INFORMATION SHEET FOR PARTICIPANTS

Protocol Title: RADIANT Consortium Clinicians Survey Project

Ethical Clearance Reference Number: REMAS: MRA-24/25-49755

SURVEY LINK CLICK HERE

A. Invitation and Introduction to the Research Questionnaire

We would like to invite you to participate in this research survey project. Before you complete the questionnaire, it is important that you understand why we are carrying out this questionnaire based research for clinicians.

B. Introduction, Project Rationale and Objectives:

RADIANT CERSI is one of seven UK Human health Centre for Excellence in Regulatory Science and Innovation, focusing on transformative digital health and healthcare AI. RADIANT CERSI outstanding includes three world-leading universities (Brunel -lead-, King's, UCL); Imperial College NHS Trust; industry partners (venture builder Zinc, and global knowledge provider BMJ Group). Funded by the Medical Research Council (MRC) to implement a shared vision, RADIANT aims to create an international network of expertise in regulatory science and innovation, with a particular focus on empowering transformative Digital Health (DH) tools and healthcare Artificial Intelligence (AI).

RADIANT's vision is to be an international network of expertise in regulatory science and innovation, empowering transformative digital health and healthcare AI. RADIANT will unleash digital health and AI businesses who want to innovate, by making regulation more proportionate, well-evidenced, business-friendly and user-focused, whilst ensuring products are safe, secure, inclusive, trusted and sustainable.

Over recent years, AI and DH technologies have become increasingly integrated into clinical practice.AI in healthcare includes computer systems capable of analysing complex data, supporting clinical decision-making, and even automating certain tasks. Digital Health encompasses a broader range of technologies, which include: electronic health records (EHR), telehealth, remote monitoring, and wearable devices that track vital signs. While these innovations promise better efficiency and improved patient outcomes, they also raise ethical challenges for healthcare professionals. These challenges range from how to protect patient privacy to ascertaining what measures should be taken when an AI system generates unexpected results. Furthermore, there are challenges with regard to the need to reconfigure core clinical skills as well as regulatory oversight.

There are important questions about safety, effectiveness, inclusivity, data governance, and regulatory oversight and clinicians' voices are central to shaping the future of regulation, as they directly experience the opportunities and challenges of these technologies in practice.

The primary objectives of this project are:

1. Capture clinicians' perspectives on the regulation of AI and digital health tools.
2. Understand the concerns and expectations regarding the regulation, safety, effectiveness, inclusivity, and trustworthiness of these technologies in healthcare.
3. Gather insights that will inform policymakers, regulators, developers, and healthcare organisations in shaping responsible, effective, and adaptive regulatory frameworks that support innovation whilst protecting patient safety and professional integrity.

The expected outcomes of the survey include:

- Provide valuable evidence on clinicians' needs and expectations regarding digital health and AI regulation.
- Identify key areas of concern around safety, inclusivity, and trust.
- Support the development of regulatory approaches that balance innovation with patient safety and professional integrity.

C. Why Have I been Invited?

You have been invited to take part because you are a clinician.

D. What Will Happen If I Take Part?

This study is a one-time, questionnaire-based survey for clinicians from different age groups, professions, and specialities. If you decide to take part, you will be asked to complete an online questionnaire by clicking this link provided or by copying the survey address into your browser: https://forms.office.com/Pages/ResponsePage.aspx?id=FM9wg_MWFky4PHJAcWVDVr0MXp_0ya1EjNtXwH4RfvNURDJaU01KUFlJOFJIVVVTT1FCVVgxUzdNWS4u

The questionnaire will ask about your awareness, trust, concerns, expectations, and views on regulation of digital health and artificial intelligence (AI). It will also explore your knowledge, experiences, and attitudes towards using these tools in clinical practice, including potential benefits, risks, and regulatory challenges.

All responses will be collected anonymously through a secure online platform. The survey is structured around four main areas:

1. Basic demographics (e.g. age, profession, speciality)
2. Awareness and access to digital health and AI tools
3. Opportunities and challenges in using these tools
4. Regulation and oversight

Completing the questionnaire should take around 10–15 minutes.

E. Ethical Considerations

Participation in this survey is entirely voluntary. You may withdraw at any point prior to submission of the questionnaire, in which case no responses will be recorded. Completion

and submission of the survey will be taken as evidence of your consent to participate. There are no foreseeable risks associated with participation.

While there are no direct personal benefits, the findings may contribute to improved understanding, regulation, and safe integration of digital health and artificial intelligence tools in clinical practice.

F. Data Management and Confidentiality

All responses will be fully anonymised before analysis, and no identifiable personal data will be collected other than that contained in Section A of the questionnaire. Data will be stored securely in accordance with GDPR and institutional data protection policies, and findings will only be reported in aggregate form in publications, reports, or presentations, with no identifiable personal data included.

G. Project Report Dissemination Plan

The RADIANT survey findings will be shared with:

- Policymakers and regulators to inform regulatory science and policy.
- Industry partners and technology developers to support user-centred product design.
- Academic and healthcare communities through peer-reviewed publications, conferences, and workshops.

H. Funding, Governance and Project Support

This project is conducted under the **RADIANT consortium**, funded by the Medical Research Council (MRC) to advance regulatory science and innovation in digital health and AI.

Oversight will be provided by the RADIANT steering group.

The project set-up was facilitated by the NIHR Healthtech Research Centre (HRC) in Cardiovascular and Respiratory Medicine, hosted at Guy's and St Thomas' NHS Foundation Trust in partnership with King's College London, which provided support in obtaining ethical and regulatory approval.

I. Who Should I Contact For Further Information?

If you have any further questions about the study please contact Professor Amedeo Chiribiri on phone: +44 (0)20 718 88259; Fax: +44 (0)20 718 85442 or email: Amedeo.chiribiri@kcl.ac.uk; a.chiribiri@nhs.net; or Andrea Nahum; k2368755@kcl.ac.uk

Thank you for reviewing this information sheet. To take part, please complete the short online questionnaire by clicking this link, or by copying and pasting the address into your browser:
https://forms.office.com/Pages/ResponsePage.aspx?id=FM9wg_MWFky4PHJAcWVDVr0MXp_0ya1EjNtXwH4RfvNURDJaU01KUFlJOFJIVVVTT1FCVVgxUzdNWS4u

The survey will take approximately 10 minutes.