

MedTech BEST

Session 5

13 March 2018

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

Business Plan & Opportunity Note

Financial requirements and sources of funding

Routes to Market

Stage Gate process

# MedTech BEST Today

## Info sessions on

- Business Plan and Opportunity Note
- Financial requirements and sources of funding
- Routes to Market
- Stage Gate

## Team sessions on

- Business plan (identify/close gaps)
- Opportunity Note
- Cashflow
- Stage Gate review

# MedTech BEST Entrepreneur

“There's one thing I've learned about entrepreneurs' business plans. Every one is wrong.”



Josh Kopelman, serial entrepreneur & venture capitalist, as quoted by BusinessWeek

# Business Plan Introduction

## Your **Business Plan**

- Is foundation of all business activities through all TRLs and Stage-Gates
- Will be your source document on which to base all proposals
- Will be based on assumptions which become more reliable as company progresses (ie de-risked through TRL journey)
- Will incorporate learning from Value Proposition
- Will be asked for by investors
- Will be used to generate your **Opportunity Note** to submit to MedTech BEST judges



# Business Plan Sections

1. Intro/Executive Summary
2. Business Overview
3. Market Opportunity
4. Product (or Service)
5. Sales & Marketing Strategy
6. Team/Advisory Board
7. Operational Plan
8. Deal Description/Structure/Details
9. Long Term Financing Plans
10. Exit Strategy

You will generate a 2-4 page

**Opportunity Note\*** which will be supported by a detailed Business Plan (20+ pages)

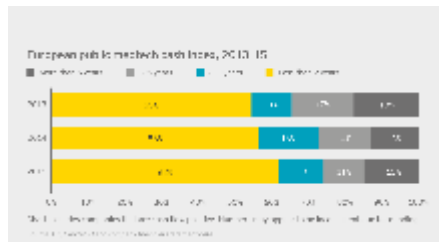
\* May also be referred to as Investment Memo



# Opportunity Note

You will generate a 2-4 page  
**Opportunity Note\*** based on your  
detailed Business Plan

- Supports/becomes part of your pitch
- Example (Swabtech, real!) circulated
- Other models – use graphics, charts, images (you have more space to play with than the Swabtech example)



GrowthAccelerator

## INVESTMENT OPPORTUNITY NOTE

### SUMMARY

**SwabTech Limited**  
Development of a device to  
remove and detect pathogens  
using a swab and a light  
source.

**Office address:**  
The Royal Victoria  
Green  
Manchester, Greater Manchester  
M1 3JH  
0161 275 5782  
[www.swabtech.co.uk](http://www.swabtech.co.uk)  
@SwabTech

**General Information**  
• Medical device  
• Concept phase  
• Established: 2012  
• Pre-revenue  
• UK market, Europe  
• Global market, potential  
• £1.5 million turnover

### Key achievements:

- Conducted successful trials using human blood, 100% detection rate
- First successful trial in a hospital setting
- UK, US and EU patent applications granted
- £1.5 million raised from private investment
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### BUSINESS OVERVIEW

SwabTech Limited is a start-up company that has developed a device to detect and remove pathogens using a swab and a light source. The device is designed to integrate with existing endoscopic procedures, which means that it can be used during surgery, a procedure that is both slow and expensive. The device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens. The device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens. The device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens.

The SwabTech device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens. The device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens. The device is designed to be used in a hospital setting, where it can be used to detect and remove pathogens.

