

## Case descriptions

### **Getinge**

Getinge aims to contribute to an environmentally and socially sustainable society, for healthcare and life science. Our sustainability program includes the intention to become a CO<sub>2</sub> neutral company in our own operations by 2025 and a net-zero emissions company by 2035. This target will be reached by taking actions in several areas, such as renewable energy sources, green certifications, cleaner vehicles, improved travel routines and smart logistics.

The aim mentioned above is a challenge, since plastics have played an essential role in healthcare. Some of the well know examples of the use of plastics are disposable plastic syringes, blood bags, heart valves, etc. The use of plastic material in healthcare is justified by multiple advantages, among which sterility, safety, comfort, speed.

The plastic single-use AppliFlex stirred tank (AF ST) bioreactor manufactured by Getinge has the advantage of reducing the risk of contamination, which is extremely important when designing a process for the expansion of cells that will be ultimately used in clinical therapies. Besides the low contamination risk, the easy scalability to reach a high number of cells, the controlled environment, and the simplicity of the design make the single-use bioreactors ideal candidates for the expansion of the cells to be used in clinical applications.

### **Pathofinder**

PathoFinder, founded in 2004, designs, develops, manufactures and markets CE-IVD multiplex real-time polymerase chain reaction (PCR) kits for detection of infectious diseases. Our proprietary multiplex PCR technology allows detection and distinction of up to 24 pathogens simultaneously, on standard real-time PCR instruments. We are currently developing a sample-to-result system to allow use of our successful product ranges at the point of need.

Nucleic acid extraction from clinical samples is an essential step in molecular diagnostics because it impacts the reliability of the actual test. The implementation of automated extraction systems in medical laboratories has reduced the hands-on-time. However, these instruments still rely on the use of chaotropic chemicals to disrupt cells and separate nucleic acids from proteins. These chemicals are corrosive and therefore unsafe for the user and they require specialized waste procedures.

Theoretically, it should be possible to omit corrosive chemicals and instead use physical methods to disrupt cells and to separate the nucleic acids from proteins and other contaminants. It is important that the method is universal. In other words, it should be compatible with all types of clinical samples (swabs, feces, urine, plasma, cerebrospinal fluid etc.) and with DNA and RNA from viral, bacterial, fungal and parasitic pathogens. In addition, the method should take no more than 15 minutes; and ideally even 5 minutes.

## Yaghma

In the rapidly evolving landscape of healthcare, the integration of Artificial Intelligence (AI) has emerged as a transformative force, promising enhanced diagnostic accuracy, treatment personalization, and improved patient outcomes. However, as we entrust AI algorithms with supporting critical healthcare decisions, a growing concern looms—the inadvertent introduction and perpetuation of systemic mistakes, false conclusions and biases. Stakeholder involvement and embedment of ethical criteria are often seen as the backbone for developing trustworthy and non-maleficent AI. These measures are however not sufficient to ensure the use of the AI is surely beneficial for the patient – guidelines for how to assess the potential ethical issues of a given AI system and how to set up practice guidelines for different kind of healthcare professionals who either impact the AI output or whose decisions may be effected by the AI outputs.

A special challenge that is very present for AI in healthcare is how to assess systems where the direct user is one or multiple health professionals but the output of the AI has direct and significant impact on the patient, the end-user. The health professionals are in many cases both an intermediary between the AI system and an integral part of generating the best possible outcome for the patient. The professionals must use their specialist knowledge and experience to evaluate the outcome of the AI and potentially disagree with the outputs of the AI. In such cases, it is not sufficient to evaluate the AI as a stand-alone system, but how to assess the impact of AI as part of the likely usage-situations in a guided manner that prevents quality to depend solely on the assessor but is still flexible enough to tackle multiple types of AI and usage-situations.

Since the assessment of an AI in a healthcare situations is closely linked to its usage, the development of an assessment framework will be closely linked to the development of practice guidelines that both fosters professional usage of AI output with a suitable balance between skepticism and trust, and fosters good communication between healthcare professionals and patients to achieve the best outcomes for patients.

To make the scope of the problem achievable, this challenge focus on assessing and providing guidelines for AI when it is already deployed (operating), and when the AI will be decommissioned. Furthermore, we find it very interesting to look at the impact of AI from a value perspective and have a focus on Bias, Explainability, transparency, reliability and trust. Solutions and analysis that focus on the development of the framework generation are equally appreciated as those that dive into specific (hypothetical) use cases and explores the details of how such an assessment of the AI would be carried out, how realistic answers may look like and what practice guidelines ensure the best possible use of AI.