

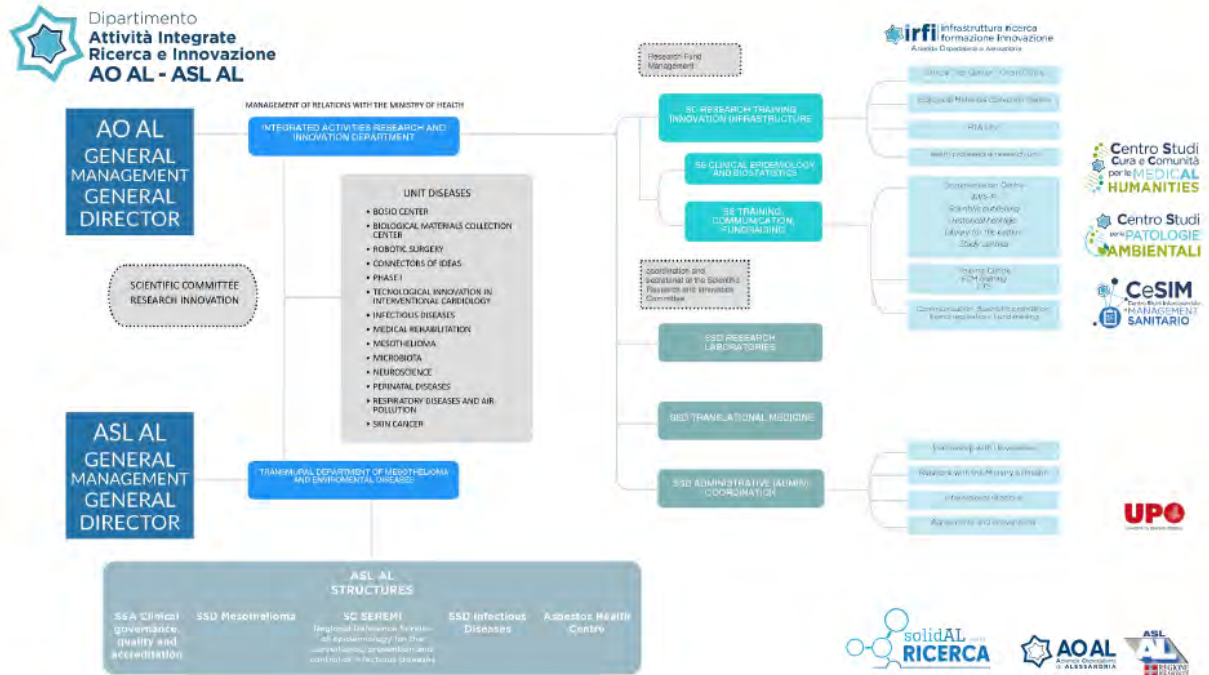
Appendice 1

Brochure del Clinical Trial Center di Alessandria



Clinical Trial Center

- The Clinical Trial Centre (CTC), the first in Piedmont, has been operating since 2013 (Resolution n°256 of 11-10-2013).
- The CTC is a centralized sector of the inter-company Research and Innovation Department (DAIRI, Director Dr. Antonio Maconi) pertaining to the Research Training Innovation Infrastructure (IRFI).
- It has its headquarters at the Hospital "SS Antonio e Biagio e Cesare Arrigo" (AO AL) and a secondary office at the Hospital "S. Spirito", in Casale Monferrato of the Local National Health Service of Alessandria (ASL AL).



CTC

Clinical Trial Center

VISION

Becoming an appealing Centre for Clinical Research


MISSION

Improving the populations' health through ethical and quality research based on the research lines identified by the current research plan.

#researchcuresandcare

CORE VALUES

- We are strong when working as a team
- We have all stakeholders at heart
- We work according to Good Clinical Practice guidelines
- We pay more attention to the centrality of the patient
- We optimize processes using lean thinking




CTC Clinical Trial Center

FEATURES

The Clinical Trial Centre (CTC) is a Centre aimed at designing and conducting quality clinical studies: it promotes efficiency during the study activation phase and it optimizes study and data management according to the Good Clinical Practice (GCP) principals.

The CTC is the interface for sponsoring institutions and companies and Contact Research Organizations (CROs) that recognize DAIRI as a partner for testing innovative therapeutic strategies in an effort to offer patients the best available care. The studies are designed and conducted according to quality standards, thanks to dedicated, qualified and competent personnel who support the clinician in all the various stages, from design, conduct and storage, to data collection, analysis and finally publication.

CTC staff are constantly trained and updated on issues related to clinical research and areas of specific sector competence.



CTC Clinical Trial Center

FEATURES


A team that constantly promotes the development of research in all areas, from the research of new medicines and treatments to research in integrated approaches of new processes, for patients.

