

MedTech BEST  
Session 6  
17 April 2018

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

Investor's view  
Mock Stage Gate Review

# MedTech BEST

## Today

### Info session on

- Early Stage MedTech Opportunities – the Investor’s View: Mark Wyatt, Mercia Technologies

### Team sessions on

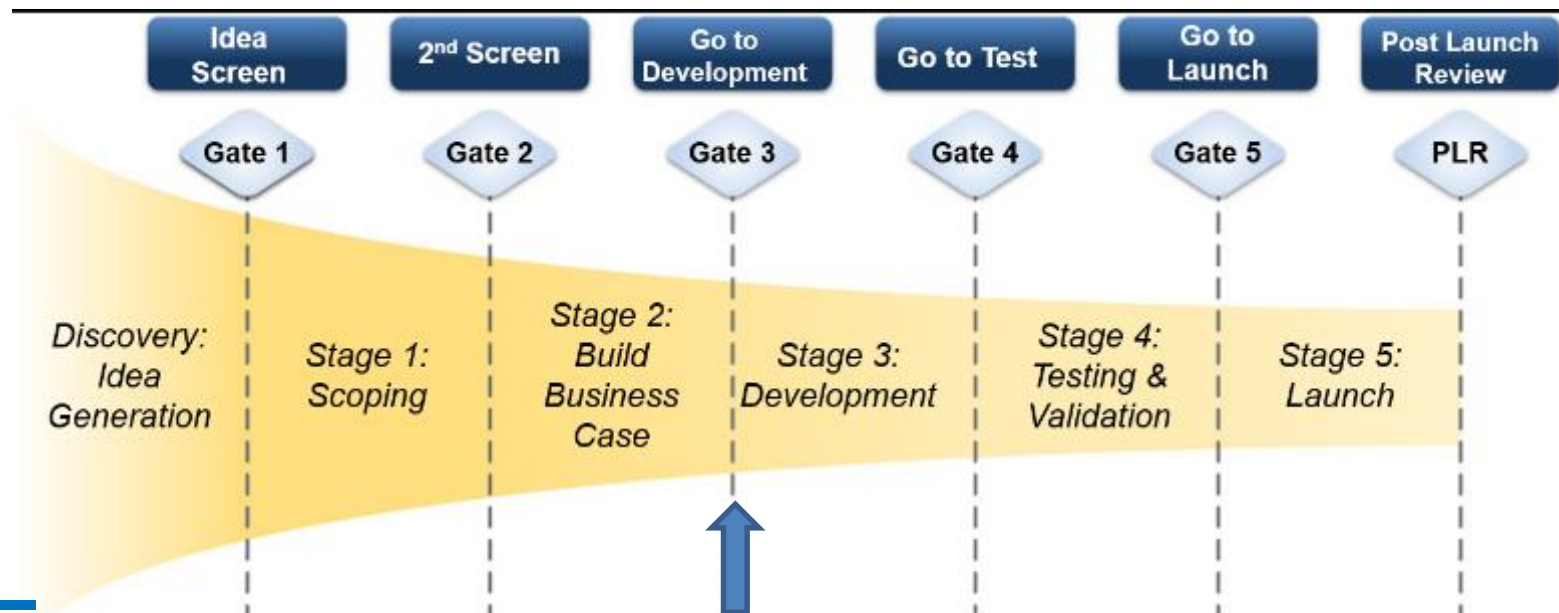
- Business plan (identify/close gaps), Cashflow
- Preparation of Gate 3 presentation for Stage Gate Review

