



Translating ambition into reality: *A Collaborative Industry-led Framework For The UK Government Replacing Animals In Science Strategy*

by Lhasa Limited

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The discussion brought together senior representatives from industry, academia, non-governmental organisations and research funders, reflecting the breadth of expertise required to deliver the [UK Government Replacing Animals in Science strategy](#) in practice.

We specifically acknowledge the perspectives shared by representatives from AstraZeneca, Cruelty Free International, GlaxoSmithKline (GSK), Kirkland Consulting, Labcorp, Liverpool John Moores University, UK National Centre for the Replacement, Refinement and Reduction of Animals in Research, Syngenta and Unilever.

Their contributions ensured that the insights presented here reflect real-world regulatory, scientific and implementation considerations across sectors.

Roundtable Attendees	
Dr Chris Barber, Roundtable Co-Chair	Chief Executive Officer, Lhasa Limited
Dr Crina Heghes, Roundtable Co-Chair	Deputy Chief Executive Officer, Lhasa Limited
Dr Rhiannon David	Senior Director, Head of Advanced Cell Models, Safety Sciences, AstraZeneca
Dr Charlie Stevenson	Senior Chemicals Regulatory Advisor, Cruelty Free International (CFI)
Dr Anthony Lynch	Executive Director of Genetic and Investigative Toxicology, GSK
Dr David Kirkland	Genetic Toxicology Consultant, Kirkland Consulting
Dr Darren Kidd	Scientific Specialist and Subject Matter Expert, Labcorp
Dr Lindsey Parkinson	Associate Director, Drug Development and Regulatory Strategy, Labcorp
Dr Steven Enoch	Academic/Computational Toxicologist, Liverpool John Moores University
Dr Fiona Sewell	Head of Toxicology, UK National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)
Dr Eva Lessmann	Senior Toxicologist (Human Safety), Syngenta
Dr Zofi McKenzie	Senior Technical Expert in Toxicology - Lead, Syngenta
Dr Katy Bridgwood	Senior Technical Expert in Toxicology, Syngenta
Dr Steve Gutsell	Head of Regulatory Science - Chemical Safety, Unilever
Agnieszka Ceszlak	Associate Director of Science, Lhasa Limited
Grace Kocks	Head of Toxicology, Lhasa Limited
Upasana Sonigra	Senior Marketing and Communications Partner, Lhasa Limited

Foreword



The publication of the UK Government strategy, ‘Replacing Animals in Science: A strategy to support the development, validation and uptake of alternative methods,’ represents a significant milestone for UK science.¹

There is now a clear, cross-departmental commitment spanning the Department for Science, Innovation and Technology (DSIT), the Home Office, and the Department for Environment, Food & Rural Affairs (DEFRA), to align the national world-class life sciences infrastructure with the goal of phasing out animal testing where reliable alternatives exist. This strategy, supported by a £75 million funding commitment, provides a foundation for the transition toward human-relevant models that offer scientific validity and predictive accuracy.

Translating policy into industrial implementation is inherently complex. The adoption of non-animal approaches is a systemic undertaking, influenced by regulatory uncertainty, international divergence and the need for trusted, interoperable data infrastructure. Delivering on this ambition will require structured collaboration, proportionate validation frameworks, and sustained regulatory confidence.

Lhasa Limited is an independent, not-for-profit organisation and for over four decades has acted as the UK’s trusted neutral steward of safety-relevant data, enabling regulators, industry and academia to collaborate with confidence.²

Through this model, Lhasa has enabled the generation of new shared knowledge, led the development of best practice approaches to safety assessment, and contributed to more consistent, data-informed decision-making across regulatory and industrial contexts. The Lhasa strategy is centred on enabling successful regulatory submissions by developing intuitive software and stewarding trusted, pre-competitive data.

Bringing together over 570 member organisations worldwide, Lhasa demonstrates that secure, cross-sector data-sharing is both achievable and essential to advancing scientific progress. Many of the mechanisms described in the UK Government strategy, including *in silico* approaches and secure data-sharing, are already being applied across research and development organisations in the UK and internationally.

Strategies succeed or fail in their implementation. Implementation depends on the scientific community

articulating clearly what is required, what is already working and where further coordination is needed. This paper, informed by a high-level cross-sector roundtable held in February 2026, outlines practical steps toward a mechanistic, risk-based approach to safety science in response to the UK Government strategy.

Lhasa stands ready to contribute its expertise, infrastructure and convening capability to support the delivery of the UK Government Replacing Animals in Science strategy.

We welcome the UK Government and its regulatory agencies to partner with Lhasa and UK-based stakeholders to turn this strategy into reality for the benefit of science and public safety.

Chris Barber

Leeds, June 2026
Dr Chris Barber
CEO, Lhasa Limited

Crina Heghes

Leeds, June 2026
Dr Crina Heghes
Deputy CEO, Lhasa Limited

Key information

Effective delivery of the UK Government strategy depends on progress across five priority areas identified through the roundtable. For each, this section sets out the challenge, what is needed, and how delivery can be supported in practice.

