

Press Release

## MedAlliance relies on ClinFlows' decidemedical for world's largest DEB study

**Teaser:** *MedAlliance is initiating the largest sirolimus drug-eluting balloon (DEB) study ever conducted with the objective of demonstrating non-inferiority at one year as well as superiority at five years for target vessel failure (TVF). This requires the collection, review, and valuation of thousands of medical images (DICOM) from sites located all over the world. To manage this great organizational effort, MedAlliance relies on ClinFlows' web-based decidemedical platform.*

### Images



Logo Selution DeNovo Study

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Uwe Gladbach, founder and CEO of ClinFlows

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**Hüllhorst/Nyon, Germany/Switzerland September 20th, 2021.** With SELUTION DeNovo, MedAlliance Swiss Medical Technology is initiating the largest sirolimus drug-eluting balloon (DEB) study ever conducted: Approximately 3,300 patients will be implanted with the novel DEB compared to a limus drug-eluting stent (DES) at 50 sites in 15 countries, with the goal of demonstrating non-inferiority at one year as well as superiority at five years for target vessel failure (TVF).

This requires great organizational effort: medical data from the different sites located all over the world must be reviewed, collected, and evaluated. To manage this, MedAlliance relies on ClinFlows' web-based decidemedical platform, which has been successfully on the market for ten years and is already used in 91 countries worldwide. For good reasons: Via decidemedical, participating sites can upload angiograms in DICOM format and submit them for central review easily and in a GDPR-compliant manner thanks to automated DICOM header pseudonymization. "For the organizational success of such a large study, it is crucial to have a reliable and stable technology for online image submission," said Pedro Eerdman, VP Clinical Operations, MedAlliance. "We have used ClinFlows technology in several clinical projects over the past years and are very confident that it will make our job easier this time as well, and uncomplicatedly allow us to comply with all regulatory guidelines in the process," he added.

The largest randomized Drug Eluting Balloon trial kicked off back in August, with the first patient enrolled and treated, and the first images uploaded via decidemedical. "We are pleased to be able to contribute to such an important clinical trial with our secure and efficient online technology," said Uwe Gladbach, CEO of ClinFlows.

### **About ClinFlows**

ClinFlows is the leading provider of online solutions to share clinical data and medical images between various stakeholders involved in Clinical Decision Support and Clinical Research. The German company has been connecting medical staff and clinical experts for almost 10 years. Its product portfolio comprises of the web-based applications decidemedical, a customizable, powerful platform that simplifies the process of collaborating on clinical cases, and dicomdrop, which offers the possibility to automatically send deidentified and anonymized medical images (DICOM) instantly from A to B. Users in 91 countries worldwide - among others the leading medical device makers in the cardio-, endo- and neurovascular market - choose ClinFlows web-based applications regularly because of their innovative and safe approach. All type of clinical data as well as large volumes of medical images are handled in compliance with EU data protection laws, HIPAA and 21 CFR Part 11 requirements.

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