10 St Bride Street
London EC4A 4AD
T +44 (0) 7331 2000

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Building an integrated, rules-based medical technology (medtech) pathway: engagement on proposals

techUK response to NHS England's and the National Institute for Health and Care Excellence's (NICE) proposals for an integrated, rule-based medical technology pathway

August 2024

Contact: Robert Walker | Head of Health & Social Care
E robert.walker@techuk.org

techUK

10 St Bride Street
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About techUK

techUK is the trade association which brings together people, companies and organisations to realise the positive outcomes of what digital technology can achieve. With over 1000 members (the majority of which are SMEs) across the UK, techUK creates a network for innovation and collaboration across business, government and stakeholders to provide a better future for people, society, the economy and the planet. By providing expertise and insight, we support our members, partners and stakeholders as they prepare the UK for what comes next in a constantly changing world.

Executive Summary

techUK broadly welcomes the intention to build an integrated, rules-based medical technology pathway as outlined by NHS England (NHSE) and the National Institute for Health & Care Excellence (NICE).

techUK has strongly advocated for clear, consistent rules for medical technology innovation pathways and supports closer engagement between the health system and sector innovators to ensure the right conditions are created for new medical technologies to thrive and scale across the health and social care sector. We welcome the intention to consolidate multiple access points into a single point of contact.

However, whilst supportive of the wider aims and intentions of the outlined proposals, techUK members have highlighted some concerns, including:

- Clarification regarding what digital healthcare products are included within the scope of the proposed medtech pathway.
- How digital products will be prioritised and if NICE has the necessary resources to meet the increased demand.
- If the proposed pathway will impact the re-tendering of products that are currently in use but haven't undergone NICE evaluation.
- If the proposed pathway will be the only route to market, and what the future relationship will be between this intended pathway and already existing regulations like the Digital Technology Assessment Criteria (DTAC).
- What methodology will be used to calculate cost-effectiveness, particularly for products with significant initial expenditure but generate savings over time.
- Whether cost-effectiveness calculations account for savings across the entire healthcare, including primary care and social care.
- Acknowledgement that broader systemic factors, including connectivity and procurement, significantly impact the adoption of new technologies. A comprehensive approach addressing these challenges is necessary for optimal results.

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Working in partnership with the digital health and care industry will be fundamental to ensure policymakers and health and care organisations can benefit from the expertise and guidance industry has to offer. techUK continues to convene key actors across the digital health and care system to support the development of a wide range of policies and practices focused on the use of digital, data and technology in health and social care. techUK would greatly encourage further industry engagement in supporting the potential implementation of the outlined proposals.

Guiding Principles

Question 1 – Are there any other important principles that should guide the development of an integrated, rules-based medtech pathway?

Whilst techUK members were widely supportive of the guiding principles outlined in the document, they felt they were too limited in scope. In addition to the existing principles, we advise including more explicit references to the following aspects:

- **Guidance for innovators**: Industry recognises the benefits of support and guidance implied throughout the proposal. techUK would encourage guidance to be explicitly stated via a clear and comprehensive set of guidelines for organisations seeking to introduce innovative technologies to the NHS. While grouping similar technologies can streamline processes, it risks commissioners overlooking crucial differences between products, potentially leading to incorrect comparisons or suboptimal purchasing decisions.
- **Principles of implementation:** The success and impact of a new technology is dependent on the success of its implementation. Implementation costs and processes need to be integrated more prominently in the evaluation of innovative technologies and stated in the principles guiding the pathway.
- **Priority setting:** techUK members would encourage NHSE to map technologies to existing priority areas in order to identify unmet needs and identify where new medical devices could add value to areas with significant treatments delays.

Question 2 – What positive or adverse impacts could the integrated, rules-based medtech pathway have on protected characteristic groups and people at particular risk of health disparities? How do you think those impacts should be addressed?

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techUK members would welcome further engagement to address potential unintended consequences to the system at large of what is a well-intentioned principle. Members also felt the question was limited in scope. TechUK would encourage NHSE / NICE to consider:

- **Further collaboration:** members would welcome further collaboration with the Medicines and Healthcare Products Regulatory Agency (MHRA) to mandate its recent *Equity in medical devices: independent review – final report* recommendations. techUK members would also encourage collaboration with National Standards Organisations such as the British Standards Institution in order to integrate health equality into standards and allow industry to adopt these principles early in the design process. This collaboration would also lessen the burden on NHSE and NICE.

