

Mental Health Databank Scoping and Proof of Concept Request for Proposal (RFP)

1. RFP Background

Wellcome is seeking to commission a learning partner to prototype and test best ways to build a databank that holds rich longitudinal data at scale from different global locations on approaches, treatments and interventions potentially relevant to anxiety or depression in 14-24 year olds in order to help answer the question : “what works for whom and why in relation to prevention, treatment, stopping relapse or managing ongoing difficulties for anxiety or depression including at least some 14-24 year olds”.

This databank must also include the following key features:

- those banking their data have a high degree of involvement in decisions about the use of data and opportunities to act as citizen scientists
- the data collected is made readily accessible to a wide range of researchers
- to support cutting-edge scientific research, ensure there is sufficient ongoing engagement from those banking their data and those who might analyse it to answer important research questions

In order to test out whether this is feasible, Wellcome have allocated a prototyping phase to be completed in January 2022. See Appendix 1 for approach as agreed by our Board.

We are seeking a learning partner for this phase to lead on developing and testing this databank. A key requirement is that any data collected during this prototyping phase can be readily transferred to another host at the end of this commission (always assuming necessary permissions were in place).

We are developing clear go/no-go criteria which will determine whether we proceed to scale at the end of the feasibility testing period. See Appendix 2 for our current draft potential go/no-go criteria, though please note these criteria are still in draft and will be further refined.

For the avoidance of doubt this commission is to test feasibility. To do this we will need the learning partner to develop and test options and produce a functional databank BUT the ultimate yardstick of success is that we learn what is and is not feasible NOT that we end up with a functional database if this does not meet our stated aims.

We are therefore looking for a supplier who will work closely alongside the commissioning team at Wellcome, shares our values of open science and shared

learning and is prepared to openly share learning with Wellcome and others and not be afraid to share when things are not working as well as when they are working.

Key features of the databank to be developed include the following (all within the context of safe and secure data storage compliant with the necessary legislation):

- 1) **Ability to capture rich longitudinal data about what helps prevent or address anxiety and depression.** Whereas other databanks are focussed on collecting rich data about an individual, this databank seeks to have both rich data about the individual AND detailed information about aspects of that person's life that may relate to prevention, intervention, stopping relapse or managing ongoing anxiety and depression. This involves trying to capture WHAT people do, and, crucially, WHY they do it using the lens of "[core components](#)" of what might constitute effective interventions. Please see Appendix 3 for details of the sort of data we are seeking to collect. For a summary on what we mean by core components see this [blog post](#) by our Evidence Lead.

Given the need is not just to capture events but to try and capture the relationship between events, we recognise this is not a simple ask. We welcome applications from suppliers who have no expertise in this subject area, and even for those who do, we are happy to consider proposals from suppliers which include suggestions of how they might draw on Wellcome to convene relevant mental health expertise to support them in achieving this complicated goal.

- 2) **Potential for iteration of what data is collected:** The databank will need to be established in a way that allows further refinement and iteration as knowledge of what and how to capture these data develops. The sort of data that this is likely to comprise includes data from passive wearables, documentary data such as from individual's journals, audio and video data as people capture elements of their lives, questionnaire data, and potentially biological and cognitive information. We therefore need suppliers to advise on how they will hold such data and allow for new data sources as they arise.
- 3) **Empowered users:** we are looking to develop innovative models of data control. The emphasis is on individuals who are banking their data being involved in decisions about what data is collected and how it is analysed and used. This should also allow us to iterate at a faster pace as end users are more involved in making decisions about changes to data capture and use rather than agreeing all details up front as part of a traditional consent model.

There may be options for different agreements with different end users on this akin to people investing in the stock market with different levels of risk for example or other innovative models of data trusts or data commons Wellcome is interested in potential suppliers advising on how they would explore and develop different models

- 4) **High engagement** with those who are banking data and ability to achieve this ultimately at scale with very large numbers of users – so that the databank is able to ultimately engage with hundreds of thousands if not millions of users. To note that during the initial prototyping stage this level of engagement is not required but considering engagement at scale will be a key feature in order to ensure that good quality data is collected over time to support meaningful science. We recognise this is a challenge and look forward to suppliers sharing creative approaches to achieve this.
- 5) **Global reach:** we are looking for a databank that can hold data from individuals from varied geographies and in low-resource settings. We seek a supplier who can trial this approach using data from UK, South Africa and India. Longer term we hope to hold data from a wider range of geographies, so suppliers need to address how they are able to support international scale up.
- 6) **Easy access for a wide range of mental health scientists;** we are seeking a databank that can be used as a “living lab” by a wide range of mental health scientists who can both easily know about and access the data collected and interact via appropriate governance channels with those banking the data such that the databank can be used as a platform for trials etc as agreed to by those wanting to take part. We therefore seek proposals from suppliers on how they will ensure this level of access is not just possible but probable.

