# Organ on Chip in Development (ORCHID)

## EU – H2020 project grant agreement no 766884 (AMD-766884-3)

**Website: www.H2020-ORCHID.eu**

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|---|---|
| **Deliverable Number** | 3.2 |
| **Deliverable Title** | Current and future potential business models |
| **Short Title** | Business_models |
| **Lead beneficiary** | Fraunhofer |
| **Del. Date (Annex 1)** | 31/03/2019 |
| **Achieved Date** | 30/03/2019 |
| **Nature** | Report |
| **Dissemination Level** | PU |
| **Document Filename** | D32-Business_models-PU-v1.0 |

| Date | Authors/Reviewers | Remarks | Version |
|---|---|---|---|
| 04/03/2019 | Thomassen | Format Deliverable provided | 0.1 |
| 22/03/2019 | Loskill | | 0.2 |
| 29/03/2019 | All consortium partners, Loskill | Review, final editing check | 0.3 |
| 30/03/2019 | Thomassen | Final Version submitted to EC | 1.0 |

# Contents

# Current & future business models of commercial Organ-on-Chip providers

Based on stakeholder consultations, we generated an overview of examples of commercial Organ-on-Chip (OoC) providers that are currently active in the market (Table 1) and attempted to categorize their respective business models.

The different business models these commercial providers employ may be placed into four distinct categories:

a) **Chip Sales**
   Chip sales, with or without training
b) **Chip & Instrument Sales**
   Chip sales with companion instrument(s) needed to operate chips, with or without training, custom model development
c) **Contract Research Services**
   Performing experiments with chips/instruments from in-house manufacturing or other commercial OoC providers
d) **Hybrid**
   Various combinations of the abovementioned business models (a-c)

***Table 1**: Exemplary overview of commercial Organ-on-Chip providers*

| Name | Homepage | Business model |
|---|---|---|
| AlveoliX | http://www.alveolix.com/ | Chip Sales, Instrument Sales |
| Ananda | https://anandadevices.com/ | Hybrid |
| BI/OND | https://www.gobiond.com | Chip Sales |
| BLB (Barcelona Liver Bioservices) | https://liver.barcelona | Contract Research Service |
| Cellanyx | https://cellanyx.com/ | Contract Research Service |
| CN Bio | https://cn-bio.com/ | Chip Sales, Instrument Sales |
| Emulate Inc. | https://emulatebio.com/ | Hybrid |
| HμREL Corporation | http://hurelcorp.com/ | Hybrid |
| Hesperos | https://www.hesperosinc.com/ | Contract Research Service |
| inSphero | https://insphero.com/ | Chip Sales, Instrument Sales |
| MicroBrain Bt | https://microbrainbiotech.com/ | Unknown |
| Microfluidic ChipShop | https://www.microfluidic-chipshop.com/ | Chip Sales |
| Micronit | https://www.micronit.com/ | Chip Sales |
| Mimetas | https://mimetas.com/ | Chip Sales, Instrument Sales |

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|---|---|---|
| Nortis | https://www.nortisbio.com/ | Hybrid |
| SynVivo | https://www.synvivobio.com/ | Hybrid |
| TARA | https://tarabiosystems.com | Contract Research Service |
| TissUse | https://www.tissuse.com/ | Hybrid |
| Xona | https://xonamicrofluidics.com/ | Chip Sales |

## Weaknesses/Strengths of currently employed business models

The discussions with the stakeholders identified various strengths and weaknesses of the different business models, which are obviously depending on the respective individual strategy and goals of each company, but can be generalized as:

a) Chip Sales

+ Lean and focused business model

- Sales of application-specific chips only provide an unsteady revenue stream, which necessitates higher profit margins, which weakens competitive strength.

- Limited opportunities to learn about customers' needs and developing market opportunities

b) Chip, Instrument Sales

+ Sales of instruments to customers increase chances of future use and repeat purchase of consumables/chips that are compatible with the particular instruments

+ Customer binding through co-development of customized models

+ Training of personnel and maintenance of equipment provide an additional source of revenue

- High initial costs for customers

c) Contract Research Services

+ High flexibility in terms of services by either using self-developed chips or those from competitors or foundries

+ Regular customer and long-term projects can provide a stable stream of revenue

+ Constant CRO-customer interactions provide detailed insights into customers' needs.

