VE3 RESPONSE TO NHS ENGLAND'S CONSULTATION ON INTEGRATED, RULES-BASED MEDTECH PATHWAY

Feedback on the Proposed MedTech Pathway

Abstract

VE3 welcomes the opportunity to provide feedback on NHS England's consultation for developing an integrated, rules-based pathway for medical technologies. Our response focuses on enhancing the principles guiding the pathway, ensuring robust data collection for horizon scanning, and informing the value of MedTech to the NHS early in the product development VE3 is pleased to submit feedback on NHS England's consultation for an integrated, rules-based MedTech pathway. We focus on enhancing guiding principles, ensuring robust data collection for high-quality horizon scanning, and establishing a shared understanding of MedTech value early in the development cycle. Our recommendations aim to improve patient outcomes, streamline processes for innovators, and ensure value for taxpayers. We are committed to contributing to the successful implementation of these proposals.

VE3

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Introduction:

In response to NHS England and NICE's recent consultation on the development of an integrated, rules-based MedTech pathway, VE3 is excited to provide a comprehensive review and commentary on the proposed framework. As a leader in MedTech innovation, VE3 recognizes the critical importance of establishing effective regulatory pathways that foster innovation, improve patient outcomes, and ensure value for money.

This document outlines VE3's perspectives on several key areas discussed in the consultation, including the enhancement of guiding principles, ensuring robust data collection for high-quality horizon scanning, and informing a shared understanding of MedTech's value to the NHS early in the product development cycle. By addressing these areas, VE3 aims to support the development of a MedTech pathway that is inclusive, transparent, flexible, collaborative, and sustainable.

Company Introduction

About VE3

VE3 is a leading MedTech innovator committed to advancing healthcare through cutting-edge technologies. Our portfolio includes a diverse range of medical devices, diagnostics, and digital health solutions aimed at improving patient care and health system efficiency. With a strong emphasis on innovation and collaboration, VE3 strives to bring transformative healthcare solutions to market, positively impacting patients and healthcare providers alike.

VE3's MedTech Expertise

At VE3, we focus on the development and implementation of advanced medical technologies that address critical healthcare needs. Our expertise spans several key areas, including diagnostics, medical devices, and digital health solutions. We prioritize the integration of innovative technologies into clinical practice, aiming to enhance patient outcomes, streamline healthcare delivery, and ensure cost-effectiveness.

Key Highlights of Our MedTech Capabilities Include:

1. **Innovative Diagnostics:** Developing state-of-the-art diagnostic tools that provide accurate and timely results, improving patient care and enabling early intervention.

2. **Advanced Medical Devices:** Creating medical devices that enhance treatment options, increase precision in surgical procedures, and support patient recovery.

3. **Digital Health Solutions:** Leveraging digital technologies to improve patient monitoring, enhance data management, and support telehealth services.

Our Commitment to Quality and Compliance

VE3 is dedicated to maintaining the highest standards of quality and compliance in all our products and processes. We adhere to rigorous regulatory requirements and continuously seek to improve our practices to ensure the safety and efficacy of our technologies.

5. Are there any other important principles that should guide the development of an integrated, rules-based MedTech pathway?

VE3 agrees with the principles outlined in the consultation document and believes they provide a strong foundation for the development of the integrated, rules-based MedTech pathway. In addition to these, VE3 proposes the following principles to further enhance the pathway:

1. **Real-World Performance and Value:** The pathway should prioritize and incentivize the collection and evaluation of real-world evidence (RWE) to assess the effectiveness and value of MedTech in real-world clinical practice. This would ensure that decisions about adoption and reimbursement are based on comprehensive and robust evidence, reflecting the actual impact of technologies on patients and the healthcare system.
2. **Continuous Improvement and Learning:** The pathway should be a dynamic and evolving system, incorporating a mechanism for continuous feedback and improvement. This could involve regular reviews of the pathway's processes and outcomes, as well as opportunities for stakeholders to provide feedback and suggestions for enhancement. A learning-oriented approach would ensure that the pathway remains adaptable and responsive to the changing needs of patients, clinicians, and the MedTech industry.
3. **Sustainable Funding and Resource Allocation:** The pathway should ensure sustainable funding and resource allocation for MedTech evaluation, adoption, and implementation. This includes adequate funding for NICE evaluations, support for evidence generation, and resources for training and education to ensure the successful integration of new technologies into clinical practice.
4. **International Collaboration and Harmonization:** The pathway should seek opportunities for international collaboration and harmonization of regulatory and assessment processes. This could involve sharing best practices, aligning evidence requirements, and exploring collaborative evaluation approaches with other countries. International collaboration would streamline the pathway for multinational companies, reduce duplication of efforts, and facilitate faster access to innovative technologies for patients across different healthcare systems.

