



Centro Cardiologico
Monzino

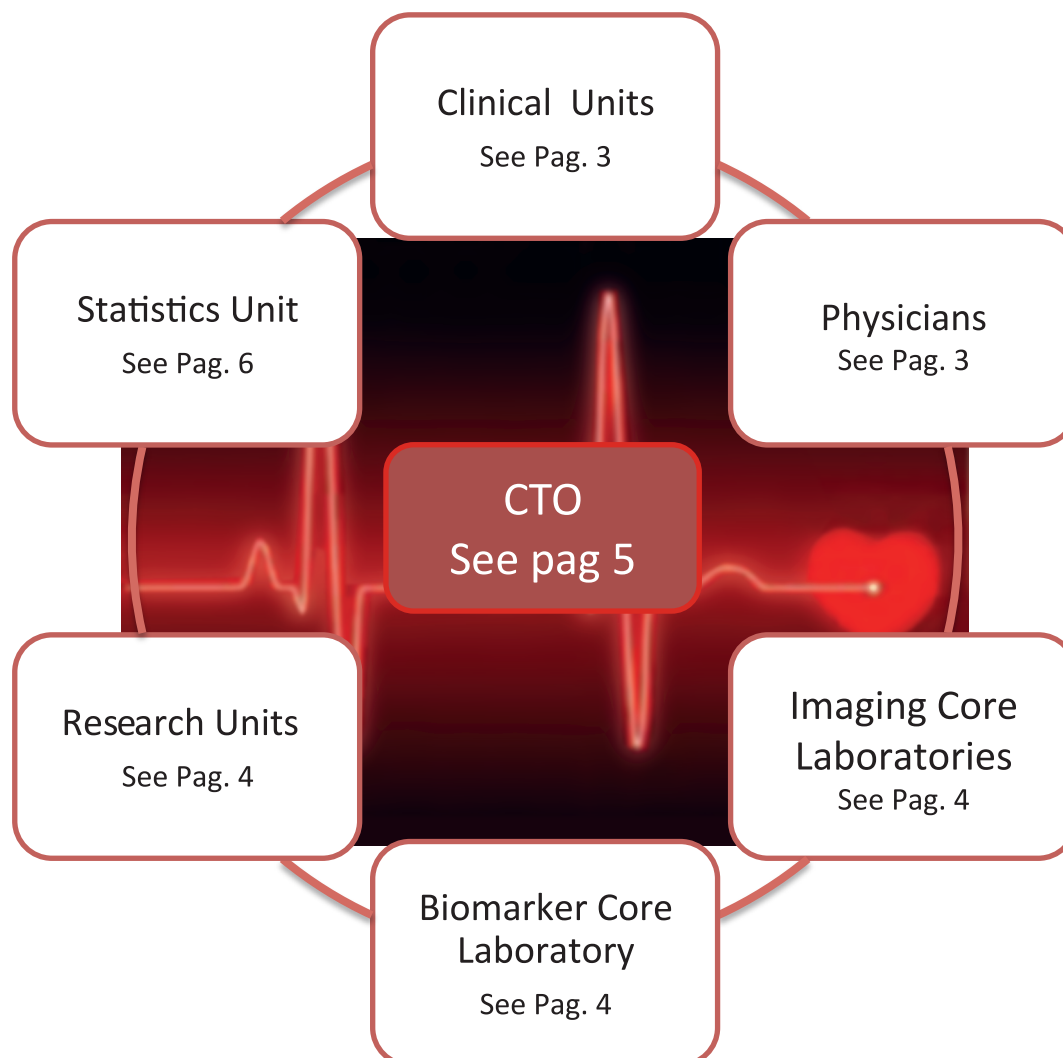


Clinical Trial Office



For successful cardiovascular clinical trials

- Built upon the expertise of leading clinicians and scientists, CCM has a strong competence in cardiovascular diseases that is recognized worldwide.
- Our group consists of experienced and qualified clinician, researches, pharmacologists and administrative staff with demonstrated performance in clinical trials.



Physicians

Our hospital can provide experts in all cardiovascular specialties and it is well known:

- for its **excellence**;
- for its **high specialization** in the cardiovascular field;
- for its **cutting-edge technologies**.

Beyond their clinical expertise, our physicians are involved in the development and conduct of international multicenter clinical trials.