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### MARKET INFORMATION

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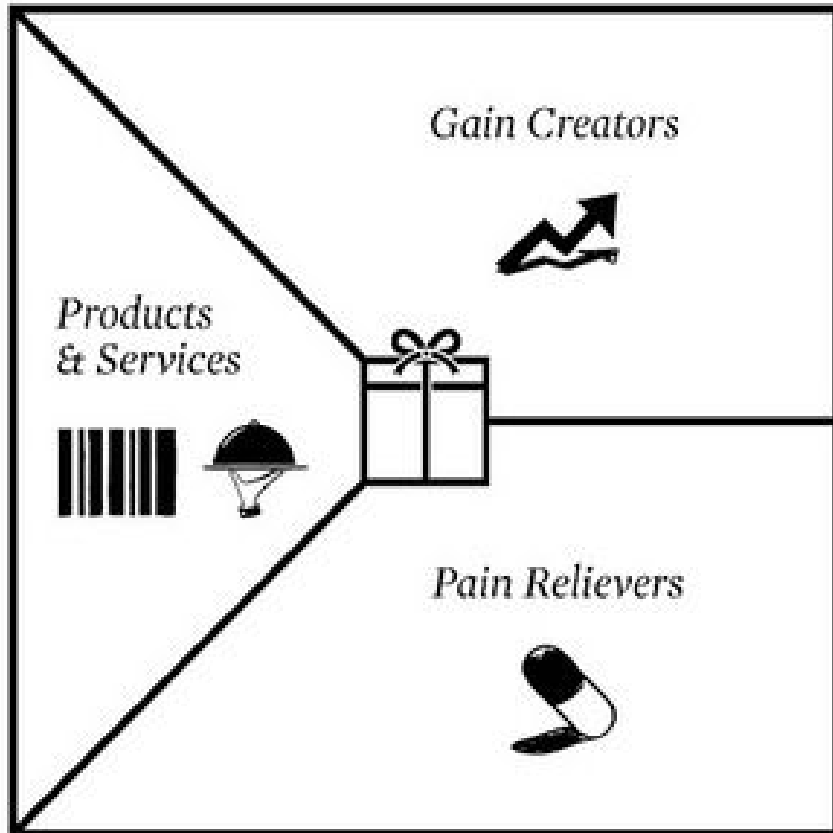
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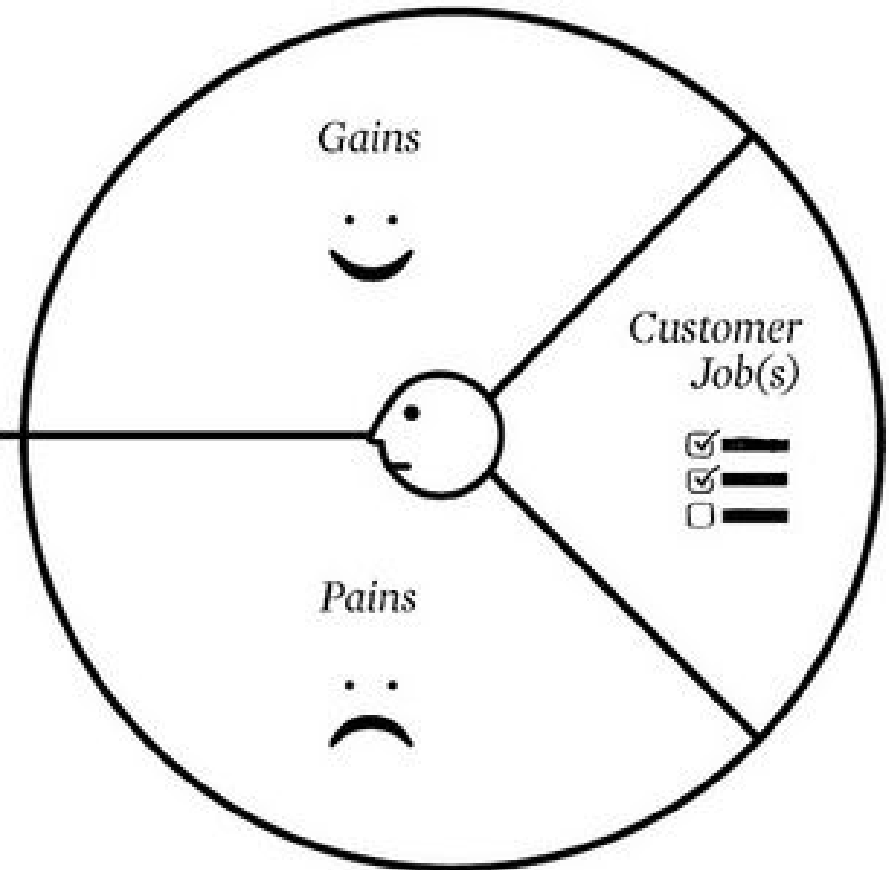
# Value Proposition Canvas – Modified #2

## Use this for your Business Plan/ON

Product:



Customer:



Substitutes:



# Financial requirements and sources of funding



# MedTech BEST Entrepreneur



**PAUL  
GRAHAM**

*Founder,  
Y Combinator*

#1

“That's the secret.


**Convince yourself that  
your startup is worth investing in,  
and then when you explain this  
to investors they'll believe you.”**



**THE SECRET OF RAISING MONEY:**  
THE ENTREPRENEUR'S GUIDE TO  
GETTING FUNDED

# Financial requirements and sources of funding

- All project/NPD stages have a cost!
- These get more expensive as project moves through TRL stages
- You will have a go at estimating these
- Will be needed for:
  - Business Plan
  - Opportunity Note
  - Stage Gate Review
  - Pitch to judges
- Use TRL, Stagegate or NPD Process as your model – the choice is yours.....
- Online tool suggested (see Slide 16)



