

MedTech BEST

Session 2 23 January 2018

# **B**usiness and **E**ntrepreneurial **S**kills **T**raining

Stages of Translation

Translation Gaps

Drivers for Innovation

# MedTech BEST

## Module Objectives

- Training in business skills needed for translation of MedTech research into the clinic and market
- Learn about how to put a business plan together and how to make a pitch
- Learn about what makes a good (successful) product
- Learn about the barriers to translation of MedTech
- Compete with other teams
- Have fun!

“Nothing is accomplished in the real world unless it is adopted by industry.

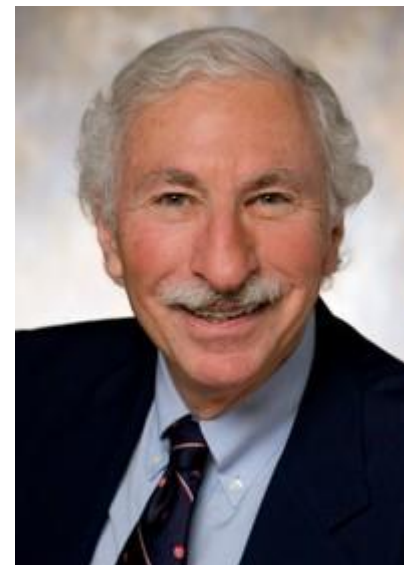
Academic scientists do not manufacture devices.

A paper in Science cannot save lives.

How to repay the taxpayers supporting academic research?”

*Buddy Ratner*

*Biomaterials Scientist & Entrepreneur*



See David Farrar talk on NPD on MedTech BEST site (Sector Specialist Presentations, January 2017)

# MedTech BEST

## Today

- Lekha Koria – MedTech BEST 2017
- Info session on Translation, Translation gaps and why we need innovation
- Team session on idea generation for products to meet your chosen clinical need

# Lekha



# Importance of Translation

Translation is Key to Technology Adoption and Commercialisation!

Adapted from:  
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glasbergen.com

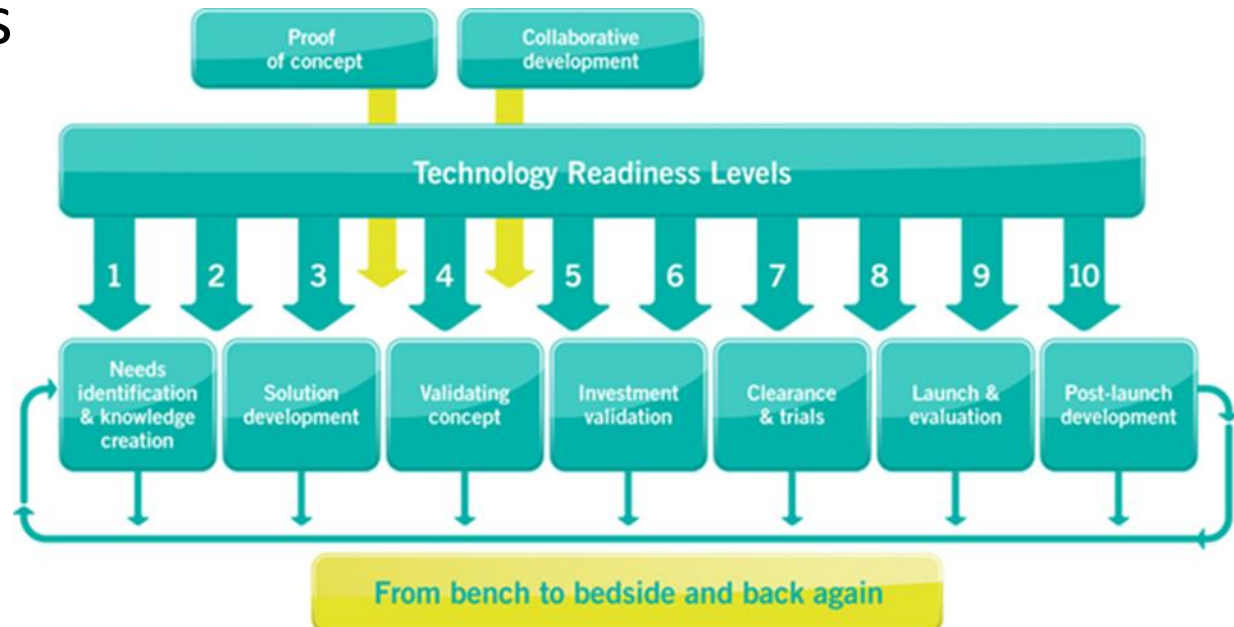
*"I'm afraid you're suffering from an increased IL-1 $\beta$  and an aberrant miR843 expression"*



Translation allows academic researcher to understand the language of business and medicine ...as they come to understand the needs, challenges and constraints faced by these stakeholders