Implementation priorities and delivery

Regulatory submission confidence is a barrier to implementation

1

Scientific capability is advancing at pace, but adoption is limited by uncertainty in how non-animal new approach methodologies (NAMs) evidence is interpreted and accepted within regulatory frameworks.

What is needed

- Clear evidential standards for regulatory acceptance
- Defined validation and qualification pathways aligned to decision context
- Transparency in validation activity and funding

Delivery in practice

- Cross-sector and cross-agency dialogue to align evidential expectations
- Application of structured weight of evidence (WoE) frameworks in regulatory contexts
- Use of real-world case studies to demonstrate best practice in regulatory submissions

Context of Use (CoU) must underpin validation

2

Evaluation frameworks not aligned to the risk profile of the defined CoU risk, applying disproportionate evidential requirements and limiting practical adoption of non-animal approaches.

What is needed

- Validation approaches aligned to defined decision contexts
- Case-based evaluation to support regulatory familiarity
- Clear guidance across screening, WoE and regulatory expectations for decision-making

Delivery in practice

- Application of CoU-led evaluation approaches and cross-sector consensus building
- Structured assembly of NAMs evidence in submissions
- Ongoing engagement between regulators and scientific experts

Benchmarking must reflect modern science

3

Reliance on legacy *in vivo* datasets can obscure the value of mechanistic and human-relevant approaches.

What is needed

- Use of contemporary, well-characterised datasets
- Clear articulation of dataset limitations and comparability
- Demonstration of NAMs within WoE frameworks
- Continued development of non-animal approaches, including Defined Approaches (structured NAMs-based frameworks used to inform regulatory decisions), for more complex endpoints

Delivery in practice

- Curation of high-quality benchmark datasets
- Integration of mechanistic data within structured frameworks
- Publication of applied case studies

Data infrastructure is pivotal to regulatory and industry confidence

4

Limited access to secure, interoperable datasets continues to constrain model qualification and regulatory confidence.

What is needed

- Trusted, well-governed data-sharing frameworks
- Federated approaches to protect proprietary data
- Alignment with national infrastructure initiatives

Delivery in practice

- Cross-sector data-sharing consortia
- Neutral governance enabling secure collaboration and consensus building
- Scalable models for pre-competitive data-sharing

International alignment and capability are key to successful implementation

5

Global regulatory alignment and workforce capability are critical to ensuring that non-animal approaches and their data are used, accepted and applied consistently.

What is needed

- Alignment with international frameworks and guidelines (OECD, ICH, VICH) to support consistent evidential standards and regulatory expectations
- Structured professional development in NAMs interpretation
- Clear frameworks for artificial intelligence (AI) and mechanistic modelling

Delivery in practice

- Participation in international scientific collaboration
- Targeted training and technical workshops
- Cross-sector and cross-agency knowledge exchange

Priority action for the UK Government and partners

The following actions represent priority steps to support effective delivery of the UK Government strategy.

They are grouped by stakeholder to enable a coordinated implementation across the UK government, regulators and industry.

For the DSIT and the Home Office

Priority actions

1. Establish a distributed leadership model for non-animal approaches across regulatory bodies, with sustained cross-sector collaboration.
2. Define and fund multi-year key performance indicators (KPI) baseline assessments.
3. Publish annual budgets for validation studies.
4. Publish regular updates on accepted non-animal approaches and priority areas for further development.
5. Establish governance frameworks for national data initiatives.
6. Develop a national framework for NAMs skills development and training.

For the UK Centre for the Validation of Alternative Methods (UKCVAM) - once established

Priority actions

1. Establish clear processes for engagement on evidential standards.
2. Develop performance standards frameworks alongside validation pathways.
3. Implement CoU validation sandbox approaches with transparent evaluation frameworks.
4. Provide guidance on proportional evidential expectations.
5. Curate a catalogue of NAMs with defined contexts of use and performance assessments to promote wider adoption.

For industry and scientific partners

Priority actions

1. Co-publish frameworks for assembling NAM evidence within regulatory submissions.
2. Develop and share benchmark datasets and case studies.
3. Participate in structured data-sharing collaborations.
4. Contribute to international harmonisation and expert review frameworks.



Introduction



In November 2025, the UK Government released its Replacing Animals in Science strategy, a landmark step in accelerating the development and uptake of alternative methods to animal testing.

The UK Government strategy confirms a commitment to work with scientists and industry to phase out the use of animals in science where reliable alternatives exist.

Implementation arrives at a critical point for the UK life sciences sector. The UK alternative technology market is projected to reach £2.5 billion by 2026.³ At the same time, safety assessment responsibilities span multiple departments and regulatory bodies, creating coordination challenges that require structured collaboration.

