



## QUESTIONS AND ANSWERS

### Request for Proposal (RFP): Digital tools for recruitment and retention in mental health

#	Supplier Question	Wellcome response
1	What budget (approximately) do you have in mind?	Wellcome will be guided by the supplier as to what a reasonable budget for this activity is, as we do not want to limit ambition or innovation. Proposals are in part assessed on value for money and as such we would expect to see a detailed budget breakdown (for example on time and resources including day rates) to allow Wellcome to feedback as needed with the awarded supplier(s). Our priority is to ensure the package(s) of work are completed to a high standard within the time frame in a way that represents good value for money.
2	What sort of organisation are you expecting to be leading this work, eg university, a mental health trust, or a consulting firm?	We are open to and would be happy to receive proposals from any organisation. We will judge the proposal on its own merits and will consider the experience and expertise of the team leading on the work when deciding who to appoint, but we have no strong view on the type of organisation we would most like to carry out the work. If you feel you have the necessary expertise to deliver the work, please do apply.
3	How long do you expect the project to last?	We will look to suppliers for how long they think is required to deliver on the work outlined in the RFP. However, in general, we expect promising proposals to deliver the final report within 6 to 12 months from contract start.
4	Are there any deadlines that must be considered when designing the project timetable?	There are no hard deadlines, but any future activity in this area is dependent on this project. And so while we are keen to explore



		future opportunities, we also want to give this project the time it needs.
<b>5</b>	Can you confirm the geographical scope for the primary research involved in this project - would it be limited to the UK?	<p>No, we expect that the research commissioned here will have a broader geographic focus than the UK alone. We're looking to understand challenges with recruiting and retaining participants in high-income and low-/middle-income countries, and we'd like to understand how these different settings present different challenges. Understanding these things will help Wellcome to fund solutions that have a more global impact in the future.</p> <p>That all said, we appreciate that the scope here needs to be kept manageable. For example, prospective suppliers might decide to focus their efforts on a small number of exemplar countries. So long as the aims of 1) understanding challenges in different settings and 2) understanding the perspectives of different groups are met, we are of course open to methods for limiting scope.</p>
<b>5.5</b>	Do you have any preferences regarding the location of participants and the researchers/practitioners whose interviews are required?	No, so long as the aims of 1) understanding challenges in different settings and 2) understanding the perspectives of different groups are met. For a more detailed rationale, see our answer to 5.
<b>6</b>	Has Wellcome already identified the 'Wellcome representatives' to be included to be involved in the Governance and Evaluation Structure and, if so, is it possible for their roles/titles to be shared?	The lead for this project is Gwydion Williams, Technology Manager. He will be the main Wellcome point of contact for the duration of the work. Others from Wellcome will be involved, both in selecting suppliers and in evaluating and shaping the work as it progresses. Those individuals have not yet been agreed, but we expect there to be representatives from Wellcome's Mental Health and Community Engagement teams present at a minimum.



7	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 teams?	We expect to engage with our nominated supplier regularly to discuss progress; at least monthly, possibly fortnightly depending on pace. This is an opportunity for us at Wellcome to receive general updates and to provide our own input on how the work could best fit our needs, and it is an opportunity for open discussion between the Wellcome team and the successful supplier on any questions concerning the direction of the work. The Wellcome team will not work directly on the project beyond these discussions, except when providing feedback on deliverables, with the inception and draft final reports being most in focus here. We are happy to discuss any other arrangements with the supplier once the work has been awarded.
8	To what extent do you expect the recommendations to focus on what is needed from the ecosystem and / or various funders, vs being specific to Wellcome and your investments?	We want to understand: 1) the state of recruitment and retention in mental health clinical trials at large, and 2) what Wellcome could do to support innovation in the space. We do not expect the commissioned work to over-index on Wellcome's existing investments towards meeting the first of these two aims as the intention here is to understand the landscape, but we do expect the supplier to work to understand how Wellcome operates as a funder towards the second. As outlined in the RFP, we want actionable recommendations from this report, and that will require an understanding of what is/isn't feasible for Wellcome to pursue.
9	Do you have any specific requirements or expectations for capturing diverse input e.g., from LMICs?	Please see our answer to question 5.
10	Who is the intended primary audience(s) for the final report? Is it an internal report or for an external audience? If the latter,	The intended primary audience for the final report is Wellcome, given that the primary aim of this work is to help Wellcome identify opportunities to advance recruitment and retention in mental health



	are you able to share any additional details on the final report at this stage?	clinical trials. However, if there is value in publishing the report externally (with Wellcome-specific recommendations removed), then we may decide to do so. That said, we understand that the approach taken when writing a report for internal use at Wellcome may be quite different to the approach taken when writing a report for external publication. We are happy to discuss what would make best use of the research completed by our nominated supplier while still achieving our primary aims with our nominated supplier before beginning the work.
<b>11</b>	Are you looking to understand differences in clinical trial recruitment between different conditions, ie psychosis and anxiety/depression? We believe that the challenges would be quite different between psychosis and non-psychosis-related conditions.	Yes – we want a deep understanding of how recruitment and retention are difficult <i>specifically</i> within the mental health context. That includes understanding differences between different conditions. Though note that the conditions in focus should be limited to anxiety, depression, and psychosis, in line with Wellcome’s mental health strategy.
<b>12</b>	Is the focus of the work on all clinical trial interventions (ie pharmacological, behavioural)? Again, we believe that the challenges are likely to be different so it would be good to understand if you have a particular focus or priority.	Yes, all mental health clinical trials are to be included.
<b>13</b>	Is the work UK specific? If no, are there particular countries of focus? How representative would you want the research to be?	Please see our answer to question 5.
<b>14</b>	By lived experience experts, are you referring to patients or ‘expert patients’?	We understand lived experience as a unique form of knowledge, insight, and expertise, that comes from having experience of mental health challenges. When we refer to ‘lived experience experts’ or ‘people with lived experience’ we are referring to people who identify as having experienced mental health problems, either in the



