



QUESTIONS AND ANSWERS

Request for Proposal (RFP): Understanding challenges for informative clinical trials in digital mental health

#	Supplier Question	Wellcome response
1	Are you able to share any budgetary information?	We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.
2	Would it be possible to have an idea of funding amounts and time limits to give an idea of scope?	<p>In terms of funding, we will not be sharing budgetary information, and we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.</p> <p>In terms of time limits, we will ask for all work to be completed by Spring 2024. We may ask for a draft report to be submitted by the end of March 2024. Otherwise, the supplier is free to arrange their time as they see fit.</p>
3	Will it be possible for us to publish our findings in a peer-reviewed journal, or otherwise publicly disseminate them?	Yes, suppliers are free to publish their research in academic journals. Separately, we will also publish the final report (minus any recommendations the supplier makes for Wellcome).
4	I would like to enquire as to more information on the Wellcome's expectations regarding costings, specifically as to (i) The envisaged total costings for applications (including maximum amount), and (ii) any expectations from Wellcome on how the budgeting / costings will be used for research support, PPI, and dissemination.	We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.



		We have no expectations on how budgets are divided between research support, PPI, dissemination (or any other activity), and we leave this to the discretion of the supplier.
5	The scope of the call is quite large within the given timeframe and we were interested in understanding if there is any flexibility in the deliverables or are these fixed?	There is some flexibility in defining the scope of the research with Wellcome. However, we will ask for all three deliverables outlined in the RFP (namely, an inception report, a full report, and a presentation of findings) to be delivered.
6	To achieve the deliverables in the timeframe, this would require quite significant funding. I cannot see a specific funding amount listed in the grant, so my impression is that this is open, however would like to know if there was a range that Wellcome is expecting?	Please note this is a contract not a grant. We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.
7	If awarded the RFP, does this exclude the awardees from applying to the future funding call that this contract is designed to shape?	No – the chosen supplier for this research will be free to apply for funding from our planned digital mental health funding call.
8	Are Wellcome expecting outputs to be publishable in academic journals, and if not, are the successful applicants able to publish the outputs in academic and peer-reviewed journals?	Suppliers are free to publish their research in academic journals if they wish. Separately, we will also publish the final report (minus any recommendations the supplier makes for Wellcome).
9	Are Wellcome expecting/requiring that stakeholder engagement or any project activities that constitute research have human ethics research approvals? If not, what are the implications of this on the potential for publishing.	We expect all research reviewed for the work commissioned here to have the appropriate ethical approval.
10	Are Wellcome expecting that any systematic literature reviews conducted within the contract, have their protocols approved/registered prior to starting?	We do not require pre-registration of protocols, but we encourage open science and would be supportive of any plans to do so.
11	Do the applicants have the potential to shape the scope of the deliverables in more detail than what is provided in the initial call?	There is some flexibility in defining the scope of the research with Wellcome. However, we will ask for all three deliverables outlined in the



		RFP (namely, an inception report, a full report, and a presentation of findings) to be delivered.
12	To what extent are interventions accessible and acceptable to hard-to-reach populations, including mobile and migrant populations, and persons with disabilities?	This is an open question, and the answer will likely change for different interventions. It may be a relevant question to answer as part of the commissioned research.
13	To what extent does Wellcome want the vendor to explore equity considerations, and to what extent is Wellcome able to facilitate the participation of stakeholders into the work?	<p>Equity considerations should be considered insofar as they are relevant for investigating common features of uninformative clinical trials. For example, it may be that certain equity considerations impinge on the informativeness of a clinical trial, and we would welcome discussion of this in the final report.</p> <p>Wellcome may be able to facilitate participation of stakeholders by making introductions, though this should not be relied upon in general. The supplier should consider how the input of stakeholders will contribute to the work and describe this in the methodology. They should also consider any costs related to involving stakeholders and cost their proposal appropriately.</p>
14	What priority countries/regions does Wellcome want the vendor to include? Is Wellcome able to facilitate introductions?	<p>The commissioned research should consider the global landscape of digital mental health trials, though the supplier is welcome to propose a focus on specific geographies of interest (with sufficient justification).</p> <p>Wellcome may be able make introductions, though this should not be relied upon in general.</p>
15	Does Wellcome have an intended sample size that it would like to inform the stakeholder interviews?	We leave it to the supplier to decide on and justify a sample size for stakeholder interviews.



