EightAdvisory



From Animals to Humans:

How innovation is reshaping biotech R&D

November 2026

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Executive Summary

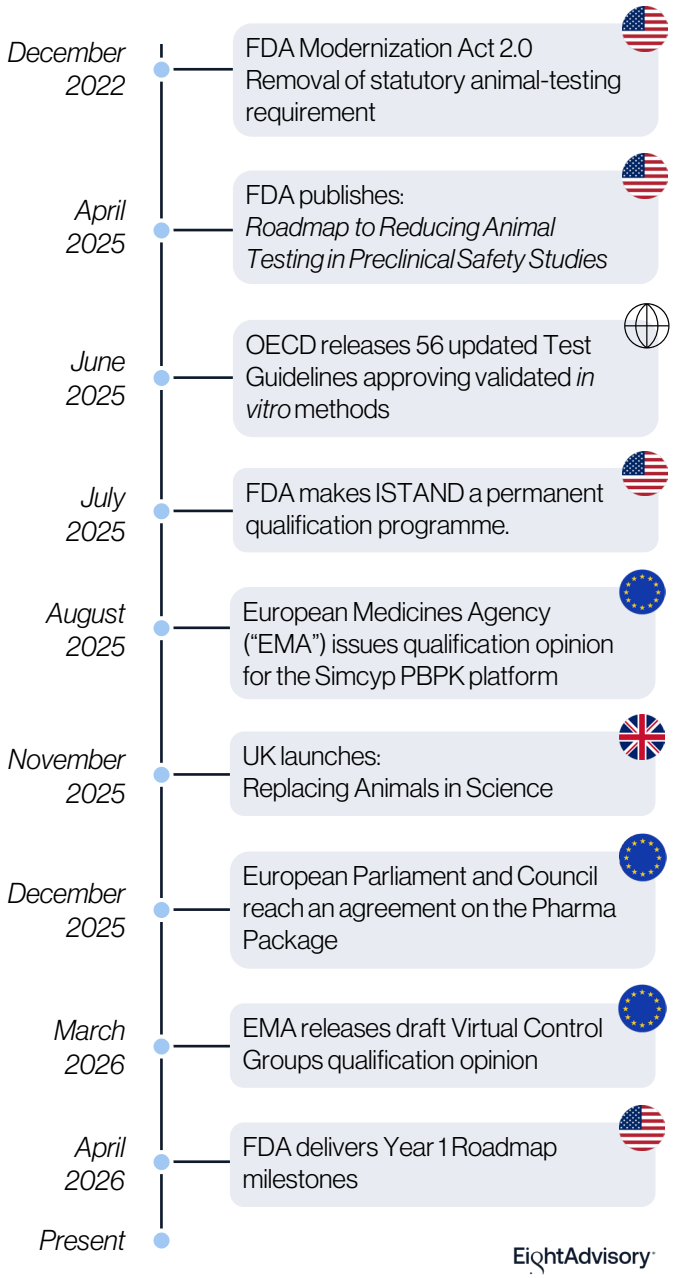
Biotech R&D is moving beyond animal testing

Drug development is shifting from animal-based testing towards human-relevant, technology-enabled methodologies. What began as an ethical debate is now also a strategic one, as the poor predictive power, slow pace, and high cost of animal testing weigh on R&D. Under the traditional, animal-based model, **~90% of drug candidates fail during clinical development**[1], with an overall likelihood of approval from Phase I of just 7.9%[2]. These high attrition rates contribute to **R&D cycles of 10–15 years** and capitalised **costs reaching $3.3 billion per approved drug**[3] (2022 real terms).

Recent advances in organ-on-chip systems, AI-driven in silico modelling, and advanced human in vitro platforms now offer regulators and developers credible alternatives. The **FDA Modernization Act 2.0 (2022) authorised the use of validated non-animal evidence packages** for the first time[4,5]. By April 2026, the US Food and Drug Administration ("FDA") had achieved all Year 1 goals under its *Roadmap to Reducing Animal Testing*[6], including qualifying the first AI-based drug development tool and issuing a draft guidance on the regulatory use of New Approach Methodologies ("NAMs"). The UK followed in November 2025 with a £75.9 million national strategy[7], and the OECD updated 56 Test Guidelines in June 2025, including guidance covering validated in vitro methods[8].

