

The Landscape for Digital Psychosocial Interventions

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BPI Trainer

(Disclaimer: Although employed part time by NHS England I am not speaking on behalf of, nor representing NHS England in this presentation)

Declaration of interests

- I am employed by NHS England part time and will speak about MindEd an NHS England Program: please note I am not speaking here on behalf on NHS England nor am I representing NHS England in this talk, nor the DHSC.
- I am a cofounding director of CambridgeBPI Ltd who are partners with the University of Cambridge and other investigators on an NHS NIHR HSDR Grant funded research program that I will speak about.
- As a director and shareholder of CambridgeBPI Ltd I will speak about BPI and our development of digital BPI, for which CambridgeBPI holds the IP and copyright on licence from the University of Cambridge. CambridgeBPI Ltd is an ongoing commercial interest.

Agenda

01

History and Futurology: my two pence worth

02

Translation from lab to bedside planning for success

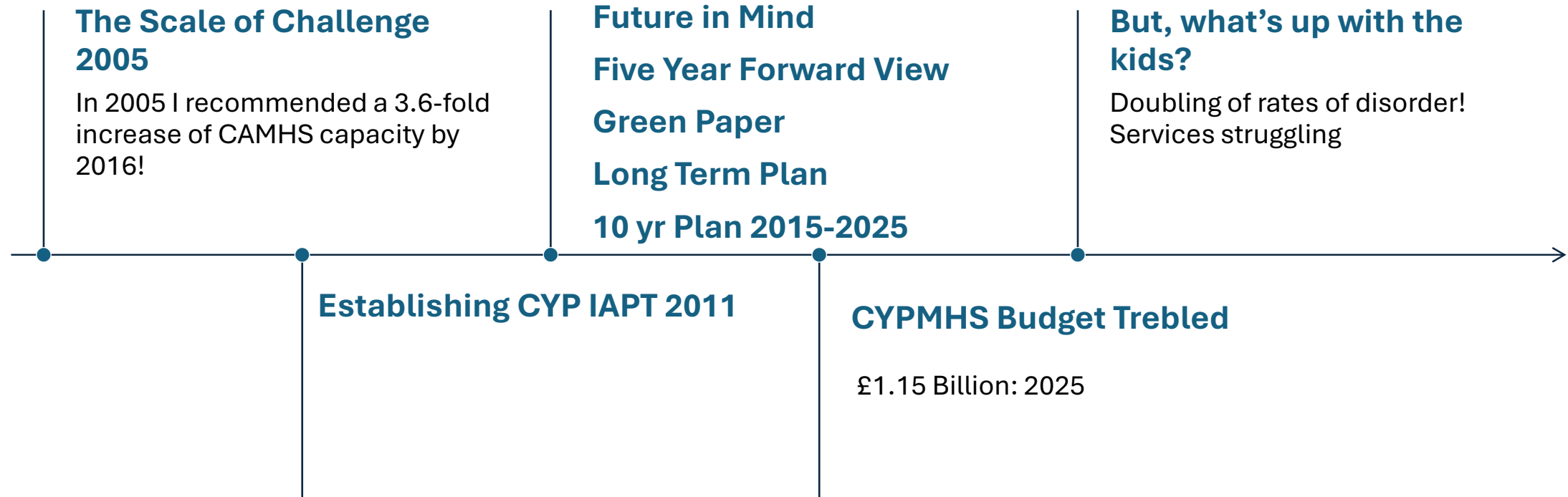
03

Summary

04

References

Timeline



10 yr Health Plan, For England(2025)!

- from hospital to community
- from analogue to digital
- from sickness to prevention

Why might digital BPI be part of the answer?

Digital Mental Health has to be part of the solution: why BPI?

- BPI is NICE approved
- BPI delivers an holistic, formulation driven, biopsychosocial (B-P-S) intervention
- Our College wants us all to ‘reclaim our medical identity’ using holistic B-P-S formulation-based practice

Validations of this approach also include recent eLearning modules

- The new Suicide Prevention: Staying Safe from Suicide (NHS England) Best Practice Guidance
- And the holistic care for CYP who are gender questioning

www.minded.org.uk

Capacity of Tier 2/3 CAMHS and Service Specification: A Model to Enable Evidence Based Service Development

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Digital mental health technology and the role of the MHRA in the regulation of software as a medical device (SaMD)



