

MedTech BEST
Session 3
7 February 2018

Business and **E**ntrepreneurial **S**kills **T**raining

Business Plan Introduction

Value Proposition

Requirements at different stages of Translation

Stages of Start Up Maturity

MedTech BEST Entrepreneur

“As scientists we always hope that our discoveries will make a difference and as entrepreneurs we strive to build sustainable companies to translate those discoveries into significant new medicines for patients.

At Astex we have been lucky enough to achieve both of these goals due largely to our highly talented team”



Dr Harren Jhoti
Founder of Astex Pharmaceuticals
on receiving the 2018 BIA Lifetime
Achievement Award



MedTech BEST

Today

- Info session on Business Plans, Value Proposition, Requirements at different stages of Translation Stages of Start Up Maturity
- Team session on
 - Product concept/value proposition refinement
 - Company identity, mission, vision and strategy

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



MedTech BEST Entrepreneur

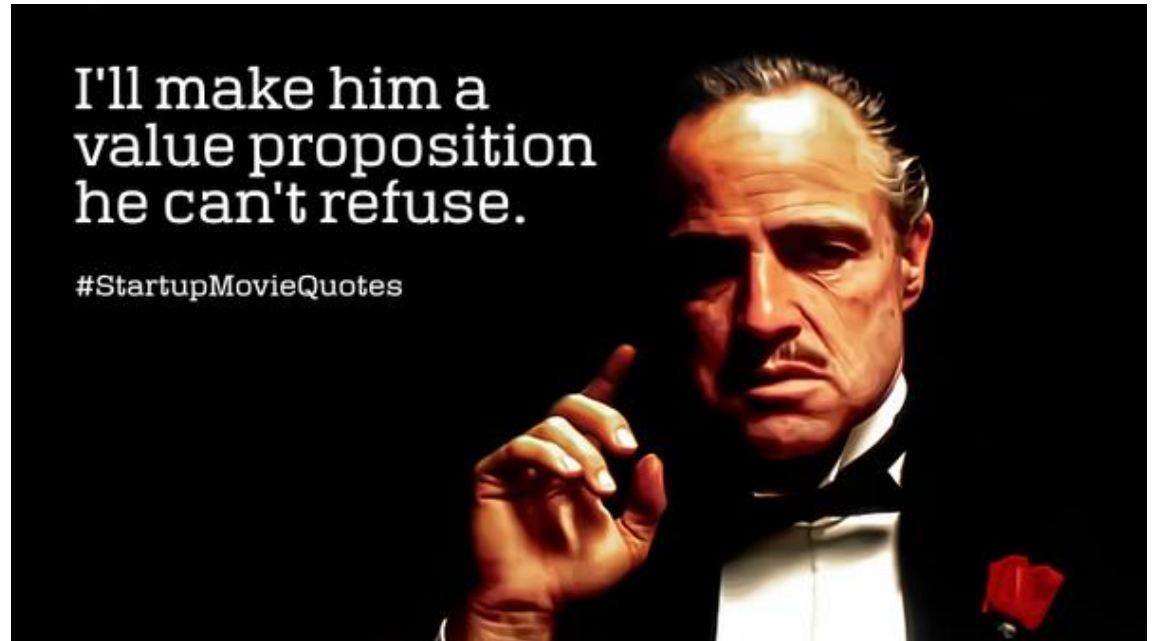
“There's one thing I've learned about entrepreneurs' business plans. Every one is wrong.”



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

Value Proposition

A business statement that a company uses to summarise why a customer should buy a product or use a service