Early adopters stand to benefit from lower preclinical costs, faster development cycles, improved R&D productivity, and stronger animal-welfare credentials. Conversely, firms that delay risk regulatory friction, capital inefficiency, and competitive disadvantage as validated human-relevant methods enter regulated use.

Figure 1: Regulatory milestones



Source: FDA, GOV, EMA, OECD, Eight Advisory Analysis

> *Reducing default reliance on animal testing is no longer only an ethical aspiration, but a strategic priority*
>
> Matthew Thumas, Partner Eight Advisory

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Poor translation and political pressure drive the shift

Animal-based preclinical testing fails at scale

Weak animal-to-human translation is a major contributor to the industry's ~90% clinical attrition. Animal models have anchored preclinical safety for six decades, entrenched by regulations following historical tragedies such as thalidomide in the 1960s. Their predictive limitations are now well documented. Across **9,704** development programmes between 2011 and 2020, the overall Phase I-to-approval rate is **7.9%**[2]. A 2022 review in Acta Pharmaceutica Sinica B attributes the two main causes of clinical failure to lack of efficacy (40–50%) and unmanageable toxicity (30%). Together, they account for 70–80% of failures, and are precisely the outcomes preclinical models are meant to predict[1]. With the capitalised cost per approved drug estimated at approximately **$3.3bn**[3] (2022 real terms), filtering out false positives before the clinic is one of the largest levers on R&D productivity.

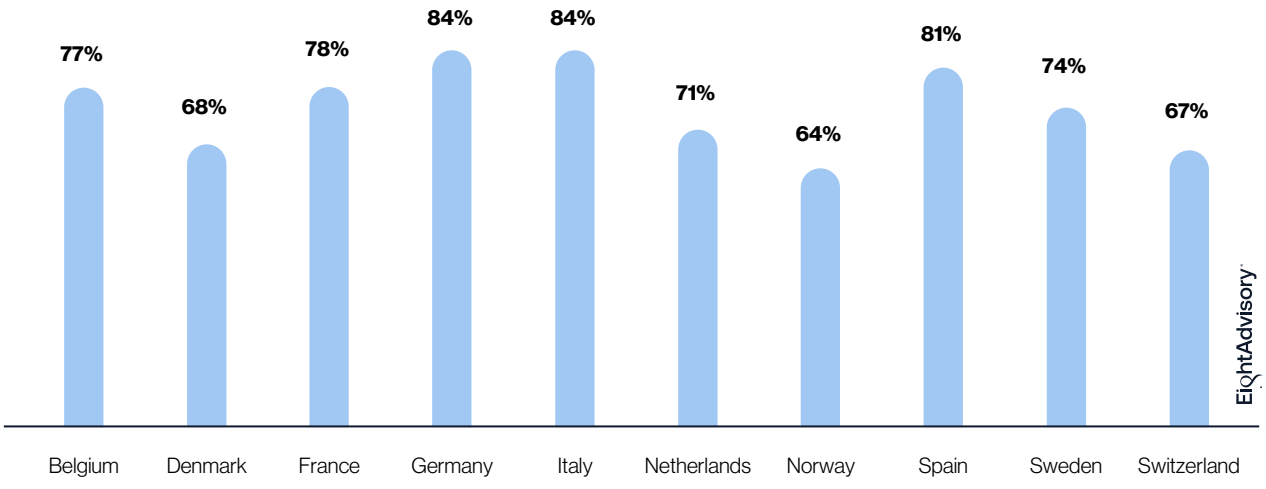
Human-relevant tools and AI are maturing fast

AlphaFold has transformed structure-based design. DeepMind's database of more than 200 million predicted protein structures covers nearly all catalogued proteins, supporting AI-led drug design at scale[9]. Induced pluripotent stem cell technology, first reported by Takahashi and Yamanaka, now sustains industrial production of patient-specific cardiomyocytes, hepatocytes, and neurons[10]. Early clinical data points are encouraging. AI-discovered molecules have cleared Phase I at 80–90%, against a historical average of ~52%[2,11], although these molecules were still tested in animals.

