



# **EUPATI guidance document for patient involvement in HTA**

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# Contents of webinar



- Why have guidance?
- Process followed (review, workshops, consultation)
- Content HTA guidance
- Key points within each chapter (referencing online guidance document)
- Questions welcome

# EUPATI guidance for patient involvement in HTA – why?



- Patients & patient organisations to be involved more widely
  - include early & post-approval stages, not confined to clinical development
- Overarching guidance on meaningful and ethical interaction is missing in many areas, especially in R&D, causing insecurity
  - Existing codes/regulations hold mostly general legal & ethical content, i.e. collaboration in general, communication, funding
- In HTA:
  - EUnetHTA HTA Core Model® - technical; patients as sources of evidence not insight
  - several sources of recommendations and good practice for involvement, but dispersed e.g. HTAi, EPF, national HTA bodies
  - huge variation in practice between nations; no European legislation
  - clear default statement that collaboration is important and valuable to patients and to process

# EUPATI Guidance documents to support systematic involvement of patients

After extensive consultation, EUPATI has developed guidances for the involvement of patient organisations with stakeholders

- in industry-led R&D
- in HTA
- in regulatory processes
- in ethics committees

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The screenshot displays the EUPATI website interface. At the top, the EUPATI logo and 'European Patients' Academy' are visible. A navigation menu includes 'Home', 'What is EUPATI?', 'EUPATI Resources', 'EUPATI in your country', 'Glossary', 'Blog', and 'Patients Involved'. A search bar is present on the left. A dropdown menu is open under 'EUPATI Resources', showing options: 'What is the Toolbox?', 'EUPATI Course', 'EUPATI Guidances' (highlighted), and 'EUPATI Publications'. Below the menu, a preview of the 'Guidance for patient involvement in HTA' document is shown. The document title is 'Guidance for patient involvement in HTA'. It includes a 'Print' and 'Save as PDF' button. An 'Index' section lists the following contents:

- 1 Overarching principles for patient involvement throughout the medicines research and development process
- 2 Disclaimer
- 3 Scope
- 4 Defining "patient"
- 5 Rationale for the guidance
- 6 Introduction
  - 6.1 Objectives of the guidance
- 7 Suggested working practices

# EUPATI guidance for patient involvement in HTA – Process



- Review of key documents
  - HTAi “values and quality standards” – consensus exercise
  - EPF survey of patient organisations and HTA bodies
  - input templates from HTAi and national bodies
  - other published literature
  
- Technical input to first draft
  - Karen Facey, HTAi, EPF, Victoria Thomas/Lizzie Amis (NICE)
  
- Internal review
  - EUPATI partners: patient organisations, industry, HTA bodies
  
- Public consultation
  - patient organisations, industry, HTA bodies

# EUPATI guidance on patient involvement in HTA – Scope/content



- Definition of “patient”
  
- HTA for medicines, not other interventions
  
- Participation in HTA process, not scientific collection of patient perspective
  
- Describes high level values, and how these can be upheld:
  - working practices for HTA agencies and patient organisations (strategies / policies)
  - specific patient involvement activities / practices
  
- Resources and references