Significant attention is placed on the development and uptake of new non-animal approaches. The ultimate measure of success will be the systematic phase-out of redundant animal testing and a demonstrable reduction in animal use.

As the UK Government strategy moves from publication to delivery, the next phase will benefit from existing experience. This includes organisations already applying and promoting validated non-animal approaches in practice.

Lhasa prepared this white paper as a collaborative effort, bringing together insights from an industry roundtable held in February 2026 to support the transition from roadmap to implementation. Drawing on practical experience across sectors, it explores how regulatory confidence, validation frameworks and data infrastructure impact the adoption of NAMs.

Leveraging non-animal approaches in discovery and regulatory research

“It seems to me that it is easier to apply these methods across agrochemicals and cosmetics than it is for pharmaceuticals at this stage.

Dr Lindsey Parkinson, Director of Drug Development and Regulatory Strategy, Labcorp

The UK Government defines alternative methods as those that can replace animals in certain circumstances. Industry roundtable participants emphasised that this framing does not fully capture the proactive value and scope of non-animal approaches within industrial discovery pipelines.

Application of non-animal approaches (including NAMs) varies, with certain industries already achieving high-quality safety decisions using non-animal approaches. Agrochemical and cosmetic sectors have integrated non-animal approaches into routine safety assessment under defined exposure contexts. Pharmaceutical development presents additional complexity due to systemic exposure and clinical risk thresholds.

“There are a lot of NAMs already deployed within industry primarily to support pipeline development decision-making rather than for regulated decisions.”

Dr Anthony Lynch, Head of Genetic & Investigative Toxicology, GSK

NAMs already contribute significantly to internal decision-making, candidate selection and risk characterisation. This contribution is often under-represented in formal regulatory narratives.

NAMs contribute to more mechanistic, human-relevant safety assessments and support management of scientific uncertainty. Participants emphasised the importance of recognising the practical value already delivered within industrial pipelines.

“The cosmetic sector is a really good example of where you can make very high-quality safety decisions now without the use of animals, because the context of the exposure is very different.”

Dr Steve Gutsell, Head of Regulatory Science, Unilever

A growing number of non-animal approaches are now incorporated within OECD Guidelines (GL), including OECD GL 497⁴ on Defined Approaches for Skin Sensitisation, which combines *in chemico*, *in vitro* and *in silico* methods. The ICH M7(R2) guideline mandates the use of two complementary *in silico* approaches to support the identification and categorisation of mutagenic impurities without animal-based testing.⁵ These precedents demonstrate that structured regulatory frameworks enable proportionate adoption of non-animal approaches.

However, in some cases, animal studies continue to be conducted despite the availability of scientifically valid non-animal approaches, due to legacy regulatory requirements embedded within sector-specific legislation. This challenge is well-documented, for example through the Cruelty Free International, Replace Animal Tests (RAT) List, which identifies areas of animal use that are scientifically ready for replacement but remain embedded in regulatory frameworks.⁶

At the same time, the continued development of new non-animal approaches, particularly for complex endpoints, remains essential to the long-term delivery of the UK Government strategy.

Table 1: Alignment of UK Government strategic objectives with industry needs

UK Government objective	Industry perspective and need	Lhasa Limited alignment
Acceleration of replacement	Development of non-animal approaches alongside removal of redundant animal tests from regulatory frameworks.	<i>In silico</i> tools like Derek Nexus and Sarah Nexus support the replacement of <i>in vivo</i> mutagenicity assays. ⁷
Equal or better outcomes	Benchmarking against human-relevant data rather than legacy animal bioassays.	Development of human-relevant, mechanistic models informed by adverse outcome pathway (AOP) frameworks. ⁸
Driving private investment	Regulatory certainty to reduce investment risk.	Pre-competitive scientific collaboration and international partnerships (e.g. eTOX ⁹ , eTRANSAFE ¹⁰ , see table 3).
Improving regulatory confidence	Greater clarity on evidential standards, qualification processes, and their interpretation.	Active contribution to ICH guidelines, OECD technical working groups and World Health Organisation (WHO) guidance. ²
Unlocking value from data	Access to curated, structured legacy and mechanistic datasets.	Established frameworks and 40 years of experience as a trusted partner for proprietary data-sharing. ²

Table 1 illustrates how UK Government strategy objectives translate into key practical industry needs for implementation, as noted by roundtable participants, including regulatory certainty, proportionate evidential expectations and improved benchmarking against human-relevant data.

The long-standing expertise of Lhasa within *in silico* modelling, data stewardship and international scientific collaboration directly aligns with these outcomes. Prioritising long-term scientific value over short-term efficiency will strengthen value-based safety assessment across life sciences sectors.

Initiatives such as the Preclinical Translational Models Hub are expected to support the development and translation of non-animal approaches into regulatory application, representing a potential mechanism for delivery of the UK Government strategy.