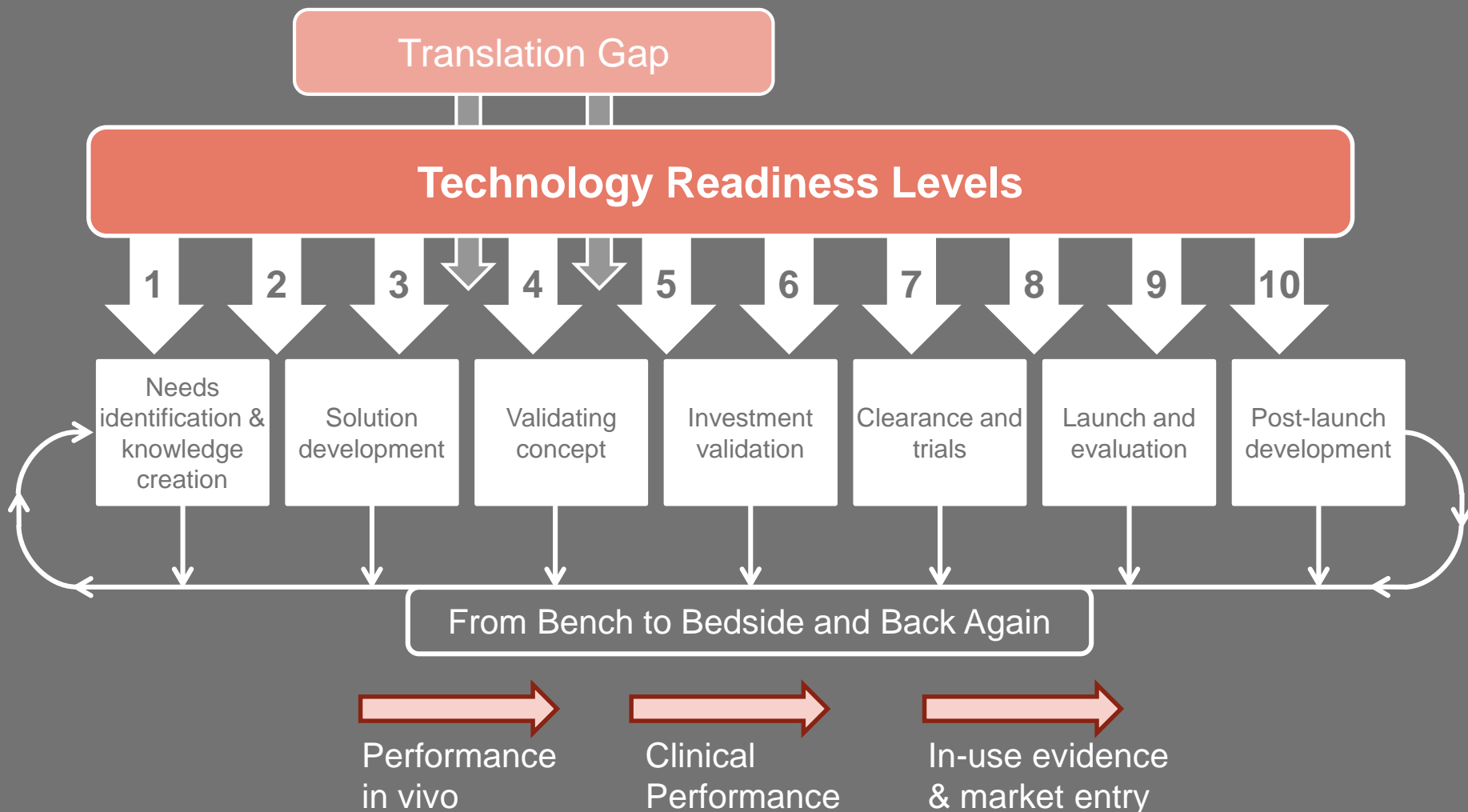
  
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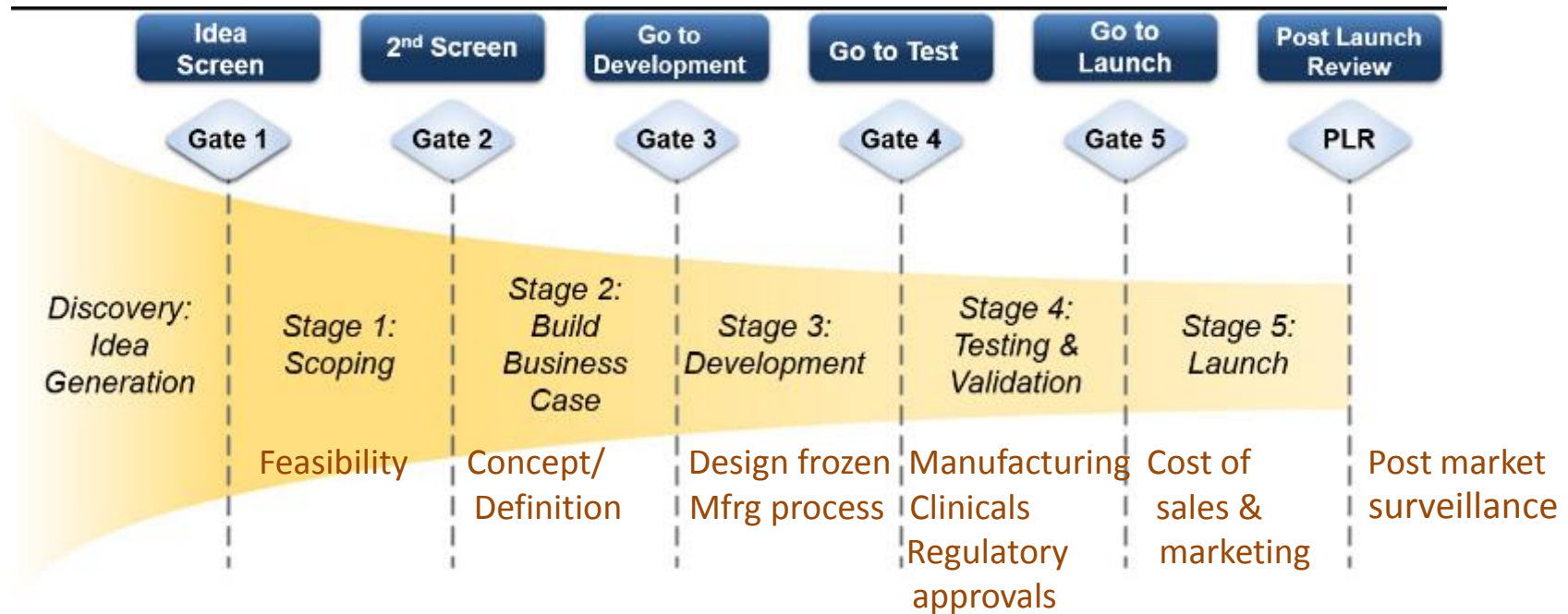
# Translation to clinic and market



