AI Airlock Phase 2: Application Form

# Form Description

This form can be used to support applicants in drafting their responses to the questionnaire. Please complete this form before the 6pm on 14th July and **submit your answers via the Microsoft Form** [**https://forms.office.com/e/LnTjsvNTwd**](https://forms.office.com/e/LnTjsvNTwd).

Candidates should complete the questions in this form to submit a proposal to the AI Airlock phase 2 application round. We will be unable to process any applications received beyond this date. When preparing answers please note the character limits may apply throughout.

The eligibility criteria for the second phase of the AI Airlock regulatory sandbox can be found on [[AI Airlock webpage](https://www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd)] including criteria for proposals that would fall out of scope. These criteria will be used by the MHRA to shortlist all applications and build a portfolio of eligible candidates, that present a broad range of regulatory challenges to be investigated.

If you have any questions or issues with the form, please contact aiairlock@mhra.gov.uk.

**Section 1: Applicant and Organisation Information**

*This part of the application will allow the programme team to better understand your organisation and AI Airlock sandbox testing requirements. All personal data will be processed in line with the [*[*MHRA’s data and privacy policy].*](https://www.gov.uk/government/publications/mhra-privacy-notice)

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| --- |
| 1. Full name (of named contact):
2. Job title:
3. Telephone number (including country code):
4. Email address:
5. Organisation legal name:
6. Trading name (if different from legal name):
7. Registered organisation address:
8. Work location address (if different from registered address):
9. Website:
10. Organisation size and type (choose from below):

[ ] Micro SME (<10 employees)[ ] Small SME (10-50 employees)[ ] Medium SME (>50 - 250 employees)[ ] Large Enterprise (>250 employees)[ ] University or academic institution[x] Charity[ ] Government entity[ ] Other (Please specify) - 1. Do you have any medical devices on the market?

[ ] Yes[ ] No1. If yes, please outline the products you are currently marketing and provide MHRA registration numbers for any Software as a Medical Device and AI as a Medical Device on the UK market.

*Public Access Registration Database (*[*https://pard.mhra.gov.uk*](https://pard.mhra.gov.uk)*)*  |

**Section 2: Product Information**

*This part of the form aims to learn more about your AI as a Medical Device product.*

1. What is the name of the product?
2. What is the development stage of the product?

[ ] Concept phase

[ ] Design verification / Laboratory studies conducted.

[ ] Operational prototype developed.

[ ] Pre-clinical studies started, in progress or concluding.

[ ] Clinical investigation study started, in progress or concluding.

[ ] Previous approval attempts unsuccessful.

[ ] Product new to the market <1 year

[ ] Product on the market 1-3 years

[ ] Product on the market >3 years

1. Please include the device’s legal manufacturer, if different from the organisation details shared above.
2. Have you had previous attempts to regulate this or similar proposals or made a business decision to not proceed due to regulatory complexity? [ ] Yes

[ ] No

1. What is the medical purpose of your product?

[ ] Diagnosis

[ ] Prevention

[ ] Monitoring

[ ] Mitigation

[ ] Prediction

[ ] Treatment

[ ] Other (specify)

1. What is the disease indication area of product? (*Please limit your response to 100 characters*)
2. What is the severity level of the disease or condition addressed by the product?

[ ] Critical

[ ] Serious

[ ] Non-Serious

[ ] Other (*Please specify*)

1. Who is the intended patient population? (*Please limit your response to 100 characters*)
2. Who is the intended user?

[ ] Lay user/nonclinical user (e.g., caregiver, patient user, user without medical qualifications)

[ ] Licenced medical professional, non-physician (e.g., registered nurse, dentist, psychologist, radiation therapist, physiotherapist, etc.)

[ ] General Practitioner (e.g., primary care physician, family doctor, registered nurse practitioner)

[ ] Specialist Healthcare Physician (e.g., radiologist, oncologist, dermatologist, pathologist, surgeon, etc.)

[ ] Other (please specify)

1. What is the use environment?

[ ] Non-clinical Environment (e.g., home-use)

[ ] General Healthcare Environment (e.g., primary care clinic, virtual primary healthcare)

[ ] Specialty Healthcare Environment (e.g., hospital, specialty clinic, virtual specialty healthcare)

[ ] Other (*Please specify*)

1. Please provide the intended use statement of the product. *(Please limit your answer to 500 characters)*
2. What is the function of AI in the product?

[ ] Decision support

[ ] Validation

[ ] Risk Prediction

[ ] Post Market Surveillance/ Monitoring

[ ] Diagnosis

[ ] Treatment recommendation

[ ] Other (please specify)

1. Please provide a brief description of the core AI technology used in your product. (e.g., traditional machine learning, deep learning, generative AI, predictive models, etc.) *(Please limit your answer to maximum 100 characters)*
2. Please summarise the target intended use for the product.