Political tolerance for the incumbent has eroded

Public consent for medical animal testing is weakening. A 2023 Savanta poll[12] of 10,706 adults across ten European countries found **77%** of citizens in surveyed EU member states support a coordinated European transition to non-animal science. In the United States, Gallup's 2025 Values and Beliefs survey[13] recorded **47%** of Americans viewing medical animal testing as morally acceptable, the **lowest reading in the 24-year series** and down from **65%** in 2001.

Figure 2: % of citizens who agree Norway's government / Switzerland's government / The European Commission and its Member States should develop a coordinated strategy to transition to scientific research, testing, and education without the use of animals



Source: Savanta: Animal Research Poll – Eurogroup for Animals – 31 March 2023[12]

Human-relevant methods reshape preclinical economics (1/2)

01. New Approach Methodologies cut preclinical cost while detecting toxicities that animal models miss

The FDA's 2025 Roadmap disclosed that typical monoclonal antibody programmes require approximately **144 non-human primates** at costs up to **$50,000 each**, implying acquisition expenses of up to **~$7.2m per programme** before laboratory and analytical costs[14]. Charles River Laboratories' January 2026 acquisition of a Cambodia-based primate supplier for $510m shows the cost of securing primate supply[15].

Human-relevant platforms detect toxicities that animal models miss. In a blinded evaluation of 870 Liver-Chips against 27 drugs with known human outcomes, the Liver-Chip delivered **87% sensitivity and 100% specificity for drug-induced liver injury.** 3D liver spheroids, a widely used in vitro model, flagged only 47% at the same specificity[16]. Combining the Liver-Chip's 87% sensitivity with the published estimate that Drug-Induced Liver Injury ("DILI") accounts for 13% of safety-driven clinical trial failures, the authors, from Emulate, derive that industry adoption **would route 11.3% fewer toxic candidates into clinical trials**, resulting in an R&D Net Present Value ("NPV") uplift of 2.8%. This is equivalent to **~$3bn per year** of industry-wide productivity gain from the Liver-Chip alone. They estimate this could rise to **~$24bn per year** if equivalent organ-chip models are validated for cardiovascular, neurological, immunological, and gastrointestinal toxicities that, together with DILI, account for 80% of safety-related clinical trial failure[16].

02. Human-relevant methods shorten studies, and AI compresses the time-to-candidate

Human-relevant methods can shorten preclinical programmes. Long animal studies, such as the two-year rat carcinogenicity study[17], create bottlenecks, and can now be avoided in defined cases under International Council for Harmonisation ("ICH") guidance[18]. Computational modelling and human-based assays enable parallel, automated testing, allowing **thousands of compounds to be screened in days**[19].

Separately, AI is speeding up discovery itself. Insilico Medicine's generative AI platform has nominated **28 development candidates** since 2021 with a **12–18-month average time-to-candidate**, against a traditional industry benchmark of more than **54 months**[20]. Rentosertib (ISM001-055), Insilico's AI-designed TNIK inhibitor for idiopathic pulmonary fibrosis, moved from programme initiation in February 2021 to Phase IIa start in June 2023, approximately **28 months**[21]. Crucially, speed did not compromise early efficacy: Phase IIa results published in Nature Medicine in June 2025 showed a mean forced vital capacity change of **+98.4 mL** in the 60 mg group versus **-20.3 mL** for placebo[22].

Figure 3: Human-relevant methods and AI improve early-stage R&D productivity

+2.8% NPV uplift from Liver-Chip adoption vs. traditional methods	12–18 months average time-to-candidate at *Insilico Medicine*, vs. 54+ months with traditional methods
87% sensitivity in detecting liver toxicity with the Human Liver-Chip, vs. 47% for 3D liver spheroids	80–90% Phase I success rate for AI-discovered molecules, vs. ~52% with traditional methods

Source: BIO[2], Jayatunga et al.[11], Nature[16], Insilico Medicine[20,21]

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Human-relevant methods reshape preclinical economics (2/2)

03. AI-discovered molecules clear Phase I at 80–90% versus a ~52% industry average

Better molecule design is showing up in Phase I success rates. A 2024 analysis of AI-discovered molecules completing Phase I trials found **success rates of 80–90%, far above the ~52% industry average**, although Phase II success of approximately 40% tracked historical norms[11]. The asymmetry is consistent with AI's strength in optimising safety and drug-like properties, which Phase I tests, while Phase II tests efficacy, which depends on disease biology no model yet captures. Better early-stage selection therefore reprices preclinical and first-in-human risk, but late-stage efficacy risk remains independent and should still be underwritten separately.



