VANTAGE
BIOTRIALS

KNOW-HOW AND ACCURACY IN CLINICAL RESEARCH

Behind every successful and growing organization lies a strong foundation and a great vision.

- Vatché Bartekian
President

A WINNING TEAM

Vatché Bartekian
President

Vatché founded Vantage BioTrials in 2007. His experience working with big pharma and CROs in monitoring, clinical operations and project management roles has established him as a trusted expert and partner to numerous clients over his many years of passionate service with patients continuously in mind. His goal has always been straight-forward: enable speed, safety and effectiveness of therapies for those who need it most urgently, bringing them to market sooner rather than later.

Vahé Bartekian
Vice President
Quality Management

Vahé's guidance as a Co-Founder at Vantage BioTrials has played an integral role in the company's evolution by contributing valuable knowledge of the clinical trials management process through his broad expertise in GCP/GLP practices and procedures. His dedication to quality and safety to patients remains a paramount factor to the continued satisfaction of Vantage BioTrials' clients and the company's continued success.

Viken Bartekian
Vice President
Corporate Development

As a Co-Founder, Viken's responsibilities at Vantage BioTrials encompass global Business Development, General Management and Marketing activities. His vision for the future of the company is to maintain, through honesty, trust and transparency, a long lasting relationship with clients, investigators and partners. His objective is for Vantage BioTrials to always be remembered as the company driven by its passion to deliver quality results.

COMPANY OVERVIEW

Vantage BioTrials is a privately-held, Contract Research Organization (CRO) that provides Phase I-IV clinical trial management services to international pharmaceutical, biotechnology, generic pharmaceutical and medical device companies.

We believe that success is achieved through shared values, common objectives and a high level of trust & transparency whereby the following benefits can be realized:

- Common goals
- Streamlined communication
- Sharing of information
- Joint development of a strategic roadmap

We are one of the only Canadian CROs named as an “Emerging Pharma Leader” by Pharmaceutical Executive Magazine for its lean management style and effectiveness in realizing project goals.

We are experts in implementing Risk-Based Management through the use of Quality by Design (QbD) methodologies, which helps accelerate the conduct of a study, reduces overall risk and ensures that your trial is performed correctly, the first time!

SERVICES

À la carte or Full Service

Through our unique lean operational model, we continue to perform trials (from the smallest to the largest) by offering expert know-how which results in flexibility of choosing a-la-carte or full service.

Our range of services includes:

- Study Design Input
- Feasibility Assessments
- Protocol Development
- Site Selection
- Clinical Trial Agreements (CTAs)
- Project Management
- Risk-based Monitoring (RbM) (Bilingual)
- Regulatory
- Vendor Management
- Data Management & EDC
- Biostatistical Analysis
- Statistical Programming
- Investigator Meeting Planning
- Patient Recruitment, Engagement & Retention Strategies
- Case Report Form Design
- Document Management
- Medical Writing
- Quality Assurance Audits (GCP & GLP)

Our following complementary services help add value to your programs and complete our offering:

- Study/Site Rescue
- SOP Development
- ICH, GCP & GLP Training
- Filling Resource Gaps
- Functional Service Provider (FSP)

AREA OF EXPERTISE

Phase I

With hundreds of Phase I trials managed and monitored to date for our Generic Pharmaceutical, Consumer Health, Biotechnology and Biopharma Sponsors, we are the only service provider in Canada offering clarity and proven solutions in handling the following type of early-phase trials:

- BE/BA
- PK/PD
- Food Effect Studies
- Drug Interaction Studies
- Special Population Studies
- First in Human
- Multi Ascending Dose
- Single Ascending Dose
- Proof of Concept

"The project and clinical operations team at Vantage BioTrials consistently delivered the right solutions in a timely manner for the completion of our special population study with multiple centers in Canada and USA. They worked diligently with other vendors to complete deliverables on time and on budget."

– Sr. Project Manager
Biotech Company, USA

AREA OF EXPERTISE

Phase II-IV

"Wow! Simply amazing, guys. Your hard work definitely paid off! :)

Well done, team!"

– Sr. Clinical Operations Manager
Medical Division,
Big Pharma, Canada

Our experience, support systems and unique lean operational model enable us to provide the highest level of quality when offering clinical trial management services for Phase II-IV studies.

All of our associates are specially trained to trouble-shoot, manage and deliver quality results in a pro-active way.