# Stages of Translation

- From bench to bedside is important statement of intent!
- Idea has to be translated in stages to the market
- Technology Readiness Level (TRL) system one tool to manage this

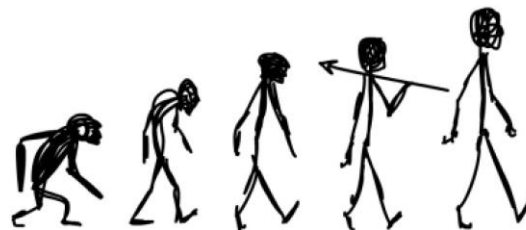


# TRLs

- Introduced by NASA in mid-1970s as a discipline-independent process to allow assessment of the maturity of new technologies.
- Also proved useful as a communication tool describing these technologies
- TRL scale strengthened in 1995 by definitions of each level, along with examples (J. Mankins, NASA White Paper)
- Now widely adapted and used by diverse organisations – eg new Royce Institute in Manchester organised into early stage TRLs (1-5 “Academic Research”) and “Industry-led” (3-6)

## Technology Readiness Level

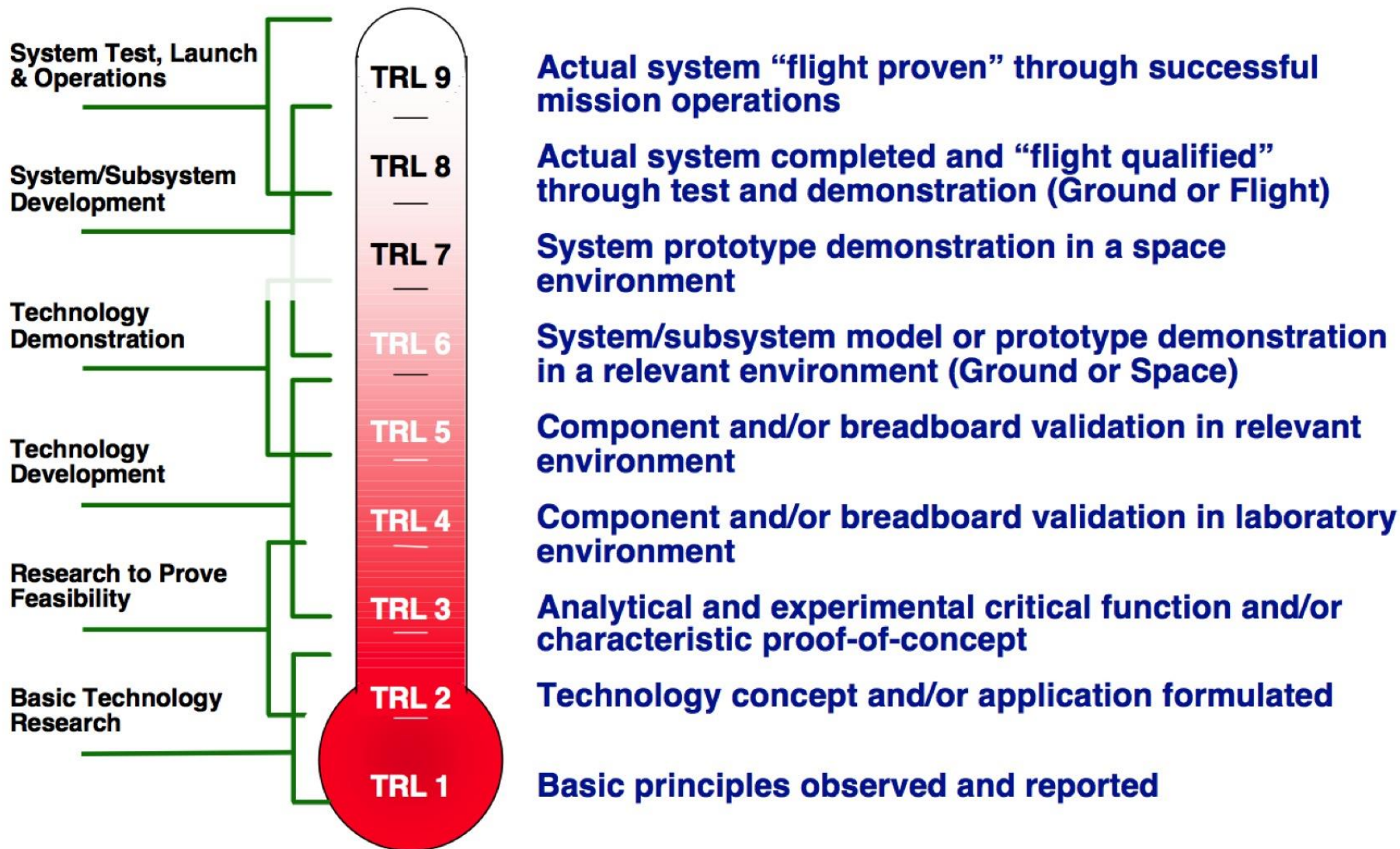
# TRL







# NASA/DOD **Technology** Readiness Level

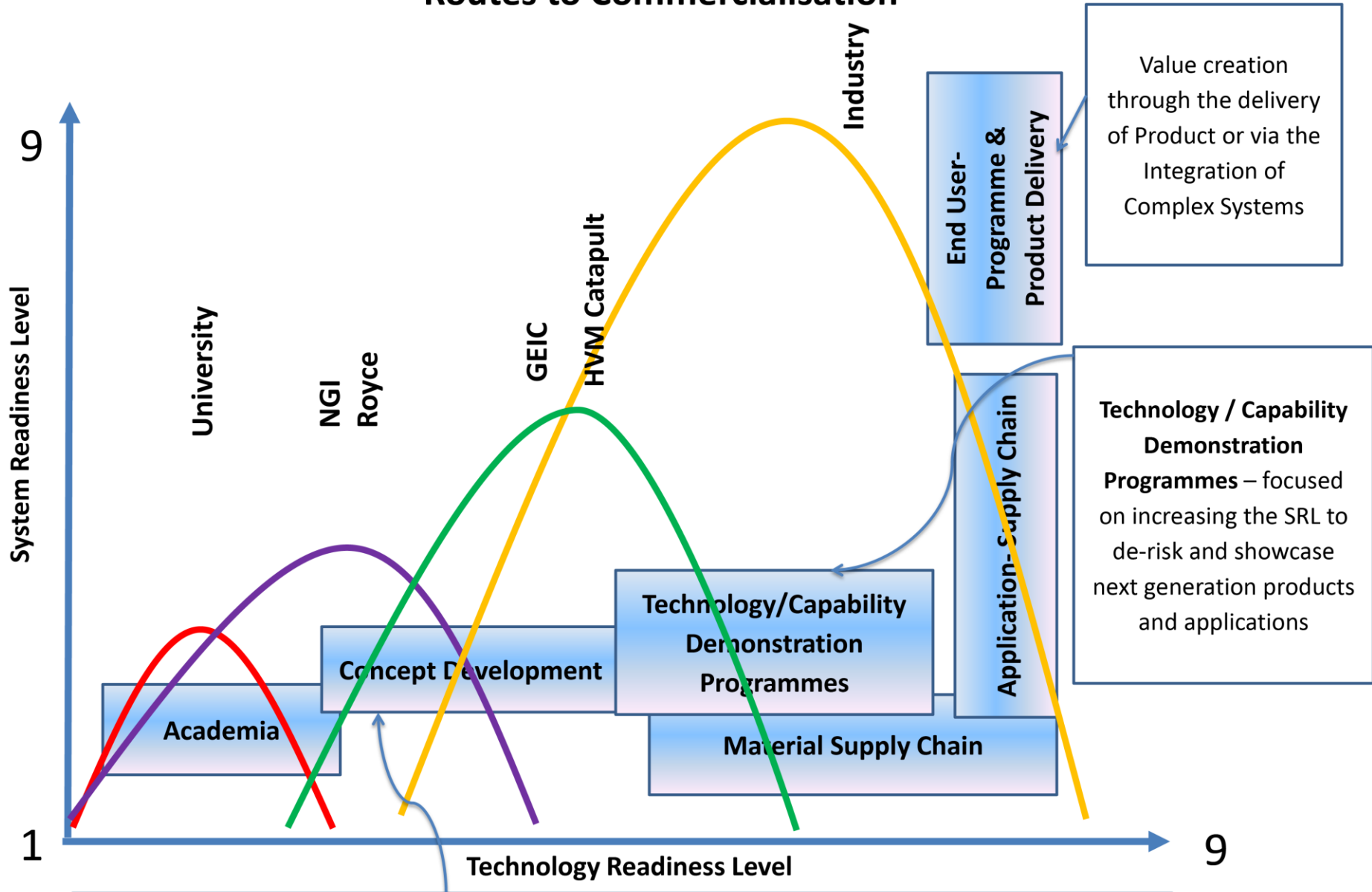




# Technology Readiness Levels

- TRL 0: Idea.** Unproven concept, no testing has been performed.
- TRL 1: Basic research.** Principles postulated and observed but no experimental proof available.
- TRL 2: Technology formulation.** Concept and application have been formulated.
- TRL 3: Applied research.** First laboratory tests completed; proof of concept.
- TRL 4: Small scale prototype** built in a laboratory environment ("ugly" prototype).
- TRL 5: Large scale prototype** tested in intended environment.
- TRL 6: Prototype system** tested in intended environment close to expected performance.
- TRL 7: Demonstration system** operating in operational environment at pre-commercial scale.
- TRL 8: First of a kind commercial system.** Manufacturing issues solved.
- TRL 9: Full commercial application,** technology available for consumers.

