VERISTAT

Unrivaled Regulatory Submission Experience & Expertise

Preparing & Defending Regulatory Submissions to Their Successful Conclusions Is Our Focus

Veristat delivers integrated submission preparation expertise with a track record of success and achievement of seemingly impossible deadlines. Our success lies in our ability to navigate operationally complex submissions, overcome data analysis challenges, and streamline the medical writing process with an integrated team focused on creativity, flexibility, and quality.

Veristat's highly experienced cross-functional team **works intimately with you throughout the regulatory submission process** so together we can bring new medical products to those who need them.

Veristat teams have worked on **more than 70 submissions** with more than **40 approvals to date**

8% **of New Molecular Entities** approved by the FDA were supported by Veristat in the past 5 years

Our 5-year track record includes:

>35
submissions projects worked on

>20
submission projects worked on received approval to-date

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Unrivaled Regulatory Expertise and Experience

Veristat is proud to be a part of many regulatory approval successes. While we can't claim credit for developing these new products, our team of over **20 regulatory submission experts** helped along the way and executed a flawless regulatory submission process which helped lead to the **successful approval of over 40 life-changing or life-saving therapies.**

Veristat Staff Expertise

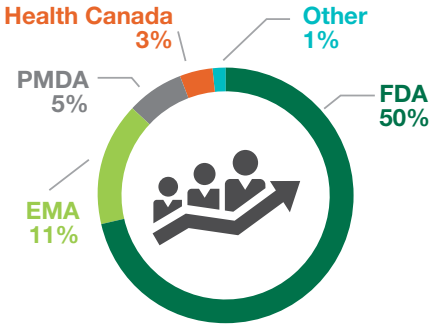
52% of our biostatisticians have attended FDA meetings

13% of all employees have regulatory submission experience

20% have doctorate degrees and another 60% have advanced degrees

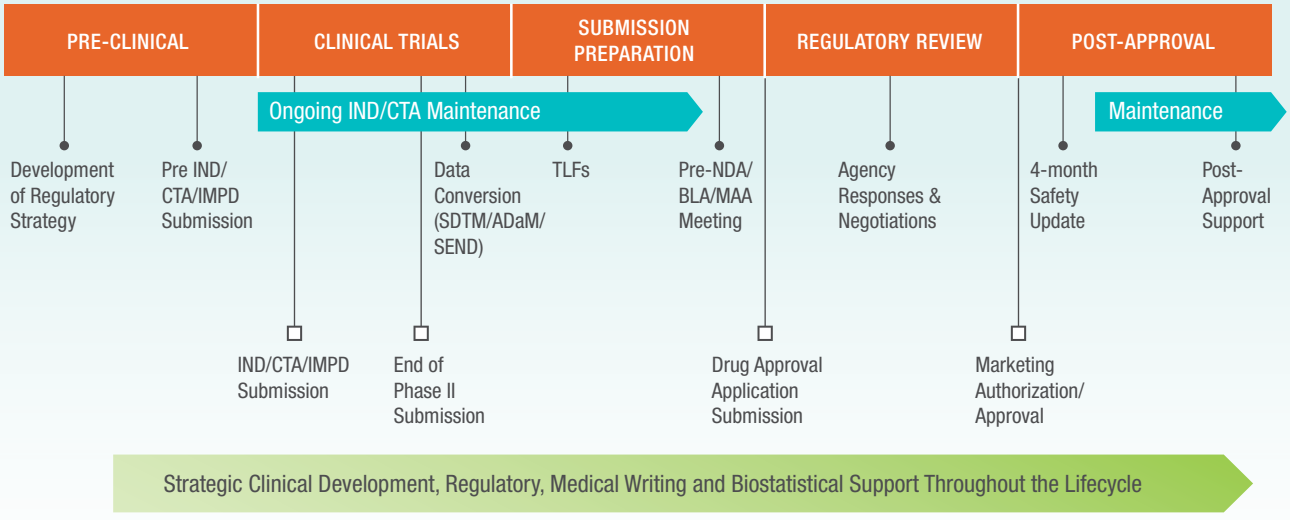
Our teams represent pharmaceutical and biotechnology companies in direct regulatory interaction with the **US FDA, Health Canada, European Medicines Agency (EMA), Korea FDA, and Japan FDA**. We participate in on-site regulatory agency meetings, and act as statistical, clinical, and medical experts for advisory panel meetings.

