



Our expertise

- ◆ Management of agreements and contracts with Ethics Committee/AIFA and regulatory affairs
- ◆ Clinical Trial Quality Assurance and Training
- ◆ Scientific and Methodological support in Clinical Trial design
- ◆ Central statistical monitoring (CSM)
- ◆ Statistical analysis and online reporting
- ◆ Archiving of sensitive data through FDA validated system
- ◆ Conduction of health surveys and management of administrative health records.

SCTB

Service for Clinical Trials and Biometrics

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UNIVERSITÀ
DEGLI STUDI
DI PADOVA

SERVICE FOR CLINICAL TRIALS AND BIOMETRICS



Department of
Cardiac
Thoracic
and Vascular
Sciences



Center for Clinical Trials and Biometrics is a new highlight of the Department of Cardiac, Thoracic and Vascular Sciences, University of Padua. It provides research excellence and longstanding experience for healthcare and pharmacology practitioners from public sector, industry and international organizations, for profit and non profit activities.

Our mission:

Provide robust empirical evidence and highest ethical standards, while pursuing time and cost optimization of decisional and management processes.

The scope of the center is to accompany a practitioner/investigator on his pathway from elaboration and construction of clinical trial protocols, to provide 360° assistance in data management and analysis and to facilitate the interpretation and reporting of the results.

Our workflow relies on Electronic Data Capture (EDC), a computerized system designed for the collection of clinical data, that allows:

- ◆ To build **eCRF** (electronic Case Report Forms)
- ◆ To manage clinical data through **Clinical Data Management System**
- ◆ To acquire data from any device with only the need for an internet connection.



We base our EDC system on cutting edge professional tools such as:

OpenClinica®: the fastest growing clinical research software worldwide that allows for major flexibility given its open standards and architecture.

REDCap™: browser-based, metadata-driven EDC software solution and workflow methodology for designing clinical and translational research database.



Advantages

- **Central statistical monitoring**
data checks are performed by the coordinating centre, avoiding the need to visit all sites.
- **Data Analysis with R and**
for a flexible and comprehensive approach in computational statistics, visualization and data science.
- **Instant analysis and reporting**
web-based customizable tool that allows for real time update of analysis, results and summary reports.
- **Personalized Helpdesk**
prompt HELPDESK assistance service for any issue of technical or methodological nature.