Incorporating these additional principles would further strengthen the integrated MedTech pathway, ensuring it remains patient-centric, evidence-based, adaptable, and sustainable in the long term. VE3 is committed to working with NHS England, NICE, and other stakeholders to develop and implement this pathway to maximize the benefits of MedTech for patients and the NHS.

6. 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?

The integrated, rules-based MedTech pathway presents a significant opportunity to address health disparities and improve health outcomes for protected characteristic groups and individuals at higher risk. However, it also carries the potential for unintended adverse impacts if not carefully designed and implemented.

Potential Positive Impacts:

- **Increased access to innovation:** The streamlined pathway could accelerate access to innovative MedTech for underserved populations, potentially reducing existing health disparities. By prioritizing technologies that address unmet needs in these groups, the pathway can drive innovation towards more equitable healthcare solutions.

- **Tailored solutions:** The pathway could incentivize the development of MedTech specifically tailored to the needs of diverse patient groups. This could include devices designed for different body types, cultural preferences, or specific health conditions prevalent in certain populations.
- **Reduced bias in data and algorithms:** With a focus on diversity and inclusion in data collection and analysis, the pathway can help identify and mitigate biases in MedTech algorithms, ensuring fair and equitable treatment for all patients.
- **Enhanced patient engagement:** By actively involving patients from diverse backgrounds in the evaluation and decision-making processes, the pathway can ensure that the voices and needs of underserved populations are heard and considered.

Potential Adverse Impacts:

- **Exacerbation of existing disparities:** If not carefully considered, the pathway could prioritize technologies that primarily benefit the majority population, leaving behind those with unique or less common needs.
- **Cost barriers:** Cost-effectiveness analyses may not fully capture the value of MedTech for certain populations, potentially leading to the exclusion of technologies that could significantly improve their health outcomes but are not considered cost-effective from a broader perspective.
- **Limited representation in clinical trials:** If clinical trials for new technologies do not adequately represent diverse populations, the evidence base for their use in these groups may be insufficient, hindering their adoption and potentially perpetuating disparities.

Addressing the Impacts:

VE3 proposes several strategies to mitigate potential adverse impacts and maximize the positive outcomes of the integrated MedTech pathway:

- **Equity-focused evaluation:** Incorporate equity considerations into all stages of the pathway, from topic selection to evaluation and implementation. This includes assessing the potential impact of technologies on different population groups and actively seeking out solutions that address health disparities.
- **Diverse data collection and analysis:** Ensure that data used to develop and evaluate MedTech are collected from diverse populations, including protected characteristic groups and those at risk of health disparities. This involves ensuring representation in clinical trials and collecting real-world data from diverse settings.
- **Meaningful patient and community engagement:** Actively involve patients, carers, and community representatives from diverse backgrounds in all aspects of the pathway. This includes seeking their input on research priorities, participating in technology evaluations, and providing feedback on implementation and adoption strategies.
- **Targeted funding and support:** Establish targeted funding streams and support mechanisms to encourage the development and adoption of MedTech that specifically addresses the needs of underserved populations. This could include grants, tax incentives, or priority access to regulatory and assessment pathways.
- **Education and training:** Provide education and training to healthcare professionals and researchers on the importance of diversity and inclusion in MedTech development and implementation. This includes raising awareness of health disparities and promoting culturally competent care.

By proactively addressing these issues and incorporating these recommendations, the integrated MedTech pathway can become a powerful tool for promoting health equity and improving the lives of all patients, regardless of their background or circumstances. VE3 is committed to working with NHS England, NICE, and other stakeholders to ensure the pathway's success in achieving this goal.

7. Do you agree that the timely and accurate provision of information by industry should be a pre-requisite for National Institute for Health and Care Excellence evaluation?

VE3 agrees that the timely and accurate provision of information by industry is crucial for NICE evaluations. High-quality, comprehensive, and timely data enables NICE to conduct robust assessments of a technology's clinical and cost-effectiveness, ultimately leading to informed decisions that benefit patients and the NHS.

Additional Comments:

- **Clear Guidelines and Support:** To facilitate the timely and accurate provision of information, it is essential to establish clear guidelines and expectations for industry regarding the type, format, and timeline for data submission. This includes specifying the required evidence levels for different stages of the pathway (e.g., EVA, MTG, LSA) and providing templates or standardized formats for data submission.
- **Early Engagement and Collaboration:** Encourage early and ongoing engagement between NICE and industry to discuss data requirements, address potential challenges, and foster a collaborative approach to evidence generation. This could involve pre-submission meetings, workshops, or dedicated communication channels to facilitate information exchange and resolve any queries or concerns.
- **Flexibility and Pragmatism:** Recognize that early-stage technologies may have limited data available. In such cases, the pathway should allow for a more flexible approach, with the possibility of conditional recommendations based on the available evidence and a commitment to generate further data post-launch.
- **Data Quality Assurance:** Implement robust data quality assurance mechanisms to ensure the accuracy and reliability of the information provided by industry. This could involve independent audits, peer review of evidence, or the use of standardized data collection and analysis tools.
- **Incentives for Data Sharing:** Consider introducing incentives for industry to share data in a timely and transparent manner. This could include expedited review timelines for technologies with comprehensive data packages, or recognition for companies that demonstrate a commitment to data transparency and collaboration.

