

Case Study

Efficient Onboarding as a Success Factor for PMCF Studies

Starting Point

Auto Tissue Berlin GmbH was founded more than 20 years ago as a spin-off from the Cardiac Surgery Clinic of the Charité Berlin and produces cell-free biological implants. Currently, the only commercially available product is a cell-free patch derived from the equine pericardium. This patch is used to repair defects in the cardiac and vascular systems, primarily in children. The risk class III product has a CE certificate and is also approved in Russia, Saudi Arabia, Iran as well as India.



Figure 1: Manufacturing processes and products of Auto Tissue Berlin

As part of the recertification process due at the end of 2022, a **PMCF study** was planned to generate further data on the clinical safety of the product. For this purpose, the company CSG ("Clinische Studien Gesellschaft mbH") from Berlin was engaged as a Contract Research Organization (CRO).

In previous years, **data collection** had been done with the help of Microsoft Excel. Although this solution generally worked, it required relatively **frequent queries**. The main problem with Excel was the difficulty in finding a balance between **clarity and complexity**. In addition, it is not easy to make certain fields mandatory. Last but not least, the clinic is responsible for anonymizing the data sets. As a result, Excel no longer meets the requirements of today's data protection laws.

Getting clinics to participate in PMCF studies is a particular challenge. For the clinic's staff, conducting a study primarily means additional work. Patients who are included in a study – even if it is purely an observational study – quickly feel like "guinea pigs". It takes additional time to **convince patients to participate** in a study and to reduce fears.

An **EDC system** can simplify some of these requirements. For example, it is possible – similar to an interview – to start with just a few questions. If an answer raises further questions and requires more information, these can then, and only then, be displayed. It is also easy to **mark certain fields as mandatory**. Follow-up questions resulting from specific answers can be processed within the system. In addition, certain answers can **trigger notifications**.

Climedo Health's solution appealed to Auto Tissue Berlin for several reasons. It offers an **attractive, web-based user interface** that users can quickly navigate. The **scope of services** and **pricing model** were tailored to Auto Tissue Berlin's study size. Climedo offers a **proven, validated and certified standard solution** that is independent of the choice of CRO and can be managed by the manufacturer if necessary.

Project

The study will be conducted across **five European pediatric cardiac surgery hospitals**, which will provide data on the safety of the patch. A total of **100 patients** will be followed up with over **six months**. This early primary endpoint was chosen because the few problems observed to date occurred during the first three months.

Data will be collected as part of a purely **observational study**. No additional data will be collected. The **electronic Case Report Forms (eCRFs)** will include questions on patch performance and handling, in addition to general data on **medical history** and the **planned surgery**.

Patients receive a short questionnaire **once a year for a total of five years**, which is automatically sent by the Climedo system in the correct local language. The questionnaire

can be completed and submitted using any **web-enabled device**. The display automatically adapts to the size of the user's screen. The time required by the patient is **only a few minutes**. If the answers are not submitted on time, the Climedo system sends **automatic reminders**.

Familiarization with the Climedo system was quick and easy. After only a **two-hour introduction**, it was already possible to map the questionnaire described in the **study protocol in the eCRFs**. The programming was done similarly to modern **web programming** with a **modular system**. The questions could be placed almost freely on a page. Various field types such as **open text fields** or answer options were available. Furthermore, it was very easy to program automatic **plausibility checks** and **dependencies**. This way, many errors can probably be avoided already during data entry. The entire system is "responsive" and thus automatically adapts to the available screen size.

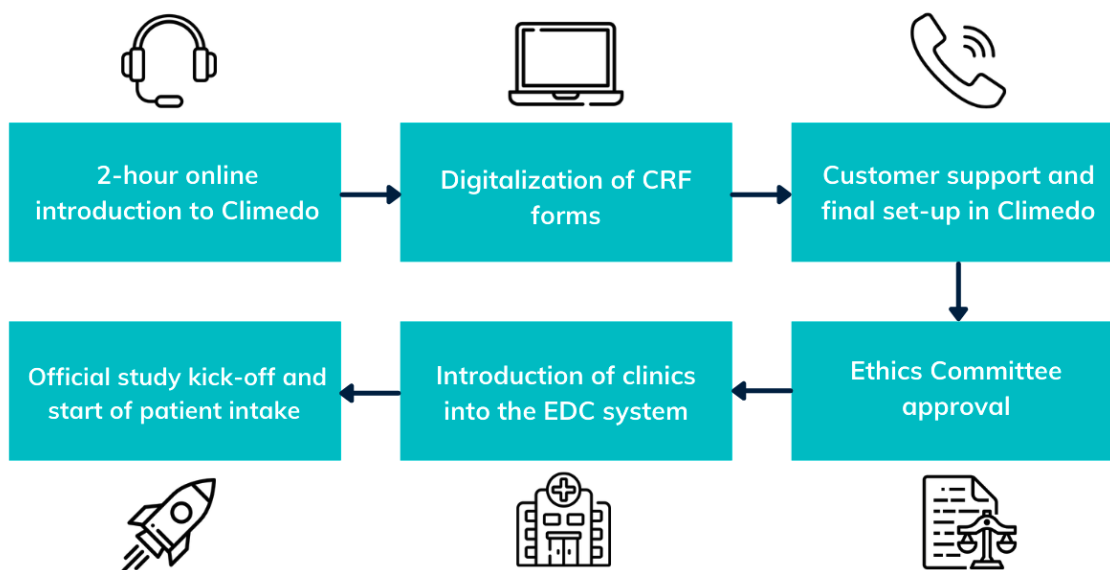


Figure 2: Climedo's onboarding process for Auto Tissue Berlin

Results and Benefits

The Climedo Health team was always approachable during the implementation of the project and also available at short notice when questions needed to be answered. Overall, the cooperation between the clinics, the CRO, Auto Tissue Berlin and Climedo Health was **highly professional and pleasant**. As a result, the project was implemented in a very short time. Climedo's EDC system is still a relatively young program that is constantly being improved and developed.

