Naru: adapting the product design to regulatory standards

> *It was really important for us to have this workshop in the early development stage of our product and we can recommend to other startups to receive advice on CE certification as early as possible*

Naru Intelligence Solutions   Eider Sanchez, CEO and co-founder   www.naruintelligence.com   Spain

My challenges

Our product STEP is a system to predict Severe Adverse Events in cancer patients, so that oncologists can personalize the follow up to improve results. We integrate clinical information with patient reported data that we gather from a mobile app. Our proprietary algorithms in our cloud platform analyse the data and generate the predictions. We wanted to know if our product or some parts of it are a medical device and how to classify them. We also wanted to understand which are the steps required to obtain the CE certification.

eHealth HUB support

Regulatory Guidance [July 2017]. eHealth HUB help us to obtain the very valuable support from CEplus as an expert of the Regulatory Network. It included an internal face-to-face workshop and follow-up advice which helped us to better understand the regulatory requirements and the limits of our system.

After the workshop with CEplus we decided to change the architecture and technical development of our product to make it more scalable in the future. It was very convenient for us to have the workshop at a very initial point of the project, so that the architecture change suited correctly under our timeline.

The company

Naru Intelligence develops Artificial Intelligence systems for oncology. We are focused on improving outcomes of every patient and optimizing hospital performance and clinical research. We specialize in the development of machine learning algorithms that integrate Real World Data in order to support and enhance clinical decisions. Our main objective is to improve personalized care through the analysis of each patient's experience.

eHealth HUB Stories

Learning points

"We were really satisfied with the support from CEplus. At the moment we are focusing on launching our product and are working on the CE marking process together with CEplus".

Eider Sanchez, CEO and co-founder

eHealth HUB services

Regulatory Guidance

eHealth Hub Regulatory Network helps European eHealth SMEs to be compliant with regulatory requirements and develop reimbursement strategies across the European Union.