NEXTRASEARCH

About Us

Nextrasearch is an Italian Contract Research Organization (CRO) accredited by AIFA, serving clients across Italy and Europe. We embody a forward-thinking approach to global contract research, delivering bespoke solutions either directly or through our network of specialized, qualified partners. We provide tailored services to pharmaceutical, medical device, cosmetic, and food supplement companies.

Our services

1. Clinical and Preclinical Research

For pharmaceuticals, medical devices, cosmetics, and food supplements:

- Clinical Studies (Phase II–IV)
  - Study design and risk management
  - Protocol development
  - Site and investigator selection
  - Feasibility and sample-size analysis
  - Ethics Committee and regulatory submissions
  - Integrated monitoring and quality control
  - CRF/eCRF design and implementation
  - Investigational product and placebo logistics
  - Study reporting and documentation review
  - Scientific writing and publication support

- Observational and Real-World Evidence (RWE) Studies
  - Study planning and protocol design
  - Site and investigator selection
  - Feasibility and sample-size analysis
  - Ethics Committee and regulatory submissions
  - Data collection, validation, and analysis
  - Study reporting and documentation review
  - Scientific writing and publication support

- Preclinical studies
  - In vitro testing support
  - In vivo testing support (ADME; PD/PK; toxicology; biocompatibility)
  - Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER) for medical devices

2. Regulatory affairs

- Interim or fractional regulatory support for staffing gaps or peak workloads
- End-to-end lifecycle support at scalable service levels
- Project-based consultancy for pharmaceuticals and medical devices
- Acting Regulatory Affairs (RA) role compliant with current legislation
- Preparation of dossiers for submission to health authorities
- International registration support (EU, Middle East, Far East, US, South America)

3. **Quality management**
    - Development and review of QMS under ISO 9001 and ISO 13485
    - Pre-audit assessments and support for notified-body audits
    - Supplier and third-party quality-system audits
    - Acting Quality Assurance (QA) role compliant with current legislation

4. **Pharmacovigilance and vigilance on medical device**

    Scalable service levels to meet any requirement
    - Post-marketing surveillance, database, and source monitoring
    - Medical evaluation of adverse events
    - Scientific review of safety documentation
    - Local Qualified Person for Pharmacovigilance (LQPPV) compliance

Our competitive advantage

We deliver a holistic, integrated approach to product development, offering bespoke services that precisely address our clients' needs while optimizing cost, speed, and efficiency. Our solutions seamlessly integrate at every stage of the product lifecycle, reducing both time-to-market and total cost without sacrificing quality or customization. Our multidisciplinary team combines deep bioscience expertise with strategic business acumen, with particular strength in dermatology and skincare innovations.

Contact us

To learn more about our services or discuss your project requirements, please get in touch:

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