We are experts in the following areas:

- Single & Multi Center Studies
- Interventional Studies
- Post-Market Observational, Registry and Safety Surveillance Studies
- Meta-Analysis
- Health Outcomes Research
- Health Economics Research

Specifically about our niche experience in Phase IV trials:

Due to the breadth of size, scope and timelines of most late phase trials, Vantage BioTrials ensures that the studies' logistics, recruitment & operational site requirements are well assessed and maintained. We understand the unique challenges late phase studies pose with regards to extensiveness of data gathering and potential cost overruns due to the sheer volume of sites and patients being managed in a strict timeline. This is why we match our best team members to the requirements of each study on a case-by-case basis to ensure pro-active mitigation and management of potential obstacles, leading to the best outcomes and results.

Our team will address regulatory & risk management considerations, create meaningful data reports, and stay on track with key deliverables.

We also provide strategy consulting in the areas of Market Access and Product Planning in a manner intended to facilitate our clients' meeting their requirements. We design health economic studies that assess real-world treatment patterns and drug costs to payers. Our studies can also evaluate the appropriateness of a product's price or the market's acceptance mechanisms. We provide health economic services in many areas including the following:

- Burden of Disease
- Cost per Responder
- Cost-effectiveness/Cost-benefit/Cost-utility analyses
- Direct/indirect utility assessment
- Budget Impact Models

AREA OF EXPERTISE

Medical Device

"It was my pleasure to work with Vantage BioTrials on two highly successful, multi-center, medical device, clinical trials in Canada. The Vantage BioTrials team conducted all aspects of the trials with outstanding professionalism. They were fast and efficient in responding to any issue that came up and their careful reviews during site visits ensured quick lock and publication of the results."

– Medical Director
Medical Device Company, Israel

Vantage BioTrials has a deep understanding of the challenges faced in clinical development for medical devices: intense competition, precise regulatory requirements and shortened product exclusivity and life cycle. Medical devices are not like drugs or vaccines. They even differ greatly from each other.

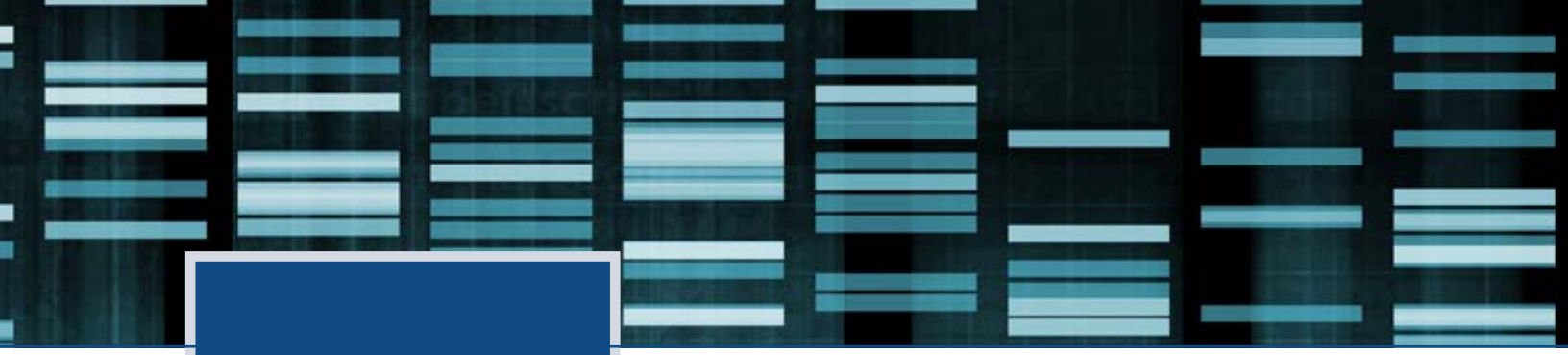
That's why you need a Medical Device & Diagnostics group with the broad experience of our project teams. We have the capability to meet your clinical development needs for both pilot and pivotal studies using efficient study management strategies that can reduce costs and shorten timelines by:

- Developing well-designed protocols and case report forms (CRFs) to ensure high quality data and efficient monitoring
- Site/End-User identification and feasibility analysis
- Support Services to meet ISO 14971-2012 "Application of risk management to medical devices" requirement; management procedures and practices to analyze, evaluate, control, and monitor risk relating to the safety of a medical device throughout the protocol design, development and product lifecycle
- Application to Health Authorities, IRB/EC submission, labeling assistance, and other global requirements. Efficiently managing study start up, and execution in accordance with ICH GCP & ISO 14155-2011
- Project risk analysis/mitigation and risk-based monitoring approach

As one of the only Canadian CROs that have established a niche for the management of Medical Device trials, Vantage BioTrials has successfully obtained numerous agency approvals, PMAs and FDA 510(k) clearances.

