

Landscape analysis on machine learning tools and capabilities for drug and biologics development

Questions and Answers

#	Question	Wellcome Response
1	Wellcome has asked costings to factor in time for two senior academic consultants. Is Wellcome expecting this contribution to be factored in as part of the governance panel set up or is the supplier expected to bring on board academic consultants/partners and factor in their time into the proposal?	Separate. Though note the governance panel could be very simply comprised of the experts, the supplier, and internal Wellcome stakeholders with the experts paid to be part of the panel and for additional consultations.
2	What is the nature of the proposed governance panel's role in evaluation? What is Wellcome's expectation on what the panel would do in an evaluative capacity? Is this limited to quality assuring and evaluating the approach taken and outputs produced by the supplier?	The governance panel is simply to ensure alignment with Wellcome strategy and to ensure the methodology taken by the supplier is sensible. The panel may simply be the supplier, experts, and Wellcome stakeholders.
3	To what extent, in what manner, do you want to apply a lens of adoption, uptake or applications of these methods for drug development in low-resource settings?	We want to ensure that the analysis covers research in a way that is fair, equitable, and realistic. To that end the supplier will be expected to landscape existing work in LMICs and also to identify barriers that are particular to LMICs. Whilst the supplier is expected to expend resources on finding research in LMICs, this should not take up a significantly disproportionate amount of time (we note this will be such a barrier to uptake).

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4	In strategic questions #4 and #5 the terms “subject area experts” and “researcher community” are used. Can you provide a relevant definition for these terms?	By 'subject area experts' we mean any non-developer academics/researchers/industries. For example in that question we are interested in answering questions such as "are vaccine developers using cutting edge machine learning to develop vaccines?". By 'researcher community' we simply mean any community of researchers in a non-ML area or in an area of ML where cutting-edge research may not have filtered down to the community at large - for example, are there instances of cutting-edge ML methodology in journals that are not accessible because of a lack of tools or software? Or are there instances of methodology developed in LMICs that has not been recognised in HIC communities?
5	Is there an opportunity for co-branding the outcome of this exercise?	Yes. As with previous reports (e.g. https://cms.wellcome.org/sites/default/files/2022-01/climate-lps-landscaping-report.pdf) team descriptions will be given as well as affiliations. We welcome more hands-on collaborations with our branding team.
6	Do you have any Machine Learning use cases on drug discovery identified that you would want to include/validate during this engagement?	In short, yes. The supplier will be expected to work with Wellcome to 1) go through our existing portfolio of ML projects, we will be interested to know how these can be leveraged further in the future; and 2) interview members of our infectious disease and mental health teams to look into questions of particular strategic alignment, we have already begun compiling these. However this is only a part of

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		the project and otherwise we are open to a wide variety on use cases. The supplier will be expected to work with internal stakeholders to prioritise our interests.
7	What's the end goal of this exercise by Wellcome trust? Are you intending to publish a white paper or point of view on leveraging ML for drug discovery?	<p>The report will be published on the Wellcome website as with previous similar work https://wellcome.org/reports/combining-climate-and-health-data-challenges-and-opportunities-longitudinal-population</p> <p>. The end goal is for Wellcome to be able to make more targeted investments based on the findings in the report.</p>
8	We anticipate speaking to multiple scientific researchers and AI/ML experts in this space, will Wellcome trust work with us to identify these experts or it is our responsibility completely?	Mixed. We are compiling a list of experts/researchers in the space that we are aware of but the supplier will also be responsible for identifying further experts/researchers There should be no expectation that Wellcome will provide any names (or that the names we supply will be available) and similarly there is no expectation that the supplier must utilise the names we supply.
9	Broad applications of interest to the development pipeline: how would you prioritize your interest focus (e.g. applications to drug discovery over long-term follow up, etc.)?	The supplier will be expected to work with Wellcome to: 1) go through our existing portfolio of ML projects, we will be interested to know how these can be leveraged further in the future; and 2) interview members of our infectious disease and mental health teams to look into questions of particular strategic alignment, we have already begun compiling these. However this is only a part of the project and otherwise we are open to a wide variety on