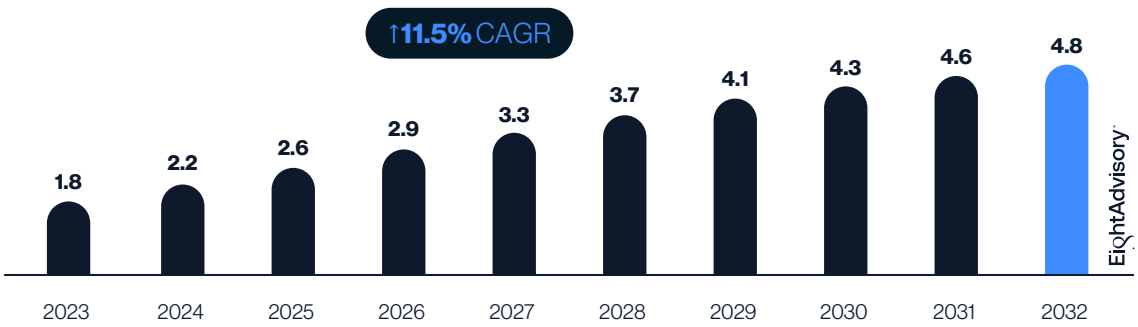
04. Investor scrutiny has moved animal welfare from disclosure to engagement

Federated Hermes EOS dedicated its Q2 2024 Public Engagement Report to pharmaceutical animal testing, pressing issuers on their involvement, with "*a focus on the **three Rs**: replacement, reduction, and refinement*"[23]. Corporate commitments are also becoming more concrete. For example, **Sanofi** has committed to halving animal use between 2020 and 2030, with progress reported via its Animal Protection Policy[24], while **Novartis** discloses annual 3Rs research grants in its 2024 Integrated Report[25].

05. Growth of the enabling ecosystem

The global market for non-animal testing technologies was valued at approximately $1.8 billion in 2023 and is projected to reach approximately $4.8 billion by 2032, reflecting an 11.5% CAGR[26]. The organ-on-chip sub-segment alone is projected to grow from $157 million in 2024 to $952 million by 2030 at a 35.0% CAGR[27]. Capital is flowing into platform developers, validation services, and predictive software providers as pharmaceutical sponsors integrate these tools into regulated programmes.

Figure 4: Global Non-Animal Testing Market Size Projection (in $bn)

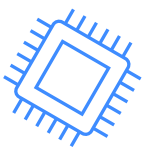


Source: Global Market Insights: Non-animal Alternative Testing Market Size & Share 2024–2032 (in $bn)[26]

Selected technologies show growing regulatory acceptance (1/2)

Human-relevant platforms are demonstrating stronger predictive performance than traditional animal models for defined endpoints, and, increasingly, formal regulatory acceptance.

Technology	Primary application	Regulatory maturity	Potential impact on animal use
Microphysiological Systems	Safety and efficacy testing	Accepted for defined contexts	Can reduce or replace selected toxicology studies
PBPK /In silico	Pharmacokinetics and dose selection	Formally qualified	Can replace selected animal PK and DDI studies
Patient-derived organoids	Patient response modelling	Case-specific acceptance	Can complement or reduce selected efficacy models
Generative AI drug design	Target and molecule design	Early clinical validation	Indirect impact through improved candidate selection



Microphysiological Systems ("MPS"), including organs on chips, are engineered in vitro platforms that use living human cells to reproduce aspects of organ-level architecture, fluid flow, and mechanical stress. They range from single-organ devices to interconnected multi-organ systems. Commercial platforms now cover liver, kidney, lung, intestine, brain, and vascular tissue, enabling forms of tissue interaction that conventional two-dimensional cultures cannot reproduce[28].



PBPK / In silico tools replace empirical animal data with mechanistic mathematical modelling to predict drug behaviour within defined regulatory contexts of use. They comprise physiologically-based pharmacokinetic ("PBPK") models, quantitative systems pharmacology models and virtual control groups, each qualified by the EMA or FDA for the scope its qualification opinion sets[29,30].



