

# Contract research organization: Driving success in clinical research and development

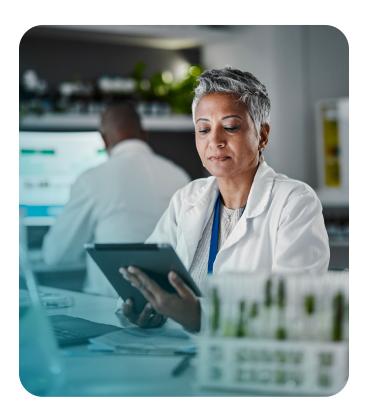
Personalized, expert guidance for navigating the clinical development process

As a full-service contract research organization (CRO), Calian has the knowledge and experience to help you achieve success in your product development programs. Whether you are a pharmaceutical or biotech company, or a medical device manufacturer, our CRO team will support you at every stage, offering a personalized and flexible approach to help you maximize your impact for positive health outcomes.

# Why choose us?

Our corporate DNA is based on putting you first. It's part of our core values. Everything we do is measured against the confidence, progress and success of our clients.

- Extensive knowledge and industry expertise: Our team of experienced clinical research professionals delivers exceptional quality across a wide range of subject matter, providing you with the expertise needed to advance your research.
- Commitment to integrity and quality standards: We adhere to the highest standards to meet all international guidelines and regulations and maintain transparency and trust throughout the process.
- Comprehensive and collaborative services: We guide you along your entire product development journey, from literature and systematic reviews to clinical study reports, technical briefs and manuals, fostering a collaborative and client-focused relationship.



# **Key services**

# **Clinical study management**

- Implement a collaborative approach for a responsive, client-driven environment
- Manage every step of the process, from site selection and feasibility assessments to start-up, study planning, risk management and interaction with regulatory authorities and ethics committees

# **Clinical monitoring**

- Provide exceptional attention to detail and in-depth knowledge to verify compliance with protocols, quality standards, data collection and regulatory guidelines
- Offer site selection, site initiation, interim monitoring and close-out visits, as well as remote monitoring, site personnel training, mentoring and guidance
- Assess protocol compliance and data integrity, as well as a host of other monitoring services

# Medical and scientific writing

• Leverage experienced writers and subject matter experts in a wide range of biomedical science areas for clinical trial design, protocol development, data analysis, clinical study report writing and support with regulatory submissions

#### Data management

- Use a full spectrum of data management services to optimize your data
- Rigorously follow standard operating procedures that encompass security, industry regulations and ICH/GCP to ensure all stakeholders' needs are met

• Offer comprehensive, user-friendly, cloud-based clinical data management platform that supports a wide range of study types and designs

# **Biostatistics**

- Establish a sound biostatistical plan for optimal study design and high-quality data output
- Comprehensive statistical input during the early stages of a clinical development program means decreased overall costs and accelerated timelines to regulatory approval
- Manage sample size calculation, protocol development support, statistical analysis plans, interim and final data analysis, support for medical writers and more

### Quality assurance

- Provide compliance oversight and guidance through carefully planned audits and detailed reports for continuous process improvements
- Offer quality assurance services that are also independent audits of clinical investigational sites, processes, documentation and assessment of the quality of data collected and processed

# **Regulatory affairs**

- Expert consultants facilitate the regulatory process
- End-to-end strategic regulatory support throughout the lifecycle of the project—from the early stages of product development through ongoing maintenance and post-registration

#### **Contact Us**

Reach out to our team today at <u>healthinfo@calian.com</u> to discover how we can support your product development and commercialization needs, drive innovation, maximize ROI and improve patient care together.





Calian<sup>®</sup> helps people communicate, innovate, learn and lead safe and healthy lives. Every day, our team embodies our core principles of unwavering customer commitment, integrity, innovation, respect and teamwork, to engineer reliable solutions that solve complex challenges. That's Confidence. Engineered.

We are a growing company headquartered in Ottawa with offices and projects spanning North American, European and international markets with a focus on innovative healthcare, communications, learning and cybersecurity solutions.

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