- **Inequity test:** techUK members also highlighted that NHSE / NICE should consider requiring evidence from medical devices that address inequalities and disparities by implementing an 'inequity test' to assess the impact of new innovations on different patient groups. Innovators should also be required to provide evidence on reaching underserved populations. This is of paramount importance when considering the implementation of Artificial Intelligence, which should always be developed on diverse datasets.

Pre-Authorisation

Question 3 – Do you agree that the timely and accurate provision of information by industry should be a pre-requisite for NICE evaluation?

techUK members agreed on the broad premise of the question, that industry should provide timely and accurate information as a pre-requisite for NICE evaluation. However, they also raised some concerns and areas that require further clarification:

- **Product type:** Stakeholders required clarity on the product type within the pre–authorisation phase. It would be a challenge to provide all information about early products at the pre-authorisation phase as the information required may not be known.

- **Application fees:** There were concerns that the increasing number of innovators could place such a strain on NICE evaluation services that application fees could be introduced. Guarantees that this will not happen would be welcomed.

- **Regulatory crossover:** Members also raised concerns over how current regulations, such as DTAC, would be assessed in conjunction with the proposed pathway. Clarity is required over whether DTAC would be a prerequisite for Early Value Assessment.

- **Market impact versus clinical performance:** Importance of understanding the breadth of information required for pre-authorisation. As currently stands, this seems

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to be focusing on the technology's potential market impact rather than clinical performance.

- **Clear definitions:** Clear definitions of required information are critical for industry planning and ensuring the correct evidence generation.

Question 4 – How could all partners work with industry to ensure data coming from emerging innovations is robust and supports high quality horizon scanning?

Industry would like to emphasise the importance of clear communication, data quality and alignment between industry and regulators to optimise the evaluation and adoption of medical technologies. Key issues raised by techUK members include:

- **Guidelines, data standards, and channels**: Regulators should provide clear guidelines for what data they wish to receive and in which format (structured or unstructured). Members also highlighted that data for evaluation and data for horizon-scanning fulfil different purposes. Indeed, members were unsure why horizon-scanning data would be needed for NICE evaluation. Furthermore, to ensure that the analysis of the data remains consistent and accurate, data should be audited regularly to have the “correct” and “necessary” data.

- **Data interpretation:** Members advised having the following additions to the pathway to improve data collection and data interpretation: (1) Limited free text fields so data can be analysed succinctly; and (2) include an ongoing audit of the data provided. This would ensure that the necessary data is being collected.

- **Signalling market direction / demand signalling:** NHSE and NICE should communicate exactly which areas they require innovation in. Clarity of direction allows industry to inform product development and evidence generation. Members suggested having two different processes to look at all technologies and their cost effectiveness to give guidance to clinicians on how to treat a therapeutic area: (1) health technology evaluation; and (2) the guidelines process. Additionally, NHSE should provide clarity on what is truly meant by ‘demand signalling’ in this context.

- **NHS England guidance:** NHSE should guide appropriate data variables/structures for NICE consideration. NHSE should also work with industry partners to manage and secure data via Secure Data Environments.

- **International collaboration:** techUK members would encourage NHSE / NICE to collaborate with international forums such as the International Medical Device Regulators Forum. Industry would encourage the adoption of international evidence

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quality standards and assessment techniques, which would also reduce the burden of assessing unstructured and fragmented data quality standards.

Question 5 – Should the NHS Innovation Service provide any additional functionality to act as the 'centralised front door' for all innovative technologies in the NHS?

Industry representatives called for improved collaboration among NHS innovation bodies, such as the NHS Innovation Service and Health Innovation Networks. They emphasised the need for clear roles and responsibilities for each organisation to simplify the application process for new medical technologies. Concerns were also raised about the lack of clarity around the role of Health Innovation Networks. Greater sign-posting for grant and investment funding would also be welcomed.

Question 6 – How can stakeholders inform a shared understanding of the value of medtech to the NHS earlier in a product's development cycle?

Industry members expressed concerns about this questions, and also raised concern regarding inadequate procurement processes, and suboptimal funding models for digital health technologies. These include:

- **Clarifications:** Members called for clarification of this question. There was confusion as to whether is meant communicating the potential benefits of a product or if it was regarding the horizon-scanning aspect of the consultation.

- **Engagement:** Members also called for greater engagement with procurement personnel to ensure they have greater understanding of the products available on the market. Furthermore, members highlighted the need for funding for Digital Health Technologies to be structured correctly and encouraged a move away from capital expenditure models.

