

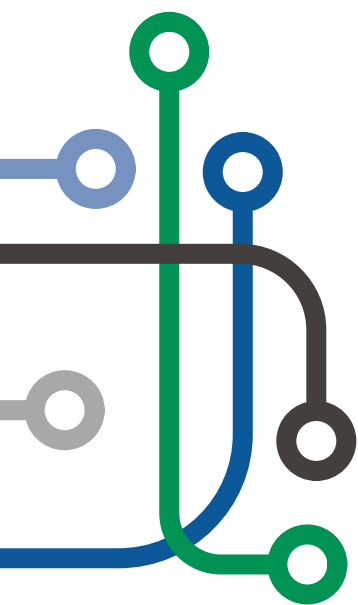


SERVIZIO SANITARIO REGIONALE  
EMILIA-ROMAGNA

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



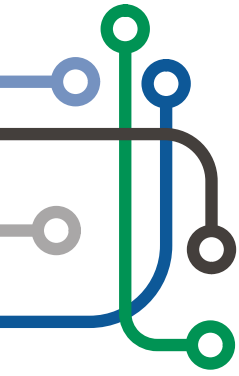
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# CONTRACT RESEARCH ORGANIZATION

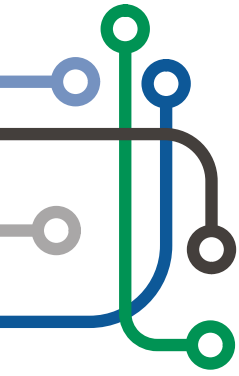
The Contract Research Organization of the Romagna Institute for the Study of Tumors “Dino Amadori” IRCCS represents a strategic infrastructure for oncology clinical research at both national and international levels. Operating in compliance with **Good Clinical Practice (GCP)** and European and Italian 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.





# 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

## Headquarters

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## Operating Office

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