By implementing these measures, the integrated MedTech pathway can strike a balance between ensuring the availability of robust evidence for NICE evaluations and supporting the development and adoption of innovative technologies, ultimately improving patient care and outcomes.

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

To ensure that data coming from emerging innovations is robust and supports high-quality horizon scanning, all partners, including NHS England, NICE, MHRA, academia, and industry, can collaborate on the following strategies:

1. Establish Standardized Data Collection and Reporting Frameworks:

- Develop and implement standardized templates, guidelines, and data dictionaries for data collection and reporting across different types of MedTech innovations. This will ensure consistency, comparability, and ease of analysis.
- Leverage existing data standards and ontologies (e.g., SNOMED CT, LOINC) to facilitate interoperability and integration of data from different sources.
- Consider developing specific data collection requirements for different stages of the innovation lifecycle, recognizing that the level of evidence may vary for early-stage versus late-stage technologies.

2. Foster Early and Ongoing Engagement:

- Create platforms and forums for early dialogue and collaboration between industry, regulators, HTA bodies, and the NHS. This will allow for the identification of data needs, clarification of expectations, and co-development of evidence generation plans.
- Encourage regular communication and feedback between stakeholders throughout the product development and evaluation process to address any data gaps or concerns in a timely manner.

3. Invest in Data Infrastructure and Analytics:

- Establish a centralized data repository or platform to collect, store, and analyse data from emerging innovations. This will facilitate data sharing, enable comprehensive analysis, and support robust horizon scanning activities.
- Invest in advanced data analytics tools and expertise to derive meaningful insights from the collected data, identify trends, and inform decision-making.
- Explore the use of artificial intelligence and machine learning techniques to enhance horizon scanning capabilities and identify promising technologies early on.

4. Promote Data Sharing and Transparency:

- Encourage voluntary data sharing among industry partners by establishing incentives and recognizing companies that demonstrate a commitment to transparency.
- Explore the feasibility of creating a secure data-sharing platform where industry can share pre-competitive data with relevant stakeholders while protecting their intellectual property.
- Publish anonymized and aggregated data from emerging innovations to inform the broader healthcare community and promote transparency.

5. Build Capacity and Expertise:

- Provide training and education programs to industry, researchers, and healthcare professionals on best practices for data collection, analysis, and reporting.
- Support the development of expertise in data science, biostatistics, and epidemiology within the NHS and regulatory/HTA bodies to ensure robust evaluation of emerging innovations.

6. Leverage Real-World Evidence (RWE):

- Develop and implement strategies to collect and utilize RWE to complement data from clinical trials and provide a more comprehensive understanding of the effectiveness and value of MedTech in real-world settings.
- Collaborate with industry to design and conduct pragmatic clinical trials and observational studies that capture real-world data and generate robust evidence.

By working together and implementing these recommendations, all partners can ensure that data coming from emerging innovations is robust, reliable, and supports high-quality horizon scanning. This will enable the NHS to identify and adopt the most promising technologies, ultimately improving patient care and outcomes.

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

VE3 strongly agrees that the NHS Innovation Service should be enhanced to serve as a comprehensive "centralized front door" for all innovative technologies entering the NHS. We believe that this approach would significantly streamline the innovation adoption process, reduce administrative burden, and foster greater collaboration between innovators and the NHS.

Additional Functionality Recommendations:

In addition to the existing features of the NHS Innovation Service, VE3 recommends the following additional functionalities to further enhance its role as a centralized hub:

- **Integrated Application and Submission Portal:** A single, unified platform for innovators to submit their technologies for evaluation, incorporating standardized templates and data requirements for different stages of the pathway. This would simplify the submission process and ensure consistency in the information provided.
- **Enhanced Collaboration and Communication Tools:** Provide a secure and interactive platform for innovators to communicate with relevant stakeholders, including NICE, NHS England, MHRA, and clinical experts. This could involve discussion forums, virtual meetings, and Q&A sessions to address queries and facilitate knowledge exchange.
- **Real-Time Tracking and Feedback:** Enable innovators to track the progress of their submissions in real-time, receive regular updates on the evaluation process, and access feedback from assessors. This would improve transparency and provide valuable insights to innovators.
- **Knowledge Hub and Resource Centre:** Create a comprehensive repository of information on the MedTech pathway, including guidance documents, regulatory requirements, case studies, and best practices. This would serve as a valuable resource for innovators to navigate the pathway and understand the expectations and requirements at each stage.
- **Matchmaking and Networking Opportunities:** Facilitate connections between innovators and potential partners, including investors, clinical experts, and NHS organizations interested in adopting innovative technologies. This could involve organizing networking events, virtual matchmaking platforms, or showcasing innovative technologies to relevant stakeholders.
- **Post-Market Surveillance and Evaluation:** Integrate mechanisms for collecting and analysing real-world data on the performance and impact of adopted technologies. This would provide valuable feedback to inform future decision-making and continuous improvement of the pathway.

