

# INGENIEURIE MEDICALE

DE LA RECHERCHE AUX PREMIERES UTILISATIONS CHEZ L'HUMAIN

ANNE VANHOESTENBERGHE

Manufacture of Active Implants and Surgical Instruments (MAISI)  
School of Biomedical Engineering and Imaging Sciences King's College London

8 OCTOBER 2024



**Manufacture of  
Active Implants &  
Surgical Instruments**



# IMPACT OF HEALTHCARE ENGINEERING RESEARCH

IMPACT

PIPELINE

TRANSLATION

REGULATORS

TIME

FUNDING

- Improve quality of life
- Improve healthcare services
- How?
  - ▶ NEW MEDICAL DEVICE: clinical adoption
  - ▶ NEW “BASIC SCIENCE” DEVICE: new understanding of physiological process
  - ▶ NEW TECHNOLOGY: used in novel medical or basic science devices

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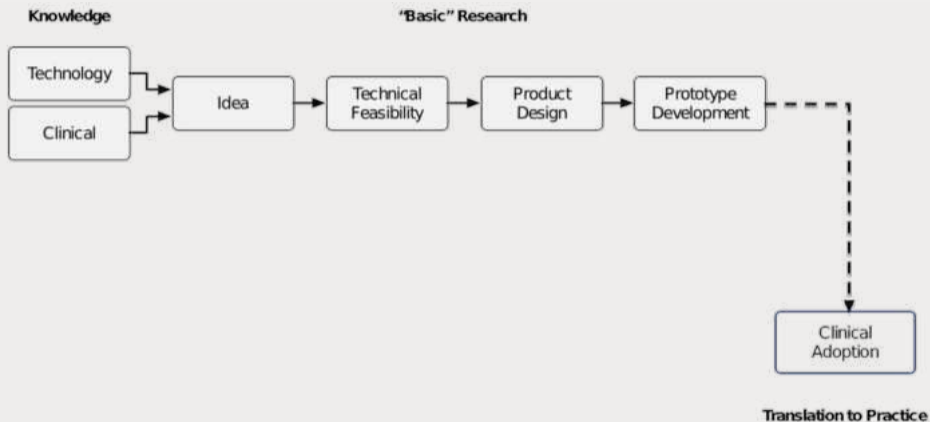
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# HEALTHCARE INNOVATION

Healthcare Engineering translation pipeline.



# TECHNOLOGY READINESS LEVELS?

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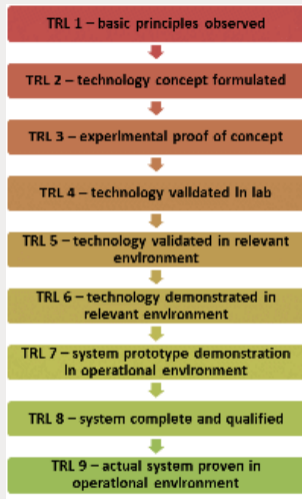
TRANSLATION

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- Early TRL: new material, new actuation method, new sensor, new algorithm...
- TRL 4-7: Validation, systematic testing, multiple batches, statistics
- Need system integration
- Progression through TRLs is not linear