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		use cases. The supplier will be expected to work with internal stakeholders to prioritise our interests.
10	Are we meant to cover all three of these therapeutic areas equally in the machine learning landscape or just focus on infectious disease?	We would expect the project to start with equal commitment to exploring the opportunities in mental health and infectious disease drug development. However, with progress it may be that priorities shift and a collaborative decision between Wellcome and the Supplier will be taken as to how to manage that.
11	“Outputs” : same questions on how you would prioritize	Prioritisation of outputs will be developed between the supplier and relevant stakeholders. The supplier is expected to use regular check-ins with Wellcome to help focus in/out of scope areas
12	What are the “barriers that prevent uptake of your funding” for you?	The supplier is expected to interview Wellcome stakeholders (and external parties that fund similar work) during the contract to comprehensively answer this question.
13	What do you mean by “ a committee of expert consultants ”? What is the mission / the objectives of such committee? (e.g. is it an “ML technology / opportunity evaluation committee” to help you decide on your funding allocation?)? How will this expert committee be involved with the landscaping work ?	The supplier is expected to demonstrate how they will utilise such a committee to ensure the report is as useful as possible. For example experts may be able to facilitate introductions to researchers in the field, to advise on areas of interest to landscape, to provide advice on

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		jargon or technical detail, etc. Note the supplier is not expected to tell Wellcome how to allocate funds.
14	What profiles are you looking for? How would you use them? (=mission)	This is for the supplier to decide.
15	Is their activity in the Expert Committee to provide direction and advice or is more expected from them?	Just direction and advice. The supplier is expected to demonstrate how they will utilise such a committee to ensure the report is as useful as possible.
16	Can you give us an example of similar “committee” which you have been using and for what goal? -and type of governance used	This is just an informal committee to help the supplier achieve its goals. The supplier is expected to demonstrate how they'd utilise such a committee.
17	History of ML approaches (question 1): What do you mean by “ auxiliary fields ”?	Any related fields where ML has been used and can demonstrate potential (or effectiveness) of ML.
18	Is this to indicate that you are looking to understand the impact of ML on primary research in those fields?	Yes, to inform areas that are of direct strategic interest.
19	How far / granular in the insights gathered are you expecting us to go in the analysis of the history of ML approaches to development?	We do not expect granular insights into the history of approaches. This report is to understand the current landscape and reasonable future developments. Our interest in history is about learning how ML has been used well or poorly in the past to inform future decisions.
20	Should each approach be analysed for success or failure?	The level of individual detail should be decided by the supplier, committee, and internal Wellcome stakeholders. The supplier is

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		expected to clearly articulate why some areas are deserving or more/less focus than others.
21	How would Wellcome define success or failure? Would this simply be marketed drugs would be success and mistargeting would be failure or would intermediate steps be defined?	The supplier is expected to interview Wellcome stakeholders during the contract to comprehensively answer this question.
22	If labelled as a failure, should the analysis be provided on whether or not there is any further utility in exploration along this path?	Yes. This would be classified as understanding 'barriers to uptake' (or barriers more generally).
23	Currently available tools " Open source vs. proprietary " (question 2): how would that drive your decision to fund or not?	Wellcome has historically engaged with both developers of open-source and proprietary (but made free for academic research) software. In essence, the licensing model would not solely determine any decision to fund (or not), although our expectations would obviously differ. This is an issue we would expect the supplier to explore in more detail during the landscaping.
24	Is there a strong preference for open-source or proprietary? Are their concerns about open-source tools involving security?	Misuse of software/research outputs is already covered in our application process, so whilst we are aware of and interested in this risk, we do not consider it a reason to avoid open-source software.
25	For proprietary tools, how much detail should be provided on terms of use, openness to partnership, etc.?	This will depend on how valuable the tool is deemed; something that would be determined through engagement with Wellcome and external partners.

