    1. Implementation of the Data Management Plan
    2. Development and maintenance of the eCRF
    3. Data cleaning and database lock
    4. Implementation of the Statistical Analysis Plan (SAP)
    5. Statistical analysis and reporting

Contribution to the HEAL ITALIA Program and Precision Medicine

Expected Benefits

- Increased efficiency in clinical research
- Reduction in time and costs associated with studies
- Improvement in the quality of collected data
- Enhanced collaboration among researchers
- Reduction of inequalities in the management of clinical studies in Italy