



## REMOTE MONITORING FOR SMART IMPLANTS

A Swiss medical device startup is developing an active implant to support the orthopedic industry in the treatment of complicated bone fractures. The goals are to improve control of the healing process, reduce the number of follow-up examinations necessary, and achieve better healing results. The customer needed an external software solution to control and monitor the implant during initial preclinical and clinical studies. The system requirements were for an MVP with a smartphone application including BLE synchronization over the cloud plus a web application dashboard for the doctor to view the data.

### MVP for clinical trials

konplan supported the customer in defining the scope of services for the MVP based on the system requirements. An agile approach with user stories and sprints was mutually selected to stay on top of ongoing developments. A mock-up and architecture prototype were quickly developed to enable iterative trials of the product in animal tests and clinical studies. An interdisciplinary team was required for implementation. konplan immediately organized specialists in the areas of requirements engineering, mobile and cloud development, and testing. It was a major advantage for the customer to get everything necessary from a single source which included the applicable background knowledge of medical software regulatory requirements, implants, and clinical studies.

### IT security under control

Through teamwork with konplan, an agile process was implemented to develop a system which could be used for preclinical trials without extensive overhead costs and subsequently used in clinical trials. Part of the development focus was data management and infrastructure in preparation for future, more extensive, requirements involving maintenance, data privacy, and cybersecurity.

### Result

- MVP for clinical trials
- Evaluation tech stack
- Readiness for GDPR and cybersecurity
- State of the art cloud infrastructure

### Methodology & Technologies

- C#/.Net
- Azure Cloud & DevOps
- Xamarin
- BLE sync

### Scope of Services

- Architecture & concept
- Mobile app, cloud solution, web app
- Documentation
- Data privacy and security assessment, threat modeling

 16 months

 3-6 employees – konplan

 Conception, development