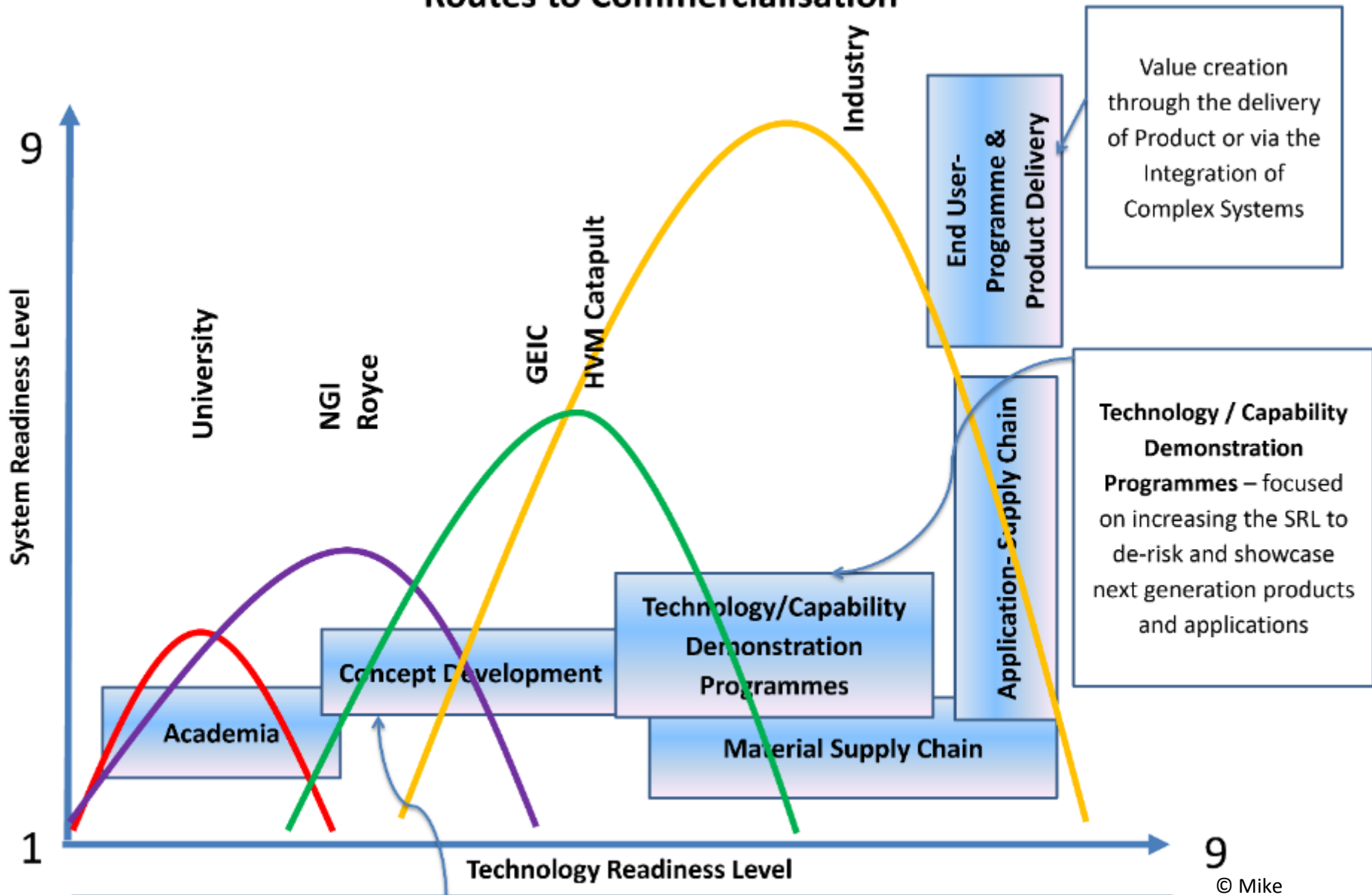
# Development Process

Stage	Description/Activities	
0: Idea creation/gathering	<ul style="list-style-type: none"> <li>Brainstorming</li> <li>Internal R&amp;D</li> <li>Technology scouting</li> </ul>	<ul style="list-style-type: none"> <li>Literature review</li> <li>Companies/Universities</li> </ul>
1: Initiation/Feasibility	<ul style="list-style-type: none"> <li>Initial proposal &amp; business case</li> </ul>	<ul style="list-style-type: none"> <li>Initial proof-of-concept and prototypes</li> </ul>
2: Concept/Definition	<ul style="list-style-type: none"> <li>Full business case &amp; project plan</li> <li>Research Customer Requirements</li> <li>Market evaluation</li> <li>IP Review</li> </ul>	<ul style="list-style-type: none"> <li>Initial regulatory plan</li> <li>Manufacturing plan</li> <li>Further develop/test prototypes</li> </ul>
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4: Transfer to Manufacturing	<ul style="list-style-type: none"> <li>Establish and validate process</li> <li>Approve suppliers</li> </ul>	<ul style="list-style-type: none"> <li>Document procedure</li> <li>Train operators</li> </ul>
5: Regulatory	<ul style="list-style-type: none"> <li>Prepare Technical File</li> <li>Regulatory submission</li> </ul>	<ul style="list-style-type: none"> <li>Obtain regulatory approval</li> </ul>
6: Post Launch	<ul style="list-style-type: none"> <li>Surgeon training</li> <li>Product/Process improvements</li> </ul>	<ul style="list-style-type: none"> <li>Complaints</li> <li>Post-market surveillance</li> </ul>