		past or currently. People with lived experience do not need to have been diagnosed by professionals or have accessed formal mental health services.
<b>15</b>	Do you have a lived experience panel that you work with already?	Wellcome has its own lived experience team, which includes globally representative lived experience advisors. Our advisors have helped shape the project, will participate in supplier selection, and will continue to participate from the Wellcome side throughout. However, suppliers should not rely on Wellcome’s own lived experience advisors for their work.
<b>16</b>	Is it expected that the supplier will be handling all recruitment, or does Wellcome have a good network of people to tap into?	Wellcome can offer limited support with recruitment (by e.g., connecting suppliers with networks we know), but this should not be relied upon as the primary avenue for recruiting research participants.
<b>17</b>	What work has Wellcome done on this already? Will you be sharing any existing insights prior to the work commencing?	Wellcome has completed light scoping of the area and we have consulted with select experts in the field. Suppliers should not rely on Wellcome’s own internal work (past or present) for the project, but we are of course happy to discuss our thoughts with our nominated supplier.
<b>18</b>	Is there an existing audit of digital or other innovation recruitment tools, or is doing a review of this part of the scope of this work?	There may be existing work that will provide a useful starting point for this project. For example, the <a href="#">Trials@Home</a> initiative have completed scoping work on the landscape of digital tools used to support decentralised clinical trials. There may be other similar work, and we would look to our nominated supplier to identify and build on that work.



19	Are you looking for one supplier to do both the barriers to recruitment/retention research and the evaluation of innovation tools?	We are looking to contract a single organisation to deliver all work outlined in the RFP. Suppliers may, if they wish, subcontract portions of the work to other organisations, but this intention must be made clear to Wellcome together with a clear rationale for why this is necessary and why the intended sub-contractor is appropriate.
20	How would you define success on this project? What are you looking for in a partner?	<p>In terms of delivery, this project would be a success if, after receipt of the final report, we (Wellcome):</p> <ol style="list-style-type: none"> <li>1. Understand the key challenges blocking effective recruitment and retention in <i>mental health</i> clinical trials.</li> <li>2. Understand current 'best practice' when recruiting and retaining participants in mental health clinical trials.</li> <li>3. Have a clear set of recommendations for ways in which Wellcome could improve recruitment and retention in mental health clinical trials.</li> </ol> <p>In terms of procedure, the project would be a success if: we have clear and open communication (in both directions) with our supplier; we are kept up to date with progress throughout the work; all deliverables are submitted on time; and all feedback is thoughtfully considered, discussed, and integrated into your/our (if you have feedback for us) work.</p> <p>Finally, on what we are looking for in a partner: in addition to the above points, we are looking for a diverse team who will take an inclusive approach to the work and will meaningfully and ethically involve and collaborate with people with lived experience expertise.</p>
21	We have contracts with pharmaceutical clinical trials companies to deliver clinical trials marketing, patient communications,	Here we would ask that you justify that you will be able to deliver the work in view of any commitments to/affiliations with any other



	<p>clinical trials recruitment and research and insights into clinical trial patient journey and experience. Our longstanding expertise in both the clinical trials recruitment and research of clinical trials patient experience makes us uniquely placed to deliver this contract. Please can you confirm that our contractual obligations to pharmaceutical companies (we are independent) do not constitute a conflict of interest from Wellcome's perspective.</p>	<p>organisations that may introduce perceived or real conflict of interest. You should consider not only whether such collaborations introduce real bias into the work, but also whether affiliations (e.g., with private pharmaceutical companies) creates a perception of bias that might undermine the credibility of the results.</p> <p>If you feel that there truly is no issue with real/perceived conflicts of interest, and you feel you have the expertise required to deliver on the work, then we encourage you to apply.</p>
<b>22</b>	<p>As a private organisation would we be subject to following Wellcome data protection and GDPR (given we would be working with potentially vulnerable people) OR are we able to employ our organisational practice and process for this programme of work. This may influence the way in which we write the full rfp and cost for data protection/GDPR/data handling.</p>	<p>As per our draft standard terms provided with the tender documentation, Wellcome expects suppliers to comply with all applicable laws when carrying out the work, including relevant data protection laws. This project will involve the collection and use of personal data, bringing into scope the need to comply with data protection law when processing this data.</p>
<b>23</b>	<p>As suppliers will we have access to the Wellcome MH strategy team from the original report in order to refine any process / ask questions to ensure alignment.</p>	<p>Yes – you will have opportunity to discuss the exact scope of the work (and anything else) both at interview and later (if successful).</p>
<b>24</b>	<p>We understand the study has a focus on digital tools for improving recruitment and retention in mental health clinical trials. In terms of the mental health interventions being tested in clinical trials, please could you clarify what types of interventions are in scope for the study e.g. pharmaceuticals, digital apps etc.</p>	<p>The trials in scope for this work are any clinical trials testing an intervention of any type (i.e., pharmaceutical, digital intervention, talking therapy, or any other category) for anxiety, depression, and psychosis. We understand there may be different challenges with recruitment and retention for different intervention types and for different conditions – suppliers may want to account for this in their proposals.</p>



<b>25</b>	Is there a minimum number of interviews mandated for either the participants or the researchers/practitioners?	There is no minimum number, but we expect suppliers to recruit enough participants so that their research is robust and their findings valid.
<b>26</b>	Should the proposed work address all the 4 objectives, to be competitive, or can the proposed project address only some of the 4 objectives?	We are looking to contract a supplier to deliver all the objectives outlined in the RFP.