Patient-derived tumour organoids are three-dimensional cultures grown from individual patient biopsies that retain the tumour's genetic and histological architecture. Now banked across colorectal, pancreatic, gastric, breast, hepatobiliary and bladder cancers[31], they are named a priority NAM for oncology in the FDA's 2025 Roadmap, as they preserve patient-specific tumour heterogeneity[14].



Generative AI platforms are protein-language and diffusion models that design novel antibodies, peptides and small molecules against a target without prior screening libraries. Many draw on AlphaFold's database of more than 200 million predicted structures, a near-complete map of the protein universe[9] to design candidates directly rather than screen for them[11].

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Selected technologies show growing regulatory acceptance (2/2)

Case study	Performance	What it demonstrates
Cardiac proarrhythmia safety assessment	87% accuracy in distinguishing high-risk from low-risk compounds, validated blind across 10 independent laboratories and 28 drugs in a multi-site study[32]	ICH E14/S7B Q&As (finalised February 2022) allow nonclinical evidence to support replacing the TQT study in defined cases[33]
EMA qualification of the Simcyp PBPK platform	EMA issued its first qualification opinion for a commercial PBPK platform in August 2025, covering drug interaction evidence across seven CYP enzymes[34] A draft opinion on Virtual Control Groups followed on 31 March 2026[35]	Together, the two opinions represent EMA's growing formal acceptance of in silico methods within defined contexts of use
Metastatic gastrointestinal cancer response prediction	Across 71 metastatic GI cancer patients: 100% sensitivity, 93% specificity, 88% positive predictive value, and 100% negative predictive value against actual clinical outcome[36]	A human-based alternative to mouse models that preserves patient-specific tumour heterogeneity, enabling individual-level treatment prediction
ABS-101, Absci	ABS-101, designed de novo by Absci's generative AI platform, cleared IND review, with first Phase I dosing in May 2025[37]. Interim Phase I data showed extended half-life and no serious adverse events, but Absci has stopped internal development to prioritise another programme[38]	Generative AI can produce IND-ready, well-tolerated candidates, but progression still depends on where the sponsor allocates capital
Rentosertib (ISM001-055), Insilico Medicine	Phase IIa results published in Nature Medicine[22]: +98.4 mL improvement in forced vital capacity at the 60 mg dose vs −20.3 mL for placebo. The programme is now in Phase III, with its first patient dosed in September 2026[39]	Demonstrates translation of an AI-designed asset into advanced clinical development
REC-4881, Recursion	Phase Ib/II TUPELO trial: 87% of patients improved, with a 47% median reduction in polyp burden after 12 weeks, and most stayed below baseline 12 weeks off treatment. Recursion now targets a registrational trial for H2 2027, subject to FDA discussions[40,41]	AI-guided repurposing can surface strong signals in rare diseases with no approved therapy
REC-2282, Recursion	POPLAR-NF2: Phase II showed only the 40 mg cohort passed the futility threshold, with limited tumour shrinkage. Recursion discontinued the programme in May 2025[42,43]	AI-identified candidates remain exposed to the same efficacy risk as conventional ones
EXS-21546, Exscientia (now Recursion)	Phase Ia confirmed target engagement and full tolerability in 60 healthy volunteers[44] Exscientia wound down the Phase I/II IGNITE trial. Preclinical modelling predicted an insufficient therapeutic index in patients[45]	Target engagement in healthy volunteers did not translate to a viable dose window in patients. AI molecules face the same therapeutic index constraints as any other drug

The US leads as EU validation remains fragmented

The transition to human-relevant preclinical testing is underway in every major market, set against the OECD's 56 updated Test Guidelines, now recognised across 37 countries[8], with medicines following ICH guidelines. With the science proven, regulatory structure, political will, and capital depth now determine how fast each market will progress.