# Routes to Commercialisation

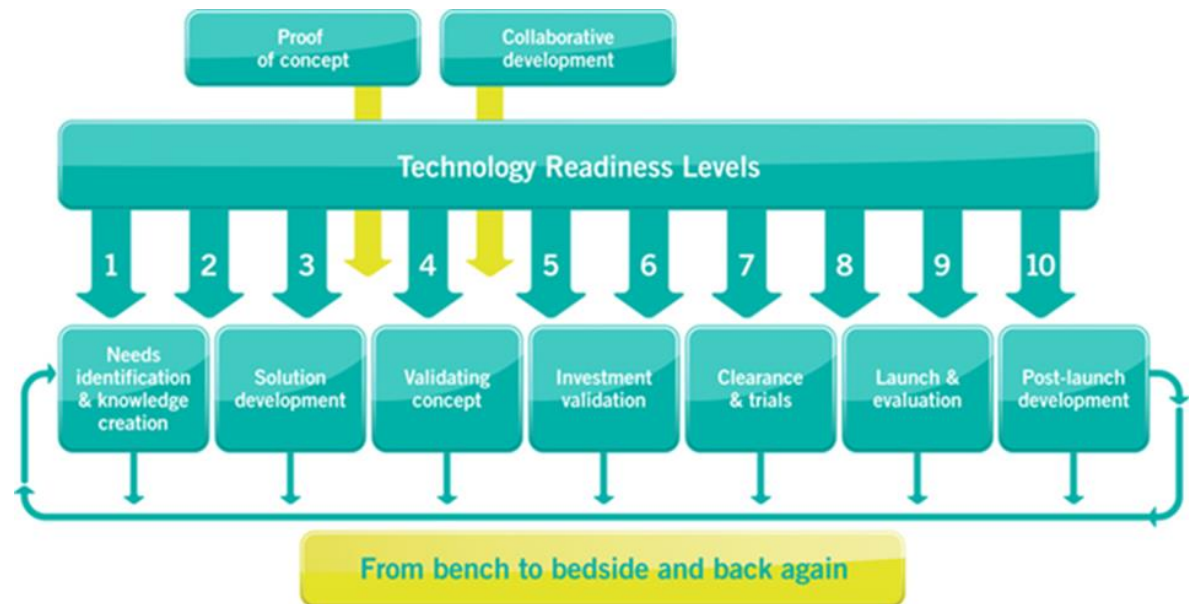


**Concept Development** – focus is on a) increasing the technology development TRL – manufacturing scale up, characterisation and measurement, b) experiment with the art of the possible future applications and concepts and c) provide inputs to Concept Development.



# TRLs in MedTech

- Good way of breaking process into key phases
- Objective criteria need to be developed as deliverables required from each stage
- Different skills and resources needed in different stages
- Lends itself to Stage Gate Management process (discussed last time)
- Note that stage 10 added



*Example of Technology Readiness Levels (TRL) using in medical device development*

# TRLs in MedTech

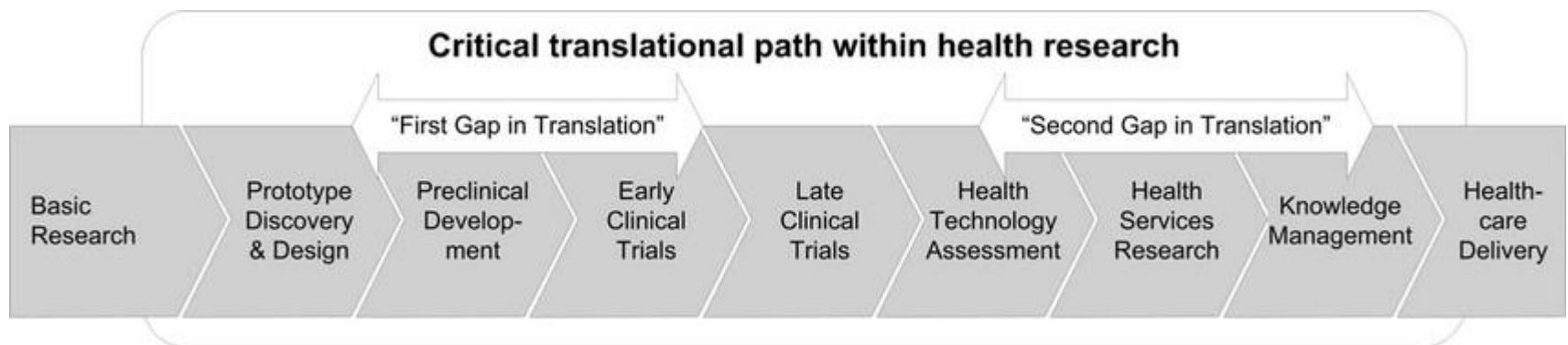
Used in project proposal, scoping and management by MedTech IKC