By incorporating these additional functionalities, the NHS Innovation Service can truly become a one-stop shop for innovative technologies, streamlining the adoption process, fostering collaboration, and ultimately accelerating the delivery of innovative solutions to patients across the NHS.

10. How can stakeholders inform a shared understanding of the value of MedTech to the NHS earlier in a product's development cycle?

To inform a shared understanding of the value of MedTech to the NHS earlier in a product's development cycle, stakeholders can adopt a multi-faceted approach that emphasizes collaboration, communication, and a comprehensive value assessment framework.

1. Early and Continuous Engagement:

- **Initiate Early Dialogue:** Encourage proactive engagement between MedTech developers and NHS stakeholders, including clinicians, procurement specialists, and health economists, as early as the conceptualization and design phases of the product development cycle. This early dialogue can help align expectations, identify key value drivers for the NHS, and inform product development strategies.
- **Establish Regular Forums:** Create regular forums for knowledge exchange and discussion between stakeholders, where MedTech developers can present their technologies, gather feedback, and understand the NHS's evolving needs and priorities. These forums can be in the form of workshops, webinars, or advisory board meetings.

2. Collaborative Value Assessment:

- **Develop a Comprehensive Value Framework:** Establish a standardized value framework that considers a broad range of factors beyond traditional clinical and cost-effectiveness measures. This could include patient-reported outcomes, quality of life improvements, impact on healthcare utilization, and potential cost savings through reduced hospitalizations, readmissions, or complications.
- **Co-create Value Propositions:** Collaboratively develop value propositions for MedTech innovations, involving both developers and NHS stakeholders. This ensures that the value proposition aligns with the NHS's strategic priorities and addresses the specific needs of patients and clinicians.
- **Utilize Real-World Evidence (RWE):** Generate and share RWE early in the product lifecycle to demonstrate the value of the technology in real-world clinical settings. This can be achieved through pilot studies, observational studies, or registry data collection.

3. Transparent Communication and Knowledge Sharing:

- **Publish Guidance and Case Studies:** Develop and disseminate clear guidance documents and case studies that illustrate best practices for demonstrating the value of MedTech to the NHS. These resources can help developers understand the expectations and requirements for evidence generation and value demonstration.
- **Facilitate Access to Data and Expertise:** Provide access to relevant data sources and expertise within the NHS to support MedTech developers in generating robust evidence and developing compelling value propositions. This could include access to clinical registries, patient-reported outcome measures, and health economic modelling tools.

4. Incentivize Early Value Demonstration:

- **Consider Conditional Reimbursement:** Explore the potential of conditional reimbursement models, where early access to promising technologies is granted based on preliminary evidence, with continued reimbursement contingent on the generation of further evidence demonstrating value in real-world settings.
- **Offer Early Adopter Programs:** Establish early adopter programs that provide a platform for testing and evaluating new technologies in a real-world environment, generating valuable RWE, and facilitating early market access for high-potential innovations.

By implementing these strategies, stakeholders can foster a shared understanding of value and create a collaborative environment that supports the development and adoption of MedTech that delivers meaningful benefits to patients and the NHS. This early engagement and alignment of expectations can streamline the evaluation and adoption process, ultimately accelerating access to innovative technologies and improving patient care.

11. How can all partners better signal demand to industry, academia, innovators, and investors? What information channels should NHS England, the National Institute for Health and Care Excellence and the Department of Health and Social Care use?

Effective demand signalling is crucial for guiding industry, academia, innovators, and investors towards developing and delivering MedTech solutions that align with the NHS's priorities and address unmet clinical needs. VE3 suggests a multi-pronged approach, utilizing diverse communication channels and engagement strategies to ensure clear, consistent, and targeted messaging.

1. Enhanced Communication Channels:

- **Centralized Online Platform:** Establish a dedicated online platform (e.g., an enhanced NHS Innovation Service) as a central repository for information on NHS priorities, unmet needs, and

funding opportunities. This platform should be easily accessible, user-friendly, and regularly updated with the latest information.

- **Targeted Newsletters and Publications:** Develop and disseminate regular newsletters, reports, and publications that highlight specific areas of unmet need, showcase successful case studies of MedTech adoption, and provide insights into emerging trends and technologies. These publications can be tailored to different audiences, such as industry, academia, and investors.
- **Social Media and Digital Engagement:** Utilize social media platforms (e.g., Twitter, LinkedIn) and digital engagement tools (e.g., webinars, virtual conferences) to reach a wider audience and foster dialogue with stakeholders. This allows for real-time interaction, feedback, and the sharing of information in a dynamic and engaging way.