United States

The US leads, combining legislative reform, dedicated funding, and the world's largest market for new medicines. The FDA Modernization Act 2.0 removed the statutory animal-testing requirement in 2022[4]; by early 2026 the agency had delivered all eight Year 1 Roadmap milestones[46,6], issued draft NAMs guidance[47], and made its ISTAND qualification pathway permanent[30]. With the US accounting for more than 67% of global sales of new medicines launched between 2018 and 2023[48], FDA methodology effectively becomes the world standard. NIH's Complement-ARIE programme adds more than $150m of dedicated funding[49,50].

United Kingdom

The UK has regulatory autonomy and dated, test-by-test replacement targets. Its November 2025 Replacing Animals in Science strategy commits £75.9m and sets endpoint deadlines: skin and eye irritation testing by end-2026, adventitious agent and botulinum testing by end-2027, and a cut of at least 35% in dog and primate pharmacokinetic studies by 2030[51]. Domestic authority over the Animals (Scientific Procedures) Act lets the UK move without waiting for EU legislative windows[52]. A dedicated validation centre, UKCVAM, and a £30m translational hub are due by end-2026[51].

European Union

The EU has the scientific capability to lead but the slowest execution, because validation capacity is split between EU agencies and national authorities. Two decades and over €1bn across 300+ projects have not matched the FDA's operational pace[53]. EMA has acted on three fronts: implementing the ICH S1B(R1) weight-of-evidence approach[18], the Simcyp PBPK qualification[34], and a draft Virtual Control Groups opinion[35]. EU research funding[54] supports PARC (€400m, half from member states)[55] and ASPIS (€60m)[56], both focused on chemical safety. Meanwhile, the EU Pharma Package defers structural integration to around 2028[57], and no EU-wide medicines validation body exists.

China

China is positioning itself as a fast follower, using state-led pilots and national standards to build validation capacity. Its Centre for Drug Evaluation launched PIONEER in September 2026, a five-year pilot to validate organoids, organ-chips and computational models for drug registration[58,59], and the Standardization Administration released the first national standard for skin-on-a-chip in October 2024[60]. Commercial signals are strengthening: Insilico Medicine's December 2025 HKEX IPO raised roughly $292m[61], and Chinese drug R&D provider Pharmaron agreed in 2025 to validate and deploy CN Bio's organ-on-chip platform across its global facilities[62].

Regulatory readiness varies sharply across major markets

Major regulators are opening pathways for human-relevant methods, but not every market can yet deploy them at scale. The US has already established a statutory pathway for alternative evidence, while the EU and China are still building the capacity to deliver.

	United States	United Kingdom	European Union	China
Legislative reform	FDA Modernization Act 2.0 (2022)[4]	Replacing Animals in Science strategy (Nov 2025)[51]; domestic authority via ASPA[52]	EU Pharma Package integration deferred to approximately 2028[57]	PIONEER pilot launched in Sep 2026, no primary law[58,59]
Dedicated funding	*NIH Complement-ARIE, >$150m[49,50]*	*£75.9m combined package[51]*	*€400m via PARC[55] + €60m ASPIS[56]*	*State-directed, scale undisclosed*
Funding discipline	Programme-linked	Project-based allocation	Not linked to adoption deadlines	Centrally planned
Regulatory milestones	8 Year 1 milestones delivered by early 2026[6]; NAMs draft guidance[47]	Skin/eye irritation by end-2026; adventitious agent & botulinum testing by end-2027; ≥35% cut in dog/primate PK studies by 2030[51]	3 EMA instruments: ICH S1B(R1)[18], Simcyp[34], Virtual Control Groups[35]	First organ-on-chip national standard (Oct 2024)[60]
Validation infrastructure	ISTAND, permanent since mid-2025[30]	UKCVAM + £30m hub by end-2026[51]	No EU-wide medicines validation body	CDE-led validation pilot[59]
Execution	Leading Reform is enacted and the FDA is delivering	Advancing Dated targets and funded validation centre in progress	Building Validation capacity is split across EU and national bodies	Building Private investment, validation pathway is now launching

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Investment value depends on regulatory acceptance and recurring adoption

Business models differ in how they create value and carry risk

Headline funding demonstrates investor interest, but it does not make the underlying assets comparable. Investors should distinguish regulated software, human-relevant tools, validation services, and AI drug discovery platforms, then assess whether scientific performance converts into accepted evidence and recurring revenue.

