axelys SANTÉ

Partner of healthcare stakeholders

www.axelys-sante.com

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Content

Who are we?

2025

Axelys Santé receive **ISO9001:2015** certification by Bureau Veritas for our Quality Management System.

2023

Axelys Santé celebrates its 10th anniversary and looks forward to continuing to meet the challenges of healthcare.

2015

Axelys Santé sets up in Algeria, opening the doors to the MENA (Middle East & North Africa) region.

2013

Axelys Santé is a French CRO founded in 2013.

Our purpose

As your reliable partner

1. Support pharmaceutical industries, biotech companies & academic institutions throught a **broad** & **detailed** range of services.

2. Provide **high-level** expertise backed by more than 10 years' experience to propose **relevant solutions** from **development** to **post-marketing** activities.

3. Ensuring **integrity**, **commitment** & **operational efficiency** for meaningful & impactful partnerships.

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Our services

360° expertise throughout the life cycle of your healthcare product

Clinical Operations & Biometrics

Medical Information

Pharmaceutical & Regulatory Affairs

Medical Affairs & Scientific Communication

Market Access

Wide range of therapeutic areas

Oncology

Breast cancer, lung cancer, etc.

Inflammation & Immunology

Inflammatory Bowel Diseases, diabetes,etc.

Dermatology

Atopic dermatitis, alopecy, wound healing, etc.

Orphan diseases

Duchenne Muscular Dystrophy
Spinal Muscular Atrophy, etc.

Hematology

Thalassemias, leukemias, etc.

Biosimilars & Gene therapy

Infectious diseases & epidemiology

HIV, HCV, HBV, etc.

Rhumatology

Sport medecine, rheumatoid arthritis, etc.

Other

Cardiovascular diseases, dental care, etc.

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Clinical Operations & Biometrics

1

Feasibility study

- Literature review
- Organization of KOLs* boards
- Preparation of **methodology** and **statistical design**
- Identification of **logistical** and **regulatory requirements**

2

Study start-up

- **Clinical plan development**
- Invest and **sites selection**
- **Essential doc** preparation
- eCRF configuration
- **Regulatory submissions** in accordance with current regulations*
- Staff **training**

3

Conduct phase

- Investigation **site activation**
- Participants enrollment & **monitoring**
- **Regulatory compliance & data management**
- Ongoing **staff assistance** with technical problems (eCRF*, protocol questions, etc.)

4

Close-out phase

- Close-out monitoring
- Cleaning and locking of databases
- **Statistical analysis**
- **Medical writing** & drafting of reports
- Preparation of abstracts and articles for **publication**

Audits & subcontractors' management

Regulatory Intelligence

Quality Management System
Data protection

**KOL : Key Opinion Leader ; Regulations : Jardé law, European regulations n°536/2014 on CTIS, n°2017/745 and n°2017/746 ; eCRF : electronic Case Report Form*

Pharmaceutical & Regulatory affairs

Pharmaceutical assistance

- **Advertising control**

- Management of subcontractors (e.g.: PV* & MedInfo*)

- Activities related to r**egulatory affairs** and **quality assurance** (*batch tracking, quality claims management, deviation management, etc.*)

- Offer **Interim Responsible Pharmacists** registered within the French Order of Pharmacists

Regulatory submissions

- **Medicines** - Marketing Authorization applications and variations

- **Medical Devices** - Drafting of CE labeling technical files (compliance with ISO 13485)

- **Cosmetics** - PIF* preparation, notification on the european CPNP*

- **Clinical research** - regulatory submission in accordance with current regulations* & RWD submissions

Compliance

- Create a **laboratory account** on the platform of the French National Medical Council (CNOM) or another professional order

- Drafting of agreements in French and application to the competent authorities under the **French Anti-Gift Law**

- Declaration of links of interest on the French public database **Transparence Santé** (French Sunshine Act)

Quality Assurance

- Support in setting up a **Quality Management System**

- **Audits** of subcontractors

**PV : pharmacovigilance ; MedInfo : Medical Information ; PIF : Product Information File ; CPNP : Cosmetic Products Notification Portal ; Regulations : Jardé law, European regulations n°536/2014 on CTIS, n°2017/745 and n°2017/746.*