The initial data parameters to be held in the databank have been defined by the Wellcome Trust Mental Health priority area team, involving people with lived experience, mental health scientists and data scientists and drawing on our recent call on what might be considered the likely [core components of effective interventions by the mental health science](#). These can be found in Appendix 3.

We are looking for a learning partner that can prioritise within these and iterate this over time. We are happy to receive applications from partners who bring their own in house or collaboration expertise in this area but are equally open to suppliers who wish to work closely with Wellcome and seek Wellcome to convene such expertise, either to complement inhouse expertise or where the supplier does not have expertise in the area to be the key source of such expertise.

We are seeking proposals to develop a databank as part of a proof of concept stage, which will end in January 2022 after which the go -no go criteria will be reviewed, and a decision made as to whether to proceed.

During the proof of concept phase, we are looking to work with a databank developer who will work closely with us as a learning partner, to trial new methods of data control and data collection, and involve young people including those with lived experience of anxiety or depression. We aim to identify as many issues as possible, as early as possible, to reduce the cost and impact of any change of course.

During this feasibility testing phase we are exploring the possibility of inviting members of existing cohorts in the UK and South Africa to join the new databank in

order to understand more about who does and doesn't engage. We will also test out reaching out direct to new individuals to participate who are not currently involved in any data collection. So, the databank must be able to upload existing data - where there is consent for opt in by the relevant participants - and link this to new data being collected, as well as collecting data from scratch.

We are not expecting at this stage to build a user interface, we want to re-use existing data input methods where possible.

2. Problem definition

We are seeking to build a databank that solves the following problems

- We lack rich and detailed longitudinal data **on what helps** in relation to prevention, treatment, stopping relapse and/or ongoing management of anxiety and depression. Whereas other databanks are focussed on collecting rich phenotypic data about an individual, this databank seeks to have both rich data about the individual AND detailed information about aspects of that person's life that may relate to prevention or treatment as detailed above. This involves trying to capture WHAT people do, and WHY they do it. Thus, the need is not just to capture events but to try and capture the relationship between events. We currently lack clear categories of approaches for collecting and analysing these data- this databank aims to help address this.
- We lack databanks that are **agile and able to iterate quickly** over time. Traditionally databanks are run by a particular research group with a particular approach in mind and those banking their data consent into a given protocol that is hard to deviate from, We are looking to build a databank where those banking their data are involved in decisions about what data are capture and used and thus the databank as a whole is able to iterate at a faster pace
- We lack databanks in which data are **easily accessible to other researchers**- even where data is apparently "open" the details are often shared in such a way as to make it complicated for other researchers to understand or access the data
- Able to ensure meaningful ongoing **engagement** with sufficient people banking their data to collect data that allows for meaningful scientific analysis.
- We lack data from populations **outside of WEIRD** contexts (Western Industrialised Educated Rich and Developed) this databank should collect data from both high resource and low resource settings
- We lack data focussed on **young people** (14-24 year olds)- this databank must include this age group, but can also include other ages.
- We lack databanks that can **easily be transferred** to another host or provider if required.

3. RFP objectives

We are inviting proposals to build a proof of concept for a databank platform that can hold longitudinal mental health prevention and intervention data and address the problem described above.

