CRO *Venture Research Organization*

Cato Research (CATO) is an international regulatory and clinical contract research organization (CRO) that has been delivering successful outcomes for its clients since 1988. Through highly qualified and experienced personnel located in offices across North America, Europe, Israel, and South Africa, supported by strategic alliances with selected regional CROs, CATO offers tried-and-trusted international coverage.

CATO has the advantage of integrated regulatory, clinical, and scientific expertise. Our highly talented and experienced international team offers services from preclinical through IND (or equivalent), clinical development, and marketing approval to Phase 4 postmarketing research. Our track record includes successes across many different health products, including small molecules, biologics, vaccines, cell therapies (including stem cells), medical foods, devices, and diagnostics. In its more than 27 years of operation, CATO has been involved in a wide variety of projects for numerous diseases and indications. This experience includes leadership of, and involvement in, some of the most challenging and innovative products.

Why Cato? Strategies. Solutions. Success.®

- We are the right size to bring even your most challenging programs to successful outcomes. All of your programs can benefit from CATO's attention to detail, tailored services, and executive guidance.
- We apply our intellectual expertise to ensure that your project is executed efficiently and on time. Our interests and priorities are aligned with yours.
- We are adept in the planning and implementation of programs through integration of our scientific, technical, regulatory, medical, and clinical expertise.
- We care about the outcome — not just for you or for ourselves, but for patients. Making a difference for patients and their families matters to CATO.
- We have an impressive track record of clinical and regulatory success across many different indications, technologies, and product types.
- Cato is proven, tried, and trusted.

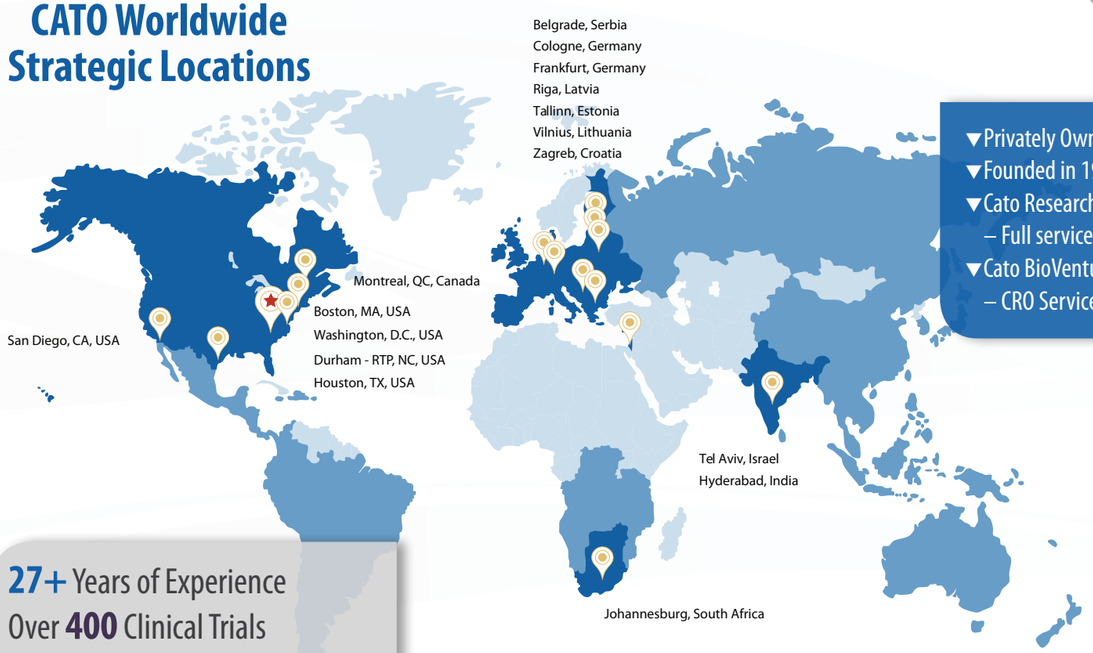
CATO® RESEARCH

Learn More about Our Strategic Solutions and Success at:

www.CATO.com
or Call and Speak to Our Experts at
+1-919-361-CATO (2286)

Cato Research
Westpark Corporate Center
4364 South Alston Avenue
Durham, North Carolina, USA 27713-2220

CATO Worldwide Strategic Locations



- ▼Privately Owned
- ▼Founded in 1988
- ▼Cato Research
  – Full service CRO
- ▼Cato BioVentures
  – CRO Service Capital

27+ Years of Experience
Over **400** Clinical Trials
Involved in **40+** Marketed Products
350 Submissions Yearly
15 Global Offices
Employees: **200+**
12 Medical Doctors
27 PhDs
8 Year Average Tenure

