From Development to Reimbursement - Evidence Generation Strategies for HealthTech in Europe

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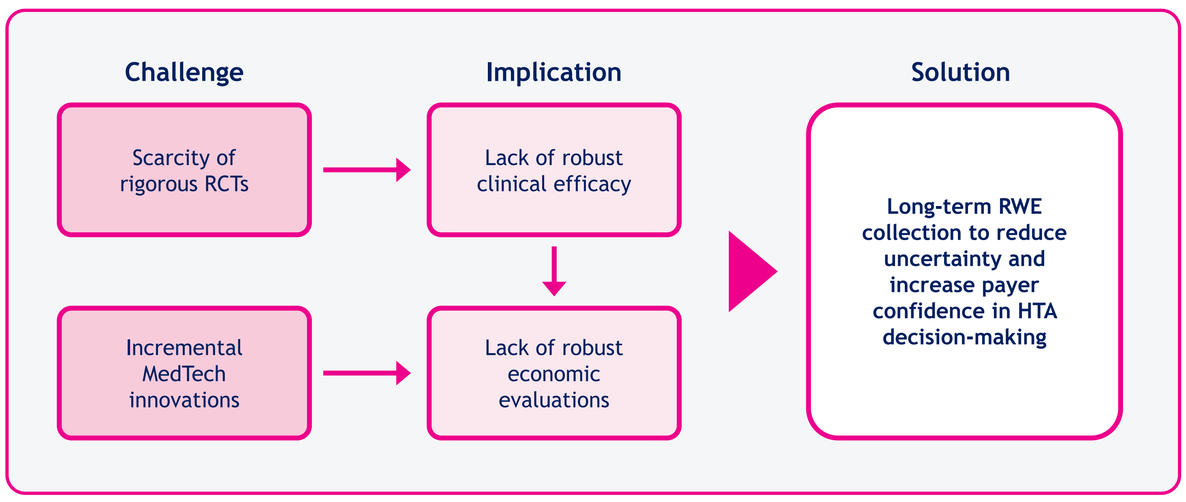
INTRODUCTION

Key challenges in evidence generation for MedTech

- Medical technology (MedTech) can frequently lack the sufficient efficacy, safety and economic data required for pricing and reimbursement (P&R) decision-making.[1] Several factors contribute to this MedTech P&R challenge (**Figure 1**):
  - MedTech can gain marketing authorisation (MA) without robust evidence from randomised-controlled trials (RCTs)[1,2]
  - Positive reimbursement decisions for MedTech products can require more robust clinical and economic evidence than that needed to obtain MA, leading to evidence gaps[1,2]
  - Medical devices often undergo incremental innovation across their lifecycle which can alter cost-effectiveness over time; this can result in hesitancy for MedTech developers to develop cost-effectiveness/cost-implication data, despite its requirement for reimbursement in certain markets[3]

Figure 1. Key MedTech evidence challenges necessitate RWE generation



Abbreviations: HTA; health technology assessment; RCT: randomised controlled trial; RWE: real-world evidence

Bridging the MedTech evidence gap

- Given that clinical evidence for medical devices can be limited, generating real-world evidence (RWE) on MedTech efficacy and safety in routine practice is recommended[1,4]
- To address these evidence-related challenges in MedTech reimbursement, several early access schemes (EAS) operate across Europe to provisionally fund MedTech, with requirements that may include structured generation of RWE to address evidence uncertainties and inform future reimbursement decisions

OBJECTIVES

- To identify key EASs across Europe that support provisional reimbursement of MedTech innovations and RWE generation to inform future reimbursement decisions
- To provide practical recommendations for MedTech developers on how to leverage the National Institute for Health and Care Excellence (NICE) EAS

METHODS

- We conducted desk research to map the availability and requirements of EASs across Europe
- UK-specific insights were informed by official NICE publications and participation in the NICE Artificial Intelligence (AI) and Digital Health Masterclass (2025), including its question-and-answer (Q&A) session

RESULTS: EARLY-ACCESS SCHEMES IN EUROPE

- There are several EASs that offer provisional reimbursement to MedTech to facilitate evidence generation across Europe (**Table 1**)
- These programs can support MedTech developers by offering guidance on study design, providing market-specific insights to inform access strategies, and facilitating early collaboration with healthcare stakeholders

