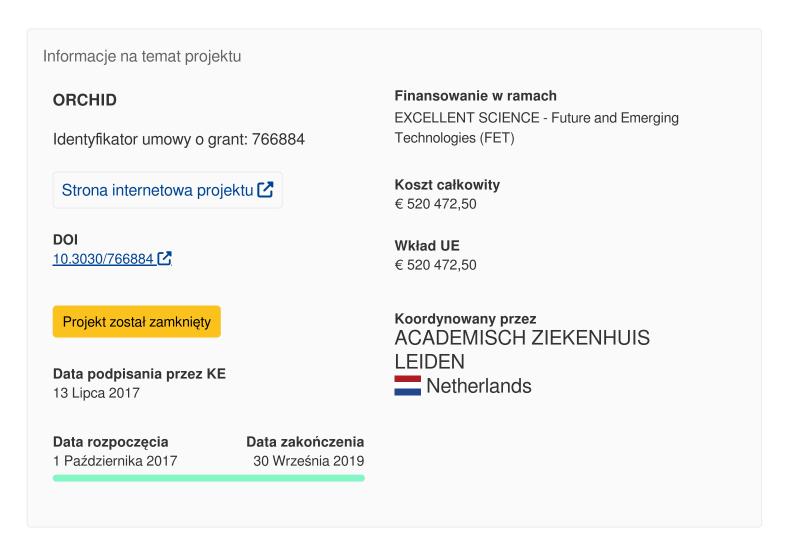


Organ on Chip in Development

Sprawozdania



Ten projekt został przedstawiony w...



Periodic Reporting for period 2 - ORCHID (Organ on Chip in Development)

Okres sprawozdawczy: 2018-10-01 do 2019-09-30

Podsumowanie kontekstu i ogólnych celów projektu

Healthcare challenges 2020

Conventional animal models and cell cultures fail to fully capture human physiology and thus predict human responses to medical treatments. This is a major contributor to late and costly drug failures in clinical trials and an important reason why new drugs are so expensive, and no medication exists for many diseases. Animal experiments raise ethical questions, increasing the societal and political pressure to reduce their number. Together this requires new ways to improve drug development and identify effective, personalized treatments. Organ-on-Chip (OoC) technology is the game changer offering solutions for personalized and affordable healthcare as cutting-edge science, which goes beyond the frontiers of knowledge and requires multidisciplinary collaboration.

Organ-on-Chip In Development (ORCHID) is a 2-yr H2020 FET Open project, that aims to create an OoC roadmap and build an ecosystem to move OoCs from the laboratory into real life medical care for citizens of Europe and beyond.

The following objectives are addressed:

- -Assess the status of OoC technology in Europe
- -Identify ethical issues, drive standardization and take steps for regulatory take-off
- -Analyse the impact on economy, society, training and education
- -Establish the OoC technology roadmap
- -Raise awareness and build the ecosystem for OoC technology

ORCHID has laid the foundations of a European ecosystem on OoC technology by bringing together many key European players in this field and strengthening this community by the establishment of the European Organ-on-Chip Society (EUROoCS). ORCHID has provided insight into the state-of-the-art, needs and challenges of the OoC technology, which formed the basis for the development of the

European OoC roadmap. As a follow-up to ORCHID, EUROoCS will facilitate implementation of the roadmap in an ongoing dialogue between developers, end users and regulators.

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

Development of the European OoC Roadmap

During the ORCHID project two workshops were held with experts from academia, pharmaceutical and cosmetic industry, patient organizations, ethics school, biotech companies and regulatory agencies. The bibliographical, bibliometric and market analyses and expert interviews, combined with the outcome of the workshops, identified current unmet needs, key challenges, barriers and perspectives of this technology as basis for developing the OoC roadmap. Six specific building blocks for the roadmap were defined, including priorities, methods and targets for each block. EUROoCS will initiate and catalyse the dialogue between developers, end users and regulators during roadmap implementation.

European Organ-on-Chip Society (EUROoCS)

An outcome of ORCHID in 2018 is the establishment of EUROoCS (www.euroocs.eu) as an international independent not-for-profit organization aiming to encourage and develop OoC research, and to provide opportunities to share and advance knowledge and expertise in the field towards a better health for all. EUROoCS will stimulate dissemination and provide a platform for dialogue and interaction between all parties involved in the OoC field. With the support of EUROoCS the OoC community will be built further in order to accelerate adoption of the OoC technology.

Societal and economic impact-training-education

A budget impact analysis of OoC technology was performed over a 5 yr period. Relative change in costs was assessed through a survey among 17 experts, based on an R&D productivity framework that considered each phase of the drug development process and corresponding main cost drivers. A reduction in total R&D costs of up to 26%, is expected through OoC technology. Savings were achieved by improving the success rates and most benefits were expected in lead optimization and preclinical phases.

The current and future business models and their strengths and weaknesses have been identified. Novel, additional customer market segments, including veterinary industry, military, and chemical industry, allow the development of new business cases and models for OoC technology, thus extending the impact of the technology beyond the scope of drug discovery & development. The training needs for promoting the development, utility, adoption and qualification of OoC systems have been identified using an online stakeholder questionnaire. The main target populations in need of training are technicians and end-users in both industry and academia, and early career researchers, including those in applied science studies.

Eco-system development and digital platform

A digital platform has been developed within ORCHID that has been integrated in the EUROoCS website. This website stimulates exchange and collaboration between academic and industrial

partners or other stakeholders including regulators and patient associations. The digital platform is a reserved area for EUROoCS members, and provides up detailed information, including experts' contacts, project descriptions and forum discussions. Aim is to encourage researchers and others to become a member and to join the community.

Regulation, Standardization and ethics

For standardization, regulation and ethics a landscape analysis was performed based on scientific and business sources, followed by a SWOT analysis with respect to the development of an innovation roadmap. Today no OoC systems are used in any regulatory approval path, there are no golden standards defined and the ethics impact of a personal OoC model is still largely unaddressed. Several primers and guidelines have been developed addressing ethical aspects in research, regulatory issues and standardization (whitepaper) for reaching out to policymakers, researchers and the public at large, and to align the debate about these topics with the technological advances.

Dissemination and communication

The ORCHID logo, website, brochure and LinkedIn group were created, and ORCHID was presented to the scientific community and companies during conferences and workshops worldwide. The Vision workshop and Strategy workshop have delivered two brochures about the European OoC roadmap that were disseminated to over 2000 people, mostly researchers. Dissemination to the general public was achieved by Twitter or during global events and special meetings with children and high school students, the next generation of OoC researchers. The final report on dissemination and communication contains the future roadmap for outreach activities, that will be covered by EUROoCS.

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

Beyond the European roadmap on OoC

During the final ORCHID meeting the European OoC roadmap has been presented to a broad audience of end users, regulators, clinicians, developers, policymakers and patient representatives. There is consensus on the central role that EUROoCS could and should play in the deployment and actualization of each building block. Since qualification and standardization will accelerate OoC technology implementation, activities in this direction will have the highest priority. Among the first are the design and implementation for a European OoC infrastructure with testing, training and data centers, resulting in independently qualified and characterized models, and the development of open technology platforms to enable customized solutions for specific applications. EUROoCS will initiate and catalyse these challenging processes.



ORCHID logo

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