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Translation of Devices into Healthcare

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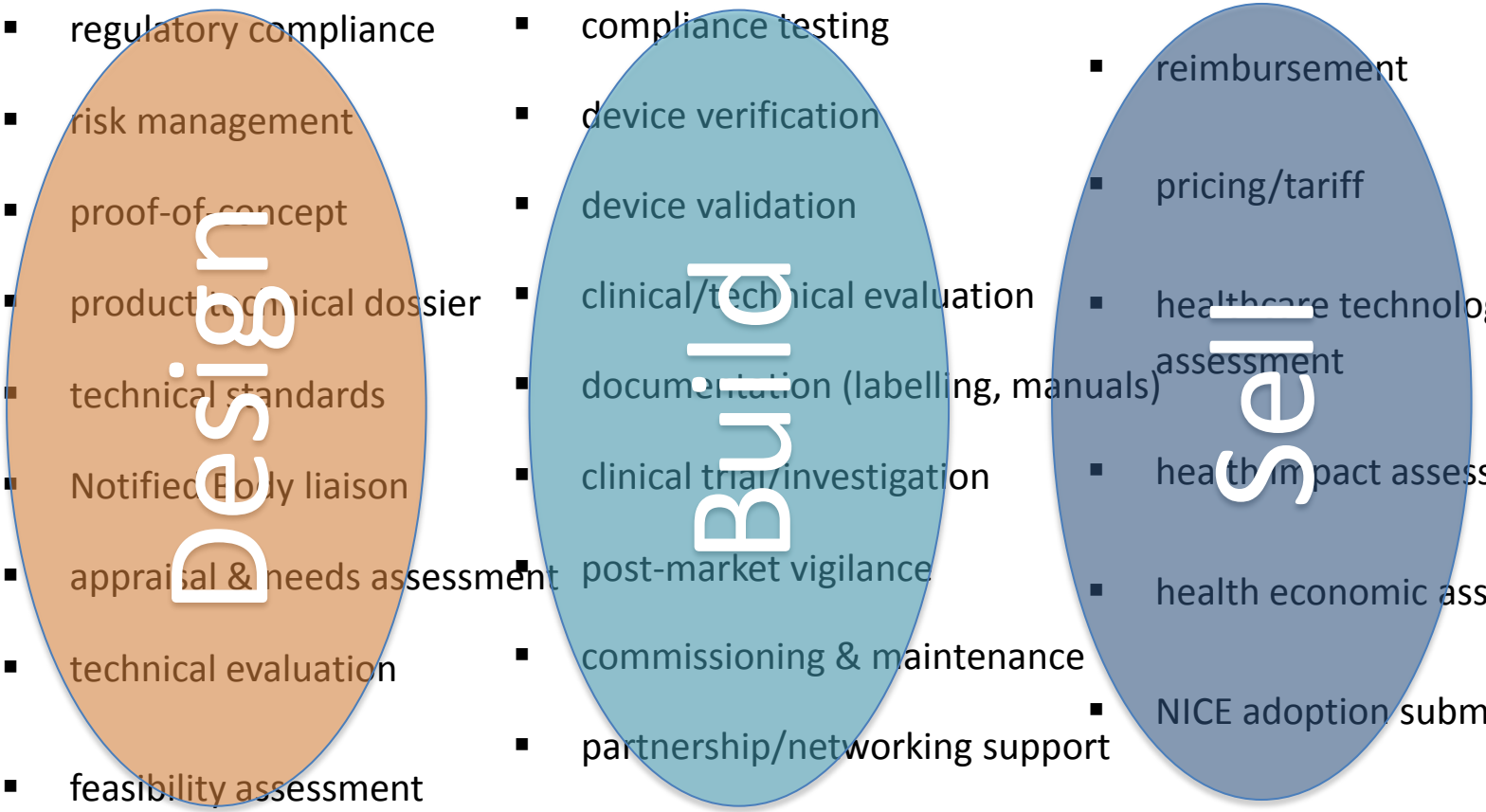
- What do we mean by translation into healthcare?
- Key Requirements for Successful Translation
- Translation pathway
  - Concept Development
  - Customer Discovery
  - Healthcare Benefit Analysis: is it worth progressing?
  - Device Development: Regulatory compliant, fit for purpose
  - Clinical Evidence
  - Right Target Audience
  - NICE
- Conclusions

Translation into Healthcare

Barriers…



Safeguards…

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Key Requirements: Starting Point

- Are you providing a solution to a real world problem?
- Pathway to Impact?
- Is it truly fit for purpose?