Regulatory Agency Experience



Many of our experts have over 25 years of experience guiding companies through the regulatory submission process. We bring together expert biostatisticians, medical writers, data standards professionals, statistical programmers, and regulatory project managers who work collaboratively to help sponsors prepare their submissions and provide support throughout the review process.

Our Regulatory Expertise Begins at Clinical Trial Planning Through to Post-Approval Updates



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We Excel at the Most Complex Therapeutic Indications – Providing Customized Solutions for Rare Disease Submissions

Many orphan diseases are serious and life threatening. Therefore, working with a development partner that understands the potential benefits of each of the accelerated development pathways (i.e., Accelerated Approval, Breakthrough Therapy, Priority Review, and Fast Track) is crucial.

Accelerated Pathways for Rare Disease Submissions

Of the total rare disease submission projects that Veristat has supported, the following have an accelerated pathway:

77%	>30%	>30%	11%	11%
Orphan Disease Designation	Fast Track Designation	Priority Review	First-In-Class	Breakthrough Designation

Making informed decisions for selection of the right regulatory pathway at the start of the orphan drug development process helps mitigate risk and ensure the fastest path to approval. We specialize in rare disease submissions – more than **55% of the submission projects** we've worked on were for rare disease indications.

Rare Disease Indications

Blood Cancers	Rare Cancers	Vaccines	Others
Cutaneous T-cell Lymphoma	Advanced NRAS-mutant Melanoma	Pancreatic Cancer	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
Mantle Cell Lymphoma	Gastro-Entero-Hepatic Neuro-Endocrine Tumors (NET)	Smallpox	Endocarditis
Peripheral T-cell Lymphoma	Renal Cell Cancer	Thyroid Cancer	Familial Chylomicronemia Syndrome (FCS)
Relapsed / Refractory Acute Myelogenous Leukemia			Homozygous Familial Hypercholesterolemia (HoFH)
Relapsed / Refractory Chronic Lymphocytic Leukemia			LAL Deficiency
Relapsed / Refractory Multiple Myeloma			Tardive Dyskinesia

Cancer treatments account for over 45% of the submission projects we've worked on

- Cardiology
- Infectious disease
- Genetic disorders
- Hepatology
- Metabolic disorders
- Gastrointestinal
- Neurology
- Oncology
- OBGYN
- Pain management

Percentage of Submissions In Each Therapeutic Area

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Helping You Achieve Regulatory Submission Success

No two New Drug Applications (NDAs) or Marketing Authorization Applications (MAAs) are the same. Therefore, our approach for creating the right submission timeline and execution strategy for your submission is customized to achieve your goals.

With Veristat you get the confidence that your regulatory submission partner has the knowledge, expertise, and proven track record to achieve the unachievable.

We Deliver on Our Promise of TRUE Partnerships

Veristat views every regulatory submission project first as an inspiring opportunity to facilitate the regulatory approval for novel products that can improve or save lives, and second as an opportunity to develop or continue a long-term collaborative relationship with our clients based on mutual **Trust, Respect, Understanding and Evolution** (TRUE partnership).

> *For those people who are unfamiliar with the writing of **an Integrated Summary of Safety (ISS)** section of the submission document, it's extremely labor intensive due to the amount of data that has to be reviewed. **This section is extremely well written, nice job."***

Vice President of Statistics, Mid-Size Biotech

CASE STUDY

Achieving an Aggressive NDA Timeline

A creative approach leads to a regulatory submission success for a rare CNS disorder

Situation: A mid-sized biopharma company hired Veristat to prepare and manage their New Drug Application (NDA) submission for the treatment of a rare CNS disorder. The client had a nine-month timeline for Veristat to complete the submission. The last two pivotal studies were still ongoing and were being managed by another CRO who ended up locking the database two months behind schedule.

Solution: Veristat created a unique data migration plan for the two ongoing pivotal studies and 18 legacy studies.

Impact: Veristat completed the submission on time, despite the two-month database lock delay caused by the other CRO. The biotech firm received FDA approval for their rare CNS treatment.

Contact Veristat Today

To learn more about Veristat or how we can assist you with your regulatory submission planning and execution, reach out to us today.

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