- Limited opportunities to develop new chips or adjust the design of existing chips, if relying on the ones from competitors, foundries etc.

- Pharmaceutical companies might be hesitant to source out the screening of novel compounds and prefer in-house testing.

d) Hybrid

+ Sales of chips with or without accompanying instruments serves as a starting point for customer binding to the product.

+ CRO services provide stable stream of revenue and detailed insights into customer needs.

+ Development of chips allows adjustment to changing needs of current and prospective customers as well as entering different markets (e.g. cosmetics, food industry, etc.)

# Potential future business cases/models

## Stakeholder profiling

At present, the OoC market features a variety of active stakeholders, ranging from

(a) well-established suppliers and microfluidic foundries that have been active in the field of microfluidics/lab-on-a-chip for several years, to

(b) young OoC startup companies that originated from academic labs that have originally developed the OoCs, which provide chips, instrument and services to, e. g., pharmaceutical companies and academic research groups.

In recent years, governmental funding agencies around the world have become increasingly interested in supporting new research approaches to improve drug discovery & development and reduce animal testing by academic research groups and startup companies.

Based on extensive stakeholder consultations and individual discussions, we categorized the importance and influence of each stakeholder for the OoC market (Figure 1).

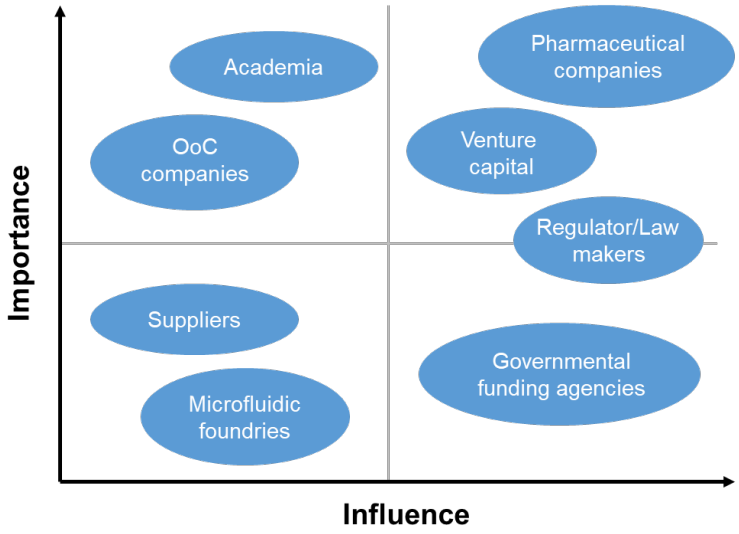


***Figure 1**: Overview of current key stakeholders in the OoC market and their respective importance and influence*

The various stakeholders differ in their specific interests in the OoC field, their impact on the field, and their responsiveness to other stakeholders. Table 2 provides an in-depth profile of the different stakeholders in the market, detailing their interests and their influence that shape the market.

***Table 2**: Stakeholder profile of multiple key players in the OoC market, detailing stakeholders' interests, their influence on the field, and the means by which they may be involved / addressed most effectively by other stakeholders.*

| Stakeholders | Interests | Influence | Involvement |
|---|---|---|---|
| Pharmaceutical (and cosmetics, chemical,…) industry | • Saving drug development time and cost<br>• Reducing late-stage failures in clinical trials | Very strong:<br>• can determine the progress / survival of the entire field and individual OoC companies | • Building strong networks with researchers in R&D departments (via conferences, etc.) to show practical benefits of using OoC systems |