We seek to commission a databank developer who will work closely with us to develop a databank with the following requirements:

1. Able to hold rich longitudinal data on approaches, treatments and interventions to prevent, treat, stop relapse, or manage ongoing anxiety or depression in 14-24-year olds across a range of geographies. This involves collecting and categorising a wide range of data including from passive wearables, documentary data such as from individual's journals, audio and video data as people capture elements of their lives, questionnaire data, and potentially biological and cognitive information.
2. Be able to adapt and collect new types of data or recategorize existing data in line with learning.
3. Be able to upload existing data such as personal data held by those banking data already held in other databanks, whether commercial or non-commercial, with the individual's permission, and link this to new data being collected, as well as collecting data from scratch.
4. Be capable of merging and combining data at the individual level, so that they may be analysed at the level of the individual. For example, survey answers, fitness tracking information, images/videos.
5. Be able to hold data from individuals from varied geographies and in low-resource settings. We will initially trial this approach using data from UK, South Africa and India. Longer term we hope to hold data from a wider range of geographies, so this aspect needs to be considered in all proposals. Thus, the databank must be able to collect information in different languages but should use English as the main language for scientists and for the infrastructure.
6. Provide infrastructure to allow remote access to a wide range of geographically dispersed mental health scientists and citizen scientists to analyse the data, including the ability to use machine learning and other artificial intelligence techniques to model the data.
7. Share learnings of the various approaches taken to building the databank with Wellcome, through frequent and regular sharing of progress and learnings. Throughout the process the key focus will be to help Wellcome to learn about key challenges to developing a databank of this sort and how these are best addressed or mitigated. This includes regular review of progress against the go/no-go criteria, see Appendix 2.
8. Act as and be responsible as an independent data controller and hold data with relevant levels of security and compliant with all data protection and security requirements of the selected geographies (e.g. PII - HIPAA, GDPR). Including being able to work through issues of consent, trialling different approaches, learning what works and doesn't and sharing the learnings with Wellcome. This includes setting up a contractual relationship with individuals banking the data, aligned with Wellcome's commitment to promoting as much

involvement in decision making of those banking the data as is feasible. This to be done in conjunction with Wellcome's work on developing innovative governance structures, such as use of data trusts. This needs to include consideration of what data controls are viable at scale.

9. Work closely with potential end users aged between 14-24 from the initial geographies (UK, India, South Africa), including those with experience of depression or anxiety, to take their views and perspectives into account both to inform usability design but also to shape the approach to data collection and use and ensure meaningful ongoing engagement. We see it as integral to include people with lived experience in the development of this databank, including through user research, engaging with young people in creating concepts, and in identifying, testing and reviewing ethical and governance structures put in place to manage the data.

To note: we don't expect suppliers to have previous experience of working with lived experience input, but we expect suppliers to be committed to ensure young people contribute to the design and build process. Wellcome's Mental Health Priority Area has expertise in coordinating and collaborating with those with lived experience and will be supporting this objective. The supplier will make sure to facilitate involvement from these groups as relevant (e.g. through usability testing and user research into behaviour), as well as work closely with Wellcome's Lived Experience and Public Engagement Lead and expert advisors.

10. Develop the databank in such a way as to both be accessible to a wide range of diverse researcher and allow maximum portability of data, including use of open source software where possible, and maximum ease of transfer of data to another supplier if required. Please note: This requirement will receive extra weighting as part of assessment of meeting criteria.

We are not expecting at this stage to build a user interface, we want to re-use existing data input methods where possible.

We are working to the following timeline:

- the initial databank needs to be able to store data by November 2020 by the latest,
- the suppliers to work closely with Wellcome on iteration and refinement in the light of learning through to the end of the contract in January 2022.

Note: suppliers are to advise frequency and process for iteration that they think viable and optimal.

We are not specifying a budget but value for money will be one of our key considerations.

4. Response

We are carrying out this procurement in two stages

Expressions of interest stage; where we invite potential suppliers to address the following questions:

1. Describe how you would work with Wellcome including how you would ensure Wellcome learnt from your work on this project and what expertise you would want from Wellcome (100 words).
2. Outline your current thoughts on how to ensure innovative models of end user data control for those banking data (100 words)
3. Outline your current thoughts on how you will engage with likely end users of the databank including young people with experience of mental health problems (100 words).
4. Outline your current thoughts on how you would ensure that the data collected were accessible to a wide range of researchers (100 words).
5. Evidence of track record of software development in this area – including any failures that can be learnt from in this project (200 words).
6. Suggest any comments or amends to the go-no go criteria (annotate and amend table from Appendix 2 and attach to your EOI).
7. Provide a non-binding overall cost estimate (single figure).
8. Suppliers should also add in any questions they want addressed (max 100 words) but to **note we will only answer questions from suppliers invited to submit a full proposal.**

From these answers we will invite up to 5 suppliers to submit a full proposal.