Validation and qualification: bridging regulatory expectations and industry adoption

Adoption of non-animal approaches is strengthened where clear expectations exist. These expectations must be shared between method developers and regulatory assessors. Participants highlighted the need for greater clarity on evidential criteria for qualified models to prevent duplication and avoidable testing.

Validation demonstrates that a method is reproducible and relevant for a specific purpose, while qualification establishes that it is fit for a defined CoU within a regulatory framework.¹¹

Participants noted that assessment of non-animal approaches is sometimes framed in terms of direct, one-to-one replacement of an animal study. This can narrow consideration of how mechanistic, *in silico* models and integrated data streams contribute within a defined CoU.⁸

“Context of use is really important – regulators need to be able to understand what decisions a method is intended to support, and at what level of risk. Regulatory confidence comes from seeing methods evaluated proportionately, within a clearly defined context, rather than expecting direct one-to-one replacement of animal studies in all cases.”

Dr Fiona Sewell, Head of Toxicology, NC3Rs

Building regulatory familiarity with emerging data types is central to adoption. Clear qualification frameworks, structured review mechanisms and transparent evidential expectations reduce uncertainty for both developers and assessors. Open communication throughout regulatory submission timelines can further support confidence in the application.

Bodies such as UKCVAM, once established, will play an important role in supporting the evaluation and acceptance of non-animal approaches within regulatory frameworks.

Participants also reflected on the varying maturity of non-animal approaches across endpoints, as illustrated below:

Table 2: UK Government-defined three baskets of method maturity - industry interpretation

Basket category	Maturity description	Specific endpoints and example approaches
Basket 1: ready now	Validated methods suitable for immediate integration.	• Skin and eye irritation (<i>in vitro</i> assays) • Skin sensitisation (Defined Approaches) • Pyrogenicity (<i>in vitro</i> methods)
Basket 2: nearing readiness	Approaches undergoing benchmarking against species-relevant data rather than animal legacy bioassays.	• Aquatic toxicity (e.g. fish toxicity alternatives) • Genotoxicity (e.g. micronucleus/comet assays, error corrected sequencing, human 3D models)
Basket 3: future goal	Complex endpoints requiring further research and development (R&D).	• Endocrine disruption • Chronic toxicity • Cholestasis • Complex biologics (e.g. antibody–drug conjugates).



Assays such as ToxTracker^{®12}, an *in vitro* genotoxicity method, have generated substantial mechanistic and performance data across multiple sectors, yet remain within extended international validation processes. This reflects the structured and rigorous nature of OECD validation processes, which are necessarily methodical and require time to support confident regulatory application.

“Industry routinely generates additional studies and scientific argumentation to support safety assessment decisions beyond what is formally required. Too often, that broader evidence base is not reflected in regulatory assessments.”

Dr Eva Lessmann, Technical Team (Genetic Toxicology), Syngenta

Participants highlighted that, in parallel with formal validation, robust scientific argumentation grounded in mechanistic understanding and structured WoE should be more consistently incorporated into regulatory consideration.

In this context, neutral scientific stewards play an important role in convening data, curating benchmark datasets and supporting transparent interpretation and communication of evidential standards.

By aggregating high-quality datasets from *in vitro* methods and existing *in vivo* studies, supported by structured expert review, Lhasa enables clearer articulation of scientific validity beyond reliance on historical bioassays alone.

However, reliance on legacy *in vivo* datasets, often generated under older study designs, can limit assessment of newer, mechanistic and human-relevant approaches.

Modern benchmarking approaches should therefore incorporate well-characterised contemporary datasets alongside legacy *in vivo* data, enabling proportionate and scientifically grounded comparison.⁸

Supporting the application of non-animal approaches across discovery and regulatory decision-making will encourage innovation and more confident safety assessments.

“
The elephant in the room is we don’t have the regulatory clarity on what those criteria are for an accepted qualified model [...] until we get some steer on that, we’re all working a little bit in the dark.

Senior scientific leader, pharmaceutical sector

“
Studies that have been done within the last 10 to 15 years [...] will be a more reliable benchmark against which to compare the performance of a new test.

Dr David Kirkland, Genetic Toxicologist Consultant, Kirkland Consulting

Strengthening UK data infrastructure and stewardship

“
The UK already possesses strong experience in shared data stewardship [...] Lhasa is perfectly placed to do that data sharing and those wide compound sets are really what we need to qualify these models.

Senior scientific leader, pharmaceutical sector

Strengthening clarity around qualification principles, benchmarking standards and CoU application must be supported by secure, well-governed data infrastructure. Model qualification and regulatory confidence are fundamentally data dependent.

Realising the potential of initiatives such as the Preclinical Translational Models Hub depends on access to secure, interoperable and well-governed data.

