

Response ID ANON-3TC9-KGN5-R

Submitted to Building an integrated, rules-based medtech pathway

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About you

1 In what capacity are you responding?

Other

If you have selected 'other', please specify:

Representative body

2 Are you responding on behalf of an organisation?

Yes

If you have selected 'yes', which organisation are you responding on behalf of?:

The Royal College of Ophthalmologists

Section 2: guiding principles

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

Please provide comments:

The Royal College of Ophthalmologists (RCOphth) believes that a key and essential principle of the medtech pathway needs to be interoperability – both with electronic patient records, and patient-generated data sources such as via apps. This will help ensure ophthalmic imaging devices deliver their transformational potential in the NHS.

Another important principle is that we have a simple proportionate process for those seeking approval for medtech devices and innovators looking to scale up, especially for lower-risk software as a medical device (SaMD) and patient-facing apps.

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?

Please provide comments:

It is vital that sampling biases are addressed as part of developing the medtech pathway. For example, pulse oximeters, designed to identify falls in oxygen levels of COVID patients, did not work as well for those with darker skin (see <https://www.bbc.co.uk/news/health-58032842>).

Steps also need to be taken to address the digital divide, which could mean people without digital devices or internet access miss out on the benefits of medtech. The solution is that validation should include testing among a variety of demographic and ethnic groups, with any subsequent mitigations ensuring there is an improvement to equality of access. To some extent this is covered by the digital technology assessment criteria (DTAC).

Section 3 - part 1: key elements of the pathway

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?

Not Answered

Please provide any additional comments:

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

Please provide comments:

RCOphth agrees with the proposed pathway sequence as outlined in Figure 1. We particularly wish to emphasise the importance of proactively monitoring and tracking uptake. RCOphth, through its National Ophthalmology Database (<https://nodaudit.org.uk/>), is currently mapping uptake of technologies relevant to interventions for cataract or age-related macular degeneration.

Early and regular dialogue between innovator and assessor is also important. This will ensure that innovators are aware of the level of evidence required, and can build their in their funding plans.

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

Not Answered

Please provide any additional comments:

It is important that there is a single well-signposted point of entry for innovators, which includes details of local support.

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

Please provide comments:

The pathway should facilitate innovations being pitched to NHS England at an early stage. This will enable feedback, reveal potential barriers and encourage innovation in the NHS.

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?

Please provide comments :

Granular data on demand and prevalence for individual conditions may help all stakeholders to better understand where medtech innovations are most needed.

RCOphth has collated such data, grouped at the sub-specialty level, which we would be happy to share.

Section 3 - part 2 : Key elements of the pathway

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?

Please provide comments:

Consideration should also be given to artificial intelligence (AI) as part of the medtech pathway. RCOphth's recent position statement on artificial intelligence in ophthalmology (<https://www.rcophth.ac.uk/wp-content/uploads/2024/05/240521-Position-statement-artificial-intelligence.pdf>) outlines the role AI can play in strengthening patient care, streamlining processes and advancing research. We believe AI tools should be adopted via an iterative process, with ophthalmology services conducting regular audits, quality assurance and inclusive patient engagement to ensure safe, equitable and effective implementation.

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

Please provide comments:

NHS Trusts could pilot technology and concurrently undertake quality improvement and health economic analysis. These trusts could have an innovation lead who can undertake the DCB 0160 assessments and support the technology through phases such as information governance, that can be barriers to implementation.

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?

Please provide comments:

Section 3 - part 3: key elements of the pathway

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

Not Answered

Please provide any additional comments:

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.

Please provide comments:

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?

Please provide comments: