Life Sciences

# The Promise of Non-animal 'New Alternative Methods' (NAMs) in the Outsourced Pharma Industry

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# Contents

# Foreword

Following the FDA Modernization Act 2.0, a new market opportunity has emerged for non-animal 'New Alternative Methods' (NAMs).

NAMs have been developed for decades in research labs and are today being introduced to the outsourced pharma industry to 'Reduce, Refine and Replace' (3R) animal models. These NAMs comprise many biotechnologies, ranging from 3D cell-based models such as organoids to organ-on-chip or even alternative *in vivo* models. The diversity of NAMs will continue to expand as new models emerge to better emulate biological system's complexity.

According to the Organoids Society, the organoid market alone is poised to grow by 21.7% over the next three years and is estimated to reach $3.3bn in 2027. Following the same trend, the number of CRO-type providers offering NAMs boomed over the past 10 years and increased by 31.9%. There is a strong market attractiveness for NAMs as large pharmacos are now adopting and investing in these non-animal methods. Because of the complexity of biological systems, the provider landscape is highly fragmented and mainly composed of specialised players with unique technologies.

Today, the market for NAMs represents a significant investment opportunity. Collaboration between the different stakeholders will strengthen market growth going forward.

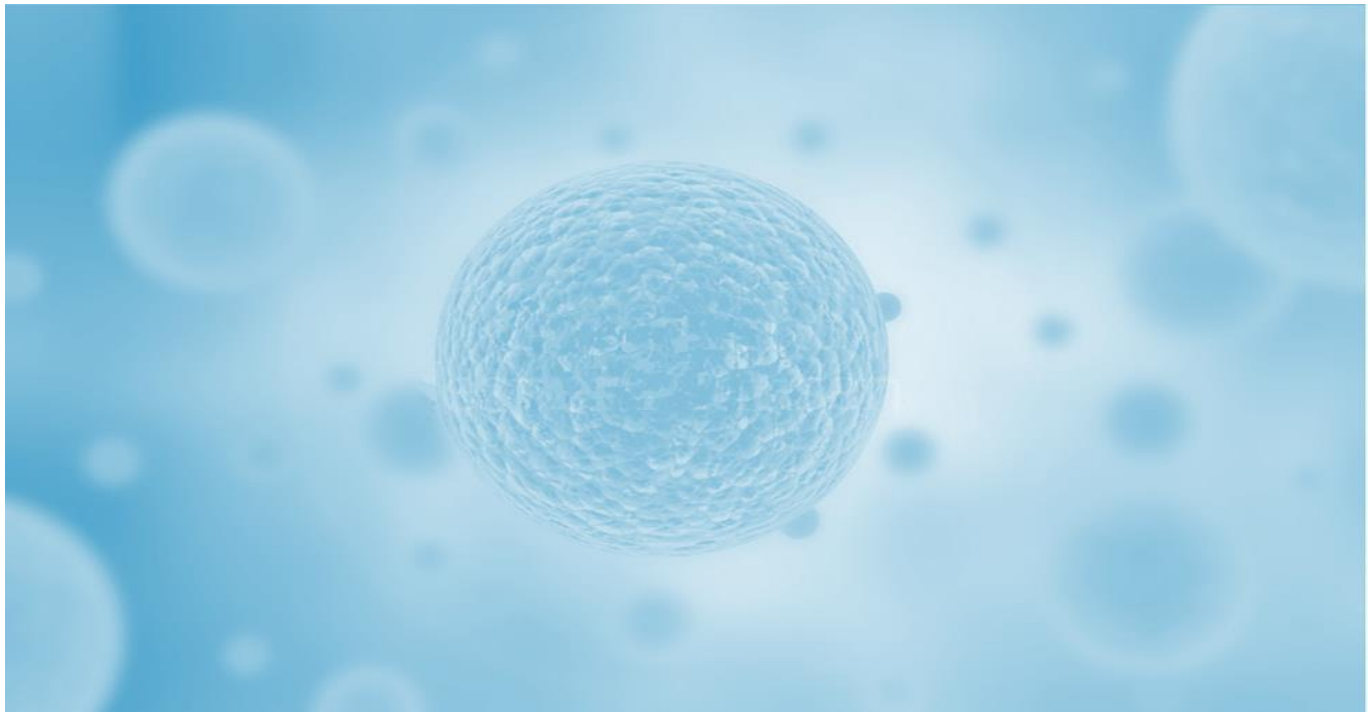
**CHARLOTTE COLLE**
**ENGAGEMENT MANAGER**
STRATEGY
LIFE SCIENCES
M&A ADVISORY

+44 (0) 7443 241 404

charlotte.colle@bdo.co.uk

Charlotte has over five years of experience in life science mid-cap assets working on strategy and commercial due diligence for the BDO London corporate finance team and Candesic. She has specific experience in the following sectors: stem cell therapies, molecular therapies, molecular and cell research consumables, molecular analysis tools and software, CGT analytical services, biobanks, fertility clinics and treatments.

Charlotte started her career as a developmental biologist. She completed her PhD under the Wellcome Trust after working at Harvard Medical School. She specialises in molecular, cellular, stem cell, development and regenerative biology. She holds a record of top-tier scientific publications.



*Source: The Organoid Society, Pharmacircle*

# Background

## FDA Modernization Act 2.0

Over the past few decades, 3D *in vitro* models have emerged in research settings to significantly enhance the study of human biology. As NAMs become commercialised in drug discovery and pre-clinical studies to better predict clinical outcomes, this represents a shift for the pharmaceutical industry. Indeed, current animal models are not suitable for the design of drugs:

- **9/10 drug candidates are eliminated because of their lack of efficacy and safety before even entering clinical trials**
- **only 5% of drug candidates have the desired effect on patients**

Regulatory, macroeconomic, and ethical factors are all supporting the adoption of NAMs. A landmark bill, **FDA Modernization Act 2.0 (2022 – S. 5002)** was signed into law to remove the requirement for animal studies to obtain a license for a biological product. In addition, the COVID-19 pandemic led to shortages in the animal supply chain, especially in primates, and more scrutiny was pointed toward the handling of animals in laboratories

This imminent shift away from animal models is supported globally. Over the past two decades, **the European Commission invested €700m in NAM projects** and a new bill was recently submitted to **banish the use of animals when a replacement model was available by 2028.**

Today, drug manufacturers are eager to start using NAMs set to **"Reduce, Refine and Replace"** animal testing (3R) and optimise the development of drugs that will be more impactful for patients. These 3R guidelines are aimed to optimise the information gained about an investigational drug by reducing the number of animals used in experimentation and refining procedures to minimise potential animal discomfort.