We will use the assessment criteria below to make this selection.

Assessment Criteria for EOI	Weighting
Strength of answers to Q1-5 in response to requirements set out in this RFP	70%
Track record and expertise in software development (Q6)	30%

The exact form required for the full proposal will be shared with the selected suppliers. Below is what we anticipate may be included but we reserve the right to amend or adapt as relevant having reviewed expressions of interest.

Anticipated full proposal stage

For those suppliers invited to make a full proposal your response is likely to need to include the following:

- How you would address the 10 requirements as set out in the objectives above? (word count: up to 200 words on each requirement)
- Your methodology for building the databank, i.e. what you are developing based on something you already have and what you would be building from scratch (word count: 400)

- How you would ensure you reach the milestones set out in the timeline above? (word count: 400)
- What resources you will use and cost breakdown? (word count: 400)
- Any major risks and how you will address these (word count: table, no more than 400 words)
- A worked example of the journey of an individual using the databank to (a) opt in with appropriate consents to be part of the data bank (b) bank data and (c) use the data for their research (could be the same individual or different individuals) (400 words)
- A similar project you have undertaken in the past including any feedback from end users or other stakeholders in that project (word count: 400)
- How you intend to work with us on an iterative basis? (word count: 400)
- Advice or comments on current proposed data parameters and how you would go about prioritising between these and/or developing these further (word count: 400). Please include details of how you would work with the commissioning team at Wellcome to convene expert input to inform your decision making in this regard.

Assessment Criteria	Weighting
How well the proposal meets specification of requirements	50%
Track record and expertise	30%
Value for money	20%

4. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	15 May 2020
2	Submission of expression of interest to RFP (Email with expression of interest – structured as specified above)	Supplier	12 midday AOE (anywhere on earth) on 8 June 2020
3	Submission of Supplier Q&A to Wellcome Contact (by email, in same email as expression of interest- to note only those suppliers invited to full proposal will have their questions answered)	Supplier	12 midday AOE on 8 June 2020
4	Advice to suppliers as to whether they have been invited to submit a full proposal and Return of Supplier Q&A to Suppliers (collated response to all shortlisted suppliers at the same time)	WT	12 midday AOE on 15 June 2020

5	Submission of RFP Response	Supplier	12 midday AOE on 29 June 2020
6	RFP Evaluation Period	WT	29 June to 6 July 2020
7	Supplier Presentations	WT & Supplier	6 July to 10 July 2020
8	Notification of Contract Award	WT	15 July 2020
9	Contract Negotiation	WT & Supplier	15 July to 24 July 2020
10	Contract Start Date	WT & Supplier	3 August 2020
11	Contract End Date	WT & Supplier	3 February 2022

5. Supplier relationship

We're looking for a partner to have a framework agreement, who will build prototypes and proofs of concept, and intelligently work with us to answer some of the questions that we want to answer during the proof of concept process.

We want to establish a learning partnership with the supplier, working in an iterative way, learning together throughout the 18-month proof of concept phase what works and does not work. Wellcome will maintain an active relationship with the supplier, assigning a dedicated member of staff with expertise in the field of Mental Health to support the work as needed.

6. Response Format

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

Expression of Interest

Suppliers are asked to address questions in their expression of interest detailed in section 3 above.

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. All questions from shortlisted suppliers will be collated and shared with all suppliers so please do not include any confidential information. All questions are to be submitted to the Wellcome Contact by e-mail in accordance with the RFP timetable. Please note we cannot enter into any individual correspondence with potential suppliers during this period and questions from suppliers not shortlisted will not be answered.

RFP Proposal

Invited suppliers are required to submit full proposals which respond to the sections detailed in Section 4 above.

Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which may 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

Only suppliers who are registered companies will be considered. Suppliers submitting proposals should review this [document](#).

RFP Questions

As noted above, all questions should be made at the expression of interest stage. Note we will only answer questions from suppliers invited to submit a full proposal.

7. About Wellcome

Wellcome exists to improve health by helping great ideas to thrive. We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research. We are a politically and financially independent foundation. Find out more about Wellcome and our work: wellcome.ac.uk.

