Innovative Licensing and Access Pathway (ILAP) for Medicines
https://www.gov.uk/government/publications/innovative-licensing-and-access-pathway-ilap-for-medicines

- The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to ***all innovative medicine products including new chemical entities, biological medicines, new indications and repurposed medicines***.
- The ILAP is open to both commercial and non-commercial developers of medicines and is geared towards applicants at the **early stages of product development**.
- The ILAP awards a new **"innovative medicine" designation (*Innovation Passport*)** and then utilises tools from a toolkit and a "Road Map" (**Target Development Profile, TDP**) that bring together innovative approaches to support the safe, timely and efficient development of innovative products.
- The ILAP provides opportunities for enhanced regulatory and other stakeholder input including interactions with partners: National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC) (Healthcare Improvement Scotland) and National Health Service (NHS England and Improvements) plus other organisations such as the Health Research Authority (HRA) and the National Institute for Health Research (NIHR)
- Horizon scanning and regulatory science will ensure that the pathway is at the forefront of cutting-edge developments and has the framework to develop evidence-based practice as new technologies and methods emerge.
- The pathway will allow entry very early, based on non-clinical data, where all the regulatory tools described below might be options, as well as catering for products with mid-development 'global' dossiers.
- Early pipeline discussions with developers are encouraged. *Any information shared during the ILAP is confidential and will be held on a secure shared digital platform for access by the ILAP partners, as agreed by the applican*t.

Target Development Profile (TDP)
A product-specific team of experts will help define the "target development profile" (TDP) based on the product's characteristics. The TDP, which can only be accessed via the *Innovation Passport* will define key regulatory and development features, identify potential pitfalls and create a road map for delivering early patient access.

MHRA fees
Innovation Passport fee: £3,624*
Initial Target Development Profile (TDP) fee: £4,451*
The stated fees may be subject to change.

Products nearing the end of their development programme are generally not suitable for the ILAP but opportunities *may* exist for early access to patients for these products in areas of *unmet medical need and where major advantage over existing therapies can be demonstrated* through the Early Access to Medicines Scheme (EAMS)

Early Access to Medicines Scheme (EAMS)

https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

- The early access to medicines scheme (EAMS) aims to give patients *with life threatening or seriously debilitating conditions* access to medicines that do not yet have a marketing authorisation when there is a *clear unmet medical need*.
- Under the scheme, the Medicines and Healthcare products Regulatory Agency (MHRA) will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available when the EAMS submission was made.
- The opinion lasts for a year and can be renewed.
- The scheme is voluntary and the opinion from MHRA does not replace the normal licensing procedures for medicines.
- The scientific opinion will be provided after a 2-step evaluation process:

    1. the promising innovative medicine (PIM) designation
    2. the early access to medicines scientific opinion

Promising innovative medicine (PIM) designation

The PIM designation will give an indication that a product may be eligible for the EAMS based on early clinical data. The PIM designation will be issued after an MHRA scientific meeting and could be given several years before the product is licensed.

Scientific opinion

The scientific opinion describes the risks and benefits of the medicine based on data gathered from the patients who will benefit from the medicine. The opinion supports the prescriber and patient to make a decision on whether to use the medicine before its licence is approved.

Fees

PIM designation is £3,624.
Assessment of the scientific opinion for new chemical or biological medicinal products is £25,643 and the renewal fee (if applicable) is £12,821.
The fee for the assessment of the scientific opinion for new indications is £8,309 and the renewal fee (if applicable) is £4,154.