



Clinical trials

Information for developers and CROs

Index

Clinical trials	1
Information for developers and CROs.....	1
Institutional Overview	3
Experience and Clinical Research Areas	4
Clinical Trial Support Staff	5
Clinical Trial Coordinators.....	5
Specialized Clinical Trial Nursing.....	5
Infrastructure	6
Clinical Trial Pharmacy.....	6
Clinical Analysis Laboratory.....	6
Diagnostic Imaging.....	7
Information Systems and Clinical Data Management.....	7
Ethical and Operational Management of Clinical Trials	9
Contact for Sponsors and CROs	10
Clinical Trials Unit (IRIS-CC) – Althaia Foundation.....	10
Institutional Contacts.....	10

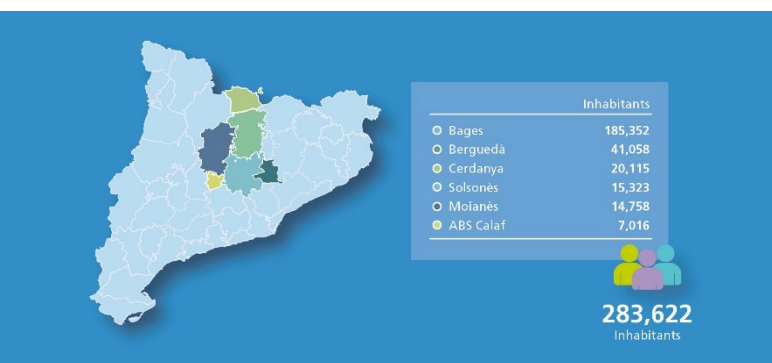


Institutional Overview

The Althaia Foundation – Xarxa Assistencial Universitària de Manresa is a private, non-profit healthcare institution integrated into the public health system of Catalonia (SISCAT), with public, mutual and private activity, providing healthcare coverage to a reference population of approximately 280,000 inhabitants in Central Catalonia.

feature of the Althaia Foundation, as it enables the conduct of clinical studies across a wide range of healthcare settings (hospital-based, outpatient, mental health, primary care, sports medicine, traumatology and rehabilitation), facilitating the identification of diverse target populations and longitudinal patient follow-up throughout the entire care process.

Althaia combines healthcare, teaching and research activities in collaboration with the University of Vic – Central University of



Healthcare, teaching and research activities are mainly concentrated at Hospital Joan de Déu de Manresa, a reference university hospital where most public and academic activity is carried out. Complementarily, Clínica Sant Josep primarily hosts mutual and private activity, expanding opportunities for patient recruitment and the development of clinical studies in different healthcare settings.

Catalonia (UVic-UCC) and is part of the Institute for Research and Innovation in Life and Health Sciences in Central Catalonia (IRIS-CC), strengthening its capacity to participate in multicenter clinical trials, industry-sponsored studies and national and international collaborative projects.

Althaia's healthcare network is completed by a territorial reference mental health center, integrated primary care centers, and a specialized center for sports medicine, traumatology and rehabilitation.

This integrated and diversified healthcare structure represents a key differentiating

Experience and Clinical Research Areas

The Althaia Foundation has been conducting clinical trials on a continuous basis since 2009, reflecting a consolidated track record in clinical research and sustained experience in collaboration with sponsors and CROs.

Clinical research experience covers a broad range of therapeutic areas, including:

- **Oncology**
- **Hematology**
- **Internal medicine**
- **Allergology**
- **Rheumatology**
- **Gastroenterology**
- **Ophthalmology**
- **Otorhinolaryngology**
- **Primary care**
- **Neurology**
- **Traumatology**
- **Nephrology**
- **Mental health** (*including child and adolescent psychiatry*)

Among these areas, particularly consolidated experience exists in oncology.

Research activity is mainly focused on Phase II and Phase III clinical trials, as well as observational studies with medicinal products, with significant participation in pharmaceutical industry-sponsored studies, complemented by projects promoted by cooperative groups and academic institutions.

Clinical Trial Support Staff

Clinical research activity at the Althaia Foundation is managed and coordinated by a specialized clinical research unit, which provides operational support to principal investigators and the healthcare teams involved in the studies.

Clinical Trial Coordinators

The institution has its own team of clinical trial coordinators with specific training in Good Clinical Practice (GCP) and experience in the operational management of clinical studies across different hospital care settings.