Our experience includes:

- Proof of Concept Studies
- Companion Diagnostics
- Implantables
- Combined Device/Drug Systems
- Orthopedics



AREA OF EXPERTISE

Audits

"Our success rate in performing clinical studies within expected deliverables stems from asking the right questions resulting in getting the right solutions for a given problem. Our quality management systems guide our staff in their day-to-day work to produce top results and surpass our clients' expectations."

– Vahé Bartekian

Quality is one of Vantage BioTrials' most important elements when conducting quality assurance audits of investigational sites or Contract Research Organizations.

Here's a list of what we can do for you to help maintain Quality for your studies:

- Generate audit reports and review for accuracy, clarity and completeness.
- Ensure that impact/validity assessments are clearly written and, where appropriate, support the facts.
- Manage event investigation process and ensure regulatory compliance for all studies reviewed.
- Conduct general audits of Phase I-IV studies in compliance to Protocols, SOPs, GLPs, GCPs and generally accepted scientific principles.
- Audit raw data records for completeness and within compliance to Protocols, SOPs, GLPs, GCPs, 21 CFR Part 11 and generally accepted scientific principles.
- Audit of reports to ensure that the results incorporated accurately reflect the raw data.
- Gap analysis of processes and organization
- Vendor audits
- Quality System Optimization including development of quality manuals and policies, SOPs, work instructions, QA processes, training, and regulatory inspection readiness programs.

COMPLEMENTARY SERVICES

"The road we paved since our inception is one of solid foundation built on trust, integrity, quality, transparency and dedication."

– Viken Bartekian

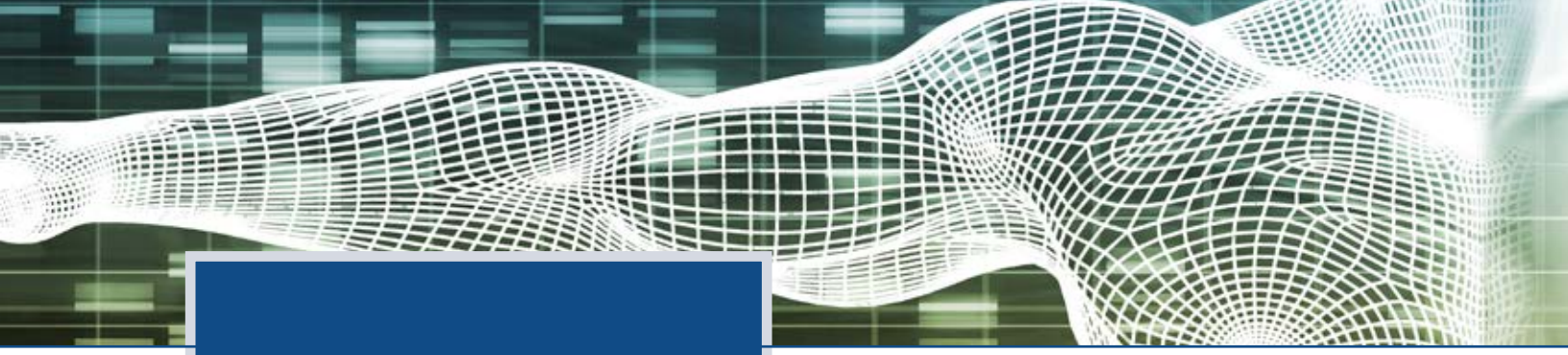
Site and Study Rescue: Unfortunately it is a fact of life in clinical research to encounter issues that negatively affect or hinder the progress of your studies, especially with problematic investigative sites or poor quality of work provided by other CROs. With our experience handling complicated trials, our Sponsors come to us to implement our Strategic Working Action Teams (SWAT) into a cohesive unit to address the issues and efficiently rescue your study from disastrous consequences. Our SWAT team is comprised of a small number of carefully chosen experts (including at least one senior project manager and clinical monitor) who come up with action plans to get your study back on the right track and on the road to a successful conclusion.

SOP Development: Vantage BioTrials' team of auditors and operational associates work together with you to develop, review, and revise (as necessary) your own Standard Operating Procedures in order to make them more efficient and confirmatory to all regulatory and GCP/GLP requirements.