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|---|---|---|---|
| Suppliers (hardware, media, cells) | • Demonstrating profitability in this new emerging market, to sell existing hardware / consumables | Weak:<br>• depend on other stakeholders in the market (OoC companies, Academia, etc.) | • Keep updated / informed about the progress in the field |
| Academia | • Developing novel or advancing current OoC systems (e.g. development of multi-organ systems)<br>• Employ OoC systems for mechanistic studies<br>• Developing new in vitro models to better understand diseases | Weak<br>(as developer)<br>• problematic technology transfer to end-users<br>• Development of novel and improvement of existing systems / concepts provides a viable source of R&D for OoC companies<br>Intermediate<br>(as end-users)<br>• Huge market that ,however, requires cheap and accessible OoC (“open source” platforms | (as developers)<br>• Early interaction and collaboration on need-focused development<br>(as end-users)<br>• early adopter / starter kits at low prices to benchmark OoC systems; publish results in high-ranking journals to spread awareness of the company / brand and product |
| Funding agencies | • Advancing scientific knowledge<br>• Promoting the concept of 3Rs and reduce animals used in testing<br>• Funding OoC startups to create new jobs in the feature | Strong:<br>• provide funding to academia to develop new systems or advance existing systems<br>• initial funding for startup companies | • Continually inform representatives nationally and beyond that (EU, globally) about the potential of OoC technology and new advances |
| Microfluidic foundries | • Becoming the main source for producing OoC at high scales | Weak:<br>• strongly depend on the need from customers and the willingness of OoC companies to outsource their own production capabilities | • Keep informed about production needs and material requirements |

| | | | |
|---|---|---|---|
| OoC companies | • Make profit by selling chips/instrument and/or services to the pharmaceutical industry | Weak<br>• highly dependent on the pharmaceutical companies to adapt the new technology and on funding agencies to provide capital | • Early interaction and collaboration on need-focused development |
| Regulators/Law makers | • Implementing & executing regulations by law makers (respective government)<br>• Reporting back to law makers/public about effectiveness of regulations<br>• Increasing safety of drugs released to the markets<br>• Reducing the use of animals in testing (law makers) | Very strong:<br>• decision makers on how drugs have to be tested to be approved | • Stakeholder which is the least prone to be influenced by other stakeholders<br>• Influenced by public opinion (law makers)<br>• Early involvement and information about the benefits and limitations of the new technology. |
| Venture capital firms (VC) | • Supporting new ways to disrupt the current market producing major, long-term revenues | Very strong,<br>• provide the necessary capital to transfer the technologies and e.g. scale up production. | • OoC companies have to provide both vision and business implementation emphasizing long-term benefits for revenue. |

Yet, not only the individual stakeholders in their entirety play an important role for the success of this new technology. The interactions between the different players within a particular customers company may as well determine whether a new technology is adopted or not. Here, it is helpful to categorize the different players within a business e.g. from the pharmaceutical industry, to identify the ones which influence most effectively the outcome, i.e., whether the product/services is purchased or not.

Individual roles within a customer business can be categorized as follows:

- Initiators: Suggesting the purchase of a product or service

- Deciders: Choosing the product among all available options
- Financiers: Providing funding/budget for the purchase
- Gatekeepers: Controlling the flow of information to and among the other stakeholders in the customer's business
- Influencers: Helping develop specifications that a new technology has to fulfill and evaluate alternative products
- Buyers: Selecting suppliers and negotiate the terms of purchase
- Users: Using the product and evaluating performance

When one applies these categories to the current OoC market, and considers pharmaceutical companies as the main customers, it becomes evident that researcher in the R&D department(s) of pharmaceutical companies have the biggest influence on the adoption and implementation of new technologies (Figure 2).