Technology Readiness Level (TRL)							
1-2	3	4	5-6	7-8	9		10
Clinical need defined & knowledge created	Solution Generation	Investment Validation	Development & Validation	Clearance & Clinical	Outputs	Outcomes	Post Launch Market Support
Define clinical need/relevance Develop/refine solution IP	Generation of Prototypes IP Preliminary Value Proposition Risk Assessment	Market Research FTO searches Pilot Studies	Design Control Regulatory Capability	Market support data Supply Chain Reimbursement considerations Capability Clinical	Regulatory Approval Closure & Evaluation Metrics Feedback	Launch SOP	Product Support data White Paper Product Recall Support
<p><b>TRL:</b> Based on current activities, please indicate “C” for which TRL your project is at, “P” for the TRLs the project expects to progress through to &amp; indicate appropriate dates that these might be achieved by:</p>							

# Translation Gaps

Cooksey Review\* of 2006 identified two major gaps in translation:

- First gap (T1) of “...translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness”
- Second gap (T2) of “...implementing those new products and approaches into clinical practice”
  - ie disconnect between the development and the implementation of new interventions



\*A review of UK health research funding. London: HM Treasury, 2006

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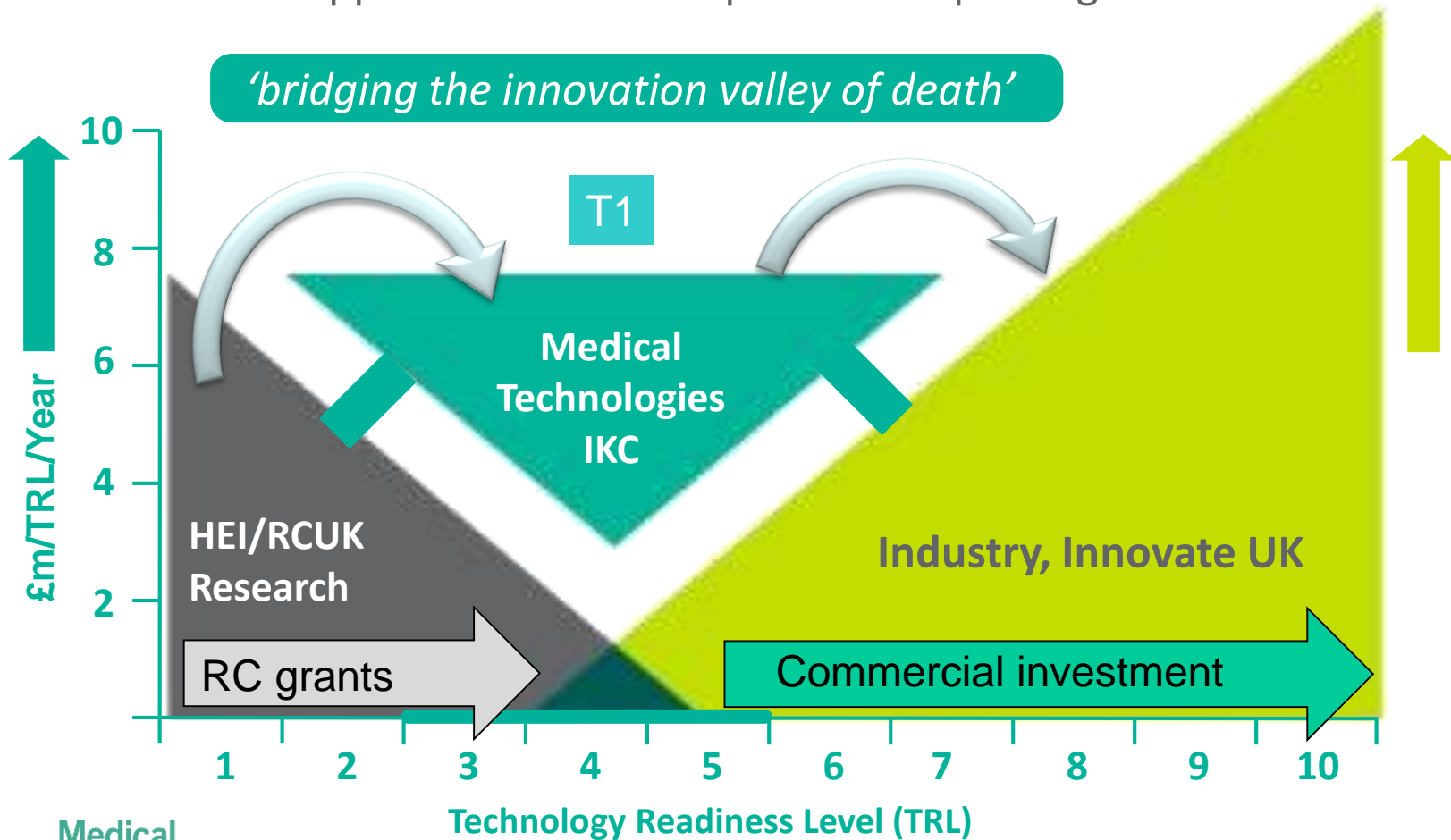
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# Translation gaps are real!