8. 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.

9. 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.

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. 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. Working During Covid-19

Given the current working situation and impact of the current lockdown and possibility of future lockdowns we require all suppliers to think hard about how they will work with Wellcome during this time. Suppliers must cost and build in contingency for potential delays due to Covid-19 and ensure that they are set up to work remotely with Wellcome on this contract. Further questions relating to Covid-19 should be addressed to Wellcome as part of the RFP questions.

17. Wellcome Contact Details

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

Name: Katie Taylor
Role: MHPA Databank Lead
Email: MHdatabank@wellcome.ac.uk

APPENDIX 1

Mental Health Priority Area approach to databank as agreed by Board of Governors,

Please note: the Board are aware this is an ongoing agile and iterative programme of work, ideas may change. We are sharing the below for clarity on what has been signed-off by the Wellcome board in December 2019.

The problem

Research to date has focused on limited populations and questions. It has frequently failed to consider the wider picture that may be most relevant to finding best ways forward for anxiety and depression. International longitudinal research studies suggest that most people will experience anxiety and depression before middle age. Few will access professional help and most do not have chronic problems (Schaefer et al 2017, Kwong et al 2019, Beesbo et al 2012, Markkula et al 2016, Whiteford 2013). Yet the research has focused almost exclusively on that small population who do access treatment, and who moreover come from contexts which can be characterized as “WEIRD” (Western, Education, Industrialized, Rich and Developed) (Henrich et al 2010).

Despite the growing agenda to empower people to be more active agents in monitoring and managing their own health (e.g. Mulley et al 2015, Elwyn et al 2012) young people with anxiety or depression are advised that the only solution to their difficulties is professional help. There has been virtually no research on other approaches. While over 100 different potential interventions not involving professional input have been described as ways young people might address anxiety and depression, such as exercise, participation in arts, peer support, listening to music, engaging with nature and community engagement; virtually none of these have been scientifically researched (Wolpert et al 2018).

Current research datasets rely on questionnaires and biological samples taken at discrete time points and related to a research question from a research community. In part due to prior limitations of technology, researchers have not collected granular enough information on a range of aspects that may be highly relevant, such as life events and social and economic context (Pickett and Wilkinson 2010, Bringmann et al 2013).

There is an ever-growing range of commercial technological innovations which seek to support people to manage and monitor their own mental health, (e.g. Daylio, Headspace, Shout, Pesky gnats). They generate quantities of data, but do not support end users to be actively involved as citizen scientists in learning from the data, nor are they readily available for research use. A combination of concerns over data privacy combined with commercial and academic protectionism make it very hard for researchers to analyse data from existing datasets.

Our solution

We propose to create a new catalytic infrastructure in the form of a Mental Health Science databank. This will allow us to collect large-scale data over extended periods in a flexible way. This would include collection of data, relevant across the full span of the Mental Health Science community including behavioural, biological, affective, cognitive, social and cultural data. The databank will have a twin focus of supporting long term scientific findings whilst

enabling end users to learn from the data rapidly to help them manage and monitor their own mental health, with an emphasis on the start of end user feedback and the radical premise that control of data will rest with end users rather than researchers (Delacroix & Lawrence 2018, Taylor & Wilson 2019). The databank will support enhanced understanding of the potential core components of effective interventions and how these relate to outcomes based on the core outcome metrics. It will support modeling of individual and group differences (Jaques et al 2017, Wright and Woods 2019) as well as acting as a platform for embedding research trials ranging from multi-site randomized control designs to single case studies.

We recognise this databank is a high-risk endeavor. The history of health research and innovation is littered with wonderful-sounding tech-based propositions that have failed to meet their promise. We think in this instance the high stakes warrant the risk. We have built in stringent scoping and feasibility testing. We don't ultimately believe the main challenge here is a technical one (although we anticipate many technical challenges as well!). The main issues we believe are related to ethics and engagement. Can we find a governance structure that genuinely vests control with the end users? Can we engage end users with the databank at enough scale and coverage to provide meaningful data for analysis and support meaningful feedback in a timely way to end users? Only if these conditions are satisfied will we progress.

We are already working closely with the Understanding Patient Data team and allied data expert teams at Wellcome to align and share learning and approaches. We will set out clear gateway points for decision on the databank before going forward with any design and build.

