The Comparative Analysis of Accelerated Coverage Pathways for Innovation (ACPI) for Digital Technologies

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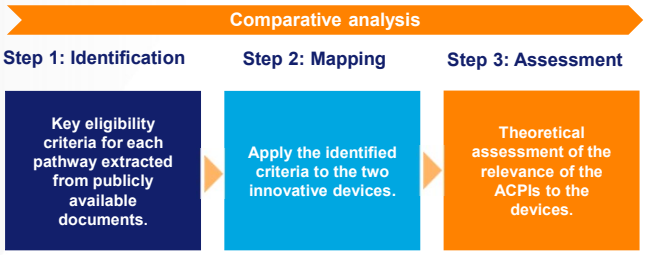
INTRODUCTION AND OBJECTIVES

- Accelerated Coverage Pathways for Innovation (ACPI) are formal early access programs, which governments have put in place to adopt and incentivise innovation of medical technology (Digital Health, IVD and Therapeutics). They provide support in obtaining either **clinical** or **economic endpoints.**
- Digital Health Technologies (DHT) encompass a diverse array of products, including apps, software, and online platforms designed to benefit **individuals and the healthcare system**, either as standalone solutions or in combination with medical devices or diagnostic tests.
- The timely integration of DHTs into health systems relies on Accelerated Coverage Pathways for Innovation (ACPIs) which facilitate early access to these innovative solutions.
- **This research aims to** compare the various ACPIs for DHT coverage in Germany, France, and the United Kingdom.

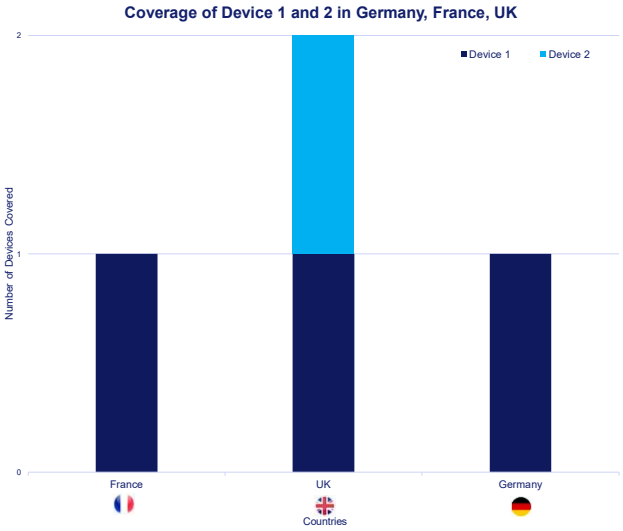
METHODOLOGY

Performing a theoretical assessment was the final step in the comparative analysis. The first two steps comprised of collecting data on the ACPIs: **AI in Health and Care Award in the UK, DiGA in Germany and PECAN in France,** followed by dissecting the eligibility of the devices.



RESULTS

Countries	Eligibility Criteria Considered	Device 1- Non-invasive Measurement of a Biomarker for Remote Patient Monitoring	Device 2 – Tailored Therapeutic Exercices to Relieve pain
🇩🇪🇫🇷	CE mark	X	√
🇩🇪	Class of device (I/IIa)	√	√
🇩🇪🇫🇷🇬🇧	Available evidence of the medical benefit or of a positive organizational impact	√	√
🇩🇪🇫🇷🇬🇧	Not funded by another pathway	√	√
🇩🇪🇫🇷🇬🇧	Innovative characteristic (clinical or organizational)	√	√
🇩🇪	Main Function achieved through digital technologies	√	√
🇩🇪🇫🇷	Validated technical requirements (e.g. data protection, interoperability, etc)	X	√
🇬🇧	Use of AI	√	√
🇩🇪	The solution is not only about remote patient monitoring	√/X	√



- Overall, the **eligibility criteria are similar** across the three pathways. The main differences would be in the requirements of CE marking and the integration of the AI.
- To date, DiGA is the only pathway that doesn't **heavily emphasise Remote Patient Monitoring** (RPM), which could hinder access for a solution strongly reliant on RPM. However, given the increasing integration of AI algorithms into RPM, future DiGA development might incorporate more RPM solutions.
- This study has **some limitations** : Up to the date of completion of this analysis, **no assessment report of a PECAN application** has been published yet, and therefore, there is **limited visibility about the detailed requirements** and eligibility criteria. Moreover, **variations in interpreting** and applying eligibility criteria in the other two pathways may lead to uncertainty regarding the alignment of the analysis results with real-world outcomes.

CONCLUSION

From this theoretical evaluation, it is seen that innovative pathways for DHT adoption in the three countries all aim to expedite the delivery of life-saving, revolutionary technology. However, each pathway targets different types of solutions and different stages of development. AI in Health and Care focuses on earlier-stage developments, while DiGA and PECAN prioritise direct patient accessibility. Simultaneously, AI in Health primarily supports the development of novel healthcare solutions. These pathways collectively contribute to the advancement of healthcare and the improved well-being of individuals.

REFERENCES

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- NICE, "Evidence standards framework for digital health technologies: user guide", 2022
- NIHR, "Artificial Intelligence in Health and Care Award - Guidance for Competition 3 All Phases", 2021
- RPM: remote patient monitoring

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