The UK is well-positioned in this respect. It hosts the largest data market in Europe and ranks as the third largest venture capital market globally³. This position is reinforced by the Government’s £600 million investment in the Health Data Research Service (HDRS), designed to unlock the value of national data assets and position the UK as a hub for life sciences innovation.¹³

Secure, well-governed data-sharing frameworks enable organisations to contribute sensitive datasets within a neutral environment. As an independent charity, Lhasa supports this model by enabling shared data to advance scientific understanding and regulatory application rather than commercial gain.

Access to high-quality data for academia remains a parallel priority.

Early-stage NAM development depends on foundational datasets, yet traditional funding mechanisms often prioritise direct replacement metrics over long-term capability building.

“If you’re really serious about engaging academia, funding remains a challenge, as criteria often require direct animal replacement metrics.”

Dr Steven Enoch, Academic and Computational Toxicologist, Liverpool John Moores University

Through provision of scientific software and curated datasets to academic partners on preferential terms, Lhasa supports training and early-stage model development, strengthening the next generation of toxicologists and data scientists.

A long-standing example is the Lhasa Carcinogenicity Database (LCDB), a searchable repository of chronic-exposure carcinogenicity studies covering 1,771 chemicals.¹⁴

The LCDB builds upon the Carcinogenic Potency Database (CPDB) developed between 1980 and 2005 by Lois Swirsky Gold and colleagues, ensuring that legacy public-domain data remains structured, accessible and scientifically robust.¹⁵

Table 3: Lhasa Limited data-sharing initiatives and scientific impact

	Initiative	Objective	Key scientific/regulatory outcome
Established collaborative initiatives	eTOX Est. 2010	Preclinical toxicology sharing	Integration of legacy studies into a predictive database. ⁸
	eTRANSAFE Est. 2017	Translational safety data-sharing	Improved cross-species and cross-compound interpretation, supporting approaches such as virtual control groups to reduce animal use. ⁹
Lhasa-led data-sharing initiatives	Lhasa data sharing intermediaries Est. 2006	Facilitation of pre-competitive data-sharing	Foundation for structured, secure multi-partner data collaboration.
	Lhasa Excipients data sharing initiative Est. 2008	Formulation safety	Structured data sharing on the tolerability of excipient formulations.
	LCDB Est. 2016	Public carcinogenicity data access	Maintenance and enhancement of a trusted reference dataset. ¹⁴
	Lhasa AI/PDE data sharing initiative Est. 2017	Compound-specific exposure limits	Harmonisation of exposure limits for commonly used materials.
	Federated learning consortium Est. 2019	Privacy-preserving (Q)SAR modelling	Model improvement without direct data transfer. ¹⁶
	Lhasa Complex Nitrosamines data sharing initiative Est. 2021	Impurity risk assessment	Sharing <i>in vitro</i> and <i>in vivo</i> mutagenicity data to reduce duplicate testing.

The Lhasa data-sharing model provides a practical framework aligned with the objectives of the proposed Preclinical Translational Models Hub. Acting as an independent data steward, Lhasa manages and maintains collaborative consortia that transform siloed proprietary data into structured scientific knowledge.

The initiatives in *table 3* illustrate how collaborative and Lhasa-led data-sharing models support regulatory and scientific challenges. This includes major European pre-competitive data-sharing initiatives such as eTOX⁸ and eTRANSAFE⁹, demonstrating the value of collaborative toxicology data integration.

Together, these initiatives demonstrate that secure, cross-sector and cross-agency data collaboration can scale while maintaining confidentiality and scientific integrity.

Case study: Optimising mutagenic impurity assessment through data-sharing

~90%
faster
read-across
evaluation

6x
growth in global
data-sharing
consortia
since 2020

35+
organisations
sharing
data

~30%
Derek Nexus
knowledge base
from shared
data

The identification of widespread nitrosamine contamination in 2018 exposed structural limitations in impurity risk assessment frameworks and created significant regulatory and industrial pressure.¹⁷ The need to determine acceptable intake limits for novel nitrosamines required rapid integration of mutagenicity data, understanding of risk of formation and read-across reasoning under ICH M7 (R2).⁵

In response, Lhasa established the Nitrites Data Sharing Initiative in 2020, followed by the Complex Nitrosamines Data Sharing Initiative in 2021. These initiatives were designed to address both formation risk within drug products and mutagenic potential associated with drug substances, supporting more structured and proportionate assessment of nitrosamine risk.²

The consortia include more than 35 organisations sharing analytical data and *in vitro* and *in vivo* mutagenicity data within secure governance frameworks.² This collaborative model reduces duplicate testing, strengthens read-across strategies and supports more defensible surrogate selection for mutagenic potential.

The integration of curated mutagenicity data into *in silico* workflows has significantly improved efficiency in nitrosamine risk assessment.