Providing training and operational tools, CTC coordinates and supports the activation and conduction of clinical studies with both the "Unit Diseases", areas of excellence and high training, established and based on AO AL's research lines or projects of strategic importance, and the Unit of Nursing and allied Healthcare Professionals (URPS), pertaining to IRFI.

It operates in synergy with the Biological Materials Collection Centre, an operational IRFI structure to promote and encourage basic and translational research through the availability of biomaterials, essential for clinical studies. The systematic and prospective collection of biological samples and associated data is an important tool for translational research, whose positive results are then integrated into diagnostic-therapeutic pathways: from screening, to diagnosis, to treatment and follow-up.

CTC operates in close synergy with the DAIRI's administrative coordination office, which supports scientific and clinical research activities, from an economic and administrative point of view.

The office manages institutional relations with scientific institutes, national and International Hospitals as well as Universities. It also negotiates agreements and conventions and ensures the management of authorization, regulatory and legal aspects of research.



CTC Clinical Trial Center

ACTIVITY

1

FEASIBILITY E START-UP

Carolina Pelazza, Serena Penpa, Fabio Giacchero, Costanza Massarino

2

PLANNING-DESIGN E STUDY MANAGEMENT

Marinella Bertolotti, Marta Betti, Annalisa Roveto, Tatiana Bolgeo, Stefania Crivellari, Francesca Ugo, Carolina Pelazza, Serena Penpa, Fabio Giacchero, Costanza Massarino, Roberta Di Matteo, Menada Gardalini, Denise Gatti, Antonella Cassinari

3

KPI MONITORING

Annalisa Roveto, Filippo Pietro Fabbio, Marta Betti, Carolina Pelazza, Antonella Cassinari

4

"UNIT DISEASE" COORDINATION

Annalisa Roveto, Filippo Pietro Fabbio, Serena Penpa, Menada Gardalini

5

EDUCATION AND TRAINING

MariaTeresa Docquino, Marta Betti, Annalisa Roveto, Marinella Bertolotti, Tatiana Bolgeo



CTC Clinical Trial Center

ACTIVITY

FEASIBILITY E START-UP

- Centralization of feasibility requests for new studies and support to the Principal Investigator
- Addressing the request for authorization to conduct the clinical study
- Drafting of the (technical-scientific and/or economic) investigation related to the congruity evaluation of the compensation proposed by the promoter and, in the case of a non-profit study, to the estimation of direct and indirect costs
- Interfacing with sponsoring institutions, CRO, Ethics Committees and Regulatory Agencies
- Supporting in the clinical study's authorization process as far as competence is concerned, to the General Director's Office.

PLANNING-DESIGN E STUDY MANAGEMENT

- Drafting of the study protocol and the related attached documents
- Preparation of the center-specific documentation and evaluation of costs
- Registration of clinical studies in reference databases (e.g. clinicaltrials.gov)
- Implementation of CRF
- Data entry
- Data analysis
- Recollection and conservation of biological samples, expected from the study according to the most shared ethical principles



CTC Clinical Trial Center

ACTIVITY

KPI MONITORING

- Updating data of clinical research activities in a database implemented through the Redcap (Research Electronic Data Capture) web platform
- Monitoring of scientific data
- Reporting clinical research activities

"UNIT DISEASE" COORDINATION

- Coordination of data management and reporting of the Unit Diseases' active clinical trials



CTC Clinical Trial Center

ACTIVITY

EDUCATION AND TRAINING

- The organization and management of Annual training courses in Clinical Research, for the different professional figures part of the research team (physicians, biologists, clinical study coordinators, research nurses and administrative staff)
- The organization and management of training courses in research for general practitioners (MMG) and free choice pediatricians (PLC), that may conduct observational studies (AIFA determination 20-05-2008) as investigators. They can also conduct Stage IV clinical trials of medicines and treatments and particular Stage IV clinical trials with prior authorization and registration on the specific register, Introduced and updated by each Local Health Authority (ASL) (DM 10-05-2001). Since 2018, the ASL AL has activated the MMG and PLS Medical Register of Investigators, that currently includes 30 professionals.
- A 1° level Master in "Data Management Coordination of Clinical Trials" in collaboration with the Department of Science and Technological Innovation (DISIT) of University of Eastern Piedmont and AO AL with the patronage of the Italian Data Manager Group, activated from the academic year 2019/2020



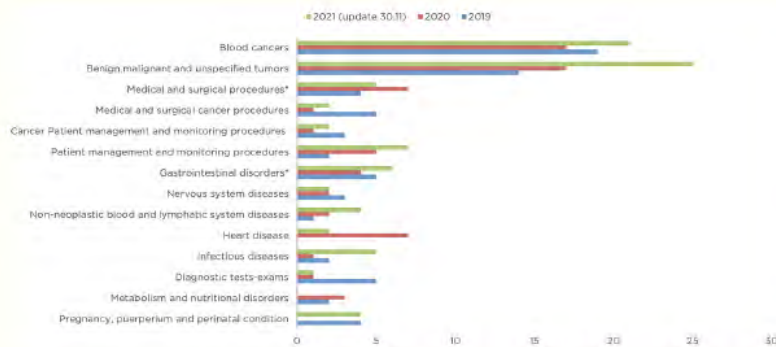
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ACTIVATED CLINICAL TRIALS



