A Review and Analysis of Medicines Following the Innovative Licensing and Access Pathway (ILAP) in the UK: Does the Pathway Lead to Faster Regulatory Approval and HTA Recommendation?

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Background

- On January 1st, 2021, ILAP was introduced to support safe, timely & efficient development of innovative products. ILAP builds on sustained collaboration with partners (**Figure 1**) and drug developers in the UK[1]. ILAP comprises an Innovation Passport (IP) designation, a target development profile, and provides applicants with access to a toolkit to support all stages of the design, development and approvals process.
- To be awarded an innovation passport a product must address a life-threatening or seriously debilitating condition, there is a significant patient or public health need, the medicinal product fulfils one or more of a specific area (innovation, new indication, treats a rare disease), and the medicinal product has the potential to benefit patients.

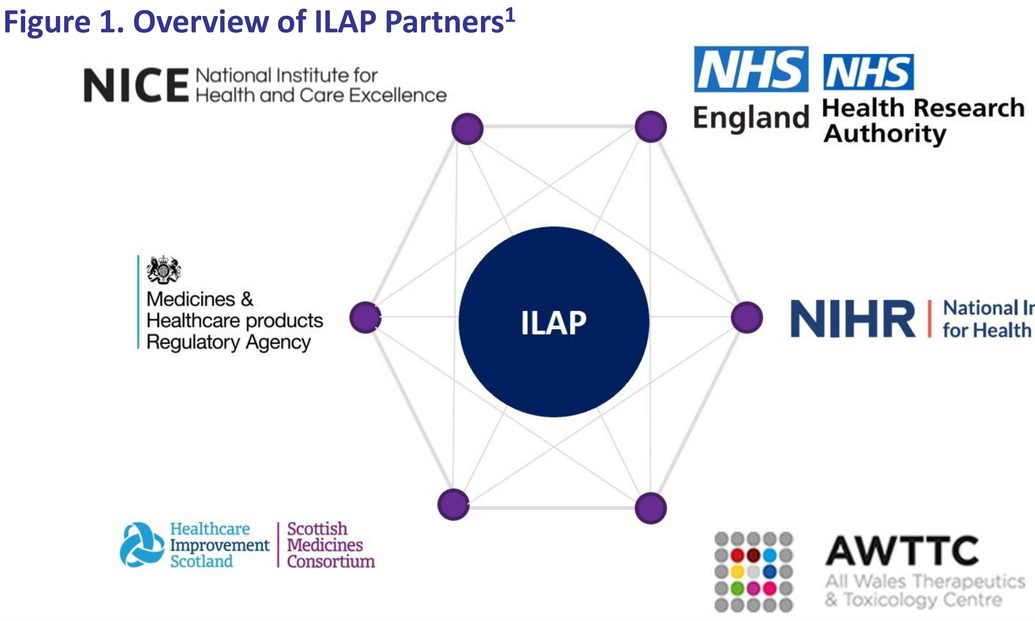
Objectives

- To analyse the time to HTA recommendation for medicines going through ILAP and evaluate how the pathway is delivering against its stated objectives from a manufacturer, regulatory, HTA, and payer perspective.

Methods

- Review of public information by targeted searches mentioning 'Innovative Licensing and Access Pathway' to identify companies that reported that they had been awarded an IP.
- Analyses performed include quantitative analysis through descriptive statistics of the mean time from ILAP designation to regulatory approval and HTA recommendation, and qualitative analysis based on published statements including company stakeholders, regulatory, HTA, and payer opinion.

Figure 1. Overview of ILAP Partners[1]

