

# **Translational Data and the Next Era of Drug Development: Insights from an Executive Discussion with Biopharma, CRO, and Life Sciences Technology Leaders**

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## Positioning Statement

Drug development does not lack data; it lacks consistently decision-grade translational evidence. As human-relevant models, New Approach Methodologies (NAMs), AI-enabled analytics, and evolving regulatory frameworks gain momentum, the opportunity is not simply to generate more information or replace existing models in isolation. It is to build coherent evidence architectures that begin with a defined development decision, test a human biological hypothesis, connect model outputs to clinical biomarkers and outcomes, and establish clear thresholds for progressing, redirecting, or stopping a program.

Indeed, the next era of drug development will be shaped by tools and strategies that convert biological complexity into evidence that is human-relevant, reproducible, interpretable, and credible enough to change real go / no-go decisions.

## 1. Executive Summary

Drug development continues to face a persistent translational gap. Despite the growing volume of data available to development teams, too many programs still fail because early evidence does not translate into meaningful clinical benefit. These failures become especially costly at Phase II, when substantial capital, time, patent life, organizational effort, and patient participation have already been committed.

Against this backdrop, human-relevant models and New Approach Methodologies are gaining strategic importance. Organ-on-chip systems, bioprinting, computational tools, AI-enabled analysis, and integrated evidence packages are increasingly being explored to complement, reduce, or, in defined contexts, replace traditional animal testing. However, the central issue is no longer whether these approaches are scientifically promising. It is whether they can produce evidence strong enough to influence real development decisions.



## ROCKETBIO

At the RocketBio Reception in San Diego, held as a satellite event to BIO International 2026, RocketBio convened leaders across the CRO, biopharma, technology, and life sciences ecosystem to discuss how translational data will shape the next era of drug development. The discussion, featuring Julie Frearson, Global Executive Lead, Discovery Sciences at IQVIA Laboratories, alongside live audience polling, surfaced a clear message: promising science becomes valuable only when it reduces uncertainty around a defined decision.

Several key themes emerged:

- The translational gap is multi-dimensional. Poor translation is not caused by one isolated weakness, but by a combination of biological relevance, model selection, biomarker strategy, clinical linkage, reproducibility, interpretability, and operational execution.
- Poor translation becomes most costly at proof of concept / Phase II. By this stage, failure is no longer only a scientific setback; it becomes a strategic and economic constraint on the future of the program.
- Decision-grade translational evidence starts with human relevance and predictive performance. Audience participants identified human relevance, predictive performance, and regulatory acceptability as the leading drivers of go / no-go decision-making, ahead of speed or cost.
- Trust depends on clinical anchoring and reproducibility. Human-relevant models are most likely to influence decisions when they are benchmarked against known clinical outcomes, including both successes and failures, demonstrate reproducibility across laboratory sites, and clearly define their domain of applicability.
- Context of use matters. As Frearson emphasized, a model does not need universal validation to be useful, but it must be fit for the biological question, development stage, decision context, and evidence threshold it is intended to support.
- AI is an enabler, not a substitute. AI can help integrate complex evidence streams, identify patterns, support biomarker strategy, and clarify decision criteria. However, it cannot compensate for poor-quality, poorly anchored, or biologically irrelevant input data.
- Regulatory acceptance is moving toward totality of evidence. The emerging regulatory question is not whether a model is broadly accepted, but whether it reduces uncertainty for a specific regulatory or development decision.

Taken together, the discussion points to an important reframing: translational data should not be treated as a collection of disconnected assays, models, or biomarkers. It should be treated as a decision architecture. A strong translational strategy starts by defining the decision, mapping the human hypothesis, selecting models by use case rather than novelty, establishing biomarker bridges, benchmarking against known outcomes, and setting thresholds for what evidence will progress, pause, redirect, or stop a program.



**Key takeaway:** The question is no longer whether the industry needs more translational data. It is whether that data can reliably predict human biology and clinical response, and whether the resulting evidence is strong, reproducible, and interpretable enough to reduce uncertainty, justify a high-cost clinical decision, or confidently stop a program.

## 2. Setting the Scene: The Costly Impact of Sticking with the Status Quo

Drug development continues to face a persistent translational gap. Many preclinical systems, including conventional 2D cell cultures and animal models, are limited in their ability to capture the complexity, heterogeneity, and dynamic biology of human disease. This gap is one contributor to high clinical attrition, with industry studies commonly estimating that only around 10-15% of drug candidates entering clinical development ultimately reach approval [1].

The consequences grow sharply when failure appears in Phase II, after substantial capital, time, patent life, organizational effort, and patient participation have been committed. At that point, poor translation becomes both a scientific setback and a strategic constraint, particularly when there is little time to rework or reposition the asset.

