



Request for Proposal (RFP) for

exploring opportunities to develop tools to support recruitment and retention in mental health clinical trials

1 RFP Background & Objectives

Wellcome is a politically and financially independent charitable foundation. We improve health for everyone by funding research, leading policy and advocacy campaigns, and building global partnerships. In 2020, Wellcome announced our new strategy to tackle three global health challenges: mental health, infectious disease, and the impact of climate change on health.

1.1 Mental Health Vision and Mission

Our vision for mental health (MH) is a world in which no one is held back by MH problems. To advance this vision, our mission over the next 10 years is to drive a step change in the ability to intervene as early as possible in the course of anxiety, depression, and psychosis.

Wellcome has two core goals in MH:

1. Improve understanding of how the brain, body, and environment interact in the trajectory and resolution of anxiety, depression, and psychosis.
2. Find new and/or improved usable ways to predict, identify, and intervene as early as possible in anxiety, depression, and psychosis.

We are aiming to support a vibrant global MH science community to produce breakthrough discoveries that are rapidly translated to develop targeted, effective, and scalable early interventions in one or more of anxiety, depression, and psychosis.

1.2 Tools to support recruitment and retention in mental health trials

Recruiting and retaining clinical trial participants (i.e., finding eligible participants and keeping them engaged) is difficult. Around [40%](#) of trials fail to recruit enough participants on time. Even if enough participants are recruited, participant samples often lack diversity. For example, only [25%](#) of global trial participants are people of colour, despite people of colour making up around [85%](#) of the global population. Once recruited, retention becomes an issue; over the past decade, trial dropout rate has been estimated to be around [26%](#). This is a problem: challenges with recruitment and retention lead to increased costs, delayed timelines, underpowered and biased trial results, and, in many cases, trial failure.

We want to know whether clinical trials in MH face specific challenges with recruitment and retention, and/or whether any general challenges with recruitment and retention are more



pronounced in MH clinical trials. Researchers in MH clinical trials face difficulties with recruitment and retention as do researchers in other domains. But it's unclear whether any of these difficulties are more pronounced in MH clinical trials, or whether there are issues specific to MH clinical trials that make it difficult for participants to engage with trials. For example, some symptoms of MH conditions, such as low motivation and low mood, might make it difficult for participants to engage consistently in trial activities and trials may not do enough to accommodate for that. Cultural or social attitudes in some populations may also prevent some people from participating. Challenges like these could block progress in developing novel, inclusive, and effective MH interventions.

We also want to know where there is innovation in the methods used to recruit and retain participants in MH clinical trials. While we're open to any solutions that work, we're particularly interested in exploring the potential of digital tools, i.e., digital programs, platforms, applications, resources, or other digital processes to support recruitment and retention. There are signs that digital tools could increase trial accessibility and offer more ways to tailor trial engagement to participant needs. For example, some [online platforms](#) allow participants to enrol in trials and report intervention outcomes in their preferred environments (e.g., in their homes). Digital tools also open the door to using AI to boost recruitment and retention rates (e.g., see the use of [CogStack](#) to increase recruitment rates). We want to know what the opportunities are for using digital (and other) solutions to support better recruitment and retention in MH clinical trials.

We want solutions that are not only effective, but also safe, inclusive, and considerate of user/patient needs. On safety: solutions should securely manage participant data, and they should take steps to ensure that participant safety is maintained throughout the trial. On inclusivity: we want solutions that benefit as many people as possible, and to that end, participants should be actively involved in their development. Designing and developing solutions together with trial participants, lived experience experts etc., should also ensure that those solutions are sensitive to the needs of trial participants. We expect the work completed here to also take on this approach when considering who faces barriers to joining and staying engaged with trials and how well different solutions address those barriers.