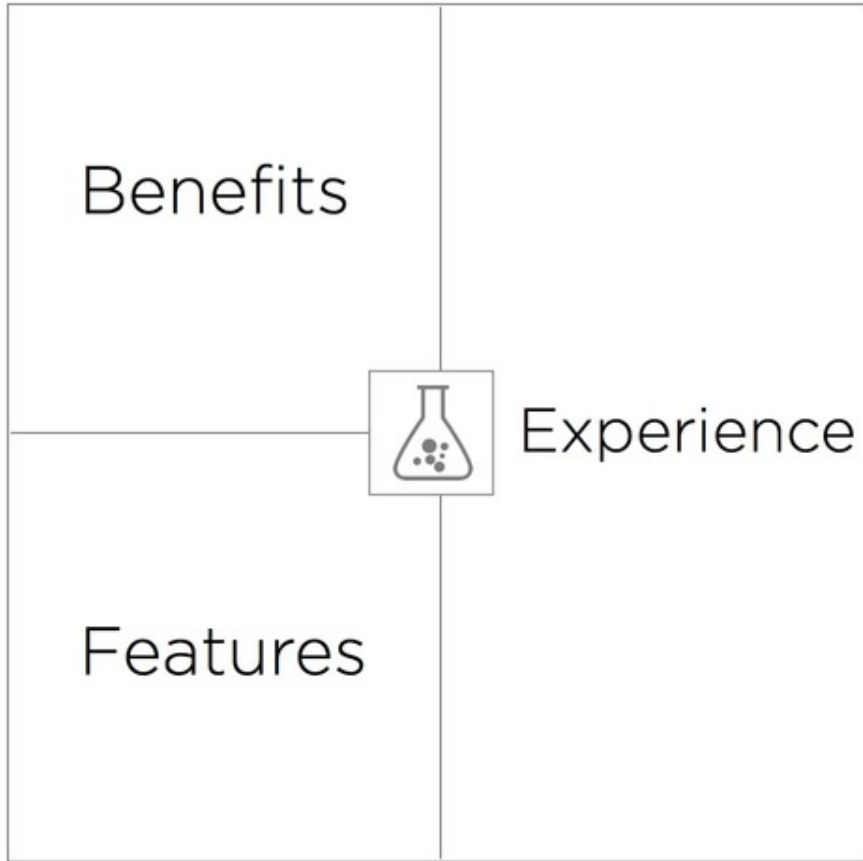
Value Proposition

- A business statement that a company uses to summarise why a customer should buy a product or use a service
- It is a clear statement that explains how the product solves a **pain point/clinical need** and communicates the specifics of its added benefit
- It convinces a potential customer that one particular product or service will add more value or better solve a problem than other similar offerings
- Companies use this statement to target customers who will benefit most from using the company's products, and this helps maintain an “economic moat”



Value Proposition Canvas - Original

Product



Customer



Company:

Product:

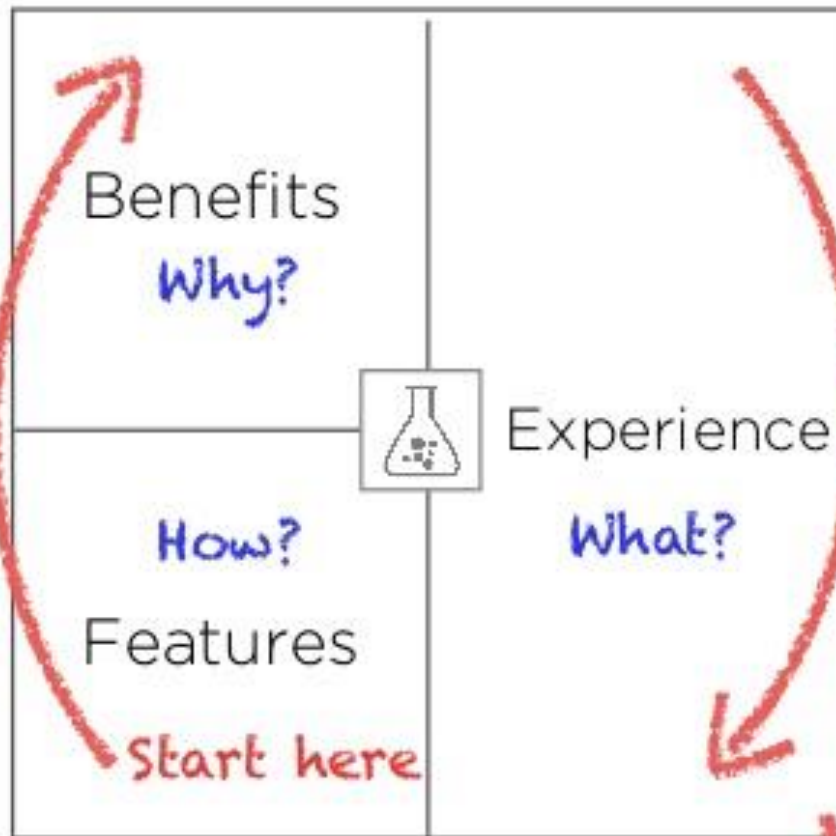
Ideal customer:

Substitutes

Value Proposition Canvas

Product

Customer



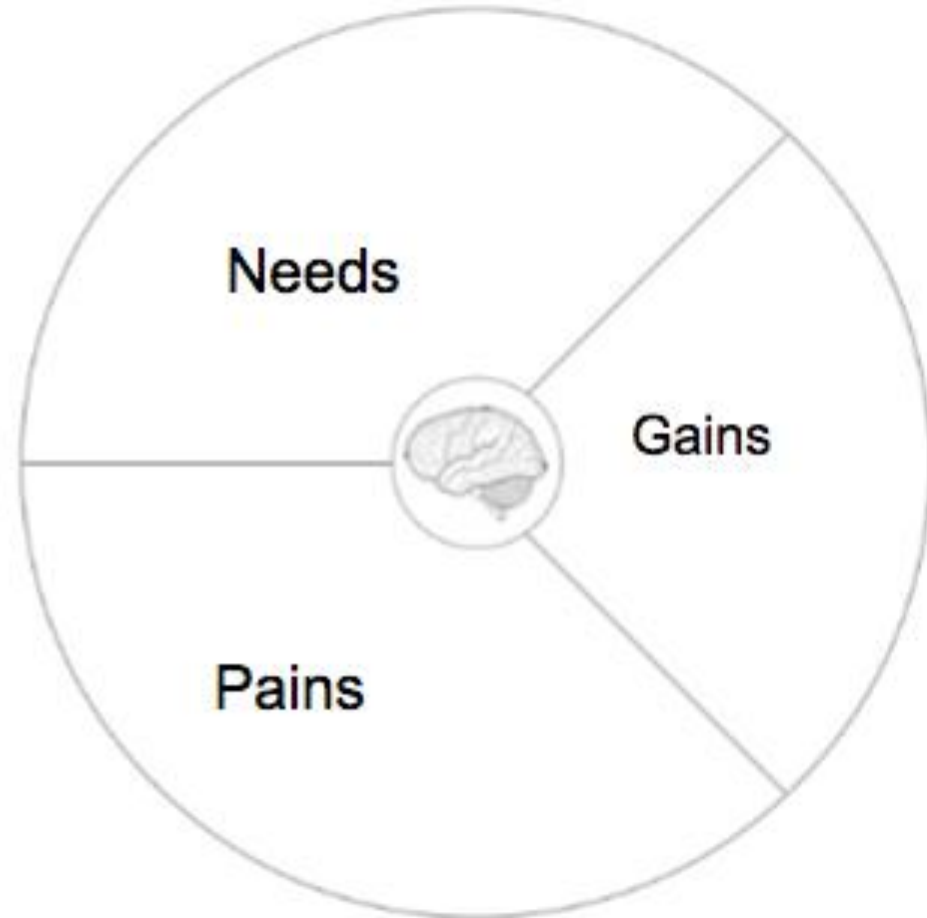
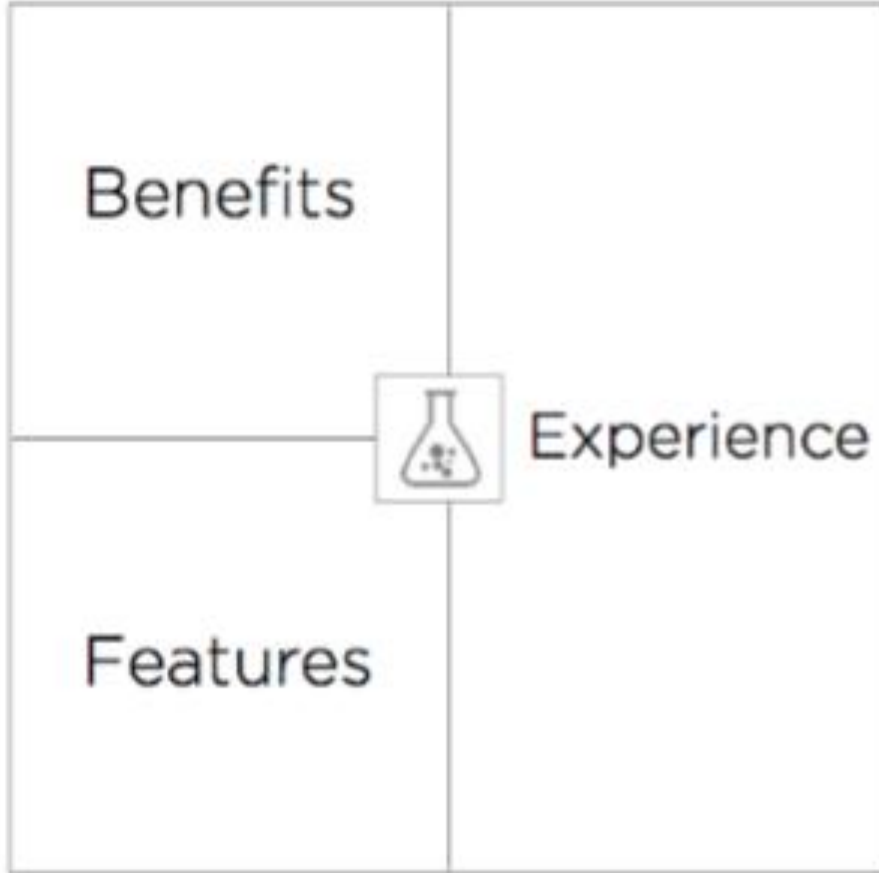
Company:
Product:
Ideal customer:

Substitutes
Inertia

Value Proposition Canvas - Modified #1

Product

Customer

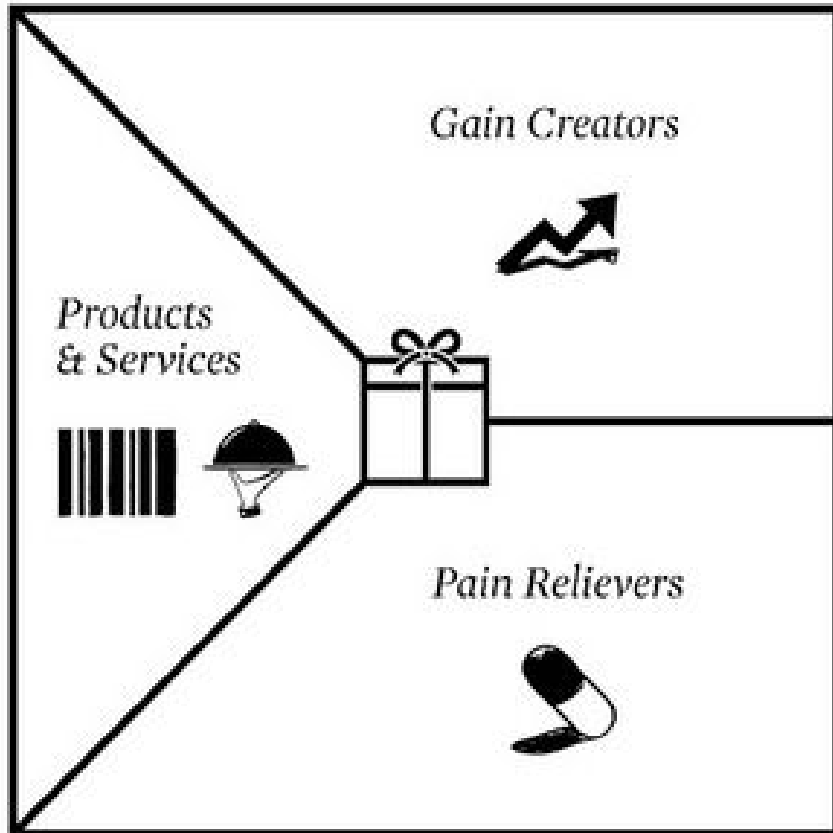


Company:
Product:
Ideal customer:

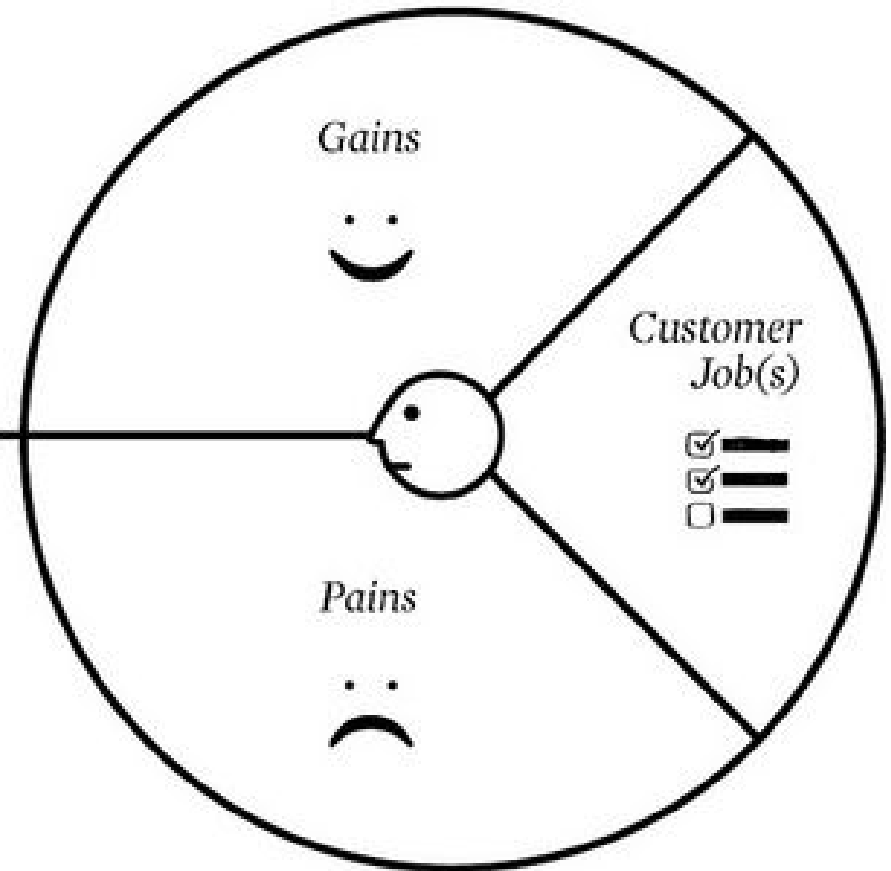
Substitutes

Value Proposition Canvas – Modified #2

