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The Innovative Licensing and Access Pathway (ILAP): Early Pathway Experience, Examining Process Adaptations and Industry Impact

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Background and Objective

- The Innovative Licensing and Access Pathway (ILAP), launched in 2021, aims to accelerate drug approval and patient access through multi-agency collaboration, including the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), and others.
- In March 2025, ILAP was relaunched with significant revisions. This research reviews these changes and summarises experience to date.

Methods

- ILAP policy updates, eligibility and selection criteria were reviewed using MHRA public sources.
- Publicly available information on products granted an Innovation Passport (IP) from ILAP's inception in January 2021 to 30th April 2025 were extracted and analysed.

Table 1: Overview of key changes to ILAP process

	What are the noteworthy process changes in the refreshed ILAP program?
Single Point of Contact	Developers will have a single point of contact assigned to coordinate all support provided through the ILAP.
Selective Entry Criteria	**Only applicants meeting ALL eligibility criteria will be thereafter assessed against the selection criteria.** **New eligibility criteria** – the product must be a medicine or drug–device combination with a therapeutic aim (excluding immunisations); be in early clinical development with available preliminary human safety data; the applicant must have a UK legal entity intending to market the product and meet HTA standards; and must commit to working with ILAP partners on a Target Development Profile and UK clinical trial site feasibility. **Selection criteria** – Key updates from 2021 ILAP process: • Products must now meet both criteria of addressing a life-threatening condition and an unmet medical need, whereas previously meeting just one was sufficient. • The criteria for product innovativeness have been simplified and broadened, with the removal of specific sub-criteria (e.g. targeting rare diseases or special populations, or alignment with UK public health priorities). The emphasis is now on demonstrating innovation compared to existing therapies. • Sub-criteria related to the product's potential to deliver a step change in managing the condition have been expanded, now covering both health outcomes and cost-effectiveness—replacing the earlier single, general criterion focused on patient benefit.
NHS Involvement	NHS has been brought in as a core partner to provide inputs on operational planning and system readiness for the introduction of new innovative medicines. Developers gain the opportunity for early discussions with ILAP partners on how their new treatments will be used in clinical practice thereby ensuring their smooth and efficient adoption within the healthcare system.
Expanded Scope	The new pathway features an expanded scope and now includes drug–device combinations.
Prioritized Review	ILAP products will receive prioritized review timelines within partner agencies, including: ILAP Joint Scientific Advice (JSA), ILAP Access Forums, MHRA scientific advice (pre-submission meetings), Clinical Practice Research Datalink (CPRD), NICE Advice services (e.g. health economic model advice service), Scottish Medicines Consortium (SMC): prioritisation for evaluation and potential eligibility for interim acceptance, National Institute for Health and Care Research (NIHR): Support with study delivery and performance.

Results

- Between January 2021 and November 2024, 235 IP applications were submitted, of which 160 were granted.
- Data on indication and issuance date were available for 72 IPs, corresponding to 62 unique medicines—47% of which held Orphan Drug Designation (ODD).
- At the time of IP award, 15% of products were in Phase 3 or Phase 2/3, 24% in Phase 2, 36% in Phase 1 or Phase 1/2, and 17% were in preclinical development (Figure 1).
- More therapies entering the ILAP pathway were in earlier stages of development (Phase 1/2 or preclinical), a trend expected to increase with the ILAP relaunch, which prioritizes products before initiation of confirmatory trials.
- Among the 53% of IPs were granted to non-orphan drugs (Figure 2), the most common therapeutic areas were oncology (37%), central nervous system disorders (29%), and cardiovascular/ metabolic disease (18%) (Figure 3A). Most therapies were small molecules and gene therapies (66%) (Figure 3B), and 53% targeted conditions for which no treatments are available, or where existing options are only symptomatic (Figure 3C). Given the revised, more stringent selection criteria for IPs, these conditions are expected to account for the majority of future ILAP applications.

Conclusions

- The new ILAP policy introduces somewhat more stringent eligibility criteria while aiming to deliver targeted and timely support for qualifying products.
- Although diagnostics, immunisations, and medicines already in confirmatory clinical trials are now excluded, the scope has expanded to include novel drug–device combinations.
- The real-world impact of these changes on patient access remains to be fully evaluated.

