

Request for Proposal: A Review of the State-of-Play and Future Trends regarding the development of Governance Frameworks Applicable to Emerging Technologies

1. RFP Background

Science is essential to solving the world's health challenges. This is why supporting bold & creative research across a wide range of disciplines to discover more about life, health and wellbeing and open up unimagined possibilities for the future has remained at the core of [Wellcome](#)'s mission since 1936.

Wellcome is spending more money than ever before supporting people and places to undertake curiosity-driven research. Our Discovery Research Portfolio is global and diverse, with

- around 1500 active awards worth £3.2bn across 58 countries;
- major investments in areas such as genetics and genomics; cell biology development and physiology; brain and behavioural sciences; molecular mechanisms; immune system in health and disease; pathogen, biology and disease transmission; population and public health; and social sciences and humanities.

In the long-term, Wellcome remains committed to supporting bold science, with a total of £16bn to be spent over the next ten years.

In parallel, Wellcome works with a wide range of partners around the world, including governments, research funders, non-governmental organisations, charities, community organisations and the private sector, influencing and informing policy to help create the conditions for science to thrive globally and improve human health.

2. RFP Specification

Emerging science and technologies have the potential to improve our lives in many ways. Yet, disruptive technologies are neither without controversy nor risk. This is why it is important that their development is accompanied with an effective level of oversight, i.e. one that allows for researchers to continue learning, for technologies to reach their full potential quickly and safely, and for research organisations and their funders to proactively engage the public and maintain their trust.

Nevertheless, jurisdictions around the world often have very different views as to how emerging science should be overseen and so this often gives rise to a fragmented global regulatory picture. In some cases, legislative requirements may exist while in others technological development may take place under guidance and voluntary codes of practice developed by researchers and industry players.

To further complicate things, many of the technologies of interest to Wellcome depend on foundational digital infrastructure, which is itself governed and regulated differently in different jurisdictions. For example, foundational electronic health record and data exchange systems are critical for the deployment of AI in healthcare, for genomics research, and for longitudinal population studies. Policies that restrict how these foundational systems are developed can therefore indirectly affect how emerging technologies are researched and deployed.

In this context, the Policy Team is looking for a supplier to conduct a review of the state-of-play and future trends of the governance frameworks applicable to emerging technologies of particular interest to Wellcome, and their applications in a research context.

In more detail:

- Research disciplines and tools of particular interest to Wellcome include:
 - Human, animal and plant genomics – both from a perspective of increasing diversity of datasets as well as trends towards editing and synthesis of genomic data;
 - Human embryology – the study of early human cell biology with a view to developing new cures for congenital anomalies;
 - Organoids, particularly embryoids and brainoids – simple tissue-engineered cell-based in vitro models to allow for the study of disease and treatment pathways in real organs;
 - Neurotechnology (neural implants & brain-machine interfaces) - devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons;
 - Artificial Intelligence - particularly its application and use as a research tool;
 - Data platforms and longitudinal population studies – issues related to personal data collection, access and use.
- **Phase I** - For each of the research disciplines and tools outlined above, Suppliers should initially provide an overview of the state of play globally when it comes to investing in research, development and deployment of such technologies and tools. This may include identifying which geographies are receiving largest investments both in terms of numbers of research grants and/or total value of such research; where both industries utilising such technologies and tools, and the markets for such products, are based. On the basis of such findings, suppliers will make recommendations to Wellcome on a shortlist of a maximum of five jurisdictions for each of the technologies and tools above that should be investigated further in Phase II.
- **Phase II** – Governance frameworks in scope of this exercise include a) any laws or regulations, either in place or being debated, applicable in key jurisdictions shortlisted in Phase I; b) any ethical or self-regulatory frameworks created by industry bodies or the research community to operate within for the development of such technologies, applicable in key jurisdictions shortlisted in Phase I; c) any relevant global initiatives or discussions relating to the development of governing bodies or frameworks applicable to these technologies, which may include supranational bodies such as UN agencies, global fora such as G7 or G20 or civil society/community representatives; d) any laws, regulations, or governance frameworks that impact the digital infrastructure supporting research, development, and deployment of the disciplines and tools in focus (for example, longitudinal population studies, genomics,

and deployment of AI in healthcare all depend on robust electronic health record systems, and we would welcome an analysis of any policies that target these foundational systems but impact our target research areas).

At the end of the project, suppliers are expected to deliver a final report outlining its findings and key recommendations to Wellcome, no later than 28th July. In addition, suppliers will present the key findings of this report to Wellcome's staff.

Suppliers should use this section to fully understand Wellcome's requirements and to inform their response. Wellcome will be guided by the supplier as to what is a reasonable budget for this activity as we do not want limit ambition or innovation.