TRLs from Horizon Europe

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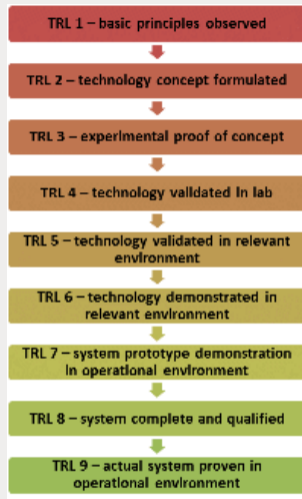
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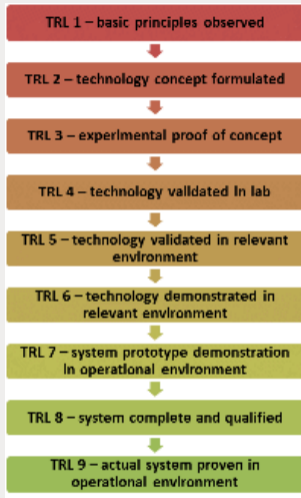
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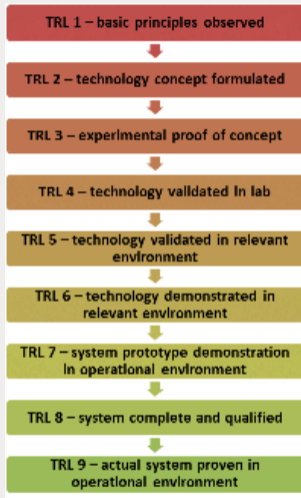
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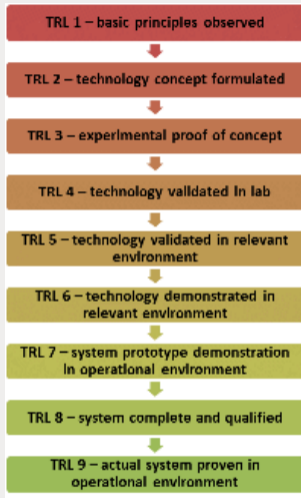
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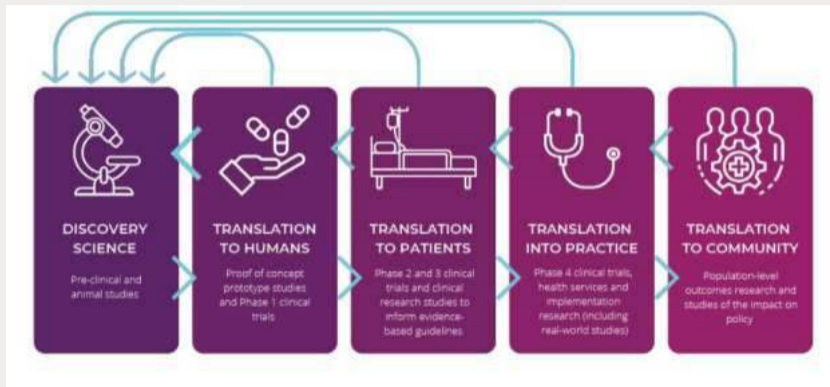
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NCRI Beyond the Horizon - Bridging the translational Gap

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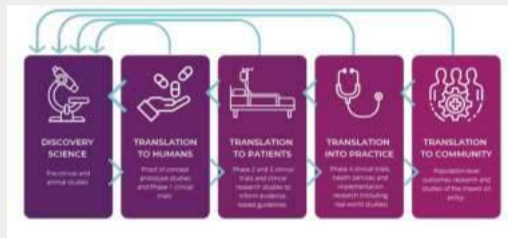
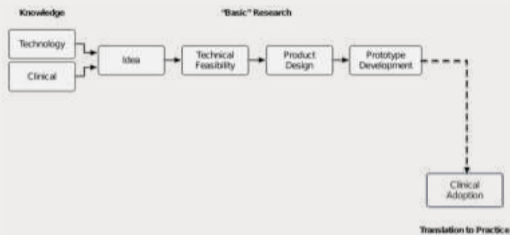
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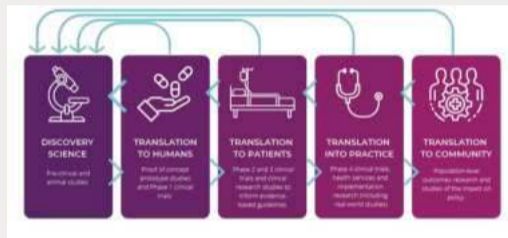
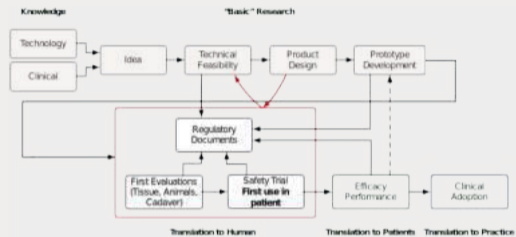
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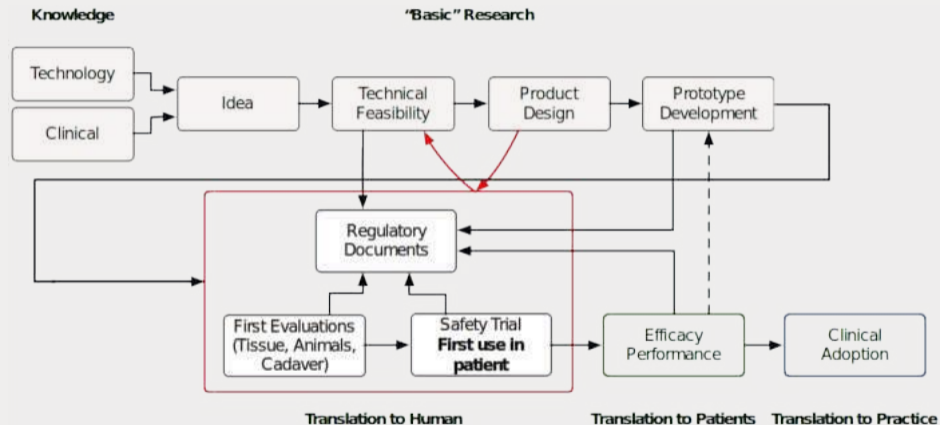
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# TRANSLATION: BENEFITS OF A CULTURE CHANGE

