

# Optimize

your safety and clinical activities



**ADD S**

ADVANCED DRUG DEVELOPMENT SERVICES

# Advanced Drug Development Services

is a leading European Contract Research & Safety Organization (CRO & CSO)

- Expertise in CNS, Cardiology, Oncology and Medical Devices
- Strong know-how and offices in Western and Central Europe, Israel and North Africa
- Global Safety and Risk Management approach: integrated, proactive and science-based

Our teams have been committed to timely and accurate results since 1995 and adapting to your specific needs, whether you are a pharmaceutical, a biotech or a medtech company.

Customer service and quality are our priorities. We guarantee you the highest levels of performance, reactivity and scientific integrity.

Our experienced and permanent team of clinical and safety professionals will offer you efficient and integrated solutions:

## Assisting you in your Clinical development programs:

- Conceive your complete development plan
- Secure administrative submissions
- Select right investigators
- Shorten recruitment time
- Improve patient retention ratio
- Anticipate risks
- Meet regulatory requirements

## Providing you full Safety and Risk Management services:

- Conceive your complete risk management plan
  - Fully outsource your Pharmacovigilance
  - European Qualified Person for Pharmacovigilance (EU QPPV)
  - Technical assistance: Data entry, Eudravigilance
  - Operational support and consultancy
- All along the product lifecycle

ADDS benefits from a strong medical expertise and well-established scientific Key Opinion Leader network.

The commitment of all our collaborators is to bring you results respecting your deadlines and budget.

Our presence and experience in Western and Central Europe, Israel and North Africa, our fully integrated solutions and thorough knowledge of targeted therapeutic areas will ensure you the best results.





# Clinical

As a CRO, ADDS offers full coverage of **pre-registration and late phase clinical studies for drugs and medical devices** in Western and Central Europe, North African and Near-East regions.

## **Our services include:**

- Consulting
- Conception of clinical studies
- Medical writing
- Regulatory and submissions
- Project Management
- Monitoring
- Data Management and Statistics
- Safety

> Customized and integrated outsourcing services to meet your specific needs

> Whatever your size and capabilities

# Streamline

your clinical development

## Dedicated teams

As a human-sized company, our strength is our flexibility and capacity to rapidly mobilize the most efficient team of experts according to your clinical program and therapeutic area. Our operational teams have an in-depth knowledge and understanding of European and local regulations.

- > Broad scientific network and Key Opinion Leaders
- > Experienced Project managers and Clinical Research Associates (CRA)

## Significant highlights

We use state-of-the-art IT Tools and Quality Assurance processes and the knowledge of our teams is constantly updated by training:

- > Quality Management System: ISO 9001:2000, Internal and external audits...
- > Customized web study portals and databases, e-CRFs...

## Strong and targeted expertise

- > CNS with a focus on Alzheimer, Psychiatry
- > Cardiology
- > Oncology
- > Medical Devices and Combination Products

## Your success

Our presence and knowledge of Western and Central Europe and North Africa enables privileged access to investigators, faster patient recruiting and highly reliable results.

# Safety and Risk Management

ADDS, as a CSO, will help you to meet the growing amount of European and international requirements by **outsourcing part or whole of your pharmacovigilance activities to our Safety & Risk Management Department.**

We specialize in fully integrated services for all vigilances:

- Pharmaceuticals
- Biotechnologies
- Blood Products
- Medical Devices
- Combination Products
- Advanced Therapies
- Cosmetics
- Nutraceuticals

Our European Qualified Person for Pharmacovigilance (EU QPPV) and English-speaking team are highly experienced in Pharmacovigilance and Eudravigilance certified.

## Extensive safety services

- > Consultancy & Strategy:
  - Integration of Safety into your company's strategy and into your Clinical Development Plan
  - Safety sections of Marketing Approval Dossier
- > Technological Solutions
  - Customised Safety database, E2B compliant, electronic reporting
  - Call centre, 24/7/365, Multi lingual
  - Data Mining tool and signal detection
- > Training
  - On site or e-learning
  - Simulation and case studies

# Be in line with European requirements

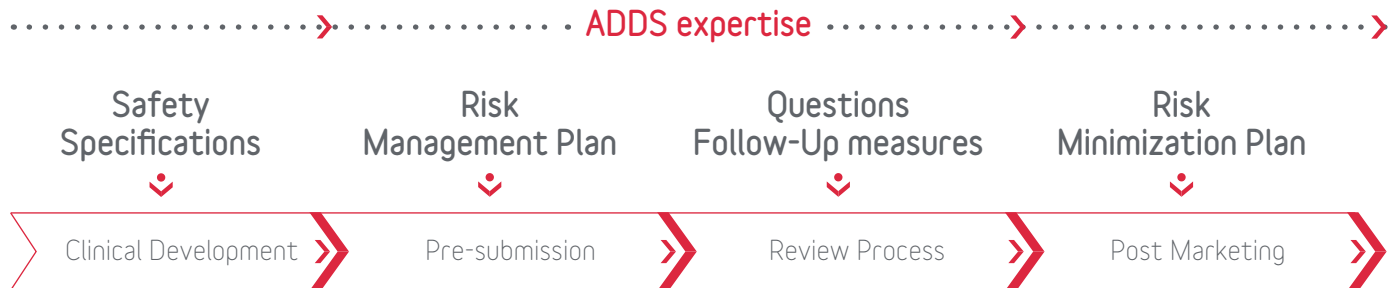
## > Operations

- In Clinical Trials and Post-Marketing area
- Case management
- Periodic and ad hoc safety reports: PSUR, DSUR, answers to Authorities queries, investigator brochure...
- Medical Information
- Regulatory & Literature Survey

## > Quality Assurance

- Set up of the Pharmacovigilance System Master File
- SOPs & workflow mapping
- Quality Plan
- Training Plan
- Audits
- Inspection readiness and assistance

## Risk Management System, all along the product lifecycle



# Advanced Drug Development Services

## locations

### Headquarter

France

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### Czech Offices

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### ADDs North Africa

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### Israel Offices

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