- **Patient and Public Involvement (PPI) sessions:** Members also called for more PPI sessions, bringing innovators together to improve the understanding of the product's value, in terms of who is receiving and making use of the product.

Question 7 – How can all partners better signal demand to industry, academia, innovators, and investors? What information channels should NHS England and the National Institute for Health and Care Excellence use?

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techUK members have advocated for a more structured approach to problem identification and solution development. They propose that clear, data-driven problem statements should be provided by the NHS to guide innovation. Improved access to data, efficient communication channels, and streamlined regulatory processes are essential. Collaboration with stakeholders and continuous monitoring of solutions are also crucial for successful outcomes.

In essence, the industry seeks a more collaborative and evidence-based approach to innovation, with a focus on addressing real-world healthcare challenges including:

- **Problem statement approach:** Members called for greater clarity over how an issue is stated as opposed to how it is communicated and NHSE, NICE and DHSC should provide detailed descriptions of current issues including clinical, operational and patient impact assessments. They argued that a 'problem statement' or 'case study' approach providing greater context would be more useful. This should include quantifiable metrics and data which illustrates the economic and clinical value of addressing these issues. This approach aligns economic activity with overarching societal goals, driving innovation and investment towards solving critical challenges. It would also foster cross-section collaboration, maximise resource efficiency, and ensures economic growth contributes to meaningful and sustainable improvements in public well-being which are directly aligned to NHSE requirements.

- **Data access:** Members highlighted that if data access is likely to be required for the development, clinical validation, regulatory process, adoption, scaling and continuous evaluation of the product then details of this should be included in the problem statement. Indeed, NHSE / NICE should work with data controllers such as Health Data Research UK (HDRUK), to enable innovators the necessary access to data.

- **Information channels**: Members called for the creation of an NHSE portal/webpage to disseminate information efficiently to all suppliers and ensure transparency. There were concerns that current methods of communication (emails and events) were exclusive and may be missed.

- **Regulation:** Members also called for Regulatory Authorities to fast-track technologies which could tackle the issues outlined within the problem statement.

- **Engage stakeholders:** Members encourage NHSE / NICE to engage with clinicians, patients, economists and other stakeholders to ensure that problems are accurately identified and prioritised. Stakeholders should further define what the measurements of success would be at a national level. Additionally, if integration is required with the current technology supplier for new innovation to be adopted, the current system supplier should help NHSE / NICE frame the problem so that innovators understand potential implementation mechanisms and build these into their designs from the outset.

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- **Monitor and adapt:** Members would encourage the continuous monitoring of implemented solutions and to adapt the demand-signalling process based on the outcomes and emerging needs.

Evaluation and Guidance

Question 8 – What additional factors should NHS England, the National Institute for Health and Care Excellence and the Department of Health and Social Care consider when selecting technologies and categories of technologies for the pathway?

Industry representatives emphasise the importance of a holistic approach that considers not only product features but also implementation challenges, system integration, and broader societal impacts. Members have highlighted several key areas for improvement in the evaluation and implementation of new medical technologies:

- **Evaluation biases:** Members welcomed the clarity of the decision criteria for the prioritisation board. However, they noted that it would be beneficial to include at this stage a set of standards to ensure that the evaluation board remains unbiased over time.

- **Implementation costs:** Members argued that to effectively measure a product's economic value and cost effectiveness it is fundamental to factor in the costs of implementation. This is critical as the success and impact of a product is determined by how well it is implemented and embedded within a system. While the members recognised that an implementation analysis would be included in the commissioning stage, they argued that it is critical to incorporate it earlier in the pathway. This means focusing holistically on an *implementation lifecycle* to factor in the technical complexities, the initial implementation costs, the roll-out costs, and the overall maintenance in support of each solution.

- **Viability of scaling:** Members would encourage NHSE, NICE and DHSC to consider additional factors when selecting technologies to scale across the healthcare system including; if the technology needs to integrate with other systems; if there are any potential services, service level changes or other change management needed in order to drive adoption; if the technology is compatible, and interoperable, with existing NHS IT systems (i.e. Electronic Health Records) and if the technology is dependent on future network upgrades or additional infrastructure.

- **Others:** techUK members also highlighted that NHSE, NICE and DHSC should have consideration to patient confidentiality; evidence supporting value proposition; external evidence; transformational impact; environmental impact and internal barriers to adoption.

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Question 9 – How can products that receive a positive early value assessment recommendation best be supported to develop evidence?