" From both amoral and practical perspective, passage of the act addressed entrenched aspects of the regulatory process at the FDA. The costs in time, funding, and life are incongruous to outcomes related to the ultimate goal of protecting humans"

***- Co-chair, Michelson Philanthropies and the Michelson Center for Public Policy***

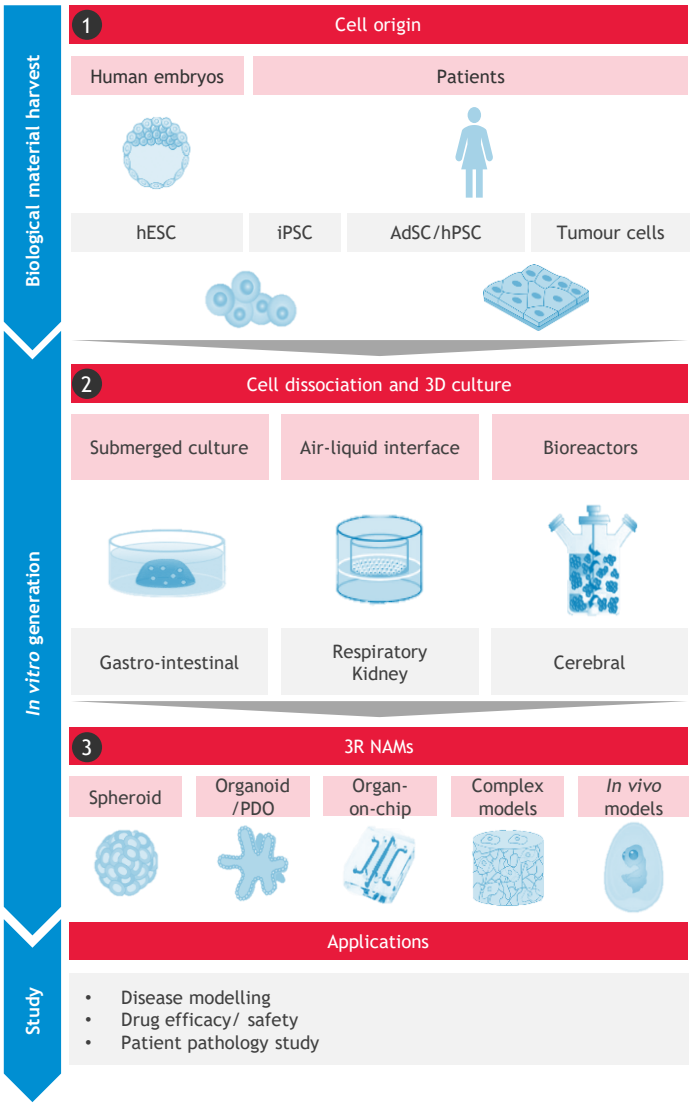
*" Evidence suggests that the secondary effects of many therapies in humans cannot be accurately predicted in animal models. Non-animal alternative methods either under development or currently available allow a more physiologically relevant approach to evaluating drug-specific outcomes"*

***- Professor, Johns Hopkins Bloomberg School of Public Health***

*Source: Science, News articles, BDO research and analysis*

# Engineering alternative methods

## Engineering NAMs



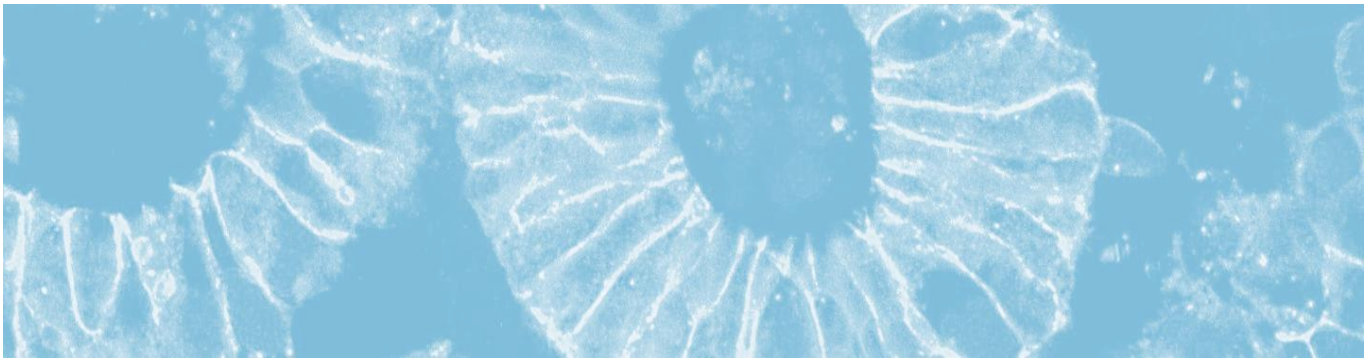

## Cellular-origin of cell-based models

1 3D cell models such as spheroid or organoids originate from various cell sources:

- **Human embryonic stem cells (hESC):** hESC are collected from donated human embryos and can differentiate into any human cell type, forming complex 3D models. However, their use is limited due to ethical concerns and the availability of donations
- **Induced progenitor cells (iPSC):** In 2012, Nobel laureate Shinya Yamanaka discovered iPSC, by reprogramming any adult cells into stem cells using only four transcription factors. These cells can differentiate into any cell type and are used to generate 3D cell models
- **Adult stem cells (AdSC) or human pluripotent stem cells (hPSC):** AdSC or hPSC are pluripotent cells that can differentiate into certain types of adult cells. These cells are found in stem cell niches in adult organs and can be extracted to create 3D cell models
- **Tumour cells:** Mutated tumour cells rapidly reproduce. *In vitro* 3D cell models can be created from patient biopsies, forming a biobank with various patient-specific mutations.