Although consequences are felt sharply in Phase II, Frearson noted that these failures usually originate earlier - in target selection, translational hypothesis design, biomarker strategy and model choice. By the time a program reaches proof of concept, the failure is rarely a single handoff problem. It is more often a compound failure across biological relevance, endpoint translatability, clinical linkage, reproducibility, and interpretability.

Against this backdrop, stakeholders are calling for more predictive, human-relevant models and the momentum behind NAMs is accelerating. This shift is being reinforced by a changing policy and regulatory environment. Recent developments include the FDA Modernization Act 2.0 and FDA roadmap activity aimed at reducing reliance on animal testing, EMA pathways for regulatory interaction and qualification of NAMs, NIH initiatives prioritizing human-based research, WHO guidance on replacing or removing animal tests for biological product quality control, and the UK's strategy to phase out animal use where reliable alternatives exist.

This momentum also reflects a wider societal push to reduce reliance on animal testing and move away from research practices increasingly viewed as ethically problematic, particularly when more human-relevant alternatives are available. The objective is not simply to generate more translatable data, but to enable more robust, data-grounded assumptions, identify risk earlier, prioritize stronger candidates, reduce avoidable late-stage failure, and support safer, more effective therapies.

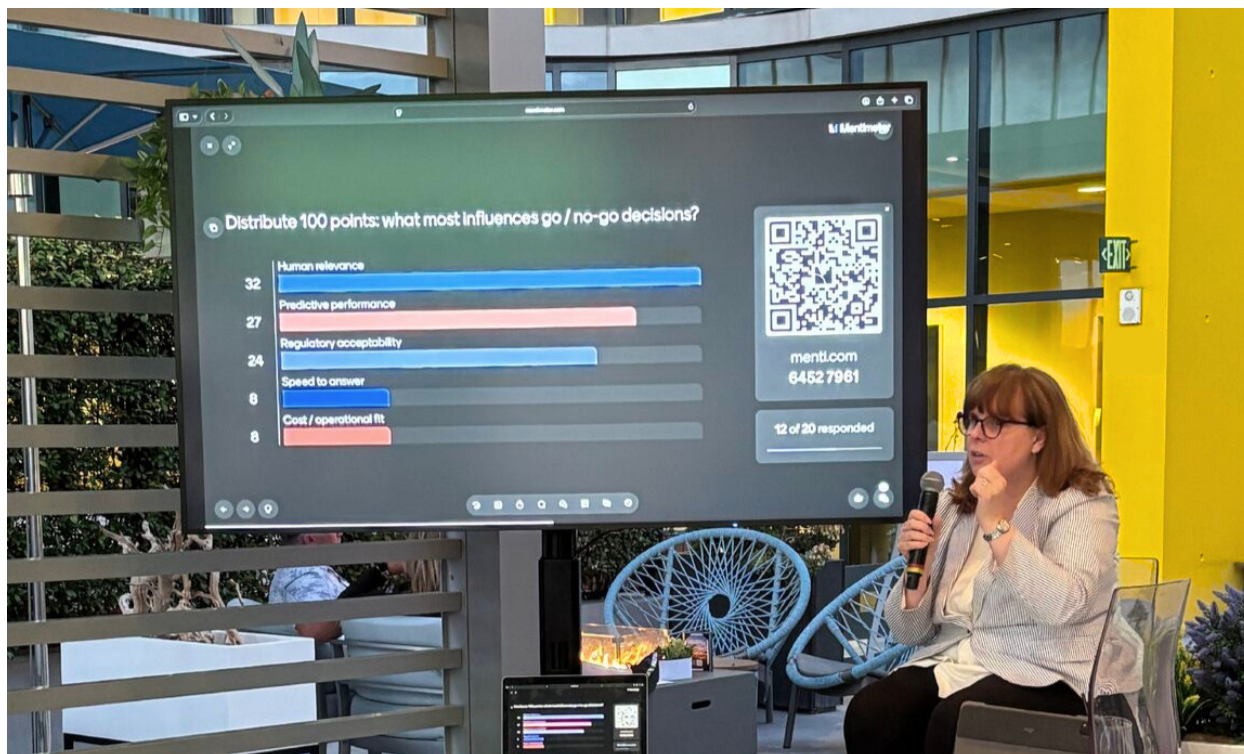
Adoption nevertheless depends on more than scientific promise. Biopharma, CROs, investors, method developers, and regulators apply different requirements and thresholds for trust. Understanding those expectations is essential to moving human-relevant models from promising technologies to decision-grade tools.

### 3. Event Overview and Methodology

Building on the themes of the translational data gap and stakeholder adoption, RocketBio, a family office and long-term investment platform focused on life sciences tools and enabling technologies, convened a focused reception as a satellite event to BIO International 2026. The event centered on the question of how translational data will shape the next era of drug development.