Cato Research History and Overview

- ▼Over 27 years experience in drug development serving pharmaceutical and biotech companies
- ▼Involvement in 40+ marketed products
- ▼Product development experience includes:
  - ▼Small molecules
  - ▼Biologics (including mAbs, cell-based therapies, vaccines, peptides)
  - ▼Natural products
  - ▼Medical Foods
  - ▼Devices
  - ▼Diagnostics
  - ▼Combination products (including drug-device / drug-biologics products)

Cato Research – A History of Impact

- ▼Pivotal role in marketing approval of multiple sponsors' compounds and therapeutic products
- ▼Involved in 2-4/per year (~10%) of the FDA approvals for new molecular entities over the last years
- ▼CATO has successfully conducted over 400 Phase 1-4 clinical trials, achieving enrollment targets, and meeting timelines (often aggressive) while adhering to budget
- ▼CATO has designed and conducted many proof-of-concept trials and pivotal trials leading to approval
- ▼Never had a refusal to file (electronic or paper)
- ▼4 FDA inspections, no 483s

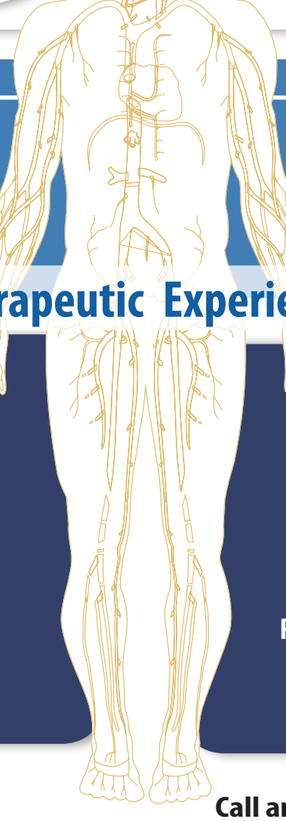
Cato Research – Drug Development Strategies

- ▼Senior experts in medicinal product development
- ▼Drugs, Biologics, Devices, Combination products
- ▼Integrated and interdisciplinary approach
- ▼Specialists in regulatory affairs, manufacturing, nonclinical, clinical, medical, statistics
- ▼Broad therapeutic experience
- ▼Emphasis on innovative technologies

Full Drug Development Services

Full Regulatory Services
Quality Assurance
Chemistry, Manufacturing, and Controls (CMC)
Nonclinical/Preclinical
Medical Writing
Strategic Consulting
Full Clinical Trial Services – Phases 1 to 4
Pharmacovigilance
Pharmacokinetics
Medical Monitoring
Data Management
Biostatistics

CATO has a successful track record for managing multi-center studies with large numbers of subjects .



Therapeutic Experience

Anesthesiology/ Pain
Cardiology
Dermatology
Endocrinology/ Metabolic Disorders
Gastroenterology
Hematology
Immunology
Infectious Disease
Nephrology
Neurology
Oncology
Ophthalmology
Orthopedics
Pulmonology
Rare - Orphan Diseases
Rheumatology
Vascular Disorders

REGULATORY Highlights and Services

- ▼ >250 Yearly Regulatory Submissions
- ▼ Average of 2 formal FDA meetings per month
- ▼ Average of >17 regulatory contacts per month
- ▼ 4-5 initial filing of INDs (Regulatory Strategy, Medical Authoring, IND filing) per year
- ▼ Significantly involved in 40+ Marketing Applications that were subsequently approved
- ▼ Full Regulatory Services
  - ▼ Regulatory Consulting
  - ▼ Regulatory and legal representation
  - ▼ Development Plans – GAP analyses
  - ▼ Medical Writing
  - ▼ Submissions (e-submissions)
  - ▼ Audits
  - ▼ Development Program Management
  - ▼ ODAs and Fast Track Applications

CLINICAL Highlights and Services

- ▼ Full Clinical Services
  - ▼ Clinical Trial Operations
  - ▼ Global network of experienced investigators
  - ▼ Detailed project & risk management plan
  - ▼ Proactive project leadership
  - ▼ Rapid site activation
  - ▼ Effective site support system
  - ▼ Enrollment management
  - ▼ Quality study monitoring
  - ▼ Study documents
- ▼ Clinical Trial Management
  - ▼ Study feasibility
  - ▼ Study start-up
  - ▼ Investigator's essential documents
  - ▼ Investigator's meeting, budget and payment
  - ▼ Trial execution
  - ▼ Clinical trial management system
  - ▼ Data safety monitoring board management

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