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ACTIVATED CLINICAL TRIALS FOR THERAPEUTIC AREAS



*studies also in the pediatric area

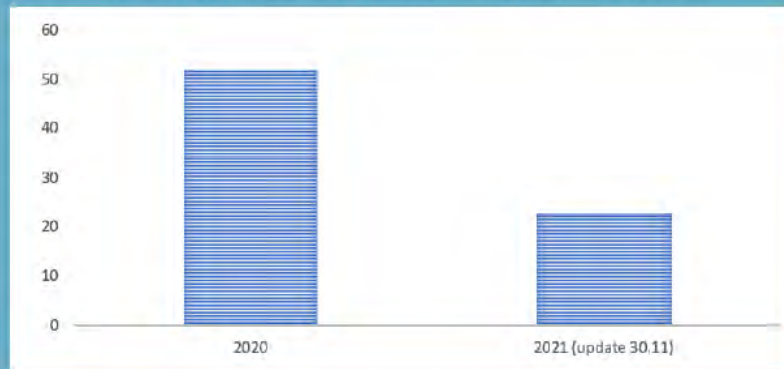
OTHER THERAPEUTIC AREAS

- BEHAVIOUR AND BEHAVIOURAL MECHANISMS
- CONGENITAL, FAMILY AND GENETIC DISEASES
- SKIN AND SUBCUTANEOUS TISSUE DISEASES
- KIDNEY AND URINARY DISEASES
- SYSTEMIC DISEASES
- PATHOLOGIES OF THE MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE
- EYE DISEASES
- RESPIRATORY, THORACIC AND MEDIASTINAL DISEASES



CTC Clinical Trial Center

ACTIVATED COVID-19 CLINICAL STUDIES



*studies also in the pediatric area

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LEAN METHODOLOGY IN CLINICAL TRIALS



Despite the excellence of many research Centers and the quality of researchers, in Italy numerous factors limit the attractiveness of the Italian Clinical Research System within the European panorama.

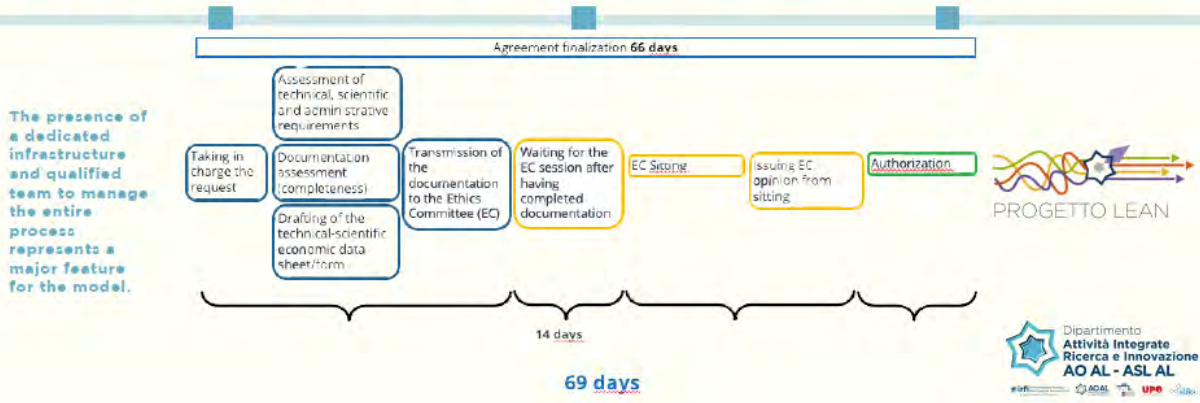
In the field of clinical research, the complexity of the process and the activation timing are longer than the European average and frequently at a regional level timing scheduled by legislation is not respected.

Based on lean thinking and in view of the company's efficiency and optimization of business processes, CTC in collaboration with the Administrative Coordination, supported by the Operational Management, has structured an organizational model to manage the activation process of Clinical Trials within AO AL, in order to be attractive within the European scene.

The goal was to reduce time between taking in charge the request and authorization, reducing and standardizing the whole process.

CTC Clinical Trial Center LEAN THINKING TOOLS

The lean thinking tools have permitted to analyze systematically the activation process, identifying the critical issues, the resources and skills needed, proposing solutions and stimulating the team, helping to develop observational, understanding and problem solving skills. The implementation of an organized, controlled and coordinated model to manage the activation of clinical trials, has allowed to optimize the entire process reducing initially to 98 days and to date 69 days the time between taking charge of the request and authorization, compared to 218 initial days.



CTC Clinical Trial Center

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CTC Clinical Trial Center

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