



*National Institute for
Health and Clinical Excellence*

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Medical Technologies Evaluation Programme

Process guide

National Institute for Health and Clinical Excellence

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Contents

List of abbreviations	5
1 Introduction.....	5
2 What is the Medical Technologies Evaluation Programme?.....	8
2.1 Aims	8
2.2 Key activities	8
2.3 Key audiences	8
3 Who is involved in the Medical Technologies Evaluation Programme?	9
3.1 The Medical Technologies Evaluation Programme team	9
3.2 Editors.....	10
3.3 Implementation	10
3.4 Information services	10
3.5 The Patient and Public Involvement Programme	11
3.6 The Medical Technologies Advisory Committee	11
3.7 Expert advisers	12
3.8 Patient and carer input.....	14
3.9 External Assessment Centres	15
3.10 Technology sponsors	15
3.11 Registering an interest	15
3.12 Members of the public.....	16
4 How are technologies identified, selected and routed for evaluation?	17
4.1 How NICE becomes aware of new medical technologies	17
4.2 Selecting topics.....	18
4.3 Routing topics	19
4.4 Information published about eligible and selected technologies	20
4.5 Timeline	20
5 How is medical technologies guidance developed?	24
5.1 Equality considerations	24
5.2 Agreement of evaluation schedule	24
5.3 The scope	25
5.4 The sponsor's submission.....	26
5.5 Assessment report	27
5.6 Contributions from expert advisers.....	28
5.7 Contributions from patient and carer organisations.....	28
5.8 Meeting to develop draft recommendations	29
5.9 The medical technology consultation document	30
5.10 Consultation	31
5.11 Final guidance.....	33
5.12 Suspending or cancelling an evaluation.....	34
6 Resolution.....	34
6.1 Resolution grounds	35
6.2 Eligibility to make a resolution request.....	35
6.3 Resolution requests	35
6.4 Initial scrutiny of resolution requests	36
6.5 The resolution panel.....	37
7 Publishing medical technologies guidance	38
7.1 Timeline	39

8	Reviews	42
9	Updating the process guide	42
10	More information.....	43
	Appendix A: Glossary	44
	Appendix B: Eligibility criteria	47
	Appendix C: Selection criteria and scoring used by the Programme team in developing the briefing notes	48
	Appendix D: Criteria for suspending or cancelling an evaluation	50



NHS Evidence has accredited the process used by the Medical Technologies Evaluation Programme to produce guidelines. Accreditation is valid for five years from November 2011 and is applicable to guidance produced using the processes described in the Medical Technologies Evaluation Programme Process and Methods guides. More information on accreditation can be viewed at www.evidence.nhs.uk.

List of abbreviations

MTAC	Medical Technologies Advisory Committee
NICE	National Institute for Health and Clinical Excellence
PPIP	Patient and Public Involvement Programme

1 Introduction

The National Institute for Health and Clinical Excellence (NICE) provides guidance, sets quality standards and manages a national database to improve people's health and prevent and treat ill health. Further details about NICE and its work programmes are available in 'NICE: our guidance sets the standard for good healthcare' (available from www.nice.org.uk/aboutnice/whatwedo).

Technical terms in this document are given in **bold text** on their first mention and are defined in the glossary (appendix A).

NICE selects and evaluates **medical technologies** to determine whether the **case for adoption** in the NHS is supported by the evidence. For the purposes of the Medical Technologies Evaluation Programme a medical technology is defined as outlined in table 1.

Table 1 Definitions of medical technologies for the Programme

Term	Definition	Source
A medical device	<p>‘any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:</p> <ul style="list-style-type: none"> • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury or [disability], • investigation, replacement or modification of the anatomy or of a physiological process, • control of conception, • and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means’ 	European Parliament and the Council of the European Union (2007) Council Directive 2007/47/EC of 5 September 2007 amending Council Directive 93/42/EEC concerning medical devices
An active medical device	‘any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity’	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
An active implantable medical device	‘any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure’	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

Term	Definition	Source
An in vitro diagnostic medical device	<p data-bbox="547 282 1098 618">'any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:</p> <ul data-bbox="563 629 1098 929" style="list-style-type: none"> <li data-bbox="563 629 991 696">• concerning a physiological or pathological state, or <li data-bbox="563 707 1098 775">• concerning a congenital abnormality, or <li data-bbox="563 786 1098 887">• to determine the safety and compatibility with potential recipients, or <li data-bbox="563 898 1038 929">• to monitor therapeutic measures. 	European Parliament and the Council of the European Union (1998) Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

A [diagnostic technology](#) is a medical technology with a diagnostic purpose. Diagnostic technologies are a subset of medical technologies.

Genetic tests are covered by the Programme provided they have a medical purpose and fall within the scope of Council Directive 98/79/EC.

The Medical Technologies Evaluation Programme identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.

This process guide describes how NICE selects medical technologies for national evaluation. It also describes how the Medical Technologies Advisory Committee (MTAC or 'the Committee') develops guidance on selected technologies routed to it for evaluation. The procedure is designed so that guidance is developed for the NHS in an open, credible, transparent and timely way, allowing appropriate input from relevant stakeholders. This process guide should be read in conjunction with the 'Medical Technologies Evaluation Programme methods guide', available on NICE's website (www.nice.org.uk/mt).

Nothing in this document will restrict any disclosure of information by NICE that is required by law (including, in particular but without limitation, the Freedom of Information Act 2000).

2 What is the Medical Technologies Evaluation Programme?

2.1 Aims

The aims of the Programme are:

- to promote faster uptake of new medical technologies in the NHS
- to encourage collaborative research, in both industry and the NHS, to generate evidence on the [clinical utility](#) and/or healthcare system benefits of selected technologies.

2.2 Key activities

The key activities of the Programme are:

- identifying and selecting appropriate medical technologies that would benefit from national evaluation
- [routing](#) these medical technologies to a NICE guidance programme for evaluation
- evaluating medical technologies routed to the Committee, which involves:
 - developing and publishing guidance for use by the NHS in England and its social care partners, including recommendations for further research
 - developing and publishing implementation tools
 - reviewing and updating guidance when required.

2.3 Key audiences

The Medical Technologies Evaluation Programme has several audiences that are expected to take note of NICE's [medical technologies guidance](#):

- Practitioners, including clinicians, who use medical technologies in clinical or research settings.

- NHS commissioners – for example, when specifying services incorporating use of medical technologies.
- Healthcare operational and planning managers in primary and secondary care provider organisations, particularly when planning services or facilities in which medical technologies are used.
- Purchasing and procurement organisations, when planning procurement of these products.

Patients and carers of people who may be affected by the technology are an important audience for the guidance because it can help them, in consultation with their clinicians, make informed decisions about their treatment.

3 Who is involved in the Medical Technologies Evaluation Programme?

3.1 *The Medical Technologies Evaluation Programme team*

The Medical Technologies Evaluation Programme is part of NICE's Centre for Health Technology Evaluation. The Programme team consists of the associate director, technical, project management and administrative staff who support the Committee in developing medical technologies guidance. The main tasks of members of the team are to:

- assess notified technologies against the eligibility criteria
- prepare [briefing notes](#) used by the Committee during selection and routing
- carry out the following for technologies that are routed to the Committee for evaluation:
 - prepare scopes
 - commission External Assessment Centres to assess evidence
 - prepare [overviews](#) of the [assessment reports](#), and additional analyses and evidence where required
 - arrange public consultation on the Committee's draft recommendations
 - prepare guidance for publication
 - ensure agreed timelines and quality standards are followed.

