



Data protection and privacy information

1. Introduction

You can read the [MHRA Privacy Notice](#) to find out in general terms the types of personal data we process and why; as well as information about your rights and how to raise concerns.

This privacy notice sets out the approach that the Innovative Licensing and Access Pathway (ILAP) partners and the MHRA will take to handle your personal data, sensitive/confidential company information appropriately and to comply with data protection legislation.

This privacy notice covers documents gathered and created during the Innovation Passport application process and anything in which information of any description is recorded, whether in paper or electronic form.

2. Legal requirements for information management and privacy

The ILAP complies with data protection legislation including the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR).

We rely on UK GDPR Article 6(1)(a) as our legal basis for processing your personal data. This allows us to process personal data as you have given consent to the processing of your personal data for the outlined purposes.

3. Lawful basis and purpose of processing personal information

The ILAP registration portal will collect personal data for the purpose of identifying who the application belongs to and to contact you regarding your Innovation Passport application. If selected for ILAP, you may also be contacted in relation to topics including feedback surveys and updates on your application.

The Innovation Passport registration portal will also give you the opportunity to provide the contact details of additional people who need to be kept updated on the progress of the Innovation Passport application. These additional people may also be contacted on topics including feedback surveys and updates on the application. You must ensure that these additional contacts have been fully informed and have consented to their personal data being provided and used for this purpose.

By submitting your Innovation Passport application, you consent for your personal data to be held by the MHRA and used by the ILAP Partners for the purposes outlined above.

You may withdraw your consent for MHRA to process your personal data at any time by contacting InnovationPassport@mhra.gov.uk. If you withdraw your consent to be contacted about an Innovation Passport application, you must provide replacement contact details to be associated with the application and that individual must also provide consent for their data to be used in accordance with the ILAP Data Protection and Privacy Information.

There will be no other use of personal data.

4. Security and confidentiality

In addition to supplying your personal data which will be used as described above, individuals applying for an Innovation Passport will also be asked to supply potentially sensitive/confidential commercial information relating to their application.

By submitting your application, you confirm that you understand that all ILAP Partners will have access to all data submitted through the Innovation Passport registration portal for the purpose of reviewing Innovation Passport applications and if selected, supporting your application through the ILAP.

The ILAP partners are as follows:

- The Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Health and Care Excellence (NICE)
- NHS England (NHSE)
- The All Wales Therapeutics and Toxicology Centre (AWTTC) (on behalf of Health Boards and NHS Trusts in Wales)
- Scottish Medicines Consortium (SMC) (on behalf of NHS boards in Scotland)
- Department of Health and Social Care (DHSC)
- Health Research Authority (HRA)
- National Institute for Health Research (NIHR)
- Office for Life Sciences (OLS)

- Scottish Government
- Welsh Government
- Department of Health Northern Ireland
- Patient and Public Representatives
- External Clinical Experts

All personal and sensitive/ confidential commercial information that you submit as part of the Innovation Passport application form will be held on a secured shared digital platform by the MHRA. The MHRA will ensure all of the information is stored securely and access is kept up to date to prevent loss or inappropriate access.

Those who have access are aware of their obligations and responsibilities when handling personal and sensitive/confidential commercial information. They are subject to employment, contractual and other professional obligations regarding confidential and official information, both during the ILAP process and afterwards.

5. Sharing information

The MHRA will hold the personal data provided in the Innovation Passport registration portal, share it with ILAP partners through a secured shared digital platform for the purpose of identifying who the application belongs to and to contact the individuals regarding ILAP activities.

The MHRA will hold the sensitive/ confidential commercial information provided in the Innovation Passport registration portal, share it with ILAP partners through a secured shared digital platform for the purposes of reviewing Innovation Passport applications, and if selected for ILAP, supporting your application through the pathway.

If any new partner is identified, the MHRA will contact you to inform you of this and check that you are happy for information supplied in the Innovation Passport application form to be shared with them.

The MHRA will not share your personal data with any other third party other than our data processors who act only upon our instructions. We will handle any specific requests from a third party for us to share personal data with them in accordance with data protection law. We will not sell your personal data.

We will not share your information with any third parties for the purposes of direct marketing.

Information from the ILAP process, including personal information, may be disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), the UK General Data Protection Regulation 2016 (GDPR) and the Environmental Information Regulations 2004.

The MHRA will process personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that personal data will not be disclosed to third parties.

The ILAP partners will adhere to relevant institutional confidentiality and non-disclosure agreements.

6. Retention and destruction of documents

All information submitted through the ILAP registration portal will be held by the MHRA for 10 years.

7. Rights

You have several rights which are outlined in the MHRA Privacy Notice: <https://www.gov.uk/government/publications/mhra-privacy-notice>. For greater detail on when they apply, please refer to the [Information Commissioner's website](#). If you wish to exercise any of your rights, or have any questions or concerns, please contact our Data Protection Officer at dataprotection@mhra.gov.uk.