ATHERION BIORESEARCH

Clinical Research Services

www.atherion-bioresearch.com

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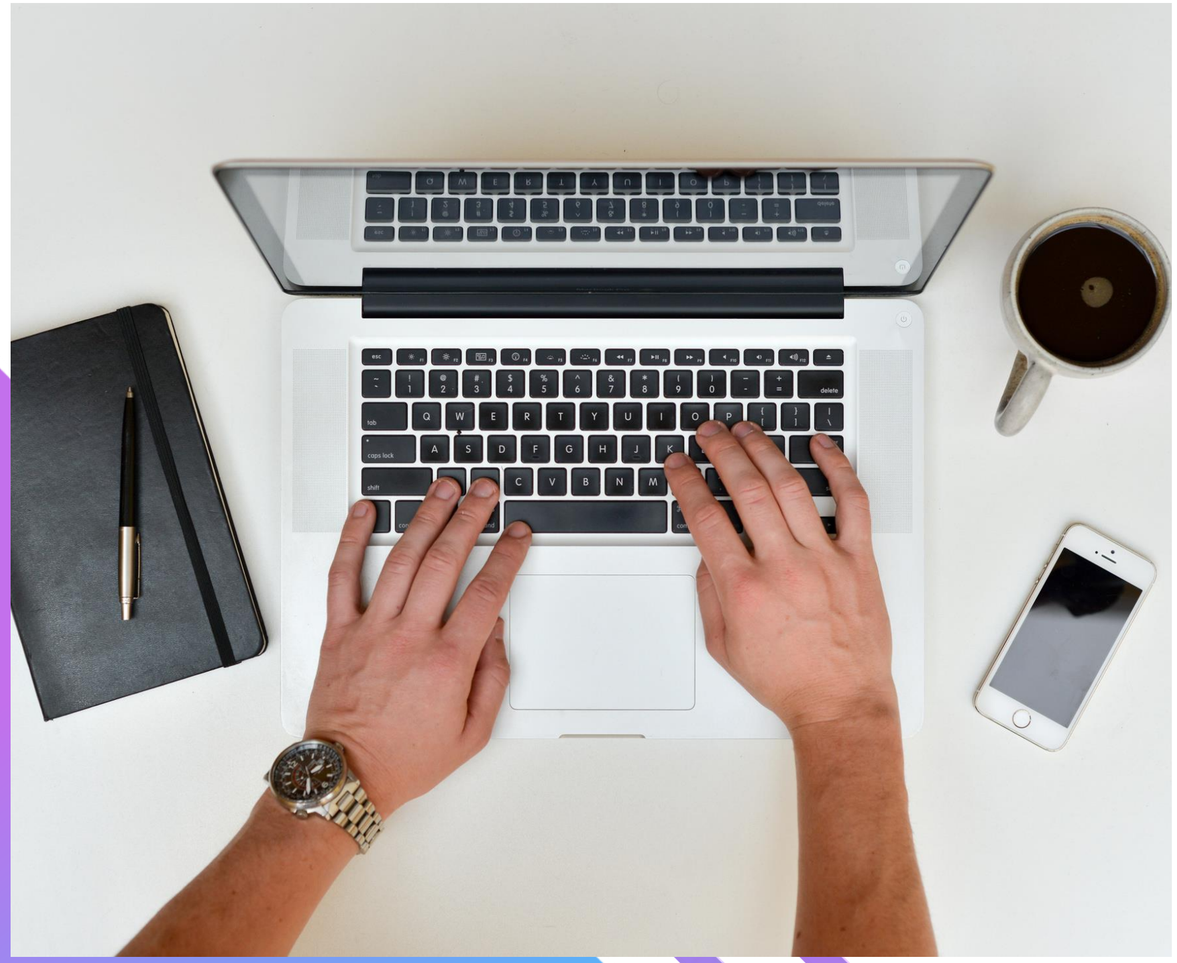

About us

Atherion was formed by a group of drug development professionals with extensive industry experience. We offer our expertise to help you with projects large and small, maximizing efficiency and minimizing cost and delays at each stage of the process. We are here to serve as your true partner in drug development.

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Our Services

Drug Discovery

- Preclinical study design
- Safety and toxicology
- Efficacy studies
- Lead candidate selection
- Manuscript writing

Clinical Trials

- Clinical trial design
- Protocol development
- Study start-up
- Project management
- Monitoring
- Data management
- Vendor management
- Image core lab services

Regulatory & CMC

- Regulatory consulting
- Regulatory filing preparation & submission
- GMP manufacturing
- CMC oversight
- Medical monitoring
- Post-approval communications

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Clinical Trial Management

- Study start-up:
  - Protocol development and writing
  - Vendor RFP and selection
  - CRF and EDC development
  - Site identification, qualification, and selection
- Study monitoring:
  - Data management and monitoring
  - Management of central vendors
- Study close-out:
  - Data cleaning and database lock
  - Statistical analysis
  - Data interpretation and clinical study report writing
  - Manuscript writing

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Clinical Imaging Management

- Study start-up:
  - Imaging manual
  - Image acquisition guideline
  - Independent review charter
  - Site identification, qualification, and selection
  - Instrument qualification
  - Site and reviewer training
- Study management:
  - Image acquisition oversight and QA
  - Image data management and monitoring
  - Image analysis/reader workflow management
- Study close-out:
  - Data cleaning and database lock
  - Image data storage
  - Data export

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Regulatory, CMC, and Medical Writing

- Early development:
  - Regulatory consulting
  - Pre-IND study planning
  - Regulatory filing preparation & submission- IND
  - GMP manufacturing
- Development:
  - CMC oversight
  - Medical monitoring
  - Protocol review and filing
  - CSR review and filing
  - NDA preparation and submission
  - 510(k) clearance appropriateness assessment, preparation, and filing for medical devices
- Post-approval:
  - Medical communications
  - Post-approval communications

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Experience Across Platforms and Indications

- Radiopharmaceuticals
- Imaging
- Oncology
- Rheumatology
- Ophthalmology
- Pulmonology
- Cardiology
- Neurology
- Musculoskeletal

CONTACT

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