3.2 Editors

The editors review the documents that are produced during guidance development, including assessment report summaries and draft and final guidance. NICE editors also provide a lay explanation of the recommendations when needed.

3.3 Implementation

NICE provides advice and tools to support the local implementation of its guidance. In general NICE's implementation team:

- ensures intelligent dissemination to the appropriate target audiences
- actively engages with the NHS, local government and the wider community
- works nationally to encourage a supportive environment
- provides tools to support putting NICE guidance into practice
- demonstrates significant cost impacts – either costs or savings at local and national levels
- evaluates uptake of NICE guidance
- shares learning
- develops educational material to raise awareness of NICE guidance and encourages people to input into its development.

There is an implementation support plan for each piece of guidance. The implementation team produces implementation support tools, such as costing tools and audit tools. These tools are developed with advice from [expert advisers](#), [patient and carer organisations](#), the sponsor and Committee members, as appropriate.

3.4 Information services

The information services team searches for information and evidence from conventional sources and 'grey' literature. This information is used by the Programme team to prepare information for the Committee, including the briefing notes for selection and routing.

3.5 *The Patient and Public Involvement Programme*

The Patient and Public Involvement Programme (PPIP) recruits and supports lay members of the Committee, identifies patient and carer organisations (see section 3.8), encourages members of the public and patient organisations to respond to consultation, and establishes links with patient organisations with an interest in medical technologies guidance. NICE uses the terms 'patient organisation' and 'patient group' when referring to patients, carers, and community and other lay organisations and charities, including those representing people from groups protected by equalities legislation.

3.6 *The Medical Technologies Advisory Committee*

The Medical Technologies Advisory Committee is an independent standing committee consisting of about 25 members with a range of expertise. The Committee includes clinicians who develop and use medical technologies, scientists, people who can provide a lay perspective on the issues affecting patients and the NHS, experts in regulation and the evaluation of healthcare, and people with experience of the medical technologies industry.

The Committee normally meets monthly (excluding August) in public. Agendas and minutes of Committee meetings are published on the NICE website (www.nice.org.uk/mt). The minutes record only what was discussed by whom and in what order. They do not record the Committee's draft recommendations. Committee members are required to submit a declaration of interests every year, and to declare any conflicts of interest at each Committee meeting, in line with NICE's code of practice for declaring and dealing with conflicts of interest (www.nice.org.uk/declaring_and_dealing_with_conflicts_of_interest).

3.6.1 The roles of the Committee

- To identify medical technologies suitable for evaluation and route them to the appropriate NICE programme for evaluation.
- To develop NICE medical technologies guidance for suitable technologies, including, if appropriate, recommendations that further research is needed.

The 'Medical Technologies Evaluation Programme methods guide' has more information about how the Committee makes its decisions, and the types of recommendation it makes.

3.6.2 How Committee members are appointed

Committee members are recruited through an open advertisement (normally posted on the NICE website). They are appointed for a period of up to 3 years by a panel consisting of an executive or centre director, a non-executive director and the chair of the Committee. The time period may be extended for a further term by mutual agreement, and in exceptional circumstances up to a maximum of 10 years. A list of current members is published on the NICE website (www.nice.org.uk/mt).

NICE is committed to having due regard to the need to eliminate unlawful discrimination and promote equality, and fostering good relations between people with a characteristic protected by the equalities legislation and others. NICE welcomes applications for membership of the Committee from all sectors of the community.

3.7 Expert advisers

Expert advisers are usually healthcare professionals or technical specialists who use or potentially would use the medical technology being evaluated in a clinical or research setting.

3.7.1 The role of expert advisers

NICE seeks advice from expert advisers on each technology before the Committee considers it. Expert advisers provide advice about medical technologies which complements clinical evidence and findings from research. New medical technologies often have potential benefits and risks that are not yet fully described in the scientific literature. Expert advisers provide insight into these issues, supported by accounts of their clinical or technical experience, which complement the published evidence, particularly when this is limited. Expert advisers may not be familiar with the technology in question, in which

case they provide advice and opinion based on their clinical or technical experience, and insights into the potential usefulness of the technology.

Expert advisers may be asked to give advice on:

- the validity of the [notification](#) and whether the technology is relevant to the NHS
- the scope
- the assessment report
- implementation support tools, such as costing tools and audit tools (see section 7)
- any potential equality issues in relation to the technology.

Expert advisers are asked to declare conflicts of interest in line with NICE's code of practice on declaring and dealing with conflicts of interest ([www.nice.org.uk/declaring and dealing with conflicts of interest](http://www.nice.org.uk/declaring_and_dealing_with_conflicts_of_interest)). These are presented to the chair and the Committee when their topic selection questionnaires are considered and at meetings when expert advisers advise the Committee.

NICE appoints expert advisers for a 3-year term and gives them the option to renew their term. Clinicians are not eligible to advise the Programme once they retire from clinical practice.

3.7.2 Identifying expert advisers

Expert advisers are identified as follows:

- NICE asks professional bodies (including Royal Colleges, specialist societies and other professional associations) to nominate expert advisers.
- NICE identifies expert advisers on a topic basis from NICE's existing pool of expert advisers, all of whom have been ratified by their professional body.
- Current expert advisers may recommend others with relevant knowledge; expert advisers identified in this way are ratified by their professional body.
- The [manufacturer](#) or [sponsor](#) (referred to as the sponsor in this document) suggests clinicians with experience of using the technology, or technology

developers with relevant knowledge; expert advisers identified in this way are ratified by their professional body.

- The chair, vice chair or Committee members recommend people with relevant knowledge; expert advisers identified in this way are ratified by their professional body.

NICE welcomes expert advisers from all sectors of the community.

3.7.3 Selecting expert advisers

Topic selection

At the selection phase expert advisers complete a standard questionnaire about the topic (a sample is available on NICE's website, www.nice.org.uk/mt). On request, NICE sends copies of the completed questionnaires to the professional body that nominated or ratified each expert adviser. Completed questionnaires are also available from NICE on written request, in accordance with the provisions of the Freedom of Information Act 2000.

The Committee chair and the Programme team review the completed questionnaires and select suitable expert advisers to advise the Committee, in person or by telephone, when the Committee meets to select topics.

Evaluation

At the start of the evaluation phase, the Programme team assesses whether the expert advisers identified at the topic selection stage continue to have relevant experience and expertise. All those who do are invited to comment on the scope and to provide written comments to the Committee during the evaluation phase. If alternative expert advisers are needed to ensure an appropriate balance between knowledge of the technology and knowledge of the care pathway, they are selected in the same way as for the topic selection phase.

3.8 Patient and carer input

NICE asks patient and carer organisations to provide information about living with the condition to which the technology relates, about any patients who may need

special consideration, and about using the technology and/or [comparator](#) technologies. Patient and carer organisations can provide insight into outcomes, and describe ease of use, discomfort, impact on diverse activities and other aspects of quality of life.

3.9 External Assessment Centres

NICE commissions External Assessment Centres from a range of organisations, including the NHS and academic bodies. These centres are chosen by public tender and must meet quality control requirements. The centres provide independent assessments of the evidence and produce assessment reports for the Committee (see section 5.5). The centres have knowledge of and expertise in appropriate methods of evaluation. The External Assessment Centres are listed on NICE's website (www.nice.org.uk/mt).

3.10 Technology sponsors

Normally, sponsors of medical technologies notify technologies to NICE for evaluation. They should provide sufficient information for the Committee to decide whether or not to select the product for evaluation. The sponsor also provides information for the briefing note.

