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Αξιολόγηση της Ιατρικής Τεχνολογίας στην Ψηφιακή Υγεία

Assessment of GR Digital Medical Technology

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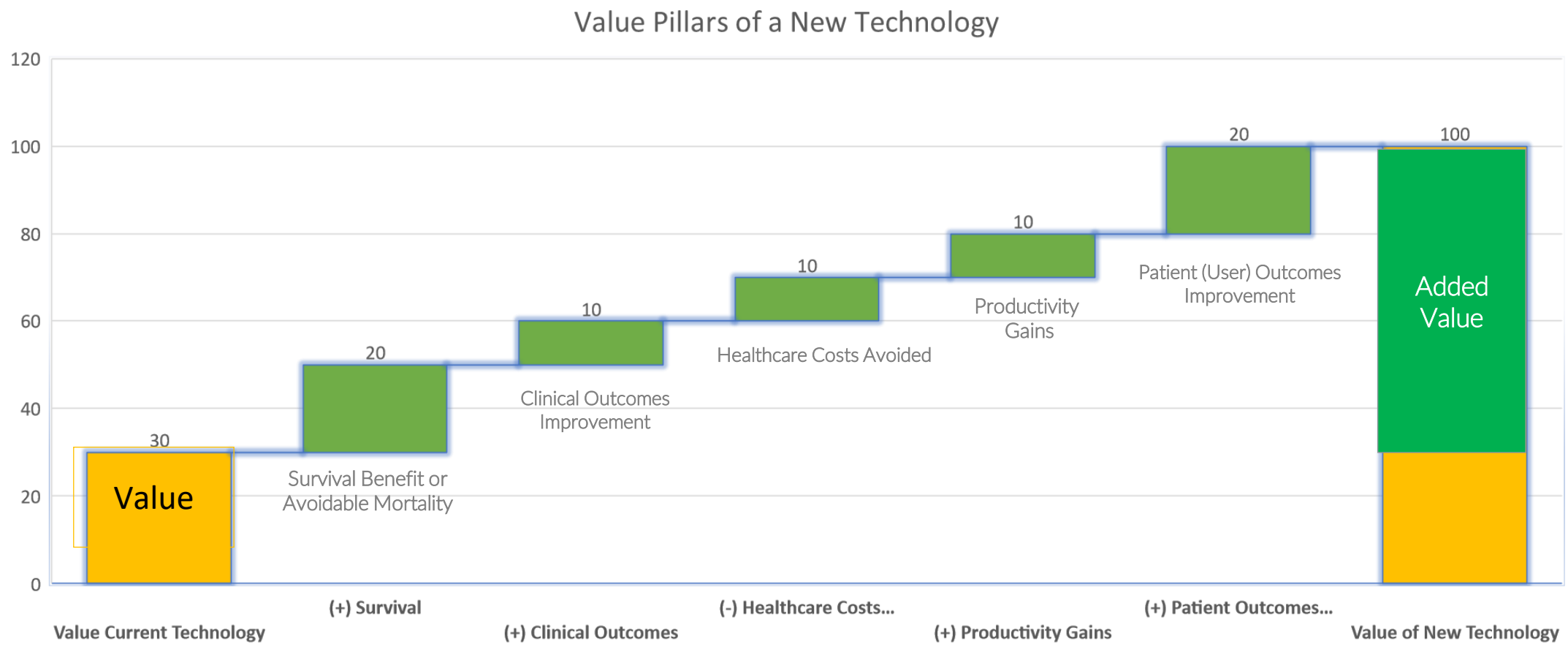
The Identification of the Added Value of a New Technology