### Stage Gate Review

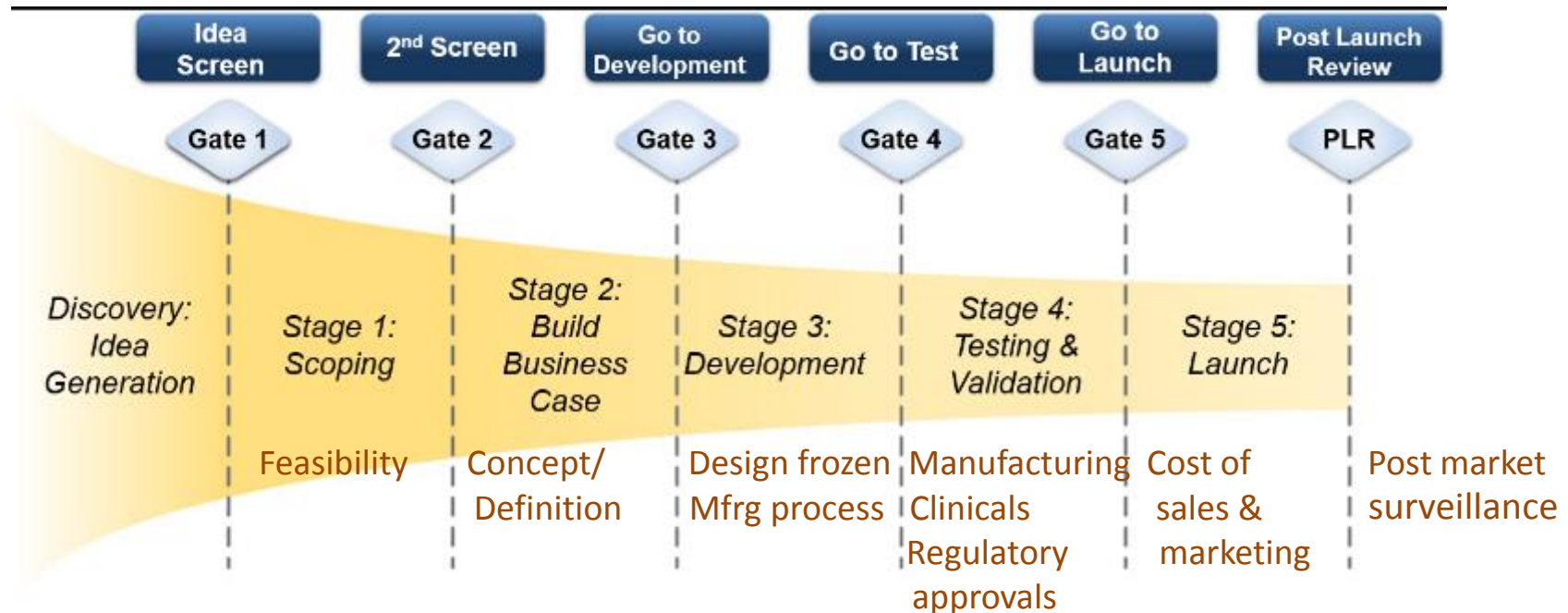
- Presentations to panel
- Panel Q&A
- Recommendations and decisions

# 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



# Product Development - Stage Gate Process

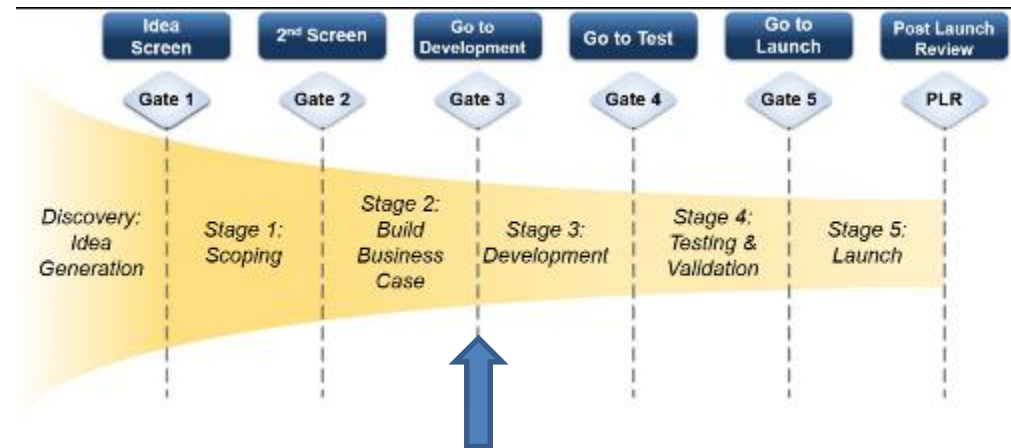


- Use the cashflow tool to estimate required resources (including personnel, facilities, patent costs, supply chain partners, materials, equipment, process development, legal, regulatory & compliance costs, clinical, scale-up, market access etc)
- Prepare a case (to present to panel) for progression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

# MedTech BEST

## 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]

# 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>
3: Design & Development	<ul style="list-style-type: none"> <li>Define design inputs</li> <li>Verification &amp; Validation Plan</li> <li>Further testing/development</li> <li>Risk assessment</li> <li>Develop/review manufacturing process</li> </ul>	<ul style="list-style-type: none"> <li>Develop/test final prototype</li> <li>Design packaging/labelling</li> <li>Update market, IP, regulatory reviews etc.</li> </ul>
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>

# Business Plan Introduction

We will work through this in more detail in next session

but **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
- Will be asked for by investors
- Will be used to generate your **Opportunity Note** to submit to MedTech BEST judges



Send to Mike Raxworthy by 09.00 on Monday 30 April for submission to 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



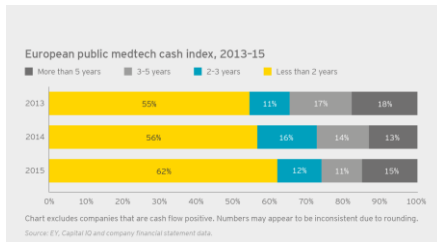




# Opportunity Note

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

- Supports/becomes part of your pitch
- Example (real) circulated
- Other models – used graphics, charts, images



## INVESTMENT OPPORTUNITY NOTE

### SUMMARY

#### SwabTech Limited

Development of a device to recover red blood cells from used surgical swabs during surgery.

