SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori"
Istituto di Ricovero e Cura a Carattere Scientifico

ISTITUTO ROMAGNOLO PER LO STUDIO DEI TUMORI DINO AMADORI

TECHNOLOGY ASSETS&SERVICES

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DESCRIPTION

The Contract Research Organization of the Romagna Institute for the Study of Tumors “Dino Amadori” IRCCS represents a strategic infrastructure for oncology clinical research at both national and international levels. Operating in compliance with **Good Clinical Practice (GCP)** and European and Italian regulations, the CRO ensures high standards of quality, reliability, and regulatory adherence.
Its mission is to **provide comprehensive and tailored support to sponsors**, **pharmaceutical and biotech companies**, **and academic institutions** throughout the entire clinical trial lifecycle, from early-phase studies (**Phase I**) to post-marketing trials (**Phase IV**).

Services include study design, regulatory management, site monitoring, pharmacovigilance, reporting, statistical analysis, and data validation, ensuring transparency, traceability, and patient protection.

A distinctive feature of CRO-IRST is its **integration within an oncology IRCCS, fostering synergy between basic, translational, and clinical research, and accelerating the translation of results into clinical practice**. With a multidisciplinary, expert, and continuously updated team, the CRO stands out for its timeliness, precision, and tailored approach, generating scientific value and real impact on patient care.

CRO
IRST “Dino Amadori” IRCCS

EQUIPMENT

CRO-IRST relies on a certified, multidisciplinary team with extensive experience in managing both profit and non-profit clinical studies. It offers partners reliability (AIFA recognition), integration within a leading oncology IRCCS, ethical conduct with patient safety at its core, and a broad national and international network. More than a service provider, CRO-IRST is a strategic partner in the development of new therapies and in the advancement of clinical research.

SERVICES

- Preliminary & Start-Up Activities: Study planning, organization, investigator selection, preparation of regulatory files, authorization requests, and submissions.
- Types of Studies: Interventional pharmacological and non-pharmacological, observational, and biological studies.
- Ethics & Regulatory Authorizations: Management of Competent Authority (AIFA) approvals, Ethics Committee submissions, administrative authorizations, portal management, and protocol amendments.
- Project Management & Coordination: Monitoring coordination, logistical support, site communication, training, protocol/CRF support, SAE management, and GCP compliance.
- Monitoring Activities: Development of monitoring plans, pre-study visits, initiation visits, routine monitoring, close-out visits, and telephone/centralized monitoring.
- Safety & Pharmacovigilance: Pharmacovigilance activities, SAE/SUSAR reporting, DSUR management, and regulatory reporting in EudraVigilance.
- Quality Assurance: Audits and QA activities, ensuring compliance with DM 15 November 2011 and other relevant regulations.
- Statistics & Data Analysis: Sample size calculation, randomization, statistical analysis plans, programming, data analysis, reporting, and DSMB reporting.
- Documentation & Reporting: Management of Trial Master File, Investigator File, statistical reports, newsletters, and study archives.
- Training & Communication: CRA training, sponsor-investigator communication, and support in study procedures.

CONTACT

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