Industry stakeholders have highlighted several challenges in the development and adoption of medical technologies. These include the need for improved data collection and sharing, increased funding, and enhanced collaboration between industry, regulators, and NHSE. To accelerate innovation and improve patient outcomes, stakeholders recommend streamlined evaluation processes, greater support for early adopters, and the development of a partner network to share expertise and resources. Several areas identified are:

- ***Quid pro quo* agreements:** Members suggested that support could come in the form of a *quid pro quo* agreement, where innovators would receive early approval to implement a technology under the obligation to provide data back to the larger system.
- **Proactive approaches to data gathering:** Members mentioned that currently, when technologies get implemented, innovators are required down the line to harvest data from external sources (e.g. Clinical Practice Research Datalink) to see whether their data reflected how the interventions played out. There is an opportunity to set up a proactive approach to data gathering and for regulators to offer more clarity on: (a) what data that needs to be captured for appraisal and (b) closing the evidence gaps that are needed to move away from contingent approvals to official approvals later. Data should be proactively collected rather than captured retrospectively.

- **Early adopters and automatic funding:** Members outlined that funding and the long evidence generation development cycle are two of the main blockers to innovation. As such, members welcomed the commitment to identify automatic funding for Medical Technology Guidance but would welcome similar commitments in working with the Accelerated Access Collaborative where research funders could easily identify technologies that have received conditional recommendation as part of the Early Value Assessment. Members also called for better identification of NHS organisations which are willing to be early adopters of technology, for example a register of interested organisations.

- **Implementation and change management:** Members further highlighted NHS capacity issues to implement innovative technologies. Members encouraged the NHS to engage in comprehensive change management programmes when a new technology is implemented, particularly when moving to a new product.

- **Data responsibility and impact assessment**: Members expressed concerns about how NICE and NHS England will handle the responsibility of data management for impact assessments, given the current overstretched healthcare system.
  While the responsibility for data and impact assessment lies with NICE and NHS England, it ultimately depends on an already strained healthcare system to generate early findings. Additional concerns were raised over capacity to harness the date

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effectively and how it will be disseminated across Integrated Care Systems and Integrated Care Boards. This raises further concerns over who will manage this data and its impact upon the system.

- **Centralised resources:** A proactive approach involving a central resource could alleviate the burden on the frontline NHS by providing early data. This would prevent the cyclical problem of repeatedly tasking the NHS organisations with data collection, which is already a challenge given the disparate budgets across multiple organisations. Off-the-shelf evidence could demonstrate the budgetary impacts of solving these problems, thereby saving the frontline staff from additional workload and allowing them to see the benefits clearly.

- **Developing a partner network:** techUK members outlined the need for the development of a *partner network* which would have expertise in evidence generation in specific areas and would include private, public and academic organisations. There are already ongoing examples of this public private partnership which ensures that research does not take place in a vacuum, independent of the system itself and reduces the time from evidence generation to patient benefit.

Question 10 – To what extent do you think there is an opportunity to streamline existing innovation funding streams to provide a more systematic approach to supporting conditional reimbursement for early value assessment recommended medtech?

Industry representatives called for a clearer understanding of how new funding streams align with existing financial resources within the NHS. They emphasised the need for a comprehensive mapping of funding sources to identify overlaps and gaps, ensuring that new initiatives support broader strategic goals. Additionally, it was suggested that Early Value Assessments should be integrated into routine commissioning to ensure the long-term sustainability of successful innovations, reducing reliance on limited innovation funding and facilitating seamless adoption within the healthcare system. Further details include:

- **Funding stream clarity:** Members called for greater clarity on understanding how new funding aligns with existing financial resources and mandates is essential for maximising investment impact. This would involve clearly mapping out all sources of funding to identify overlaps and gaps and ensuring that the goals and objectives of new funding initiatives are aligned with existing mandates and strategic priorities. Streamlining funding would also increase transparency and allow the NHS Innovation Service to centralise information.

- **Integration into baseline commissioning:** Members have suggested that Early Value Assessments should be integrated into baseline commissioning to ensure ongoing availability and accessibility, moving from managed access funds to routine funding after a full appraisal, and preventing reliance solely on innovation funding for

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sustainable long-term support. This integration promotes the seamless integration of EVAs into the healthcare system.