2. Targeted Engagement Strategies:

- **Stakeholder Workshops and Conferences:** Organize regular workshops and conferences that bring together representatives from industry, academia, the NHS, and patient groups to discuss clinical priorities, technology needs, and potential solutions. These events provide a platform for networking, collaboration, and knowledge exchange.
- **Challenge-Led Initiatives:** Launch challenge-led initiatives that invite innovators to develop solutions to specific clinical or operational challenges faced by the NHS. These initiatives can stimulate innovation, foster competition, and provide a clear signal of demand for specific types of MedTech solutions.
- **Direct Engagement with Key Stakeholders:** Establish regular communication channels with industry associations, academic institutions, and investor networks to share information on specific areas of unmet need and potential investment opportunities.

3. Clear and Specific Messaging:

- **Prioritized Needs:** Clearly articulate the NHS's top priorities for MedTech innovation, highlighting areas of unmet need where new technologies could have the greatest impact on patient outcomes and healthcare delivery.
- **Evidence-Based Rationale:** Provide a clear and evidence-based rationale for the identified priorities, demonstrating the potential clinical and economic benefits of addressing these needs.
- **Actionable Information:** Offer actionable information on funding opportunities, regulatory pathways, and potential collaborators within the NHS to support the development and adoption of innovative technologies.

Specific Information Channels for NHS England, NICE, and DHSC:

- **NHS England:** The NHS England website, social media channels, the NHS Innovation Service, and relevant industry publications.
- **NICE:** The NICE website, scientific advice service, MedTech innovation briefing, and engagement with professional bodies and patient organizations.
- **DHSC:** The DHSC website, policy papers, consultations, and engagement with industry associations and trade bodies.

By adopting a comprehensive and multi-channel approach to demand signalling, NHS England, NICE, and DHSC can effectively communicate their priorities to the MedTech community, stimulate innovation, and accelerate the development and adoption of technologies that will ultimately improve patient care and outcomes.

12. 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?

In addition to the factors already outlined in the consultation document (budget impact, system impact, population impact, evidence quality, health inequalities, and environmental sustainability), VE3 proposes the following additional factors for NHS England, NICE, and DHSC to consider when selecting technologies and categories of technologies for the MedTech pathway:

1. **Workforce Implications:** Assess the potential impact of new technologies on the healthcare workforce, including the need for new skills, training, and potential displacement of existing roles. This analysis should inform workforce planning and development strategies to ensure the successful implementation and adoption of new technologies.
2. **Ethical and Social Considerations:** Evaluate the ethical and social implications of new technologies, including potential risks to privacy, data security, and patient autonomy. Engage with relevant stakeholders, such as ethicists, patient groups, and the public, to ensure that ethical considerations are adequately addressed in the decision-making process.
3. **Long-Term Sustainability and Scalability:** Consider the long-term sustainability and scalability of MedTech solutions, including their potential for wider adoption across the NHS and their ability to adapt to changing healthcare needs and technological advancements. This assessment should consider factors such as the technology's compatibility with existing infrastructure, the availability of ongoing maintenance and support, and the potential for future upgrades and enhancements.
4. **Patient Experience and Satisfaction:** Evaluate the potential impact of new technologies on the patient experience, including factors such as usability, convenience, and overall satisfaction. Gather feedback from patients and carers to understand their perspectives and ensure that new technologies are designed with their needs in mind.
5. **Global Health Impact:** Consider the potential global health impact of new technologies, particularly those that address global health challenges such as infectious diseases, antimicrobial resistance, or non-communicable diseases. Supporting the development and adoption of such technologies can contribute to the UK's global health leadership and improve health outcomes for populations worldwide.

By incorporating these additional factors into the topic selection and prioritization process, NHS England, NICE, and DHSC can ensure a more comprehensive and holistic assessment of MedTech innovations. This will enable the identification and adoption of technologies that not only offer clinical and economic benefits but also address broader workforce, ethical, social, and global health considerations.

13. How can products that receive a positive early value assessment recommendation best be supported to develop evidence?

Products that receive a positive Early Value Assessment (EVA) recommendation represent promising MedTech innovations with the potential to address unmet clinical needs. To support the development of robust evidence for these technologies and facilitate their transition to full NICE approval and widespread adoption, VE3 recommends the following comprehensive support mechanisms:

1. Streamlined Funding for Evidence Generation:

- **Dedicated Funding Streams:** Establish dedicated funding streams specifically for post-EVA evidence generation. These funds could be allocated through competitive grants or conditional reimbursement schemes, where further reimbursement is contingent on the successful completion of evidence generation studies.
- **Collaboration with Research Funders:** Explore partnerships with research funders, such as the National Institute for Health and Care Research (NIHR), to co-fund evidence generation studies.