#### Office address:

The MedTech Centre  
Greenheys  
Manchester Science Park  
Pencroft Way  
Manchester  
M15 6JJ  
0161 276 5782  
[www.swabtech.co.uk](http://www.swabtech.co.uk)  
@SwabTech

#### General information:

- Medical devices
- Concept proven
- Established 2012
- Pre revenue
- UK market, £4million
- Global market, £60million
- An EIS eligible investment

#### Key achievements:

- Concept proven in lab trials using human blood via £100k NIHR grant
- Ethics approved clinical trial started Dec'14
- UK, EU and US patent applications progressing
- Dec'14 secured £150k equity investment from Spark Impact,
- Dec'14 secured £156k grant from Regional Growth Fund,
- Jul'15 initiated £250k InnovateUK grant funded work,
- CEO appointed Dec'14
- 2x Product Technologists appointed Jan'15
- Conference Poster presentation at NATA'15
- Oct'15 secured £23k award from GMAHSN

### BUSINESS OVERVIEW

SwabTech Limited, a spinout company from the NHS was incorporated in October 2012 to develop and commercialise a novel device to automate the process of recovering reusable red blood cells from surgical swabs. The device is designed to integrate with existing Intraoperative Cell Salvage (ICS) machines that recover blood during surgery a process that is both safer and cheaper than the use of donated blood.

The utility of ICS is dependent on the volume of blood that can be recovered and many hospitals attempt to recover blood soaked up in surgical swabs by manually washing them, a dirty, time consuming and labour intensive process. The Surgical Swab Washer has been designed to replace the manual process which will significantly increase the take-up of swab washing in hospitals and increase the use of ICS during surgery.

The SwabTech device is designed to replace the established practice of manual swab washing and will:

- Offer a cleaner process, with less risk of spillage and contamination.
- Offer more consistent red cell yields and recover red cells from swabs that are unsuitable for manual washing, such as those recovered from orthopaedic surgery where shards of bone might be present.
- Free up the scrub nurse to focus on assisting the surgeon.
- Drive utilisation of existing ICS machines by increasing their yield and extending the range of procedures for which ICS machines offer good value.
- Provide a low-tech, easy-to-use way to embed good blood management policy into standard operating procedures.
- Increase the validity of the health economics case for ICS, thereby reducing the cost of blood transfusions and reducing the need for additional blood donors.

The SwabTech device is protected by UK and international patent applications with minimal competing prior art. SwabTech will have three revenue streams from sales of operating theatre equipment, sales of a per-patient single use disposables and an annual maintenance / service contract. The UK and worldwide market sizes are in the region of £2million p/a and £40million p/a respectively.

### MARKET INFORMATION

The related ICS market is estimated to be worth £160m/a and is dominated by three vendors: Haemonetics, Sorin and Fresenius. Haemonetics, a \$900m turnover business based in Massachusetts, has 40% market share, worth \$100m in 2013 (up 10% on the previous year). Milan-based Sorin (now part of LivaNova) generated €57m of its €731m 2012 turnover from ICS. Hamburg-based Fresenius Kabi, part of the €20bn Fresenius group, has an estimated 15% of the ICS market.

A bottom-up market assessment based on current use of ICS indicates a Global market for a swab washing device is £30m with associated annual sales of single use Swab-Washing consumables in the UK of £3m/a and worldwide markets approximately £33M/a. These are conservative estimates as a swab washing device will increase the number of procedures for which ICS is a viable blood recovery technique.

In Europe and North America the ICS market is mature and currently experiencing modest growth. In these markets ICS vendors are focused on product differentiation and increasing utilisation through training and education. ICS vendors are projecting high growth in the Middle East and emerging economies, in particular Russia, Brazil, India and China, all of which have very large populations spread over wide geographic areas and do not have such well-developed blood bank infrastructures capable of transporting blood over large distances increasing the requirement for ICS.

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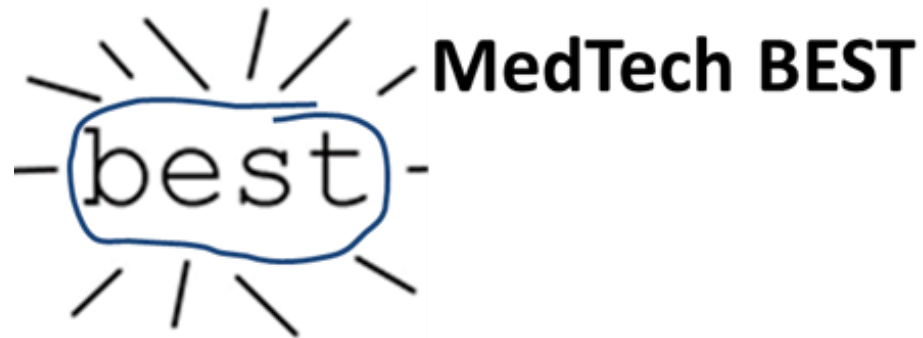
# For next time.....

## Thursday 03 May 17.00 – 20.00

- Pitch Final for the MedTech BEST trophy!



- Judges from Royal Academy of Engineering, JRI Orthopaedics, Swabtech, Angel Investor, University of Leeds



Professor Mike Raxworthy  
x101 Medical Technologies  
[m.j.raxworthy@leeds.ac.uk](mailto:m.j.raxworthy@leeds.ac.uk)