The sponsor provides a clinical and economic evidence submission, based on the scope, which includes relevant cost modelling. This may be based on published or unpublished data, including confidential data prepared for regulatory purposes (see section 5.4 for more information on the submission).

The sponsor has the opportunity to comment on the draft scope (see section 5.3) and on the Committee's draft recommendations during consultation (see section 5.10), and to request clarification during resolution (see section 6).

3.11 Registering an interest

NICE encourages interested parties (people and organisations) to register an interest in a technology through the NICE website. Registration is allowed at any time during the course of an evaluation. NICE sends electronic updates to people and organisations who have registered an interest throughout the evaluation.

These updates are triggered by changes to the website page for the technology (for example, when consultation begins).

The Programme team notifies relevant professional bodies and the PPIP notifies relevant patient and carer organisations when a technology that may be of interest to them is first mentioned on the website. People and organisations who have registered an interest are invited to comment on the draft scope.

3.12 *Members of the public*

To promote public attendance at Committee meetings NICE publishes a notice and draft agenda on its website announcing each meeting at least 20 working days before the meeting. At this point, members of the public who wish to attend the meeting can register on NICE's website. Up to 20 places are available, depending on the size of the venue. In the event that attendance at any meeting is oversubscribed, NICE selects attendees according to its allocation procedure (for further information, see www.nice.org.uk/media/FC7/9D/PublicMeetingsInformation.pdf). To allow wide public access, NICE reserves the right to limit attendees to one representative per organisation. The closing date for receipt of completed application forms is 10 working days before the meeting. NICE publishes the final agenda on its website 5 working days before the meeting. Once registration has closed, NICE contacts successful applicants to invite them to the meeting. Along with the invitation, applicants receive a code of conduct for public attendees and frequently asked questions. If a meeting is cancelled, NICE gives attendees as much notice as possible.

Public access to meetings is granted in accordance with NICE policies and subject to the standing orders of the Committee.

4 How are technologies identified, selected and routed for evaluation?

4.1 *How NICE becomes aware of new medical technologies*

4.1.1 Notifications from sponsors

Notifications are made through the NICE website (www.nice.org.uk/mt) and are received primarily from product sponsors.

The Programme team first considers notified medical technologies using the following eligibility criteria (see appendix B for details):

- They have a [CE mark](#) or equivalent regulatory approval, or this is expected within 1 year.
- The topic is within the remit of a NICE evaluation programme, and is not currently being evaluated.
- The technology is either new or an innovative modification of an existing technology, with claimed benefits for patients or healthcare systems.

NICE asks sponsors of medical technologies that meet the eligibility criteria to provide additional information to be used in the briefing note, as outlined in section 4.2.

NICE informs sponsors if medical technologies do not meet the eligibility criteria for the Programme. Sponsors may re-notify NICE about medical technologies even if they have previously been assessed as ineligible. However, sponsors are encouraged to discuss this with NICE in advance because technologies need to have changed in such a way that they meet the eligibility criteria.

4.1.2 Other sources of information on new medical technologies

Horizon scanning is a process by which technologies are identified before they are commercially available. The National Horizon Scanning Centre, based at the University of Birmingham, undertakes this process on behalf of NICE. Once the

centre identifies a medical technology as being at a suitable point in development, it may suggest that the sponsor notify the technology to NICE.

People and organisations other than manufacturers can make notifications. If the technology is selected for the Programme, the manufacturer will need to provide NICE with information about their product, and make a formal submission.

Therefore, people considering making a notification are encouraged to discuss their intention with the manufacturer of the product before they do so as a manufacturer may not wish to undergo an evaluation at that time.

4.2 *Selecting topics*

Selection is the process by which NICE identifies and decides which medical technologies should be evaluated. Because the number of technologies that can be evaluated at one time is limited, the Committee selects technologies that are likely to have the most benefit to patients and the NHS.

Sponsors of eligible technologies are asked to provide information on the technology, including its uses, costs, sources of evidence and benefits to patients and the NHS. The benefits include:

- benefit to patients: the medical technology claims measurable benefit to patients over currently available NHS technologies
- benefit to the NHS: the impact of the medical technology is likely to reduce the burden on NHS staff or reduce resource use, for example, staff or facilities.

The Programme team prepares briefing notes for the Committee on eligible technologies. Briefing notes include:

- information provided by the sponsor (in particular the claimed benefits)
- input from the expert advisers and the names of professional societies that were approached for expert advice
- input from the relevant patient and carer organisations whose views on the technology, and its potential benefits, are sought by the PPIP team; these views are sought in all cases, and presented to the Committee when they are received

- information relating to potential equality considerations (see section 5.1)
- a score for the technology developed by the Programme team according to the selection criteria in appendix C; this score is used by the Committee to inform their selection decision; it is not used as a threshold for selection.

The contents of briefing notes are checked by the sponsor for accuracy.

Using the briefing notes, the Committee selects from the eligible technologies those suitable for evaluation. The Committee normally makes selection decisions at each of its monthly meetings, during a session that is not open to members of the public or press. Expert advisers (see section 3.7) may be invited to attend these meetings to advise the Committee, but do not participate in the part of the meeting where the Committee makes its selection decision.

4.3 *Routing topics*

Once it has selected a topic, the Committee routes the topic to the most appropriate NICE guidance programme (or other national evaluation programme) using the criteria presented in appendix C of the 'Medical Technologies Evaluation Programme methods guide'. These criteria are based on the published remits for the programmes.

4.3.1 Routing to the Medical Technologies Advisory Committee

In summary, the criteria for routing a technology to the Medical Technologies Advisory Committee are:

- the technology is likely to be cost saving or cost neutral
- the technology can be evaluated as a single technology
- the technology can be evaluated on a short timescale.

4.3.2 Routing to any other NICE guidance programme

A technology routed to any other NICE guidance programme is evaluated according to the processes, methods and timelines of that programme.

4.4 Information published about eligible and selected technologies

The following information is published on the NICE website (www.nice.org.uk/mt):

- The topics that MTAC selects for evaluation by itself: information about each technology, and links to the evaluation documents.
- The topics MTAC selects for consideration of evaluation by another NICE guidance programme; information about guidance development for these technologies appears on the web page for the relevant programme.
- The eligible topics that MTAC does not select: NICE provides detailed confidential feedback to sponsors of technologies that are not selected and publishes one of a series of standard terms on its website giving the reason for non-selection. If the sponsor disagrees with the term used, no information is published about the reason for non-selection.

No information is published about topics notified to the Programme that do not meet the eligibility criteria.