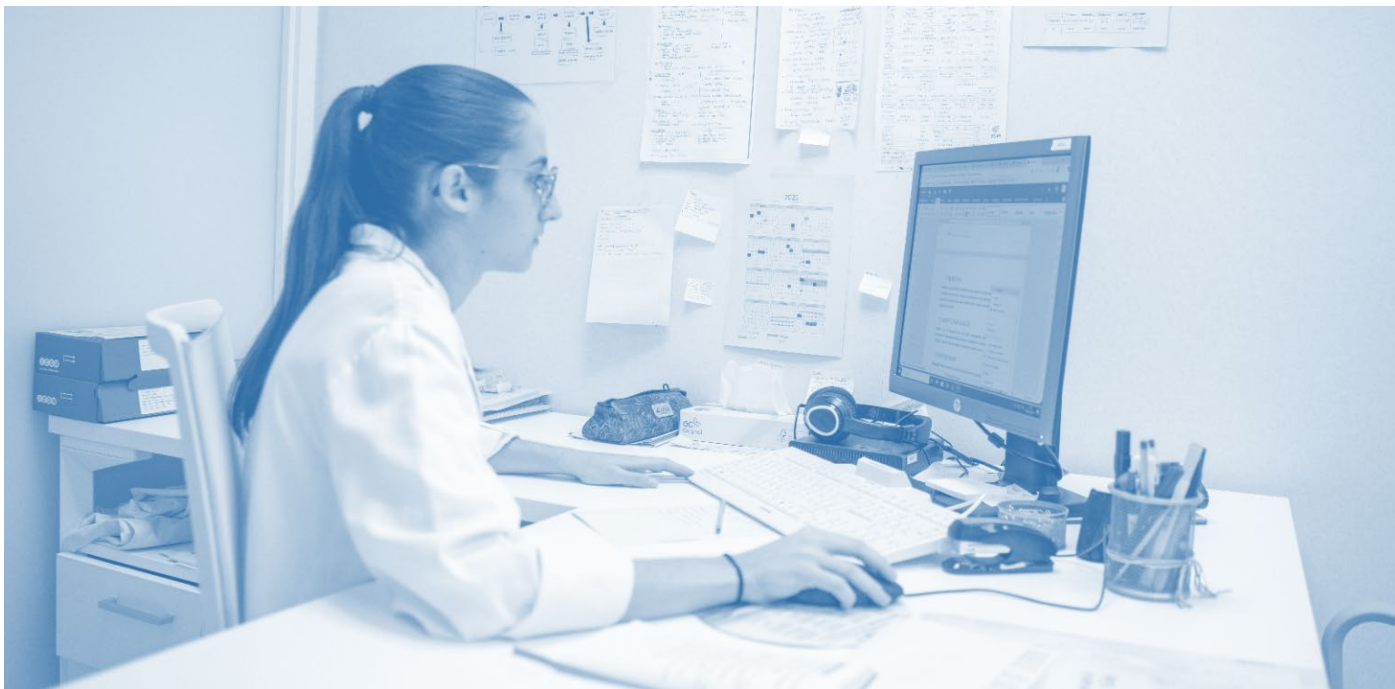
Coordinators provide direct support to principal investigators and accompany all phases of the study, from feasibility assessment and site initiation to execution,

monitoring and close-out. They act as the main liaison with sponsors and CROs, ensuring compliance with ethical, operational and quality requirements in accordance with applicable regulations and GCP.

Specialized Clinical Trial Nursing

The Althaia Foundation also has nursing staff with specific experience in clinical trials and in-depth knowledge of research procedures and hospital care pathways.

The nursing team participates in study procedures, clinical follow-up and safety monitoring of participants, in coordination with investigators, the Pharmacy Department and monitors. The team also has experience in pharmacokinetic (PK) procedures, including intensive sampling, in accordance with protocol requirements.



Infrastructure

Clinical Trial Pharmacy



The Althaia Foundation has a recently renovated Pharmacy Department with dedicated infrastructure for clinical trials and differentiated circuits that ensure safe management in compliance with Good Clinical Practice (GCP).

The Pharmacy includes clean rooms (2 rooms with 3 hoods each), automated storage systems and continuous temperature monitoring (ambient, refrigerated and frozen), ensuring proper conservation of investigational medicinal products.

Clinical trial medication is managed through a specific and differentiated circuit, with dedicated clinical trial areas, controlled access and full traceability via FUNDANET, including designated spaces for monitoring visits and for the work of monitors and auditors in an appropriate and controlled environment.

The Pharmacy Department has staff with specific experience in clinical trials, including a pharmacist and a pharmacy technician who provides daily support to studies, ensuring operational continuity.

The team actively participates in site initiation, monitoring and close-out visits, and supports receipt, storage and dispensing of IMPs, sterile preparation and blinding when applicable, as well as treatment validation and individualized pharmacotherapeutic follow-up, contributing to strict protocol compliance and GCP standards.