# Product Development - Stage Gate Process



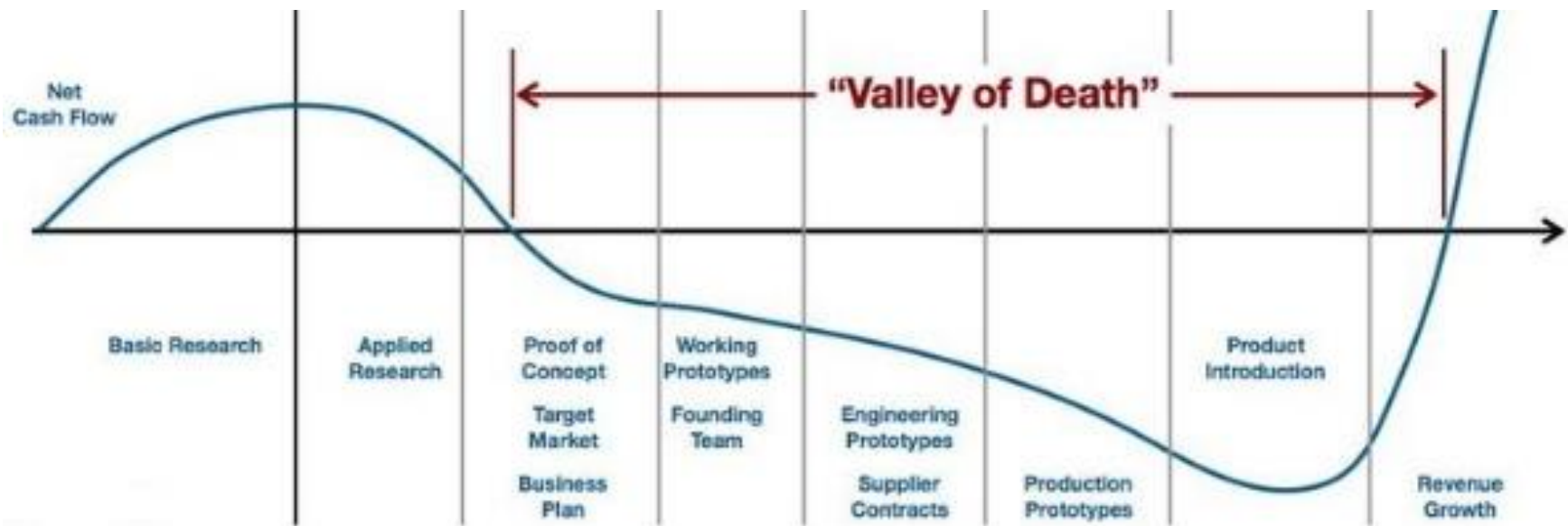
# Routes to Commercialisation



**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.

# Cashflow during Translation

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

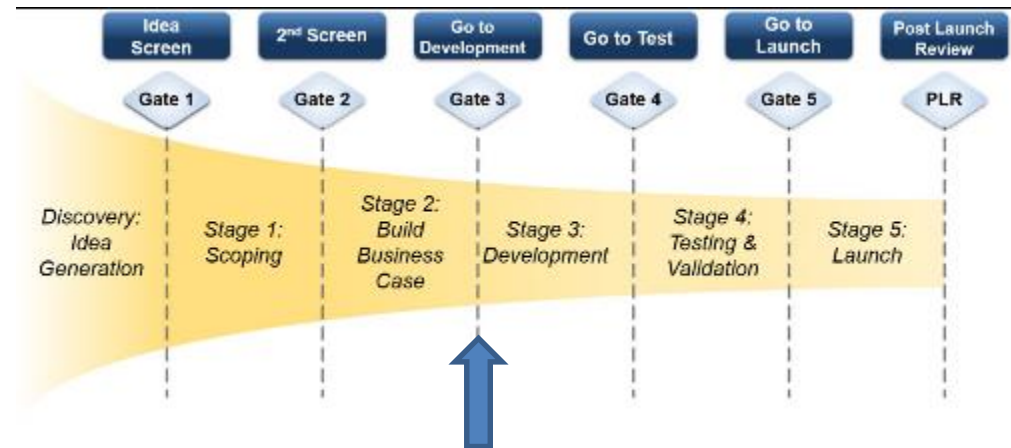




# MedTech BEST

## Financial requirements

How much do you need?  
 Where will you get this from?  
 Use cashflow tool to model?  
[www.startuprunway.io/#/](http://www.startuprunway.io/#/)  
 Do it yourself with Excel?



### You now need to model:

- Costs required to reach **Gate 3**? [assume you have reached this stage and raised/spent this money!]
- Costs required for **Stage 3** (Development) [assume you want to move to this now]
- Cost to reach **product launch**? [Your funders/investors will expect you to have a decent estimate now]

