

# OpenSAFELY Oversight Board - 06/10/2022

## Minutes

Ratified at 02-03-23 Oversight Board

<b>Attendees</b>	<p><b>Chair:</b></p> <ul style="list-style-type: none"><li>• Prof. Nigel Shadbolt</li></ul> <p><b>Bennett Institute:</b></p> <ul style="list-style-type: none"><li>• Prof. Ben Goldacre - Director and OpenSAFELY PI</li><li>• Seb Bacon - Chief Technology Officer</li><li>• Amir Mehrkar - Head of IG and external relationships</li><li>• Jess Morley - Policy Lead</li><li>• Pete Stokes - Director of Platform Development</li></ul> <p><b>Board Members:</b></p> <ul style="list-style-type: none"><li>• Rony Arafin - ApHA</li><li>• Chris Bates - Director of Research and Analytics, TPP</li><li>• Nicky Brassington - Deputy Director of Data &amp; Analytics, NHS Transformation Directorate, DHSC</li><li>• Mark Coley - GP, BMA</li><li>• Stephen Evans - Professor of Pharmacoepidemiology, LSHTM</li><li>• Alex Freeman - Executive Director, Winton Centre for Risk &amp; Evidence Communication, University of Cambridge</li><li>• Sean Kirwan - Senior Data Sharing and Privacy Manager, NHSE</li><li>• Tariq Khokhar - Head of Data for Science &amp; Health, Wellcome Trust</li><li>• Kevin Minier - Expert patient representative</li><li>• Shaun O'Hanlon - CMO, EMIS</li><li>• Jeni Tennison - Connected by Data</li><li>• Laurie Tomlinson - Associate Professor, LSHTM</li><li>• Sam Smith - MedConfidential</li><li>• Johnny Stewart - GP, RCGP</li></ul> <p><b>Attendees:</b></p> <ul style="list-style-type: none"><li>• Ian Douglas - Professor of Pharmacoepidemiology, LSHTM</li><li>• David Hoy - Head of Data Policy, DHSC</li></ul> <p><b>Secretariat:</b></p> <ul style="list-style-type: none"><li>• Liam Hart - Research Administrator; Bennett Institute</li></ul> <p><b>Apologies:</b></p>
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|  | <ul style="list-style-type: none"> <li>• Wendy Harrison - Head of Data Governance / Deputy Data Protection Officer, NHSE</li> </ul> |
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## Terms of Reference

Amir proposed minor changes to the ToR, to reflect the current membership of the Board.

Board members were happy with the changes, but asked when it would be appropriate to undertake a fuller review of the ToR, to ensure they remained comprehensive and relevant.

### **Decision: Updated ToR approved**

**Action: Ben and Pete to consider when and how to review ToR, and update Board at next meeting**

## Director's Update

Ben gave the Board an update on progress on a wide range of fronts, for OpenSAFELY, including that:

- All milestones due by this meeting have been completed as scheduled.
- OpenSAFELY has been granted a bespoke Covid-19 COPI regulation 3(4) extension, running until 31st Oct 2023, ensuring continued legal permission to access Primary-Care data. Longer-term plans were discussed later in the meeting.
- All current grants are being actively managed, with no underspend projected for the financial year (which had been a concern previously). Several new grant applications are currently in progress.
- The Bennett Institute staffing structure has been updated, as the team continues to grow. New recruits since the last meeting include:
  - Pete Stokes, who joined from ONS, where he was the Director responsible for TREs and Information Governance
  - Andrea Schaffer and Caroline Walters, who have joined the research teams
  - Liam Hart, who has joined the Information Governance team and will provide secretariat to this Board as part of his role
- OpenSAFELY is now used by 22 external organisations, and NHSE have approved 125 projects
  - The Co-pilot scheme is working very well, in supporting these new users

Board members welcomed Ben's update, and ask for further information on a number of points:

- How do people find out about OpenSAFELY, and what proportion of projects are by external researchers?
  - OpenSAFELY isn't widely publicised at the moment, with most people hearing by word of mouth, but interest continues to grow
  - Around 35% of projects are undertaken by external researchers

- Does the Bennett Institute monitor the diversity of its workforce, and has it engaged with the Athena Swan Programme?
  - Workforce diversity is monitored, and Institute plays an active part of wider Departmental engagement with Athena Swan Programme (where we hold a Silver Award)
- Are there any restrictions on analysis of Ethnicity data through OpenSAFELY?
  - No. Ethnicity can be analysed in any project where that is approved by NHSE

## PPIE

Jess gave an update on the proactive approach to PPIE for OpenSAFELY, working with the Digital Critical Friends (DCF) group.