*Guidance:* [*https://www.gov.uk/government/publications/crafting-an-intended-purpose-in-the-context-of-software-as-a-medical-device-samd*](https://www.gov.uk/government/publications/crafting-an-intended-purpose-in-the-context-of-software-as-a-medical-device-samd)

* *Structure and Function: The clinical indication including disease and stage of disease.*
* *Patient Population: Epidemiology, including special populations and any foreseen specific inclusions/exclusions, and potential issues of health equity.*
* *User: the individual, or range of individual users*
* *Environment: The likely physical and or virtual space and context, including the current standard of care.*

*(In your response to this question, you should make clear any regulatory issues, specific sections of healthcare/clinical disciplines and its level of regulatory maturity. You should state who will use the product, when and where as well as why. Additionally, if your “target” intended use is an extension of an existing intended use then please also provide your baseline intended use as per your regulatory certification as appropriate.)*

*(Please limit your answer to 2500 characters)*

1. Lay persons summary of proposed product.
*Guidance -* [*www.nihr.ac.uk/plain-english-summaries*](https://www.nihr.ac.uk/plain-english-summaries)
2. Do you have a Quality Management System?

[ ] Yes – Certified

[ ] Yes – Not Certified

[ ] No

1. Please select all the documents available for your product.

[ ] Instructions for use (IFU)

[ ] Weblinks

[ ] User training materials

[ ] Marketing materials (brochures, leaflets etc.)

[ ] Presentations

[ ] Other materials/links that would help understand the product

**Section 3: Eligibility and Regulatory Challenge**

*This section allows you to outline your eligibility and the regulatory challenge proposal you would like to bring to the AI Airlock regulatory sandbox, including questions regarding access to the data required for testing the proposal.*

30. Please select all **eligibility criteria** that are applicable for your application to the AI Airlock sandbox.

[ ] The product is aiming to be a medical device as defined by the UK Medical Devices Regulations 2002 [https://www.legislation.gov.uk/uksi/2002/618/contents/made] which utilises Artificial Intelligence (AI).

[ ] Applicant is a legal entity with the rights to market their medical device in the UK and access to relevant technical and regulatory information.

[ ] Applicant commits to working with the AI Airlock programme team and evaluation partners

[ ] The product has potential to deliver benefits for patients

[ ] The product or prototype is innovative or a novel application

[ ] The product presents a regulatory challenge.

[ ] The proposal is ready to be trialled.

31. Please elaborate on how your product meets the eligibility criteria selected. *(Please limit your answer to 2000 characters)*

32. Please select the regulatory challenge area(s) you would like to explore as a part of Airlock.

[ ] Competencies in development – educational aspects, navigation of regulation landscape

[ ] Documentation – creating a tech file, reg affairs skills

[ ] International differences – regulatory alignment

[ ] Borderline products, qualification

[ ] Risk classification issues

[ ] Scope of intended use, expansion of intended use vs new intended use

[ ] Broad functionality products

[ ] Data access and management

[ ] Clinical or performance evaluation

[ ] Product safety or reliability

[ ] Human – AI interaction

[ ] Validation

[ ] Useability

[ ] Bias, fairness metrics

[ ] Deployment and installation

[ ] Product or model development

[ ] Cyber security

[ ] Post-market surveillance, adverse reactions and corrective actions

[ ] Retraining or model drift

[ ] Change management planning

[ ] Decommissioning

[ ] Other

33. **If you have selected 'Other' for regulatory challenge area(s)** please outline the regulatory challenge area that you would like to explore within Airlock. *(Please describe in 500 characters).*

34. Please elaborate on the regulatory challenge(s) selected and how you are looking to address it in the Airlock regulatory sandbox.

*(Include as much detail as possible about the specific regulatory framework/ guidance or legislative challenge area experienced by your product proposal)*

*(Please limit your answer to 2000 characters)*

35. Do you have access to all data required immediately.

[ ] Yes

[ ] No

36. If no, please provide the timelines and plan for sourcing the data.

*(Please limit your answer to 250 characters)*

37. If you do not have access to data ready or have arrangement to gain access to data, do you intend to use synthetic data?

[ ] Yes

[ ] No

[ ] Not applicable

38. If you intend to use synthetic data, provide the type of data needed.

[ ] Text

[ ] Tabular

[ ] Image

[ ] Other (please specify)

[ ] Not applicable

39. Briefly outline where you think AI Airlock will have the greatest impact for your device and organisation.

*(Include detail on the specific aspects of your device that you would plan to test)* *(Please limit your answer to 250 characters)*

**Section 4: Declaration and Submission**

*During the application process consent can be withdrawn at any time by contacting aiairlock@mhra.gov.uk. If consent is withdrawn, the application will not be taken forward in the AI Airlock. The Airlock programme reserves the right, at any time, to remove candidates from the Airlock if no longer able to meet the commitment and eligibility requirements.*

40. Select the below options to continue with the application submission.

[ ] I have read and understood the data protection and privacy information provided with this application form and will abide by this. If an individual is signing on behalf of an organisation, any parties with access to the application will abide by data protection and privacy information.

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[ ] By selecting this, I consent to the information submitted in this application form being shared with the AI Airlock partners [[AI Airlock partners](https://www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd#collaborating-with-partners:~:text=many%20unanswered%20questions.-,Collaborating%20with%20partners,-Team%20AB%3A%C2%A0launched)]

[ ] I confirm that there are no foreseeable hinderances in my ability to commit to this project i.e. that I have the capacity and necessary resources to fully commit to and actively participate in all aspects of the project for its entire duration.

[ ] I confirm that the information provided in this application is, to the best of my knowledge, true, accurate, and complete. I understand that any false or misleading information may result in the application being rejected or any subsequent participation being reviewed.