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26	What level of development of tools are you interest in vs not? (Early research, validated/Proof of concept, pre-commercialized, marketed and applied tool)	We are happy to consider development of tools however the supplier will be expected to work with internal Wellcome stakeholders to identify at what stage is useful in the report and to Wellcome.
27	“Active players in ML”: what are your preferences and limitations in types of players you fund (in Academics: how early in research?; in Industry: how early in development of tools)?	This is a critical question we expect to collaboratively answer with the selected supplier.
28	We are not sure to understand your question #4 and intent: “ are subject area experts utilizing ML? ”	By 'subject area experts' we mean any non-developer academics/researchers/industries. For example, in that question we are interested in answering questions such as "are vaccine developers using cutting edge machine learning to develop vaccines?".
29	How do you define “subject area experts”? Should they be focused on the utility of ML in translating basic research into drug development targets or all along the drug development pathway?	By 'subject area experts' we mean any non-developer academics/researchers/industries. For example, in that question we are interested in answering questions such as "are vaccine developers using cutting edge machine learning to develop vaccines?". The supplier is expected to interview Wellcome stakeholders during the contract to comprehensively answer the second part of the question.

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30	Similarly in question 5: how do you define “ ML experts ”? – what are trying to understand with this question? How would the answer drive your opportunity funding activity?	An ML expert may be anyone who researchers or employs ML for drug development - it is down to the supplier to articulate how the term is defined for the purpose of the report and how experts are found and engaged. The supplier is expected to interview Wellcome stakeholders during the contract to comprehensively answer the second part of the question.
31	All along the clinical development pathway or restricted to the drug design process?	This is a critical question we expect to collaboratively answer with the selected supplier.
32	About question 6: What more can you tell us on the main axes of Wellcome’s strategy and current portfolio which could drive our investigation toward relevant ML technology development programs and players recommendations?	This information is not currently in the public domain. The supplier is expected to interview Wellcome stakeholders during the contract to comprehensively answer this question.
33	“How can Wellcome incentivize the industry to share cutting edge research” (question 7): what are the related challenges/hurdles you have met? what are you trying to achieve, ideally?	The supplier is expected to interview relevant stakeholders during the contract to comprehensively answer this question.
34	Is Wellcome only trying to encourage academic-industry research partnerships or hoping for more open unrestricted use of these tools?	The supplier is expected to interview relevant stakeholders during the contract to comprehensively answer this question.
35	Overall, what is the expected level of detail you need on the description and qualification of the ML tools, applications, and players? What is the key information needed for you to make funding decisions? What is nice-to-have information?	The supplier is expected to interview relevant stakeholders during the contract to comprehensively answer this question.

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36	Why is your interest in research and researchers based in LMICs ?	Wellcome's strategy focuses on benefitting communities that are most affected by escalating infectious disease, mental health issues, and climate change - this usually means that most of our funded research must have impact either globally or in LMICs.
37	What is the purpose for the allocation of funds for “ at least two senior academic consultants ”? Are these academic consultants included in the Expert Committee? Why two of them?	The supplier is expected to engage with experts to help guide the project and identify areas to investigate or to provide advice. They will form the expert committee (as well as anyone else you may identify). Two as it is unlikely one person can help landscape the entire field.
38	What type of “ final design ” support would you need from us on the report formatting by the Wellcome’s branding team? (How/to what audience will you communicate the report <u>before</u> and after such “final designing”?) So, what is expected in the “ internal report ” vs “ externally published report ” (type and level of information, analysis and recommendations)	Support with the branding team is likely to be minimal and will primarily focus on ensuring that you are happy with the design and that it represents your work clearly. You will also be expected to help the Wellcome branding team understand who the key stakeholders and audience of the report will be and how this might change the report (e.g. describing jargon and technical terms). The supplier will not be responsible for separating the internal and external reports, this will be handled by Wellcome staff who are able to redact required information.
39	Who at Wellcome will be part of the project operational team which Alcimed will interact with on a day-to-day/weekly basis? Who needs to be involved in an extended team (e.g. steering committee)?	You will meet regularly with one member of the DSH team. The wider committee may consist of more members of Wellcome staff from our mental health and infectious disease teams, though this will be discussed once the supplier is chosen.