Our organization counts a scientific Advisory Board and Steering Committee Members who can develop, finalize and manage studies focusing on reliable and valid endpoints.

Cardiologists, surgeons, engineers and researchers working closely in team are the added value that provides efficient contributes to the performance of the trial.

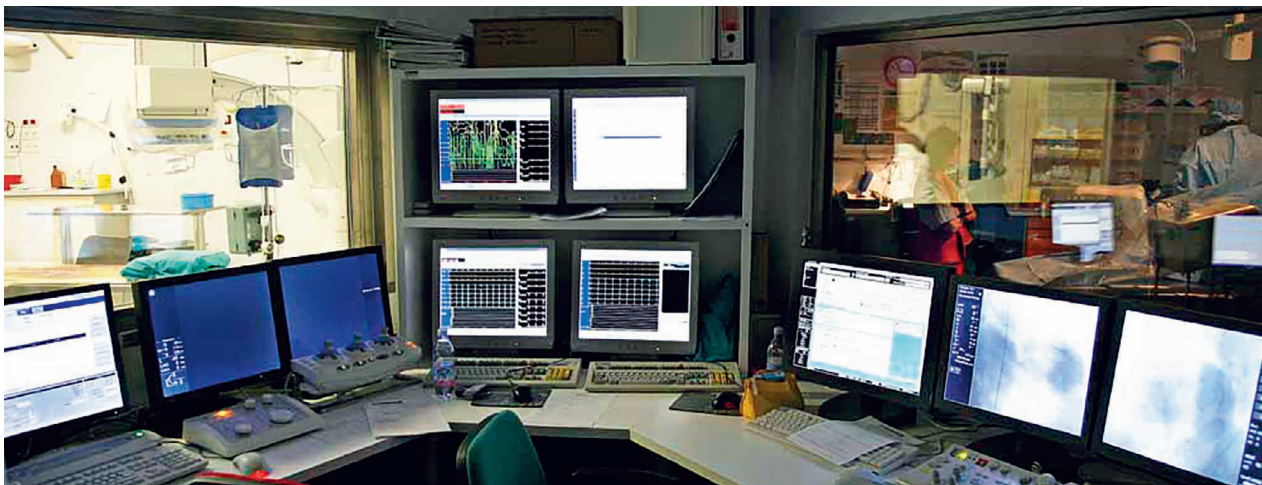
Clinical Units

With decades of experience in trials, we've built an organization with staff that ensures the integrity of clinical trials and protocol compliance.

By developing customized services in response to the clinical requirement of the protocol our organization can be involved in trials from phase I up to post marketing studies.

Our clinical areas are:

- **Critical Care Area**, equipped with last generation technologies to reach the highest level of assistance thanks to:
 - o Emergency Unit;
 - o Acute Cardiac Care Unit
 - o Intensive Cardiac Care Unit
 - o Heart Failure, Clinical Cardiology and Cardiac Rehabilitation Unit.
- **Interventional Cardiology**, with a very high technology content, deals with the non-surgical management of cardiovascular diseases.
- **Electrophysiology** deals with all electrophysiological procedures and cardiac pacing treating every type of arrhythmia and is the national training center for the so called "one shot" techniques.
- **Cardiovascular Surgery**, besides the surgical routine, has a strong expertise in minimally invasive endovascular techniques and transcatheter Valve Repair.



Imaging Core Laboratories

We are recognized leaders in imaging analysis thanks to the most updated imaging techniques in three main areas: Echocardiographic Laboratories, Cardiovascular Radiological Imaging (Computed Tomography), Cardiac Magnetic Resonance.

Several research protocols strictly related to new advanced techniques have been conducted and many are ongoing. Our program consists of personnel and resources for image data management dedicated to clinical trials:

- site training;
- image processing;
- inventory and status reporting;
- analysis;
- data transfer;
- image data storage.

Biomarker Core Laboratory

Equipped with recent and updated analyzers, providing a good analytical and clinical performance, certified ISO 9000, the Laboratory Medicine Unit encompasses the fields of biochemistry, coagulation, hematology, infectious disease serology, cardiac biomarkers, drug monitoring and microbiology.

The daily internal quality controls, the involvement in external quality assessment programs, guarantee the reliability of the test results.

Thanks to an updated online computerized system the results of the tests are rapidly available immediately after validation.