Automated read-across (RAX) frameworks reduce the time needed for RAX evaluation by around 90% compared to manual methods, supporting more consistent and efficient decision-making. Lhasa software solution, Acrostic, streamlines this process by embedding curated datasets within the assessment workflow, enabling consistent RAX reasoning and structured scientific documentation.²

Through collaboration with members, approximately 30% of the Derek Nexus knowledge base is derived from proprietary data shared through cross-sector collaboration.² This illustrates how pre-competitive data-sharing can generate valuable insight while preserving confidentiality, strengthening predictive performance and scientific integrity. The scientific outputs from these initiatives have informed regulatory guidance internationally, including adoption by Health Canada and WHO in the assessment and control of nitrosamine impurities.^{27 28}

Implications for national implementation

This case study illustrates how neutral data stewardship, combined with modelling and structured *in silico* integration, can accelerate scientific responses to emerging regulatory challenges.

The collaborative infrastructure developed through these initiatives reflects the same principles underpinning the proposed Preclinical Translational Models Hub, including secure data-sharing, cross-sector collaboration and translation of data into regulatory application.

Operational experience, governance frameworks and technical capability are already well established through these initiatives. However, wider implementation across the UK ecosystem will require continued investment in the development, validation and regulatory integration of non-animal approaches.

Realising this potential will depend on aligning infrastructure with continued development of scientific capability and confidence.

Applying scientific best practice in regulatory contexts

Through consortium-driven research and peer-reviewed publications, Lhasa contributes to the development of best practice approaches that support the regulatory application of non-animal approaches.

These publications translate complex scientific methodologies into structured, decision-ready frameworks that enable industry to meet regulatory data requirements.

In several cases, this work has informed how regulatory guidance is interpreted and applied in practice, supporting consistent, evidence-based decision-making across regulators and industry.

As regulatory guidance is not always updated at the pace of scientific development, these frameworks provide a practical bridge between emerging methodologies and their application within existing regulatory structures.

The examples in *Table 4* and *Table 5* illustrate how Lhasa-led scientific work supports regulatory implementation in practice:

Table 4: Lhasa best practice publications

Regulatory context	Importance to implementation	Practical contribution
ICH M7 expert review	Establishing best practice in the application of expert review of mutagenicity under ICH M7 ¹⁸	Sets out criteria, documentation and WoE principles for applying expert judgement to (Q)SAR predictions in regulatory submissions, supporting both submitter and assessor.
ICH M7 Option 4 control strategies	A consortium-driven framework to guide the implementation of ICH M7 Option 4 control strategies ¹⁹	Provides a structured, industry-led framework for implementing Option 4 control strategies, translating regulatory guidance into consistent, defensible practice.
Nitrosamine read-across and surrogate selection	Establishing best practice for N-nitrosamine read-across and surrogate selection ²⁰	Defines criteria and methodology for applying read-across and selecting surrogates in nitrosamine risk assessment, supporting consistent and scientifically defensible regulatory submissions.

Table 5: Lhasa publications cited in regulatory guidance

Regulatory guidance	Issuing body	Publication or Lhasa tool	Impact
ICH M7 Q&A, Questions and Answers on the ICH M7 Guideline	EMA/ICH (2020) ²¹	Barber et al. (2017) ¹⁸	Supports consistent industry implementation of control strategies across international submissions.
Carcinogenic Potency Categorisation Approach (CPCA) for N-nitrosamines	EMA (2023) ²² FDA (2024) ²³	Cross & Ponting (2021) ²⁴ Thomas et al. (2022) ²⁵ Ponting et al. (2022) ²⁶ LCDB (Lhasa) ¹⁴	Directly underpins the structural scoring framework used to assign acceptable intake limits for Nitrosamine Drug Substance-Related Impurities, adopted internationally by multiple drug regulatory authorities.
Guidance on nitrosamine impurities in pharmaceutical products	WHO (2025) ²⁷ Health Canada (2023) ²⁸	Boetzel et al. (2023) ²⁹	Supports formulation-level, nitrosamine risk assessment across global and national regulatory frameworks.
Test Guideline No. 497: Defined Approaches on Skin Sensitisation	OECD GL 497 ⁴	Derek Nexus (Lhasa) ⁷	A validated tool within defined approaches for skin sensitisation, directly supports replacement of animal testing in regulatory submissions globally.

“
Over the past decade, Lhasa has worked at the intersection of science and regulation. Our science has shaped the frameworks regulators now rely upon, and our best practice papers have defined the standards by which expert review makes regulatory submissions defensible.

Dr Chris Barber
CEO, Lhasa Limited

Together, examples from *Table 4* and *Table 5* demonstrate how collaborative scientific development can support the generation of data, and the consistent application of regulatory science in practice.

Lhasa supports chemical safety assessment across over 570 member organisations globally spanning the pharmaceutical, agrochemical and cosmetics sectors, including the top 20 global pharmaceutical companies.² This level of adoption demonstrates the scalability of a neutral data-sharing model and its relevance to regulatory and industrial application.