Figure 1: IP decisions by development stage

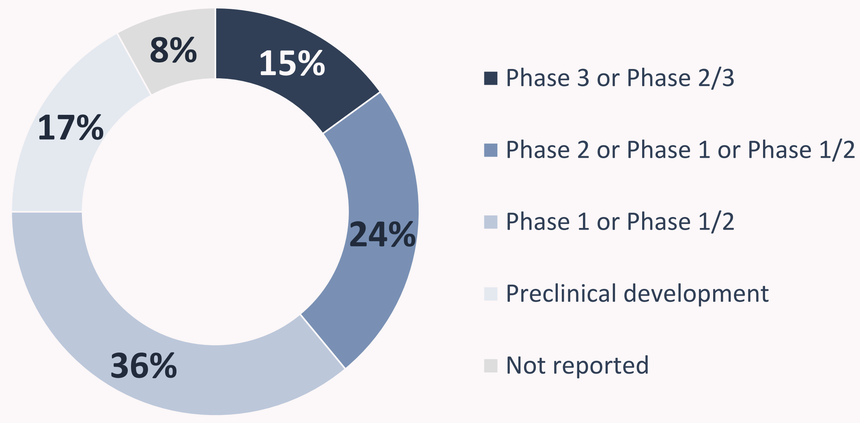


Figure 2: IP decisions by ODD status

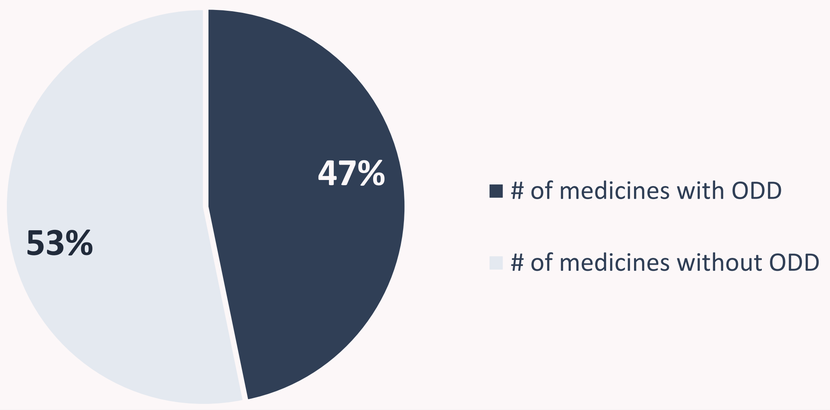
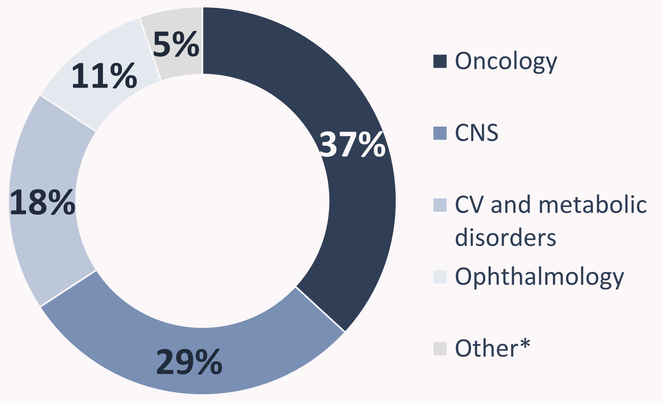
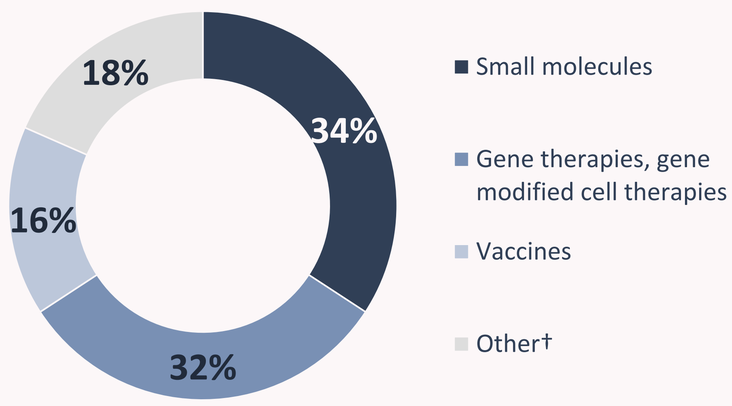


Figure 3: Characteristics of non-ODD medicines with granted IPs

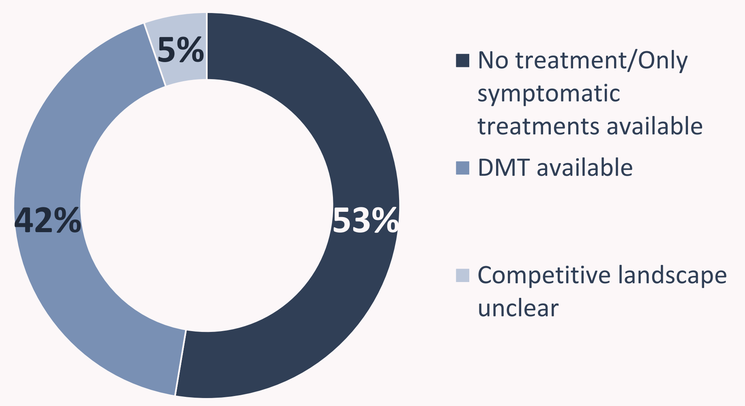
A. IP decisions by indication



B. IP decisions by molecule type



C. IP decisions by treatment landscape in respective relevant indication



Legend

*Respiratory, Infectious diseases, Immunology; †Monoclonal Antibody, Recombinant Protein, Polysaccharide, RNAi Oligonucleotide, DNA Vaccine

Abbreviations

CNS, Central nervous system; CV, Cardiovascular; CPRD, Clinical Practice Research Datalink; DMT, Disease modifying treatment; ILAP, Innovative Licensing and Access Pathway; IP, Innovation Passport; JSC, Joint Scientific Advice; MHRA, Medicines and Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence; NIHR, National Institute for Health and Care Research; ODD, Orphan Drug Designation; SMC, Scottish Medicines Consortium

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