Research Units

Our researchers working closely with the clinicians perform their activity focusing on the development of new translational approaches.

Besides their own projects, our expert researchers can help and offer solutions to scientific problems in order to improve:

- **diagnosis**, finding and recognizing new biomarker also thanks to a number of “omic approaches” that allow thinking in terms of construction of conceptual models with sufficient predictive capacity;
- **treatment**, such as cell therapy for no-option cardiovascular ischemic disorders or the design of advanced strategies to generate bioengineered cardiovascular tissues;
- **prevention**, such as development of guidelines to transfer the scientific knowledge into the clinical practice (c IMT) or epidemiologic analysis.

Clinical Trials Office

CTO will...

- Focus on** the needs of the study sponsor and/or of the researcher and help with its expertise
- Elaborate** a study protocol to “answer the question” in compliance with GCP
- Support** the study submission to Ethical Committee setting all the necessary documentation
- Organize** the study with integrity being responsive to the investigator needs, in respect of pre-defined timelines

Project Management

From the sponsor to the site, the project managers of our Clinical Trials Office are engaged in proactive and regular communication. PM have years of clinical practice experience and work with all project team members to assure **problem identification, resolution and adherence to study timelines.**

All this brings a value in clinical practice management and provides essential input into the **trial design** and a valuable input into the **feasibility** of clinical trials.

Contracts & Finance

The team performs administrative accounting functions for the clinical trials.

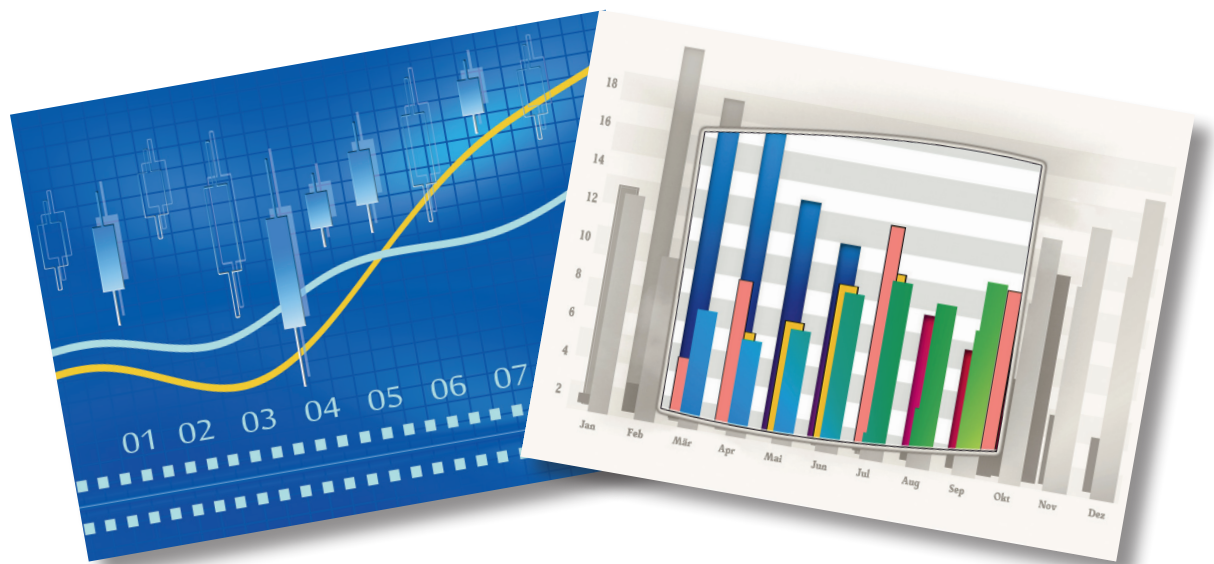
CTO is available to assist the PI and the sponsor in the **development of clinical trial budgets** evaluating the financial feasibility. The cost analysis identifies all the costs associated with the clinical trial, ranging from the standard of care procedures costs to staffing needs.

