MEDELIS
Clinical answers, faster.

ACCESS TO THE U.S. DRUG STUDY MARKET

FOR SPONSORS WITH LITTLE TO NO U.S. PRESENCE, DESIGNING AND MANAGING CLINICAL TRIALS FOR ONCOLOGY DRUGS IN THE U.S. IS AN ARDUOUS TASK

It's difficult to be effective from afar, without the deep first-hand knowledge required to navigate the FDA, design the right protocol, select the best investigators, accrue patients, and analyze the data.

OUR OFFERING

Medelis will design the plan for bringing a non-U.S.-based company's drug into the clinic. This short-term consulting engagement can have a dramatic impact on your pathway to the U.S. market — giving you the assurance of a team of oncology experts, who have a comprehensive understanding of the nuances of the U.S. market, to guide your drug development plan.

VALUE

Having our team of oncology drug development experts guiding your U.S. development plan gives you:

- A detailed understanding of the U.S. market and regulatory environment
- The best solutions for a study design that works for your product or treatment
- Recommendations for the most effective investigators and the right mix of sites (of all sizes) for your trial
- Solid relationships with key thought leaders and patient advocacy groups needed to support your study design
- A full-service CRO to handle all aspects of the trial (if desired)

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ABOUT MEDELIS:

As a single-source provider for clinical trial planning, trial management, and drug development planning, Medelis delivers the best total solution — and all the support required — for biotechnology and pharmaceutical companies to optimize their return on clinical research investments. And we accomplish that in the quickest, most responsive way possible.

OUR EXPERIENCE:

Medelis' medical founders, team physicians and advisors are internationally-recognized oncology thought leaders. They organize and chair sessions at national and international oncology meetings and serve as officers and board members of professional oncology organizations, including The American Association for Cancer Research and The American Society of Clinical Oncology.

Our clinical operations team and medical personnel have critical first-hand experience with the complex issues often associated with oncology clinical trials, and they have handled most targets in oncology, which means that highly experienced resources will be working on your study.

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