Wellcome is commissioning research to provide a comprehensive view of 1) the barriers to effective recruitment and retention in MH clinical trials and 2) where innovation can help lift those barriers. We want to know whether and how recruitment and retention are difficult specifically within MH clinical trials. We also want to know what approaches are currently used to improve recruitment and retention rates, with a specific focus on digital tools, and we want to know how safe and acceptable (from a participant's point of view) these approaches are. Once we have understood what makes recruitment and retention difficult in MH clinical trials and current best practice, we want to know how we can support innovation in the space to move things forward. The objectives of the work are to:



1. Identify barriers to participant recruitment and retention in MH clinical trials. For each barrier, outline:
 - a. Whether and how it is more pronounced in/specific to MH clinical trials.
 - b. How it affects trial outcomes, e.g., recruitment rate, retention rate, sample representativeness, power, bias, validity, cost-effectiveness, participant experience etc.
 - c. Who are affected and how they are affected. For example, who are least likely to participate, most likely to drop out, and why?
2. Detail the needs and expectations of different stakeholders during MH clinical trials.
 - a. For researchers and practitioners, investigate their experience of using different approaches to recruitment and retention and what their ideal solutions might look like.
 - b. For participants, investigate:
 - i. What motivates and incentivises them to join and stay engaged with a trial?
 - ii. What (from the participant's point of view) are other factors that increase and diminish recruitment and retention rates?
 - iii. How do different approaches to recruitment and retention (including digital tools) impact on the above?
 - iv. What (from the participant's point of view) would make for a good digital platform for managing trial engagement?
 - v. How can lived experience input best inform the development of solutions for improving recruitment and retention?
3. Outline and evaluate recent innovations in improving participant recruitment and retention in MH clinical trials (and other domains where relevant). Investigate whether, where, and how new approaches can improve recruitment and retention outcomes in MH clinical trials.
 - a. Evaluate the strengths and weaknesses of the approaches identified, including an assessment of the impact the approaches have had and how well they cater to researcher, trialist, and participant (i.e., lived experience) needs.
 - b. Consider whether and how approaches to recruitment and retention in MH clinical trials need to be tailored to the MH context. Consider also whether approaches in other domains could be valuable if applied to MH clinical trials.
 - c. Consider how well these approaches work in different contexts, e.g., in high- vs low-income settings, or in different populations/communities, e.g., by MH condition or level of digital literacy. Consider also how cultural and social factors affect user experience and engagement.



- d. We are particularly interested in the potential that *digital tools* hold for supporting recruitment and retention. While we are open to any innovative methods for improving recruitment and retention, we do expect to see a specific focus on digital tools when answering the above questions.
4. Based on the above research and any other relevant information, make actionable recommendations for what is needed to improve recruitment and retention rates in MH clinical trials while being sensitive to the needs and expectations of trial participants and people with lived experience of mental health conditions.

To be clear, the scope for trials to be included in this work should follow Wellcome's MH strategy, which is focussed on anxiety, depression, and psychosis (broadly defined), and [the World Health Organisation's definition of a clinical trial](#).

2 RFP Specification

This section sets out the specification of goods and/or services for this RFP exercise. 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.

Key proposed deliverables to be included:

- D1 Form a **governance and evaluation structure**. This could consist of: expert consultants (e.g., academics or practitioners with expertise in the development/use of tools for recruitment and retention for MH clinical trials), Wellcome representatives, lived experience representatives, representation from low-/middle-income countries, and/or other individuals with expertise that will support successful delivery of the proposed work.
- D2 **Inception report**, to include the detailed scope of the work, a detailed outline of the methodology that will be used to answer the research questions outlined above, and a detailed timeline for completion of the work.
- D3 **Final report**, delivered in two stages:
 - i. A **draft final report**, which will be shared with Wellcome 2 weeks (minimum) in advance of the end date to allow Wellcome staff and other stakeholders involved in the work (e.g., lived experience advisors) to give feedback, raise questions, and make recommendations for further improvements.
 - ii. A **final report**: a clean and final copy which will be delivered after incorporating feedback on the draft report from Wellcome.



D4 A **slide deck** of summary findings.

D5 A **presentation** of the findings to the Wellcome team, to be delivered virtually or in person, with time for Q&A from the Wellcome team.