Cell samples are mainly collected from patient's healthy organs (AdSC, hPSC) or tumours. Today, pharmacos would like to test drug candidates using NAMs offering certain patient mutation profiles. Biotechnologies offering NAM as services should therefore strengthen their collaboration with hospitals to access a wide diversity of patient samples.

**While some players are eager to invest huge CAPEX into the creation of biobanks, others have strengthened collaboration with hospitals to minimise costs and access a large pool of patients on demand.**



*Source: BDO research and analysis*

# Different alternative methods

## Engineering cell-based alternative methods

2 3D cell-based models are derived from various cell sources, namely, iPSC, AdSC, hPSC, or tumour cells, and can be cultured in multiple settings (see previous slide) such as:

- Submerged culture where 3D cell systems are cultured in 3D gels within a liquid media. Submerged cultures are well-suited for certain types of 3D cell-based models such as gastrointestinal
- Air-liquid interface culture systems where 3D cell systems are kept at the interface between the air and the culture media. Air-liquid interface culture systems are well suited for certain types of 3D cell-based models such as kidney or respiratory
- Bioreactors, where 3D cell-based models can float and expand in fluid columns. This system is particularly relevant for scale-up methods and is well-suited for certain types of 3D cell-based models such as cerebral.

## Characterisation of NAMs

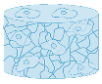
3 Several alternative models have emerged over the past decade with various levels of complexity. They can be split into different categories: 3D cell-based models such as spheroids and organoids and other more complex models such as organ-on-chip (OOC), various complex models and *in vivo* models.

Complex models such as OOC or co-cultures gather 3D cell-based models allowing an environment where different cell populations (2D or 3D) can communicate. *In vivo,* models allow the study of cell-based models in a complete system.

**NAMs are now well-characterised and better predictive than animal models.** In 2019, Emulate, a spin-out from the Wyss Institute at Harvard, developed liver chips that were able to predict human toxicity with an 87% accuracy rate. These chips detected toxicity that was not identified in animal models. The breakthrough prevented a $3 million loss in clinical development after 11 molecules tested on animals proved to be toxic. These results show that NAMs have the potential to identify drug candidates that have a higher potential for success in clinical trials. Although NAMs are very promising, they do have limitations *(discussed below):*

Complexity: Low → High

NAMs

| | 3D cell-based models | | Other models | | |
|---|---|---|---|---|---|
| | Spheroids | Organoids | Organ-on-chip | Complex models | *In vivo* models |
| |  |  |  |  |  |
| Description | Spheroids are simple and inexpensive 3D cell systems that resemble cell aggregate. They represent a simple in vitro tumour model | Organoids are 'mini-organs' in a dish. They are more complex structures and exhibit polarity, different tissue layers, and self-organisation. They are increasing in popularity because they recapitulate the biology of organs in a dish | Organ-on-chips (OOC) are multi-channel microfluidic cell cultures that allow the study of physiological and mechanical responses between these different 2D or 3D cell-based models. They provide the functionality of certain organs in a dish | Other complex models aim to recapitulate a more systemic model in a dish by putting different 2D or 3D cell-based models into contact. This can be done in a 3D extra-cellular matrix, droplets, or encapsulation to allow communication between cells from different organ's origin | Very few *in vivo* models can recapitulate human development under 3R conditions and be considered as non-animal. This is the case of the avian model which is very effective at doing so and provides the best *in vivo* models for testing *in vivo* parameters of cell-based models such as organoids or any other cell lines |
| Limitations | ▶ Size variability<br>▶ Reproducibility<br>▶ Lack of polarity<br>▶ Necrotic long-term cultures<br>▶ No tissue-like structure<br>▶ Lack of vascularisation<br>▶ Lack of systemic approach<br>▶ Animal implantation for in vivo studies<br>▶ Lack of *in vivo* validation | ▶ Size variability<br>▶ Reproducibility<br>▶ Difficult access to internal structures<br>▶ Limited long-term cultures<br>▶ Lack of vascularisation<br>▶ Lack of systemic approach<br>▶ Lack of *in vivo* validation | ▶ Simplistic systemic approach<br>▶ Short time scale study<br>▶ Limited cell-based model complexity<br>▶ Limited long-term cultures<br>▶ Poor vascularisation<br>▶ Lack of *in vivo* validation | ▶ Complex approach to cell culture model<br>▶ Incomplete systemic model<br>▶ Medium term study<br>▶ Limited long-term cultures<br>▶ Lack of vascularisation<br>▶ Lack of *in vivo* validation | ▶ Require PDX engraftment<br>▶ Manipulation and reliability of engraftment |

*"Alternative models have the potential to enhance and accelerate our ability to translate science into innovative medicines for patients. Our collaborative work on the development and characterisation of the Liver-Chip represents valuable progress to enable us to more broadly apply this model as we aim to improve our ability to better predict adverse drug reactions before drug candidates enter clinical trials."*

***- Senior VP, Clinical Pharmacology and Safety Sciences, AstraZeneca***

*Source: Science Translational Medicine, Sigal lab, Charite/MDC (image), BDO research and analysis*

# Comparison of Alternative methods

## Comparison of different NAMs*

| | | | Low → Complexity → High | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 3R | | | | | |
| | Mice | 2D Cell Culture | Spheroids | PDX/mice | Human organoid models | Organ-on-chip | Complex systems | PDX/ *In vivo* avian model |
| Ease of establishing system | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 |
| Ease of maintenance | 2 | 5 | 3 | 2 | 3 | 2 | 2 | 3 |
| Recapitulation of developmental biology | 5 | 1 | 2 | 1 | 3 | 1 | 1 | 5 |
| Duration of experiments | 3 | 5 | 5 | 5 | 5 | 3 | 3 | 5 |
| Genetic manipulation | 2 | 5 | 5 | 1 | 5 | 3 | 3 | 2 |
| Genome-wide screening | 1 | 5 | 4 | 1 | 4 | 4 | 4 | 4 |
| Physiological complexity | 5 | 1 | 2 | 5 | 2 | 4 | 5 | 5 |
| Relative cost | 1 | 5 | 3 | 2 | 3 | 2 | 2 | 5 |
| Recapitulation of human physiology | 2 | 2 | 2 | 4 | 4 | 4 | 4 | 3 |
| Overall score | 23 | 31 | 29 | 23 | 32 | 25 | 26 | 35 |