President,
Dr Lade Smith CBE



Dean,
Professor Subodh Dave



Registrar,
Dr Trudi Seneviratne

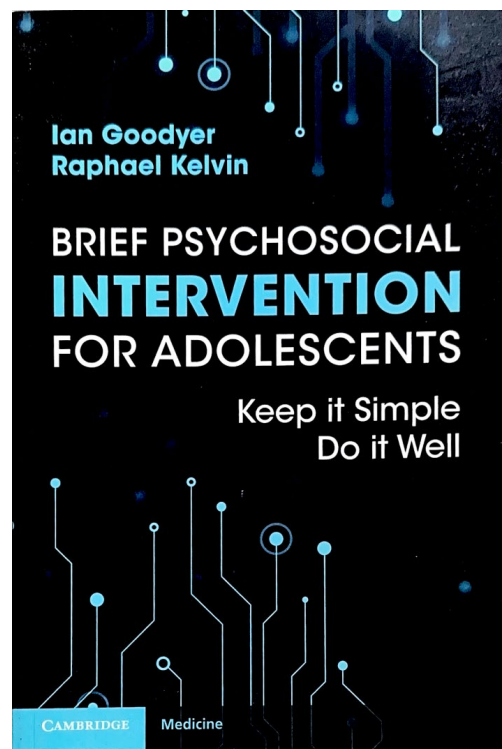


Treasurer,
Professor John Crichton

Reclaiming our medical identity

The College Officers stress the need to safeguard the full scope of psychiatric practice, reaffirming its unique ability to integrate biological, psychological and social approaches.

psychiatry rewarding. Many enter the field to make a real difference in people's



Part 1: An introduction for health and education professionals working with children and young people with gender-related questions or distress

Select the information icon **Q** for more project information or to use the search function and glossary.

Select the dyslexia icon to reveal the dyslexia overlays.

Select the exit icon to exit the session.

Select the heading to find out more.

NHS England Introductory statement (please read)

Welcome to part 1 of this 2-part MindEd course which has been created for all frontline professionals working with children and young people. This learning aims to give professionals information and ideas on how to support when gender-related questions and distress first emerges for children and young people.

Please note this learning has not been created to provide detailed information on the assessment and intervention processes that are followed by specialist gender services. Please also consider reading our 2-part course for parents and carers as you may wish to share this with families in your work.



Dr Raphael Kelvin 25th Sept 2025



Staying safe from suicide: Best practice guidance

In this session, we will introduce the Staying safe from suicide guidance and help mental health practitioners learn to apply it in practice.

1. Introduction	2. Safety assessment	3. Safety formulation and case studies	4. Safety management and planning and case studies
5. Language	6. Implementation guidance	7. Assessment	8. Summary and further information



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How can we achieve Translational Success?

- From lab to bedside a key national priority for the NHS
- Best practice guidance to implementation



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Enablers

The 10 yrs plan is very strong on this:

- Plans for digital health store
- For making it easier for DMH tech companies to partner NHS
- Making it easier to bring new products into the NHS
- Speeding up RCT delivery
- Enhancing appropriate DMH science evaluation and regulatory support to be more enabling



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Current DMHI landscape

Evaluation Regulation and Implementation

- Let me tell you its not simple!
- But to help we are finalising new MindED 'Tipsheets' with the MHRA explaining their role in regulation of software as medical devices



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From Concept to Bedside- YP Self Service eBPI

- I will use our current NIHR WaitLess Study to illustrate our journey...we are in mid flight!
- Changing the vehicle but retaining the essence of its effectiveness
- What is the process?