Medical affairs & Scientific communication

Medical and scientific writing

- **Medical writing** of *articles, posters, reports, protocols, etc.*

- **Literature review** and **state-of-the-art research**

- **Medical claims** revision & scientific data valorization

Relations with healthcare stakeholders

- Organization and management of **scientific events** & **advisory boards**: KOLs* engagement, staff provision, moderation and logistics

- Foster and expand a **medical network** across any therapeutic area

- Build and strengthen relationships with **healthcare authorities** and **patient associations**

Training and support of operational teams

- Design and development of **training materials**

- **Training sessions** for sales representatives, KAMs & MSLs*

- Support in **certification*** of promotional information

Regulatory support

- **Medical** & **regulatory guidance** for both promotional and scientific communications for external dissemination

- **Compliance** with Anti-gift law & French Sunshine Act

**KAMs : Key Account Managers, KOLs : Key Opinion Leaders, MSLs : Medical Science Liaison, Certification : "Charte de l'information promotionnelle is a french certification that regulates the promotional information practice, by ensuring the quality of the information provided to healthcare professionals and improving the proper use of medicines.*

Medical Information

Management of Medical Information requests

- Outsourcing of product portfolio according to technical specifications
- Handling **level 1 & 2 requests**
- **Medical** and **scientific monitoring**, bibliographic research
- Drafting FAQs* and standard responses

Phamacovigilance & Quality complaints

- **Identification** and **notification** of **pharmacovigilance** cases and **product quality complaints**
- **Data protection and management** according to **Quality Management System**

Crisis management

- **Fast deployment** of a dedicated unit: batch recalls, out-of-stocks, quota systems, etc.

Call center

- **24/7** requests reception

*Support in drafting specifications & SOP**

Quality Management System
Data protection

**FAQ : frequently asked questions ; SOP : Standard Operating Procedure.*

Market Access

Strategy

- **Develop** and **implement** local market access strategy

- **Competitive positioning** including analysis of comparable products on the market, clinical data valorization, etc.

- Organization of **experts meetings** in close collaboration with medical and regulatory teams

- Monitoring and analyzing **French & European regulatory frameworks** to ensure **compliance** and **strategic alignment**

Reimbursement & price

- Development of pricing and reimbursement strategies

- Drafting and submissions of **reimbursement** files (to HAS* or CNEDiMTS*) and **pricing** file to CEPS*

- Presentation of **supportive arguments** for conferences and strategic meetings

Derogatory Accesses

- **Drafting** and **submission** of applications for derogatory accesses* in France

- **Stakeholders engagement** : laboratories, authorities, lawyers, healthcare professionals, patient associations

Real World Data

- Design and management of **post-AMM* studies** to generate real-life data

- Analysis from **French databases** (SNDS, PMSI, etc.)

- Qualitative and quantitative studies to assess stakeholder expectations

**AAP : Autorisation d'Accès Précoce, Early access ; AAC : Autorisation d'Accès Compassionnel, Compassionate access ; HAS : French National Authority for Health ; CEPS : Economics Committee for Health Products ; CNEDiMTS : HAS commission for Medical Devices.*

Our values

Innovation

Healthcare is an **exciting** field, and there are still many challenges ahead. We meet them with **determination** and **dedication**. We remain proactive, proposing **relevant** and **innovative** strategies and solutions adapted to the specificities of your project.

Expertise

Axelys Santé has over **10 years** of experience and in-depth knowledge of the field. Our team of experts can support you on a **wide range** of technical issues, to respond **precisely** and **efficiently** to your requests and concerns.

Integrity

We attach the highest level of **ethics** and **rigor** to the **quality** of our work. We firmly believe that **transparency**, collaboration and **communication** are the key to our **collective achievement**.

Commitment

We are committed to making your project **successful**. This means paying particular attention to each partner, while guaranteeing **operational efficiency** through **agility** and **adaptability** in the management of our assignments.

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Our network

Axelys Santé is an active member of …

AFCROs
LES ENTREPRISES DE LA RECHERCHE CLINIQUE

france biotech
biotech | medtech | e-santé | IA
LES ENTREPRENEURS DE LA HEALTHTECH

France Innovation

mabdesign
THE BIOTHERAPY EXPERT

EUCROF
European CRO Federation

Let's keep in touch!

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