16	Would Wellcome Trust share a budget range for this procurement?	We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.
17	Has WT a preference of in-scope countries or priority countries across which the review, landscaping, survey respondent sample should cover? or would Wellcome prefer a Global Approach?	The commissioned research should consider the global landscape of digital mental health trials, though the supplier is welcome to propose a focus on specific geographies of interest (with sufficient justification).
18	Are there any key time points across the project where interim feedback or data is needed to input into WT strategy?	We may ask for a draft of the final report, including all key findings of the research, to be submitted to us by the end of March 2024. There are no other relevant timepoints.
19	Is there a preferred format for the full report (e.g., MS Word file)?	MS Word is preferred for drafts, and a PDF for the final professionally formatted report.
20	Can an honoraria be paid to respondents participating in the qualitative analysis?	Yes, and this should be costed into the full proposal.
21	Would Wellcome Trust accept a variation in their T&Cs if they do not align with supplier's policies?	If suppliers have any proposed amendments to the T&Cs, please make use of the contract feedback annex in the RFP document when submitting the full proposal to raise these. Amendments that are only raised once the supplier has been awarded the contract are unlikely to be accepted.
22	Does TPSRA2 assessment form need to be completed for every single procurement from Welcome Trust, or once we complete the form, the information would be valid for a period of time for subsequent RFPs (.should there be no variations to our original input)?	If the TPSRA2 form has been completed within 12 months it does not need to be re-done. However depending on the specific nature of the project there may be further documentation requested from our Information Governance team at the point of the contract being awarded.
23	Does Wellcome have fixed points or milestones throughout this project that we should keep in mind when we consider the approach and delivery plan, beyond a 15 th April 2024 deadline?	The only other relevant timepoint is that we may ask for a draft of the final report, including all key findings of the research, to be submitted to us by the end of March 2024



24	In the RfP, you mention our budget should include allocation of funds for at least two senior academic consultants. Can you please elaborate on any specific preferences around the role they play and engagement model?	The research we are commissioning here is very close to academic mental health research. As such, we believe the output would benefit from input from diverse academic experts. Therefore, if you do not have these experts on your core team, we ask that you source that input from by consulting with at least two academics.
25	We assume Wellcome will have an internal working team – what is the expectation on level and model of engagement between Wellcome's internal team and our team?	Wellcome will not contribute to delivery of the commissioned research, but we are available to help define scope at the initial stages and to provide input and guidance throughout. We ask that suppliers propose a model of engagement with Wellcome in their proposal.
26	Are you interested in analysing informativeness through a geographic lens? Or do you have any specific geographies you would like the landscaping to focus on?	The commissioned research should consider the global landscape of digital mental health trials, though the supplier is welcome to propose a focus on specific geographies of interest (with sufficient justification).
27	Do you have a preference for the focus of the digital mental health trials we look at (e.g., by tool type (therapeutics, diagnostics or triaging) or mental health conditions addressed)?	We would like the supplier to consider all digital mental health trials, including therapeutics, diagnostics, and triaging tools. We ask that mental health conditions are limited to anxiety, depression, and psychosis (broadly defined).
28	To what extent (if at all), did you want us to focus on specific implications for Wellcome (e.g., investment approach)?	We are looking for recommendations for how we at Wellcome can monitor and evaluate the informativeness of the trials we fund. We are not looking for a focus on any other implications for Wellcome.
29	Who is the intended primary audience(s) for the final report? Are you able to share any additional details on the final report at this stage?	The intended audiences are: Wellcome and other funders of mental health research; regulators or other bodies that set guidance for clinical trial conduct; and mental health researchers/triallists.
30	What is the estimated budget range for this project? This will help us refine our approach.	We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we



		are legally obligated to obtain value for money and this will form part of our evaluation criteria.
31	We would appreciate any information you can provide regarding an established or proposed budget for the project.	We will not be sharing budgetary information, but we encourage suppliers to cost their proposals as accurately as they can. Note that as a charity we are legally obligated to obtain value for money and this will form part of our evaluation criteria.