Table 1. Early-access schemes for MedTech in Europe

Country	Early access scheme	Details
UK	Early Value Assessment (EVA) programme[5]	A pilot fast-track evaluation programme for digital health tools, devices and diagnostics that address national unmet needs; EVA speeds up patient access and provides temporary reimbursement and evidence generation planning support to generate RWE prior to full NICE evaluation* ***Please refer to poster #MT38 for further details on NICE EVAs***
Germany	DiGA Fast Track[6]	Digital health applications may obtain provisional reimbursement by statutory health insurance, usually for up to 12 months, to complete comparative studies. BfArM uses this as a basis to decide on permanent reimbursement
France	Early Access to Reimbursement for Digital Devices (PECAN)[7]	Enables temporary reimbursement for 12 months to support evidence collection on clinical and/or organisational benefits to inform digital MedTech reimbursement decisions
	Forfait Innovation[8]	Enables temporary reimbursement of MedTech and innovative procedures to support the structured collection of missing clinical and/or medico-economic data to inform subsequent reimbursement decision-making
Netherlands	Reimbursement Within Research (Vergoeding in Onderzoek)[9]	Allows temporary reimbursement on a basic health insurance package for specialist care and MedTech with uncertain effectiveness, conditioned on further evidence collection
Belgium	mHealthBelgium[10]	As part of the tiered validation system for digital MedTech apps, 'Level 3-' enables provisional reimbursement by NIHDI for further evidence collection to confirm socio-economic value

*Please see "Newsflash: Proposed changes to the NICE HealthTech Programme" for information of upcoming changes
Abbreviations: BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte; DiGA: Digitale Gesundheitsanwendungen; EVA: Early Value Assessment; NICE: National Institute for Health and Care Excellence; NIHDI: National Institute for Health and Disability Insurance; PECAN: Provisional Coverage of Innovative Medical Devices; RWE: real-world evidence

RESULTS: EARLY ACCESS IN THE UK

- Drawing on desk research and primary insights, we propose key recommendations to help MedTech developers engage effectively with NICE's early use process (**Figure 2**)

Figure 2. NICE Early Use (formerly EVA): Recommendations & opportunities

Participation in NICE's early access process is by invitation rather than request

To ensure early access selection, we recommend that MedTech developers should:

- **Enrol with NICE's Innovation Service during pre-market or pilot phases** to increase product visibility
- **Engage early with key NICE stakeholders and NHS clinicians** to establish visibility of the technology and its potential benefits (clinicians can nominate technologies for early access consideration)

Engagement with NHS stakeholders to demonstrate system value is essential

To aid effective dialogue with decision-makers, we recommend that MedTech developers should:

- **Clearly position** their technology in the NHS care pathway
- **Define NHS cost-savings/system efficiencies** over standard of care
- **Develop value propositions** demonstrating how the MedTech addresses areas of national unmet need contributing to the NHS long-term plan

NICE affiliates will support evidence generation planning to ensure alignment with HTA requirements

To maximise the benefits of participation in NICE's early-access programme, we recommend that MedTech developers should:

- **Plan future evidence generation strategies,** with particular emphasis on collecting clinical effectiveness, economic value and systems outcomes data