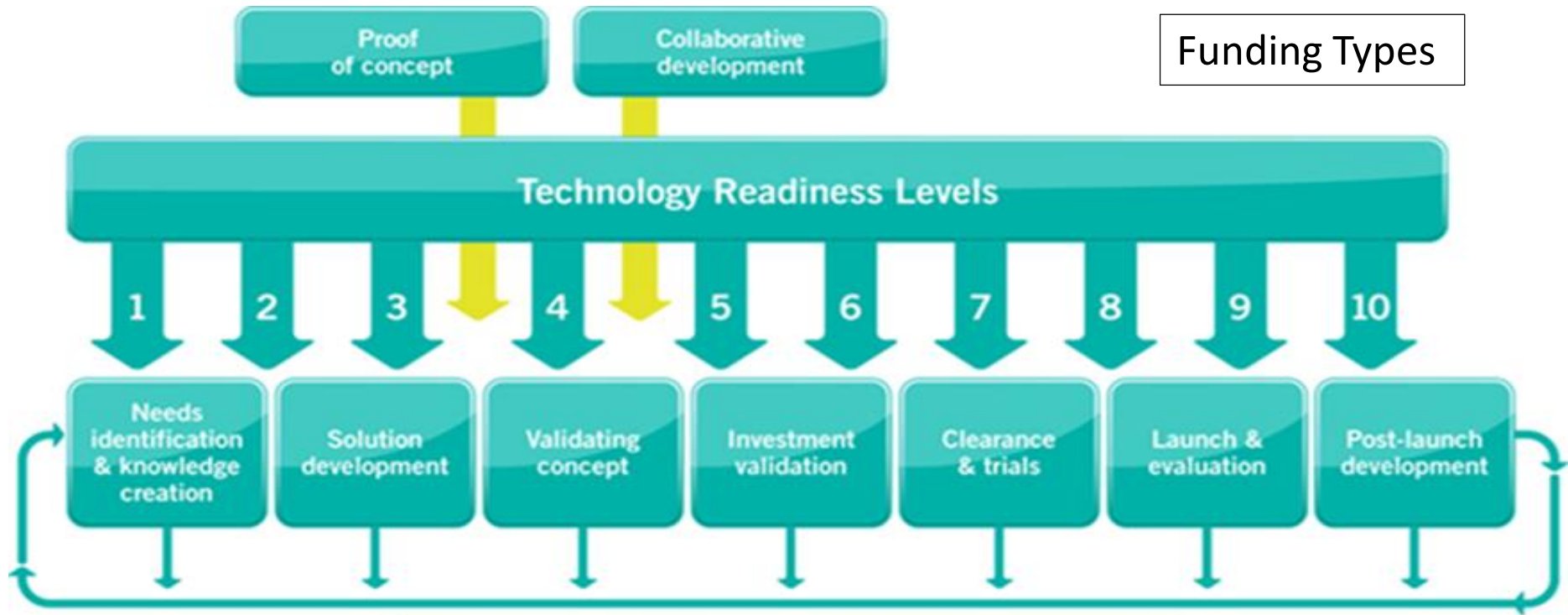




# Financial requirements and sources of funding

- Different stages and TRLs demand different types of funder
- Build the right mix into your business plan

# Funding Types



Day job!  
Friends &  
Family!

Friends &  
Family!  
Seed  
investment  
PoM grant  
Feasibility/  
PoC grant  
Start-up loan  
Innovation  
voucher  
Crowdfunding  
Charities

PoC grant  
Developmt  
grant  
Angel  
investment  
Seed  
investment  
Corporate  
venturing  
Family  
offices

Developmt  
grant  
Angel  
investment  
Corporate  
venturing  
Family offices  
Translational  
grant  
VC investment  
LEP

Corporate  
venturing  
Translational  
grant  
VC investmt  
Licence





Corporate  
venturing  
VC investmt  
Licence  
Convertible  
loan

Corporate  
venturing  
VC investmt  
Licence



Key: PoM = Proof of Market; PoC = Proof of Concept; VC = Venture capital (equity); LEP = Local Enterprise Partnership

# MedTech BEST Entrepreneur

WEIGHING THE PROS AND CONS OF FUNDING SOURCES		
	ADVANTAGES	DISADVANTAGES
 <p>DEBT</p>	Bank debt allows the founder to <u>maintain full control of the business</u> .	Bank debt is mainly about cash—it doesn't provide any of the <u>non-financial benefits</u> of other types of financing.
 <p>EQUITY</p>	VC-backed companies have <u>faster employee growth, greater sales, and faster sales growth</u> .	Misaligned incentives can cause firms to IPO earlier than optimal, or <u>founders to be replaced</u> .
 <p>CROWDFUNDING</p>	Crowdfunding can help entrepreneurs <u>get feedback</u> and determine the validity of their idea.	Crowdfunding may lead entrepreneurs to disclose business details or intellectual property, thereby exposing them to competitors.
 <p>GRANTS</p>	Grants can stimulate R&D and technology commercialization that <u>would not have happened otherwise</u> .	Most grants are very specific. For example, more than two-thirds of SBIR-funded companies <u>had a founder who was previously an academic</u> .

<sup>1</sup> See *The State of Small Business Lending: Credit Access During the Recovery and How Technology May Change the Game* in the "For More Information" section for a discussion about home equity lines of credit.

<sup>2</sup> The four main types of crowdfunding are: donation-based (e.g., Kiva), reward-based (e.g., Kickstarter), debt-based (e.g., Prosper, Lending Club), and equity-based.

# MedTech BEST Entrepreneur



## DEFINITIONS

**ANGEL INVESTOR:**  
An investor providing financial backing to small startups / entrepreneurs.

**VENTURE CAPITAL:**  
Financing provided by a group of investors to small firms with perceived long-term growth potential.

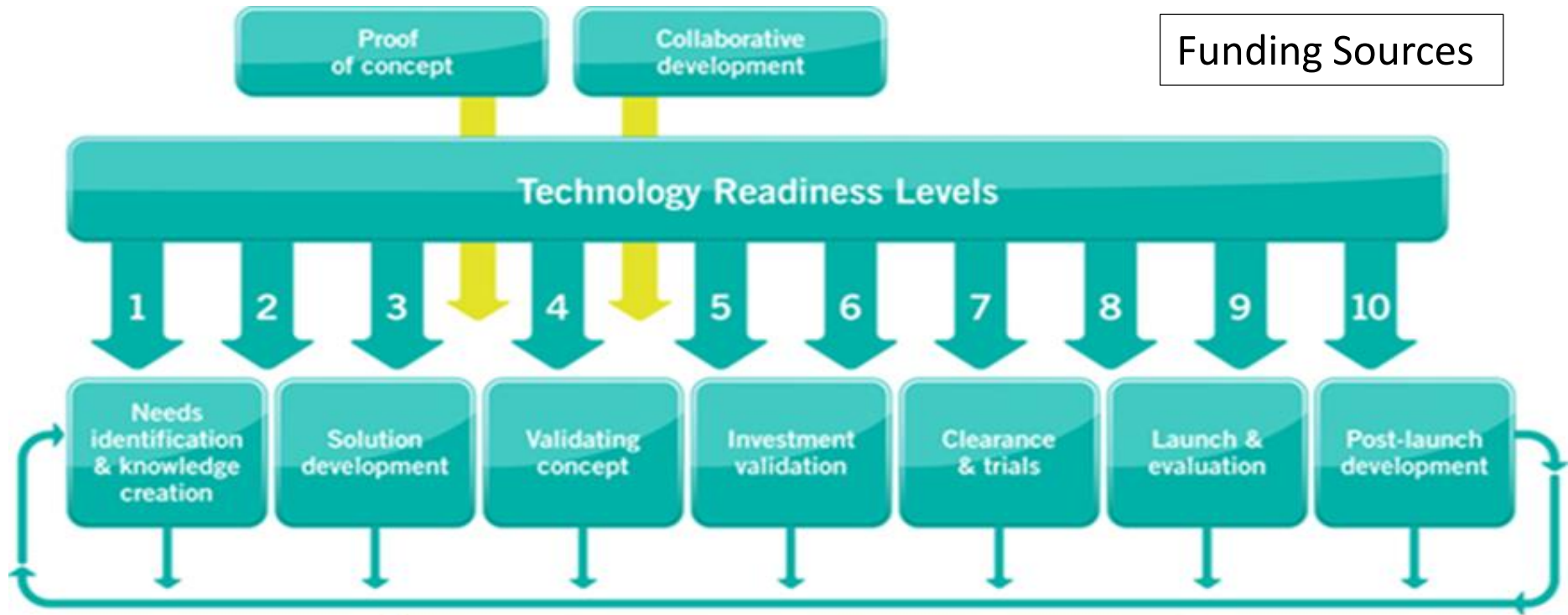
Note that both expect percentage of equity (share ownership) in return for investment.