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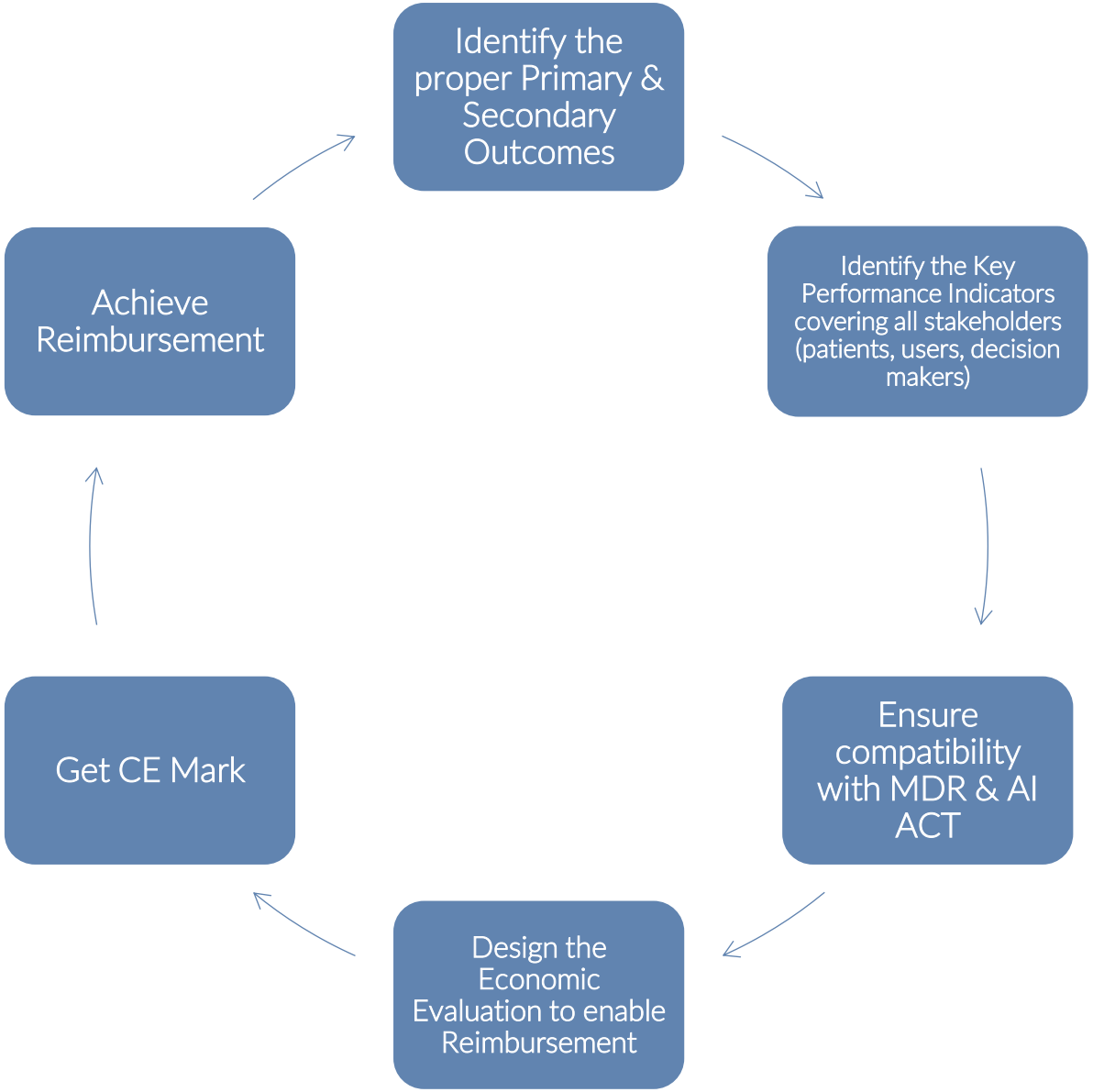
Evaluation Step Wise Process



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Reimbursement (Early) Recommendation for Digital Therapy by UK NICE

NICE National Institute for Health and Care Excellence

Digital therapy for chronic tic disorders and Tourette syndrome: early value assessment

Health technology evaluation | HTE25 | Published: 07 May 2025

1 Recommendations

Can be used while more evidence is generated

1.1 Online Remote Behavioural Intervention for Tics (ORBIT; Mindtech) can be used with standard care in the NHS during the evidence generation period as an option to treat chronic tic disorders and Tourette syndrome in children and young people 9 to 17 years. It can only be used if the evidence outlined in the evidence generation plan for ORBIT is being generated.

1.2 The company must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan). They must contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance for a technology if these conditions are not met.

1.3 At the end of the evidence generation period (about 3 years), the company should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

What evidence generation is needed

1.4 More evidence generation is needed on:

- long-term clinical effectiveness (further analyses)
- the technology's effect on quality of life
- adherence
- how the conditions progress without the technology
- adverse events
- the impact of long-term effectiveness on long-term costs
- long-term follow-up costs needed to maintain effectiveness
- clinical and cost effectiveness within subgroups
- views on the effects of the technology from people with tic disorders or Tourette syndrome and their carers.

1 Recommendations | Digital therapy for chronic tic disorders and Tourette syndrome: early value assessment | Guidance | NICE

Where Does Greece Stand in the Assessment of Digital Technologies?