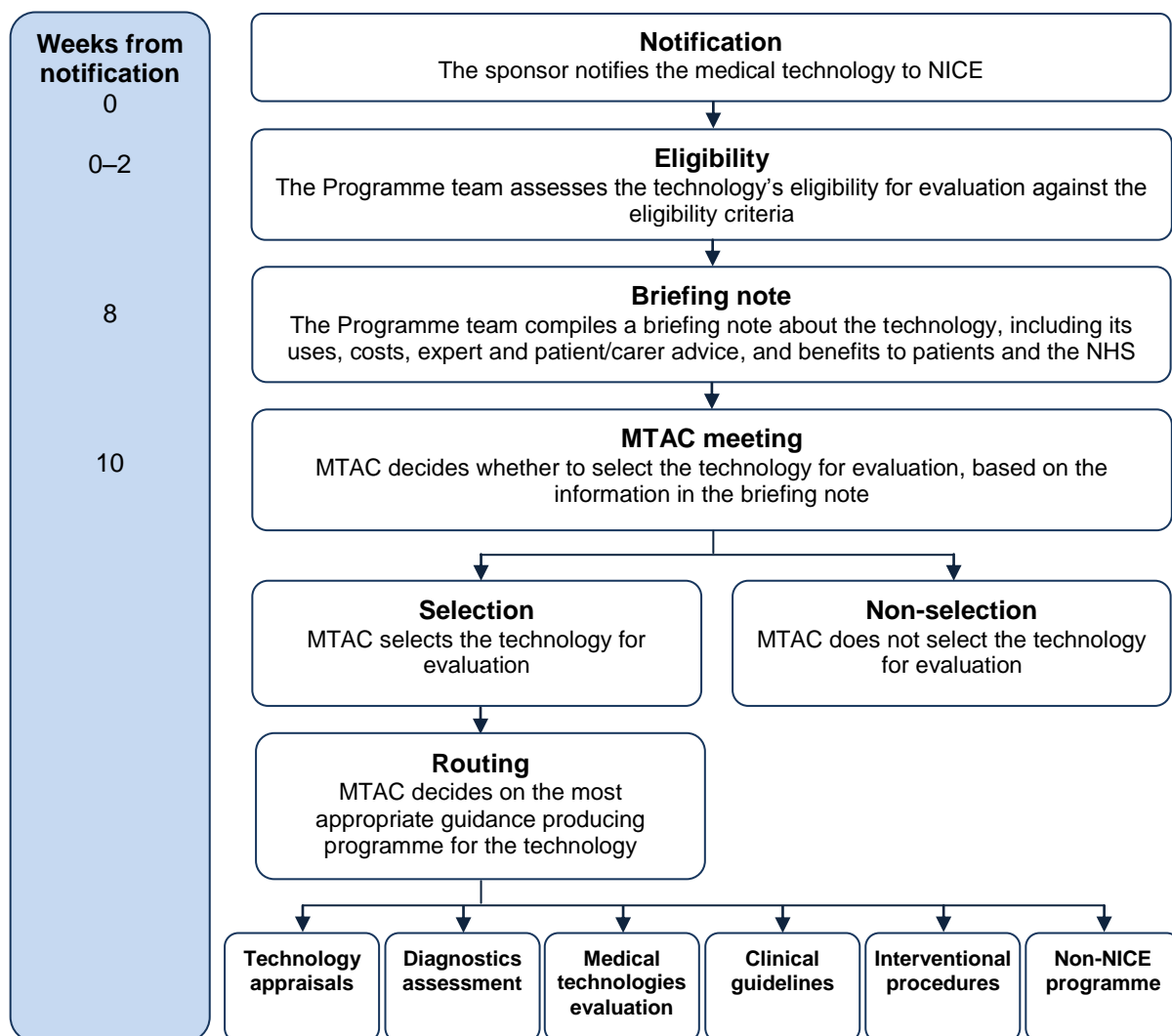
4.5 Timeline

NICE needs to collect sufficient information on individual technologies to select and route them correctly. Table 2 is an indicative guide of the time taken for selection and routing.

Table 2 Approximate timeline for selection and routing

Weeks (average) from notification	Event
0	The sponsor notifies the medical technology to NICE
0–2	<p>The Programme team considers the technology against the eligibility criteria (see appendix B)</p> <p>If the technology is eligible, NICE starts to prepare a briefing note, which includes:</p> <ul style="list-style-type: none"> • carrying out a literature search • requesting advice from expert advisers and patient and carer organisations
8	NICE completes the briefing note
10	<p>MTAC reviews the briefing note and either selects the technology and routes it to the appropriate programme for evaluation</p> <p>or does not select the technology for evaluation</p>

Figure 1 Summary of selection and routing process



The rest of this guide describes the process of developing guidance on medical technologies that are routed to the Medical Technologies Advisory Committee. A technology routed to any other NICE guidance programme is evaluated according to the processes, methods and timelines of that programme – see the NICE website for more details (www.nice.org.uk).

5 How is medical technologies guidance developed?

For information on the technical assessment of medical technologies, please refer to the 'Medical Technologies Evaluation Programme methods guide'.

5.1 *Equality considerations*

The Medical Technologies Evaluation Programme was developed in accordance with the NICE equality scheme (available from www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp). How medical technologies guidance may potentially impact on equality is considered by the Committee at specific stages of guidance development, including topic selection, scoping, and when the Committee produces draft and final recommendations. Any potential equality issues raised and considered for a topic are recorded in an equality impact assessment, which is completed in accordance with the Medical Technologies Evaluation Programme equality impact assessment procedure. The equality impact assessment is approved by the programme or centre director and published with the scope and the final guidance. Any relevant equality issues that relate directly to the guidance topic and recommendations are also accounted for in the final guidance itself.

5.2 *Agreement of evaluation schedule*

Once a topic is selected for MTAC evaluation, NICE schedules the evaluation. If the sponsor does not consider the timing to be appropriate, NICE is not able to guarantee when the evaluation will start.

5.3 *The scope*

Once the start date for the evaluation has been agreed, the Programme team prepares a draft scope. The scope is intended to define the most important questions about clinical and resource impacts. It sets the boundaries for assessing the evidence and for the Committee's decision-making. The scope includes:

- a description of the technology and its claimed benefits
- information about the disease, condition or clinical problem relevant to the technology
- the regulatory status of the technology
- the Committee's rationale for developing medical technologies guidance, which can include any relevant equality considerations
- the [decision problem](#) to be addressed by the evaluation of the technology
- a list of the professional and patient organisations involved in providing comments on the technology
- a list of the societies or organisations to be invited to comment on the scope.

The scope may also include technical questions raised by the Committee or the Programme team at selection stage, which may relate to the technology's ease of use or ability to generate the claimed patient or healthcare system benefits. The technical questions do not extend to a full technical evaluation of the device.

The draft scope is then available for comment by the sponsor, the expert adviser(s), relevant patient and carer organisations, professional societies and others who register an interest. An interest can be registered at any time after the selection decision is published (section 4.4). NICE alerts a range of stakeholders that the draft scope is available for comment. They have 5 working days to comment. The Committee vice chair reviews the comments and agrees changes to the scope as appropriate. The Committee vice chair and the programme director then agree the final scope and it is published on the NICE website. The medical technology formally becomes part of the Committee's work programme

and the website records that guidance development for this technology is in progress.

5.4 *The sponsor's submission*

The sponsor makes a submission to NICE using NICE's template and guidance notes to help them complete the template (both available on NICE's website (www.nice.org.uk/mt)). The contents are based on the scope, which guides the selection of relevant clinical and economic evidence and analysis.

The submission is made in two parts:

- Clinical evidence submission: no more than 2 weeks after the scope is released, the sponsor submits all relevant clinical evidence to NICE. This submission includes the decision problem.
- Economic evidence submission with cost model: no more than 6 weeks after the scope is agreed, the sponsor submits all relevant economic evidence with its model of relevant costs.

If the sponsor has developed an economic model, they must submit a fully executable electronic copy of the model to NICE with full access to the programming code. The submitted versions of the model and the written content of the evidence submission must match. NICE accepts executable economic models using standard software – that is, Excel, TreeAge Pro, R or WinBUGs. If the sponsor plans to submit a model in a non-standard package, they should inform NICE in advance. NICE, in association with the External Assessment Centre, will investigate whether the requested software is acceptable, and establish if NICE and the External Assessment Centre need temporary licences for the non-standard software for the duration of the assessment. NICE reserves the right to reject economic models in non-standard software.