ICH, GCP & GLP Training: With the vast years of experience, Vantage BioTrials can help you with all of your training requirements for ICH (International Council on Harmonisation), GCP (Good Clinical Practice) & GLP (Good Laboratory Practice). Our core team consists of experienced, knowledgeable individuals who have been in the industry for many years. Vantage BioTrials will help you indentify certain topics, new or refreshers, and will customize the training sessions to your needs. We will ensure that you benefit from our real life case studies.

Filling Resource Gaps: Let's face it, there are times that even you are overwhelmed with your duties but are limited or cannot afford to hire someone full time to assist you. With Vantage BioTrials' extensive data base of professional consultants, we will find and ensure that the right person is placed on your study.

Functional Service Provider (FSP): You can take advantage of Vantage BioTrials' unique model by allowing us to provide you with the flexibility of choosing the type of service you wish to have. An FSP model will allow you to have a dedicated team for a dedicated task or studies. Talk to us today to determine the right kind of fit for your needs.



THERAPEUTIC EXPERIENCE

"I strive to always exceed my clients' expectations and I expect no less from our employees by asking them how they can improve study timelines, increase all stakeholders' cooperation, and achieve better cost savings by increasing project efficiencies. It also helps that our business is based on strong family-oriented values.
Working with your own brothers helps you learn how to treat each other with respect and clearly communicate ideas to move forward and progress through challenges."

– Vatché Bartekian

- ALLERGY
- CARDIOLOGY
- CRITICAL CARE
- DERMATOLOGY
- DIABETES
- ENDOCRINOLOGY
- GASTROENTEROLOGY
- GENERICS
- IMMUNOLOGY
- INFECTIOUS DISEASE
- MEDICAL DEVICES
- MENTAL HEALTH
- MUSCULOSKELETAL/RHEUMATOLOGY
- NEUROLOGY
- NEUTRACEUTICALS
- ONCOLOGY
- OPHTHALMOLOGY
- OSTEOPOROSIS
- PAIN MANAGEMENT
- PEDIATRIC
- RARE DISEASES/ORPHAN DRUGS
- RESPIRATORY
- UROLOGY
- WOMEN'S HEALTH

"Life is like a landscape. You live in the midst of it, but can describe it only from the vantage point of distance."

STRATEGIC ALLIANCES

While continuing to remain focused on delivering quality service, Vantage BioTrials has established strong Alliances with other carefully selected Service Providers in order to complement its own offerings to its Sponsors.

Types of services through our Strategic Alliances include:

- Data Management
- Pharmacogenomic Studies & Sub-Studies
- Electronic Data Capture
- Scientific Affairs
- Biostatistics
- Central IRB
- Patient Recruitment
- Central Labs
- CROs in Emerging Markets

We Are Industry Leaders Providing Educational Forums

CANADATALKS PHARMA

Not only do we provide drug development solutions, but we also bring together experts from around the world to share best practices.

Vantage BioTrials currently spearheads the organization of an annual clinical trials conference called Canada Talks Pharma; a key event within the Canadian drug development arena that brings together important stakeholders, decision-makers, thought leaders and industry disruptors to one single location for two full days of sharing practical ideas and building valuable networks.

We usually host more than 300 delegates and around 30 speakers with more than 10 hours of effective networking opportunities.

As one past attendee affirmed, “The intimate setting, impeccable organization and the attendance of key stakeholders from around Canada and internationally makes it an effective venue for creating new connections and progressing innovative ideas forward.”

To learn more, sign-up for our newsletter on the event website: www.canadatalkspharma.com

AI 2018 Global Excellence Awards

Vantage BioTrials
Canada's Most Trusted
Clinical Research
and Trial Management
Organization 2018

ghp International Life Sciences Awards 2018

Vantage BioTrials Inc.

Biotechnology CRO of the
Year 2018 - Quebec

CORPORATE LiveWire
Healthcare& Life Sciences
AWARDS 2016
WINNER
Excellence in Clinical Trial Management Services
Vantage BioTrials

AI 2017 Global Excellence Awards

Vantage BioTrials Inc.
Most Client Focused
Clinical Trial
Management Firm
- Canada

International Life Sciences Awards
Winner 2016

Vantage BioTrials Inc.
Best for Phase I-IV Clinical Trial Management Services

GHP global health & pharma

International Life Sciences Awards 2017

Vantage BioTrials Inc.
Best Pharmaceutical CRO - Quebec
& GHP Innovation Award for Clinical Trial
Management 2017

EMERGING PHARMA LEADERS 2011
MANAGING IN THE ERA OF LEAN

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