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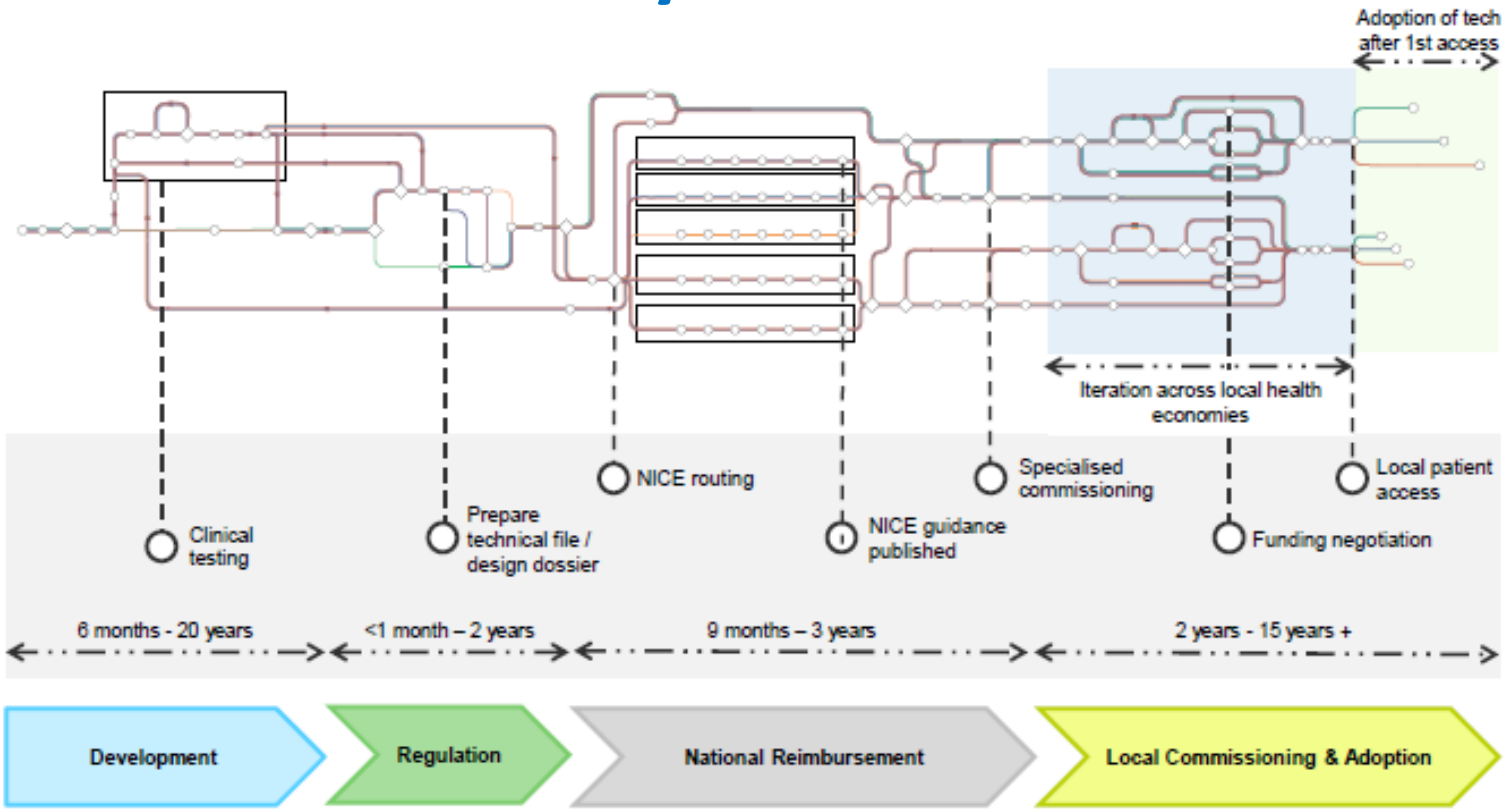
Translation Pathway



