# Evaluation Pathway Programme Awareness 2010 Survey

## 1. Introduction

**Medical Devices Evaluation Survey**

This survey is intended for manufacturers, and distributors, of medical devices for the UK. The aim is to research the awareness of evaluation of medical devices. It has been commissioned by NICE (National Institute of Health and Clinical Excellence) to inform the development of its medical technology guidance programme

The survey is undertaken by ImPACT, which is an independent specialist medical technology evaluation organisation within an NHS medical physics unit.

The questionnaire is short, there are 17 brief questions, and should only take about 10-15 minutes of your time.

It is designed to be completed *on-line*: Click **'next'** below

However, as an alternative to completion on-line, a copy can be downloaded from the ImPACT website and mailed to us, or we will be happy to take your answers over the telephone. (The pdf can also be used if you want to preview the questions prior to on-line submission.)
*Hard copy*: www.impactscan.org/epawareness.pdf, *Telephone*: call us on 020 8725 1524 or email us at impact@impactscan.org and we will call you at a time convenient to you.

Any information you supply will be combined with results from others and presented as pooled data to NICE; no individual or individual organisation will be identifiable outside ImPACT from the data presented.

The results will be reported to NICE but the design, analysis and conduct of the survey are entirely ImPACT's.

Thank you for agreeing to complete our survey.

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## 2. About you

To help us ensure that we have covered a broad range of specialties and locations, it will help us to know who you are and what you do. Any personal information will remain within ImPACT.

### * 1. Please give us some information about your organisation, and your role within it.

Company name

Product area

Address in UK (Town)

Country of headquarters

Your role/job title

### 2. Additional personal information (optional)

Your name

Your telephone number

Your email address

### 3. It would help to know whether your company is a manufacturer, a supplier or both

- Manufacturer and supplier/distributor
- Supplier/distributor only
- Manufacturer only

other (please specify)

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## 3. Medical product regulation and evaluation

### 4. What is the main body responsible for medical device regulation in the UK?

- British Standards Institute
- MHRA
- CE
- NICE
- Don't know
- Department of Health
- Other (please specify):

### 5. What is the main body responsible for medical device evaluations in the UK?

- Don't know
- Department of Health
- MHRA
- NICE
- CE
- British Standards Institute
- Other (please specify):

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## 4. More on Medical Product Evaluation

**6. If available, what type of independent evaluation would, in your opinion, be most advantageous to you in terms of facilitating the uptake of your device in the health service? (Please tick as many as apply)**

- Technical investigation and assessment
- Research study on usability
- Study of clinical effectiveness
- Analysis of cost impact
- Review of existing technical research
- Review of existing usability research
- Review of existing clinical effectiveness studies
- Review of existing cost-effectiveness studies
- Other (please specify), or Comment

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## 5. About NICE

### 7. What are the roles of NICE? Please tick as many as apply.

- Evaluation of pharmaceuticals
- Evaluation of medical devices
- Clinical guidelines
- Regulation
- Research
- Product safety alerts
- Food safety
- Health education
- Don't know

Other (please specify):

### 8. The NICE Evaluation Pathway relates to Medical Devices. Had you heard about the NICE Evaluation Pathway Programme prior to today?

**If you answer 'no', please proceed straight through to question 14, section 8.**
**If the answer is 'yes' please proceed with the next questions.**
**If the answer is 'possibly/not sure' please answer the following questions, if appropriate.**

- Yes
- No
- Possibly / not sure

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## 6. Awareness of the NICE Evaluation Pathway Programme

### 9. How did you hear about the NICE Evaluation Pathway Programme? Please tick all that apply.

- NICE website
- Other organisation's website
- Direct communication from NICE
- Direct communication from other organisation(s)
- Personal communication
- Other (please specify):

### 10. How well do you feel you understand the NICE Evaluation Pathway Programme?

- Very well
- Reasonably well
- A little
- Not at all

Comments (optional):

### 11. How does your knowledge of the NICE Evaluation Pathway Programme today compare to your knowledge of it 6 months ago?

- I know much more now
- I know a little more now
- I know much the same now
- I know less now
- I still know nothing about it
- Other (please specify):

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## 7. Evaluation of medical devices within the NICE Evaluation Pathway Programme

### 12. What aspects do you think are covered in an evaluation in the NICE Evaluation Pathway Program? (Please tick all that apply)

- Technical
- Clinical
- User
- Economic

### 13. In terms of the NICE Evaluation Pathway Programme, what describes your understanding of 'evaluation' of a medical device, or diagnostic technology, ? (Please tick as many as apply)

- Hands on technical assessment
- Assessment of usability
- Assessment of clincial effectiveness
- Economic assessment
- Review of manufacturer evidence (in areas such as technical, clinical, user, or economic)
- Meta-analysis (literature search) of effectiveness (eg. Technical, clinical, user, or economic)
- Review of a diagnostic test in the context of a specific clinical condition
- Don't know
- Other (please specify)

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## 8. The NICE Evaluation Pathway Programme

The NICE Evaluation Pathway Programme focuses on the evaluation of innovative medical technologies (including devices and diagnostics). This programme both complements and operates in conjunction with NICE's existing technology appraisal capacity, which continues to evaluate new pharmaceutical and biotechnology products.

The Evaluation Pathway programme is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

The types of products which might be included are medical devices that deliver treatment, technologies that give greater independence to patients, or diagnostic devices / tests used to detect or monitor medical conditions.

### 14. What would encourage you to submit a product, or diagnostic technology, to the NICE Evaluation Pathway Programme?

- é Products will be assessed by experts in their field
- é Opportunity to interact with the process
- é Publication of a report comparing all similar types of product
- é Rapid assessment of the product
- é Evaluation assesses only my product
- é A guaranteed evaluation
- é Evaluation assesses all competing products in the field
- é Publication of a report on the specific product
- é Other (please specify):

### 15. What would discourage you from submitting a product, or diagnostic technology, to the NICE Evaluation Pathway Programme?

- é Lack of knowledge of NICE and/or the Evaluation Pathway Programme
- é Lack of trust in an unbiased evaluation
- é Costs involved in preparing proposals
- é Delays in publication of evaluation report
- é The report will be freely available
- é Costs involved in submitting equipment for evaluation
- é Limited opportunity to include modifications or updates
- é Other manufacturers' products will be included in the evaluation
- é Other (please specify):

**16. Do you have any other comments on the submission of devices, or diagnostic technologies, to the NICE Evaluation Pathway Programme?**

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## 9. More on the NICE Evaluation Pathway Programme

### 17. How important do you expect the NICE Evaluation Pathway Programme to be to your business?

- Very important
- Quite important
- Only slightly important
- Not at all important
- Don't know

Comments (optional):

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## 10. Finally...

### 18. We are very keen to explore further your opinions and understanding of medical device evaluations and NICE. May we contact you to discuss further?

- Yes - by email
- Yes - by telephone

Please include your contact details (email address, telephone number) here if you did not enter them in question 1 and you are happy for us to contact you:

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## 11. Thank you

Thank you for your time. Your response will be useful to better understand your needs, and to help with the direction of medical device evaluation in the UK.