NICE requires sponsors of medical technologies to sign a statement declaring that all material and knowledge relevant to the evaluation of their product has been disclosed to NICE. This includes unpublished data such as register data compiled for regulators or post-marketing surveillance. Where the manufacturer

is not the data owner (for example, of register data), it should provide NICE with information to identify all relevant data owners.

To ensure that the process is as transparent as possible, NICE considers it essential that evidence on which the Committee's decisions are based is publicly available. Unpublished evidence is accepted under agreement of confidentiality and is not made available to the public. Such evidence includes 'commercial-in-confidence' information (for example, the findings of a research project defined as 'confidential' because its public disclosure could have an impact on the commercial interests of a particular company) and certain data that are awaiting publication ('academic-in-confidence').

If the owner of any unpublished data included in the submission believes the data should be treated as 'commercial-in-confidence' or 'academic-in-confidence' they should clearly state the rationale, taking into account the following principles:

- Information and data that have been made publicly available anywhere in the world are not considered confidential.
- When trial results are to be published in a journal at a date later than the first public release by NICE of documentation quoting data from these trials, a structured abstract relating to the future journal publication should, as a minimum, be made available for disclosure.

NICE asks data owners to reconsider restrictions on release of data either when the reason for the restrictions is not clearly explained, or when such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance.

5.5 *Assessment report*

The External Assessment Centre (see section 3.9) reviews the sponsor's submission and prepares an assessment report to the technical standard required by NICE. An assessment report template is available on NICE's website (www.nice.org.uk/mt).

The assessment report reviews and critically evaluates the sponsor's clinical and economic evidence and cost model. Exceptionally, if the External Assessment Centre considers that the sponsor's submission does not adequately address the issues in the scope, the centre may suggest to NICE that additional analysis should be undertaken, which could include a new cost model. In these circumstances the additional analysis is usually carried out by the External Assessment Centre, as directed by NICE, and forms part of the assessment report. If changes are made to the submitted cost model, the External Assessment Centre includes technical details of these amendments, and their impact, in the assessment report.

The External Assessment Centre approaches NICE's expert advisers for the technology under consideration if they need advice when preparing the assessment report. These expert advisers are listed in the report.

The External Assessment Centre may ask the sponsor questions during the preparation of the assessment report. The sponsor is given the opportunity to review the report for factual accuracy.

External Assessment Centres are asked to declare conflicts of interest in line with NICE's code of practice on declaring and dealing with conflicts of interest ([www.nice.org.uk/declaring and dealing with conflicts of interest](http://www.nice.org.uk/declaring_and_dealing_with_conflicts_of_interest)).

5.6 Contributions from expert advisers

Depending on the scope and the characteristics of the technology, one or more expert advisers (see section 3.7) advise the Committee, in person or by telephone, when the Committee meets to develop its draft and final recommendations. A structured summary of their advice is published alongside the draft and final guidance.

5.7 Contributions from patient and carer organisations

The PPIP always approaches patient and carer organisations to obtain their views on the technology. The Committee may identify a need for detailed information from patient organisations or individual patients and carers (for

example an insight into living with the condition to which the technology relates or the use of the technology and/or comparator technologies). If the Committee does not identify any specific questions or issues, a standard list of questions is used (a sample questionnaire is available on NICE's website, www.nice.org.uk/mt). All the information the PPIP receives from patient and carer organisations is presented to the Committee when it meets to develop its draft recommendations on a technology.

Patient and carer organisations are asked to declare conflicts of interest in line with NICE's code of practice on declaring and dealing with conflicts of interest ([www.nice.org.uk/declaring and dealing with conflicts of interest](http://www.nice.org.uk/declaring-and-dealing-with-conflicts-of-interest)). These are presented to the chair and the Committee when they consider the information provided by these organisations.

5.8 Meeting to develop draft recommendations

The Committee meets to develop draft recommendations on the technology under evaluation. It considers:

- the assessment report and the sponsor's submission
- an [overview](#), prepared by the Programme team, highlighting the significant findings of the assessment report. This may include key features of the evidence base and the cost model, any additional analysis carried out, additional information, uncertainties and key issues the Committee may wish to discuss, and the need for further research,¹ if appropriate
- the contributions of the expert advisers
- important outcomes reported by patient and carer organisations, including outcomes not identified in the literature or by the expert advisers.

The Committee meets in public, in line with NICE's commitment to openness and transparency. This allows stakeholders and the public to understand how evidence is assessed and interpreted.

¹ See the 'Medical Technologies Evaluation Programme methods guide' for more information about how the Committee develops research recommendations.

In the public part of the meeting (part 1) the Committee considers the evidence and commentary on the technology and invites expert advisers, the External Assessment Centre and the sponsor's representatives to respond to questions from the Committee and provide clarification.

In the private part of the meeting (part 2) the Committee considers any commercial-in-confidence or academic-in-confidence information and agrees its recommendations on the technology. The chair may ask the sponsor's representatives to remain for part of the private session, specifically to respond to questions from the Committee about confidential information in the submission. Otherwise this part of the meeting is closed to the public, including the expert advisers and the sponsor's representatives.

On occasion a meeting may be entirely public or entirely private – public if there is no confidential information and the Committee is not making any decisions, and private if all the content of the meeting is confidential. This decision is made by the Committee chair and the programme director. This is published on the NICE website.

5.9 *The medical technology consultation document*

When the Committee has made draft recommendations, NICE issues a [medical technology consultation document](#). This includes:

- the draft recommendations
- a brief description of the technology, the indications under review and its intended benefits
- a summary of the evidence considered by the Committee, including a summary of the advice from expert advisers and patient and carer organisations
- the issues the Committee took into account when it developed its recommendations
- information about the implementation support tools that may be available for the guidance
- research recommendations

- related NICE guidance that has been published or is in development.

5.10 Consultation

Any person or organisation may comment on the medical technology consultation document. NICE informs the following groups when consultation starts and where to find the consultation document on the website:

- national patient organisations
- the Association of British Healthcare Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA), who in turn inform their members
- relevant expert advisers
- professional bodies of the relevant expert advisers, and professional bodies whose members might use the technology
- the sponsor of the technology that is the subject of the draft guidance.

In addition, people and organisations who have registered an interest on the website receive an automatic email alert when consultation starts (see section 3.11).

NICE publishes the following documents on its website for the 4-week consultation period:

- the medical technology consultation document
- the scope
- the sponsor's submission (with confidential information removed)
- the assessment report
- the overview
- the names and professional organisations of the expert advisers on the technology
- a summary of comments from expert advisers and patient and carer organisations.

NICE makes an executable version of the cost model available to those who register an interest in the topic, on request and with the following conditions.

NICE releases the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model. The recipient is required to sign a confidentiality undertaking and is advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document. The recipient agrees to these terms in writing before receiving the model.

Anyone may submit comments through the website, by email, fax or post. Comments longer than 20 pages are not normally accepted, other than at NICE's discretion in exceptional circumstances.

NICE is committed to having due regard to the need to eliminate unlawful discrimination and to promote equality, and fostering good relations between people with a characteristic protected by the equalities legislation and others. NICE encourages comments from all sectors of the community and specifically asks if there are any equality-related issues that need special consideration which are not covered in the document.

The Committee particularly welcomes the following:

- comments on the draft recommendations
- notification of factual inaccuracies
- additional relevant evidence, with bibliographic references if possible
- views of patients, their parents or carers and patient organisations on how well the technology works, including benefits or risks to the patient that were overlooked.

All comments are important and potentially influential in developing the guidance, including those that entirely support the draft recommendations.

Only people who comment during consultation can be involved in the resolution process (see section 6.2).