The pilot programme comprised three sets of activity: Explain and Engage; Evolve and Iterate; Participate and Promote. This work, planned to ensure that the DCF group had a good understanding of OpenSAFELY, and the wider health data research environment, was progressed through meetings every 2-4 weeks.

The pilot proved successful, the DCF group and OpenSAFELY team collaborated on a range of valuable public-facing outputs, including guides to specific concepts, an extensive FAQ document and an explainer video.

The current approach to PPIE will continue, and the content and structure of discussions will continue to evolve, based on feedback from, and the wishes of, the DCF group. In particular, the group will be given more opportunity to engage directly with a wider pool of people from the OpenSAFELY team to (for example) ask detailed questions about technical developments.

**Action: Jess to circulate slides after the meeting**

## Industry

Ian introduced two applications for research projects that would be undertaken in OpenSAFELY, which would include researchers from industry - no projects with industry involvement have yet been approved, and the Board were asked for views on the risks involved with such projects and whether/when they might be permitted.

Concerns were raised about the potential for conflicts of interest within such projects, and about whether researchers from industry would be comfortable with the requirements of OpenSAFELY to publish all outputs and code.

The transparency requirements of OpenSAFELY, particularly where a researcher may have a perceived conflict of interest, may make it the most appropriate route for any such research to take place using primary care data, as concerns around (for example) selective reporting would be wholly mitigated.

It was noted that NHSE are currently developing a set of principles for industry use of their SDEs - it may be appropriate, once these are in operation, for the same principles to apply

for use of OpenSAFELY. There was agreement that any industry use of OpenSAFELY must deliver clear benefits to patients and the NHS.

It was suggested that the OpenSAFELY Digital Critical Friends group should be given an opportunity to discuss the principle of Industry use of the service, before any decision is made on whether to proceed with specific projects.

**Decision: No projects with industry involvement should proceed until the DCF group has had an opportunity to offer its views, and that discussions with NHSE about project approvals have concluded**

**Action: Jess to lead discussion on potential for industry use of OpenSAFELY with DCF Group**

### Information Governance - Post-COPI Legal Basis

Nicky Brassington from DHSC / NHS England gave an update on progress in ensuring the ongoing legal basis for OpenSAFELY, which is being pursued by a Working Group with representatives from NHSE, NHSD and DHSC. The likely outcome of that work was a further six-month extension of the COPI notice for OpenSAFELY, to give time for a long-term solution to be agreed and implemented.

The Board expressed concern that there was little time left to get such an extension in place, and disappointment at the lack of visible progress in securing a long-term solution during the current COPI extension, especially considering that OpenSAFELY has unprecedented positive support in an area where previous projects on the same data have been controversial. If a further extension is not in place imminently, OpenSAFELY would need to stop access to primary care data immediately, which would be a bad outcome for all parties, including patients - removing access to the most comprehensive GP data available in the country would reduce the accuracy of research and, thus, policy and care decisions made as a result. It was suggested by Board members that it may also create public controversy to close a GP data project that has strong positive support from e.g. citizens juries and privacy campaigners while other potentially more controversial NHS data projects are continuing.

It was agreed that, if a further extension was not confirmed very quickly, that the Board would hold an extraordinary meeting, later in October, to discuss how to escalate the situation. Nicky and David agreed to continue pursuing this, as a matter of urgency, within DHSC and the NHS.

*N.B. Shortly after the Board meeting, following further work between DHSC and the NHS, Nicky was able to confirm a six-month extension to the COPI notice for OpenSAFELY. Therefore, the extraordinary meeting was not required.*

**Action: Nicky to provide an update on long-term solution at next meeting**

## Actions

Item	Action	Owner	Status Notes
21	Consider when and how to review ToR	Ben/ Pete	Complete - on Agenda for next meeting
22	Circulate PPIE Slides	Jess	Complete
23	Discuss Industry Projects with DCF Group	Jess	Ongoing
24	Update on long-term legal basis for OpenSAFELY	Nicky	On agenda for next meeting