



Request for Proposal (RFP) for

Understanding challenges for informative clinical trials in digital mental health

1 RFP Background and 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 is a world in which no one is held back by mental health problems. To advance this vision, our mission over the next 20 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 mental health:

- A)** improve understanding of how the brain, body and environment interact in the trajectory and resolution of anxiety, depression, and psychosis
- B)** find new and/or improved usable ways to predict, identify, and intervene as early as possible in anxiety, depression, and psychosis

In the next 10 years we are aiming to support a vibrant global mental health science community to produce a pipeline of breakthrough discoveries that are rapidly translated to develop targeted, effective, and scalable early interventions in one or more of anxiety, depression, or psychosis.

1.2 Clinical Trials in Mental Health

To drive a step change in early intervention for anxiety, depression, and psychosis, Wellcome plans to fund the development of new and improved interventions and diagnostic tools. A key methodology for assessing whether and how these interventions and tools work is through conducting clinical trials.

We define an informative trial as one that meets the following seven criteria (which are an adaptation of the definition given by [Zarin, Goodman, & Kimmelman, 2019](#); note that the first deliverable for this RFP will be to refine this definition):

1. Addressed an important and unresolved scientific, medical, or policy question.
2. Designed to provide meaningful evidence related to this question.
3. Demonstrably feasible (e.g., must have a realistic plan for recruiting sufficient participants).
4. Recruited a sufficiently large, diverse, and representative sample of participants.
5. Conducted and analysed in a scientifically valid manner.
6. Reported methods and results accurately, completely, and promptly.
7. Collaboratively designed and developed with lived experience experts.



Trials can be deemed 'uninformative' if they fail to meet some, or all, of these criteria. How evaluation of these criteria is performed and their relative importance is unclear, and this is an area we would like to see explored in the work supplied for this RFP. Note that a well-designed trial with negative results (such as where an intervention was not effective) is still informative. From a funder's perspective, uninformative trials represent wasted resources, and from a participant's perspective they are not a good use of time and lead to a breach of trust and potential harm for participants and intended end users. Ultimately, uninformative clinical trials slow and weaken any attempt to develop better mental health interventions.

At Wellcome, we want to ensure that our funding is as impactful as possible. We want to achieve this by understanding what are some of the common issues in digital mental health which lead to trials being uninformative. The primary objective of the research we are commissioning is to generate a detailed analysis of the landscape of digital mental health trials, common elements of trial conduct and design which lead to trials being uninformative, as well as actionable recommendations for improving our ability to assess how informative a digital mental health trial will be. In this RFP we focus specifically on mental health trials of digital tools and interventions, although we welcome insights that are relevant for the wider field of mental health science, as well as health more broadly, if the supplier considers appropriate.

2 RFP Specification

We are commissioning research to:

- 1) Expand on and adapt work by Zarin and colleagues to build a framework for digital mental health trial informativeness.
- 2) Analyse the digital mental health trials landscape to 1) assess how informative digital mental health trials have been and 2) identify the most common elements which lead to trials being uninformative.
- 3) Analyse current best practice guidelines to identify any gaps between what is recommended and what is found to be important for DMHT informativeness.
- 4) Provide recommendations that digital mental health researchers and funders could adopt relating to how to design more informative trials and to assess trial informativeness. We have a particular interest in recommendations which may be unique for digital mental health interventions and tools in addition to recommendations applicable to clinical trials more widely.

Through this research we aim to understand:

1. How frequently digital mental health trials are/are not informative
2. The common features of uninformative clinical trials in digital mental health
3. The different barriers to informative clinical trials in digital mental health perceived by a range of stakeholders (including, but not limited to researchers, clinicians, participants, and end users)
4. Where and how current guidance for informative trial conduct is lacking, including guidance for how lived experience input should be included
5. How Wellcome can evaluate and monitor the informativeness of the trials we assess and fund throughout the lifetime of a grant

This RFP should focus on digital non-pharmaceutical clinical trials in mental health (from here referred to as digital mental health trials, or DMHTs). For the avoidance of doubt, trials



of pharmaceuticals alone are out of scope, as are all non-digital non-pharmaceutical trials. Trials of digital interventions, digital diagnostics, and digital tools for triaging are in scope. The exact remit will be discussed and agreed with Wellcome.

We are interested in pilot and clinical trials at all stages of intervention/tool development (i.e., from early development and testing to late-stage translation). We are also interested in the full life cycle of a trial. That is, we would like to understand the common features of uninformative trials at all stages of trial conduct: from study design and peer review, through to study protocols, execution and data collection, data analysis, and reporting.