The time required for programming an EDC system was of course initially higher than listing the questions in a simple Excel spreadsheet. However, due to the **intuitive operation**, Auto

Tissue Berlin expects **significant time savings** in entering and **monitoring the data** as well as in compiling the data for evaluation. In addition, as the sponsor of the study, Auto Tissue Berlin has a **quick overview of the current status** of data collection at all times, unlike when using Excel.

"Climedo Health has an incredibly dedicated and customer-focused team. I was convinced by the solution as it offers the perfect combination of simplicity and elegance. In the short time we have been working with Climedo, the first suggestions for improvements we submitted have already been implemented. In addition, the solution has a very attractive user interface. It is simply fun to work with. Climedo's pricing model is also very attractive for our task and study size. We look forward to a successful long-term collaboration!"

- Prof. Dr. Christoph Schmitz, Chief Medical Officer, Auto Tissue Berlin GmbH

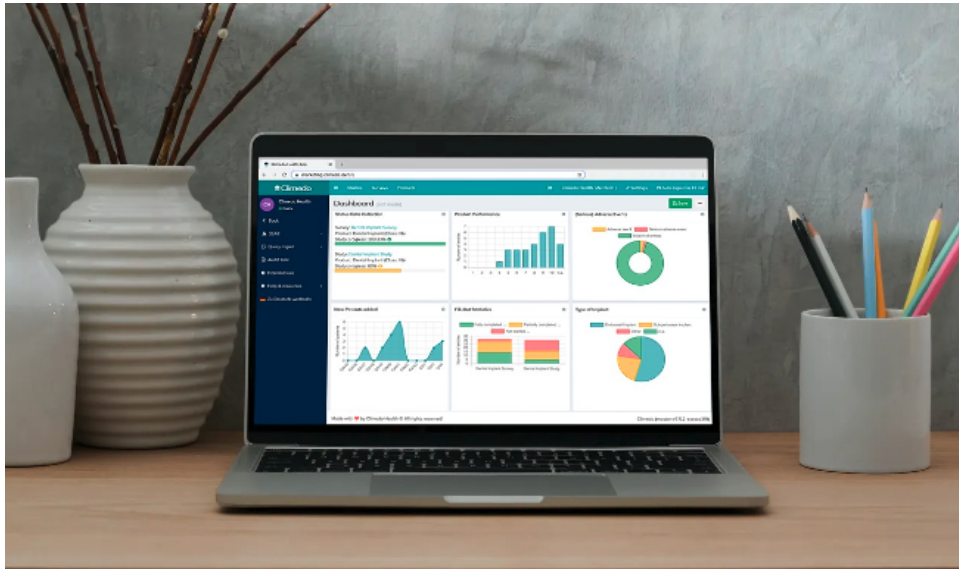


Figure 3: Climedo's intuitive user interface

Conclusion and Outlook

The ethics committees had no objections to the conduct of the study, so the next step is to **enroll the clinics in the EDC system**.

A **registry** will be launched in parallel with the PMCF study. This will include a subset of the questions from the PMCF study. The registry will collect data from clinics not participating in the PMCF study as well as data from patients who cannot participate in the study due to exclusion criteria. The clinics participating in the PMCF study and in the registry have **access to their own data at any time** and can **evaluate** and, if necessary, **publish** them themselves.

Climedo is a **modern, easy-to-use and flexible EDC system** for any type of collection of

clinical data relevant to clinical approval. The certified and validated standard solution of Climedo guarantees **compliance with all current data protection requirements**.

Auto Tissue Berlin also plans to realize its new developments, such as a patch from the bovine pericardium, with the support of the Climedo EDC system.

On behalf of Climedo Health, we would like to thank Auto Tissue Berlin, in particular Prof. Dr. Christoph Schmitz and Mr. Stefan Seidl, for their kind support in the preparation of this case study!

About Climedo Health

Climedo's mission is to bring the best treatment to every patient by empowering healthcare professionals with intelligent software solutions. Together with Europe's leading hospitals, we have developed a cloud-based platform for cutting-edge clinical validation and post-market surveillance of medical devices and pharmaceutical products.

By digitally connecting all stakeholders (Medical Device manufacturers, Pharma companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies – and ultimately – accelerated medical innovation. Learn more: www.climedo.com.

About Auto Tissue Berlin

Auto Tissue Berlin is a certified manufacturer specialized in the development and production of cell-free biological implants. The company also offers contract development and manufacturing of biological implants. Learn more: www.autotissue.de.

April 2021

© Climedo Health GmbH

www.climedo.com | hello@climedo.de

+49 89 3220 9394 0