STENTYS

www.stentys.com

Industry:

Medical devices

Sales revenue:

1-10M€

Employees:

40

Project size:

42 sites

700 patients included (target: 3000)

Medsharing Services:

Web Portal and eCRF EOL

Customisation and support services

"Medsharing EOL software is easy to work with; for example we can easily extract data and create reports ourselves. Medsharing have always been very responsive to our requests and the eCRF has excellent response times. The screen layout and the inclusion of graphics in the CRF pages facilitate patient data entry for site personnel."

– Sandra van Guldener, Clinical project manager, STENTYS

STENTYS successfully collects real-world data for post marketing surveillance in eight European countries

Founded in 2006, STENTYS is a fast growing medical device company; it develops and commercializes innovative solutions for the treatment of patients with acute myocardial infarction (AMI, or heart attack) and complex coronary artery disease.

STENTYS' Self-Apposing stents are designed to adapt to vessels with ambiguous or fluctuating diameters, particularly in the post-infarction phase, in order to prevent malapposition problems associated with conventional stents.

Headquartered in Paris, France, STENTYS has offices in the US and Europe.

In 2012, Dr René Spaargaren, Chief Medical Officer at STENTYS, launched with his team the SIZING registry; its objective is to collect patient data during 3 years, to examine the real-world use of the STENTYS solutions where stent sizing is a concern.

The registry is now active in 42 sites in 8 European countries: Denmark, Finland, France, Germany, Netherlands, Poland, Sweden, and Switzerland.

Challenges

- Collect data for post-marketing surveillance,
- Identify for which patients the stents are used
- Record and monitor Major Adverse Cardiac Events (MACE)
- Facilitate adoption by European sites with an easy-to-use internet based registry

Solution

- Internet registry from Medsharing: web portal and secured eCRF in SaaS mode
- Available to investigators and CRAs in English and French
- Real time support and consulting services
- Portal personalized to STENTYS' design and color codes
- Graphical map to indicate coronary segments with significant stenosis

Next steps

Given the success of the SIZING registry, and its recent international sales development, STENTYS considers opening the SIZING registry to Asian countries and extending the inclusion period beyond the initial 3 years.

medsharing
partager pour réussir