*Monitor Deloitte, CASMI & Kings Fund.
Medical device pathway summary, Accelerated Access – Innovative Medicines & Medical Technologies Review, March 2015

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Translation Pathway: Concept Development

- Research & Development
- Partners
- Grants / Funding

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Translation Pathway: Customer Discovery

- Advisory Board
  - Advice & views of experts
- Power in numbers?
  - Widespread consensus

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Translation Pathway: Healthcare Benefit Analysis

Patient Benefit





Healthcare System Benefit


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The Matrix

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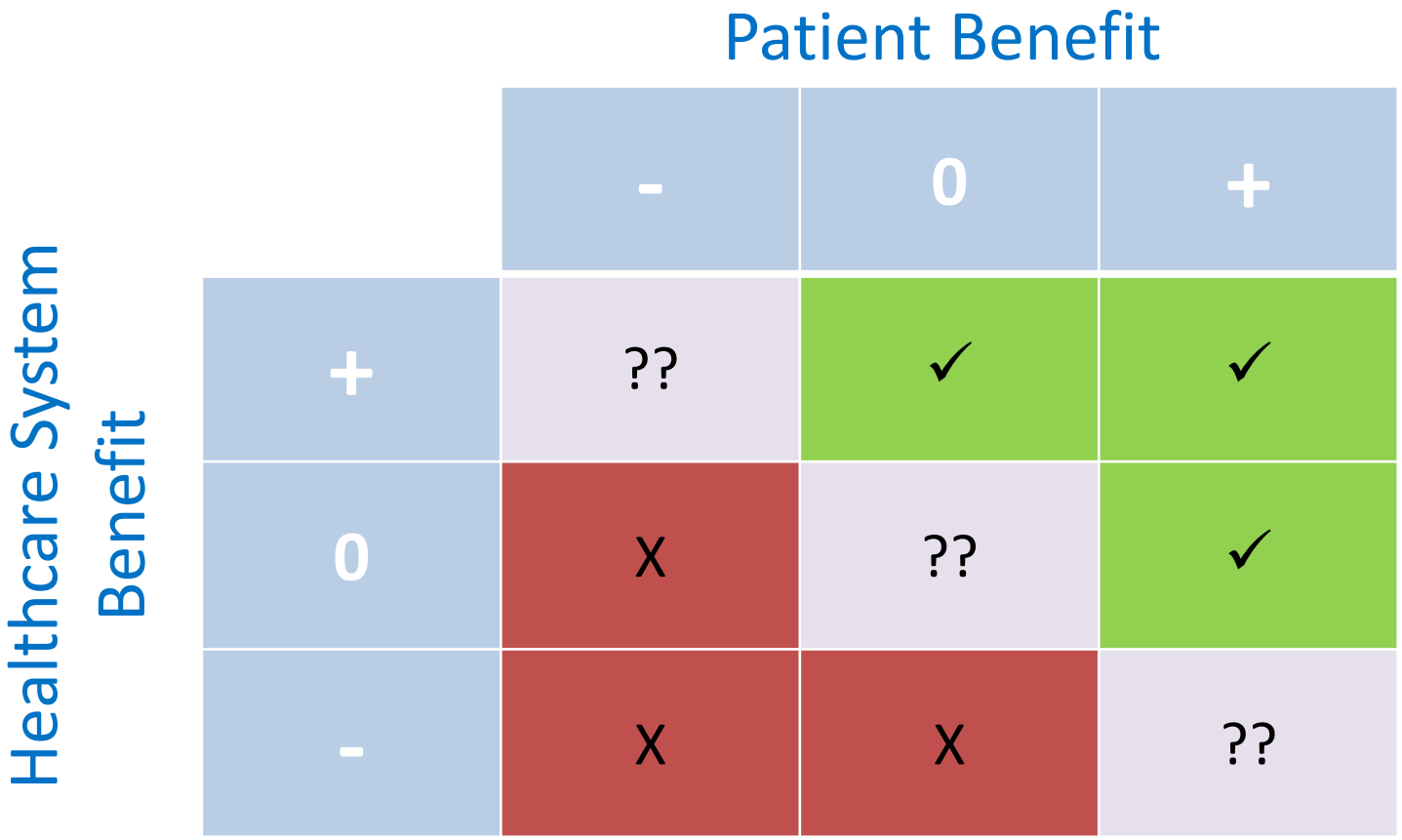
The Matrix