We are proposing the unusual model that Wellcome will be centrally involved in the actual development of this initiative, working with key partners. This is because we believe that Wellcome is uniquely placed to support a truly transformative infrastructure development and prevent it being "hijacked" by a research agenda. However, we would work from the start to ensure ongoing sustainability and independence from Wellcome by 2030.

Appendix 2: Draft potential go/no-go criteria

	Key area to be covered	Go	Not sure	Stop
1	<p>Ethical & governance</p> <p>Q: “How do we make sure the model for data control is sustainable, responsible and fair”</p>	<p>Clear governance structure in place</p> <ol style="list-style-type: none"> Written down Adhered to 90% of time and any exceptions noted and logged High acceptability to data contributors- 60% say that they are clear and happy with the principles laid out <p>This works in practice in all key geographies</p> <ol style="list-style-type: none"> Clarity about access for researchers Clarity about what data controls are practical to offer at scale 	<p>Clear governance structure in place</p> <p>This works in practice in at least one geography</p> <p>Adhered to 70-90% of time in either geography</p> <p>40- 60% say acceptable</p>	<p>Not possible to agree approach</p> <p>Approach agreed but not adhered to</p> <p>Less than 70% adherence</p> <p>Less than 40% say acceptable</p>
2	<p>Data specification structure & Analysis</p> <p>Q: How should the data be specified and structured to make sure useful studies can be done?</p>	<p>Set of core data items agreed that relate to relevant potential research questions.</p> <p>How these data are structured in database is specified</p> <p>How these data can be combined with data from other datasets as relevant (e.g. from data from other geographies using same databank approach)</p> <p>Analytic plan allows researchers to at least consider the possible answers to the question “what works for whom and why in relation to one or more of prevention, treatment, stopping relapse or managing ongoing difficulties for anxiety or depression including at least some 14-24 year olds”</p> <p>How we support multiple languages clear</p>	<p>Data items too poorly specified to be clearly captured</p> <p>Data items unrealistic and cannot be captured</p> <p>Specification of database overly complicated</p> <p>Analytic plan not realistic</p>	<p>Data items cannot be specified or captured,</p> <p>No specification for database</p> <p>No analytic plan</p>
3	<p>Engagement data contributors</p> <p>Q: “How do we collect high quality mental health data?”</p>	<p>At least 1% or 100 people, of those who start using the databank contribute their data according the protocol agreed with them over a 6-month period (Nov 2020- April 2021) such that have data on at least 100 people in at least two geographies</p>	<p>At least 1% of those who start using the databank contribute their data according the protocol agreed with them over a 6- month period (Nov 2020- April 2021) such that have data on at least 100 people in one geography</p>	<p>Cannot gain 1% engagement or 100 people in any geography</p>
4	<p>Sustainability of databank</p> <p>Q: “What business model will create a sustainable databank?”</p>	<p>Clear plan written down and agreed this might include a time-limited databank that ends when MHPA ends, or could be an agreed commercial or other model from the start</p>	<p>Plan written down but not acceptable to Board</p>	<p>Not possible to come up with plan</p>

Appendix 3: Metrics

Wellcome are in the process of funding research teams to consider existing literature on potential key ingredients ('core components') to prevent or address anxiety or depression in 14-24s. We aim for the databank to advance understanding of who these core components help and who they don't and ideally how and why they help or don't, including in what combinations, and in what contexts. .

Below we share some the core components we are focused on in this initial stage to give a sense of the range. We seek a learning partner who can help us capture and evidence as many core components as possible.

We recognise the complexity of trying to determine metrics to capture many these including getting the right balance between self-report and more objective measures. We are also aware of the complexity of modelling impact or causal pathways.

We anticipate it will not be possible to collect all the metrics we may be ultimately interested in during this prototyping phase. During this prototyping stage we will focus only on data that can be digitised **and we are not looking for suppliers to store biological material**.

We are looking for a learning partner to work with us to consider what best to focus on initially, what metrics to suggest trialling in the first instance and at what frequency (recognising the need to balance burden with utility for research).

We are happy to work with a learning partner such that Wellcome supports the supplier by bringing to bear a range of academic expertise to help consider these issues

Table 1: Selected core components and potential that we consider to be in scope for this proof of concept stage.