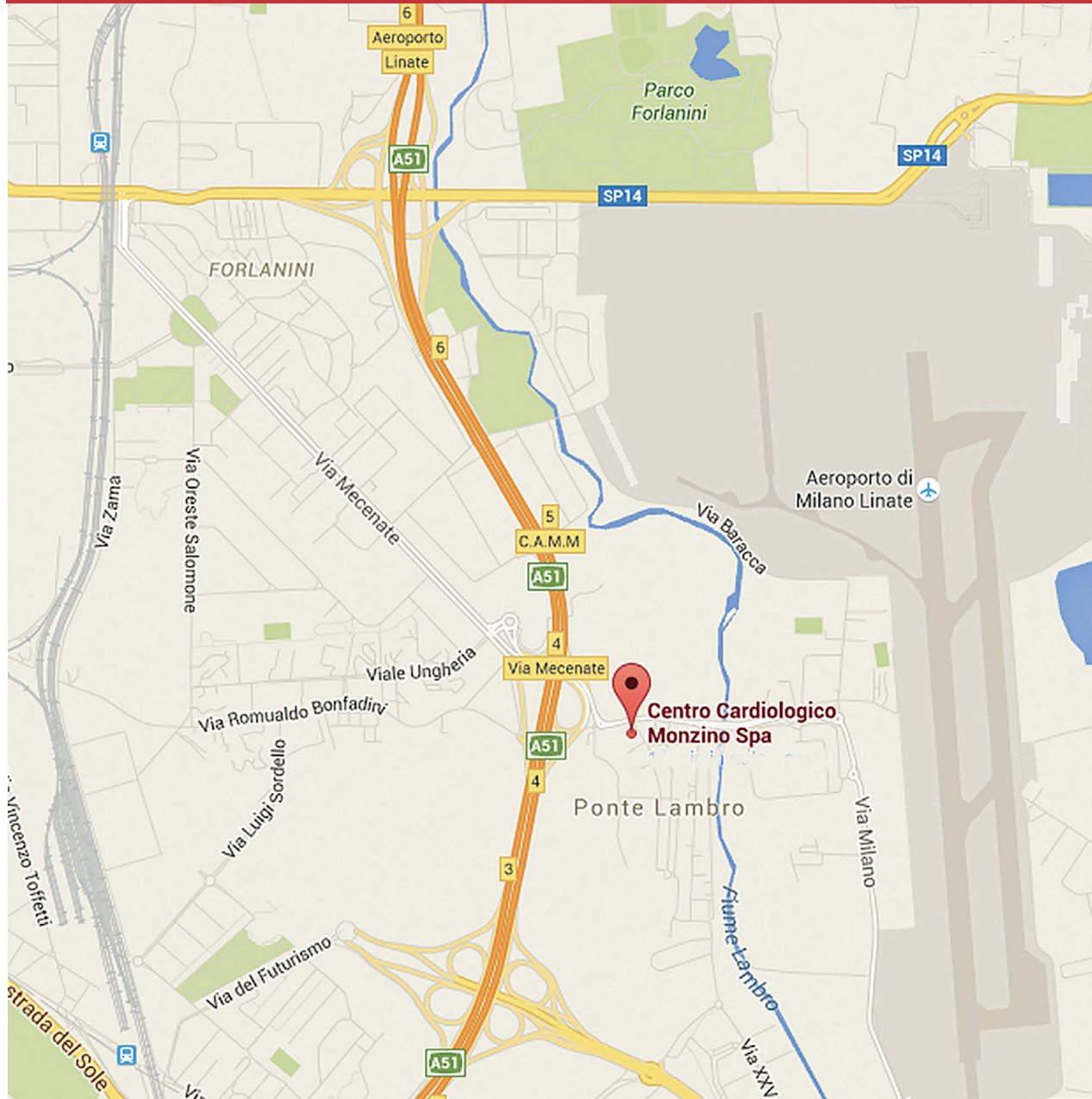
Our team will work closely with the sponsor in order to **formalize the best terms and conditions** between the parties. The CTO will assure a dynamic process of review, negotiation and execution of all necessary trial documentation **keeping the timelines** from submission to trial activation.



Statistics

The statistical team provides advice and support to the investigators examining the protocols, calculating the correct sample size and proposing the most appropriate statistical tests. The team, in cooperation with the project team members, manages the quality control of the database and data coding, reviews the input of the CRFs and performs statistical analysis of clinical trial data. It also provides services such as independent validation of the results and support for the publication of the manuscripts.





How to reach us

In the map above, you can find the indications how to reach us by car. Please note that Milano Linate Airport is just 9 minutes from us by car or taxi.

www.cardiologicomonzino.it



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