
Sintesi
Research
CLINICAL TRIALS MANAGEMENT

Sintesi Research
CLINICAL TRIALS MANAGEMENT

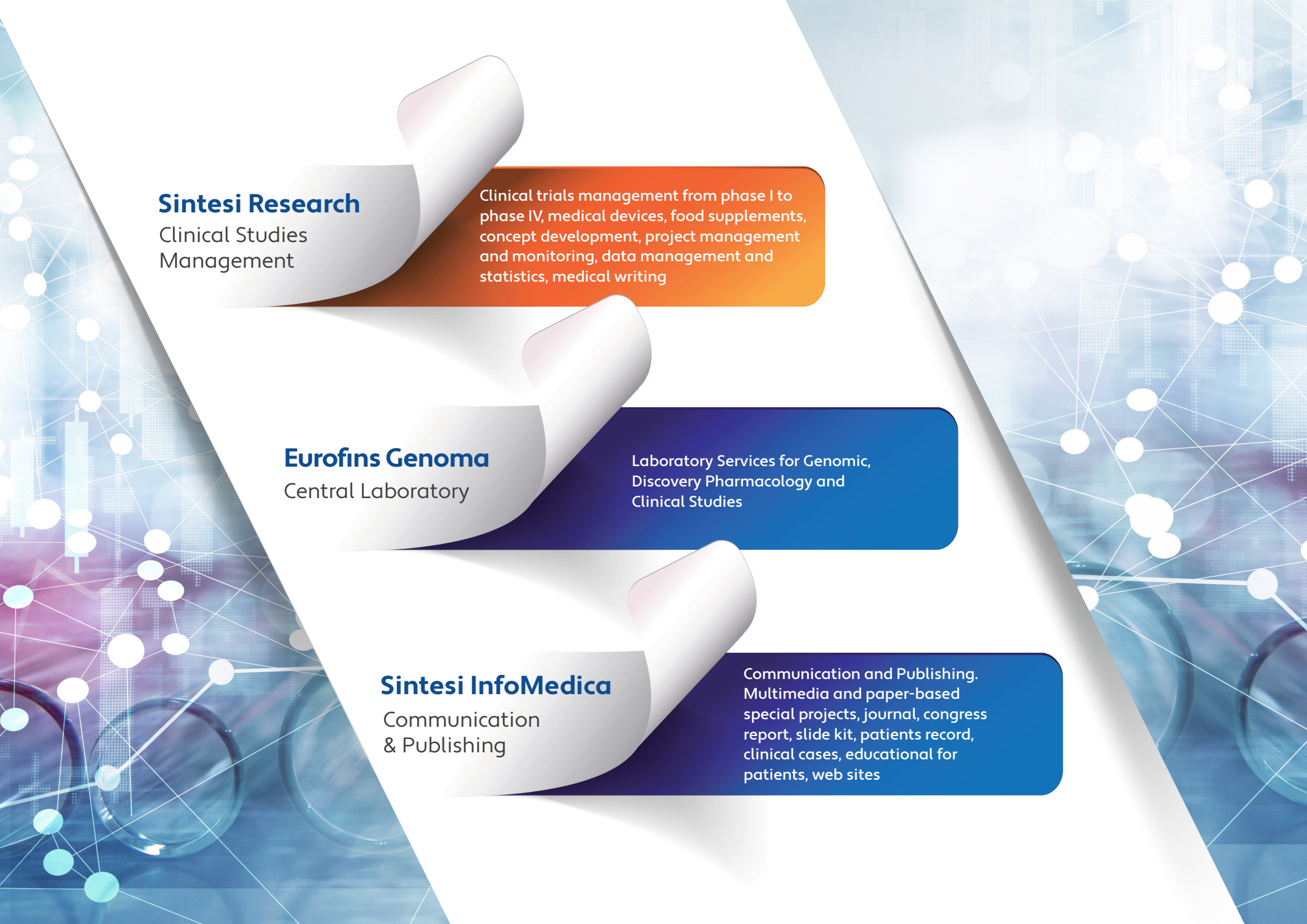
Every client is a "new" client for us.
We execute every project with the utmost attention to details, and uncompromised focus on quality which has earned us the confidence and trust of national and international biotechnology and pharmaceuticals companies.