Translation Pathway: Clinical Investigation?

Non CE-marked medical device?

or

CE marked device used for new purpose?

and

Commercial Intent

=

- MHRA must be notified
- Regional Ethics Committee approval
- NHS R&D approval

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Translation Pathway: Clinical Investigation?

- Technical File/ Design Dossier
- Essential requirements met; exception of those which will be demonstrated by clinical investigation (safety & performance)
- Notify MHRA
- Submit documentation
- MHRA has 60 days to object

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Translation Pathway: Truly fit for purpose?

- Regulatory Compliant
- Truly fit for purpose
- Simplicity to Integrate
  - Essential Performance & Electrical safety testing
  - User training and competency assessment

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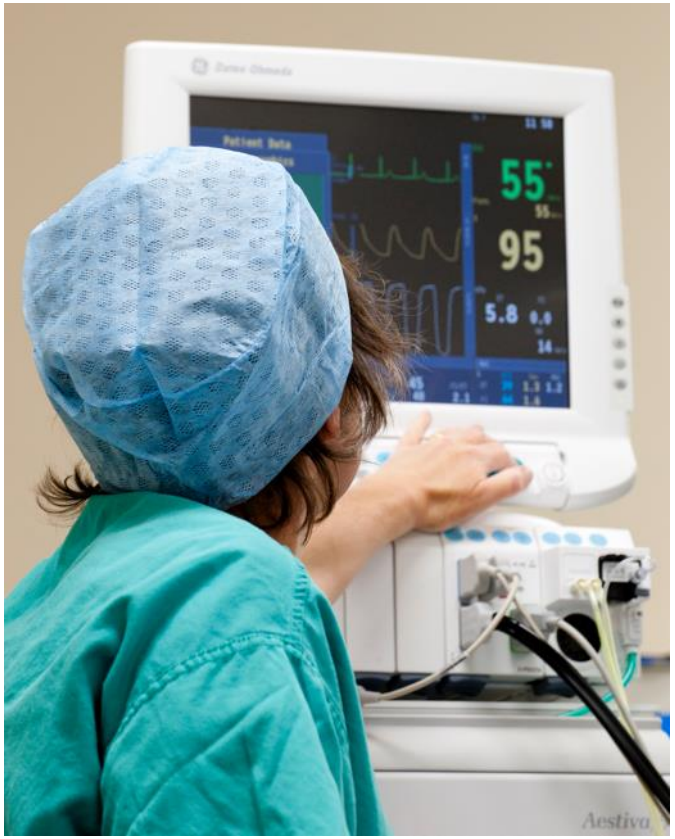
Translation Pathway: Right Target Audience



- Who's the end user?
- Who makes decision?

Translation Pathway: Clinical Evidence

- Can you evidence your claims?
- Planning:
  - Correct sample size
  - Correct sample cohort
  - Correct end points

Translation Pathway: Icing on the Cake?

- Best Practice Guidelines
- NICE – Medical Technologies Evaluation Programme

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Successful Translation

Not all about having a CE marked device

- Understand healthcare system benefit
- Know your place in the care pathway
- Know your end user & buyer
- Evidence your claims

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