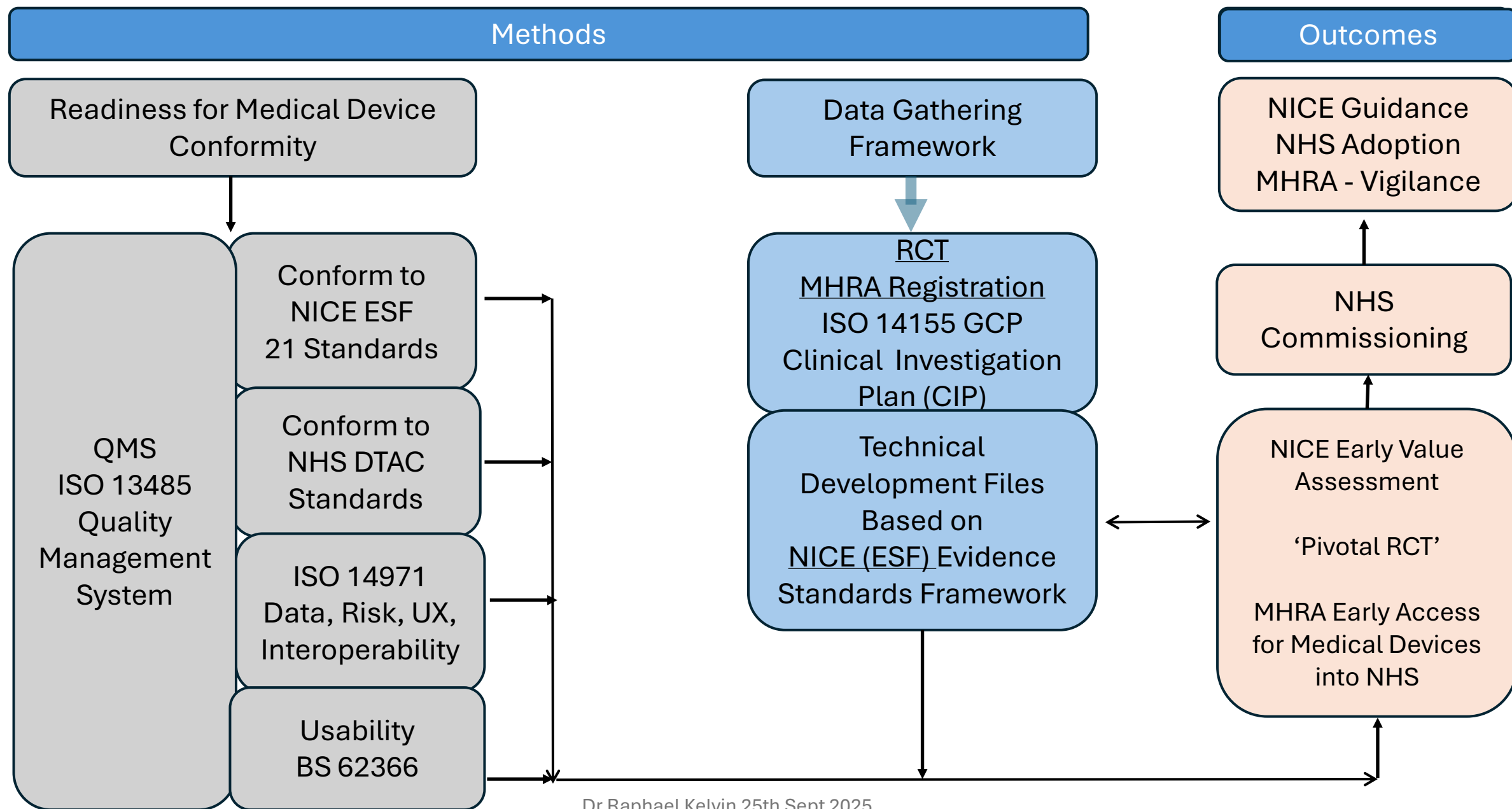
A small thought experiment:

- consider how this compares to talking treatments, and digital products that are NOT regulated as medical devices?

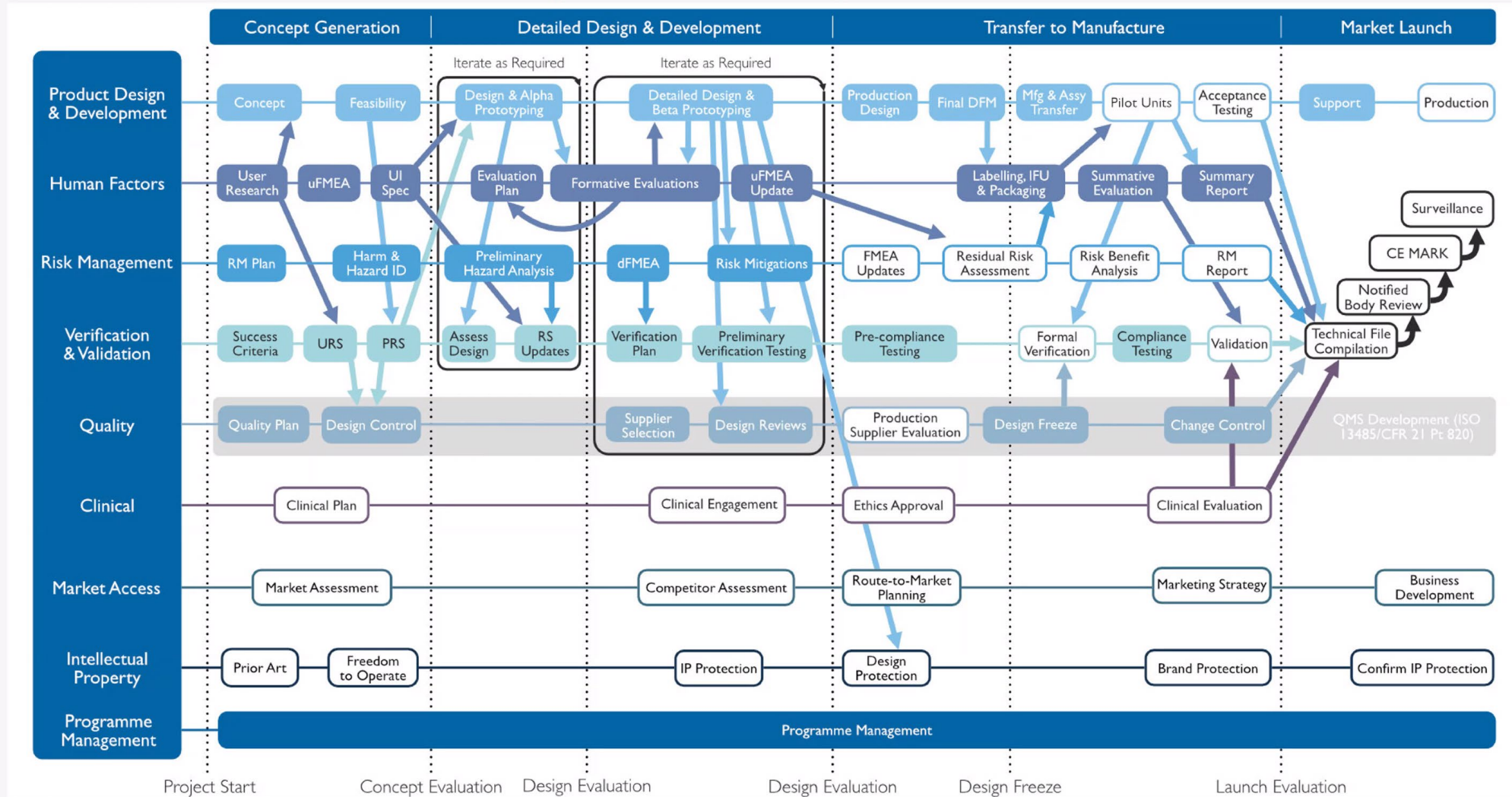
eBPI Product Development & Research Cycle