The reception featured a moderated executive discussion with Julie Frearson, Global Executive Lead, Discovery Sciences at IQVIA Laboratories, alongside live audience polling through Mentimeter. The objective was to surface practical perspectives on where translational science is falling short today, what makes human-relevant data credible enough to influence development decisions, and what barriers remain to broader adoption of NAMs.

Insights were gathered through live audience polling during the event. The findings presented in this paper reflect both the expert discussion and the live polling from a targeted executive audience and should be interpreted as directional insights rather than as a statistically representative survey. Audience composition was weighted toward CRO and industry participants, with respondents identifying as follows: CRO, 43%; Pharma R&D, 19%; Pharma BD or Strategy, 13%; and Other, 25%, including method developers or equipment providers.





## 4. Key Findings from the Audience

The Mentimeter results highlighted a clear message: stakeholders are not simply looking for new translational technologies because they are novel or scientifically elegant. They are looking for human-relevant evidence that can support real development decisions, reduce uncertainty, and build confidence across scientific, operational, and regulatory stakeholders. Across the responses, five major themes emerged.

### **Theme 1: The translational gap is multi-dimensional, not a single failure point**

When asked where translational science fails most today, the audience pointed to challenges spanning the full development pathway—from incomplete biological understanding and limited patient relevance to weak clinical predictability, inconsistent reproducibility, and practical constraints around timing, cost, and safety. The breadth of these responses suggests that the translational gap cannot be traced to a single weakness. Rather, it reflects a system-level challenge in connecting model selection, biological relevance, clinical outcomes, and operational execution into evidence that supports confident downstream decisions. As Frearson noted, there is simply “not one failure point.”

This is important because it means that no single technology, model, or dataset will be sufficient on its own. Human-relevant systems add value only when their outputs are interpretable, reproducible, and linked to clinical outcomes.



*Figure 1: Audience word cloud — “Where does translational science fail you most today?”*



## Theme 2: Poor translation becomes most costly when programs approach clinical proof

Audience responses agreed with Frearson that poor translation is felt most acutely later in development, with Phase II receiving the highest number of responses. By contrast, no respondents selected Discovery as the stage where poor translation costs the most. This does not mean that early-stage translation is unimportant. Rather, it suggests that the consequences of poor translation become most painful when programs have already consumed significant capital, time, patent life, organizational attention, and patient participation.

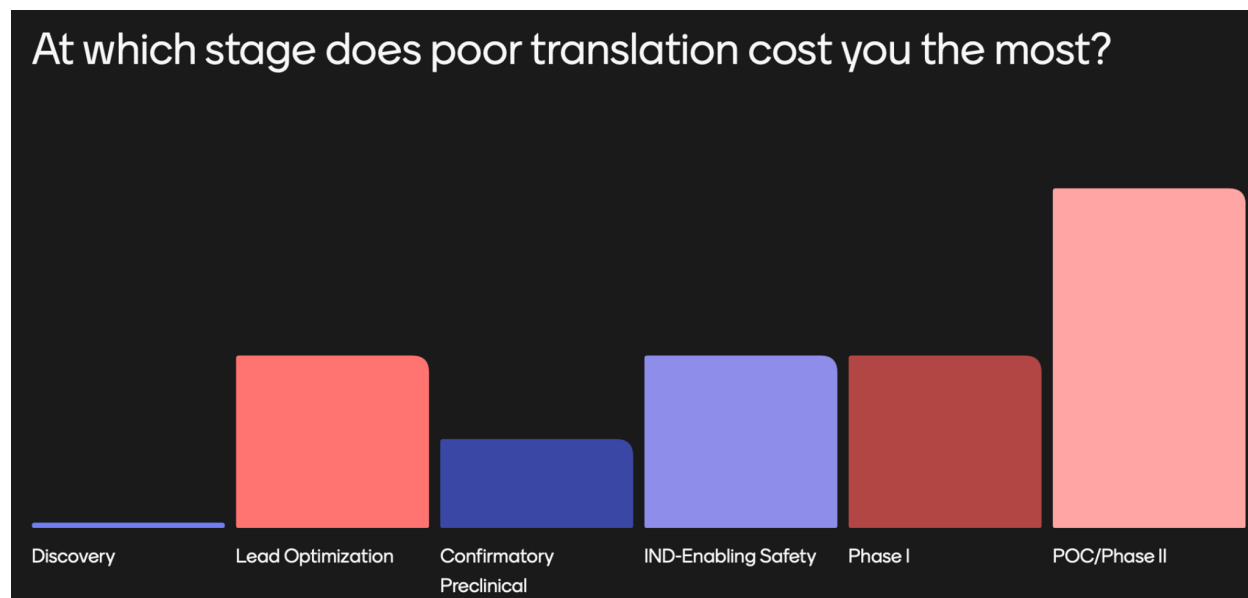


Figure 2: Audience responses to: “At which stage does poor translation cost you the most?”

