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Role of the Digital Mental Health Technology (DMHT) Working Group

Summary

The DMHT working group was established as part of phase 1 of the Wellcome funded project focusing on effective regulation and evaluation of DMHTs. This was a collaborative project led by the MHRA in collaboration with National Institute for Health and Care Excellence (NICE) to clarify the regulation and evaluation of DMHTs that qualify as software as a medical device (SaMD).

The first meeting of the working group was held in September 2023 and it met monthly initially moving to meetings every other month until April 2026. A wide range of diverse expertise was represented on the working group including: MHRA regulatory experts, NICE health technology assessment (HTA) experts, NHS England policy expertise, lived experience advisors, psychiatrists, clinical psychologists, mental health nurses, General Practitioners (GP's), and academic researchers. We are very grateful to each of the members who are acknowledged below for their valuable expertise and contributions, without which the success of the project could not have been achieved.

How the working group contributed

The working group played an important role across both phases of the programme. Its discussions ranged from early exploration of key concepts to detailed refinement of project outputs, and it helped shape priorities for phase 2, particularly the Digital Mental Health Technology Artificial Intelligence (AI) Airlock.

How meetings were structured

Meetings provided a structured forum for discussion of regulatory and health technology assessment topics relevant to digital mental health technologies. They also reviewed how feedback from earlier sessions had been reflected in subsequent outputs through a clear “You Said, We Did” approach. Further details of each meeting are set out below.

Meeting date	Main discussion	“You Said, We Did”
September 2023	Introduction to project and group discussion on DMHT insights MHRA presentation and group discussion around user and public perspectives research plan	User and public perspectives research plan updated based on discussion. Full report - Digital mental health technology: user and public perspectives - GOV.UK
October 2023	MHRA and NICE presentation and group discussions around core considerations for regulation and evaluation of DMHTs	Discussion helped shape publication - Considerations for regulation and evaluation of digital mental health technologies. Sage Journals Digital Health, November 2024
November 2023	MHRA and NICE presentation and group discussions around categorisation frameworks for DMHTs	Discussion helped shape publication - Toward a New Conceptual Framework for Digital Mental Health Technologies: Scoping Review. JMIR Mental Health, February 2025.
December 2023	Discussion on opinions of app store responsibilities Interim findings from the user and public perspectives research presented and discussed	Discussion on app stores helped shape team thinking in this area Discussion on interim market research findings helped refine focus for next phase of research.
February 2024	Discussion around wider considerations on DMHT ecosystem Reflections on work package 1	Discussion on DMHT ecosystem impacted the project stakeholder list

		Reflections on work package 1, shaped following work packages
April 2024	First in-person meeting. MHRA presented framework for device characterisation, qualification and classification for DMHTs and asked for feedback on approach.	Led to updates to the framework and drafting of the MHRA guidance
May 2024	An additional May meeting was scheduled to follow up the qualification proposal and reach a more focused consensus.	Led to updates to the framework and drafting of the MHRA guidance
June 2024	NICE presentation and group discussion on importance and challenges of measuring quality of life (QoL) for DMHTs.	Impacted research and team publication – The impact of choice of health-related quality of life measure on outcomes in mental health: A systematic review and meta-analysis of head-to-head comparisons. Value in Health, June 2026.
August 2024	Page by page detailed review of the draft MHRA guidance for DMHTs – device characterisation, regulatory qualification and classification.	Led to updates to the draft and future approval and publication - Digital mental health technology: qualification and classification - GOV.UK
October 2024	Guest speaker presentation and group discussion on academic papers on regulation of DMHTs (e.g. Developing a process for assessing the safety of a digital mental health intervention and gaining regulatory approval: a case study and academic's guide Trials Springer Nature Link)	Shaped project teams thinking around assessing safety for DMHTs and documents required for clinical investigations.
December 2024	MHRA presentation and group discussion around NHS England e-learning	Helped shape the MHRA – NICE - NHS England e-learning for public, patients and carers - MindEd Hub – and for health, social care and education professionals - MindEd Hub .
February 2025	Second in-person meeting Group discussions around what evidence is needed to demonstrate the effectiveness and cost-effectiveness of DMHTs using 4 case studies.	Helped shape IMDRF workshop on DMHT session on evidence generation Helped shape the BSI standard providing recommendations for performing clinical studies to generate clinical evidence for DMHTs.
April 2025	MHRA presentation and group discussion on DMHT adverse event reporting Group discussion about potential project phase 2 topics	Led to including more DMHT examples in the MHRA guidance for manufacturers on reporting adverse incidents

		<u>involving software as a medical device under the vigilance system</u> Helped shape the project phase 2 proposal
June 2025	MHRA and NICE presented project overview and progress. Group reflection on progress and outputs achieved to date.	This helped shape ongoing phase 1 work packages and the planned phase 2 work packages.
August 2025	No meeting held due to many members having leave over August but instead a written feedback exercise was completed	Project team compiled a summary of the feedback for members to review, and this feedback triggered the focus of the next working group meeting.
October 2025	NICE presentation on selecting outcome measures in DMHT clinical studies. Group discussion on strengths and limitations of different outcome measures and benefits and challenges to standardising collection of outcomes.	Helped shape the BSI standard providing recommendations for performing clinical studies to generate clinical evidence for DMHTs.
December 2025	Update that phase 2 of the project has been awarded Wellcome funding. MHRA led a discussion on a dissemination strategy for the e-learning resource. MHRA facilitated discussion around experiences and risks of generative AI in mental health.	Led to working group members helping with the dissemination of the MHRA – NICE - NHS England e-learning. This shaped MHRA thinking around risks associated with the use of generative AI for mental health.
February 2026	MHRA presented and facilitated group discussion around the clinical investigation process and potential improvements. MHRA presented and led group discussion around potential updates to the MHRA guidance on DMHTs – device characterisation, regulatory qualification, and classification.	Discussion helped shape MHRA's thinking around clinical investigation potential improvements. Discussion led to potential updates being discussed further internally and at a workshop hosted by the Centre of Excellence for Regulatory Science and Innovation in AI and Digital Health (CERSI AI).
23 April 2026	MHRA and NICE presentation on the phase 2 work packages. Results from Delphi exercise on DMHT AI airlock priorities were presented. Group discussion around topics proposed for the DMHT AI airlock work package. Feedback gathered on experiences of phase 1 and priorities for phase 2.	Delphi results and discussion helped shape mental health AI sandbox priorities and the detail of the call for applications. Feedback to acknowledge working group members and work as part of the project led to the publication of this document.

Acknowledgement of working group members

Representatives from the MHRA and NICE coordinated the working group meetings and contributed to discussions alongside the committee members listed below;

Chris Lynch; Dionne Bowie; Eddie Alder; Ellie Thomas; Farhan Ismail; Gareth Hopkin; Grace Gatera; James Woollard; Jemma Kehoe; Joanna Gavins; John Powell; Judith Harrison; Kate Cavanagh; Laura Cox; Laura Van Staaden; Lesa Wright; Mark Salmon; Maria Loades; Matthew Moore; Melanie Calvert; Michelle Rigozzi; Phillip Stimpson; Sarah Bonney; Sarah Fothergill; Sophie Cooper; Sophie Hughes; Tom Pelly.



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