The UK Innovative Licensing and Access Pathway (ILAP) Program – Early trends in Innovation Passport awards

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Introduction

BACKGROUND

- The Innovative Licensing and Access Pathway (ILAP) is a novel route for UK market access that is open to both commercial and non-commercial developers of medicines (UK-based and or global).[1,2]
- The ILAP aims to accelerate the time to market and facilitate patient access to medicines (Figure 1).[1,2]
- The ILAP process comprises of an Innovation Passport designation, a Target Development Profile (TDP), and access to a toolkit to support all stages of the design, development, and approvals process.[1]
- The eligibility criteria for an ILAP Innovation Passport are presented in Figure 2.

Figure 1. UK market access route with and without ILAP[3]

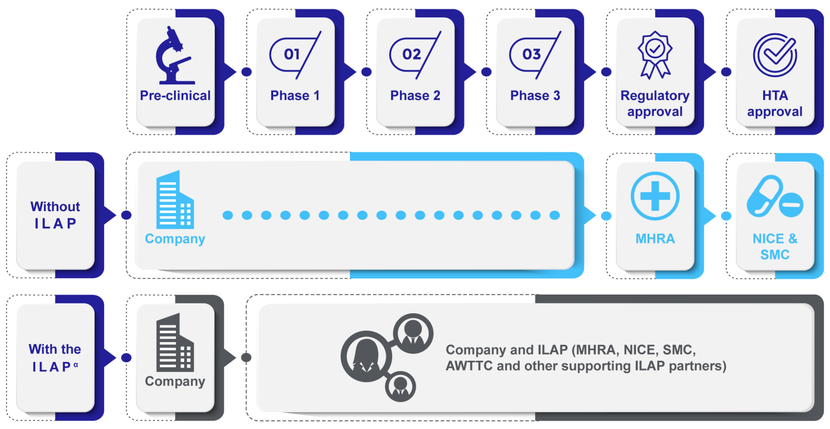
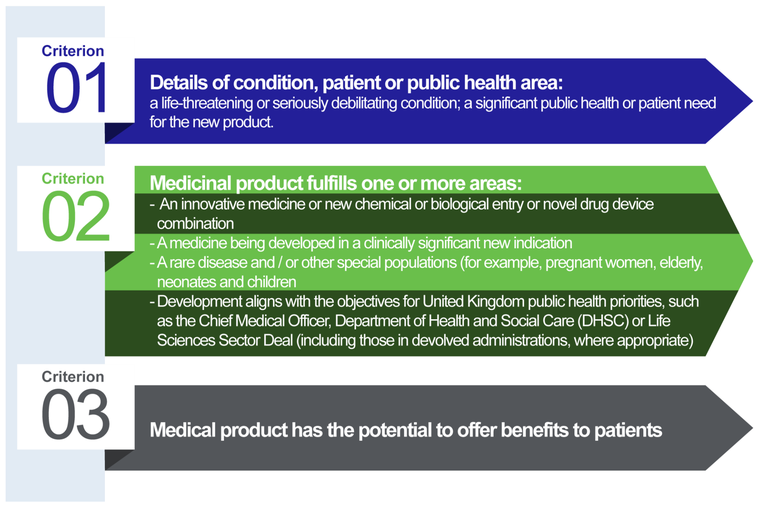


Figure 2. Eligibility criteria for ILAP Innovation Passport[4]



Objective

- **Our primary objective was to identify medical products that were awarded ILAP Innovation Passports since the program's inception in 2021.**
- **Our secondary objective was to characterize the target indication, stage of development, and regulatory status of these drugs.**

Methods

- As official details on ILAP awards remain confidential, a literature search of published information in the public domain was performed.
- English-language records, including published peer-reviewed articles, grey literature and news reports, and websites of the FDA, EMA, Project Orbis, and drug manufacturers, were reviewed.
- For each medical product, target indication, clinical trials, regulatory status, and designations were collected.
- Public records for 40 (out of 71 total) medical products awarded ILAP Innovation Passports were identified, of which 28 (70%) were awarded in 2021 and 12 (30%) were awarded in the first half of 2022 (until June).

Results

ILAP awards by indication and regulatory agency designation

- The most common target indications were oncology (n=17, 43%), followed by psychiatry (n=4, 10%), neurophysiology, dermatology and musculoskeletal diseases (n=3, 8% each) (Figure 3).
- The FDA and EMA granted orphan drug designations to 17 and 13 products, respectively (Table 1).
- Five therapies had FDA Breakthrough Therapy Designation, while four had EMA PRIME status (Table 1).
- Ten therapies received approvals through the Project Orbis scheme (Table 1).

ILAP awards by clinical development phase

- Most products were in the mid-stages of clinical development and were in Phase 2 and 3 clinical trials (n=10, 25% each). FDA and/or EMA-approved medicines represented 20% of awardees (Figure 4).
- Products in pre-clinical development and Phase 1 each represented 15% (n=6 each) of publicly disclosed awardees (Figure 4).

