Press Release
10 February 2022 No 344

AIQNET – process for practical specification of MDR requirements started

Medical technology manufacturers, doctors and notified bodies – active involvement and shared benefits

(Stuttgart/Leipzig) – The terms "post-market surveillance" (PMS) and "post-market clinical follow-up" (PMCF) are of crucial importance for manufacturers of medical technology in the context of the European Medical Device Regulation (MDR), and they are causing a great deal of uncertainty. AIQNET project participants have initiated a manufacturer-independent process that is intended to enable everyone involved to specify MDR requirements in a practical way and to simplify collection of the necessary data.

AIQNET helps manufacturers define and obtain data for clinical trials and simplifies the clinical evaluation of medical devices. The project will give manufacturers the opportunity to participate directly in consensus building on PMS endpoints for MDR purposes. Anja Reutter, Project Leader at BioRegio STERN Management GmbH, emphasises the advantages of this commitment: "If you actively help shape the state of the art with regard to suitable study endpoints for assessing the performance and safety of medical devices, you benefit from the results from the product groups and reduce your MDR-related overheads."

After the MDR came into force, the requirements relating to the clinical evaluation of medical devices changed significantly. Clinical follow-up observations in particular pose huge challenges for manufacturers. After the market launch, for example, these observations regarding performance and safety must be documented through ongoing monitoring. "Many companies have no idea how to obtain the necessary data," reports Marena Hauser, who is responsible for innovation projects at the cluster network MedicalMountains GmbH. As an AIQNET consortium partner, she moderates one of the consensus groups. "The conventional approach is time-consuming – users receive questionnaires that they are supposed to complete to assess the individual products, but the lack of personnel resources at hospitals and other facilities means the feedback is limited," comments Hauser. "If we were to succeed in making information from clinical practice available quickly, reliably and in full, the entire industry would be

relieved of an unbelievable burden," she adds. Frank Trautwein, Managing Director of Raylytic and a co-initiator of the project, endeavours to provide manufacturers with a compilation of data that is kept up to date on an ongoing basis for planning PMCF studies. "If we are successful in creating a compilation for the definition of PMCF studies that has been coordinated with manufacturers, hospitals and notified bodies, it will mean hospitals and manufacturers will be able to use AIQNET to collect and use PMCF data from routine care on a fully automated basis," he says. "That would represent an enormous step forwards for the entire industry and would save all directly affected stakeholders a substantial amount of time," continues Trautwein.

However, a lot of preparatory work is first required to achieve the shared benefits. Which measurements and properties are essential to characterise the medical device? Which measuring methods correspond to the state of the art and deliver reliable results? What level of detail is required for the data? How large does the patient cohort under consideration need to be and how long does the observation period have to be? What data quality requirements need to be complied with? These questions will be answered as part of the consensus building process for the product group-specific PMCF endpoints. "The more manufacturers, doctors, researchers and notified bodies contribute their assessments and experiences, the more standardised and straightforward the process for hospitals to record the data required and for manufacturers and notified bodies to process it," explains Trautwein, who makes the following appeal to manufacturers: "Inspire others in your profession. Only together can we succeed in handling regulatory overheads efficiently and continuously improve diagnosis, treatment and medical devices on the basis of reliable data."

Help shape consensus building!
Benefit from the advantage offered by the AIQNET initiative.
www.pmcf-consensus.org
AIQNET creates an ecosystem for the widespread use of health data for research, development, clinical trials and evidence-based medicine in compliance with international legal requirements. All relevant stakeholders are involved – from notified bodies and medical device manufacturers to doctors and scientists. Within this manufacturer-independent process, product group-specific methodologies and study endpoints are to be defined in order to reduce the MDR overheads for everyone who is directly involved. Based on the device classification in accordance with the European EMDN system, which will be binding in the future, product groups with up to ten company representatives have been formed in 13 product categories. In the coming months, they will collate preparatory work and study protocols, which are then to be

coordinated with the notified bodies. The results of this work will be accessible to interested specialist groups free of charge.

AIQNET
Medical Data Ecosystem

Supported by:

Federal Ministry
for Economic Affairs
and Climate Action

on the basis of a decision
by the German Bundestag

About AIQNET:
AIQNET is a digital ecosystem that enables the use of medical data across sectors and in compliance with data protection regulations. The entire project is coordinated by BioRegio STERN Management GmbH, Stuttgart. Initiator and consortium leader is RAYLYTIC GmbH, based in Leipzig.
The consortium consists of 16 supported and 50 associated medical technology and healthcare companies and won the German government's AI petition in 2019 under the project acronym "KIKS". The project is funded by the Federal Ministry for Economic Affairs and Climate Action. Since January 2020, the project partners have been developing the technical infrastructure and its applications. The focus is on structuring data using artificial intelligence and creating a legally secure framework for procuring and analysing clinical data. In the future, for example, the performance and safety of medical devices can be measured objectively and largely automatically. Administrative tasks of healthcare, e.g. documentation, can be handled by relevant applications. A special feature of the project is the close cooperation between industry, research and healthcare.
By providing access to technical and scientific data with great depth, the ecosystem offers future partners the opportunity to develop their own health applications at low cost and to benefit from the legally secure, validated framework of AIQNET. www.aiqnet.eu

About BioRegio STERN Management GmbH:
BioRegio STERN Management GmbH promotes economic development in the life sciences industry, helping to strengthen the region as a business location by supporting innovations and start-up companies in the public interest. It is the main point of contact for company founders and entrepreneurs in the Stuttgart and Neckar-Alb regions, including the cities of Tübingen and Reutlingen.

The STERN BioRegion is one of the largest and most successful bioregions in Germany. Its unique selling points include a mix of biotech and medtech companies that is outstanding in Germany and regional clusters in the fields of automation technology and mechanical engineering.

Press contact:
BioRegio STERN Management GmbH
Dr. Klaus Eichenberg
Friedrichstraße 10
70174 Stuttgart
+49 711-870354-0
eichenberg@bioregio-stern.de

www.twitter.com/BIORegioSTERN

Editorial department:
Zeeb Kommunikation GmbH
Anja Pätzold
Alexanderstraße 81
70182 Stuttgart
+49 711-6070719
info@zeeb.info