ALTA
medical services

Transforming medical complexity into actionable insight

OUR SERVICES

Tailored Medical Affairs and Clinical Operations support across the product lifecycle

All rights reserved. Version 2023

Clinical Operations

Where science and administration meet: we help your clinical trials move forward, navigating the clinical development journey

Integrated clinical trial conduct solutions including feasibility, site selection, patient recruitment & retention, site management, site monitoring, patient safety services and a flexible trial approach.

Clinical Operations

- Scientific full-service planning and clinical trial execution
- Clinical Development Solutions
- Clinical Trial Design and Start-Up
- Project Management
- Clinical Study Design
- Study synopsis
- Patient Information Sheet and Informed Consent

Administrative Support

- Site Contract Negotiation
- Contract Negotiation with PI/other entities
- Sponsor–CRO Contract Management or other entities
- Fees payment management

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com

Statistics & Data management

Support adapted to the needs of the client

We offer integrated data management and biostatistics services, supporting clinical and real-world studies with accurate, compliant, and meaningful analyses.

Statistics & Data management

- Creation and validation of the database for form data entry
- Design of Case Report Form (CRF) template
- eCRF programming and validation
- Query management
- Sample size calculation
- Statistical Analysis –
- Final Clinical Study Report
- Post-hoc Statistical Analysis

Type of studies

- Clinical Trials with Medicines/Medical Devices
- Investigator Sponsored Research and Externally Sponsored collaborations
- Observational, non-interventional studies
- Real World Evidence & Real World Data

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com

Medical Affairs Services

Generates and communicates scientific and clinical evidence

We drive Medical Affairs performance through strategic leadership and scientific excellence.

Development of:

- Scientific exchange with healthcare professionals (HCPs)
- Advisory boards (design, moderation, and insights reporting)
- Scientific content development (slide decks, FAQs, training materials)
- Medical review of promotional and non-promotional materials
- Publication planning and medical writing
- Evidence generation support (RWE, IIS, observational studies)
- Medical input for clinical development and life-cycle management
- Support for congresses and scientific meetings
- KOL identification, mapping, and engagement strategies

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com

Medical Affairs Strategy

Medical Affairs Professionals play a critical role in the scientific exchange between companies and HCP

Due to the importance of delivering credible medical information and the increased scrutiny on Medical Affairs, companies must continually update their policies and ensure cross-training between medical and commercial departments.

Outsourcing Medical Affairs activities

- Medical lifecycle management Planning
- Product and therapeutic area strategy
- Product opportunity assessments
- Medical Affairs development and best practices
- Commercial operations best practices operations implementation
- Policies on scientific interactions, Medical Governance, off-label management, etc
- Life cycle management: mature medicines

Strategic planning

- Meaningful digital experiences
- Creativity & innovation, accurate scientific messages
- Scientific data interpretation

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com

Scientific Communications & Medical Information Management

External and Internal activities

We collaborate to generate evidence and information management at external and internal levels. We also develop clear and concise scientific messaging across different territories and delivery channels.

Medical information activities

- Response to basic enquiries (SmPC, patient leaflets, FAQs)
- Response to complex inquiries
- Preparation of written responses
- Therapeutic area updates
- Product updates
- Market access support
- Response to enquiries on scientific information on drugs
- Legislation (copyright, etc)
- Review and/or approval of promotional materials
- External user bibliography service (articles and searches)

Information management: Medical Communication

- Publications
- Conferences and congresses
- Medical information
- Marketing initiatives and events
- Continuous medical education

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com

Scientific Exchange & Medical Education Meetings

Communicate accurate scientific information that aligns with the company's vision and goals

We offer support in engaging audiences through different channels, face-to-face, and virtual events.

Outsourcing Medical Affairs activities

- Scientific exchange Organization
- Scientific symposia at congresses: organization and approval of materials
- Company organised stand-alone meetings
- Other medical, educational platforms
- Medical meeting report & dissemination to different teams (proactive, internal commercial teams, medical affairs)
- Clinical Science Area at congresses

+34 661 569 570 Rd. Sant Pere, 52 1ª annamunoz@altamedicalservices.com www.altamedicalservices.com