5.11 Final guidance

After the consultation period ends, NICE collates the comments and presents them to the Committee. Comments received after the consultation period are only shown to the Committee if agreed in advance by the programme director, who consults with the chair and associate director.

The Committee meets to discuss whether to amend its draft recommendations in view of the consultation comments. This meeting is held in public on the same basis as the first meeting.

If the Committee's recommendations change significantly after consultation (for example, if important new evidence emerges during the consultation period), it is normally appropriate to reissue the consultation document for a further public consultation. The programme director makes this decision in consultation with the Committee chair.

The Committee agrees the final recommendations and submits them to NICE's [Guidance Executive](#) for approval. After approval from Guidance Executive, the guidance proceeds to resolution as outlined in section 6.

5.11.1 Late receipt of evidence

In exceptional circumstances, for example, if relevant information is published while the final guidance is being developed or because of comments from the public consultation, NICE may undertake further analysis. The External Assessment Centre (or another organisation commissioned by NICE) normally carries out this further analysis before NICE circulates the final guidance. The Centre Director takes this decision in discussion with the chair of the Committee and the NICE Programme team. The decision is not taken lightly and is made to ensure that NICE is able to provide robust guidance to the NHS.

NICE reserves the right, while the final guidance is being developed, to refuse to accept evidence presented by the sponsor that could reasonably have been included in the sponsor's original submission.

5.12 *Suspending or cancelling an evaluation*

The criteria for suspending or cancelling an evaluation are listed in appendix D. In summary:

- the sponsor does not bring the product to market or withdraws it
- reports of adverse events emerge
- a technology is not appropriate for medical technologies guidance
- the sponsor does not provide data for the evaluation according to the agreed schedule.

Information that has been made public before the suspension or cancellation decision will remain publicly available on NICE's website.

6 Resolution

The resolution process takes place after NICE's Guidance Executive has approved the guidance for publication and before it is published. The resolution process is a final quality-assurance step to ensure that NICE acts fairly, follows its own processes and produces clear, accurate guidance. It prevents the inadvertent publication of guidance that contains factual errors or is developed other than in accordance with either this document or the programme's methods guide.

If NICE receives a resolution request, it suspends publishing the guidance while it investigates the request. If NICE does not receive a request, the guidance is published as soon as possible after the resolution period ends.

The resolution process applies only to guidance. Resolution does not apply to the Committee's decisions about selecting technologies for evaluation. It also does not apply to the assessment report or other documents produced in the course of developing the guidance, unless the resolution request on these documents is material to the issue regarding the guidance itself.

6.1 *Resolution grounds*

The resolution panel (see section 6.5) only considers resolution requests that clearly meet one or both of the following grounds:

Ground 1: Breach of NICE's published process for the development of medical technologies guidance

An example would be when a step is missed in the process.

Ground 2: Factual errors in the guidance

A factual error is an objective error of material fact in the final guidance. Conflicting scientific or clinical interpretations or judgements are not considered to be factual errors. For example, if a [consultee](#) states that a statistic quoted in the guidance is incorrect, NICE establishes whether the final guidance misquoted the statistic, or if one statistic was preferred out of several because the Committee considered it to be more reliable. The former is a factual error; the latter is a difference of scientific or clinical judgement.

6.2 *Eligibility to make a resolution request*

After the Guidance Executive approves the guidance for publication, NICE sends an email to all consultees who responded to the draft guidance. It is important that any organisation or person who may wish to make a resolution request submits a consultation response at the appropriate time. They should bear in mind that the guidance may have changed significantly from the consultation document because of comments received during consultation and considered by the Committee when formulating its final guidance.

6.3 *Resolution requests*

Consultees have 15 working days after the email alert to request resolution on one or both of the grounds given above. NICE accepts requests by email, fax or letter addressed to the associate director of the Medical Technologies Evaluation Programme. Consultees making requests should specify the resolution they seek. NICE can then fully understand the nature of their concern and take appropriate action.

6.4 Initial scrutiny of resolution requests

All eligible resolution requests are subject to an initial scrutiny process. The associate director investigates the matters raised and reports the findings to the centre and programme director, who decide whether the request falls within the scope of the resolution process. Initial scrutiny continues for 15 working days after the resolution request period ends. If multiple resolution requests are made, either from the same or different consultees, each request is treated as outlined below.

Ground 1: Breach of process

If the centre/ programme director considers that the resolution request does not meet ground 1 (breach of process), or does not have a reasonable prospect of success, the associate director informs the person or organisation who made the request and NICE publishes the guidance.

If the centre/ programme director considers that ground 1 appears to have been met, the associate director convenes the resolution panel (see section 6.5).

Ground 2: Factual errors

If the centre/ programme director considers that the resolution request does not meet ground 2 (factual errors), or does not have a reasonable prospect of success, the associate director informs the person or organisation who made the request and NICE publishes the guidance.

If the centre/ programme director considers that the guidance contains a minor factual error or a point that requires clarification but does not affect the Committee's recommendation(s), the guidance is amended and signed off by the Committee chair without being referred to the resolution panel. NICE then publishes the guidance in the usual way.

If the centre/ programme director considers that there is a major factual error that cannot be remedied by minor amendment, they instruct the associate director to convene the resolution panel.

For multiple resolution requests, not all requests may qualify for referral to the panel. In order to avoid pre-empting the outcome of resolution, NICE informs all consultees that the panel is to be convened, and that NICE will tell them the outcome of their request after the panel's decision is made.

6.5 *The resolution panel*

The panel consists of two NICE board members, one non-executive director and one executive director not previously involved in developing guidance on the technology. The aim of the panel is to decide whether there has been a breach of process or factual error and, if so, what action is appropriate.

6.5.1 Meeting

The associate director organises the resolution panel meeting, which takes place no more than 20 working days after the initial scrutiny process has ended.

The Medical Technologies Evaluation Programme team prepares a briefing, which the panel uses when considering the resolution request. For ground 1, this means establishing what process was followed when developing the guidance and what events or omissions were alleged in the resolution request. In the case of ground 2, this involves setting out what evidence lies behind the alleged errors.

The associate director and, if needed, the Committee chair and the programme director attend the meeting to provide clarification. They are not members of the panel and do not contribute to the outcome of the resolution. Members of the Programme team may also attend the meeting to answer questions.

6.5.2 The outcome

Ground 1: Breach of process

If the resolution panel decides that there has been no breach of process, NICE can publish the guidance. If the panel decides that there has been a breach of process, it decides what action is appropriate. This may involve repeating part of the assessment process and, if necessary, referring the technology back to the Committee and/or carrying out another consultation.

Ground 2: Factual errors

If the resolution panel decides that there are no factual errors, NICE can publish the guidance. If the panel decides that there are factual errors or elements to be clarified, NICE produces an amended version of the guidance. The panel must decide whether the error can be corrected and the amended guidance approved by the Guidance Executive before publication, or whether the Committee should review the amended guidance wording in light of the error identified.

NICE considers whether to publish the amended guidance or whether there is a need for further consultation. This need normally arises if:

- NICE makes a substantive change to the wording of the recommendation(s)
- changes to the guidance not involving the recommendations are significant or likely to be of interest to consultees.

The associate director implements the panel's decision and informs all the consultees who made resolution requests of the outcome of resolution. This normally occurs 2 days before NICE publishes the guidance, although this timescale does not apply if the Committee needs to reconsider their recommendation(s).

The resolution panel's decision is final and there are no further opportunities for redress within NICE.

7 Publishing medical technologies guidance

Guidance on the technology is published on the NICE website, and relevant healthcare professionals are notified. People and organisations who registered an interest in the technology are informed electronically.