Paolo De Simoni
CEO

CLINICAL TRIALS MANAGEMENT

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 **technological solutions** to pharmaceuticals and biotechnology industries, meeting our customers' requirements on time, on budget, with full transparency and focusing on **quality, flexibility and reliability.**


Sintesi Research
Clinical Studies Management
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
Eurofins Genoma
Central Laboratory
Laboratory Services for Genomic, Discovery Pharmacology and Clinical Studies
Sintesi InfoMedica
Communication & Publishing
Communication and Publishing. Multimedia and paper-based special projects, journal, congress report, slide kit, patients record, clinical cases, educational for patients, 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

Pharmacokinetics/Bioequivalence

Observational/Epidemiological

Investigator Sponsored Studies

Medical Devices

Nutraceutical

SERVICES

STUDY DESIGN

FEASIBILITY

REGULATORY

CLINICAL MONITORING

ELECTRONIC ARCHIVE

PROJECT MANAGEMENT

DATA MANAGEMENT

STATISTICS

MEDICAL WRITING

LABORATORY MANAGEMENT

SAFETY MANAGEMENT

MEETING ORGANIZATION

SUPPLY MANAGEMENT

PROJECT DEDICATED WEBSITE

PRODUCTS DISTRIBUTION

1 STUDY DESIGN

- Choice of Investigational design
- Statistic methodology
- Protocol design
- Feasibility investigation
- Risk evaluation
- Clinical development consultancy

2 FEASIBILITY

- Sites / countries identification
- Feasibility questionnaire finalization / management
- SQV on site
- Feasibility Report finalization

3 REGULATORY

- Medical document review and preparation
- IRB/IEC/RA submission
- Local insurance policies
- Economic contracts and agreement
- Medical Device: technical dossier review

4 CLINICAL MONITORING

- PIs and study staff training
- Monitoring activities (SQV, SIV, IMV, COV)
- Operational assistance
- Risk based Monitoring
- On-site Monitoring
- Remote monitoring

5 ELECTRONIC ARCHIVE

- Sidox, a validated platform for TMF and ISF
- TMF standardized on GCP-compliant template
- TMF files (gTMF, CSF, CoSF, ISF)
- Easy monitoring (i.e. Checklist function)
- Optimized inspection-readiness
- Privacy guaranteed

6 PROJECT MANAGEMENT

- Project / Monitoring Plan preparation
- Sites management
- Tracking of study activities
- Protocol deviations management
- GCP compliance assessment
- Study staff coordination
- Newsletter finalization and management
- Project website dedicated

7 DATA MANAGEMENT

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

8 STATISTICS

- Protocol design
- Sample size calculation
- Statistical Analysis Plan
- Statistical programming
- Statistical reporting

9 MEDICAL WRITING

- Clinical documents
- Study protocol
- Investigator Brochure
- Papers / Abstracts
- Clinical Study Reports
- Operating manuals
- Literature reviews
- Investigational medicine Product review
- Advisory Board Coordinating

10 LABORATORY MANAGEMENT

- In-house studies
- Client's facility studies
- Wide range of non-GLP and GLP analyses
  - Pharmacokinetic/toxicokinetic
  - Metabolism, immunology and analytical chemistry
  - Imagery, surgery and histopathology

11 SAFETY MANAGEMENT

- Safety review/preparation of clinical trials documents
- Preparation of Safety Monitoring/ Management Plans
- Individual processing for Serious Adverse Events (SAEs)
- Case narrative
- Expedited reporting (through EudraVigilance)
- Aggregate report preparation and reporting (DSUR)
- Investigation and assessment of Incidents
- Reporting Incidents with Manufacturer's Incident Report
- Pharmacovigilance governance
- Training
- Post marketing surveillance

12 MEETING ORGANIZATION

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

13 SUPPLY MANAGEMENT

Centralized path to supply and ship clinical trials drugs
Supply chain management from to shipping and replenishment
Monitoring of kits supplies onsite

14 PROJECT DEDICATED WEBSITE

Project Team contacts always available
Full and updated Site list
Key project documents at disposal
IMP / Central Lab. instructions with videos and tutorials
Project status / Newsletter
FAQs section
CRA training / Investigators meeting video materials always at disposal

15 PRODUCTS DISTRIBUTION

Support products distribution on EU / USA market
Drugs, medical devices, nutraceuticals, cosmetic

Therapeutic Areas Experience

ADVANCED THERAPY

CARDIOVASCULAR

CENTRAL NERVOUS SYSTEM

CRITICAL CARE

DERMATOLOGY

ENDOCRINOLOGY

GASTROENTEROLOGY

HAEMATHOLOGY

IMMUNOLOGY

INFECTIOUS DISEASES

NEPHROLOGY

OBSTETRICS AND GYNAECOLOGY

ONCOLOGY

OPHTALMOLOGY

ORTHOPAEDICS

PAEDIATRICS

RESPIRATORY

RHEUMATOLOGY

TRANSPLANTATION

UROLOGY

VACCINES

Coverage

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

Locations

Milano (ITALY) HEADQUARTERS
Barcelona (SPAIN)
Tel Aviv (ISRAEL)
Nashville (USA - TENNESSEE)

Strategic Alliance

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 trials 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

CLINICAL TRIALS MANAGEMENT

HEADQUARTERS

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