VERISTAT

Getting Your Product Approved Is More Complex and Competitive Than Ever

Apply Our Regulatory Submission Expertise to Improve Your Probability for Regulatory Approval Success

THE REGULATORY SUBMISSION LANDSCAPE

Drug research has skyrocketed over the past 5 years, where today, over 7,000 drugs are being developed and the numbers of drugs being submitted for approval over the past few years has increased.[1] Success rates of drugs making it from Phase I to approval are also increasing, where now 13.8% of compounds make it to approval.[2]

FDA DRUG APPROVALS 2013-2017

2013	2014	2015	2016	2017
27	41	45	22	46

Highest number of FDA approvals since 1996

Looking at the US Food and Drug Administration (FDA) alone, the industry is experiencing an increase in regulatory submission approvals in the past few years.[3]

Similarly, the European Medicines Agency (EMA) saw an increase in the number of new drugs and biologics it recommended for marketing authorization in 2017.[4]

In 2017, EMA recommended 35 new active substances (NASs) for marketing authorization, **up from 27 in 2016**. Of the 2017 NASs EMA recommended:

11 were new drugs & biologics to treat cancer

5 to treat neurological disorders

5 each for infectious diseases & immunology/ rheumatology

Other therapeutic areas that saw new approvals in 2017 include endocrinology, hematology, nephrology, hepatology, and dermatology

Getting your marketing application completed and submitted to the regulatory agencies quickly and efficiently is more important and competitive than ever.

With each submission comes a complex web of challenges:

- Special constraints
- Unique partnership dynamics
- Timing of data analysis
- Medical writing
- Project management
- Interaction with regulatory agencies

By utilizing key strategies, you can propel even the most complex submissions to successful regulatory conclusions – and Veristat has the proven processes, expertise, and track record to make this a reality.

VERISTAT'S UNRIVALED REGULATORY SUBMISSION EXPERTISE & EXPERIENCE

Our Regulatory Submission Team Members Have the Right Qualifications

13% of our staff have worked on a regulatory submission

11 team members have been to FDA meetings on behalf of clients

More than 65% of our staff have advanced degrees

Veristat Submission Team Members	Average Industry Experience
Biostatisticians & Programmers	>13 years
Data Managers	>13 years
Medical Writers	>20 years
Project Managers	>16 years

Most compounds don't make it to the submission process, so mitigate risks by working with the right team of experts to guide the strategy, preparation, and defense of your regulatory submission to the regulatory agencies.

VERISTAT HAS A PROVEN TRACK RECORD OF REGULATORY SUCCESS

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

>70 submission projects worked on by Veristat teams

>40 regulatory approvals to date

FIRST CYCLE APPROVALS* IN 2017

85% CDER approved 39 of the 46 novel drugs of 2017 (**85%**) on the "first cycle" of review

100% **100%** of the approved NDAs that Veristat supported received first cycle approval, with fast track designation, breakthrough therapy status, and priority review

FROM 2011 THROUGH 2016

81% CDER approved 204 novel drugs, of which 166 (**81%**) were approved on the first cycle

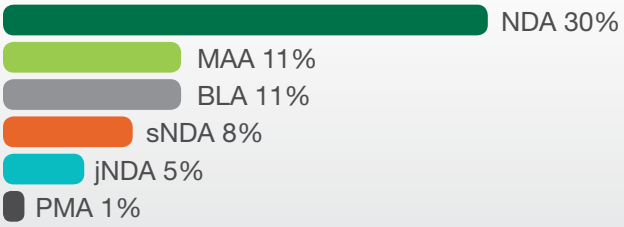
65% **65%** of the novel drugs that Veristat supported the NDA for were approved on the first cycle

Defined as FDA approvals without requests for additional information that would delay approval and lead to another cycle of review

EXPERTISE WITH REGULATORY AGENCIES WORLDWIDE

From oncology vaccines to ultra-rare diseases, our team of regulatory submission experts has extensive experience with various regulatory agencies across the globe, enabling us to offer strategic advice on the best pathway forward to achieving regulatory objectives throughout the full product lifecycle.

Types of Regulatory Documents Prepared by Veristat



WE EXCEL AT THE MOST COMPLEX THERAPEUTIC INDICATIONS

Cancer treatments account for over 45% of the submission projects we've worked on. We specialize in rare disease submissions – more than **55% of the submission projects** we've worked on were for rare disease indications.

Veristat Rare Disease Submission Experience

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

Percentage of Submissions In Each Therapeutic Area

Overall Therapeutic Expertise

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

VERISTAT'S SUBMISSION SUCCESSES OVER PAST 5 YEARS

>35 submissions projects worked on or ongoing

>30 marketing applications that we worked on were submitted

>25 submission projects that we worked on have received regulatory approval so far

VERISTAT SUBMISSION PROJECTS, 2013-2018

2013	2014	2015	2016	2017	AS OF AUGUST 31, 2018
4	4	5	9	12	10

ABOUT VERISTAT

Veristat is a smart, effective and impactful CRO focused on advancing medical therapies through the clinical development and regulatory submission process. Our work delivers meaningful clinical impact and our regulatory submission expertise is unrivaled in our industry. Ultimately, we partner with and guide biopharmaceutical companies to market success so that new therapies become available to improve and save people's lives. Explore more about our strategic consulting, data analysis, clinical trial management or regulatory submission expertise.

OUR TRACK RECORD OF SUCCESS

70+
regulatory submission projects

40+
global submission approvals

~8% of NMEs
approved by the FDA in the past 5 years

REFERENCES

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https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm

https://www.raps.org/news-and-articles/news-articles/2018/1/ema-sees-spike-in-authorizations-in-2017

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Contact Veristat Today

Learn more about Veristat and how we can assist you with your regulatory submission planning and execution.

+1 508.429.7340 | www.veristat.com