Catania Teaching Hospital CTU Phase 1 Centre is a dedicated unit, designed to conduct phase I, early phase and clinical pharmacology trials.

Catania Teaching Hospital CTU Phase 1 Centre is registered at the Agenzia Italiana del Farmaco (AIFA), in conformity with the requirements of AIFA Decision no. 809/2015.

It includes a dedicated medical team with clinical experts in clinical pharmacology, oncology and other key therapeutic areas.

It also has a dedicated clinical operations team composed of professional study coordinators, pharmacists, pharmacologists, registered nurses and laboratory specialists.

Full support on ethics and regulatory submissions is provided by ethics and regulatory specialists.

Strong data management and statistical support is guaranteed by professional data managers and medical statisticians.

Access to healthy volunteers and patients in a wide range of disease areas is guaranteed.

UNIFARM RESEARCH CENTRE provides support for clinical trials management and execution of pharmacokinetic analysis.
Our mission is to deliver excellence in the design and conduct of phase I/II clinical trials on healthy volunteers and patients and as a result contribute to gather health benefits for patients. Activities encompass all aspects and stages of clinical trials from inception to delivery. Catania Teaching Hospital Clinical Trial Unit (CTU) holds ample expertise in trial methodology and all key aspects of clinical studies in various disease areas. It works in close cooperation with the Unifarm Research Centre (CRO) to ensure that the regulatory and quality control requirements of trials are met.

Catania Teaching Hospital CTU operates within and is an integral part of the University Policlinic Vittorio Emanuele (Catania).

The Centre avails itself of specialized in-house knowledge for the following therapeutic areas and R&D activities:
- Oncology
- Pediatric Hematology/Oncology
- Hematology
- Internal Medicine

Quality assurance
Highly-experienced quality assurance is provided.

Monitoring
- Qualified monitors
- Reporting and documentation

Statistics
- In-house statistics
- Data management

Staff
- Prof. Pasquale Mario Fatuzzo, M.D. (Unit Director)
- Prof. Filippo Drago, M.D., Ph.D. (Pharmacologist)
- Prof. Pietro Castellino, M.D.
- Prof. Francesco Di Raimondo, M.D.
- Dr. Héctor Soto Parra, M.D.
- Prof. Giovanna Russo, M.D.
- Prof. Francesco Cardì, M.D. (Principal Investigators)

Our Phase I Unit
- 8 well-equipped beds in the unit located at Catania University Hospital
- Use of the medical emergency facilities of the hospital (365 days, 24 hrs)
- Special diets possible

Types of Studies
- Phase I
- Dose selection studies
- Pharmacokinetic profiling studies
- Proof of concept studies
- Interaction studies

Our clinical pharmacology studies can be performed on special patient populations and normal healthy subjects.

Catania Teaching Hospital CTU Phase 1 Centre supports operational staff in designing their Standard Operating Procedures (SOPs) and full study projects under Good Clinical Practice (GCP).

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