This collaboration could leverage existing research infrastructure and expertise to accelerate evidence generation.

2. Tailored Evidence Generation Plans:

- **Co-Development of Evidence Generation Plans:** Work collaboratively with MedTech developers to co-develop robust and feasible evidence generation plans. These plans should clearly define the evidence gaps, research questions, study designs, and timelines for data collection and analysis.
- **Flexibility and Adaptability:** Allow for flexibility in evidence generation plans to accommodate different types of MedTech innovations and adapt to emerging evidence as the technology is used in real-world settings.

3. Expertise and Mentorship:

- **Dedicated Expert Panels:** Establish expert panels comprising clinicians, methodologists, statisticians, and patient representatives to provide guidance and support to MedTech developers on study design, data collection, and analysis.
- **Mentorship Programs:** Create mentorship programs that pair MedTech developers with experienced researchers and clinicians to provide guidance and support throughout the evidence generation process.

4. Access to Data and Infrastructure:

- **Facilitate Access to NHS Data:** Provide MedTech developers with streamlined access to relevant NHS data sources, such as clinical registries, electronic health records, and patient-reported outcome measures. This data can be invaluable for conducting observational studies and generating real-world evidence.
- **Support Research Infrastructure:** Invest in research infrastructure, such as clinical trial networks and data platforms, to support the efficient and effective conduct of evidence generation studies.

5. Collaboration and Knowledge Sharing:

- **Foster Collaboration:** Encourage collaboration between MedTech developers, NHS organizations, academic institutions, and patient groups to design and conduct evidence generation studies. This collaborative approach can leverage diverse expertise and resources to accelerate the generation of robust evidence.
- **Promote Knowledge Sharing:** Establish platforms and forums for sharing best practices, lessons learned, and emerging evidence on MedTech effectiveness and value. This knowledge exchange can inform future research priorities and facilitate the wider adoption of innovative technologies.

By implementing these comprehensive support mechanisms, the integrated MedTech pathway can empower companies to generate the necessary evidence to support the full approval and widespread adoption of their innovations, ultimately improving patient care and outcomes across the NHS.

14. 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?

VE3 strongly believes there is a significant opportunity to streamline existing innovation funding streams to provide a more systematic approach to supporting conditional reimbursement for early value assessment (EVA) recommended MedTech. The current landscape of fragmented and often competitive funding streams can create challenges for both innovators and the NHS, hindering the efficient and timely generation of evidence required for full market access.

Streamlining Opportunities:

1. **Consolidation and Alignment:**
    - Consolidate multiple, disparate funding streams into a unified fund specifically designed to support evidence generation for EVA-recommended MedTech.
    - Align funding criteria and processes across different streams to reduce administrative burden and ensure consistency in decision-making.
2. **Simplified Application Process:**
    - Develop a single, streamlined application process for accessing conditional reimbursement, with clear eligibility criteria and standardized data requirements.
    - Implement a user-friendly online portal for submitting applications, tracking progress, and receiving feedback.
3. **Transparent and Predictable Decision-Making:**
    - Establish clear and transparent criteria for awarding funding, with a focus on the potential clinical and economic impact of the technology, the strength of the evidence generation plan, and the commitment to data sharing and collaboration.
    - Communicate funding decisions in a timely and transparent manner, providing feedback to unsuccessful applicants and opportunities for resubmission with improved proposals.
4. **Performance-Based Reimbursement:**
    - Explore the potential of performance-based reimbursement models, where continued funding is contingent on the achievement of pre-defined clinical and economic outcomes. This approach can incentivize the generation of high-quality evidence and ensure that resources are allocated to technologies that deliver real value.
5. **Collaboration and Data Sharing:**
    - Foster collaboration between MedTech developers, NHS organizations, and research institutions to design and conduct evidence generation studies. This can be achieved through data-sharing agreements, co-funding opportunities, and joint research initiatives.
    - Encourage the sharing of data and insights from evidence generation studies to promote learning and inform future decision-making.

Benefits of Streamlining:

- **Reduced Administrative Burden:** A simplified and unified funding process would reduce the administrative burden for both innovators and the NHS, allowing them to focus on evidence generation and technology adoption.
- **Improved Efficiency:** A streamlined approach would lead to more efficient allocation of resources, ensuring that funding is directed towards the most promising technologies with the potential for the greatest impact.
- **Enhanced Transparency and Predictability:** Clear eligibility criteria and transparent decision-making processes would provide greater certainty to innovators and investors, encouraging investment in evidence generation and supporting the development of innovative technologies.
- **Accelerated Evidence Generation:** By providing dedicated funding and support for evidence generation, the pathway can accelerate the collection of robust real-world data, facilitating faster decision-making on reimbursement and market access.