By Phase II, the cost of poor translation is no longer purely scientific. It becomes a portfolio-level issue, influencing capital allocation, clinical strategy, business development decisions, and confidence in the broader development path. This finding reinforces the need for translational tools that can help teams identify risk earlier, prioritize stronger candidates, and make more confident decisions before late-stage costs accumulate. The translational risk and cost of failure by stage is summarized in the following table:

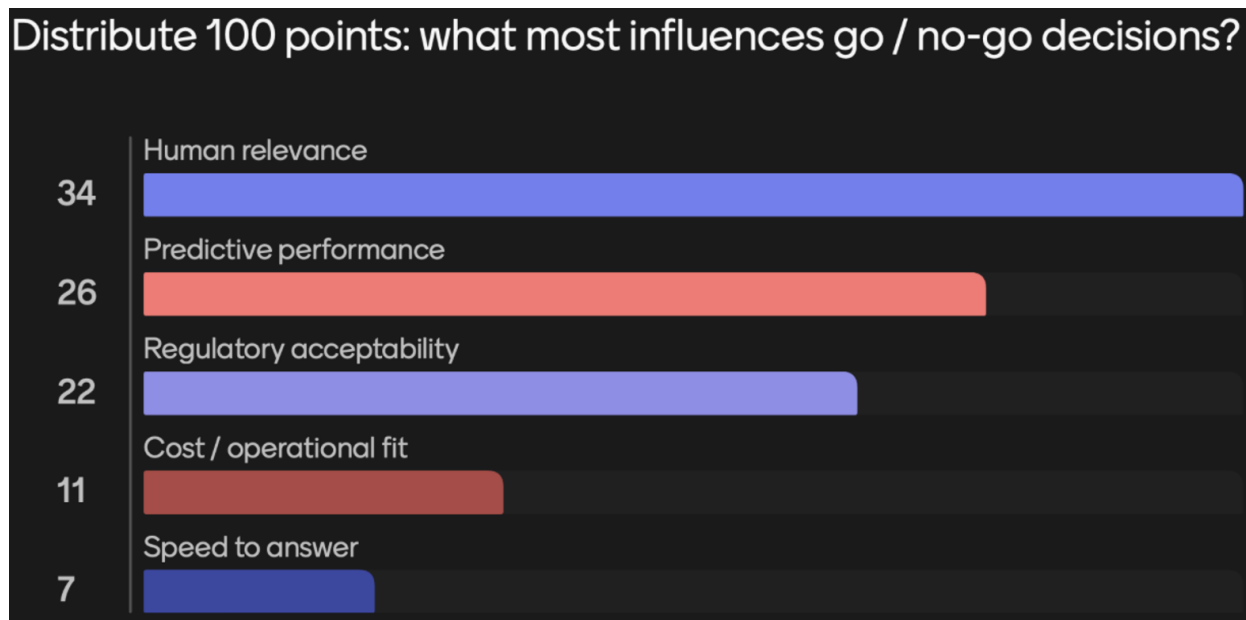


| Stage          | Translational risk                                               | Cost of failure | Strategic role                                                 |
|----------------|------------------------------------------------------------------|-----------------|----------------------------------------------------------------|
| Preclinical    | Very high                                                        | Lower           | Hypothesis formation, model selection, biomarker strategy      |
| Phase I        | High                                                             | Moderate        | Early human validation and exposure / safety understanding     |
| Phase II / POC | Real test of the human hypothesis                                | Very high       | Proof of concept, portfolio prioritization, capital allocation |
| Phase III      | Lower for true biology; high for execution and patient selection | Extreme         | Confirmation, patient selection, operational execution         |

*Figure 3: The Translational Risk Curve - Where Evidence Gaps Become Strategic Costs*

### Theme 3: Decision-grade translational data starts with human relevance and predictive performance

When asked to distribute 100 points across factors that most influence go / no-go decisions, the audience prioritized human relevance, predictive performance, and regulatory acceptability. Human relevance received the highest allocation, followed by predictive performance and regulatory acceptability. Cost / operational fit and speed to answer received comparatively lower scores.



*Figure 4: Audience responses to 100-point allocation chart — “What most influences go / no-go decisions?”*

The result suggests that stakeholders value assays for the confidence they add, not simply their speed or cost. A model must reflect human biology, predict clinically meaningful outcomes, and be interpretable within the relevant development or regulatory context.