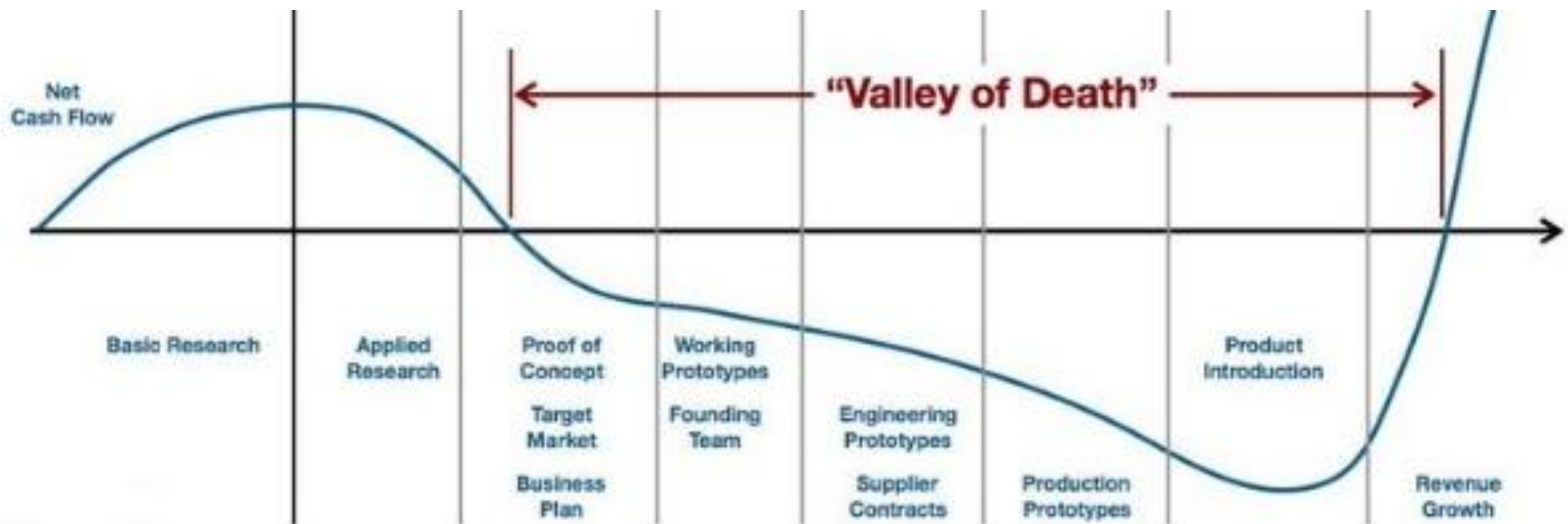
- IKC and Regener8 support innovation to reach TRL 5 and enable real commercial investment
- Limited opportunities in this space but improving





# Translation – company challenges!

- Difficult!
  - Technology is the easy part!
- Funding barriers, structural barriers
- Technology adoption





# Start Up Phases and translation



## Ideating

Entrepreneurial ambition and/or potential scalable product or service idea for a big enough target market. Initial idea on how it would create value. One person or a vague team; no confirmed commitment or no right balance of skills in the team structure yet.

## Concepting

Defining mission and vision with initial strategy and key milestones for next few years on how to get there. Two or three entrepreneurial core co-founders with complementary skills and ownership plan. Maybe additional team members for specific roles also with ownership.

## Committing

Committed, skills balanced co-founding team with shared vision, values and attitude. Able to develop the initial product or service version, with committed resources, or already have initial product or service in place. Co-founders shareholder agreement (SHA) signed, including milestones, with shareholders time & money commitments, for next three years with proper vesting terms.

## Validating

Iterating and testing assumptions for validated solution to demonstrate initial user growth and/or revenue. Initial Key Performance Indicators (KPIs) identified. Can start to attract additional resources (money or work equity) via investments or loans for equity, interest or revenue share from future revenues.