## Moving towards non-animal models

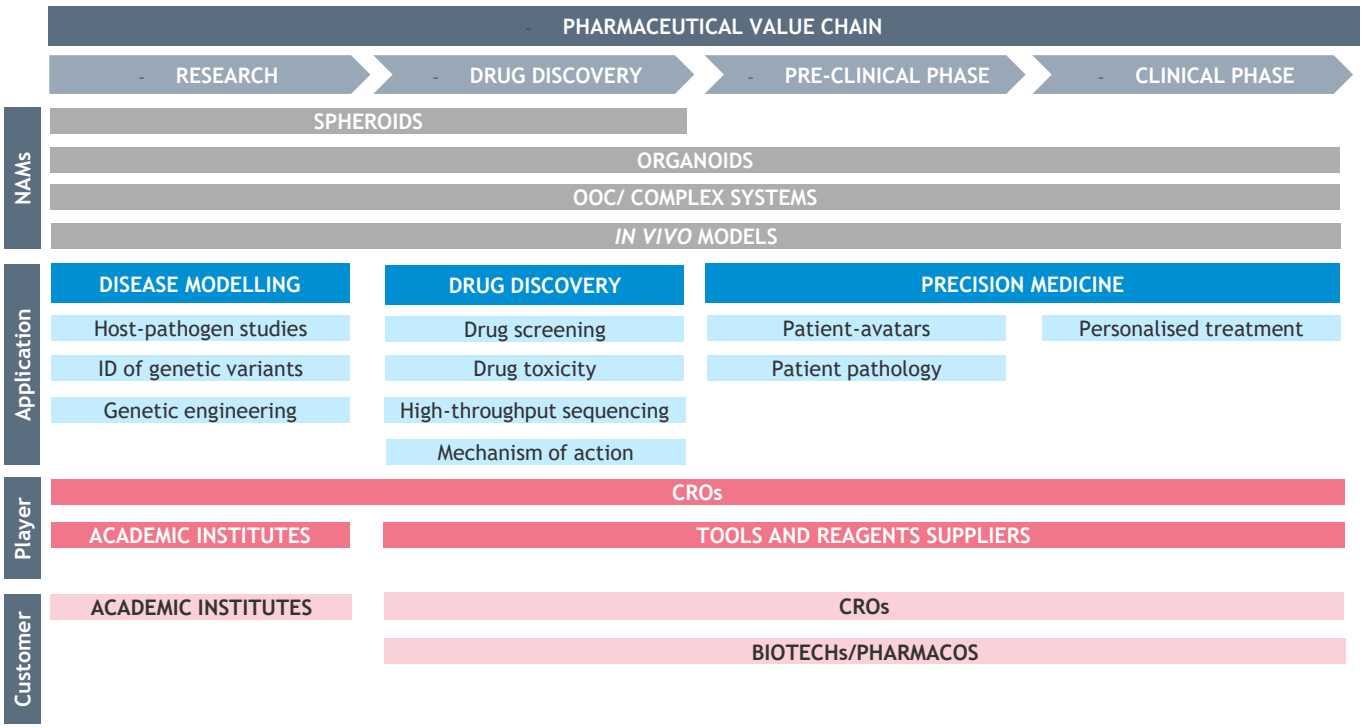
Using alternative methods provides significant advantages over other animal models such as mice:

- 2D cell cultures are easy to maintain, offer faster experimental timelines, can easily be manipulated genetically, and are much cheaper than animal models. 2D cell cultures, however, cannot provide the physiology of an *in vivo* model
- Patient-derived xenografts (PDX) are patient biopsies grafted into animal models such as mice. This hybrid model allows the study of human pathology and offers the physiological complexity of an *in vivo* model
- Human organoid models are easier to establish and maintain than animal models which may require years for the development of lines carrying specific mutations. They may be modified genetically for the study of a particular disease model. They are cheap and have fast experimental timelines but are incomplete models for the study of human biology
- Organ-on-chip and other complex models mimic the function of single organs in a dish. They offer fast experimental timelines. However, they may be relatively complex to assemble which elevates their cost
- Finally, alternative *in vivo* models such as avian that are not considered animal experimentation offer a complete alternative to animal models. These models can be used for PDX and other organoid engraftments and provide excellent ease of maintenance and fast experimental timeline at a cheap cost

** Scores are given from 1-5 against key criteria (1 being the lowest and 5 being the highest)*
*Source: Nature review, Genengnews (image), BDO research and analysis*

# Applications

## NAMs in the pharma value chain




## Used cases for alternative models

The various new alternative methods may be used in different settings along the pharmaceutical value chain.

In the research phase, NAMs can be used in disease modelling for the study of pathogens in host-pathogen studies, for the identification of specific genetic variants, or for the genetic engineering of organoids to represent subtypes of illnesses. In the research phase, organoids are developed by academic institutes and CROs.

In drug discovery, NAMs are used for efficacy studies of compounds in drug screening and to test drug toxicity. Several readouts can be performed to analyse the expression of biomarkers in these NAMs after drug treatment. High-throughput sequencing and other OMICS can be applied to NAMs to analyse their response to a drug at the molecular level. Most CROs offering NAMs provide these studies at a fee-for-service.

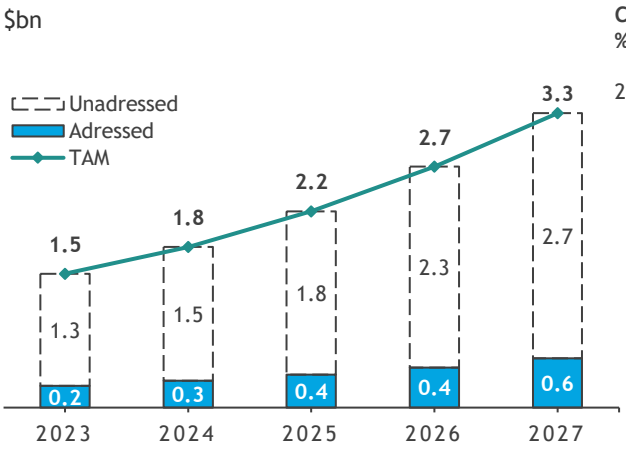
At pre-clinical and clinical stages, NAMs can be used for personalised medicine or patient stratification to select drugs that could be more impactful for individual patients. NAMs may also be used to select patient groups with more successful predictive clinical outcomes in “basket trials”. Patient avatars help connect cell types in organoids to their tissue counterparts with high throughput single-cell molecular studies to refine the selection of drugs for individual patients.