Angel investment usually not more than £500,000

VC investment > £500,000 (and more demanding than Angel!)

slideshare.net

# Funding Sources



Day job!  
Friends &  
Family!  
Research  
Councils

Friends &  
Family!  
Research  
Councils  
Innovate UK  
EU (H2020)  
Banks  
BBB  
IKC  
Crowdfunding  
Charities

Innovate  
UK  
NIHR (i4i)  
EU  
(H2020)  
Business  
Angels  
Corporate  
venturing  
Family  
offices  
Charities

Innovate UK  
NIHR (i4i)  
H2020  
Business  
Angels  
Corporate  
venturing  
Family offices  
Wellcome/  
MRC  
VCs  
LEP

NIHR (i4i)  
Corporate  
venturing  
Wellcome/  
MRC  
VCs  
Licence

Corporate  
venturing  
VCs  
Licence  
Wellcome

Corporate  
venturing  
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**Key:** H2020 = Horizon 2020 EU grant scheme; BBB = British Business Bank; IKC = Medical Technologies Innovation & Knowledge Centre; NIHR i4i = National Institute for Health Research Invention for Innovation funding scheme.

# MedTech BEST Today

## Info sessions on

- Business Plan and Opportunity Note
- Financial requirements and sources of funding
- Routes to Market
- Stage Gate

## Team sessions on

- |                                       |        |
|---------------------------------------|--------|
| – Business plan (identify/close gaps) | 20 min |
| – Opportunity Note                    | 30 min |
| – Break                               | 10 min |
| – Cashflow forecast                   | 40 min |
| – Stage Gate review                   |        |



# Stage Gate Process - recap



# MedTech BEST Entrepreneur



OPTION | *Alpha*

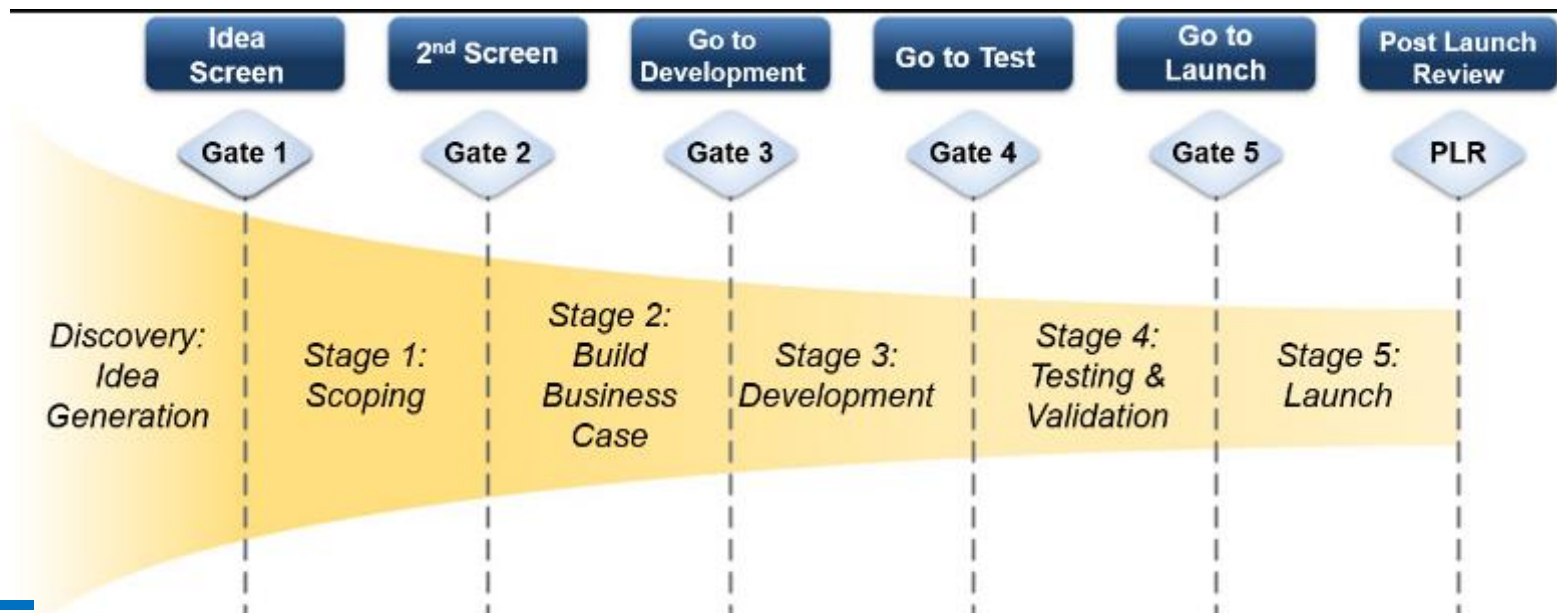
“ And finally, no matter  
how good the science gets,  
there are problems that inevitably  
depend on judgment, on art, on a feel  
for financial markets. ”

