



How do the reimbursement opportunities for Digital Health Applications vary across the US, Europe and Japan?

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INTRODUCTION

- Digital Health Applications (DHAs) deliver services meant to treat, prevent or manage specific conditions through mobile-based software.
- The role DHAs can play in delivering healthcare to patients is gaining recognition from regulators. This has led to an increase in the creation of regulatory and reimbursement pathways for approved DHAs globally. However, there are significant variations in approaches to this topic.

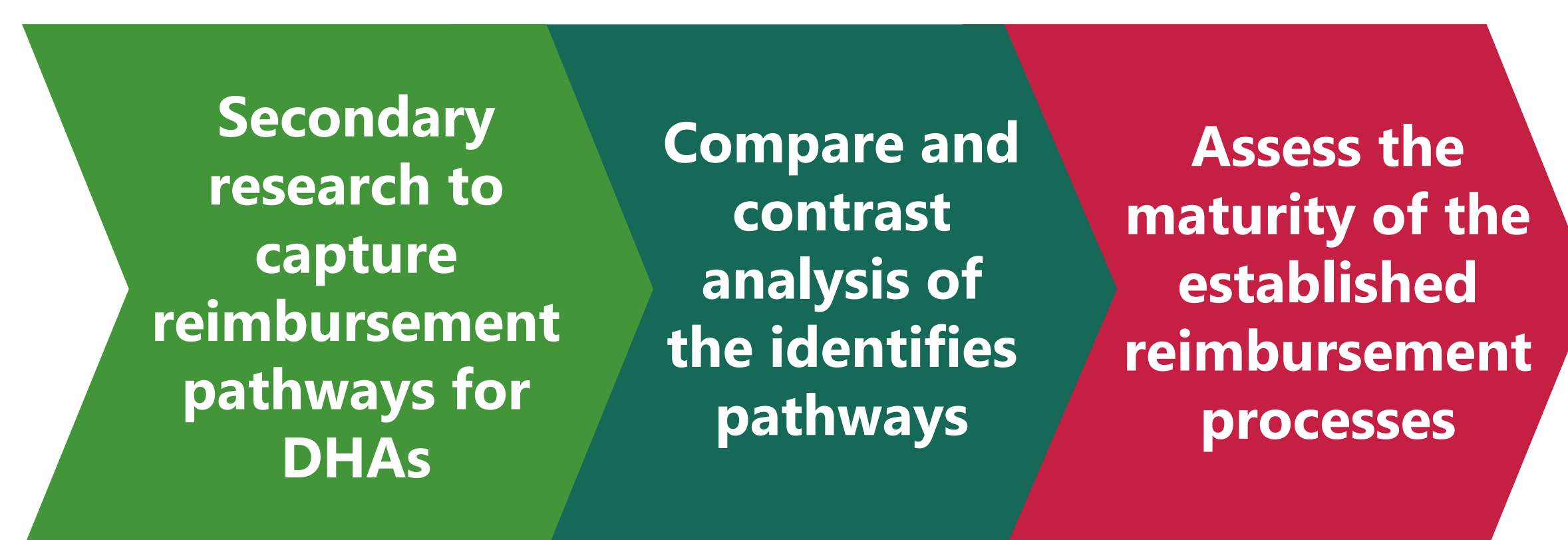
OBJECTIVES

- This study compares and contrasts the reimbursement landscapes of digital health applications (DHAs) in the US, Europe, and Japan.

METHODS

- Web pages of regulatory and private organizations were reviewed to extract data on policies and reimbursement frameworks in the US, Belgium, England, France, Germany, Netherlands, Switzerland and Japan.

Figure 1: Methodology used in this research



ABBREVIATIONS

CMS: Centers for Medicare & Medicaid Services; DiGA: Digitale Gesundheitsanwendungen; DHA: Digital Health Application; HCPCS: Healthcare Common Procedure Coding System; NICE: The National Institute for Health and Care Excellence; PECAN: Prise en charge anticipée numérique