**Source: Interviews, EPFL (image), BDO research and analysis*

# Market insights

## MARKET SIZE

### Organoids addressable and addressed market

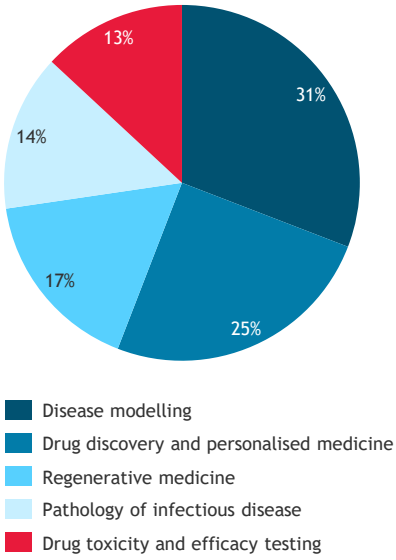



- The total addressable market size for organoids alone has been estimated at $1.5bn by the Organoids Society.
- This market estimation includes organoid cell-based models, along with tools and reagents that enable the development of these models.
- Double-digit growth is expected at a 21.8% CAGR over the next four years with the organoid market expected to reach $3.3bn by 2027.
- Most of this market remains unaddressed which gives room for current players to grow.

## MARKET SPLIT

### Market split by application type

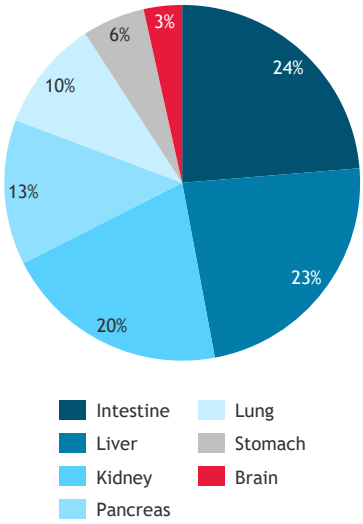
$bn, 2023




- The total addressable market for organoids can be segmented by application type. The vast proportion of the market is attributed to disease modelling (31%) and drug discovery and personalised medicine (25%). Other notable market segments include drug toxicity and efficacy (17%), regenerative medicine (14%), and infectious disease pathology (13%).

### Market split by organ type

$bn, 2023



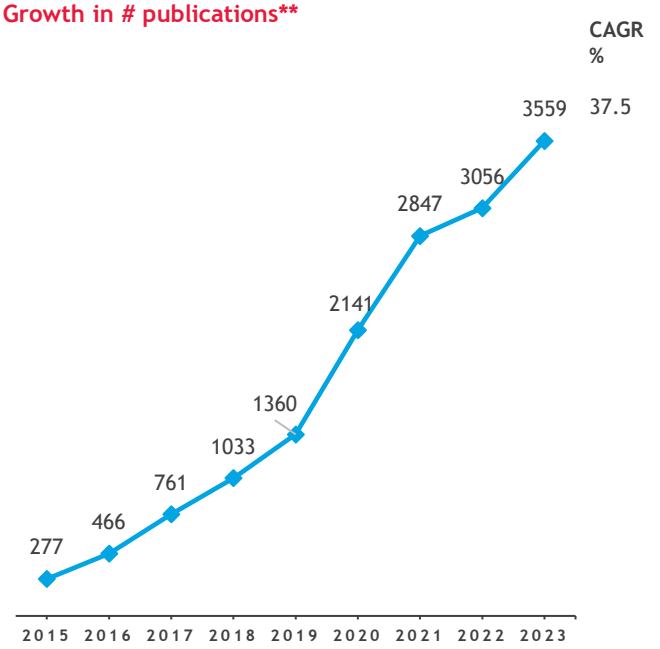

- The total addressable market can also be segmented by organ types. Most of the market concerns the gastrointestinal tract. Namely, the intestine, the liver, the pancreas, and the stomach. In 2023, intestinal organoids accounted for 24% of the market, liver organoids 23%, pancreas organoids 13% and stomach organoids 6%.
- The market also includes other organoids such as kidney (20%), lung (10%), or even brain (3%).

