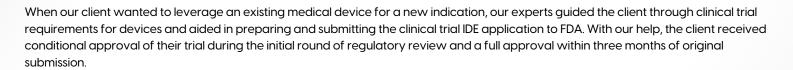


CASE STUDY

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 device.



## 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



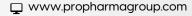
- Our experts worked with the client to educate them on FDA's investigational device exemption (IDE) requirements, and also served as a bridge between the client and the applicant holder of the approved indication.
- Our team gathered pre-clinical data from the client, provided feedback on the preclinical 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 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.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.



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