keyrus life science

The Connected-CRO

Accelerate your R&D with Keyrus Life Science

Keyrus Life Science is the **Connected-CRO** (**C²RO**) that links **Life Science** to **Data** & **Digital** fields, to improve the **efficiency**, **ambition** and **resilience** of life science projects.

Being a **mid-size CRO**, **Keyrus Life Science** is committed to proposing **end-to-end** and **integrated** clinical research services, with **agility**, **reliability** and **excellence**.

With a **longstanding presence** on the clinical research market, **Keyrus Life Science** has developed an extensive **sectorial** and **scientific expertise**, and **international footprint** for our **full-service** offering.

A comprehensive service portfolio in clinical research & innovation

Keyrus Life Science gathers all **sectorial**, **scientific** and **technical** expertises required to manage efficiently your **life science projects**.

Clinical Strategies

Clinical Development Plan
Regulatory Strategy
Design & Methodology

Clinical Development

Regulatory Affairs
Clinical Operations
Data & Biostatistics
Medical Writing

RWE & Late Phase

Non-Interventional Studies
Secondary Data Use & External Data
Compassionate Use

Life Data Science

Clinical Data Fabric
Artificial Intelligence
Sensors & Wearables
Data Science & Visualisation

Digital Innovation

Hybrid to Decentralized Trials
Patient Engagement
Remote Data Monitoring

Delivered through 3 complementary business models

Business partner of all life science companies, **Keyrus Life Science** proposes 3 **delivery models** to match every organization **needs** & **requirements** to a T!

Consulting

Functional Service Platforms (FSP)

Projects

Defining a clinical strategy adapted to your medical device

The new **Medical Device Regulation (MDR)** has been put into practice in **may-2021**. This regulation imposes **new requirements** to **obtain** or **maintain** a **CE mark**.

With a particular focus on **Safety**, **Performance**, **Transparency**, and **Quality**, the **medical devices regulatory framework** converges with **drugs'**, while retaining some **proper specificities**.

Keyrus Life Science supports you in **defining** and **carrying out** all the **clinical investigations** and **post-marketing follow-ups** required for the **CE marking** of your devices.

An expert team capable of operationalizing efficiently your studies

Regulatory & Methodological Strategy

We accompany you from the review of the **Clinical Evaluation Plan** and the **Clinical Investigation Plan**, in order to optimize the **methodology** of the trials and to **adapt** them to the **notified bodies requirements**.

Project Management & Monitoring

Trained on **ISO 14155** and **14971 standards**, our **project managers** and **CRAs** have all the expertise necessary to **manage efficiently** your **clinical investigations**, in line with the **technical specificities** of your product.

Biometry & Medical Writing

Experienced in **clinical investigations** on medical devices, our teams prepare and carry out all the necessary **statistical analyses** and **documentation**, from the project launch to **regulatory approval** of the device.

A solid experience in clinical validation of medical devices

MicroPort™

Coloplast

Peters SURGICAL

+35
Device Studies
5 past years

1 - 50
Centers

30 - 500
Patients

GaBi SMARTCARE

3prime LAB

echosens