Investment model	How value is created	Key underwriting risk
AI-enabled drug discovery platforms	Generate returns through pharmaceutical partnerships, milestone payments, royalties, and retained drug programmes	Long development timelines, clinical attrition, reliance on partners, and continued funding requirements
Organ-on-chip and other human-relevant experimental platforms	Generate revenue from instruments, consumables, assays, model licensing, and scientific services	Reproducibility, standardisation, scalability, and regulatory acceptance for defined applications
In silico and model-informed development tools	Generate licence, subscription, and consulting revenue by becoming embedded in drug development and regulatory workflows	Data quality, model validation and governance, and regulatory acceptance within a defined context of use

Headline deal values are not comparable across business models

Investors should compare committed capital and underlying risk, rather than headline values. Only $82.5m of Isomorphic Labs' nearly $3bn potential partnership value was committed upfront[63], while Altaris' ~$375m all-cash acquisition of Simulations Plus[64] prices an established software and services business with a materially different revenue and risk profile. The two figures reflect different levels of revenue visibility and retained development risk and are not directly comparable valuation benchmarks.

01. Confirm regulatory acceptance for a defined use

Has the method been accepted within a defined context of use, or is the asset still relying on scientific validation and management claims?

02. Test conversion from pilots to recurring use

Are pharmaceutical customers moving from pilot projects to repeat programmes, broader deployments, and recurring revenue?

03. Validate the platform's net economic advantage

Does the platform reduce total study cost or development time after implementation, validation, integration, and data requirements are included?

04. Separate committed value from contingent upside

How much value is committed through upfront revenue, and how much remains dependent on milestones, clinical outcomes, external funding, or a future transaction?

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Conclusion and Outlook

01. Regulatory acceptance is moving from case-by-case discretion to structured pathways

The FDA Roadmap, the UK strategy, and OECD guidance confirm that human-relevant methods are entering formal regulatory pathways. Animal studies will not disappear immediately, but their position as the unquestioned default is being challenged as regulators accept organ chips, stem-cell-derived heart cell panels, PBPK models, and other qualified tools within defined programmes.

02. Industry investment is following the scientific evidence

Where validated, **human-relevant methods can improve translation, shorten selected studies, and reduce exposure to costly animal models.** Investment is therefore moving towards platforms that can demonstrate predictive performance and regulatory acceptance, rather than those relying on AI or NAM adoption alone.

03. Europe now needs to convert scientific capability into regulatory execution

The FDA has established the clearest operational pathway through its Roadmap, ISTAND, and NAMs guidance. The UK has added a funded national strategy. **Europe has a strong scientific base, but fragmented validation and acceptance processes continue to slow adoption.**

Key Takeaways

- Animal-based testing remains a weak predictor of human outcomes, contributing to high clinical attrition and multi-billion-dollar development costs.
- Validated human-relevant methods can improve early candidate selection and reduce selected preclinical timelines and costs.
- The FDA has set the pace and the UK is following; the EU must accelerate execution to retain its competitiveness.
- Advantage will come from evidence quality and regulatory execution, not adoption alone.

Closing thoughts

Reducing default reliance on animal testing is now a strategic issue, not only an ethical objective. Science, regulation, and capital are moving in the same direction. The companies and countries best placed to benefit are those that can turn human-relevant methods into regulatory evidence at scale.

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How we can support you

1

Transaction Services

Value focused and integrated buy-side transaction services or integrated sell-side services tailored to your target.

2

Value Creation / Performance Improvement

Identification and implementation of actions to improve commercial, operational and financial value and performance.

3

Commercial Assessments

Alignment of strategic objectives, incorporating patient flow, R&D forecasts, regulatory requirements, commercial scenarios, market dynamics, and competitive landscape analysis, along with return-risk analysis.

4

Valuations & Financial Modelling

Valuations and modelling services to complete the deal process and provide ongoing support with managing investments.

5

Integration & Synergy Capture

Maximise synergy capture through ambitious operating model transformation and robust integration delivery.

Eight Advisory is an integrated transaction, transformation, restructuring, and strategy advisory firm operating globally with over 1,050 professionals, including over 130 partners. We support clients in corporates, private equity funds and investors, and navigate the complexities of a changing world: identifying, creating and realising value.

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Contact our experts and see how we can help you!



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