

# SIMEDYS

## Category:

Best Startup

## Company Name:

SIMEDYS

## Turnover and/or Funding:

2023 : 100 k€    120 k\$        (modification du modèle économique)  
2022 : 260 k€    388 k\$  
2021 : 366 k€    394 k\$

## Sub-Category:

Medical Technology / Digital Health

## Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

In 2012, the French-speaking Multi-Organ Harvesting School (EFPMO) approached us with their problem of a lack of pedagogical tools for the practical training of organ harvesters.

There was no surgical learning model that met their requirements. The solution we envisaged was to simulate life on a body donated to science. The first difficulty was our assumption that the endothelial cells that seal blood vessels were no longer functional immediately after death, so our idea was not feasible. We started by thinking about ways of supplementing the functions of the endothelial cells.

In 2014, we designed a protocol for preparing the surgical learning model: \"SimLife\". We had successfully simulated arteriovenous circulation using cannulas positioned in vessels. The function of endothelial cells has been replaced by an avatar of blood, with a viscosity to ensure tissue tightness. The turgidity of tissues and organs was ensured with a specific dye. The \"SimLife\" process has been simplified to the maximum, so that it can be utilized by people with a basic knowledge of reperfusion and fluid biomechanics. The \"SimLife\" process was validated by a cohort of learners and teachers from the abdominal and thoracic surgery fields.

In 2018, we filed the patent for the \"SimLife\" technology internationally to create a startup. Simedys was established in December 2017 by the primary inventor, after obtaining the rights to exploit the patent, to valorize his own research work. By the end of 2018, Simedys delivered its first \"Pulse for Practice: P4P\" devices, to conduct the \"SimLife\" process.

The revascularization and re-ventilation process allow learners to be immersed in a simulated operating room with an extremely high degree of realism. An avatar of blood, at 37°C, is injected into the arteriovenous system in a pulsatile manner, via injection cannulas placed on the model at the level of the neck and femoral triangles. The re-ventilation is achieved by pulsatile injection of air into the lungs. All the physiological functions of the \"SimLife\" training model are controlled by a digital application and a touch-sensitive panel (heart and respiratory rates, blood, and lung pressure, etc.) and conducted by the \"P4P\" system.

« SimLife » was initially developed for abdominal and thoracic surgeons. Today, it is also used for limb and head surgery, as well as interventional radiology.

In 2024, we launched the Live & Debrief software to simplify simulation-based training. This pedagogical tool allows you to record a simulation, evaluate learners using a grid of digitized items, quickly generate feedback and simplify debriefing.

Innovation is a fundamental value at Simedys, which is why we are moving towards immersive distance learning. As healthcare professionals' time is increasingly valuable and training is very time-consuming, we are currently developing a digital solution in which the learner is physically immersed in a simulated operating room, while the teachers and evaluators are remote.

## **History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):**

The \"SimLife\" model is the result of transdisciplinary development between surgeons and a biomechanics engineer. The \"SimLife\" process evolved gradually through individual validation of each functionality of the learning model. The surgeons desired a specific functionality in the model, and this challenge was met by the biomechanical engineer. The surgeons and learners precisely validated each feature. We had to implement multiple technological solutions to address the same desired function of the model. This multidisciplinary collaboration was both enriching and necessary for the performance and efficiency of the \"SimLife\" model.

The final validation phase was organized in two steps. Initially, we implemented the

model with one group of learners at a time to gather their feedback and impressions and refine the \"SimLife\" process. The 4 tests were conducted under the supervision of key opinion leaders (KOL) in French multi-organ harvesting.

In June 2017, with the patent filed, we implemented the \"SimLife\" model for 64 learners, during the French-speaking Multi-Organ Harvesting School (EFPMO) training course, with 12 \"SimLife\", spread over 4 practical training sessions. This was our first large-scale test under real-life conditions. Learners and teachers were thus able to assess the realism of the \"SimLife\" model, resulting in a 95% satisfaction rate. The test was conducted using 4 revascularization and re-ventilation demonstrators. These demonstrators were designed with extremely limited financial resources and reusable or reused components. The objective was to validate the proof-of-concept on a large scale.

These demonstrators contributed to the design of the Pulse for Practice (P4P) prototype. The P4P system is more robust, more dependable, easier to implement, easier to control, etc. Currently in France, 12 of the 26 surgical training centers with a body donation center are equipped with our technology.

Since 2018, the \"SimLife\" process has been protected internationally in 12 countries by an annually maintained patent. The company Simedys holds the exclusive rights to this international patent. The blood avatar is the subject of a know-how license, and its complete formulation is known only to one person.

Simedys has signed a collaboration agreement to create a surgical training center at the University of Bologna. The aim is to implement the \"SimLife\" model in Italy, which has just authorized body donation to science. We have also signed a cooperation agreement with Revinax, which designs immersive video tutorials from the operator's point of view. Both our companies engage in surgical training. We are certainly competitors, but we also complement each other. Together, in May 2024, we performed more than 50 surgeries in 4 days, all aimed at creating tutorials (in various surgical domains including damage control).

We are also in partnership with the Public Assistance - Hospitals of Paris (APHP), for the creation of the Paris School of Surgery.

## **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

Surgical training should never be performed for the first time on the patient. It is therefore necessary to provide high-performance, realistic learning models that are adapted to the pedagogical objectives and the realities of surgeons' daily lives.

According to the French-speaking Society for Health Simulation (SoFraSimS), the French Academy of Medicine and the French Academy of Surgery, the \"SimLife\" learning model is the only one to precisely meet this need for an extremely high degree of realism. This technology provides a model of an anesthetized patient in the operating room, with arterial pulsation, venous return, and breathing...

\"SimLife\" is the ideal tool for a surgical team to acquire technical and non-technical surgical skills. When the \"Simlife\" model is combined with the Live & Debrief software, you can script your pedagogical objectives, conduct digital assessments of learners, and debrief them using video recordings of the simulation.

Live & Debrief software allows the evaluation of learners' surgical skills in an objective and standardized way. The future of training involves the design of optimized, personalized pedagogical processes, based on the referencing of pedagogical data. Ultimately, the goal is to improve surgeons' training while minimizing learning time. This is especially true as the validation of surgical skills must occur throughout their professional lives. \"SimLife\" provides surgeons with personalized training tailored to their needs, through data analysis and artificial intelligence.

Coupled with today's communication tools, our \"SimLife\" technological solution will enable us to train surgeons located in developing countries, under the supervision of specialists in surgical techniques. The objective is for every inhabitant of the world to have access to the best surgical care and treatment.

\"SimLife\" technology is also necessary for the research and development of new medical devices and/or the validation of new surgical management techniques. \"SimLife\" allows pre-testing of implantable surgical devices, validating their design and functionality, before they are implanted on a real patient. To illustrate, in the pre-clinical study phase, we can validate the design of an arterial stent or a heart valve. \"SimLife\" has the advantage of providing a model with a morphology and physiology close to those of humans. It is the ideal tool for final validation and certification of medical devices.

The \"SimLife\" model can be used to design and validate new operating procedures, particularly in the field of surgical robotics, which has now become an integral part of everyday operating room practice. Our \"SimLife\" model can be used to validate the feasibility of robotic surgical management, evaluate complication risks, study optimized surgical options, and validate inclusion and exclusion criteria.

In the field of surgery, new devices or surgical procedures should never be performed on the patient first.

**Please provide appropriate references (PubMed, Abstract,**

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