3 RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers and RFP issued on Contract Opportunities webpage	Wellcome	04/03/2024
2	Submission of Expression of Interest and Supplier Q&A	Supplier	25/03/2024
3	Return of Supplier Q&A to Suppliers	Wellcome	01/04/2024
4	Submission of RFP Response	Supplier	22/04/2024
5	RFP Evaluation Period	Wellcome	22/04/2024 to 30/04/2024
6	Supplier Presentations	Supplier	13/05/2024 to 24/05/2024
7	Notification of Contract Award	Wellcome	May 2024
8	Contract Negotiation	Wellcome & Supplier	May 2024
9	Contract Start Date	Wellcome & Supplier	June 2024

4 Response Format

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

4.1 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 an organisation or individual
- If an organisation please provide registered name, address, and registration number.
- A non-binding cost estimate as a single figure in GBP
- Any questions you have about the exercise and activity

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/Q&A 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.

4.2 RFP Response

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

#	Question	Max Words
1	<p>Experience:</p> <p>Outline your experience in the area (e.g. case studies where you successfully provided similar services to those described in this RFP) and whether/how you will work with experts to cover the gaps in your knowledge. Include any relevant experience completing qualitative research and landscaping analyses. Also include any relevant experience with novel and digital recruitment and retention tools, mental health research, clinical trial research, working with marginalised groups and communities, and expertise in understanding issues of trust and access in MH science from community engagement perspectives. We expect the supplier's team to be diverse in membership and inclusive in practice. We also expect the supplier to meaningfully and ethically involve and collaborate with people with lived experience expertise in the design and delivery of the project, as relevant to the deliverables.</p>	2000 words
2	<p>Methodology:</p> <p>Detail your methodology for completing this analysis, including:</p> <ul style="list-style-type: none">• The approach and methodology, and how they answer the questions in RFP specification.• Proposed project plan, timelines with key milestones and deliverables against each of these.• Management plan, including the role of team members.	1000 words



	<ul style="list-style-type: none"> • Plan for engagement with Wellcome during the contract. • Plan for production of the final report, including copy editing, formatting and graphics. • Plan for equity, diversity, and inclusion (how you will ensure that interviews conducted will be inclusive and representative of different resource settings/groups and that your methodology does not introduce bias). • Plan for engagement with stakeholders, including people with lived experience/community engagement expertise 	
3	<p>Delivery and Output: Describe anticipated risks and challenges, ways to mitigate them, and quality assurance efforts for your work.</p>	500 words
4	<p>Budget: Provide a detailed budget including all costs and expenses, specifying all day rates of individuals involved, the allocation of days between members of the team, and the cost of activities. The budget must include allocation of funds for at least one lived experience advisor, one researcher with experience using innovative recruitment and retention methods in mental health clinical trials, and one representative of those who would benefit from new recruitment and retention methods.</p>	500 words
5	<p>Equity diversity and inclusion (EDI): What are your EDI policies and how would you ensure equity, diversity and inclusion considerations are embedded throughout the planning, development and delivery of the project?</p>	300 words
6	<p>Accessibility: All our content should be WCAG 2.2. AAA compliant. Any documents being provided to Wellcome must pass accessibility requirements. If you are unable to produce accessible documents, budget must be set aside to employ a suitable agency to do this work.</p>	N/A

4.3 Evaluation Criteria

Criteria	Detail	%
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Methodology	<p><i>Coverage:</i> How well are the desired focus areas (as outlined in the specification) covered in the proposed methodology?</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> <p><i>Equity, Diversity & Inclusivity:</i> Does the proposed methodology align with Wellcome’s EDI principles?</p>	30%
Experience	<p><i>Skills and Experience:</i> Does the supplier have the relevant skills, experience, and contextual understanding to deliver this work? Has the supplier demonstrated an ability to address potential gaps in knowledge and experience if necessary?</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>	20%
	Total:	100%

4.4 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.

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 6 below).

4.5 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.

4.6 Supplier Presentations

Following a submission of the proposal successful proposals will invited to a virtual meeting which will last 50 minutes in total and will be a PowerPoint presentation followed by questions and answers session.

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](https://www.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 [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 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 \(www.gov.uk\)](#). 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 chronic 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.

All our content should be WCAG 2.2. AAA compliant. Any documents being provided to Wellcome must pass accessibility requirements. If you are unable to produce accessible documents, budget must be set aside to employ a suitable agency to do this work.

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 single point of contact within this RFP exercise for all communications is as indicated below:

Name:	Alyce O'Connor
Pronouns:	She/Her
Role:	Procurement Officer
Email:	rfp@wellcome.org