Commercial and Commissioning

Question 11 – Do you envisage the proposed commercial activities will help the NHS to maximise value for money from new medtech?

techUK representatives have outlined several challenges hindering the adoption of medical technologies within the NHS. These include a lack of clarity around affordability assessments, insufficient data on medtech spending, and obstacles related to implementation and procurement. There is a need for a more granular understanding of available budgets to inform innovation strategies. Additionally, industry emphasises the importance of streamlined procurement processes, improved change management practices, and a clear definition of value for money to facilitate the successful integration of new technologies into the healthcare system. Specifically, members have called for:

- **Medtech spend analysis:** techUK members are sceptical that the proposed commercial activities will effect significant change. They outlined that innovators do not know if affordability will be set a national, regional or local level leading to concerns that affordability does not serve as a good indicator to innovators as to whether they will be recompensed for their innovation. To address this concern, members outlined the need to analyse medtech spend (including EHRs and other significant capital technology investment programmes) at a national, regional and organisational level would give innovators more detail of available budgets, and allow them to allocate resources appropriately.

- **Implementation and change management:** Members raised concerns regarding the proposed end-to-end process implementation. Implementation of a new product falls under the remit of the ICBs, however there is ambiguity on how this occurs. There were further concerns regarding the lack of leavers and incentives for the adoption of these technologies within ICSs/ICBs. Members further highlighted NHS capacity issues to implement innovative technologies and encouraged NHS to engage in comprehensive change management programmes when a new technology is implemented, particularly when moving to a new product. This should be combined with a dedicated funding pot for change management projects.

- **Updating procurement processes:** One significant challenge in the current procurement process is that current contract formats are outdated and do not align well with the modern technology being implemented in the NHS. This mismatch creates "*square peg, round hole*" situations, complicating the process. Particularly problematic are the separate contracts for accessing NHS login data and supply contracts, which often don't integrate smoothly. This fragmentation leads to

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substantial delays, as any necessary changes must go through an escalation process. This presents an opportunity to review and update these documents to ensure they are compatible with current technology, streamlining the process and reducing the time and effort required for negotiations. The simplification of complex NHS tendering rules and funding allocations would accelerate innovation.

- **Definition of 'value for money':** Members have called for greater clarity on how value for money will be measured (e.g. cheapest product or best outcome).

Question 12 – Please provide comments on what, if any, other commercial mechanisms/activity NHS England and NICE should consider to maximise value for money from medtech through the pathway.

techUK would like to propose several strategies to enhance the adoption of medical technologies within the NHS. These include establishing a register of NHS organizations open to innovation, developing dedicated transformation roles within trusts, and shifting procurement practices towards value-based approaches. Moreover, there is a call for innovative funding models to support the development and implementation of new medical technologies. By fostering collaboration, building capacity, and aligning incentives, these initiatives aim to accelerate the adoption of innovative solutions and improve patient outcomes. Additional details include:

- **Register of "open doors"**: One effective strategy would be the creation of a "register of open doors," which would list NHS organisations interested in participating in the testing and development of medtech innovations. This register would enhance collaboration between the healthcare sector and technology developers, serving as a valuable resource for medtech companies.

- **Capacity Building through "transformation agents"**: Members agreed that it is critical to enhance the capacity of NHS organisations to implement small-scale transformations. Some members suggested embedding '*transformation agents*' within trusts as a strategic move to champion and guide change initiatives. These agents would work closely with staff to identify opportunities for small but impactful changes, provide training and support to build the necessary skills, and monitor the progress of these initiatives to ensure continuous improvement.

- **Prioritise value-based procurement**: Members expressed the importance for NHSE to transition from Cost-Based procurement to Value-Based Procurement. This would allow NHSE to convert better outcomes into financial metrics, which can be applied consistently and independently evaluated in the procurement process. Industry recognised that this would mean that they would need to supply consistent product performance data.

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- **Funding models:** techUK would encourage DHSC/NHSE to re-evaluate current funding models. New models should consider funding in return for equity, direct partnership models for co-development, and grants and loans.

Question 13 – What further work could help to inform an understanding of the value of medtech to support sustainable commissioning, funding, and adoption through the pathway?

techUK would greatly encourage further industry engagement in supporting the potential implementation of the outlined proposals.

techUK members welcomed the responsibility on ICB Commissioners to ensure that consistent uptake in new technologies. Furthermore, members would encourage transparency from ICBs to share their digital transformation and IT across existing and new technologies and change management processes in order to audit any economic benefits of technology implementations. Industry has also called for ICBs to justify why they are not adopting technologies that have proven benefits.

Industry has also called for greater collaboration within the innovation ecosystem including healthcare trusts, commissioners and patients to ensure the wider adoption of new technologies.

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