## Scaling

Focus on KPI based measurable growth in users, customers and revenues and/or market traction & market share in a big or fast growing target market. Can and want to grow fast. Consider or have attracted significant funding or would be able to do so if wanted. Hiring, improving quality and implementing processes

## Establishing

Achieved great growth, that can be expected to continue. Easily attract financial and people resources. Depending on vision, mission and commitments, will continue to grow and often tries to culturally continue "like a startup". Founders and/or investors make exit(s) or continue with the company.



# Translation traps

- Difficult!
  - Technology is the easy part!
- Funding barriers, structural barriers
- Challenge for SMEs to avoid

“We call them the walking dead,” said one manager at a tech behemoth, who requested anonymity. “They don't necessarily die. They putter along.”



Valley of Death

or



Walking Dead

# Innovation

- Drivers for innovation?
  - Societal and demographic trends
  - Financial and market conditions
  - Regulated environment
  - Government policies and support
  - Combination – eg NHS pressures
- Innovation in resource-limited context
  - Local vs global development
  - Ensure thorough understanding of customer needs and deliverables



# Med Tech & Devices

## Global Markets and UK Industry

Global market

UK Industry GVA

Total >£1200bn

Engineering £280bn

>\$500bn

Medical  
technology

£18bn

\$75bn

MSK Implants  
+ biomaterial  
devices

£2bn

↑ \$25bn

Regenerative  
devices

*Our vision*

↑ £1bn

by 2020

# Drivers for Innovation?

- Societal and demographic trends
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- Sector trends



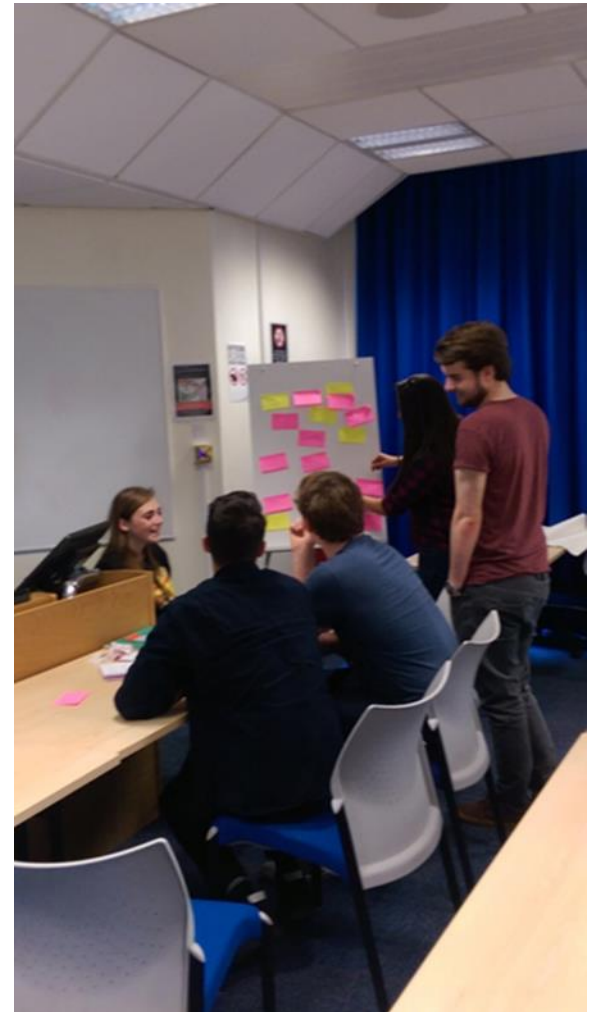
# Drivers for Innovation?

- Societal and demographic trends
  - Ageing population
  - Rise in chronic diseases
- Financial and market conditions
  - Consider strength of competition
  - Size of market and how well served
  - Customer expectations
- Regulated environment
  - Narrow window of conformance
  - Risk vs benefit – evidence needed
- Government policies and support
  - Funding programmes to stimulate
  - Taxes to restrict
- Combination – eg NHS pressures
- Sector trends
  - Short lifecycles – frequent improvements needed

