Medicines & Healthcare products Regulatory Agency

AI in Mental Health Airlock Application: Supporting information

Suitability for the AI Airlock and AI in Mental Health Airlock

- Applications are open for both the AI Airlock and AI in Mental Health Airlock, concurrently.
- Applicants may apply to both the AI Airlock and AI in Mental Health Airlock but are encouraged to review and understand the differing eligibility and regulatory focus areas of each sandbox and ensure that each application is drafted to meet the relevant programme criteria. It is unlikely that the same application will meet the needs of both sandboxes simultaneously.
- The application window for the AI Airlock will remain open and the applications will be reviewed in waves, therefore if applicants would like to be considered for the AI Airlock they should apply at their webpage - AI Airlock Phase 3 application - GOV.UK
- Applicants who may have already applied to AI Airlock but consider that they may be more appropriate for AI in Mental Health Airlock should contact the AI Airlock and AI in Mental Health Airlock programme teams by emailing DMHT@mhra.gov.uk and AIAirlock@mhra.gov.uk.
- If the respective programme teams consider that an application would be well suited to the other programme, you will be contacted and asked whether you are happy for your application to be transferred and considered directly as part of the alternative selection process.
- Alternatively, programme teams may also suggest that applicants consider making a separate application to the other Airlock. This may be the case if more information would be required to determine eligibility.
- If the respective programme teams consider that an application may be relevant to the other programme in another capacity, for example as a potential partner or expert, then applications may be shared between the two programmes in accordance with MHRA's data and privacy policy.

AI in Mental Health Airlock application process and eligibility

- For the purpose of the eligibility criteria, mental health is defined as:
    - Diagnosable mental health conditions (mental health, behavioural, and neurodevelopmental conditions) or sub-clinical signs and symptoms of mental health conditions.
- Applicants may bring a benchmarking tool, taxonomy, methodological assessment framework or evaluation approach which hasn't yet been applied in a mental health

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context but does have the potential to be applied in this context. Such applicants should demonstrate during the selection process the potential relevance to the mental health context.

- Applicants bringing benchmarking tools, taxonomies, methodological assessment frameworks or evaluation approaches which are designed for any type of AI-enabled mental health technology and any AI function/application are encouraged to apply to the AI in Mental Health Airlock.
- We are interested in benchmarking tools, taxonomies, methodological assessment frameworks or evaluation approaches which may be mature or which may be in an earlier stage of development.
- The application process includes questions on testing plans. While testing plans will be co-developed with successful candidates during the AI in Mental Health Airlock, we will consider whether the testing plans outlined seem feasible and well suited to the maturity of the approach indicated on the application form.

AI in Mental Health Airlock resource requirements

- The application form for the AI in Mental Health Airlock includes questions on funding and resource commitments. This will be used by the AI in Mental Health Airlock team to identify potential barriers to participating fully in the programme, throughout the duration of testing and reporting.
- The resource requirements of the AI in Mental Health Airlock depend considerably on the testing plan which will be co-developed between participants, experts and the AI in Mental Health Airlock programme team. With support from the AI in Mental Health Airlock programme team and experts, participants will be responsible for financing and delivering the testing and reporting.

Further Information

The AI in Mental Health sandbox is strictly exploratory. It cannot be taken as indicative or suggestive of any future position and will not be regarded as relevant to any future decision that may be taken by NICE, or as a regulatory route to market or form of assessment by the MHRA.

All outputs of the AI in Mental Health sandbox may be used for research, methods development, and learning. Any materials or findings generated through the AI in Mental Health sandbox will be treated and published on a confidential basis, ensuring that no company-specific results, analyses, or insights that could have commercial implications are disclosed publicly without explicit agreement. Any outputs arising cannot be taken as indicative or suggestive of any future position and will not be regarded as relevant to any future decision that may be taken by NICE or the MHRA.
For questions or additional information, please contact: **DMHT@mhra.gov.uk.**

Data protection and privacy information is available here MHRA's data and privacy policy.

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