Cycle	SME & PPI	Research Package	Equivalent Phase in Drug Development	Medical Device Requirements MHRA/EU MDR
Early Alpha Phase Concept Development & SME Translation	YPAG: PAG: Focus Groups SMEs Understanding our user needs	WP1: First product development: Early prototype development	Product Development Lab work	Evidence base & Effectiveness for ‘Intended Purpose’. <ul style="list-style-type: none"> ➤ Safety ➤ Reliability ➤ Data and IT management & security ➤ Acceptability ➤ Implementation
Alpha Phase Testing Healthy volunteers	YPAG: PAG: Focus Groups: SMEs: Young people: Adolescents	WP2: First Version Testing Usability, acceptability, safety, data management	Phase I	
Beta Phase Testing Patients not in treatment setting	Ditto plus: Patients & Service Staff	WP3: Second Version: Ditto, quality assurance, data collection strategy, target audience testing,	Phase IIa	
Live in subjects Testing Patients in treatment setting	Ditto:	WP4: Live in subject and setting testing RCT	Phase IIb/III (Pilot to Pivotal RCTs)	Good clinical practice (GCP ISO 14155). IRAS and MHRA aligned application.

Our NIHR Wait Less Study Strategy for Translational Success



The Development Process | What it's really like!



Summary

- Current services cannot meet current need
- Digital innovation must be part of the solution
- Policy enablers are accelerating opportunity
- But the landscape remains complex
- We recommend planning for translational success
- We hope to report our findings soon the digital BPI journey may assist others
- And most of all help more young people and families

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Thank you



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References

- **Department of Health and Social Care. (2025).** Fit for the Future: 10 Year Health Plan for England. CP 1350. ISBN: 978-1-5286-5807-2. Retrieved from <https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future>
- **Goodyer, I., & Kelvin, R. (2023).** Brief Psychosocial Intervention for Adolescents: Keep it Simple; Do it Well. Cambridge University Press. ISBN: 9781108984546
- **Kelvin, R.G. (2005).** Capacity of Tier 2/3 CAMHS and Service Specification: A Model to Enable Evidence Based Service Development. Child and Adolescent Mental Health. Volume 10, Issue 2 pp. 63-73. doi.org/10.1111/j.1475-3588.2005.00120.x
- **Medicines and Healthcare products Regulatory Agency (MHRA). (2025).** Software and artificial intelligence (AI) as a medical device. GOV.UK. Retrieved from <https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device>
- **Medicines and Healthcare products Regulatory Agency (MHRA). (2025).** Statement of Policy Intent: Early Access to Innovative Medical Devices. GOV.UK. Retrieved from <https://www.gov.uk/government/publications/statement-of-policy-intent-early-access-to-innovative-medical-devices/statement-of-policy-intent-early-access-to-innovative-medical-devices>
- **National Institute for Health and Care Excellence (NICE). (Updated 2023).** Evidence Standards Framework for Digital Health Technologies. <https://www.nice.org.uk/what-nice-does/digital-health/evidence-standards-framework-esf-for-digital-health-technologies>
- **Smith, L. , Dave, S., Seviratne, T. & Chrichton, J. (2025)** Reclaiming our medical identity. RCPsych Insight Spring 2025