– Martin Feldstein



# Product Development - Stage Gate Process

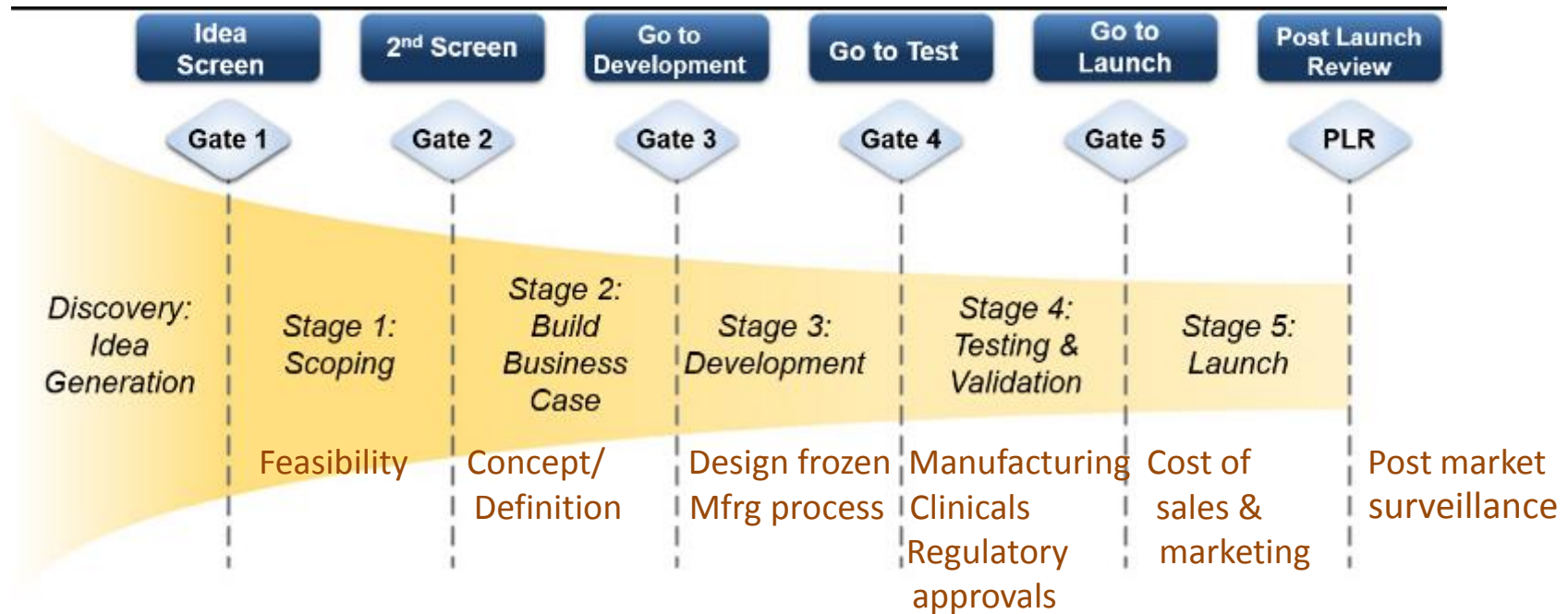
- Development process broken into key phases
- Project reviewed by management team at end of each phase – Gate Review
- **Project must successfully pass through Gate before it can proceed to next phase – minimises risk & allows portfolio approach**
- Stops projects running out of control
- Focuses team on what information/results are required



# Development Process – activities at different stages

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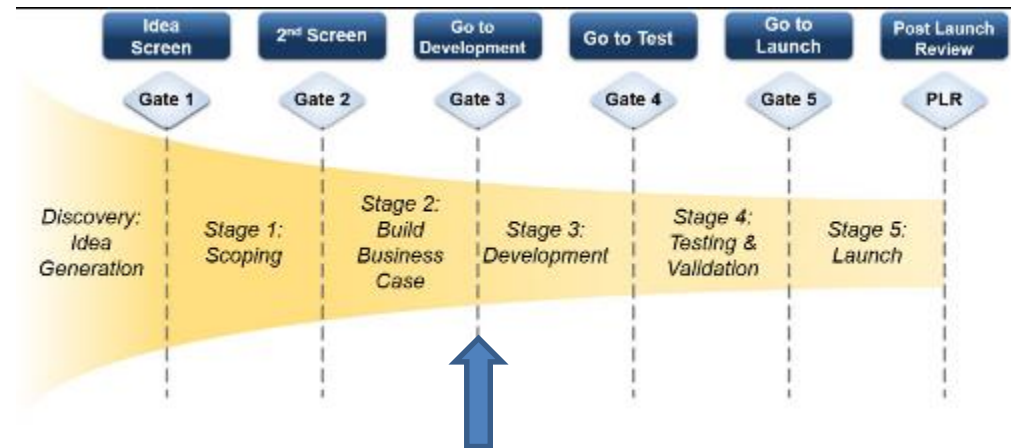


- Use the cashflow tool to estimate required resources (including personnel, facilities, patent costs, supply chain partners, materials, equipment, process development, legal, regulatory & compliance costs, clinical, scale-up, market access etc)
- Prepare a case (to present to panel) for progression through Gate 3 to Stage 3

# MedTech BEST

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|---------------------------------------|--------|
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| – Opportunity Note                    | 30 min |
| – Break                               | 10 min |
| – Cashflow forecast                   | 40 min |
| – Stage Gate activities and cost      | 20 min |

For next time.....

17 April 14.00 – 17.00 (tbc)

- Investor's view
- Presentation outline
- Business Plan and ON
- Mock Stage Gate (with external panel members)