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## SYSTEMATIC REVIEW article

Front. Digit. Health, 03 August 2022

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Implementation

<https://doi.org/10.3389/fdg.2022.957367>

## Translational research in health technologies: A scoping review



Nadja N. V. Mayrink<sup>1,2\*</sup>



Luis Alcoforado<sup>1,5</sup>



Arthur Chioro<sup>4</sup>



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 Thaisa S. Lima<sup>8</sup>,  Erika B. Camargo<sup>9</sup> and  Ricardo A. H. Valentin<sup>2</sup>

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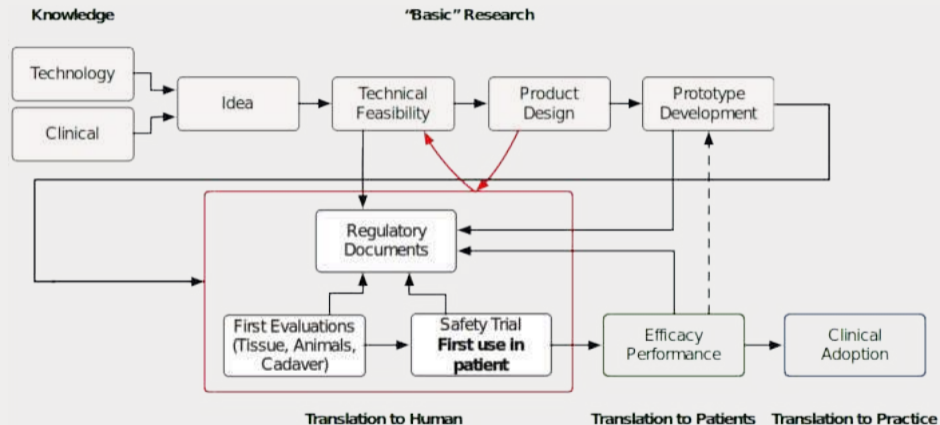


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# CHALLENGES TO TRANSLATION

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- Financial and time costs
- Regulatory approval
- Innovation risks: not undertaken by industry or commercial investors
- Manufacture under design control and quality compliance



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## 3.2 Clinical trial problem

For new kinds of devices, such as for PMA regulated in the United States, the biggest hurdle can come at the very end with the clinical trials. One never knows if it really works until clinical trials have been done at significant financial and time costs. Whenever possible, the failure risk of pro-