3. RFP timetable

#	Activity	Responsibility	Dates
1	RFP issued on Contract Opportunities webpage	Wellcome	25/09/2023
2	Submission of Expression of Interest and Supplier Q&A	Supplier	16/10/2023
3	Return of Supplier Q&A to Suppliers	Wellcome	23/10/2023
4	Submission of RFP Response (in line with requirements set out in section 5)	Supplier	2/11/2023
5	RFP Evaluation Period	Wellcome	6/11/2023 to 10/11/2023
6	Supplier Presentations	Supplier	13/11/2023 to 17/11/2023
7	Notification of Contract Award	Wellcome	End of November 2023
8	Contract Negotiation	Wellcome & Supplier	December 2023
9	Contract Start Date	Wellcome & Supplier	December 2023/January 2024

4. Response Format

The following headers support the timetable by providing further detail of the key steps.

Expression of Interest and Supplier Q&A

Suppliers are asked to submit a short expression of interest by e-mail to the Wellcome contact in accordance with the RFP timetable, which should contain the following information:

- Confirming whether you are / aren't intending on submitting a full proposal. Given the breadth of the work requested, suppliers may also submit at this stage, expressions of interest outlining partial or alternative proposals for dividing and delivering this work in stages.
- Ask any questions you have relating to this RFP
- Confirming whether you are submitting a proposal as a registered company or an individual
- If an organisation please provide registered name, address, and registration number

- A non-binding cost estimate as a single figure in GBP
- Outlining relevant subject matter knowledge and previous expertise in providing scientific and/or global regulatory issues

Prior to the submission of your full proposal to the RFP, Suppliers are provided the opportunity to submit any questions they have about the exercise and the activity. All questions will be collated, anonymised, answered and returned to all Suppliers who have submitted an expression of interest in the RFP process. Please make sure you ask all questions at this stage. Once Wellcome have responded to all questions if you have any additional questions after this deadline these will not be answered to ensure that this is a fair and equitable process.

Submitting an EOI is not a binding commitment to submit a full proposal should your organisational priorities change, you will not then be penalised for future opportunities.

Please note, if we have an overwhelming response, we may choose to use this EOI stage as a selective phase, this is at Wellcome's discretion.

RFP Response

Suppliers submitting a full proposal should cover the following areas in their response:

#	Question	Max words
1	Provide a short outline demonstrating your methodology in achieving the scope of the work.	750
2	Propose a delivery plan outlining project deliverables and timelines.	500
3	Outline the proposed project team with a brief description of their relevant experience.	500
4	Outline your approach to equity, diversity, and inclusion (EDI) in relation to your proposal for the project.	300
5	Provide a detailed budget including breakdown justifying the proposed costs to meet Wellcome's requirements. Please note that we do not provide maximum budget estimates, suppliers are encouraged to come in with a budget required for this work to be delivered effectively while also demonstrating value for money.	N/A
6	What makes you best placed to fulfil the requirements outlined in this RFP? This could include networks and previous experience, including experience of working with stakeholders and processes within the global health ecosystem. Please feel free to use any relevant case studies. Please also state whether you are planning to work with any third party in delivering certain parts of this work.	770
7	Outline any major risks and challenges you foresee with meeting Wellcome's requirements. Please include your mitigation strategies for these risk and challenges.	500

Evaluation Criteria

During the RFP evaluation period the evaluation panel will independently evaluate your proposal against the criteria outlined below. All scores will be collated, discussed and a decision will be agreed on who progresses to the next stage of the procurement exercise.

Criteria	Detail	%
Methodology	<p><i>Coverage:</i> How well are the desired focus areas (as outlined in the specification) covered in the proposed methodology address?</p> <p><i>Quality:</i> Is the proposed methodology aligned with our needs?</p> <p><i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results?</p>	30%
Experience	<p><i>Skills and Experience:</i> Does the supplier have the relevant skills, experience, and contextual understanding to deliver this work?</p>	30%
Delivery & Outputs	<p><i>Communication:</i> Is there a good plan for communicating with the Wellcome team?</p> <p><i>Delivery plan:</i> Is the proposed delivery plan appropriate and achievable?</p> <p><i>Feasibility:</i> How feasible is the delivery plan? Are there significant risks associated with the proposed timelines, and how well are they mitigated?</p>	20%
Budget	<p><i>Value for Money:</i> Is the proposed work within your budget and good value for money?</p>	10%
EDI	<p><i>Equity, Diversity & Inclusion:</i> Do they have EDI policies and are these being put into practice in the proposal?</p>	10%
Total:		100%

Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. This is the suppliers' opportunity to provide negotiation points on Wellcome's terms and conditions, we will not consider negotiations that are only raised after the contract has been awarded so as not to delay the contracting process. Please ensure you engage with a relevant legal contact if applicable. Contract feedback is to be incorporated into your proposal as an annex and in the following format;

Clause #	Issue	Proposed Solution/Comment

Suppliers submitting proposals as a registered company should review Wellcome's Standard terms and Conditions [document](#).

