
Sintesi
Research


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Every client is a "new" client for us.
We execute every project with the utmost attention to details, and uncompromised focus on quality which has earned us the confidence and trust of national and international biotechnology and pharmaceuticals companies.

Paolo De Simoni
CEO

Sintesi Research is a CRO specialized in **Clinical Trials Management** which offers **full support** in planning , running and reporting Clinical trials.

Sintesi Research provides a wide range of **professional services** and **technologies solutions** to pharmaceuticals and biotechnology industries, meeting our customers' requirements on time, on budget, with full transparency and focusing on **quality, flexibility and reliability**.

Clinical trials management from phase I to phase IV, medical devices, food supplements, concept development, project management and monitoring, data management and statistics, medical writing

Business intelligence, Solution, statistical, Data base management, ASP application, web, development

Communication and Publishing. Multimedia and paper –based special projects, journal, congress report, slide kit, patients record, Clinical case, educational for Patient, web sites.

Sintesi Research acts as a partner for the whole spectrum of clinical investigations, with ad-hoc teams led by experienced Clinical Project Managers.

Phase I, II, III, IV

Retrospective

Observational

Investigator sponsored studies

Medical Device

Nutraceutical

Services

01 STUDY DESIGN

02 REGULATORY

03 CLINICAL MONITORING

04 PROJECT MANAGEMENT

05 DATA MANAGEMENT

06 STATISTICS

07 MEDICAL WRIITNG

08 SAFETY MANAGEMENT

09 MEETING ORGANIZATION

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02
03
04

STUDY DESIGN

- Protocol design
- Feasibility investigation
- Risk evaluation
- Clinical development consultancy

REGULATORY

- Medical document preparation
- IRB/IEC/RA submission
- Local insurance policies
- Economic contracts and agreement

CLINICAL MONITORING

- PIs and study staff training
- Monitoring activities (SQV, SIV, IMV, COV)
- Operational assistance

PROJECT MANAGEMENT

- Sites management
- Tracking of study activities
- Protocol deviations management
- Study plan preparation
- GCP compliance assessment
- Study staff coordination

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DATA MANAGEMENT

- Database set-up and maintenance
- CRF design
- Online randomization
- Alert management upon specific events
- Uploading of diagnostic imaging files
- ePRO (electronic patient diary)
- Drug and supply management
- Customized report generation

STATISTICS

- Protocol design
- Sample size calculation
- Statistical analysis plan
- Statistical programming
- Statistical reporting

MEDICAL WRITING

- Clinical documents
- Papers
- Study reports
- Operating manuals

SAFETY MANAGEMENT

- Post marketing surveillance

MEETING ORGANIZATION

- Investigator meetings
- Logistic management
- Slides and report preparation and presentation

Therapeutic Areas Experience

- CARDIOVASCULAR
- CENTRAL NERVOUS SYSTEM
- DERMATOLOGY
- ENDOCRINOLOGY
- GASTROENTEROLOGY
- HAEMATHOLOGY
- IMMUNOLOGY
- INFECTIOUS DISEASES
- NEPHROLOGY
- OBSTETRICS AND GYNAECOLOGY
- ONCOLOGY
- OPHTALMOLOGY
- ORTHOPAEDICS
- PAEDIATRICS
- RESPIRATORY
- RHEUMATOLOGY
- TRANSPLANTATION
- UROLOGY
- VACCINES

Coverage

- EUROPE
- USA
- LATIN AMERICA
- MIDDLE EAST
- SOUTH / NORTH AFRICA
- INDIA
- SOUTH EAST PACIFIC

Locations

- Milano (ITALY) HEADQUARTERS
- Tel Aviv (ISRAEL)

Strategic Alliances

Sintesi Research established worldwide strategic alliances with **high specialized professionals** and **qualified companies** in the North and South America, India, Middle East, South Africa and South East Pacific.

Thanks to these very **qualified and highly technological partnership**, Sintesi Research offers a state-of-the-art expertise to **minimize risks**, optimize project development and give the working Team all possible advantages in accessing **new insights and solutions**.

Sintesi Research has developed regulatory and Monitoring services globally with **qualified personnel**.

A specific and dedicated project team is built on a trial basis according to the client requirements.

All the clinical monitors operating through the countries are coordinated by a dedicated **project manager**.

With the **knowledge** of local languages, **our international teams** provide a **high quality level** of support to the investigational sites.

With a **deep clinical and therapeutics expertise**, each subsidiary offers a complete range of customized Phase I to phase IV trials and ancillary services.

Sintesi Research

HEADQUARTERS

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