The following documents are available when medical technologies guidance is published:

- [medical technology guidance document](#)
- scope

- assessment report and overview, updated to include any new evidence emerging in the interim
- sponsor's submission, with confidential information removed
- evidence from expert advisers and patient and carer organisations
- anonymised consultation comments and NICE's responses
- implementation support tools (usually at the same time as the guidance, and within 3 months of publication at the latest)
- lay explanation of the recommendations (if appropriate).

The implementation team produces support tools that are published during the 3 months after guidance publication. These tools help the NHS to implement NICE's medical technologies guidance and may include audit support, costing tools, slide sets and bespoke products.

If NICE is advised of any potential errors in the guidance or the supporting documents after publication, these are dealt with according to NICE's standard procedures.

7.1 *Timeline*

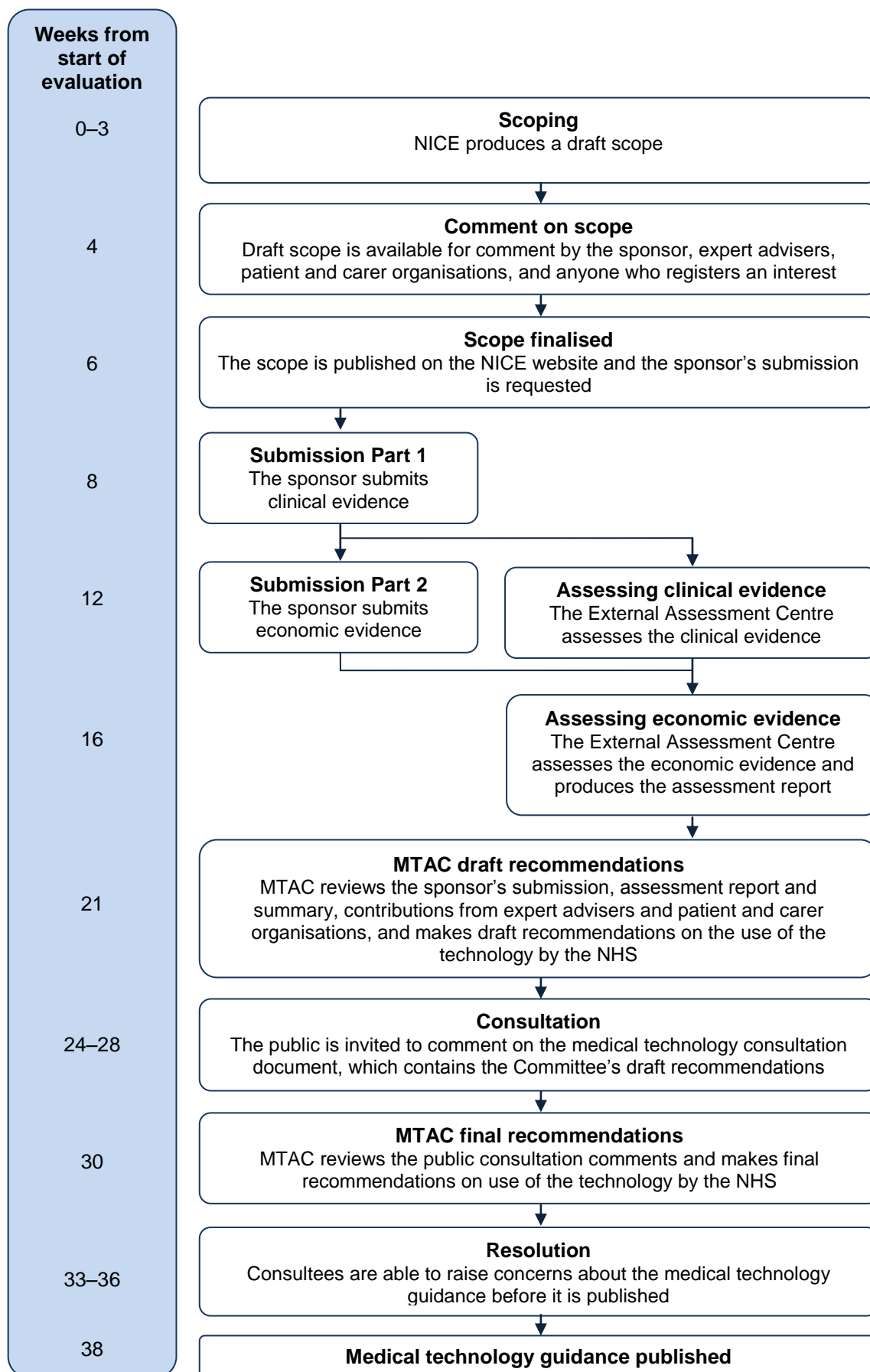
The timeline in table 3 only applies when a medical technology is selected and routed to the Committee for evaluation. Unless an alternative timetable is agreed as described in 5.2, technologies are normally evaluated in the order in which they are notified. The timings are approximate and may vary in response to individual evaluation requirements.

If a technology is routed to another programme it follows the timelines of the subsequent topic selection steps of that programme.

Table 3 Approximate timeline for evaluation

Weeks (average) from start of evaluation	Stage
0	NICE starts drafting the scope of the evaluation NICE invites contributions from expert advisers and patient and carer organisations
4	Draft scope is circulated for comment
6	NICE finalises the scope of the evaluation NICE requests the sponsor's submission
8	NICE receives the sponsor's clinical evidence submission NICE commissions an External Assessment Centre to prepare an assessment report
12	NICE receives the sponsor's economic evidence submission
8–16	The External Assessment Centre clarifies the clinical and economic evidence submissions with the sponsor
16	NICE receives the assessment report from the External Assessment Centre NICE sends the assessment report to the sponsor for a factual check
18	NICE compiles the overview
19	NICE distributes the assessment report and the summary to MTAC members
21	MTAC meets and develops draft recommendations
21–23	NICE prepares and agrees the medical technology consultation document
24	Consultation starts
28	Consultation ends
29	NICE collates consultation comments
30	MTAC considers the consultation comments and develops final recommendations
33	NICE Guidance Executive approves guidance for publication Resolution period starts
36	Resolution period ends
38	NICE publishes medical technology guidance

Figure 2 Summary of evaluation process



8 Reviews

Medical technologies guidance is not published with a fixed review date. Guidance is considered for review by the NICE Guidance Executive if significant new evidence becomes available.

The process of reviewing guidance and submitting review proposals to the Guidance Executive forms part of the normal workload of the Programme. NICE includes guidance updated as a result of the review process in the Programme's annual target for guidance development.

9 Updating the process guide

The process guide is subject to the approval of the NICE Board and a review will normally be initiated 3 years after its publication. It may be necessary to make minor changes to the procedures of developing medical technologies guidance before that time. Procedural changes will be made in accordance with NICE's policy. Minor changes that may be made without consultation are those that:

- do not add or remove a fundamental stage in the process
- do not add or remove a fundamental methods technique or step
- do not disadvantage one or more stakeholders
- improve the efficiency, clarity or fairness of the process or methodology.

Changes meeting these criteria will be published on the NICE website 4 weeks before their implementation. The electronic version of this document will also be updated at that time and a note to this effect placed on the opening page.

Any other changes will only be made after a public consultation period of 3 months.

10 More information

More information about the Medical Technologies Evaluation Programme and the work of MTAC can be found on the NICE website (www.nice.org.uk/mt). This includes:

- the Medical Technologies Evaluation Programme methods guide
- a list of expert advisers
- a list of Committee members
- minutes of Committee meetings
- frequently asked questions and answers about the Medical Technologies Evaluation Programme
- a form for notifying technologies to the Programme
- a link to medical technologies guidance – published and in development.