Figure 3. ILAP awards by indication

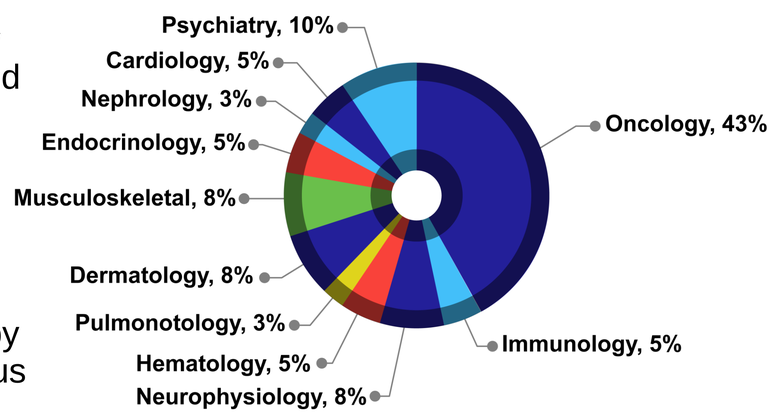


Figure 4. ILAP awards by drug phase

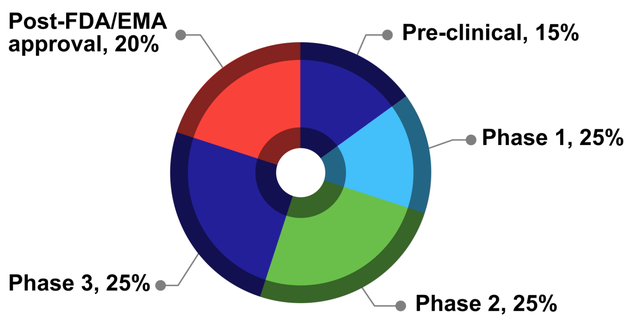


Table 1. List of ILAP awardees with regulatory agency designations

Product (trade/code name)	Indication	FDA designation	EMA designation	Project Orbis
amivantamab (Rybrevant)	Oncology	-	-	✓
atezolizumab (Tecentriq)	Oncology	Orphan	-	✓
belzutifan (Welireg)	Oncology	Orphan	Orphan	✓
encequidar (Oraxol)	Oncology	Orphan	Orphan	✗
hypericin (Hybryte)	Oncology	Orphan	Orphan	✗
imetelstat (GRN163L)	Hematology	Orphan	Orphan	✗
iptacopan (LNP023)	Dermatology	Rare Pediatric Disease (Orphan)	PRIME	✗
lorlatinib (Lorviqua)	Oncology	Orphan	-	✓
lovotibeglogene autotemcel (Lovo-cel)	Hematology	Breakthrough	PRIME	✗
LYS-GM101	Neurophysiology	Rare Pediatric Disease	Orphan	✗
mobocertinib (Exkivity)	Oncology	Orphan		✓
molgratmostim	Pulmontology	Breakthrough	Orphan	✗
midomafetamine (Ecstasy)	Psychiatry	Breakthrough	-	✗
obecabtagene autoleucel	Oncology	Orphan	PRIME	✗
osimertinib (Tagrisso)	Oncology	Orphan	-	✓
pegunigalsidase alfa (PRX-102)	Endocrinology	-	Orphan	✗
psilocybin	Psychiatry	Breakthrough	-	✗
repagermanium (DMX-200)	Nephrology	Orphan	Orphan	✗
ruxolitinib (Jakavi)	Immunology	Orphan	-	✓
sacituzumab govetican (Trodelvy)	Oncology	Orphan	-	✓
sotorasib (Lumykras)	Oncology	Orphan	-	✓
tepotinib (Tepmetko)	Oncology	Orphan	-	✓
tepelizumab (Tzield)	Endocrinology	Breakthrough	PRIME	✗
tildeglusib (Nypta)	Musculoskeletal	Orphan	Orphan	✗
hydromethylthionine mesylate (TRx0237)	Neurophysiology	Orphan	-	✗

Conclusions

- **The ILAP is a promising program with the potential to create efficiencies during medical product development, regulatory appraisal, and reimbursement.**
- **The majority of identified ILAP awardees are for medical products in oncology and are in development phase 2 or 3.**
- **The lack of transparency and limited public records of ILAP experience, particularly for medical products in early development, presents a challenge to researchers and manufacturers considering application and should be reassessed during the initial stages of the program.**

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Disclosures / Acknowledgements

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Abbreviations / Glossary

AWTTC: All Wales Therapeutics and Toxicology Centre; **EMA:** European Medicines Agency; **FDA:** Food and Drug Administration; **HTA:** Health technology assessment; **ILAP:** Innovative Licensing and Access Pathway; **MHRA:** Medicines and Healthcare products Regulatory Agency; **PRIME:** Priority Medicine; **SMC:** Scottish Medicines Consortium; **TDP:** Target Development Profile

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