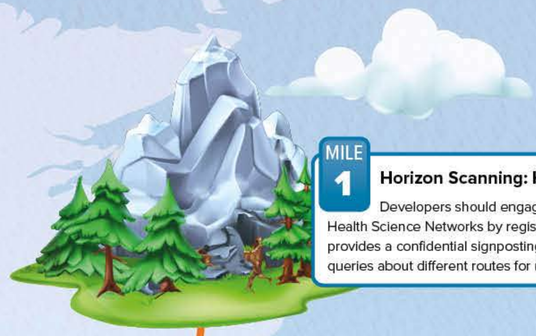
A Medtech Roadmap: New Routes to Market Access in the UK NHS

Medical devices, diagnostics and digital health technologies can improve patientoutcomes with additional benefits for health care systems. However, unlike pharmaceuticals, the route to reimbursement for medical technologies in the UK is not always clear, and the roadblocks of additional economic evidence and health technology assessment can seem impassable. This concept poster describes a practical roadmap of potential routes to market for medical technologies and describe recent initiatives to accelerate access in the NHS.



MILE 1 — Horizon Scanning: HealthTech Connect[1]

Developers should engage early with the NHS and Academic Health Science Networks by registering with HealthTech Connect, which provides a confidential signposting service that can help with initial queries about different routes for market access in the UK

Evaluate clinical evidence:
Generate efficacy and safety data

MILE 2 — CE Marking*

- CE certification is required for all devices/IVDs
- New EU MDR regulations[2] to be implemented in 2021/2022 have increased requirements for clinical evidence

*For medical devices, CE marking will continue to be used and recognised for both the UK and EU markets after the Brexit transition period; the UK-based industry will not require an authorised representative established in the EU. UK-notified bodies will continue to conduct third-party conformity assessment in the UK, and the results of these tests will continue to be used and recognised for both the UK and EU markets

Regulatory (MHRA)

Implantable intervention?

Additional safety evaluation may be required by NICE's Interventional Procedures Programme[3] for technologies that involve an incision, a puncture or entry into a body cavity, or the use of ionising, electromagnetic, or acoustic energy

All CE-marked medical devices and IVDs:

After overcoming the roadblock of regulatory approval, additional clinical and economic evidence may be needed to cross the reimbursement roadblock - but what additional evidence is needed?

Digital health technology?

DHTs have additional efficacy and safety evidence requirements for use in the NHS, described in:

- Digital Technology Assessment Criteria (DTAC beta) of clinical safety, data protection and security, interoperability and useability
- Evidence Standards Framework for DHTs[4] to demonstrate effectiveness and value

Economic evidence requirements:
Determine whether the technology is cost-saving, cost-neutral or cost-effective (more costly with additional benefits) versus the current standard of care

Additional clinical evidence requirements:
Generate comparative clinical effectiveness data versus the current standard of care

MILE 3 — Evidence gap analysis: NICE META tool[5]

The NICE META tool can assess a technology's current evidence base and determine the most appropriate route for market access and whether further evidence is required for the reimbursement processes. RTI-HS is a licensed facilitator of the NICE META tool.

MILE 4 — Scientific Advice and Evidence Generation

If new evidence-generation is required, advice and expert validation should be sought when planning new trials to determine whether outcomes and study designs are appropriate for reimbursement decision-makers for Medtech. Advice can be sought from NICE or from local health economic consultancies, such as our medical device experts a RTI-HS

MILE 5 — Reimbursement/market access in the NHS via mutiple pathways:

- NICE MTG, DG, or TA guidance
- NICE MIB publication
- Inclusion in NHS Supply Chain
- Local CCG funding
- NHS Specialised Services

Reimbursement (NICE/NHS England)*

*Currently there is no funding mandate for Medtech in the NHS unless a positive NICE TA recommendation is published for a device that is cost-effective; draft proposals for the new Medtech Funding Mandate for cost-saving devices receiving positive NICE DG and MTG are under consideration by NHS England

GOAL: Market access in the UK NHS!

CONCLUSIONS: The MedTech route to market access in the UK will vary depending on the technology. Developers should seek advice on which pathway is the most appropriate and take advantage of new initiatives that encourage adoption by the NHS

Abigail Stevenson, Liesl Gildea
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ABBREVIATIONS

CCG = clinical commissioning group; CE = cost-effectiveness; DG = diagnostics guidance; DHT = digital health technology; EU = European Union; IVD = in vitro diagnostic; MDR = medical device regulation; Medtech = medical technologies; META = Medtech Early Technical Assessment; MHRA = Medicines and Healthcare products Regulatory Agency; MIB = Medtech innovation briefing; MTG = medical technology guidance; NHS = National Health Service; NICE = National Institute for Health and Care Excellence; RTI-HS = RTI Health Solutions; SoC = standard of care; TA = technology appraisal; UK = United Kingdom

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2. Medical devices: EU regulations for MDR and IVDR. https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr
3. NICE Interventional Procedures Programme. https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-interventional-procedures-guidance
4. Digital Technology Assessment Criteria (DTAC) - beta: https://www.nhsx.nhs.uk/key-tools-and-info/designing-and-building-products-and-services/#:~:text=To%20improve%20the%20way%20the%20NHS%20assesses%20technologies,protection%2C%20robustness%2C%20stability%2C%20interoperability%2C%20usability%2C%20accessibility%20and%20responsibility
5. NICE META tool. https://meta.nice.org.uk/