



VERISTAT

Why You Need a CRO That Excels in Oncology Regulatory Publishing

Oncology submissions require speed, strategy, and therapeutic expertise.

Here are the key reasons why partnering with an experienced CRO makes a difference.



They Integrate Speed with Scientific Rigor

- Oncology submissions often face accelerated timelines.
- A CRO skilled in oncology publishing applies proactive planning, version control, and quality control to stay ahead of deadlines.
- Seamless collaboration between medical writers, statisticians, and publishers ensures no data or narrative conflicts delay submission.

They Understand the Complexity of Oncology Submissions

- Oncology submissions often include massive datasets, multiple study types, and adaptive or single-arm designs.
- Expert teams know how to align documents with FDA and EMA expectations while ensuring consistency across CTD modules.
- Experience means fewer reworks and faster approvals.

They Bring Proven Experience with Oncology-Specific Pathways

- Familiarity with RTOR, Project Orbis, and Accelerated Approval programs ensures your submission strategy matches regulatory opportunities.
- Knowledge of oncology therapeutic nuances and biomarker-driven designs improves messaging and regulatory credibility.

The Stakes Are High

In oncology, every day counts.

Complex protocols, global studies, and evolving regulatory expectations mean that submission readiness can't be an afterthought. Under **PDUFA**, the FDA reviews 90% of NDAs and BLAs within 10 months—and just 6 months for priority reviews—while programs such as **Real-Time Oncology Review (RTOR)** can accelerate timelines even further. That's why sponsors need partners who can move fast without compromising quality.

Get to Approval Faster, with Accuracy and Confidence

Veristat's regulatory publishing experts combine scientific precision, regulatory insight, and operational excellence to bring life-saving oncology therapies to patients sooner.

Partner with Veristat, and Watch Your Regulatory Submission Challenges Disappear.

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