Taken together, these structures illustrate that the governance models, technical infrastructure and collaborative mechanisms required for national data stewardship are already operating within the UK ecosystem. The opportunity is to align and integrate these capabilities to support delivery of the UK Government strategy.

Developing scientific capability and confidence

Successful implementation of the UK Government strategy depends on both technical infrastructure and sustained development of scientific capability across regulators, industry, academia and the wider scientific community.

Participants emphasised that increasing use of mechanistic data, *in silico* modelling and AI requires assessors to interpret new types of evidence within established regulatory frameworks.

Building confidence in these approaches requires structured professional development and consistent opportunities for technical exchange.

Long-term funding for validation studies remains uneven across departments. Greater clarity on roles and responsibilities within the validation landscape, including the remit of bodies such as UKCVAM, would support more coordinated development and regulatory acceptance of *in silico* approaches.



Table 6: Priority skill and knowledge areas to support adoption of non-animal approaches

Skill/knowledge area	Publication	Practical contribution
Expert review	Required for confident regulatory submissions.	Continued and expanded workshops on QSAR application and best practice.
AI suitability	Required to build trust in model outputs and algorithmic approaches.	Joint publication on criteria for AI suitability.
AOP framework	Provides mechanistic context linking molecular events to adverse outcomes.	Integrating AOP software into academic training. ⁸
Collaboration	Breaks down sector silos, supporting consistent interpretation and regulatory familiarity.	Development of a national framework for NAMs skills development, supporting joint posts and secondments.

Table 6 highlights priority skill and knowledge areas to support the adoption of non-animal approaches, alongside practical actions to build capability across sectors. Existing training initiatives demonstrate the value of hands-on technical engagement.

Lhasa facilitates cross-sector scientific exchange through collaborative technical forums focused on emerging regulatory challenges. Recent initiatives have included meetings with IPEC Europe³⁰ on nitrosamine risk assessment in excipients, alongside participation in international expert forums such as the Industrial Genotoxicology Group (IGG).³¹ These forums support shared interpretation of evolving scientific and regulatory expectations whilst demonstrating the value of sustained technical engagement across regulators, industry and scientific experts.

Structured professional exchange and targeted training help build shared understanding across sectors and strengthen the scientific foundations required for the adoption of new methodologies.

A national skills framework would further support this objective. It would enable early-career scientists, regulators and industry experts to develop practical expertise in emerging safety assessment approaches, building on existing cross-sector skills initiatives.

Training is essential to ensure that *in silico* approaches are not perceived as ‘black boxes’, but as transparent, scientifically interpretable tools that can be confidently applied in regulatory decision-making.

“
I attended the British Toxicology Society training in QSAR [...] held at Lhasa and I found that incredibly valuable.

Dr Charlie Stevenson
Senior Chemicals Regulatory Advisor
CFI

Delivery of UK Government strategy in practice

How scientific capability, data and collaboration translate policy into implementation.



UK Government objectives	Lhasa scientific and operational capability	Lhasa evidence of delivery
1 Accelerate replacement of animal testing	<i>In silico</i> tools ⁷ AcroStic · Derek Nexus · Kaptis · Meteor · Mirabilis · Sarah Nexus · Zeneth	ICH M7 requires two <i>in silico</i> approaches - Lhasa tools used across top 20 global pharmaceutical organisations. ²
2 Achieve equal or improved safety outcomes	Regulatory best practice Peer-reviewed frameworks applied in ICH M7(R2) and EMA/FDA guidance.	4 Lhasa publications cited directly in regulatory guidance.
3 Drive innovation and investment	Pre-competitive collaboration Members share sensitive data under neutral, not-for-profit governance.	570+ member organisations contributing data and expertise through consortia
4 Improve regulatory confidence and acceptance	Regulatory application frameworks Expert review and read-across approaches applied in regulatory contexts.	RAX evaluation time reduced by up to ~90% and used by industry and regulators across ICH M7(R2) submissions.
5 Enable data infrastructure and partnerships	Data sharing at scale 7 active data sharing initiatives; LCDB carcinogenicity database; federated models.	35+ organisations in nitrosamines consortia and ~30% of Derek Nexus knowledge base from member data.
6 Position the UK as a global leader	Global scientific contribution Active input to ICH, OECD and international working groups.	Lhasa science informs the application of OECD GL 497 ⁴ , ICH M7(R2) and the British Toxicology Society (BTS) training programme.

The scientific expertise, data and collaborative infrastructure required to deliver the UK Government strategy are already established, with the opportunity now to align and scale these capabilities.

