CLINICAL TRIAL CENTER, PHASE I AND TRANSLATIONAL RESEARCH UNIT

ASST Spedali Civili di Brescia, Brescia, Italy

1. INTRODUCTION The Clinical Trial Center, Translational Research and Phase I Unit aims to:

- ✓ promote research activities, in compliance with Italian and European legislations, and GCP principles;
- ✓ support our Investigators for conducting clinical (pharmacologic; medical devices; either profit or non-profit) and translational research;
- ✓ develop and strengthen sponsored and independent clinical research;
- ✓ pave the path for the process of internationalization of research being planned or conducted at our Institution.

Overall, supporting clinical trials and research activities within the biomedical field are fundamental and essential elements to guarantee patient's access to the best therapeutic approaches. This answers to the requirements of the National Health System which formalizes the importance of research activities being conducted within public hospitals (Legislative Decree n.502 / 1992; art. 12bis).

2. SERVICES OFFERED

The Unit offers the coordination of all the activities needed for planning, implementing, conducting and closing research projects.

2.1. GRANT OFFICE

It supports all the Professionals, at our Institution, within the specific field of public national and international research funding competitive calls. Main activities include:

- ✓ scouting and dissemination of research funding calls;
- ✓ networking and development of partnerships with external national and international Institutions;
- ✓ cost eligibility, budget and justification preparation, according call-specific guidelines;
- ✓ research proposal submission to the funding Entities;
- ✓ drafting of research agreements/memoranda of understanding, research contracts;
- ✓ project management;
- ✓ support to external audit;
- ✓ promotion of national and international research networks.

2.2. CLINICAL TRIAL OFFICE

It supports all the Professionals, at our Institution, within the specific field of sponsored or investigator-initiated trials/IIT (profit, non-profit; observational; interventional; any phase going from phase 1 through 4). Main activities include:

- ✓ support to the Investigator for study design, preparation of the documentation to be submitted to the Competent Authorities and Ethics Committee;
- ✓ assessment of the adequacy of funds to cover additional trial-related costs;
- ✓ connection with Italian Medicine Agency (AIFA) and Ministry of Health, for the authorization of pharmacologic trials, and studies with medical devices or genetically modified organisms, respectively;
- ✓ support to the General and Legal Affairs Unit for the revision of trial contracts;
- ✓ support to Central Pharmacy for pharmacovigilance of IIT trials;
- ✓ support to the Investigator during GCP inspections by AIFA or other Competent Authorities;
- ✓ support for the management of the profit clinical trial-related invoices.

2.3. PHASE I AND TRANSLATIONAL RESEARCH UNIT

The PHASE I Unit offers all the necessary support for conduction Phase I clinical trials, according to the requirement of the Italian Medicine Agency (AIFA, n.809/2015). The Institution is listed within the AIFA database for Phase I trials, as FI/65 and FI/112, for pediatric- and adult patients, respectively. The Phase I path is also completed with a self-certified laboratory in AIFA (FI / 96) (Good clinical practice inspections | Italian Medicines Agency (aifa.gov.it). FI/65 and FI/112 have been designed as functional Units that cover any Phase I trial at our Institution, given the verification of needed requirements by the Medical Director of the Phase I Units, Dr. Aldo M. Roccaro, whom all the inquiries related to Phase I studies need to be addressed to. The

Medical Director will evaluate the feasibility of the study, and coordinate all the necessary activities according to AIFA n.809/2015 and to study protocol.
The TRANSLATIONAL RESEARCH LABORATORY offers the management of the experimental sample of Phase I. Moreover, translational research activities, supported by funding obtained in response to national and international competitive calls are being conducted at the research lab.
In addition to quality according to GCP, the biological sample management path, within Phase I clinical trials, is ISO 9001:2015 certified.

3. CONTACT

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