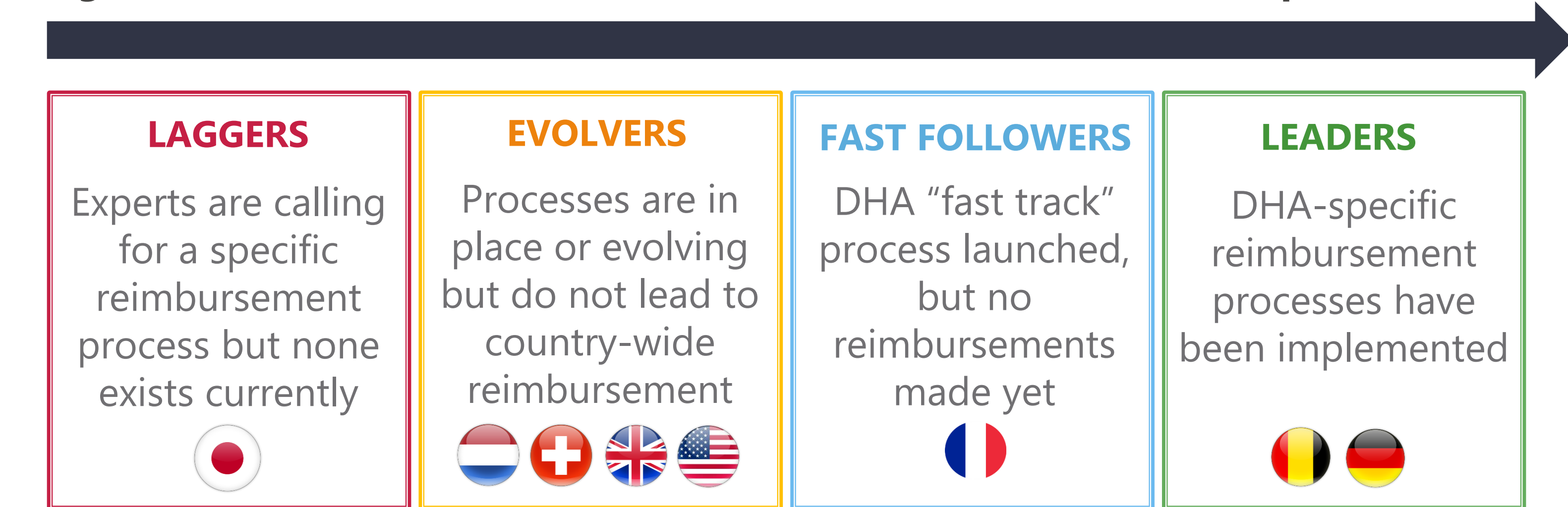
RESULTS

- The establishment of national reimbursement processes varies significantly between countries.
- Based on the maturity of the process countries can be divided into "leaders", "fast followers", "evolvers" and "laggers".

Figure 2: Comparison of reimbursement routes for DHAs

	DHA-specific national process	How viable is access to reimbursement	Alternative funding opportunities
GERMANY	DiGA Launched May 2020	Fast 45 apps reimb.	
BELGIUM	mHealth Pyramid Launched Jan 2021	Slow: 1 app reimb.	Other routes replaced with DHA-specific reimbursement frameworks
FRANCE	PECAN Launched Mar 2023	Newly launched 0 apps reimb.	
USA	CMS has recently included DHAs in a new Level II HCPCS	Limitations anticipated due to the "one size fits all" approach	Commercial health insurers reimburse DHAs on a case-by-case basis
UK	Framework for DHA evaluation exists but does not result in guaranteed funding	DHAs can be assessed by NICE but funding decisions are local	Multiple funding routes at a local level through local healthcare programs and/or direct to insurers
NETHERLANDS		Health insurers collaborate to assess DHAs	
SWITZERLAND	Some guidelines for DHA developers exist		
JAPAN	No DHA specific framework		Reimbursement through the complex and lengthy medical device route. Only 2 DHAs approved for reimb.

Figure 3: Extent of establishment of national DHA reimbursement processes

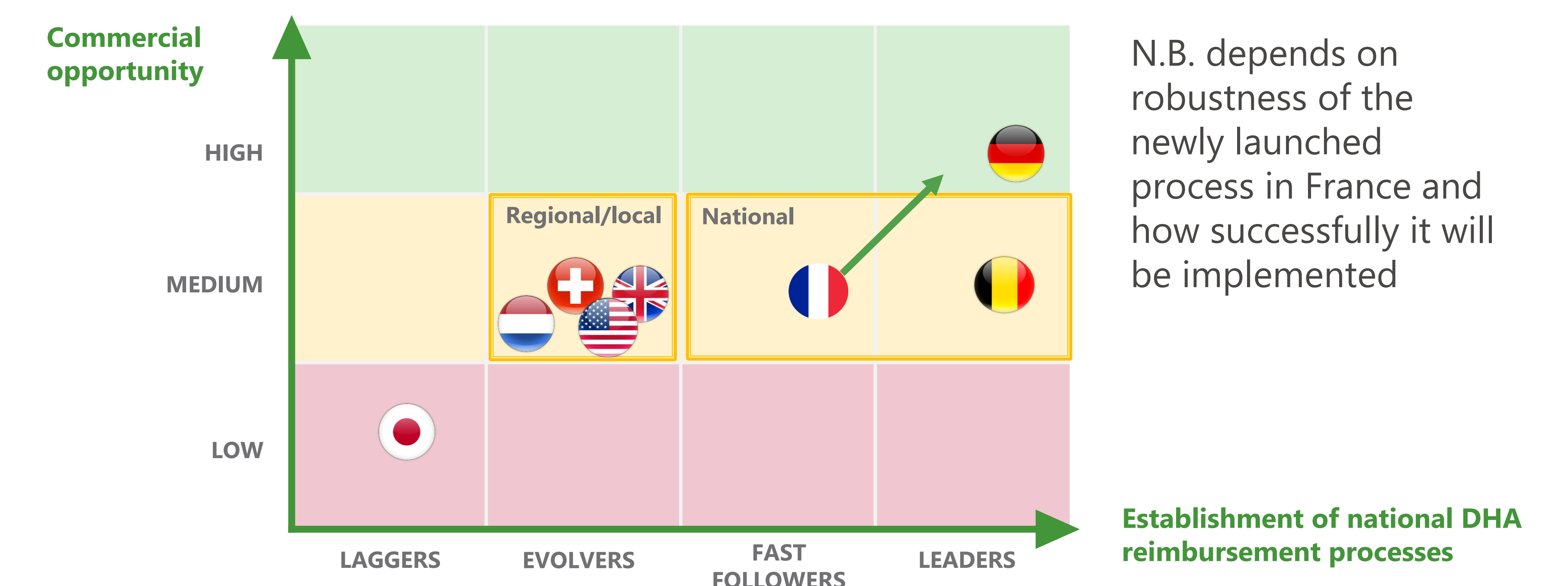


N.B. This is a qualitative assessment based on this research

CONCLUSION

- Digitalisation of healthcare is gathering pace everywhere with global reimbursement frameworks evolving to define funding standards for DHTs.
- Although the movements towards unification of assessment and funding for DHAs is seen in all countries in scope, only three have put in place a national, DHA-specific framework for funding and reimbursement.

Figure 3: Comparison of commercial opportunity with establishment of DHA reimbursement process



N.B. depends on robustness of the newly launched process in France and how successfully it will be implemented