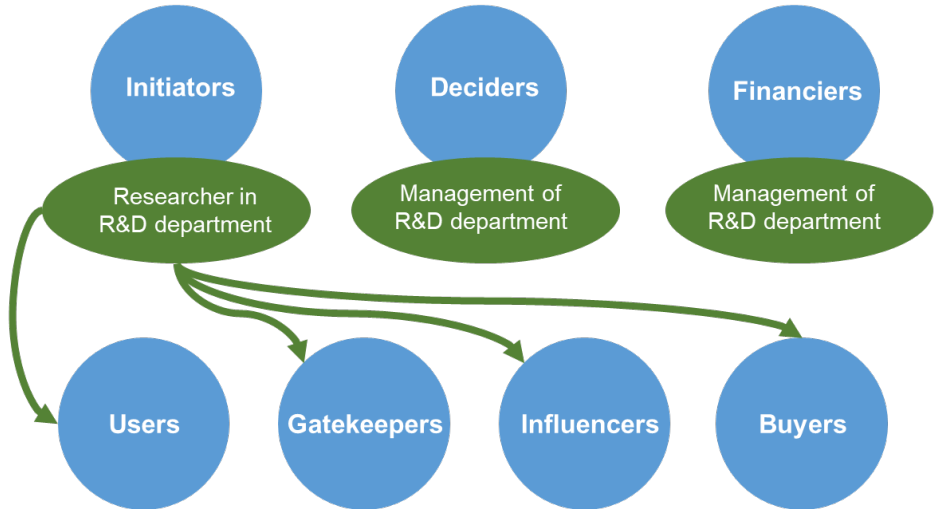


***Figure 2**: Categorization of people/persons within a customer's business. Green arrows indicated if stakeholder within the customers' business owns multiple roles.*

## Current & potential customers segments

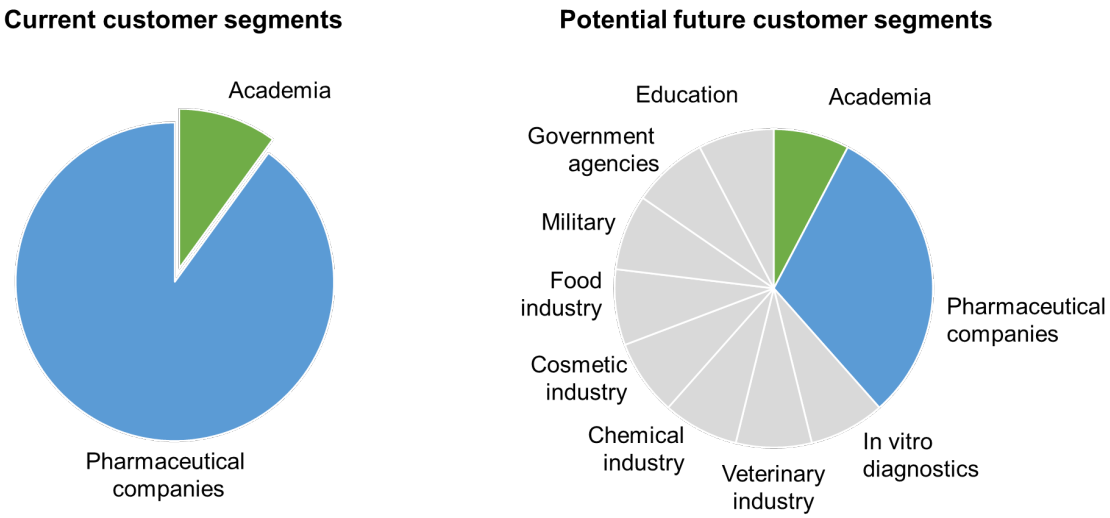


***Figure 3**: Current and potential future customer segments for commercial OoC providers. Graphs are representative estimates and do not represent the actual market share of the individual customers.*

Almost all stakeholders estimated the current clientele of commercial OoC providers to consist mainly of pharmaceutical companies and small sections of academia (Figure 3). However, the potential impact of OoC technology may extend beyond the scope of drug discovery & development, affecting a larger variety of other business sectors. We applied various brainstorming and idea creation techniques to identify novel market segments in which application of OoC technology could lead to disruptive innovations. We identified a number of examples for new potential customer segments in which the implementation of OoC technology is feasible and which might provide additional markets:

*In-vitro diagnostics (IVD)*

- OoC as “humanized” version of current IVDs, e.g., to evaluate the best treatment regime for specific cancers, thus enabling more personalized health care
- OoCs as companion diagnostics

*Food industry*

- Testing foods/food ingredients regarding their allergenic potential.
- Personalized model systems towards personalized food
- Assessing the health of the animal life stock for food production e.g. use of antibiotics.

*Cosmetic industry*

- Testing of cosmetic products/substances without animals due to new laws, e.g., the ban of cosmetic products tested on animals throughout the EU

*Chemical industry*

- Testing of chemicals to assess their hazardous potential (toxicity, irritation, etc.)
- Testing negative effects of the ingestion of residues of chemicals used in food production (e.g. pesticides)

*Veterinary industry*

- Pets are increasingly being "humanized", leading pet owners to increase their spending on pet medications and medical treatments. This market is enormous as the number of pet owners is steadily increasing worldwide (US: 55.3 million dogs, China: 27.4 million dogs)[1]. Race animals (horses, camels) provide very high value and are subject to even more expensive treatments.

