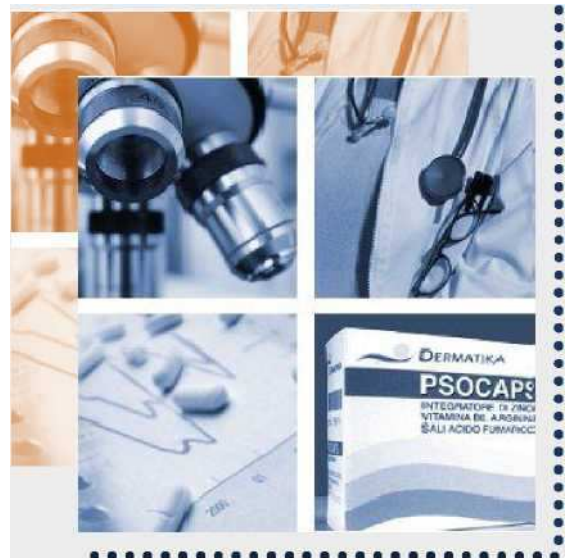




NEXTRASEARCH

Efficiency and reliability in the service of pharmaceutical





About us

Nextresearch represents a new philosophy of virtual and global contract research, made by a team of expert companies in the development of pharmaceutical projects.

Nextresearch, in fact, is a service company for pharmaceutical and para pharmaceutical area and its primary goal is to provide responsible consultancy support, flexible and effective to satisfy necessity of its customers.



Preclinical and Clinical Trials



The company operates through an internal organization of clinical services (CRO) and relies on scientific advisor and services related to pharmaceutical development comprising experts in market research and regulatory affairs; Nextresearch staff and partners have, in fact, high levels of experience both in the biosciences that in business development.

Nextresearch is looking for promising projects and molecules in the pharmaceutical industry from universities, research centers of primary importance, and small biotech companies in need of support and logistics and financial services. The company focuses on the project through the formulation of preclinical studies, which include both the pharmacodynamics, pharmacokinetics, and finally to the phase I - II - III clinical trial.

To perform these studies Nextresearch offers the following services:

- ❖ development of guidelines and strategies of the project based on a continuous statistical support;
- ❖ identification of hospital / university clinical centers;
- ❖ feasibility studies with analysis center to center for a correct evaluation, to ensure the number of patients defined by biometrics;
- ❖ planning of the Ethics Committee authorizations;

- ❖ authorization of the ISS;
- ❖ planning of material to supply centers and tables for the timing of sampling and clinical findings;
- ❖ management and control of integrated monitoring;
- ❖ reports and review of clinical trials and registration strategy;
- ❖ CRF

Preclinical and Clinical Trials



Technical Nursing Assistance

Service Goals

📁 Technical Assistance to patients with auto-injector

- ❖ Cartridge recovery & Loading autoinjector
- ❖ Proper administration technique (rotating injection sites)
- ❖ Traceability of lots (with tests of recall)
- ❖ Collection of technical complaint & Transmission adverse events

Mode of Delivery

- ❖ Visits to the patient's home & Visits to the center & Telephone contact with the patient

Contact Telephone

- ❖ Telephone contacts for follow-up of patients with particular reference to the collection of:
 - Technical Complaint
 - Adverse Event
 - Drop out
- ❖ Possibility of detailed reports O Compliance with privacy regulations





Pharmacovigilance

We guarantee the assumption of responsibility for global pharmacovigilance. Nextrasearch offers not a solution, but a range of modular solutions for pharmacovigilance, independent of each other, can cover a wide range of needs, all at highly competitive prices.

Flexible solutions for your needs of pharmacovigilance are:

O *"Economic level* package: this basis package provides the management and maintenance of the database, the generation of reports, the back-up time, a helpdesk, secure transmission of data and access data in EudraVigilance via Internet by Sponsor and/or by Nextrasearch.

O *"Professional level* package means the Economic package level can be integrated with the activities of data collection specific to each individual case, whenever their source (eg care facilities, doctors ...) has been reported by the Sponsor or, alternatively, has made contact with Nextrasearch directly. In addition includes the first contact with the source of the alert, the collection of documentation, data cleaning and coding MedDRA.

O *"Specialists level"* package: in addition to the activities described in previous levels, are carried out medical advice on the events and related reporting, including the assessment of the scientific literature about the event.



NEXTRASEARCH

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