2.1 Research Objectives

We will ask the successful supplier to include the following in their research:

2.1.1 A framework for assessing informative trials in digital mental health

1. Expand on our adaptation of work completed by Zarin and colleagues (see section 1.2) to build a framework for digital mental health tools which assesses a trial's potential to be informative. While we are interested in all trial features that influence informativeness, we invite a dedicated focus at this stage on features and associated criteria that are relevant specifically for DMHTs. For example, we are interested in how researchers quantify and monitor the ability of their interventions to sustain engagement (e.g., due to user experience and visual design). We would like to know how this impacts the informativeness of a trial by moderating how well the active components of the intervention (e.g., the therapeutic content in a CBT app) are received and able to take effect. There are likely other features specific to uninformative DMHTs, and these should be accounted for in the criteria developed at this stage and considered throughout the remainder of the research. The supplier may also wish to consult other frameworks of informativeness to create a more comprehensive framework such as work by [Hutchinson et al., 2022](#) and [Kimmelman 2022](#). Criteria are to be outlined in the *Inception Report* (see section 3) and agreed with Wellcome before commencing with the remainder of the research.
2. Explain how these criteria should be used to decide whether a trial is informative.

2.1.2 A systematic review of DMHT informativeness

1. Search clinical trials registries (e.g., WHO ICTRP, ClinicalTrials.gov, EU Clinical Trials Register etc.) to find all registered ongoing and complete DMHTs. Review those identified to ensure they are within scope for the research.
2. Apply the criteria defined in 2.1.1 to the trials under review; for each trial, determine whether all criteria were met, and provide an analysis of how frequently DMHTs were/were not informative.
3. Provide an analysis of the most common trial features that undermined trial informativeness.
4. Discuss 1) the impact of the identified features on trial informativeness (e.g., is a given feature sufficient alone to render a trial uninformative?), and 2) the specificity of the identified features to digital mental health (i.e., determine whether the identified features are relevant for DMHTs, for all mental health trials, or for all trials?).

2.1.3 Qualitative analysis of researcher and participant perspectives

1. Identify a diverse group of digital mental health clinical researchers, triallists, research participants, lived experience experts (both with/without direct experience of digital mental health interventions), industry representatives developing digital mental health interventions/diagnostics, and any other relevant stakeholders.



2. Survey/conduct interviews with this group to identify barriers they believe limit the informativeness of DMHTs. Synthesise the responses into key themes for each stakeholder group.
3. From the above analysis develop a comprehensive set of perceived barriers to informativeness, organised by stakeholder group.
4. Discuss differences and similarities between stakeholder groups in what they look for when judging trial informativeness. The supplier should consider these differences when making recommendations for Wellcome (see section 2.1.6)
5. Discuss 1) the perceived impact of the identified barriers on trial informativeness (e.g., is a given barrier sufficient alone to render a trial uninformative for a given group?), and 2) the specificity of the identified barriers to digital mental health (i.e., determine whether the barriers identified are relevant for digital mental health trials, for all mental health trials, or for all trials?).

2.1.4 Define what makes for an informative DMHT

1. Synthesise the common features of uninformative DMHTs as identified in sections 2.1.2 and 2.1.3 to propose a complete definition and framework for informative trials in digital mental health. This should build on and refine the framework outlined in section 2.1.1.

2.1.5 Landscape analysis of current best practice guidelines for trial conduct

1. Analyse current best practice guidelines for clinical trial conduct (e.g., [SPIRIT](#), [CONSORT](#), [the MRC framework for developing and evaluating complex interventions](#)) and identify gaps in the guidelines for DMHTs specifically.
2. If gaps are identified, suggest amendments to current guidelines or new guidelines that could fill identified gaps.

2.1.6 Recommendations for Wellcome

1. Provide specific recommendations on how to assess and monitor the informativeness of digital mental health trials. We are looking specifically for indicators or measures that can be employed at various stages of a grant (i.e., from reviewing applications through to monitoring ongoing trials) to evaluate informativeness.

2.2 Other Requirements

We expect the supplier's team to be diverse in membership and inclusive in practice. We expect the supplier to engage meaningfully with experts by lived experience in all areas where their input could conceivably be of use.

3 Deliverables

Key deliverables to be included are (but are not limited to):

- D1 An **inception report**, which will include:
- The detailed scope of work.
 - The proposed methodology for completing all research detailed in 2.1. This should include how you propose to identify and engage with experts and key stakeholders and how you plan to meaningfully involve people with lived experience throughout this RFP.
 - A preliminary set of criteria for DMHTs, in focus for this research, to be considered informative.



- The milestones within the study, between the completion of the inception report and delivery of the draft final report.

D2 A **full report** that answers the research areas and provides recommendations as detailed in 2.1. This will be delivered in two stages:

- A **draft final report**, which will be shared with Wellcome in advance of the end date to allow Wellcome staff time to discuss feedback, raise questions, and make recommendations for further improvement.
- A **final report**: a professionally formatted, clean, and final copy which will be delivered one week after the receipt of feedback from Wellcome. The report should include any relevant graphics. This report will include details on the methods of analysis and findings including caveats and assumptions. The report should also include recommendations for Wellcome.
- A **slide deck**: a summary of all findings in a presentable format. This can be the same slide deck used for D3.