Clinical Analysis Laboratory

The Clinical Analysis Laboratory of the Althaia Foundation operates under a quality management system certified according to ISO 9001:2015, with standard operating procedures available to sponsors and CROs.

The laboratory has technical staff with dedicated involvement in clinical trials, ensuring proper processing, analysis, storage and shipment of biological samples in accordance with protocol requirements.



As a key differentiating feature, the laboratory is equipped with two ultra-low temperature freezers (-80 °C), in addition to -20 °C storage equipment and refrigerated centrifugation, enabling safe and simultaneous management of samples from different studies while preserving sample integrity throughout the process.

The laboratory also manages shipments to central laboratories following each study's specific manuals, ensuring traceability, regulatory compliance and data quality.

Diagnostic Imaging

The Diagnostic Imaging Department of the Althaia Foundation is equipped with state-of-the-art technology and has experience in clinical trials requiring image assessment according to standardized response criteria (e.g., RECIST), as well as image transfer to central laboratories when required by the protocol.

The department's main equipment includes:

- Computed Tomography (CT): Siemens Go.Top (64×2 slices) and Siemens Scope (16-slice).
- Magnetic Resonance Imaging (MRI): Siemens Magnetom Essenza 1.5T and Siemens Lumina 3T.
- Conventional Radiology: Siemens X.Pree and Ysio.Max.
- Bone Densitometry: Horizon DX (Hologic)..

In addition, collaboration agreements are in place with associated centers for nuclear medicine procedures, including PET/CT and conventional scintigraphy (e.g., bone scintigraphy), as well as for the administration of radiopharmaceutical treatments when required by the protocol, ensuring continuity of care and compliance with study requirements.

Information Systems and Clinical Data Management

The Althaia Foundation has a robust and secure information systems infrastructure that provides comprehensive support for the conduct of clinical trials, ensuring data traceability, quality and regulatory compliance throughout the entire study lifecycle.

Healthcare Information System (HIS)

The corporate electronic health record system (HIS) allows secure, traceable and auditable access to clinical information of study participants, facilitating patient follow-up and compliance with monitoring and quality control requirements.

Access for sponsors and CROs is granted on a temporary and restricted basis, in accordance with internal procedures and



applicable data protection regulations, including:

- Activity logs with user and date identification.
- Version control and change traceability.
- Automatic backups and periodic restoration processes.
- Controlled access environments for monitoring activities.

Corporate Platform: FUNDANET

Operational, documentary and financial management of clinical trials is supported by FUNDANET, a corporate platform that enables full study traceability, milestone tracking, contract management and trial-related invoicing, ensuring transparency and control throughout the study lifecycle.

FUNDANET is validated and complies with FDA 21 CFR Part 11 and ICH GCP E6 (R3) requirements, incorporating features such as:

- Full audit trail.
- Individual credential-based access control.
- Protection against unauthorized data modification.
- Backup systems in separate locations.

Clinical Data Exploitation for Study Planning

The Althaia Foundation has a Business Intelligence (BI) system and a specialized clinical documentation unit composed of professionals with expertise in clinical coding and data exploitation, providing specialized support for study feasibility assessments.

These resources enable structured analysis of healthcare data and the generation of aggregated information to estimate potentially eligible populations and support clinical study planning, always in compliance with applicable confidentiality and data protection regulations.

Ethical and Operational Management of Clinical Trials

The Althaia Foundation conducts its clinical trial activity within the framework of the Institute for Research and Innovation in Life and Health Sciences in Central Catalonia (IRIS-CC), which has a centralized clinical trials unit responsible for providing ethical and institutional support, as well as contractual and financial support to studies.

The physical headquarters of this corporate unit is located at Hospital Sant Joan de Déu de Manresa, facilitating direct and agile coordination with the Althaia Foundation's healthcare and research teams.

IRIS-CC has its own Research Ethics Committee with Medicines (CEIm), accredited by the Directorate General for Health Organization and Regulation (DGORS) of the Government of Catalonia.



This CEIm acts as the evaluating body for observational studies with medicinal products, clinical investigations with medical devices and other projects requiring ethical evaluation.

For multicenter studies subject to the single opinion procedure in accordance with applicable regulations, both with medicinal products and medical devices, the Althaia Foundation adheres to the opinion issued by the reference CEIm, avoiding duplication and streamlining study start-up timelines.

Operational management and day-to-day coordination of clinical trials at Althaia are carried out by the Althaia Foundation's Research Unit, which acts as the local reference team for investigators, sponsors and CROs, ensuring proper study execution at the site.



Contact for Sponsors and CROs

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