Furthermore, Frearson emphasized that go / no-go decisions are not static. What makes translational data truly “decision-grade” can differ meaningfully depending on the stage of development, the type of risk being evaluated, and the decision a team is trying to make. A model should therefore be judged against the specific decision and evidence threshold it is intended to support.

| Attribute                                | Why it matters for decisions                                                                                                                      |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Grounded in human biology</b>         | The model and the hypothesis being tested should reflect the key human biology relevant to the disease, target, and safety question being tested. |
| <b>Clear link to clinical biomarkers</b> | The same biomarker or pathway should be measurable in both the model and in humans, so results can be connected to clinical meaning.              |
| <b>Dose-response relationship</b>        | The evidence should show how dose or exposure relates to biological effect and safety, rather than relying only on a yes / no result.             |
| <b>Ability to test the hypothesis</b>    | The study should be designed so that it can show whether the hypothesis is wrong, not only whether it appears to work.                            |
| <b>Predefined stop / go criteria</b>     | Teams should agree in advance what results would support continuing, redesigning, or stopping a program.                                          |

*Figure 5: What makes translational data “decision-grade”?*

#### **Theme 4: Trust in human-relevant models depends on clinical anchoring and reproducibility**

The audience identified benchmarking against clinical outcomes as the most important factor that would make them trust a human-relevant model enough to act on its results. Multi-site



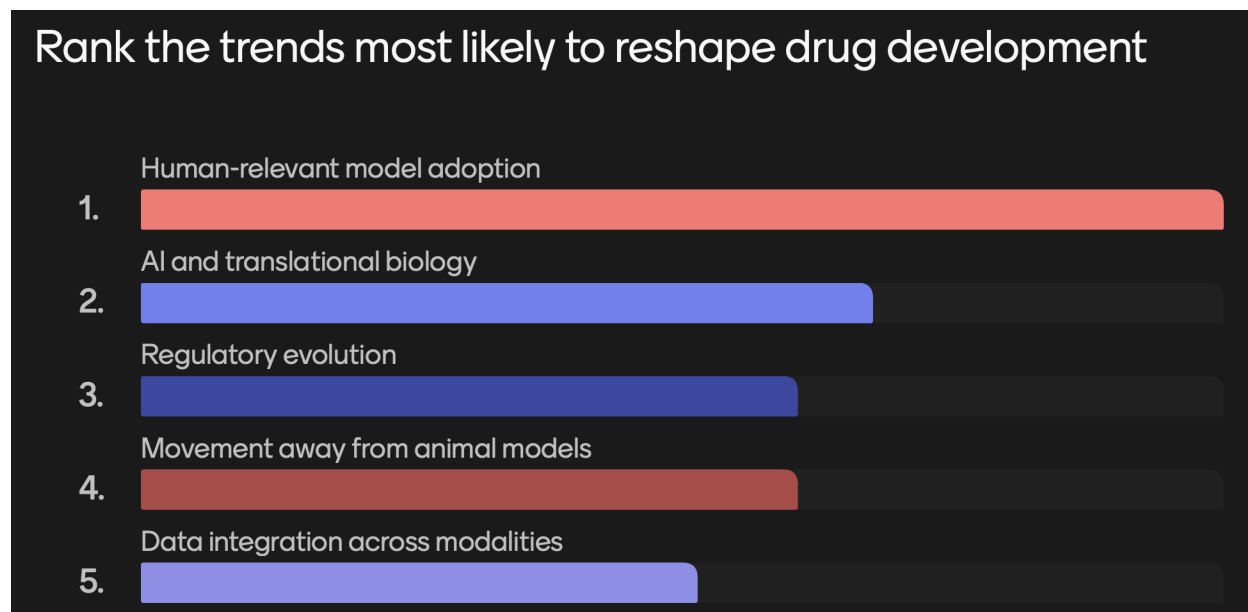
reproducibility was the next most selected factor, followed by evidence that the model catches failures and peer adoption in successful programs.

Frearson made an important point here: human-relevant models can gain practical trust without receiving full regulatory qualification or universal validation. This distinction matters. Regulatory confidence remains important, but many internal portfolio decisions are made before a model is formally qualified. For those decisions, end users appear to be looking first for evidence that a model performs reliably, reflects clinical reality, and integrates into existing workflows.

For NAM developers, the most persuasive evidence packages will be those that benchmark against clinically characterized compounds, include known failures as well as successes, demonstrate reproducibility outside a single internal laboratory, and clearly describe the model's domain of applicability. As Frearson emphasizes, in many cases, a “minimum viable model” that captures the relevant biology, produces reproducible quantitative readouts, and discriminates known positives from known negatives may be more useful than a highly complex system that is difficult to reproduce or interpret.

## **Theme 5: Human-relevant model adoption is viewed as the leading trend, but implementation remains transitional**

When asked to rank the trends most likely to reshape drug development, the audience ranked human-relevant model adoption first, followed by AI and translational biology, regulatory evolution, movement away from animal models, and data integration across modalities.



*Figure 6: Audience ranking chart — “Trends most likely to reshape drug development”*

However, the audience “readiness” results show that adoption remains uneven. Respondents appeared to cluster around exploring, piloting, or using human-relevant data in select programs, rather than treating these approaches as standard practice for regulatory submission. This reflects a field in transition: human-relevant approaches are gaining strategic importance, but they have not yet become routine across development programs.