*Source: CRO/CDMO, The organoids society, BDO research and analysis*

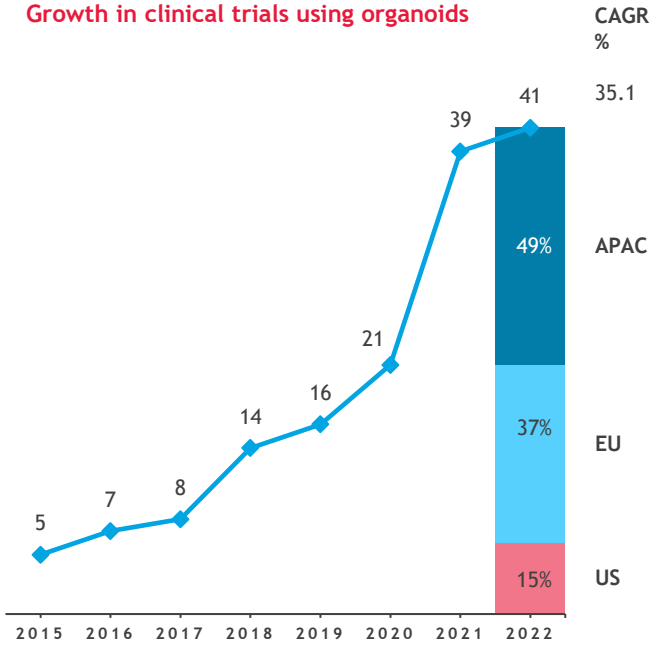
# Market attractiveness

## GROWTH IN RESEARCH PUBLICATION AND CLINICAL TRIALS

### Growth in # publications**



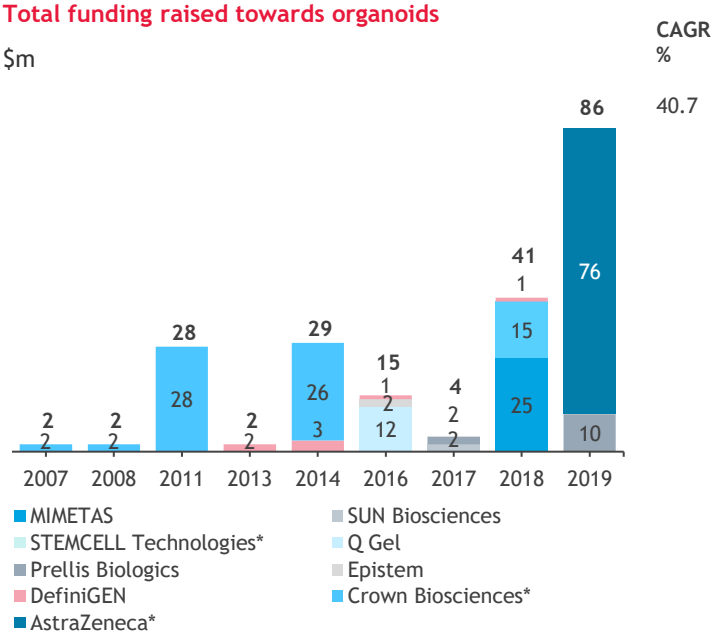

### Growth in clinical trials using organoids




Interest in organoids is peaking as can be demonstrated by the increase of publications and clinical trials. The number of publications related to organoids has grown by 37.5% over the past 8 years and reached a volume of 3559 publications in 2023. Similarly, clinical trials that have started using organoids for their study have grown by 35.1% over the past 7 years, with 41 new clinical trials started in 2023. These clinical trials were 49% based in APAC and 37% in the EU with a minority of clinical trials in the US.

## CAPITAL RAISED

### Total funding raised towards organoids




The capital raised by new businesses building their 3D cell-based models increased by 40.7% between 2007 and 2019.

Capital raised in 2019 reached $86m, double the capital that was raised in 2018.

Several players such as STEMCELL Technologies, AstraZeneca or Crown Bioscience have indicated using their funds towards several research projects related to organoids. The use of funds for organoid projects reached up to $76m in the case of AstraZeneca.

Other organoid players have also significantly raised funds. MIMETAS raised a total amount of $25m and Crown Bioscience raised a total amount of $55m.

Although most of these investments are still venture capital-backed, they clearly show a market appetite for NAMs.

***: entry for 'organoid' publications*

*Asterisk(*) indicates companies with multiple research interests that plan on using their 2019 funds raised for organoid research*

*Source: PubMed, Clinicaltrials.gov, CellPress review, BDO research and analysis*

# Market dynamics

## MARKET DRIVERS

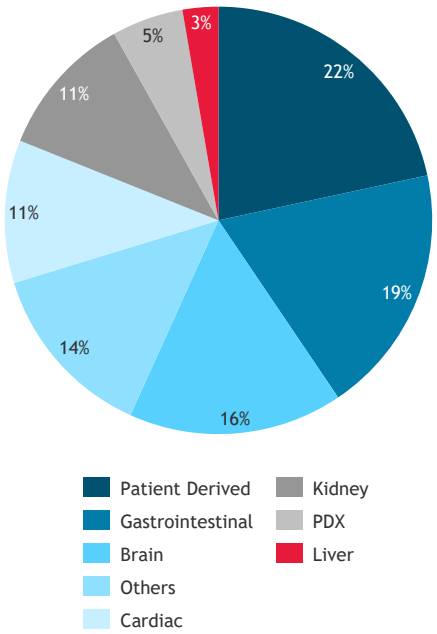
| | DRIVER | IMPACT |
|---|---|---|
| 1 | Shift away from animal models | ↗ |
| 2 | Chronic diseases | ↗ |
| 3 | Complex drugs | ↗ |
| 4 | Demand from biopharma | ↗ |
| 5 | Advances in technology | ↗ |
| 6 | Potential for personalized medicine | ↗ |

There are many positive market drivers for the use of NAMs including:

1. Shift away from animal models that is strongly supported by regulatory changes such as the FDA Modernization Act 2.0
2. The rise in chronic diseases such as cancer, autoimmune disorders, or even diabetes necessitates better disease models
3. Increasing complexity of drugs needing better predictive models
4. Demand from big pharma and biotech that have been incentivised to use NAMs increasing following the FDA Modernization Act 2.0
5. Advances in technology that have allowed the development of robust and reliable NAMs. NAMs are now well-characterised and can very well predict human biology and enhance the success of clinical trials
6. Potential for personalised medicine as NAMs are very good models for the study of individual patient mutations and can deliver results with short turnaround time.

## COMMERCIALISATION OF ORGANOIDS

**Commercialisation of organoids by type**




The largest segment of commercialised organoids are patient-derived (22%) These organoids can represent either diseased models extracted from tumour samples or can also be healthy models extracted from adult stem cell niches of different organs. Patient-derived organoids from tumours are powerful models as they allow the stratification of patient groups based on their mutation profile.

Following the increase in chronic diseases, gastrointestinal, brain, cardiac, and kidney organoids represent the second largest segment. Gastrointestinal models represent 22% of commercialised organoids with the liver, and the brain representing 16% of commercialised organoids and cardiac and kidney representing 11% of commercialised organoids, respectively.

Other patient samples grafted onto animal models called patient-derived xenografts represent only a small proportion of the market with 5% of commercialised organoids. These models have limitations when grafted in mice such as poor engraftment and require specific immuno-suppressed lines.