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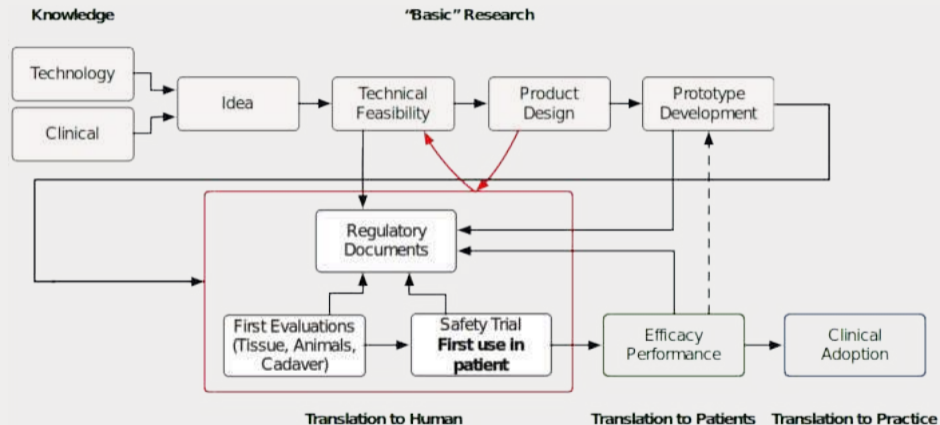
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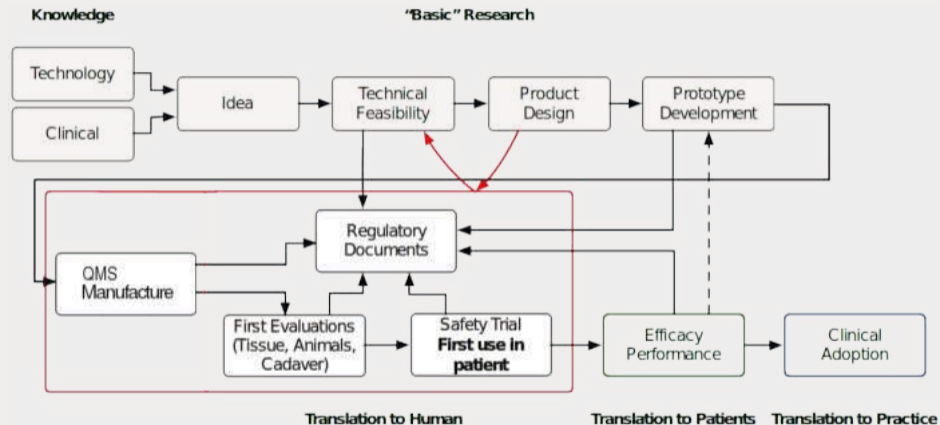
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# FROM TRANSLATIONAL PIPELINE TO MEDICAL DEVICE LIFECYCLE AS SEEN BY REGULATORS...

