A beating Heart-on-Chip for pre-clinical early detection of drugs cardiac safety

Sprawozdania

Informacje na temat projektu

uHeart

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Strona internetowa projektu

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Periodic Reporting for period 1 - uHeart (A beating Heart-on-Chip for pre-clinical early detection of drugs cardiac safety)

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Podsumowanie kontekstu i ogólnych celów projektu

The cost to develop a new single drug is estimated around 2.8B$ and the average time to market is 12 years; both trends are continuously growing. Less than 1% of the initially investigated candidate drugs reach the market, while the others fail along t he way. The further in the drug discovery pipeline the failure occurs, the higher is the waste of investment, in terms of money, time and human safety. There is thus a high risk to introduce in clinical trial ineffective of even toxic molecules due to the poor predictability of the preclinical test models. Currently available preclinical tools for testing drug safety/benefit rely on human cell culture methods poorly resembling the complexity of native tissues, being their responses to drugs barely representative of the human ones or on animal models, that however lack in predicting human responses due to inter species differences. Moreover, 3R principles is forcing Pharma to reduce the use of animals (Directive 2010/63/EU).

BiomimX aims is to offer a solution to this problem, providing advanced in vitro preclinical models of human organs and diseases, with the aim to increase the reliability of early stages of the DDP (and of MD development) and reduce the risk of taking wrong go/not-go decisions before clinical phases. BiomimX' products belong to the organs-on-chip (OoC) family, an emerging technology able to closely mimic the key physiological functions of human organs in about the size of computer memory sticks. OoC hold the promise to make preclinical drug development more reliable, mimicking human responses with unprecedented precision, potentially with in a patient-specific fashion.

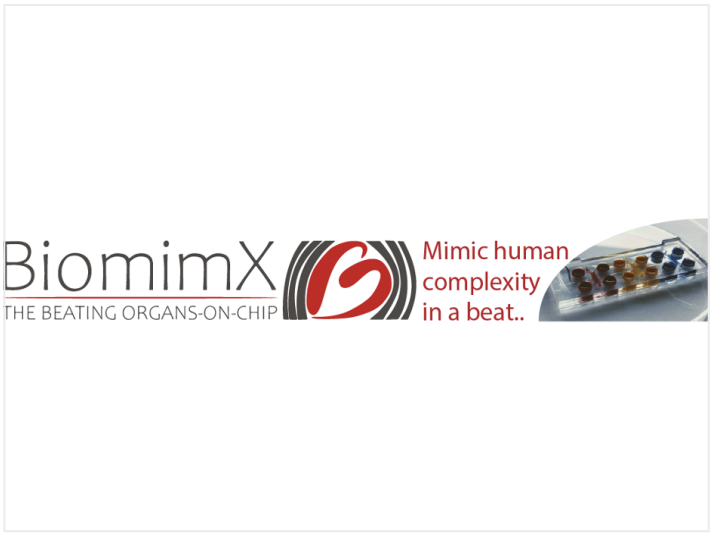
Prace wykonane od początku projektu do końca okresu sprawozdawczego oraz najważniejsze dotychczasowe rezultaty

BiomimX is a developer of beating organs on chip to be introduced as advanced preclinical tools in the drug discovery pipeline (DDP), for screening drug safety and benefit. BiomimX specifically addresses the urgent need of Pharma companies for advanced in vitro models of human organs and diseases, with the final aim to improve DDP and lead to a more efficient, faster and less expensive launch of drugs into market. This need is also driven by the 3R principles, forcing Pharma to reduce animal models (i.e. Directive 2010/63/EU). The company organs' portfolio comprises uHeart, a human beating heart-on-chip, and uKnee, a model of human osteoarthritic (OA) joint. The Feasibility study was aimed at analysing risks and opportunities correlated with both products.
In details, BiomimX performed a risk assessment analysis, consolidated strategic partnerships and established new ones, performed deep market analyses and defined a plan to proceed towards industrialization. These actions led to the release of an updated Business Plan (BP).

Innowacyjność oraz oczekiwany potencjalny wpływ (w tym dotychczasowe znaczenie społeczno-gospodarcze i szersze implikacje społeczne projektu)

BiomimX S.r.l. is an Italian Innovative Startup Company, Spin-off of Politecnico di Milano, pioneer in the generation of predictive in vitro models of human organs and pathologies that will revolutionize the way to test new drugs. Integrating 3D cell culture, mechanical stimulation (uBeat technology) and electrical recording capabilities (uECG technology), BiomimX proposes the next generation of beating

organs-on-chips, leading to more reliable, fast responsive and affordable pre-clinical models for screening drug and medical devices (MD) for efficacy and safety in reliable in vitro preclinical models. BiomimX organs' portfolio currently includes uHeart, a human beating heart-on-chip, and uKnee, the first model of human osteoarthritic (OA) joint. BiomimX's R&D Team is constantly developing new in vitro models of organs/diseases, all based on BiomimX's pillar technology (uBeat) that will eventually enter the pipeline.
BiomimX is ready to offer its in vitro human advanced models as visionary tools for reducing (and eventually replacing) animal testing in preclinical development, in line with legislations on 3R principle, pushing worldwide Pharma towards methods alternative to animals for drug/MD testing.
BiomimX vision is to be at the forefront of the OOC revolution. BiomimX strongly believes that OOC technology represents the unavoidable future in the drug development market. In the last few years, OOC companies have raised large investments for developing their organ portfolios, thus gaining the attention of Big Pharma. With the support of EU H2020 and exploiting its pillar uBeat technology, BiomimX is the first in selling beating organs-on-chip, i.e. OOC modelling tissues that are physiologically subject to mechanical stimulation, with the goal of acquiring in the next 5 years a consistent segment of the fast-growing OOC market in Europe (30%) and worldwide (10%). Notably, other than the heart, BiomimX's R&D Team is constantly working on the development of in vitro models of different organs/diseases that will eventually be inserted in its pipeline.



BiomimX vision

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