- Very high number of scientists working in digital health field (Electrical Engineers & Computer science etc).
- Low Digital Literacy Among Greek Healthcare Professionals and Limited Hospital Capacity for Supporting Digital Clinical Trials (Maybe due to low number or medical doctors? Lack of motive? Low engagement? Very bureaucratic system?)
- Not Specific Criteria for Health Technology Assessment for Medical & Digital Technologies (Just framework) – similar to pharmaceuticals.
- Is approval from Central Health Council (KESY) required for the reimbursement of a digital application? If yes, then the reimbursement duration will take appr. 2 years.
- Not specific assessment body – Price Negotiation Committee for Medical Devices at EOPYY.
- No use of Real World Evidence – similar to pharmaceuticals.
- Increased number of digital technologies in GR labs BUT Very limited number of technologies in market.
- Crucial role of the Digital Health Association: Perform Gap Analysis and proceed with training activities especially at hospital level. An intensive training program is needed.

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Healthcare Challenges of Digital & Medical Technologies

CE Mark / Patent

HTA Approval (Reimbursement)

Healthy Societies

Return on Investment (ROI)

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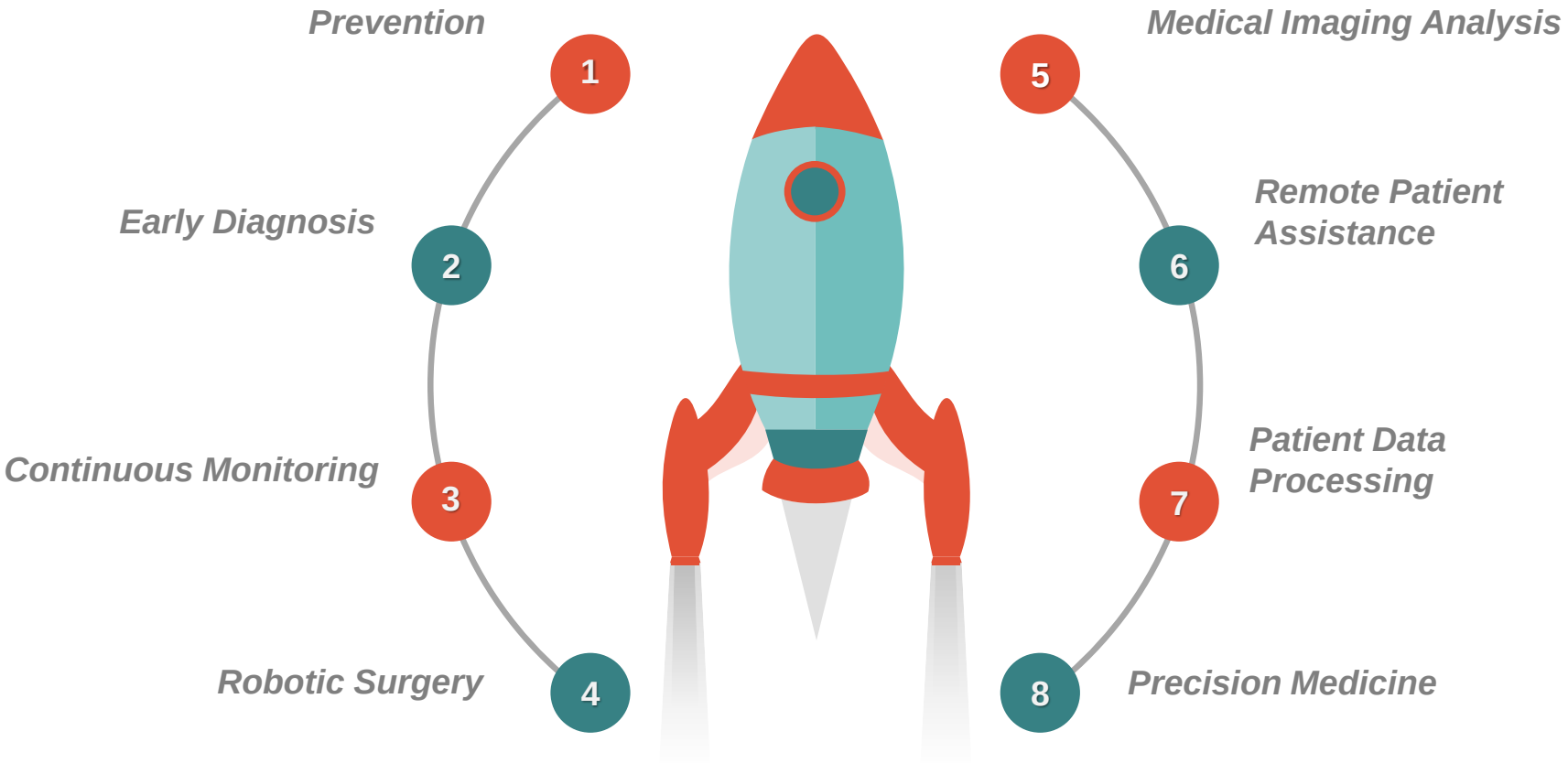
AI in Healthcare: The Journey has Already Started



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LET'S START SOMETHING GREAT

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