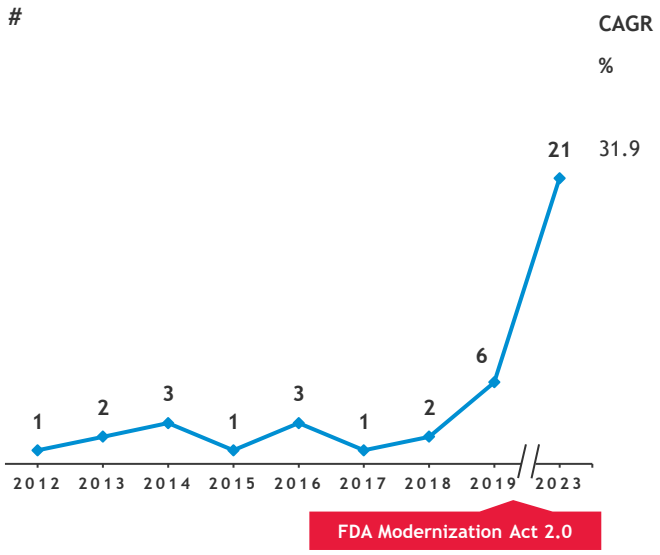
Other organs represent 13% of commercialised organoids and could be more specialised organs such as the retina or even feminine reproductive organs.

*Source: Interviews, BDO research and analysis*

# Providers landscape

## INCREASE IN NAM PROVIDERS

### Growth in organoid CROs



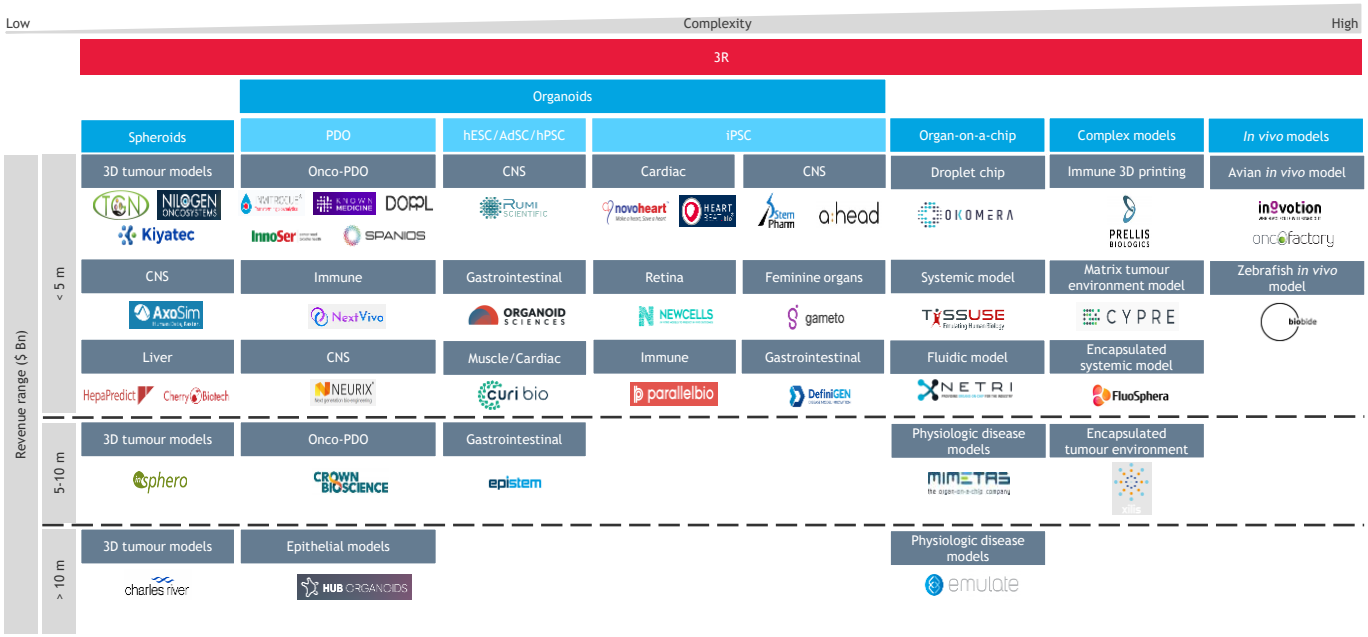

Since 2019 and following the FDA Modernization Act 2.0, the number of organoid providers with CRO-type offerings has increased by 31.9%.

A large number of commercialised service providers have spanned out from academia. Organoid models are now easily established *in vitro* and are well-characterised to provide reliable studies.

The provider landscape (below) is highly fragmented. Providers can be segmented by categories based on the cellular origin of their technologies (patient-derived organoids, hESC/AdSC, or iPSC) and the organs that they aim to reproduce *in vitro (see provider landscape below)*.

To date, most providers have revenues under £5m but are expected to grow revenue in the next 5 years following anticipated market growth. A few providers, notably organ-on-chip Emulate or Crown bioscience or epithelial model's provider HUB organoid gather revenue above $5m. These players were some of the first to provide alternative technologies.

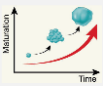
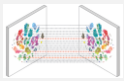
## NAM PROVIDER LANDSCAPE




*Source: Pharmacircle, Interviews, BDO research and analysis*

# Outlook

## CURRENT LIMITATIONS

| Limitations of current cell-based models | | Complementary solutions | Feasibility |
|---|---|---|---|
| Acceleration and reproducibility |  | ▶ Model-OMICS data<br>▶ Context of use assay data | ++ |
| Physiology of complex organs |  | ▶ Organ-on-Chip<br>▶ Complex models<br>▶ *In vivo* models | + |
| Multi-organ systemic approach |  | ▶ Complex models<br>▶ *In vivo* models | + |
| Tissue engineering of complex organs |  | ▶ Organ-on-Chip<br>▶ *In vivo* models | - |
| Vascularisation |  | ▶ *In vivo* models<br>▶ Some OOC but restricted | - |
| AI and data generation |  | ▶ Model-OMICS data<br>▶ Context of use assay data | - - |

Although cell-based models represent a significant market opportunity, several challenges must be overcome to enhance these models *in vitro*:

- **Acceleration and reproducibility:** organoids are very varied in size and shape. Optimisation of current will allow the engineering of cell-based models in a reproducible manner, which is necessary for scale-up
- **Physiology of complex organs:** organoids aren't complex enough to date to recapitulate the physiology of complex organs such as kidneys or heart. Organ-on-chip providers answer certain physiological limitations by providing plates that recreate a fluid-like system to mimic organ function. Other alternative *in vivo* models are also perfect for studying the indirect impact of certain drugs on complex organs
- **Systemic approach:** organoids are organ-specific and therefore cannot mimic the communication between several organs, limiting the impact of toxicology and safety studies. Several players, such as organ-on-chip or alternative *in vivo* models provide a systemic approach by providing support systems where cell-based organoids can communicate with cell-based models from different organ origin
- **Vascularisation:** the study of certain diseases requires the vascularisation of cell-based models, especially in large indications, such as oncology or any immune-related disorder. Alternative *in vivo* models are particularly relevant for vascularising cell-based models, as they have a much longer survival when vascularised
- **AI and data generation:** the study of NAMs generates an increasingly vast amount of data such as OMICS generated from each study. Consolidation and manipulation of this data through model-OMICS or context-of-use assay would greatly help the acceleration of drugs in the discovery and pre-clinical stages should this data be made more transparent between provider and users