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40	What does a successful project outcome mean to you for this project? How would the final deliverable look like?	Please see similar outputs here https://cms.wellcome.org/sites/default/files/2022-01/climate-lps-landscaping-report.pdf and here https://cms.wellcome.org/sites/default/files/2022-01/landscape-mapping-software-tools-CSID-modelling.pdf
41	How will you use the outputs of the landscape?	1) Internal Wellcome funders will use this report to identify areas of future targeted funding and to optimise chances of success for projects. 2) External funders may be able to act on findings that Wellcome cannot (out of strategy), will not (lack of expertise), or who could collaborate with Wellcome on larger investments. 3) Academics and industry may be able to action findings in the report (e.g. by advertising their own work more broadly or by identifying future research avenues)
42	What will be your next steps ?	These will depend on the report. We are hoping to use the report to identify future areas to research either by open calls or directed funding.
43	What will drive your next steps? / Where will you focus your efforts on? (e.g. which (research) organizations will you approach first?)	These will depend on the report. We are hoping to use the report to identify future areas to research either by open calls or directed funding.
44	Is the deadline of March 21st 2023 include the co-designing of the final report with Wellcome's Branding team? – if so, we would need to understand how long such phase usually take with your Branding team.	21 March 2023 is delivery of the final designed report. We anticipate design taking 1-2 weeks.

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45	Is there budget constraints we need to be aware of and work with when designing the proposal? (as a high level indication)	This is not being disclosed at this stage but will be told to suppliers who are invited to present (before the presentation). Suppliers will be judged on suitability of their budget.
46	What is the relative focus on 'Research' vs 'Development'? (this will have implications for use cases and opportunities)	The supplier will be expected to work with Wellcome to prioritise between the two. We are happy to consider both areas and there is no expectation for one to be given more focus than the other.
47	Do you have an incoming hypothesis on the area you want to focus and how you want to do it e.g. primarily small molecules, a particularly part of the value chain, a particular therapeutics area, a specific time period?	Wellcome as an organisation does not, but individual experts within the organisation may well have hypothesize, which we would expect the supplier to surface through interviews.
48	As we think about the opportunities for Wellcome, what is your perspective on the balance of enhancing existing tools vs new tools?	We are open to both opportunities however we would prefer any focus on existing tools to be primarily on barriers to uptake and how to lower these. For example in our CSID software call https://wellcome.org/news/develop-digital-tools-will-catalyse-next-generation-climate-sensitive-infectious-diseases we allowed enhancement of existing tools that could lead to increased uptake and application of tools, the same will be true here. Similarly, whilst we will fund methodology of foundational tools, our focus will still be on ensuring new tools are accessible and will have a high uptake.

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49	For external stakeholder/expert engagement, what is your goal for industry vs academia? Are you able to share any of the profiles you have selected / expect to involve?	We do not have a set ratio of industry: academia in mind but would expect the supplier to derive a sensible plan that is reflective of the landscape. For example, a panel of advisors solely in academia is unlikely to be able to help guide the consultant to commercially sensitive research in industry. We cannot share the profiles of anyone at the moment. Please also note the onus is on the supplier to find and secure experts.
50	What is the purpose of the governance evaluation structure? Is it consultative/advisory, or is it a decision making-body? What is the balance of academe vs industry?	The governance panel is simply to ensure alignment with Wellcome strategy and to ensure the methodology taken by the supplier is sensible. The panel may simply be the supplier, experts, and Wellcome stakeholders.
51	What is the process for signing off the final report - do you anticipate a "review" process by a subset of the expert board and a set of pre-agreed criteria to align on? (this will have implications for team set-up)	The final report (i.e. fully designed) will be formally signed off by Wellcome. The final content will be formally signed off by Wellcome and informally by the governance panel, this need not be a formal procedure as the expectation is that the content will have been sufficiently discussed with the panel in regular meetings.
52	The RFP indicates that the report should be finished by end of March 2023 at the latest - are there any other timelines / dates to bear in mind in the review process that might influence potentially finalizing the report earlier?	No (except for winter holidays). We are very happy for the report to be completed sooner and from previous experience we believe this could be as early as January 2023.
53	Based on our experience, we think we could do the piece of work in 2-3 months rather than the 5 months	We would not view it as a disadvantage - the timeline of the work will depend on the number of people undertaking it. However please note