# MEDICAL DEVICE LIFE CYCLE IN THE EU AND UK

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Device Lifecycle



Concept



Strategy &  
Technical  
File



Approval &  
Certification



CE/UKCA  
Mark



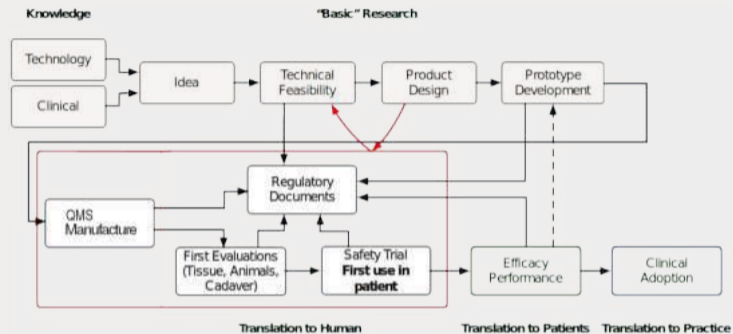
Launch



Post market

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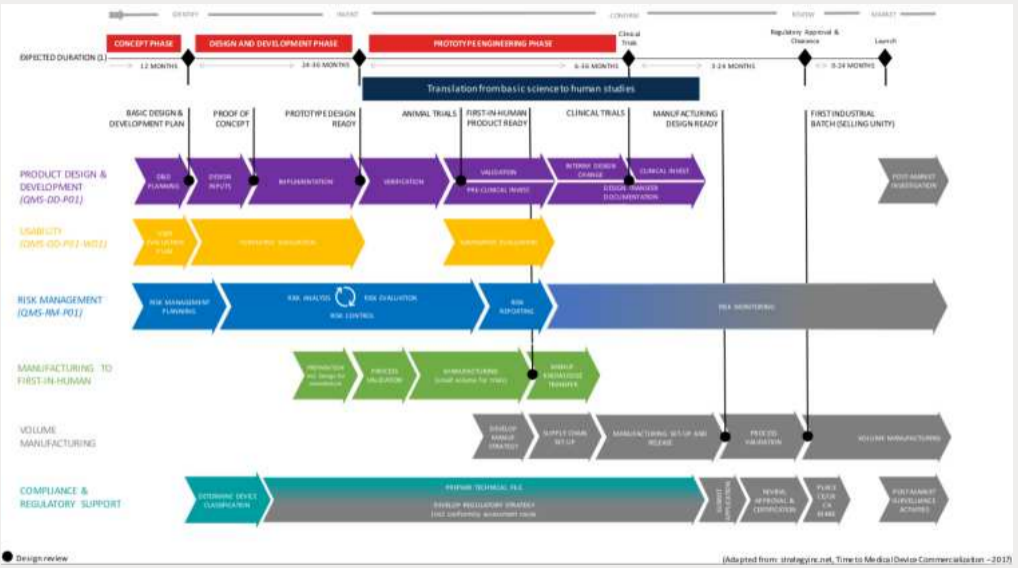
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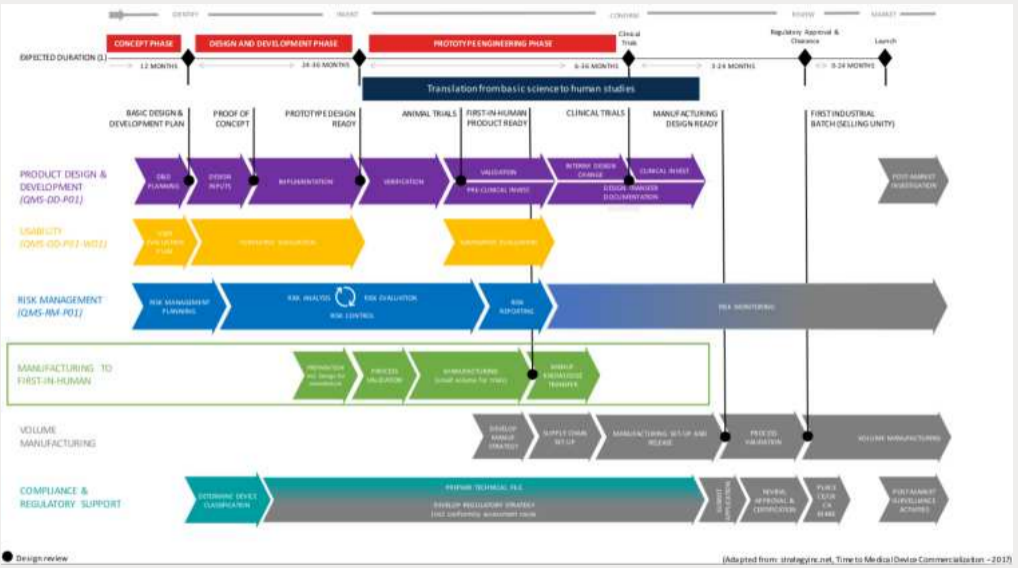
## Device Lifecycle



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# AIMD TRANSLATION: HOW LONG DOES IT TAKE?

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## UroMems Initiates First-in-Human Study of Its Smart Implant to Treat Stress Urinary Incontinence

NEWS PROVIDED BY  
[UroMems](#) →  
Nov 29, 2022, 10:00 ET

SHARE THIS ARTICLE



*This initial clinical trial is a key milestone in the development of its UroActive™ System*

GRENOBLE, France, Nov. 29, 2022 /PRNewswire/ -- [UroMems](#), a global company developing breakthrough, mechatronics technology to treat stress urinary incontinence (SUI), announced today that it has successfully completed the first-in-human implant of the UroActive™ System, the first smart automated artificial urinary sphincter (AUS) investigational device to treat SUI. This initial clinical study is a key milestone in the development of UroActive.