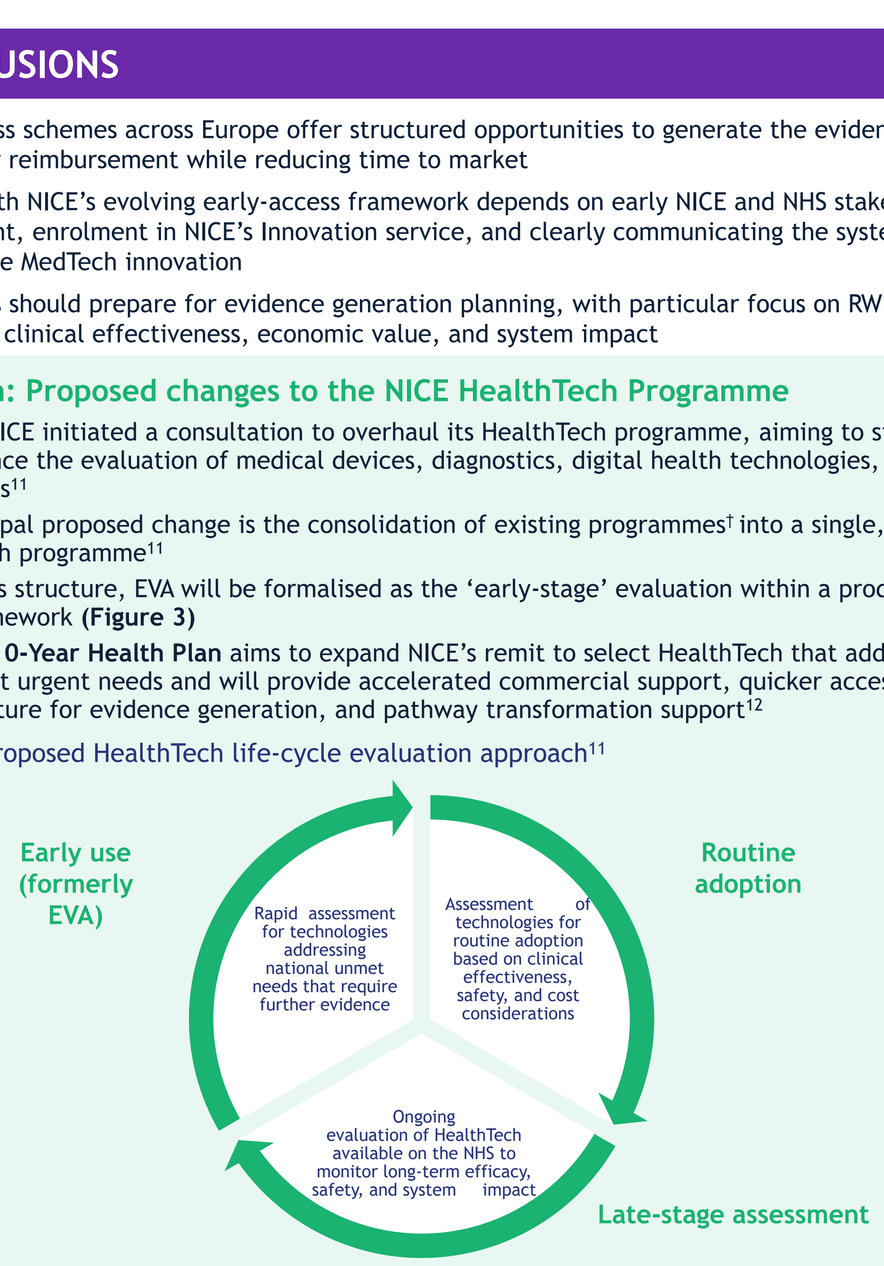
CONCLUSIONS

- Early-access schemes across Europe offer structured opportunities to generate the evidence needed for reimbursement while reducing time to market
- Success with NICE's evolving early-access framework depends on early NICE and NHS stakeholder engagement, enrolment in NICE's Innovation service, and clearly communicating the system value of the MedTech innovation
- Developers should prepare for evidence generation planning, with particular focus on RWE addressing clinical effectiveness, economic value, and system impact

Newsflash: Proposed changes to the NICE HealthTech Programme

- In 2025, NICE initiated a consultation to overhaul its HealthTech programme, aiming to streamline and enhance the evaluation of medical devices, diagnostics, digital health technologies, and procedures[11]
- The principal proposed change is the consolidation of existing programmes† into a single, unified HealthTech programme[11]
- Within this structure, EVA will be formalised as the 'early-stage' evaluation within a product life-cycle framework **(Figure 3)**
- The **NHS 10-Year Health Plan** aims to expand NICE's remit to select HealthTech that addresses the NHS's most urgent needs and will provide accelerated commercial support, quicker access to NHS infrastructure for evidence generation, and pathway transformation support[12]

Figure 3. Proposed HealthTech life-cycle evaluation approach[11]



Implications for MedTech developers

- This life-cycle approach emphasises scheduled re-evaluation of MedTech to assess evolving evidence which will require developers to engage with, and develop, structured evidence generation plans and places emphasis on collecting RWE on effectiveness, economic value and systems outcomes and to assess the impact of technologies in routine clinical practice

†Medical Technologies Evaluation Programme, Interventional Procedures, and Diagnostics Assessment Programme

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