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	proposed. Would you prefer a shorter timeline or would this be seen as a disadvantage?	that previous similar work has taken a minimum of 4 months, so we are likely to question this shorter timeline.
54	Pricing: What is your proposed budget for this piece of work	This is not being disclosed at this stage but will be told to suppliers who are invited to present (before the presentation). Suppliers will be judged on suitability of their budget.
55	For the expert committee, does Wellcome have a preferred structure in terms of expertise and other characteristics?	The supplier will be expected to design a committee that is able to help guide the project and create a comprehensive landscaping exercise. For example if you anticipate particular difficult in landscaping ML work in the Global South, then you may consider experts from this area - but this is not essential, especially as interviewed academics/industries may help form connections without the need for experts in the area. We have no D&I requirements for the committee.
56	Will Wellcome facilitate introductions to those specific experts that it would like to be included on this committee?	We are compiling a list of experts/researchers in the space that we are aware of, but the supplier will also be responsible for identifying further experts/researchers. There should be no expectation that Wellcome will provide any names (or that the names we supply will be available) and similarly there is no expectation that the supplier must utilise the names we supply. We will facilitate introductions to everyone on our list.
57	In terms of the date of delivery of the final deliverable (by 31st March) - is the final deliverable considered to	Final designed report.

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	be the final MS word document or the final designed report?	
58	While key areas of interest for Wellcome are mental health and infectious disease, do you want information on activity in other areas which is very far advanced, and which could have direct impact on these strategic areas of interest?	The supplier will be expected to meet with Wellcome staff to learn about our strategy and strategic interests. We are happy for the supplier to consider areas that are not directly related to infectious disease or mental health if there is a clear link or application of methodology (e.g. we are happy for the supplier to include advances in ML image segmentation/classification of medical scans as these could be applicable to neuroscience and mental health)
59	Would you like the scope of the research to be worldwide, or would you like us to particularly focus on any particular regions of the world /countries?	Worldwide. The supplier should also consider particular barriers that individual areas may face to uptake of ML. Note that Wellcome's strategy focus on benefitting communities that are most affected by escalating infectious disease, mental health issues, and climate change - this usually means that most of our funded research must have impact either globally or in LMICs. Therefore it would be unwise to spend too much time focusing on barriers to uptake in HICs such as US or UK.
60	In addition to looking more broadly at the ML/AI landscape, are there particular areas that you would like us to examine more closely (for example, chronic/infectious/rare disease, mental health, AMR, 'one health')	The supplier will be expected to work with Wellcome to: 1) go through our existing portfolio of ML projects, we will be interested to know how these can be leveraged further in the future; and 2) interview members of our infectious disease and mental health teams to look into questions of particular strategic

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		alignment, we have already begun compiling these. However, this is only a part of the project and otherwise we are open to a wide variety of areas.
61	Our experience from working with ML/AI companies (and drug development companies) has uncovered that some of the ethical and societal aspects of ML/AI in drug discovery face similar challenges to the use of ML/AI, robotics, and automation more broadly in society, such as data governance issues. Would you like to include the work of these broader stakeholders (e.g., Global Partnership in Artificial Alliance) or ensure the scope is solely in the biological target /drug discovery field.	We are happy for broader stakeholders to be included where relevant and societal/ethical barriers are a very good example of this.
62	Do you already have in mind the number of individuals you would like in the core expert committee? Have you considered setting up additional workstreams that have a specialist interest in a specific aspect of ML/AI that could encompass a wider number of experts that continues beyond the report publication?	Part of the report will be to work with Wellcome to plan future areas of work and we can discuss additional future workstreams as part of this. We do not have in mind the number of core experts but from previous reports this may be as few as 2-3.
63	The RFP states, 'Supplier should create a simple governance structure to ensure regular feedback and reporting to the experts and Wellcome during the landscaping'. Would virtual and/or face-to-face (or hybrid) meetings be preferred?	We are happy to facilitate face-to-face meetings and (location dependent) these may be more efficient in the first case as we can schedule 1-2 days of meetings with internal stakeholders. However there is certainly no expectation for face-to-face and we are very comfortable with hybrid or MS Teams meetings.

