Karma Oncology Limited
www.karmaoncology.com

Karma Oncology: clinical trial specialists

Karma Oncology combines a flexible virtual business model with expertise in oncology clinical trials to provide a bespoke contract clinical research service for biotechnology companies globally.

Karma Oncology Ltd. is a specialized oncology clinical development company that provides a unique service to biotechnology and pharmaceutical companies around the world. From the preparation of clinical development plans through to the design, setup, monitoring, managing, and reporting of clinical trials, Karma Oncology offers a flexible service.

Founded in 2012 by Karen J. Williams, who has more than 30 years of global clinical research experience, Karma Oncology is a virtual, niche company with remote teams based in Europe and North America. The company's business model and agility maximize cost effectiveness, enabling Karma Oncology to adhere to and achieve sponsor timelines.

"Our relatively small size allows us to be responsive and flexible in the execution of clinical trials," said Williams. "Whether we are doing full service clinical research projects or only performing individual tasks on a study, we are agile enough to adapt as things change throughout the course of the trial."

As a specialist company, Karma Oncology has a wealth of experience managing oncology trials in many types of solid tumor and hematological malignancy using a wide range of therapeutic approaches. These include the current 'hot-topic' trials with chimeric antigen receptor T cell therapies, as well as autologous cell therapies and checkpoint inhibitors.

The science-led team also keeps abreast of the latest innovations in oncology trial design. "It is important for us to constantly increase our knowledge in the oncology field and learn how we can develop our services to better serve our clients," said business development manager Kara Kennedy.

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>
> Karen J. Williams, Founder and President

Clinical development plans

Karma Oncology has experience of working with companies from the late preclinical stage, providing clinical development planning services. Drawing on its experience, Karma Oncology can advise companies on the most efficient route to market for a new drug, device, or diagnostic product.

"Our plans are driven by what we expect the landscape to look like when the product is launched rather than the landscape at the start of the trial, which is a big differentiator in our clinical development planning process," said Williams.

A team comprising experts in regulatory strategy, statistics, and clinical operations, and an oncologist works with the sponsor to devise a tailored clinical development plan. The plan provides choices for study designs for phases 1–3 trials, including recommendations for tumor types and comparator agents, along with budgets and timelines.

"It is proving to be a very successful approach," said Williams. "Our clients have used our plans to raise funding from investors, which has allowed them to move forward into the clinical phase of development."

Flexible clinical trial support

Core services include preparation of the protocol, site selection, regulatory start-up (Europe and North America), monitoring and site management, and project management of all aspects of the trial. Other specialized services, such as data management, statistics, pharmacovigilance, and medical monitoring, are provided through trusted partners when required.

The ability for sponsors to work with the same team for the duration of a project is a hallmark of Karma Oncology's service. Williams knows from personal experience how frustrating it can be for sponsors and sites when there is a constant turnover of clinical research associates (CRAs); the company therefore employs mature 'professional, career' CRAs who are very experienced, and are not looking to move elsewhere.

As well as offering stability to sponsors, Karma Oncology's approach enables the CRAs to build and maintain good relationships with their sites, which ultimately improves the quality of the trial data. Many of the CRAs have a nursing or midwifery background, and all CRAs in Eastern Europe are medical doctors.

The Karma approach

The Karma Oncology team partner with their clients to ensure oncology clinical trials always meet the timelines with good-quality data from the sites. Karma Oncology's local knowledge of sites and investigators around the globe helps the team to manage risks and suggest innovative solutions or novel approaches to save sponsors time and money.

For example, the team can recommend different trial designs, such as adaptive trials, which may be more beneficial for a small biotech. Options such as encompassing phases 1 and 2, phases 2 and 3, or multiple tumor types under one protocol have the potential to save a sponsor millions of dollars.

Similarly, Karma Oncology provides insight into the optimal country selection for clinical trials to expedite start-up and recruitment, and maximize the delivery of quality data.

Positive, informed actions lead to positive results—that is the Karma approach.

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