D3 A **presentation of findings** to the Mental Health team at Wellcome. Note that other Wellcome members of staff may be invited to the presentation.

The supplier may provide suggestions for extra deliverables, e.g., interim reports. The final deliverables will be agreed at the contract negotiation stage but please note that we expect the final deliverable by 15 April 2024 at the very latest.

4 RFP Timetable

#	Activity	Responsibility	Date
1	RFP issued to Suppliers	WT	20 th June 2023
2	Submission of expression of interest to RFP	Supplier	10 th July 2023
3	Submission of Supplier questions to Wellcome Contact	Supplier	10 th July 2023
4	Return of Supplier Q&A to Suppliers	WT	21 st July 2023
5	Submission of RFP Response	Supplier	4 th September 2023
6	RFP Evaluation Period	WT	5 th September – 22 nd September 2023
7	Supplier Presentations	WT & Supplier	9 th October – 12 th October 2023
9	Notification of Contract Award	WT	October 2023
10	Contract Negotiation	WT & Supplier	Oct/Nov 2023
11	Contract Start Date	WT & Supplier	November 2023



5 Response Format

5.1 Expression of Interest

Suppliers are required to submit a short expression of interest by e-mail to RFP@Wellcome.org in accordance with the RFP timetable, which should contain the following information.

- Confirming whether you are a company or individual, if company please provide Full company name, address, and company registration number.
- A non-binding cost estimate as a single figure in GBP

Suppliers are asked to submit a short expression of interest by e-mail to the Wellcome Contact in accordance with the RFP timetable.

5.2 Supplier Q&A

Prior to the submission of your RFP response, 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. If you have any additional questions after this deadline these will not be answered to ensure that this is a fair and equitable process.

5.3 RFP Proposal

Suppliers are required to submit proposals which respond to the following sections:

#	Question	Max Words
1	Experience: Outline your experience in the area and whether/how you will work with experts to cover the gaps in your knowledge. Include any relevant experience completing systematic reviews, qualitative research, and landscaping analyses. Include also any relevant experience with mental health research, clinical trials, and digital innovation in mental health.	500 words



2	<p>Methodology (1): Detail your methodology for completing this analysis, including:</p> <ul style="list-style-type: none"> Proposed project plan including timelines. Management plan, including role of team members. Plan for engagement with Wellcome during contract. Plan for production of final report, including copy editing, formatting and graphics. Diversity and inclusion planning (how you will ensure that: the literature reviewed and interviews conducted will be inclusive of different groups of people and locations; your methodology does not introduce bias). How will you involve people with lived experience at relevant points of this project. Justification of starting set of challenges to informative DMHTs. 	2000 words
3	<p>Methodology (2): Provide case studies of where you have successfully provided similar services to those described in this RFP.</p>	500 words
5	<p>Methodology (3): Please consider Wellcome's D&I principles (section 15) and outline any previous relevant experience that demonstrates your ability to work in line with these principles.</p>	500 words
6	<p>Methodology (4): Provide a timeline for the work, including key milestones and Deliverables against each of these.</p>	300 words
4	<p>Delivery & outputs: Describe anticipated risks and challenges, ways to mitigate them, and quality assurance efforts for your work.</p>	500 words
7	<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 two senior academic consultants.</p>	300 words

5.4 Proposal Scoring

<p>Experience 30%</p>	<p><i>Skills and Experience:</i> Does the supplier have the relevant skills, experience, and contextual understanding to deliver this work?</p>
<p>Methodology 30%</p>	<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> <p><i>Diversity & Inclusivity:</i> Does the proposed methodology align with Wellcome's D&I principles (i.e., is the planned research inclusive of different groups of people and locations, and does the methodology mitigate potential biases)?</p> <p><i>Acceptability:</i> Does the proposed methodology meaningfully include input from experts by lived experience?</p>
<p>Delivery & Outputs</p> <p>20%</p>	<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>
<p>Budget</p> <p>20%</p>	<p><i>Value for Money:</i> Is the proposed work within budget and good value for money?</p>

5.5 Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. 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 Terms and Conditions which can be found [here](#).

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 7 below).

5.6 Information Governance & Wellcome Data Protection Compliance

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 are asked to complete the [TPSRA2](#) assessment before the RFP submission deadline for Wellcome to assess how you handle data.



5.7 Supplier Presentations

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

6 About Wellcome

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, climate and infectious diseases. Find out more about Wellcome and our work at: [wellcome.org](https://www.wellcome.org).

7 Non-Disclosure and Confidentiality

Prospective Suppliers should be aware that inappropriate publicity could have a serious effect upon Wellcome's business. The information contained within this document or subsequently made available to prospective suppliers is deemed confidential and must not be disclosed without the prior written consent of Wellcome unless required by law.

8 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.

9 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.

10 Funding

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

11 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.

12 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.

13 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.

14 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.

15 Diversity & 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. 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.

16 Wellcome Contact Details

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

Name: Olivia Donovan
Role: Procurement Officer
Email: RFP@wellcome.org