Core components	Comments on metrics
Improving sleep patterns	May want to measure both the amount and quality of sleep over time using wearables but also what people do to try and improve sleep e.g. new routines around sleep etc
Increasing motor activity	May want to measure levels of activity over time but also what people do to undertake more activity e.g. joining groups etc
Stopping avoiding feared things	May want to measure levels of fear or avoidance over time and also interventions to address
Focussing on building up pleasurable daily activities	May want to measure what constitutes a pleasurable activity amount of that activity over time and barriers and facilitators to undertaking these
Monitoring own behaviour	May want to measure how people are self-monitoring over time and how using that data and what facilitates or prevents use
Using relaxation techniques	May want to measure techniques used, at what times and to what extent and may also want to measure levels of relaxation achieved e.g. by self-report or wearable such as pulse rates
Improved problem solving	May want to measure problem solving skills in a standardised way and also in natural contexts over time and also any direct intervention aimed to address this

Countering negative thoughts	May want to measure quantity and quality of negative thoughts over time and how are countered and any direct intervention aimed to address this
Increased recognising and managing emotions	May want to measure how able individuals are to recognise and address emotions in both standardised way and in natural contexts over time and any direct intervention aimed to address this
Learning self-compassion and addressing perfectionism	May want to measure levels of self-compassion and perfectionism in standardised way and in natural contexts over time as well as any direct intervention aimed to address this
Increasing sense of social connection with others	May want to measure self-reported levels of social connection but also other measures of connection e.g. from phone or other records over time as well as any direct intervention aimed to address this
Increased access to nature	May want to measure extent of access to nature over time (as defined by a chosen measure or measures) as well as measures to capture what facilitates or prevents access
Increased access or involvement in theatre and arts	May want to measure extent of access to theatre and the arts over time (as defined by a chosen measure or measures) as well as direct active involvement in producing theatre and arts well as measures to capture what facilitates or prevents access and/or active engagement
Increased engagement in meaningful activity	May want to measure what constitutes meaningful activity to the individual and then measure extent and quality over time along with measures to capture what facilitates or prevents this
Increased economic wellbeing	May want to measure levels of wealth or other metrics of socio-economic status over time
Increased neighbourhood social cohesion	May want to measure individual's perceived levels of neighbourhood social cohesion using a given measure and also measures based on information about the neighbourhood from relevant community information over time.

In the light of above we currently anticipate the databank will need to collect the following key data parameters in the first instance:

- A. Demographics (to understand who is helped)
 - a. Sex at birth
 - b. Age (year and month of birth)
 - c. Location (granularity to be specified)
 - d. Socio-economic status
- B. Measures of anxiety and depression (to understand what is helped)
 - a. Nine questions from Patient Health Questionnaire (PHQ9)
 - b. Seven questions from Generalized Anxiety Disorder scale (GAD7)
 - c. Up to 25 questions from Revised Child Anxiety and Depression Scale (RCADS25)

- C. Measures of core components (to try and capture what helps)
 - a. Structured self-reported activity data (e.g. ecological momentary assessment (EMA))
 - b. Journal: audio or written reflections from individuals which may range from structured to unstructured
 - c. Unstructured video data of activities (that will need subsequent coding)
- D. Measures of activity related to core components (to try and capture what helps and also possibly what is helped)
 - a. Sleep (amount and quality)
 - b. Activity (e.g. step counters)
 - c. Screen time
 - d. Contact with others
- E. Measures of perception of that activity (to try to capture what helps and possibly why)
 - a. Questionnaires measuring relevant aspects e.g. enjoyment, hope
 - b. Mood or thought trackers e.g. done over specific periods of time e.g. using EMA
- F. Relationship data (to try to capture what helps and possibly what is helped)
 - a. Socio-metric data
 - b. Reports from significant others

Data that we may want to collect in the future but are not looking to test in the prototyping stage

- G. Biological data (to try to capture what helps and possibly what is helped)
 - a. Cortisol levels
 - b. Genetic material
- H. Neuro-imaging (to try to capture what is helped and possibly why)
 - a. EEG scans
 - b. MRI scans
- I. Cognitive experimental data (to try to capture what is helped and possibly why)
 - a. Response to particular stimuli
 - b. Response to tests