Ref. No:	2692
Date:	09/07/26
Subject:	Adoption and business case process for new and innovative medical technologies

REQUEST

This request concerns the Trust's governance and business case process for adopting new and innovative clinical technologies. To be precise about what I mean:

In scope: technologies that are novel to the Trust; implantable devices; high-cost or specialised devices; novel diagnostics; digital health or Software as a Medical Device; and, in particular, technologies that are subject to, or recommended by, NICE guidance (for example Medical Technologies Guidance, Diagnostics Guidance, Interventional Procedures Guidance, Technology Appraisals, or an Early Value Assessment). Also in scope is significant clinical capital equipment introduced through a business case, such as robotic surgical systems, theatre tables, imaging systems, and higher-value ward equipment where it forms part of a service change or investment case.

Not the primary focus: the routine replacement, medical equipment library, clinical engineering, or general estates and facilities procurement of established, commodity equipment on a like-for-like basis (for example standard beds or blood pressure monitors purchased as replacements). Please provide that process only if the same committee, template, or route also governs the introduction of the novel and innovative technologies described above, in which case please say so explicitly.

Where responsibility for the above is split across more than one committee or group (for example a medical devices or new products committee, a new interventional procedures committee, a capital investment group, and a digital or NICE-implementation route), please provide the information for each relevant committee and identify which one owns which category.

Request for recorded information

1. A copy of the current business case or application template(s) used to seek approval for the introduction of a new or innovative clinical technology as defined above, including implantable, high-cost, and specialised devices.

2. A copy of the capital business case template(s) used for significant clinical capital equipment (for example the Strategic Outline Case, Outline Business Case, and Full Business Case, or equivalent staged templates), where these are distinct from the template at (1).

3. The name of the committee(s) or group(s) responsible for approving each of the following, and confirmation of which committee owns each: (a) new and innovative medical devices, including implantables and high-cost or specialised devices; (b) novel interventional procedures or techniques; (c) significant clinical capital equipment such as robotic systems and theatre tables; and (d) digital health or Software as a Medical Device.

4. The Terms of Reference for each relevant committee.

5. The membership of each relevant committee by role or job title, and the name or job title of the chair or responsible officer.

6. The meeting frequency of each relevant committee, the scheduled meeting dates for the current and forthcoming year, and the deadline for submission of papers ahead of each meeting.

7. Any additional standard submission forms associated with the process (for example a new product or device request form, clinical evaluation form, risk assessment template).

8. Any evaluation or scoring criteria used to assess submissions, and any financial thresholds or delegated authority limits that determine escalation to executive or Board approval, including the point at which a case moves between the revenue and capital routes.

9. The policy or standard operating procedure governing the introduction of new medical devices and innovative technologies.

Where any of the above is already published, a link or reference is acceptable in place of a copy. My preferred format for the response is electronic (email or accessible document).

RESPONSE

Nil