## WHAT NEXT?

Following the FDA Modernization Act 2.0, the interest in NAMs has largely picked up, and large pharmacos have now started to move towards using more of these methods. **The market opportunity for NAMs overall is significant** and is poised to grow **even more as biotechs and pharmacos keep adopting these new methods** and as **NAMs keep being rewarded and recognised by regulatory bodies.**

The market has seen a boom in specialised players who own strong know-how. However, **collaboration between these players will allow them to overcome challenges and fully replace animal models**. New technologies surrounding NAM will keep emerging and models will become even more predictive.

*Sources: BDO interviews, Regmednet (image), BDO research and analysis*

# Case studies

## ASTRAZENECA KIDNEY CASE STUDY

AstraZeneca's increased investment in the organoids market highlights the benefits of organoids across therapeutic areas

**ASTRAZENECA ADDS DIMENSION TO KIDNEY DISEASE RESEARCH**

- Growing and using various kidney cell cultures provides great insight into the human biology of the kidney, however, 2D cell culture does not recapitulate the full biology of a functional kidney in a dish
- AstraZeneca has raised $80m in 2019 with a keen focus for some of this funding to go towards combatting Chronic Kidney Disease (CKD)
- Kidney organoids are great models for the study of CDK and can be genetically modified with CRISPR/Cas9 for the study of specific mutations
- AstraZeneca goes all the way to considering the use of kidney organ-on-chip to fully mimic the biology of kidney *in vitro* including elements of physiology and mechanical stress

*"We have been investigating cells in isolation in a dish for four years. With organoid technology, we can go even further and add conditions such as flow and shear stress, mimicking the conditions in the kidney even further. The ultimate aim will be to try to induce disease conditions and then treat them"*

***- Bioscience CKD Director, AstraZeneca***

*"The complexity of the kidney means it has been virtually impossible to create sophisticated models that duplicate the behaviour of the human kidney… Kidney organoids are miniature models derived from stem cells that closely mimic how the cells behave in the body"*

***- Senior Scientist, Bioscience renal, AstraZeneca***

## ROCHE ACCELERATES HUMAN RESEARCH

Roche opened the Institute of Human Biology for the development of research and clinical practice which will allow the use of organoids as an alternative method

**ROCHE OPENS INSTITUTE OF HUMAN BIOLOGY**

- Roche opened its own Institute of Human Biology (IHB) which will accommodate up to 250 scientists and bioengineers from academia and the pharmaceutical sector in 2023
- Research from the IHB will speed up the adoption of human model systems in pharmaceutical R&D in addition to clinical practice
- Roche has been keenly involved in exploring the use of organoids and 'organ-on-chip'
- The knowledge gained will boost Roche's drug discovery and development projects and therefore enable drugs to reach patients faster. Roche aims to share its knowledge to the wider scientific community and regulatory services

*"It is probably going to be the biggest thing of its kind in the way it will predict what will happen next in the clinic."*

***-Former CEO*, Roche**

*"Organoids hold the promise to advance translational research and personalised medicine for the benefit of patients. I am convinced that one can implement organoids at every step of the way - from target identification and validation through preclinical safety and efficacy to stratification in clinical trials. They can be used as tools to predict an individual patient's response in personalised medicine"*

**-Head of Pharma Research and Early Development, Roche**

## CHARLES RIVER REDUCES ANIMAL MODELS

Charles River Laboratories launches alternative methods advancement project to reduce its reliance on animal testing

**The 'Alternative Methods Advancement Project' (AMAP)**

- April 2024,Charles River, the largest animal supplier, announced a total an investment of $500m for the launch of its AMAP
- This initiative will be dedicated to develop NAMs and reduce the use of animal models and based on three pillars:
  - Products and services: offer more products and services that do not rely on animals
  - Strategic Investment & Partnerships: understanding that advancement requires collaboration. AMAP strategy will rely on partnering with companies to co-develop solutions and continue to identify externally-developed technologies to enhance client offerings
  - Advocacy: acknowledge that true transformation will require acceptance of new standards by opening conversations with thought leaders, policy makers, and NGOs

*"Advances in science and technology have brought our industry to an inflection point. Alternatives are the path to the next frontier of drug development, allowing us to responsibly drive progress for the patients and animals that depend on our work. With our long history in embracing innovation in biopharmaceutical research, Charles River is well-positioned in setting this new standard for drug development"*

***-President and Chief Executive Officer*, Charles River**

*"The adoption of alternatives is a strategic imperative for the industry that requires scientific rigor to prove its possibility and expansive collaboration to drive change. AMAP is Charles River's rallying cry that we must unite in the effort to not only build these innovations but also inspire confidence and transform the systems to ensure they can be effectively implemented"*

***-President and Chief Executive Officer*, Charles River**

*Sources: Companies' website, Genennews (image), Businesswire, BDO research and analysis*

# Abbreviations

| | |
|---|---|
| 2D | Two-dimensional |
| 3D | Three-dimensional |
| AdSC | Adult Stem Cell |
| CAGR | Annual Compound Growth Rate |
| CRO | Contract Research Organisation |
| hESC | human Embryonic Stem Cell |
| hPSC | human Pluripotent Stem Cell |
| iPSC | induced Pluripotent Stem Cell |
| NAM | New Alternative Methods |
| OOC | Organ-On-Chip |
| PDO | Patient Derived Organoid |
| PDX | Patient Derived Xenograft |
| TAM | Total Addressable Market |

FOR MORE INFORMATION:

CHARLOTTE COLLE

+44 (0) 7443 241 404

charlotte.colle@bdo.co.uk



**www.bdo.co.uk**