Individuals submitting proposals as a sole trader (not registered) should review this [document](#).

Individuals submitting proposals through their own personal services company please highlight this to the Wellcome contact immediately (see point 8 below).

Information Governance

Wellcome is committed to upholding data protection principles and protecting your information. The [Wellcome-Privacy-Statement-2023.pdf](#) explains how, and on what legal basis, we collect, store, and use personal information about you. This includes any information you provide in relation to this proposal.

Under [GDPR/Data Protection law](#), Wellcome must keep a record of all personal information it is processing (i.e., collecting, using, and sharing). This record will be made available to the Information Commissioner's Office upon request.

This is Wellcome's record of data processing activities which meets GDPR article 30 requirements.

Suppliers will be asked to complete the [TPSRA2](#) assessment before presentation stage to assess how you handle data.

5. About Wellcome

Wellcome improves health for everyone by funding research, leading policy and advocacy campaigns, and building global partnerships. Collaborative research that involves a diverse range of people from different fields of interest is key to progress in health science – and to achieving our aim of fostering a healthier, happier, world. We're taking on the biggest health challenges facing humanity – climate and health, infectious disease, and mental health – to find urgent solutions and accelerate preventions. Find out more about Wellcome and our work at: wellcome.org.

6. Prospective Suppliers Personnel - IR35 and Off Payroll Working Rules

Before the RFP response deadline, Prospective Suppliers must make the Wellcome Contact aware if they are intending to submit a proposal where the services will be provided by any individuals who are engaged by the Prospective Supplier via an intermediary i.e.

- Where the Prospective Supplier is an individual contracting through their own personal services company; or
- The Prospective Supplier is providing individuals engaged through intermediaries, for the purposes of the IR35 off-payroll working rules.

7. Equity, Diversity and Inclusion

Embracing equity, [diversity and inclusion](#) is fundamental to delivering our mission to improve health, and we are committed to cultivating a fair and healthy environment for the people who work here and those we work with. We want to cultivate an inclusive and diverse culture, and as we learn more about barriers that disadvantage certain groups from progressing in our workplace, we will remove them.

Wellcome takes equity, diversity and inclusion seriously, and we want to partner with suppliers who share our commitment. We may ask you questions related to D&I as part of our RFP processes.

8. Disability Confident

The Wellcome Trust is proud to be a Disability Confident Employer (DC Level 2) and we encourage all our partners and suppliers to do the same. More information about this can be found on the government website [Disability Confident employer scheme and guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/disability-confident-employer-scheme). Disability Confident is creating a movement of change, encouraging employers to think differently about disability and take action to improve how they recruit, retain and develop disabled people.

9. Accessibility

Wellcome is committed to ensuring that our RFP exercises are accessible to everyone. If you have a disability or a long term health condition, we can offer adjustments to the response format e.g. submitting your response in an alternate format. For support during the RFP exercise, contact the Wellcome Contact.

If, within the proposed outputs of this RFP exercise, specific adjustments are required by you or your team which incur additional cost then outline them clearly within your commercial response. Wellcome is committed to evaluating all proposals fairly and will ensure any proposed adjustment costs sit outside the commercial evaluation.

10. Independent Proposal

By submission of a proposal, prospective Suppliers warrant that the prices in the proposal have been arrived at independently, without consultation, communication, agreement or understanding for the purpose of restricting competition, as to any matter relating to such prices, with any other potential supplier or with any competitor.

11. Funding

For the avoidance of doubt, the output of this RFP exercise will be funded as a **Contract** and not as a Grant.

12. Costs Incurred by Prospective Suppliers

It should be noted that this document relates to a Request for Proposal only and not a firm commitment from Wellcome to enter into a contractual agreement. In addition, Wellcome will not be held responsible for any costs associated with the production of a response to this Request for Proposal.

13. Sustainability

Wellcome is committed to procuring sustainable, ethical and responsibly sourced materials, goods and services. This means Wellcome seeks to purchase goods and services that

minimise negative and enhance positive impacts on the environment and society locally, regionally and globally. To ensure Wellcome's business is conducted ethically and sustainably, we expect our suppliers, and their supply chains, to adhere to these principles in a responsible manner.

14. Wellcome Contact Details

The point of contact for this RFP exercise is indicated below:

Name:	Ignacio Vazquez
Pronouns:	He/him
Role:	Policy Lead
Email:	i.vazquez@wellcome.org