*Figure 7: Audience readiness chart — “How ready are you to use human-relevant data in place of animal studies for regulatory submission?”*

For method developers, uneven adoption creates an opening to shape emerging standards. The advantage will go to tools designed around a clear context of use and validated within real development workflows.

## 5. Interpretation and Discussion

Taken together, the polling results and expert discussion suggest that the field is moving from enthusiasm for human-relevant technologies toward a more practical question: what evidence is strong enough to change decisions? Stakeholders recognize the promise of NAMs, but adoption still depends on whether these approaches can demonstrate human relevance, predictive performance, reproducibility, clinical anchoring, and regulatory credibility.

The discussion also points to an important reframing. Translational data should not be treated as a collection of disconnected assays, models, or biomarkers. It should be treated as a decision architecture. A strong translational strategy starts by defining the decision, mapping the human hypothesis, selecting the model by use case rather than novelty, establishing the



biomarker bridge, and setting thresholds for what evidence will progress, pause, redirect, or stop a program.

This decision-led approach is especially important because traditional models are not uniformly weak, and human-relevant models are not automatically superior. As Frearson reminds us, traditional animal and simplified preclinical systems can remain useful when biology is conserved, mechanisms are proximal, disease is relatively simple or monogenic, and endpoints are objective and measurable. They become less reliable when biology is emergent, multifactorial, human-specific, chronic, functional, behavioral, or dominated by complex immune, brain, tissue microenvironment, or compensatory mechanisms. The table below highlights both where traditional models can help and where they struggle:

| Model context                                   | Where traditional models can help                                                                           | Where traditional models often struggle                                                                                                                           |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Infectious diseases                             | Conserved pathogen biology, direct action on pathogen, clear endpoints such as pathogen kill or viral load. | Less informative where host-specific immune response drives outcome.                                                                                              |
| Oncology                                        | Targeted therapies and mechanisms linked to clear oncogenic mutations; mechanistic validation and PK/PD.    | Immuno-oncology, tumor microenvironment, resistance, heterogeneity, and patient-specific response.                                                                |
| Metabolic                                       | Reproduce many aspects of insulin resistance, lipid metabolism, and diabetes well.                          | Difficult to capture the full heterogeneity of multi-mechanism setting of NASH/MASH as well as lifestyle and co-morbidity contexts for metabolic syndrome.        |
| Cardiovascular                                  | Physiology conserved enabling evaluation of hemodynamics, hypertension, thrombosis and heart failure        | No animal model adequately recapitulates the full human syndrome to model heart failure. Ion channel differences create species translation gaps for arrhythmias. |
| Rare monogenic diseases                         | Genetically defined disease, less heterogeneity, and closer replication of causal mutation.                 | Still requires careful biomarker linkage and clinical endpoint relevance.                                                                                         |
| CNS, immunology, chronic multifactorial disease | May support hypothesis generation or mechanism exploration.                                                 | High human specificity, complex time scales, emergent systems behavior, and poor endpoint translatability.                                                        |

*Figure 8: Where Traditional Models Help — and Where Human-Relevant Approaches Are Needed*

The practical diagnostic question for development teams is therefore not “is this model impressive?” but “can this evidence prove or disprove our human hypothesis in a controlled, interpretable way, using biomarkers and thresholds that will govern a real decision?”

## 6. AI and Integrated Data: High Potential, High Need for Discipline

AI should be understood as an enabling layer within the broader move toward decision-grade translational evidence. As noted in the table below, AI may help integrate complex biological, preclinical, clinical, and translational datasets; identify patterns across heterogeneous evidence streams; support patient stratification; and improve the interpretation of model outputs. It may also play an increasingly important role in tuning human-relevant models themselves by helping define which biological parameters matter most, optimizing experimental conditions, refining assay readouts, and linking model outputs to clinically meaningful endpoints.

In parallel, AI can support the development of clearer decision criteria by helping teams understand which signals are most predictive of efficacy, toxicity, resistance, or clinical failure. This is particularly important as translational models become richer and more complex, generating multidimensional data that may be difficult to interpret through conventional analysis alone. Used well, AI can help turn these outputs into more actionable evidence by identifying patterns, ranking risk, and clarifying how model results should inform go / no-go decisions.

However, AI cannot compensate for weak input data. Training sets may overrepresent successful programs, outcome data may be sparse, and models may overfit historical patterns or fail on novel mechanisms. Explainability is therefore essential: an output that scientists, executives, and regulators cannot understand should not be considered decision-grade.

| Where AI adds value                                                                                                  | Where caution is required                                                      |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Multimodal integration across genetics, expression, pathway, phenotype, preclinical model outputs, and outcome data. | Biased training data and limited true outcome data.                            |
| PK/PD, exposure-response, and dose optimization.                                                                     | Context-dependent biology and tissue-specific effects.                         |
| Biomarker identification and trial design support.                                                                   | Overfitting historical patterns or failing on novel mechanisms.                |
| Detection of inconsistencies across translational datasets.                                                          | Insufficient explainability for scientists, development teams, and regulators. |

*Figure 9: Opportunities and Cautions for AI in Translational Decision-Making*



**Key takeaway:** AI is likely to amplify the value of better translational systems rather than replace the need for rigorous, human-relevant model validation.

