

CASE STUDY: PROVIDING SITE TRAINING AS PART OF A PA-NPP FOR A SPECIALIZED PRODUCT

About the Sponsor

The Sponsor is a commercial-stage biopharmaceutical company focused on the development and commercialization of oncology medicines. With several pivotal-stage products in its pipeline, the Sponsor aims to become a world leader in developing important new medicines to address significant unmet clinical needs.

The Challenge

The Sponsor recently received FDA-approval for its lead pipeline product for the treatment of solid tumors in infants. Following this initial approval, the Sponsor wanted to provide early access to the medicine for patients in Europe, through a Post-Approval Named Patient Program (PA-NPP).

Why Do Sponsors Provide PA-NPPs?

Through a PA-NPP, a Sponsor can supply approved medicines to patients in countries where they are not yet approved or commercially available, in order to:



Manage unsolicited patient requests for the medicine



Provide physicians early experience using the medicine



Develop an expert KOL network and advocates for medicine



Generate additional revenue stream from PA-NPP sales

The treatment that the Sponsor wanted to provide to patients through the PA-NPP is a specialized product with a very complex administration process. Because of this, the Sponsor team was aware that many HCPs at the treating sites would need additional support when providing treatment to patients.

The Sponsor wanted to find a partner that could provide an end-to-end PA-NPP service offering, which would include the provision of training and support for sites across Europe.

Our Solution

At WEP, we are proud to be able to provide nursing services for Sponsors, through our nursing company, Wren Healthcare. Wren Healthcare is global provider of healthcare services and can offer Sponsors expert training, education and support for their study sites. Wren Healthcare's nursing capabilities include:



**A global network of
nurses in 50+ countries**



**Experience across a broad
spectrum of therapy areas**



**Experience working with
100+ clinical trial sites**

As part of the PA-NPP set up phase, our Wren Nursing team worked closely with the Sponsor to understand the treatment administration process. Using the information provided by the Sponsor and our experience working with clinical trial sites on similar studies, we developed an integrated online training program. This includes directions on how to provide the treatment as well as guidance on how best to support patients and their families through the process.

Whenever a site is added to the PA-NPP, the site team is enrolled in this training and best practices program. Our Nurses work directly with the site to provide training in delivery of the medicine and are made available to the study sites throughout the program, if further support is required down the line.

Find out more about our Nursing capabilities on the Wren Healthcare website:

www.wrenhc.com