Military

- OoC systems for the assessment of threats related to nuclear, biological or chemical weapons, or warfare

Governmental agencies

- Safety assessment of food/food ingredients, environmental compounds (e.g. pseudo-hormones in water, micro plastics), chemicals, and other goods

## Development of future business cases & models for OoC technology

Besides the business models discussed above, there are further potential business models addressing the "traditional" market segments that are not yet employed. Moreover, the identification of novel, additional customer market segments, allows the development of new business cases and models for OoC technology. Here, we want to highlight a number of exemplary, potential business cases/models:

[1] https://www.forbes.com/sites/mariannacerini/2016/03/23/chinas-economy-is-slowing-but-their-pet-economy-is-booming/#3652549e4ef7 (Accessed 29.03.2019)

*Exemplary new business models*

"Selling ready-to-use OoC systems"

Besides providing CRO-like services, current OoC commercial suppliers often offer customers the possibility to directly purchase chips and companion instruments as a kit to establish OoC in vitro models by themselves. In this model, training and consumables like cells and media is the responsibility of the customer.

A further, promising business model might be to provide ready-to-use OoC systems. This approach has been adopted by numerous suppliers, who provide cells from various sources (cell line, primary, biopsies, stem cell derived) to the life sciences sector. Only limited training and skills would be required to operate these ready-to-use OoC systems, in contrast to conventional systems, which still need intensive training in order to generate functional in vitro models. Here, the biggest hurdles to overcome are of a logistic nature. Issues such as – "how to deliver ready-to-use OoC systems to potential customers worldwide, while guaranteeing that the embedded tissues stay viable and functional" – need to be addressed and evaluated for this business model. Close communication and cooperation with international logistics companies, will be essential for the success of such a business. Furthermore, for companies focused mostly on the engineering aspects of OoCs, establishing close collaborations with other companies, providing cells (stem cells, differentiated cells, primary cells, cell lines) might be a viable option to successfully establish ready-to-use OoC.

"Data analysis of OoC systems"

Similar to traditional cell-based assays, OoCs heavily depend on image-based methods, online sensors and offline measurement techniques (e.g. omics) to analyze the state of the cells/tissue over time. With increasing numbers of a) tissues per chip or b) chips per run (number of chips per experimental run), the amount of data generated over time is increasing exponentially. Thus, efficient handling, analysis & visualization of experimental data is of utmost importance to cope with the output from the increasingly complex OoCs, which may include e.g. multiple layers of cells, 3D tissues. In these cases, a potential business model could involve the development of dedicated software

tools, or the provision of services to OoC companies or customers for analyzing image-based data.

*Exemplary business case(s):*

"Veterinary industry"

The veterinary industry provides a similar business target as the pharmaceutical industry, but involves a broader variety of anatomical and physiological targets in multiple domesticated pet species. The major focus of this global industry is on dogs and cats, besides birds, rodents, horses, etc.

Using idea-generation techniques, we identified the following leading generic questions:

- How could one provide/sell OoC to veterinarians to test the health of pets?
- How could one develop OoC to identify new treatments/drugs for pets?
- How could one develop OoC to help pet owners/breeders to test/ensure the health of their pets at home/while traveling?

These questions focus on either providing OoC as novel diagnostic tools for veterinarians/pet owners, or as alternative testing models for new animal drugs/vaccines. For diagnostic-tool development, it is important to evaluate the bottleneck of existing methods, which are mostly blood-based. In contrast to applications in humans, sample retrieval from smaller animals/pets is an especially challenging aspect when developing specific applications of OoC for animal/pet health. However, starting from existing human OoC models, animal-based OoC systems can be developed rapidly. These systems could then provide a minimum viable product to first customers in order to further develop them for a broader segment of the veterinary industry. This business case could provide low-hanging fruit for current OoC companies creating a further source of revenue additional to the pharmaceutical industry.