Appendix A: Glossary

Assessment report A report produced by one of NICE's independent External Assessment Centres that reviews the sponsor's evidence submission and may include additional analysis of the submitted evidence or new clinical and/or economic evidence.

Briefing note An overview of a single technology produced by the Programme team. The Committee uses the briefing note when deciding whether to select that technology for evaluation.

Case for adoption The clinical and cost benefits that would be realised if the technology were taken up in place of the best available alternative.

CE mark The CE mark is a mandatory conformity mark for all products placed on the single market in the European Economic Area, including medical devices. The CE mark certifies that a product has met EU consumer safety, health or environmental requirements.

Clinical utility The clinical usefulness of a technology. For example, the clinical utility of a diagnostic test is its capacity to rule a diagnosis in or out, and to help make a decision about adopting or rejecting a therapeutic intervention.

Comparator The standard technology against which the technology under evaluation is compared. The comparator is usually a similar or equivalent technology used as part of current management. The comparator can be no intervention, for example best supportive care.

Consultee A person or an organisation that submits a comment during consultation.

Decision problem The decision problem describes the proposed approach to be taken in the sponsor's submission of evidence to answer the question in the scope. This includes the population, intervention, comparator(s), outcomes, cost analysis, subgroup analysis and any special considerations.

Diagnostic technology A medical technology with a diagnostic purpose.

Diagnostic technologies are a subset of medical technologies.

Expert adviser A person nominated by their professional body to advise the Medical Technologies Advisory Committee about medical technologies for which they have specific knowledge or expertise. Expert advisers may be healthcare professionals with knowledge of using the technology for treating or managing patients, or medical scientists with technical knowledge.

Guidance Executive A team comprising the executive directors and centre directors at NICE who are responsible for approving the final guidance before publication.

Manufacturer – see ‘sponsor’

Medical technologies guidance Guidance produced by the Medical Technologies Advisory Committee on technologies that are routed to it for evaluation. Guidance on medical technologies produced by another NICE guidance programme is referred to by a different name, such as ‘diagnostics guidance’ or ‘technology appraisal guidance’.

Medical technology consultation document Sets out the Committee's draft recommendations to NICE.

Medical technology guidance document Sets out the Committee's final recommendations to NICE on the use of the technology in the NHS.

Medical technology A medical device or diagnostic technology as defined in section 1 of this guide.

Notification The process by which a notifier (usually the manufacturer of the medical technology) informs NICE about a potential technology for evaluation.

Overview A document that highlights the key issues and uncertainties in the manufacturer's submission and assessment report. It is part of the information used by the Committee when they agree the draft recommendations.

Patient and carer organisations Organisations of patients, carers, communities and other lay members, including those that represent people from groups protected by equalities legislation.

Routing The decision taken by the Medical Technologies Advisory Committee about which NICE guidance programme or external organisation should evaluate a selected technology.

Sponsor The manufacturer, developer, distributor or agent of the technology being considered for evaluation

Appendix B: Eligibility criteria

	Eligibility criterion	Detail
1	Within the remit of a NICE evaluation programme and not currently being evaluated	The technology is suitable for medical technologies guidance (within the definitions of a medical technology or diagnostic technology as set out in section 1 of this guide) or for another NICE guidance programme.
2	A new or innovative technology	The technology is either new or an innovative modification of an existing technology with claimed benefits to patients or the NHS judged against the comparator(s).
3	Appropriate timing	<p>The technology has a CE mark or equivalent regulatory approval and, if not, this is expected within 12 months.</p> <p>The technology is available to the NHS, or the manufacturer or sponsor has plans for the launch of the technology in the NHS.</p>

Appendix C: Selection criteria and scoring used by the Programme team in developing the briefing notes

Selection criterion	Detail	Score
Claimed additional benefit to patients	The extent to which a medical technology claims measurable benefit to patients over currently available NHS technologies in terms of its impact on quality of life or life expectancy.	<p>Score 1–2: the technology is of negligible additional benefit compared with existing best available care, for example no difference in diagnostic speed, ease or accuracy; no difference in therapeutic ease, safety or efficacy.</p> <p>Score 3–4: the technology is of moderate additional diagnostic or therapeutic benefit compared with existing best available care.</p> <p>Score 5: the technology is of significant additional diagnostic or therapeutic benefit compared with existing best available care.</p>
Claimed healthcare system benefit	<p>The extent to which the technology is likely to reduce use of staff or facility resources. For example, the extent to which a technology:</p> <ul style="list-style-type: none"> • facilitates outpatient diagnosis or treatment • has the potential to replace several technologies in current use • requires fewer staff than the technologies in current use • reduces length of hospital stay. 	<p>Score 1–2: the technology has minimal or no claimed service or system benefit.</p> <p>Score 3–4: the technology has moderate claimed service or system benefit.</p> <p>Score 5: the technology has significant claimed service or system benefit.</p>
Patient population	The larger the number of patients on whom the technology may be used, the greater the likelihood that a national evaluation is important.	<p>Score 1: 0–1000 people.</p> <p>Score 2: 1001–10,000 people.</p> <p>Score 3: 10,001–50,000 people.</p> <p>Score 4: 50,001–500,000 people.</p> <p>Score 5: more than 500,000 people.</p> <p>Technologies for small patient populations are not automatically excluded and the Medical Technologies Advisory Committee takes into account the disease impact, claimed benefits and relevance to the sustainability</p>

Selection criterion	Detail	Score
		agenda.
Disease impact	<p>The greater the impact of the disease or condition on quality of life or life expectancy, the greater the likelihood that a national evaluation is important.</p> <p>For technologies aimed at treatment, consideration should take into account the likely degree of improvement in life expectancy, disease severity and quality of life, paying particular attention to conditions that are associated with social stigma.</p>	<p>Score ranges from 1 to 5: Score 1: a low combined morbidity, mortality and/or quality of life impact. Score 5: a high combined morbidity, mortality and/or quality of life impact.</p>
Cost considerations	<p>Consideration of the costs of the technology, including initial acquisition costs (including associated infrastructure) and running costs (including maintenance and consumables).</p>	<p>Score 1 or 5: Score 1: the costs are low. Score 5: the costs are high.</p>
Sustainability	<p>Is the technology likely to contribute to the sustainability agenda, for example, less energy usage or less waste generation during production or clinical usage?</p>	<p>Score 1–2: no or minimal contribution to sustainability (for example energy usage). Score 3–4: expected contribution to the sustainability agenda. Score 5: expected to realise sustainability benefit in the lifetime of the product.</p>

Appendix D: Criteria for suspending or cancelling an evaluation

Criterion	Detail
Altered marketing plans or withdrawal	The manufacturer decides to delay the introduction of the technology or chooses not to market the technology in the UK.
Adverse events	Adverse events associated with the product may lead to the involvement of the MHRA or the withdrawal or suspension of the marketing authorisation of the product. Adverse events may emerge at any time during the identification and evaluation of the product.
Technology not appropriate for the production of medical technologies guidance	The evidence presented to the Committee indicates that, contrary to expectation at the routing stage, the technology is not appropriate for medical technologies guidance. NICE may suspend the development of guidance and refer the technology to another programme for evaluation.
Data for the evaluation not provided according to the agreed schedule	When this is outside NICE's control (for example, a sponsor does not provide the submission on time) NICE will consider suspending the evaluation. This could lead to a delay in issuing the guidance.