Global Regulatory Strategy to Guide Your Oncology Program

A well-planned regulatory strategy is critical to the successful launch of your product on a global scale. Yet with so many priorities, it's difficult to keep abreast of rapidly changing regulatory requirements. You need a partner who understands the goals of your program and can guide you through this intricate and evolving regulatory landscape.

Catalyst Oncology has an extensive understanding of the regulations throughout North America, Europe, and the Asia-Pacific (APAC) region, and our experts will help you develop and implement a global regulatory strategy to bring your product to market. After meeting with your team, listening to your program's goals and requirements, and ensuring understanding of your asset, we will provide you with a custom regulatory strategy report, complete with deep insights, reliable recommendations, and actionable next steps.

Project Optimus leads to large, global early-phase oncology trials

New regulations and guidance impact oncology studies nearly every year. The Project Optimus guidance, finalized in August 2024 by the U.S. Food and Drug Administration (FDA), recommends oncology drug developers move away from the traditional approach for determining maximum tolerated dose (MTD) and build dose optimization strategies into their clinical development plans that balance safety, tolerability and efficacy. This new approach translates into significant changes in design, length, and cost of first-in-human (FIH) trials.

New clinical trial regulations streamline trials in Europe

The Clinical Trials Regulation (CTR), which went into effect in January 2022, streamlined the clinical trial application process across 30 countries belonging to the European Union (EU) and/or the European Economic Area (EEA). By simplifying and expediting clinical trial start-up, Europe has become a more desirable location for conducting clinical trials. Under the old regulation, clinical trial laws were implemented nationally for each country, making the EU segmented, excessively bureaucratic and challenging to navigate. Catalyst Oncology has experience working with sponsors under the CTR and submitting clinical trial applications in the Clinical Trials Information System (CTIS). We work closely with our sponsors to ensure we have the right strategy in place for the CTIS submission to ensure the most efficient regulatory approval timelines.

Global regulatory requirements by country

We understand that staying on top of rapidly changing global regulatory requirements can be daunting. Whether North American, European, or APAC regulations, our team knows the clinical trial regulatory landscape for each country and can guide you on the best path forward. Below is a snapshot of some of the major requirements you can expect by country.

	AUS	UK	US	SK	EU
Language of application	Not specified	English	English	Korean	English or commonly understood medical language of the region
Age of minors	>18	>16	By state	>19	>16 or 18 (varies by country)
Submission process guidelines	TGA, TGR, G-CTHandbook, G-Trial SOP, AUS-47	G-CTAPP, G-IRASCombRev, GBR-125	FDA: IND, 21CFR312	MFDS, CRIS, RSP	EU No 536/2014, EMA

All countries require trial registration and in-country representation, as well as allow concurrent regulatory / ethics review and sample exports.

We can help

Discover how Catalyst Oncology Consulting can help support your global regulatory strategy by visiting us at www.catalystcr.com/oncology-consulting.