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Philippe Cinquin, P. Mozer, H. Lamraoui, Agnès Bonvilain, G. Robain. Dispositif de prévention des fuites urinaires. France, N° de brevet: FR0757159. 2007. (hal-00419384)



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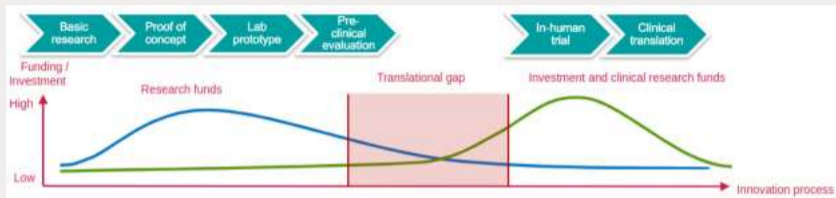
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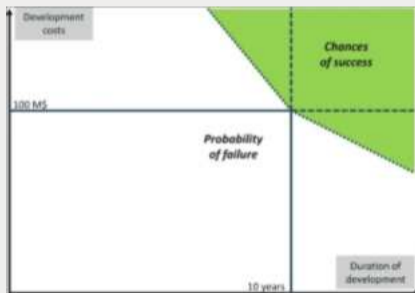
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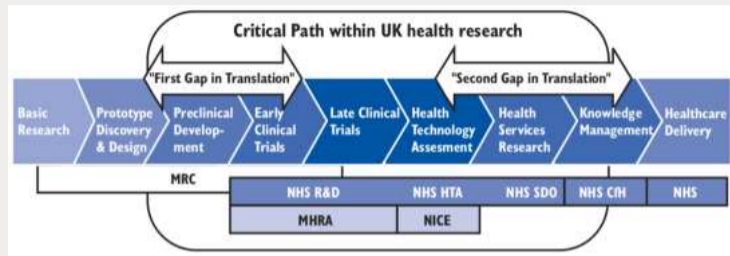


Clare Heysman - KCL



Claude Clement - BCI presentation - 2022

# TRANSLATIONAL FUNDING



Cooksey report 2006

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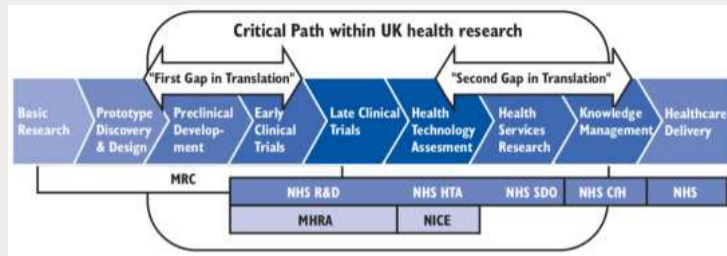
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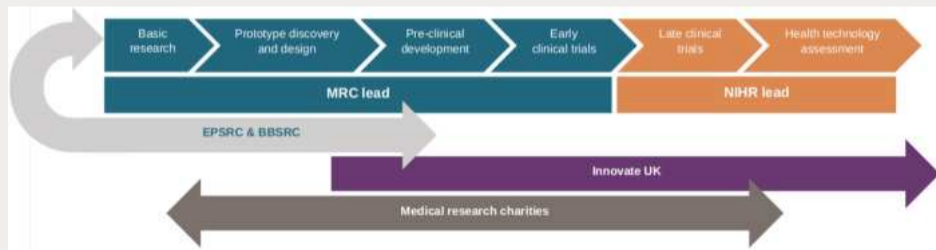
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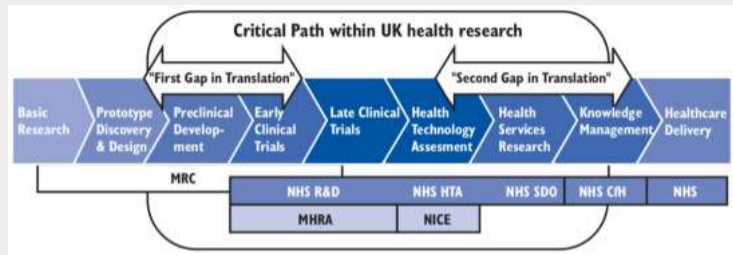
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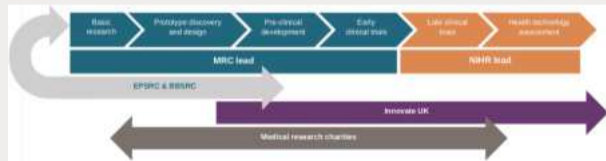
MRC report 2018

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THE END

THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS?

A . VANHOEST@KCL . AC . UK