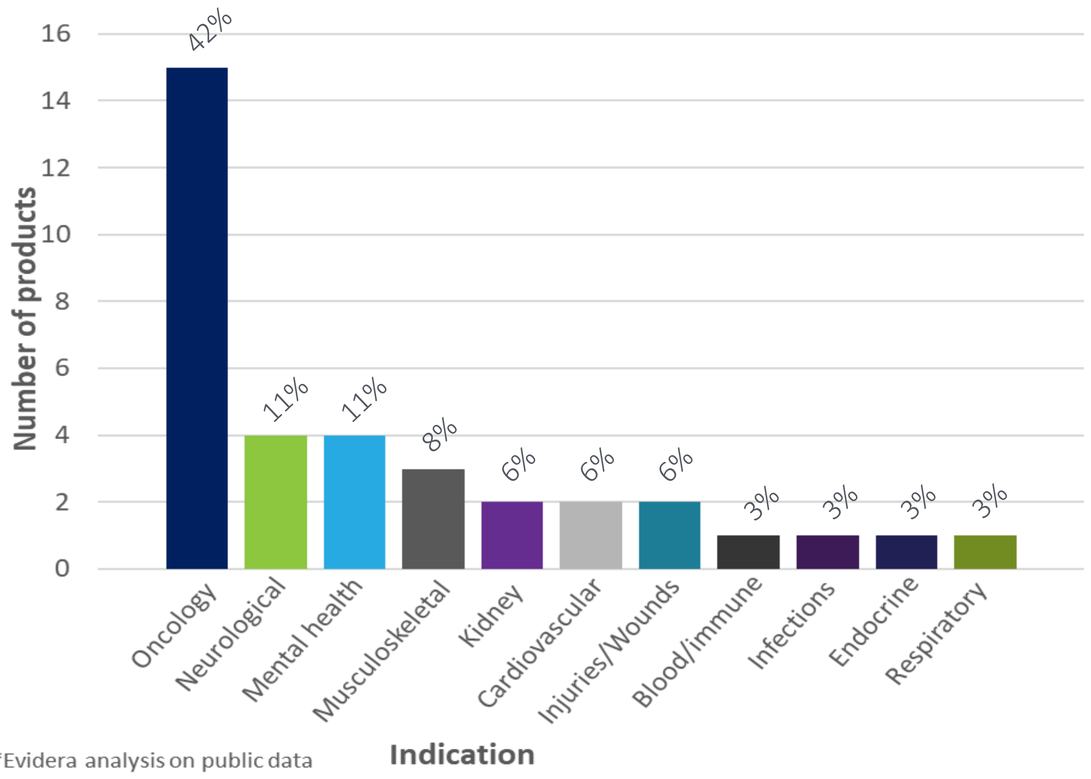


Results

Overall

- Thirty-six products awarded an IP have been publicly identified from the 1st of January 2021 to the data cut-off date of 17th June 2022.
- The majority are in oncology (42%), followed by neurological diseases (11%), mental health (11%), and other areas (36%) (**Figure 2**), including 16 products with an orphan designation.
- Six products have been prioritised for NICE appraisal, two have received a positive recommendation from NICE, and four have received a positive recommendation from SMC.
  - All products that have received a positive recommendation from NICE or SMC were in phase 3 or later at the time of IP achievement.

Figure 2. Indications of products with publicly announced Innovation Passport*



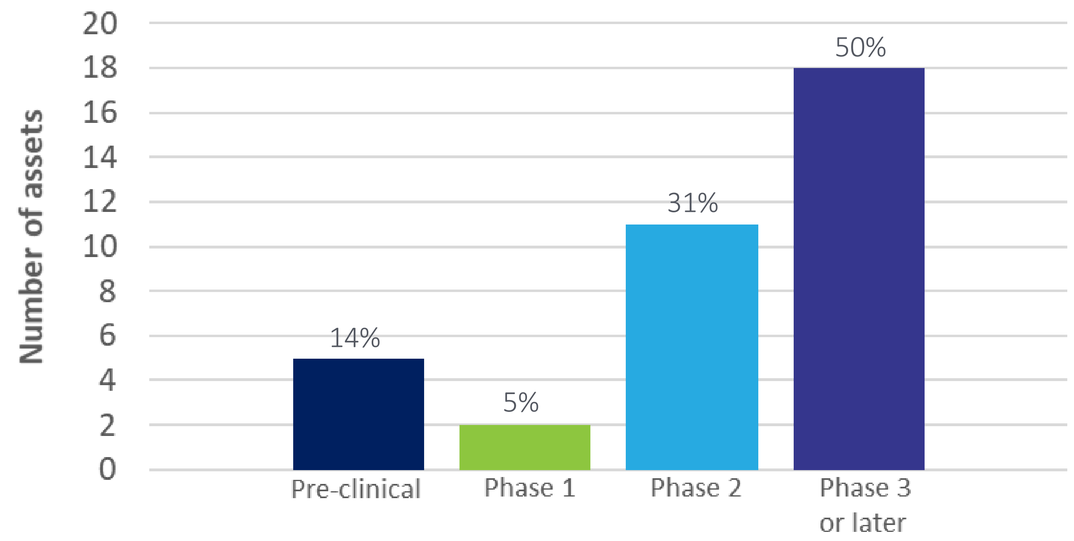
*Evidera analysis on public data

Characteristics of successful ILAP applications

- Approximately 50% of announced IPs submitted ILAP applications at Phase 3 or later, 31% at Phase 2, and 19% earlier than Phase 2 (**Figure 3**).

Results

Figure 3. Clinical development stage when Innovation Passport awarded



Quantitative Analysis: Time from IP achievement to regulatory approval/ HTA recommendation

- At the time of data cutoff, time to HTA recommendation following award of an IP was available for 1 product that received NICE recommendation and 3 products that received SMC recommendation (**Figure 4**). Mean time from IP achievement to NICE recommendation was 13 months and SMC recommendation was 11 months.
- At the time of data cutoff, time to regulatory approval (MHRA or EMA) following IP achievement was available for 3 products in total (2 received MHRA approval; 1 received EMA approval). Mean time from IP achievement to MHRA approval was 7 months and EMA approval was 9 months.

Figure 4. Average time from IP achievement to regulatory and HTA milestones

Qualitative Analysis: Commentary from stakeholders on ILAP success factors

- For the MHRA, this includes the number of applications over time and approval rate, the timing for the target development profile (TDP) roadmaps to a license and access, the attractiveness and speed of the pathway compared to other jurisdictions, and enhanced patient engagement and influence.
- Manufacturers believe ILAP may lead to faster access to market, confidence in perceived innovativeness of their product, receiving aligned advice on evidence generation plans, and potential to positively influence stock price.
- Limited commentary was available for HTA and payers.

Discussion

- Interest in ILAP has exceeded expectations, with 120 total applications received as of June 2022, and manufacturers acknowledge its potential to expedite time to marketing authorisation.
- The qualitative commentary in publications and articles for the pathway reveal some differences in the MHRA and manufacturers perspective on a successfully pathway. Limited information was found on success from the HTA body and payer perspective.
- There may be a bias towards assets from smaller companies if they are more willing to publicly share information on their participation in ILAP and award of an IP.
- Considering the small sample size from the available data, additional monitoring is required to better understand if ILAP accelerates time to marketing authorization and/or HTA recommendation.

Conclusions

- As ILAP is a relatively new pathway, available data is immature, and further monitoring is needed to determine if ILAP delivers against its goals.
- For future investigation, we propose conducting analyses on the features that lead to successful applications and the impact on regulatory and HTA processes.

References

1. Innovative Licensing and Access Pathway. MHRA, 2022. https://www.gov.uk/guidance/innovative-licensing-and-access-pathway. Accessed 20 June 2022.

Disclosures/Acknowledgments

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