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64	<p>We would normally recommend a diverse mix of stakeholders from different sectors within the expert committee (e.g., ML/AI tool experts & businesses, translational research experts, professional associations and research institutes, pharmaceutical companies, NGOs, and academics in both health and ethics). Does Wellcome already have a view on the types of experts they would like to engage? Are there any specific geographical considerations you would like us to take into consideration?</p>	<p>The supplier will be expected to design a committee that is able to help guide the project and create a comprehensive landscaping exercise. For example if you anticipate particular difficult in landscaping ML work in the Global South, then you may consider experts from this area - but this is not essential, especially as interviewed academics/industries may help form connections without the need for experts in the area. We have no D&I requirements for the committee.</p>
65	<p>In the RFP, it states, "The Supplier should write the findings of the landscaping analysis in an MS Word document that is well laid out, can be followed in a succinct and coherent manner, and is accessible to a wide range of stakeholders. Do you already have a view on the length of the report? Also, have you considered different formats, such as a longer report with a short one-page infographic executive summary of key findings or even an animated video to share findings and attract audiences to the broader report?"</p>	<p>Previous reports have been 62 pgs including graphics https://cms.wellcome.org/sites/default/files/2022-01/climate-ips-landscaping-report.pdf and 41 pgs https://cms.wellcome.org/sites/default/files/2022-01/landscape-mapping-software-tools-CSID-modelling.pdf ; we'd expect this report to be around the same length of possibly slightly longer given how broad the field is. We are open to discussing other formats with the supplier and the Wellcome branding team but this should not take significant time from the supplier's work and nor is it expected for the supplier to design the final report.</p>
66	<p>What types of stakeholders do you hope to target with this report, and ideally, what do you hope to achieve more broadly with this work?</p>	<ol style="list-style-type: none">1) Internal Wellcome funders who will use this report to identify areas of future targeted funding and to optimise chances of success for projects.2) External funders who may be able to act on

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		findings that Wellcome cannot (out of strategy), will not (lack of expertise), or who could collaborate with Wellcome on larger investments. 3) Academics and industry who may be able to action findings in the report (e.g. by advertising their own work more broadly or by identifying future research avenues)
67	To what extent should this work focus on use cases/ applications which can impact Wellcome's therapeutic areas of interest?	We would expect the project to start with equal commitment to exploring the opportunities in mental health and infectious disease drug development. However, with progress it may be that priorities shift and a collaborative decision between Wellcome and the Supplier will be taken as to how to manage that.
68	To what extent would you envisage focusing on applications beyond Discovery, into Translation and Clinical Development?	We see both as in scope and at the outset do not have an expressed preference for either, although as the landscaping progresses, we may prioritise one over the other (via collaborative decision making with the supplier).
69	To what extent should this effort explore different AI/ML methodologies/approaches vs applications of AI in the different settings (and the current proof points and future trends therein)?	We are open to well-established methodology as well as cutting-edge work and future trends. Wellcome are happy to make high-risk funding in novel technologies and as such we are willing to explore potential of these areas in the report.
70	Regarding Biologics, are there particularly modalities where we should focus? In our experience Biologics have very different applications based on specific pain points through discovery, and wonder if there would be value going deeper in certain modalities (e.g. MAbs, Protein therapeutics, RNA therapeutics)	All of the mentioned examples will be of particular interest to Wellcome, and we would expect that additional areas will be identified during the set-up phase wherein the supplier will engage with key Wellcome staff.

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71	Could you elaborate on the academic consultants role and stipulations? E.g. Would you envisage any additional roles beyond sitting on the Committee of Experts? Would two academics who are repeatedly engaged be preferred to a broad panel of external experts we interview and test our analysis with? Is there a preference for sitting academics, or are leaders within industry suitable?	The supplier may find it simplest to add the experts to the governance panel to simplify the reporting structure. The supplier is expected to engage with both academics and industry leaders as required - there is no expectation to work with one or the other as long as the supplier can demonstrate how their chosen committee will be able to guide the project in a way that is both efficient and comprehensive - i.e. can help make introductions as necessary, identify areas to explore, advise on industry and academic research, and generally provide comprehensive feedback on all areas relevant to the report.
72	Understand that delivery timelines are rather broad (Oct '22-Mar '23), are there any critical dates that we should bare in mind (e.g. stakeholder engagement points/conferences)	No critical dates.