PROPHARMA GROUP®

Improving Patient Health and Safety

CASE STUDY - REGULATORY AFFAIRS

From Rare Disease Treatment to Clinical Trials for a More Common Use

Learn how our regulatory affairs team helped a client achieve FDA approval to conduct a clinical trial using another company's device.

When our client wanted to leverage an existing medical device for a new indication, our experts guided the client through clinical trial requirements for devices and aided in preparing and submitting the clinical trial IDE application to FDA. With our help, the client received conditional approval of their trial during the initial round of regulatory review and a full approval within three months of original submission.

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Challenge

The client was new to the medical device space but wanted to determine if an available therapy for the removal of Beta-2 microglobulin protein during hemodialysis could also be successful in treating cognitive impairment for patients with end stage renal disease.

The client was faced with the **challenge of having to work with the original manufacturer of the medical device and leverage data they did not have access to**. In addition, they were familiar with pharmaceutical regulations, but not medical device regulations and although there are similarities between the two, **the requirements for clinical trials involving medical devices are different.**

Finally, **developing endpoints that included not only cognitive tests, but also functional tests** appropriate for the patient population was required.

Solution

Our experts worked with the client to educate them on FDA's investigational device exemption (IDE) requirements, and also **served as a bridge between the client and the applicant holder of the approved indication**.

Our team **gathered pre-clinical data from the client, provided feedback on the pre-clinical testing and clinical study plan, and assembled it** in a way that FDA's Center for Devices and Radiological Health (CDRH) is used to reviewing.

Results

The client has not only been able to **begin enrollment into this clinical trial**, they reached back out to us for assistance in the submission of another IDE for the same device, but for a different indication.

ProPharma Group was able to assist the client in the regulatory strategy for both IDE submissions.

We also **helped the client understand and respond to FDA requests** during the review processes.