



LIFESAVER

WHAT IS THE LIFESAVER PROJECT?

GREEN DEAL LIFESAVER PROJECT

www.lifesaverproject.eu

The LIFESAVER project addresses the current unmet societal and healthcare needs in creating a valid and scientific knowledge base, which is needed for the development and implementation of regulatory approaches relevant to maternal and fetal health. It aims to generate and validate the data that shows forecast potential effects of environmental pollutants and drug treatments for pregnant women and eventual premature births, which are usually very difficult to assess.

Pregnant women can suffer from many conditions that require continuous or acute treatments, but they also suffer from environmental pollutants such as chemicals, contaminants and others. At the moment, the only conclusive process to ensure the safety and efficacy of a biomedical product is to test it on humans through clinical assessment. Unfortunately, due to unknown and potentially harmful effects of testing biomedical products on the developing fetus, only <1% of all clinical trials in the US consider pregnant women, and >98% of trials actively exclude them.

Premature birth kills one baby every thirty seconds, and poses a serious and growing threat to the health and well-being of the future European population. The risks of preterm birth are not limited to premature death of a baby, but also may lead to serious complications in future life: the children can suffer from extra infection, poor vision, breathing problems, diabetes, hypertension, and increasing risks of cerebral palsy, bowel damage, stroke and even lower IQ. This will affect their lives and presents a significant burden to society over several generations.

Many limitations of the development of health treatment for the prenatal state are due to a lack of fundamental knowledge of realistic structure, properties, and functionality of placenta tissues. Susceptibility to interference from chemicals and medicine exposure resulting in adverse pregnancy outcomes varies at the different stages of embryonic/fetal development. Due to the crucial role of placenta in supporting the fetus development, the presence of exogenous and potentially harmful chemicals, drugs and particles is a matter of great concern.

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The LIFESAVER vision is for every pregnant woman to have a proper living environment with minimal risks to the fetus, and to be safeguarded with scientifically justified regulations of potentially harmful chemical and medicinal products. The overall objective of LIFESAVER is to create and demonstrate a new, digitally cloned in vitro system for emulation of the prenatal conditions in the vicinity of the placental interface. This in-vitro system would be capable of high biofidelity and corresponding risk prediction of a drug or a chemical substance as a potentially harmful risk factor towards unborn babies.

The groundbreaking LIFESAVER concept enables design, manufacturing, and deployment of a platform having all of the correct key components of placental tissue for sufficient emulation of typical/atypical prenatal conditions.

LIFESAVER platform can in future enable proper emulation of uteri functionalities for testing all drugs and chemicals reducing national healthcare costs.

The added value of LIFESAVER in the spirit of the Green Deal call is in scientifically-based tools for experimental screening, digital pre-screening and analysis of chemicals and pharmaceuticals on their potential to cross placental tissues barriers. This will provide rationale for a risk classification on existing and new compounds, as well as justifications of regulations and risk assessment/mitigation measures towards the potential effects of these compounds on pregnant women and fetal health.

LIFESAVER addresses new market opportunities in digitized solutions for improved healthcare and well-being of pregnant women and at large for new biodigital twin in vitro devices. It also will strengthen the competitiveness and growth of companies working in environmental, medical and lab data analysis, bioprinting, tissue and cell engineering, and pharmacology.



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