Delivering the UK Government strategy for non-animal methods: next steps

UK scientific expertise shaping regulatory practice and industry uptake

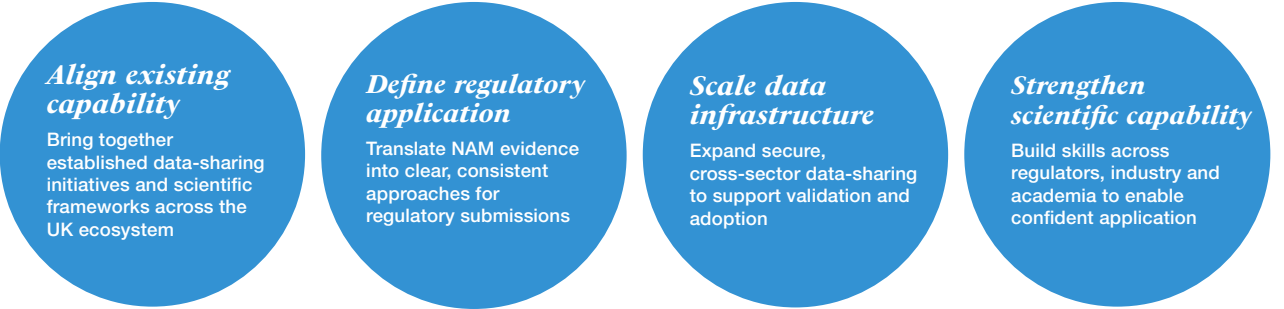
The UK Government does not need to build delivery from first principles. Established scientific capability, data infrastructure and collaborative networks already provide a strong foundation for implementation.

Basket 1: ready now	Basket 2: nearing readiness	Basket 3: future goal
Validated approaches already supporting regulatory decisions and industry workflows - Skin and eye irritation (<i>in vitro</i> assays) - Skin sensitisation (Defined Approaches) - Pyrogenicity (<i>in vitro</i> methods)	Methods in active industry evaluation requiring targeted validation and standardisation - Aquatic toxicity (e.g. fish toxicity alternatives) - Genotoxicity (e.g. micronucleus/comet assays, 3D models)	Complex endpoints with limited current industry application, requiring further development - Endocrine disruption - Chronic toxicity - Cholestasis - Complex biologics (e.g. antibody–drug conjugates (ADCs))

Lhasa evidence in practice		
- Lhasa solutions Derek Nexus and Sarah Nexus⁷ in use for ICH M7(R2) mutagenicity assessments across industry. - Best practice publications provide the evidential framework for regulatory submissions.	- Consortia generating shared datasets to accelerate qualification of emerging methods. - Lhasa proposes extending best practice model to generate the peer-reviewed evidential standards.	- LCDB carcinogenicity database¹⁴ and consortia provide the data infrastructure for future model development. - As a not-for-profit, the Lhasa neutral governance enables pre-competitive industry collaboration.

Translating priorities into delivery

These actions reflect the priorities set out in the UK Government strategy and demonstrate how they can be delivered in practice:



The role of Lhasa

Lhasa enables cross-sector collaboration between industry, regulators and academia, providing a neutral environment where scientific data, expertise and best practice can be shared with confidence.

Through established consortia, peer-reviewed publications and regulatory-aligned frameworks, Lhasa supports industry in applying new scientific approaches within regulatory submissions and decision-making.

This model allows industry to work collectively on shared scientific challenges, generating the data, evidence and frameworks required to support regulatory acceptance and practical implementation of NAMs.

Conclusion



The UK Government publication of Replacing Animals in Science represents a significant step toward a more predictive and mechanistic future for UK life sciences, with potential benefits for public health, environmental protection and scientific innovation.

The UK Government strategy establishes a clear commitment to accelerating development and uptake of non-animal methods where reliable alternatives exist.¹

Successful delivery will depend on alignment between regulatory frameworks, scientific capability and secure data infrastructure. The UK already has established data-sharing models, scientific expertise and collaborative frameworks that provide a strong foundation for this transition.

Roundtable participants highlighted several practical priorities that will strengthen implementation: proportionate validation and qualification through CoU, improved benchmarking against contemporary datasets, secure data stewardship and sustained development of scientific capability across regulators, industry, academia and the wider scientific community. Together, these elements support more consistent interpretation of evidence, reduce uncertainty in regulatory decision-making and enable more efficient adoption of non-animal approaches.

The UK is well positioned to demonstrate leadership by integrating these capabilities within the delivery of the UK Government strategy. By coordinating existing expertise, strengthening collaboration and enabling proportionate regulatory evaluation of non-animal evidence, the UK can support a transition toward more mechanistic and human-relevant approaches to safety assessment.

Lhasa plays a central role within the UK ecosystem, bringing together industry, regulators, academia and wider stakeholders through established scientific collaboration and neutral data stewardship.

The roundtable process reflects only the beginning of this convening role. Through its ability to integrate data, *in silico* methodologies and emerging approaches, including artificial intelligence, Lhasa is already enabling the scientific and regulatory foundations required for adoption of non-animal approaches.

Continued engagement with the UK Government, regulators and stakeholders will be essential to ensure that industry insight, scientific expertise and collaborative models are clearly represented and effectively integrated within delivery of the UK Government strategy.

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