## 7. Regulatory Acceptability: From Universal Validation to Totality of Evidence

The regulatory conversation is evolving in a measured way and remains an important consideration in the adoption of human-relevant models. The direction is not immediate elimination of traditional approaches, but a shift toward evidence-based acceptance, reduction, targeted replacement, and integrated evidence frameworks. NAMs can contribute when they reduce uncertainty for a defined use case, explain species differences, de-risk toxicity, support mechanism, or, in specific contexts, replace particular animal studies.

A recurring theme from the discussion was that regulatory acceptability is becoming increasingly use-case specific. Elaborating on the points mentioned in Theme 4, the more practical question is not whether a model is broadly accepted, but whether it reduces uncertainty for a specific regulatory or development decision. A model used for mechanism exploration, for example, should not be held to the same evidentiary standard as a model intended to replace a specific animal study or support an IND-enabling safety decision. This is consistent with the emerging regulatory emphasis on context of use: sponsors must be clear about the regulatory question being addressed, the intended decision, the stage of development, the model's limitations, and the evidence supporting its relevance.

In practice, NAMs must demonstrate three things: biological relevance to the question being asked; technical reliability through reproducibility, robustness, analytical performance, standardized methods, and quality controls; and fitness for the intended purpose. Important limitations remain. Organoids and organ-on-chip systems can improve human relevance without reproducing whole-body physiology. They may lack complete immune, vascular, endocrine, pharmacokinetic, or multi-organ interactions, although flow, perfusion, and tissue interfaces can address some gaps. Many NAMs will therefore remain complementary evidence, particularly for systemic toxicity, reproductive and developmental toxicology, and first-in-human safety decisions.

This creates a practical evidence burden for sponsors and technology developers. Reviewers are likely to ask whether a model is independently validated, reproducible across laboratories, predictive of known clinical outcomes, linked to human safety or efficacy, qualified for its context of use, and consistent with existing animal or clinical data. Early engagement through pre-IND, INTERACT, scientific advice, or other relevant interactions can help align expectations before submission.

The near-term path is therefore integration, not wholesale replacement. Sponsors that pair clear use cases with robust validation and early regulatory engagement will be best positioned to expand the role of NAMs over time.

| Use case                               | Indicative evidence level |
|----------------------------------------|---------------------------|
| Mechanism exploration                  | Low                       |
| Target validation                      | Medium                    |
| IND-enabling support                   | High                      |
| Replacement of a specific animal study | Very high                 |

*Figure 10: Evidence Requirements Vary by Regulatory Use Case*

## 8. Practical Implications for Biopharma, CROs, Technology Developers, and Regulators

The findings point to a shared priority: translational tools must not only perform scientifically, but also integrate into development workflows, scale reproducibly, and support clear decisions. Each stakeholder group has a role in making that possible.

### For pharma and biotech leaders

Use translational evidence to reduce portfolio risk and guide which programs to advance, redesign, or stop. This means insisting on explicit clinical hypotheses, biomarker bridges, predefined thresholds, and evidence packages designed to change decisions. The most valuable translational tools will be those that help teams progress stronger programs, stop weaker ones earlier, and learn systematically from both success and failure. Where appropriate, pharma and biotech companies should also contribute to shared data initiatives, benchmarking efforts, and collaborative ring trials that can accelerate the validation and adoption of NAMs — not only for the broader benefit of patients, but also to strengthen confidence in the tools that will increasingly inform their own development decisions.

### For CROs and service providers

Differentiate by helping clients generate decision-grade evidence, not only assay outputs. This may include building capabilities in human-relevant models, reproducibility, benchmark datasets, integrated analytics, and regulatory-ready narratives. CROs are well positioned to support adoption because they sit close to pharma workflows and can help operationalize emerging models across programs and sites.

### For technology and method developers

Remember that end users do not adopt a technology because of its technical elegance alone; they adopt it because it helps them reach a better outcome — a clearer decision, a stronger program, a lower-risk portfolio, or a more confident path toward patients. In that spirit, make sure you define the context of use, the biological question, the decision the model is intended to inform, the domain of applicability, the required comparators, and the model's limitations. Spend time with the end user - observe how decisions are actually made within existing workflows, and



incorporate that feedback into product design, assay development, reporting formats, and evidence packages. Developers that design with the end user in mind, rather than optimizing for technical elegance alone, may be best positioned for first-mover advantage as standards emerge.