Conclusion:

VE3 firmly believes that streamlining existing innovation funding streams and adopting a more systematic approach to supporting conditional reimbursement for EVA-recommended MedTech is crucial for

maximizing the benefits of innovation for patients and the NHS. We encourage NHS England, NICE, and DHSC to explore these opportunities and work collaboratively with stakeholders to create a more efficient, transparent, and predictable funding landscape that supports the development and adoption of innovative technologies.

15. Do you envisage the proposed commercial activities will help the NHS to maximise value for money from new MedTech?

VE3 agrees that the proposed commercial activities, as outlined in the consultation document, have the potential to help the NHS maximize value for money from new MedTech. The focus on early engagement, affordability assessments, and flexible payment models can contribute to a more strategic and value-driven approach to MedTech procurement and adoption.

Further Considerations for Maximizing Value:

While we support the proposed commercial activities, we believe there is room for further enhancement to ensure that the NHS extracts maximum value from new MedTech investments.

- **Outcome-Based Agreements:** Explore the broader use of outcome-based agreements (OBAs), where payment is linked to the achievement of pre-defined patient outcomes or cost savings. OBAs can incentivize innovation, ensure that technologies deliver real-world value, and align the interests of MedTech developers and the NHS.
- **Value-Based Pricing:** Consider adopting value-based pricing models that link the price of MedTech to its demonstrated value in terms of improved patient outcomes, quality of life, and cost savings. This approach can reward innovation and ensure that the NHS pays a fair price for the value it receives.
- **Total Cost of Ownership Analysis:** Conduct comprehensive total cost of ownership (TCO) analyses that consider not only the upfront purchase price but also the ongoing costs of implementation, training, maintenance, and potential system-wide impacts. This can help identify the most cost-effective solutions over the long term.
- **Data-Driven Decision Making:** Leverage real-world data and analytics to inform commercial negotiations and procurement decisions. This includes analysing patient outcomes, healthcare utilization data, and cost data to assess the value of MedTech in real-world settings.

The proposed commercial activities, coupled with the additional considerations outlined above, can help the NHS maximize value for money from new MedTech investments. By adopting a strategic, collaborative, and data-driven approach to procurement and adoption, the NHS can ensure that it invests in technologies that deliver the greatest benefits to patients and the healthcare system while promoting innovation and sustainability in the MedTech sector.

16. Please provide comments on what, if any, other commercial mechanisms/activity NHS England and the National Institute for Health and Care Excellence should consider to maximise value for money from MedTech through the pathway.

In addition to the commercial mechanisms and activities already proposed in the consultation, VE3 recommends the following additional considerations to maximize value for money from MedTech through the pathway:

1. Risk-Sharing Agreements:

- **Explore Innovative Risk-Sharing Models:** Implement risk-sharing agreements that distribute the financial risk associated with new technologies between the NHS and MedTech developers. This could involve performance-based payments, where a portion of the payment is contingent on the

achievement of pre-defined outcomes, or outcomes-based contracting, where payment is linked to long-term cost savings or improvements in patient outcomes.

- **Mitigate Financial Risk for the NHS:** Risk-sharing agreements can help mitigate the financial risk for the NHS by ensuring that payments are aligned with the actual value delivered by the technology. This approach also encourages MedTech developers to invest in generating robust evidence and demonstrating the real-world effectiveness of their innovations.

2. Subscription-Based Models:

- **Consider "MedTech as a Service" Models:** Explore the potential of subscription-based models, where the NHS pays for access to MedTech on a per-use or per-patient basis. This approach can reduce upfront costs, provide greater flexibility, and align payments with actual usage and patient demand.
- **Facilitate Technology Upgrades and Maintenance:** Subscription models can also facilitate regular technology upgrades and maintenance, ensuring that the NHS has access to the latest innovations and that equipment remains in optimal working condition.

3. Competitive Tendering and Framework Agreements:

- **Leverage Competitive Tendering:** Utilize competitive tendering processes to encourage competition among MedTech suppliers and drive down prices. This can be particularly effective for well-established technologies with multiple suppliers in the market.
- **Establish Framework Agreements:** Establish framework agreements with pre-approved suppliers for commonly used MedTech products. This can streamline procurement processes, reduce administrative burden, and ensure consistent pricing and quality across the NHS.

4. Data Analytics and Artificial Intelligence:

- **Leverage Data Analytics:** Utilize data analytics and artificial intelligence to identify opportunities for cost savings and efficiency gains in MedTech procurement and utilization. This could involve analysing purchasing patterns, identifying areas of waste or overuse, and optimizing inventory management.
- **Predictive Modelling:** Develop predictive models to forecast demand for MedTech products, enabling proactive procurement and inventory management to avoid stockouts and reduce costs.