# RECAP

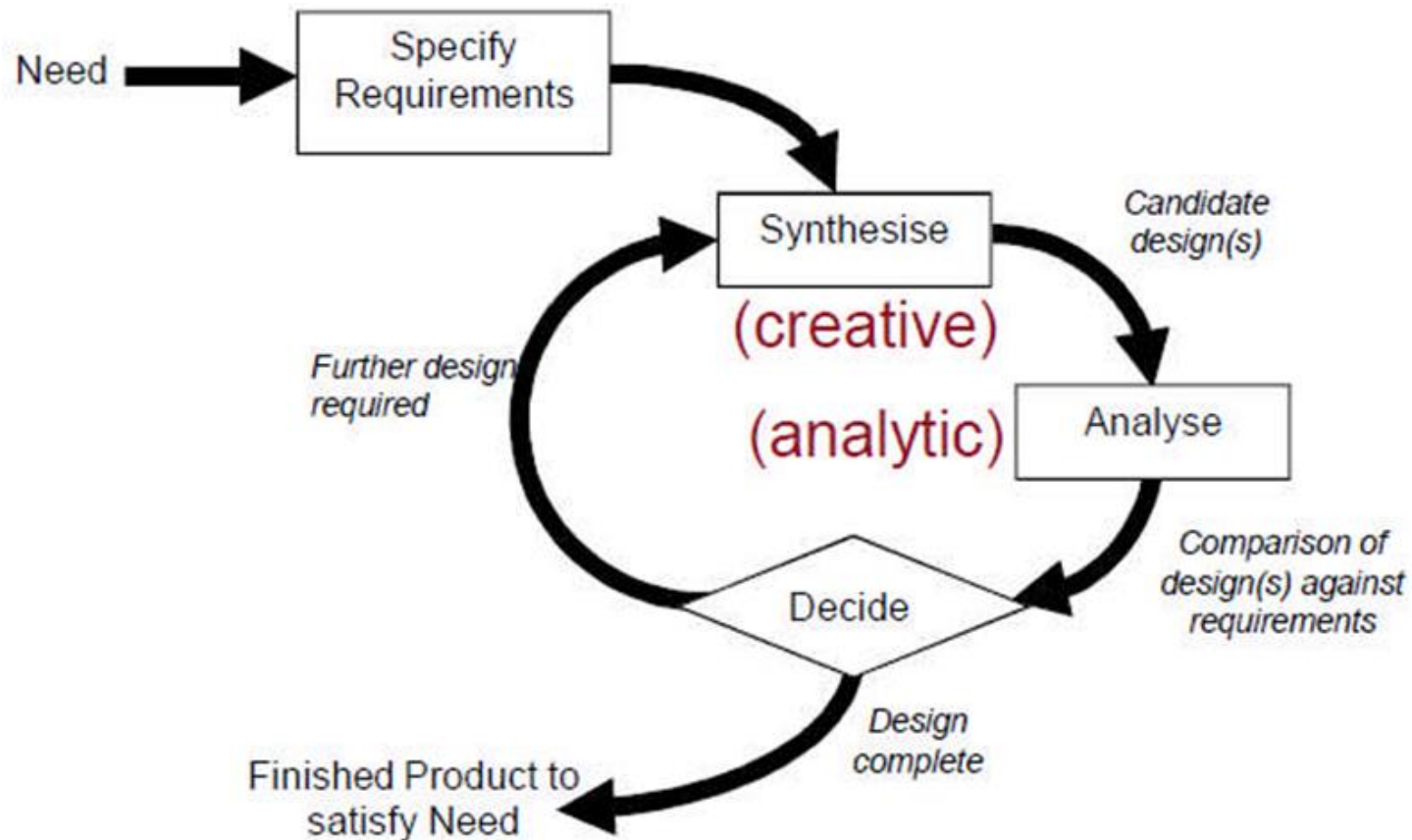
## Idea Generation and Selection – Now for your BIG IDEA!

- You are going to BRAINSTORM potential ideas
- DEVELOP the most promising ideas
- SELECT the best idea(s)
- Form into small teams





# Idea Generation and Selection – Now for your BIG IDEA!





# Idea Generation and Selection – BRAINSTORMING

- As many ideas as possible - even if they seem ridiculous!
- No such thing as a silly idea - record all ideas
- Impractical ideas OK!
- No criticism
- No judgements
- “Yes and”....not “Yes but” – build on ideas; combine and improve
- Stay focused!



## Idea Generation and Selection – IDEA DEVELOPMENT

- Cluster related ideas – can a better idea be distilled from joining these up?
- Ask questions among your team to **clarify** an idea or group – re-write/re-word the idea if needed; screen out those ideas (even though they may be good) that don't fit the **brief**.
- Each team member to cast 3 votes to choose best ideas – can place all 3 votes on the same idea if desired!



# Idea Generation and Selection – IDEA SELECTION

- Take top idea(s) and discuss “what I like” and “what needs improving” amongst your team
- Reach consensus on the idea you will go with – hold a vote only as a last resort!
- **You have your big idea!**
  - For clinical unmet need/poorly met need
  - Move on to innovation/technology/product/service that will meet this need
  - Concept outlined
  - Give it a name and identity – this will be a product name
  - Create an identity/name for the company you will form to commercialise this idea.

# MedTech BEST

## Ways of Working

- Work in teams of ~5
- Each team member to take on a role
- Mentors assigned
- Industry and sector specialists will be contributing to future sessions
- Competition (with prizes)!

# Mentors are a key resource



## Next Session

7 February 2018

- Business Plan and Value Proposition
- Requirements for translation of idea to product concept & prototype
- IP
- Stages of start-up development
- In teams: product concept refinement; company mission, value and strategy



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