## For regulators and precompetitive consortia

Support frameworks that match validation to context of use, standardize reporting, and enable shared benchmark datasets containing both successes and failures. Precompetitive collaboration and cross-sector forums can generate the breadth of evidence and alignment that individual organizations may struggle to achieve alone.

## 9. Proposed Action Agenda and Conclusion

The discussion points to a practical action agenda for stakeholders working to advance human-relevant models, NAMs, and translational data into broader drug development use:

1. **Define the decision first** – For each program or platform, clarify the explicit development decision the evidence must inform, the uncertainty it needs to resolve, and how the results will guide the next step.
2. **Map the translational hypothesis** - Link target, mechanism, biomarker, exposure-response, patient population, and endpoint into one testable narrative.
3. **Select models by use case, not novelty** - Choose models that capture the relevant biology at the right level of complexity and produce quantitative, reproducible outputs.
4. **Benchmark against known outcomes** - Use compounds with known successes and failures, with particular attention to negative predictive value and failure prediction.
5. **Create stop / go thresholds** - Define what evidence will progress, pause, redirect, redesign, or terminate a program, helping prevent continued investment in candidates that no longer have a credible path forward.
6. **Engage regulators early** - Use scientific advice, qualification pathways, and pre-IND interactions to align on how translational tools will be interpreted.
7. **Track predictions prospectively** - Follow predictions through clinical outcomes to build confidence over time and improve model performance.
8. **Use AI as an integrator, not an oracle** - Use AI to connect, stress-test, and interrogate evidence packages while requiring explainability and biological plausibility.

The future of drug development will be shaped less by any single model, platform, or algorithm than by the ability to assemble coherent, human-relevant, quantitative, and regulatory-interpretable evidence packages. The winning translational strategy will combine fit-for-purpose models, clinically anchored biomarkers, rigorous benchmarking, integrated analytics, and disciplined decision thresholds.

For biopharma companies, CROs, technology developers, investors, and regulators, the opportunity is to move human-relevant models from promising scientific tools to trusted



components of drug development strategy. In that model, innovation is valuable only when it improves confidence in the next decision and supports the development of therapies that are safer, more effective, and more likely to benefit patients.

## 10. About RocketBio

RocketBio is a long-term investment and operating platform focused on life sciences tools, infrastructure, and enabling technologies that can improve how human biology is modeled, measured, and translated into better decisions. RocketBio is particularly interested in the New Approach Methodologies ecosystem, including complex in vitro models, organ-on-chip platforms, 3D bioprinting, and other human-relevant technologies with the potential to bridge the gap between preclinical research and clinical outcomes. Through its work with companies in this space, RocketBio believes better translational data can help biopharma, CROs, clinicians, and regulators make more informed decisions earlier in development, ultimately supporting more efficient drug development and better outcomes for patients.

### Expert Contributor

**Julie Frearson** is Global Executive Lead, Discovery Sciences at IQVIA Laboratories. Prior to her role with IQVIA Laboratories, Frearson served as Corporate Senior Vice President and Chief Scientific Officer at Charles River Laboratories, where she helped lead innovation strategy, venture and technology partnerships, and scientific initiatives across the company's drug discovery and development activities. She is truly a thought leader at the forefront of the NAMs space. Her perspective at the RocketBio Reception helped frame the discussion around decision-grade translational evidence, use-case-specific adoption of human-relevant models, and the practical evidence required for new approaches to influence development and regulatory decisions.

### Our Team

**Jessica Miller** is the founder of RocketBio and invests with a long-term, patient-focused approach across tissue engineering, regenerative medicine, and next-generation preclinical tools. She serves on the Board of Directors at VoxCell BioInnovation and on the Strategic Board at NETRI, supporting both companies with strategy, partnerships, and business development. Jessica holds a degree in Materials Engineering from the University of Toronto and a master's in Nanomaterials from Imperial College London.

**Mark Miller** is Executive Chairman of Volaris Group and President of Constellation Software Inc., where he has worked with CSI and its subsidiaries for over 30 years. He co-founded Trapeze Group, CSI's first acquisition, and serves on several boards, including ventureLAB, Lumine Group, Modaxo, and VoxCell BioInnovation. Mark brings deep experience acquiring, building, and holding vertical market software businesses for the long term, with a focus on developing exceptional leaders and supporting entrepreneurs.

**Pierre Morgon** is a life sciences entrepreneur, company co-founder, board member, and advisor to venture capital and private equity funds. He has more than 35 years of global life



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sciences experience, including C-level roles in multinational corporations and CEO roles in start-up companies. Pierre also mentors life sciences CEOs through MassChallenge and holds a Doctorate of Pharmacy, a Master in Business Law, and an MBA. He is an alumnus of INSEAD and IMD.

## 11. References

[1] BIO, Biomedtracker & Amplion, Clinical Development Success Rates 2006–2015, 2016