5. Collaboration and Knowledge Sharing:

- **Establish a National MedTech Forum:** Create a national forum for collaboration and knowledge sharing between NHS procurement teams, clinicians, and industry representatives. This forum can facilitate the exchange of best practices, promote learning, and identify opportunities for joint working and innovation.
- **Share Procurement Data and Insights:** Encourage the sharing of procurement data and insights across the NHS to identify opportunities for collaborative procurement, leverage economies of scale, and negotiate better prices with suppliers.

By incorporating these additional commercial mechanisms and activities, NHS England and NICE can further enhance the value for money derived from MedTech investments. This will enable the NHS to deliver high-quality, innovative care to patients while ensuring the sustainable and efficient use of resources.

17. What further work could help to inform an understanding of the value of MedTech to support sustainable commissioning, funding, and adoption through the pathway?

VE3 believes that a deeper understanding of the value of MedTech is crucial to ensure sustainable commissioning, funding, and adoption through the pathway. To achieve this, we recommend the following areas of further work:

1. Develop a Comprehensive Value Framework:

- **Expand Beyond Cost-Effectiveness:** While cost-effectiveness is essential, the value framework should incorporate a broader range of factors, including:
    - **Patient-Reported Outcomes (PROs):** Capture patient experiences and perspectives on the impact of MedTech on their quality of life, functional status, and overall well-being.
    - **Real-World Evidence (RWE):** Evaluate the long-term effectiveness and safety of MedTech in real-world clinical practice, considering factors such as adherence, complications, and impact on healthcare utilization.
    - **System-Wide Impact:** Assess the broader impact of MedTech on the healthcare system, including its potential to improve efficiency, reduce waiting times, and enable new models of care delivery.
    - **Social Value:** Consider the wider societal benefits of MedTech, such as improved productivity, reduced caregiver burden, and enhanced community well-being.
- **Standardize Value Assessment:** Develop standardized methods and tools for assessing and quantifying the different dimensions of value, ensuring consistency and comparability across different technologies.

2. Enhance Data Collection and Analysis:

- **Strengthen Data Infrastructure:** Invest in data infrastructure and interoperability to enable the seamless collection and analysis of patient-level data, including PROs, RWE, and healthcare utilization data.
- **Leverage Advanced Analytics:** Utilize advanced analytics and machine learning techniques to analyse large datasets and generate insights into the value of MedTech across different patient populations and clinical settings.

3. Foster Collaboration and Knowledge Sharing:

- **Engage with Stakeholders:** Actively engage with patients, clinicians, researchers, and industry to gather insights and perspectives on the value of MedTech.
- **Establish Collaborative Platforms:** Create platforms for sharing data, insights, and best practices on value assessment and evidence generation across different stakeholders.

4. Promote Transparency and Communication:

- **Clearly Communicate Value:** Develop clear and transparent communication strategies to disseminate information on the value of MedTech to decision-makers, clinicians, and the public.
- **Share Case Studies and Best Practices:** Showcase successful examples of MedTech adoption and the value they have delivered to patients and the NHS.

Specific Areas of Focus:

- **Long-Term Value Assessment:** Develop methodologies to assess the long-term value of MedTech, considering the impact on patient outcomes, healthcare utilization, and societal benefits over time.
- **Value-Based Pricing:** Explore the feasibility and potential benefits of value-based pricing models, where the price of MedTech is linked to its demonstrated value in real-world settings.

- **Health Economics Modelling:** Enhance the use of health economics modelling to estimate the potential cost-effectiveness and budget impact of new technologies, considering a wider range of value dimensions.

By investing in these areas, NHS England, NICE, and DHSC can develop a more nuanced and comprehensive understanding of the value of MedTech. This will support evidence-based decision-making, facilitate the adoption of high-value technologies, and ensure the sustainable and efficient use of resources within the NHS.

Concluding Note

VE3 appreciates the opportunity to contribute to this important consultation. We are committed to collaborating with NHS England, NICE, and other stakeholders to develop a MedTech pathway that fosters innovation, improves patient outcomes, and ensures value for the NHS. Our vision aligns with the overarching goals of this consultation: to streamline the process for evaluating, funding, and commissioning medical technologies in a manner that is both efficient and beneficial to all parties involved.

VE3 is enthusiastic about the potential impact of an integrated, rules-based MedTech pathway and is eager to support its implementation. By leveraging our extensive experience in MedTech innovation, we aim to contribute valuable insights and practical solutions that can drive the successful adoption of groundbreaking technologies. We believe that through collective effort and continuous dialogue, we can achieve a pathway that not only meets current healthcare needs but also anticipates and addresses future challenges.

As we move forward, VE3 looks forward to participating in further discussions and contributing to the iterative process of refining and implementing these proposals. Our commitment to innovation, quality, and collaboration remains steadfast, and we are dedicated to playing a proactive role in shaping a healthcare system that is responsive, resilient, and ready to embrace the future of medical technology. Thank you for considering our feedback.