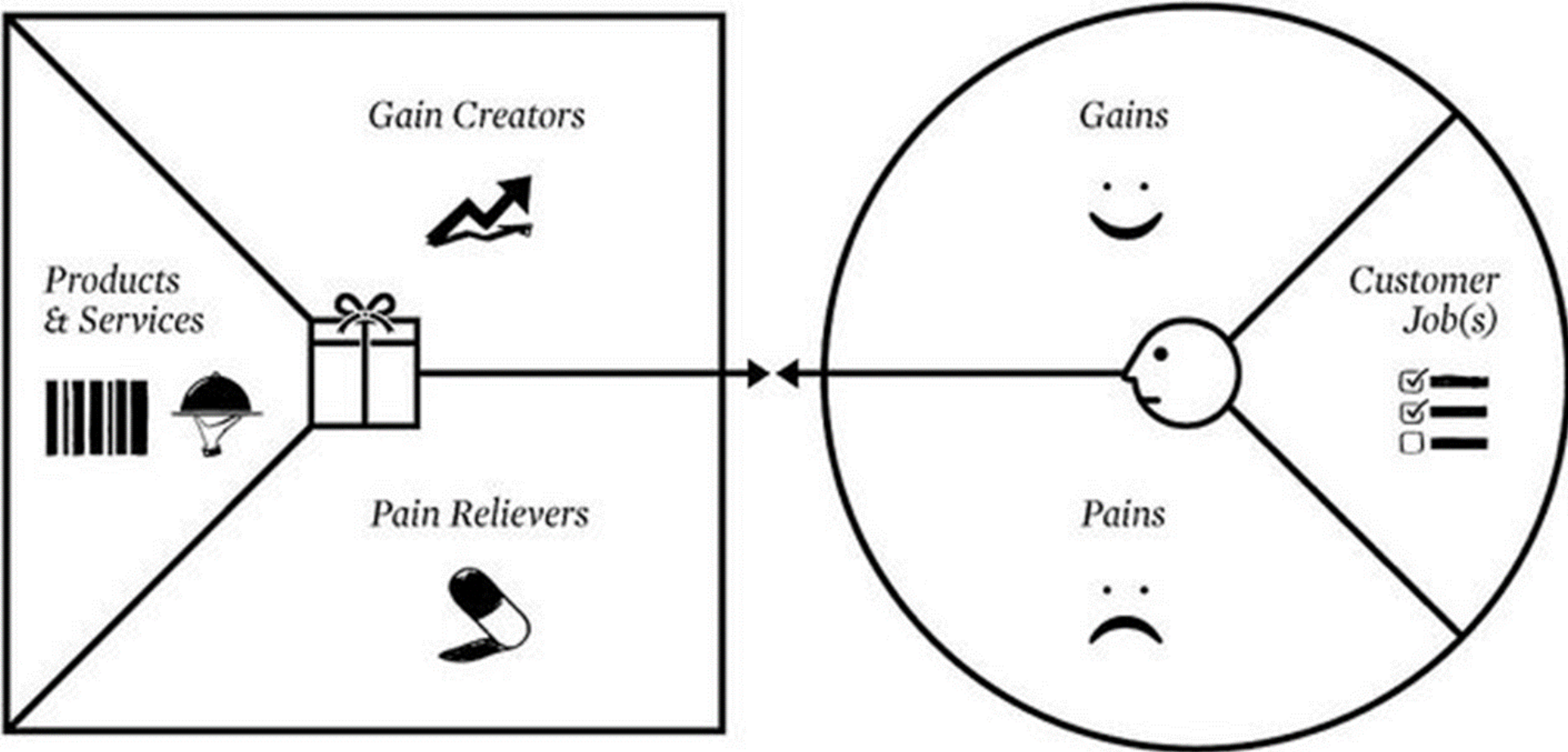
Product:



Customer:



Substitutes:

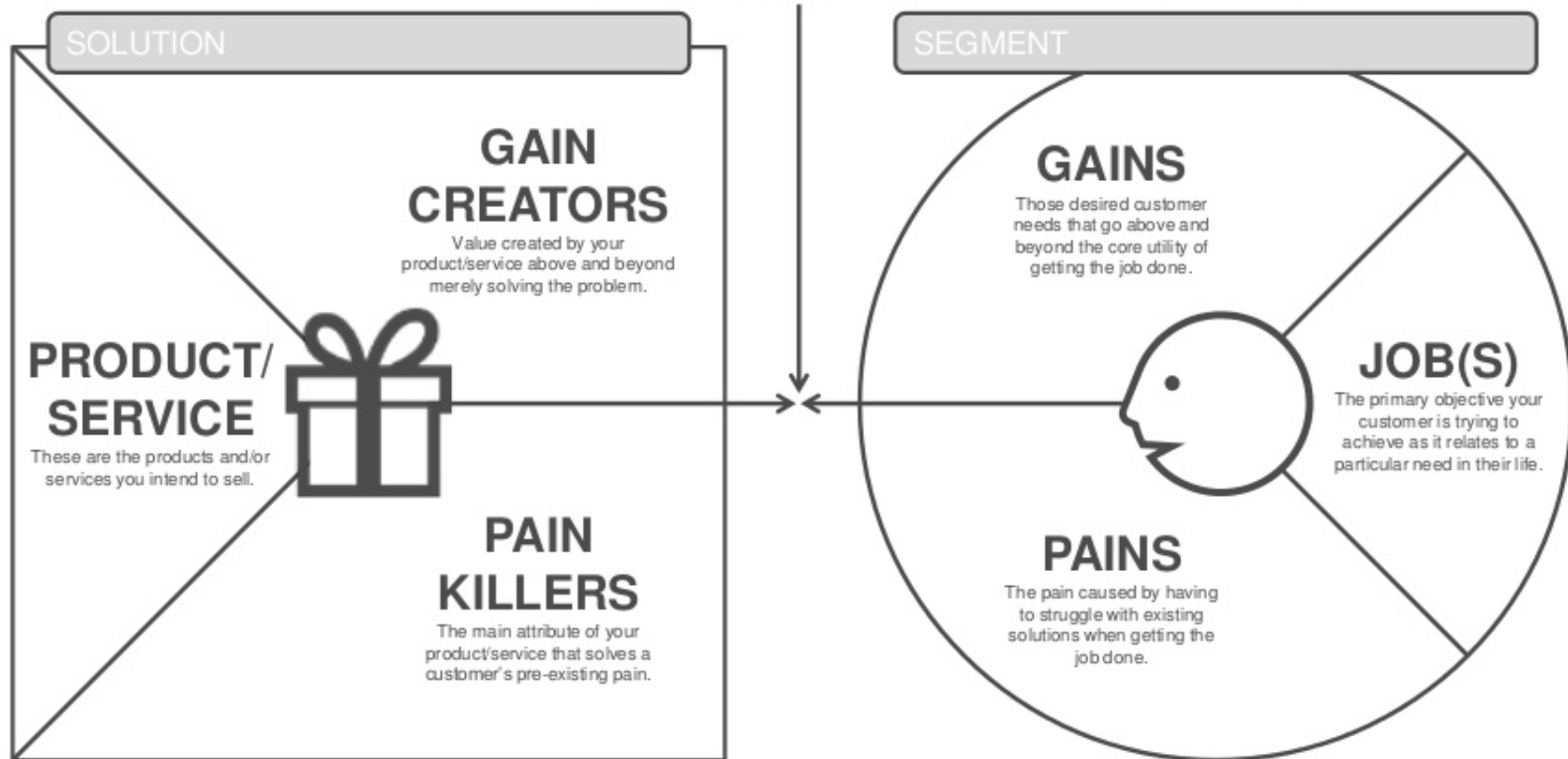


Substitutes

VALUE PROPOSITION DESIGN EXPLANATION

PROBLEM / SOLUTION FIT

You have found 15-20 people within a segment (b2c; 6-8 in b2b) who rate your value proposition as a 9 or 10 and state they would buy it right now if it was available



Value Proposition – Product Definitions



- **Features** (pain relievers, pain killers): defined as surface statements about your product, such as what it can do, its dimensions and specs and so on. Attributes that solve a customer's pre-existing pain
- **Benefits** (gain creators): the end result of what a product can actually accomplish for the user. Value created above & beyond merely solving the problem
- **Experience** (product): how your value proposition manifests itself. List everything your value proposition is built around. This includes the help the customer receives (functional, social and emotional) – ie how the customer *feels* from owning your product.

Value Proposition – Customer



Definitions

- **Needs** (jobs to be done, rational): an important issue your customers are trying to solve in their work and in their lives. It could be the tasks they're trying to perform and complete, the problems they're trying to solve, or the needs they're trying to satisfy. Some jobs will be crucial to the customers, others will be trivial
- **Wants** (pains): pain caused by having to struggle with existing solutions and which annoy your customers before, during and after getting a job done. This could be undesired costs and situations, negative emotions, or risks. Some customer pains will be severe, others, light.
- **Fears (gains)**: the outcomes and the benefits your customers require, expect, desire, or would be surprised by. They go beyond the core requirement of getting the job done and include social gains, positive emotions and cost savings.

Requirements at different stages of Translation

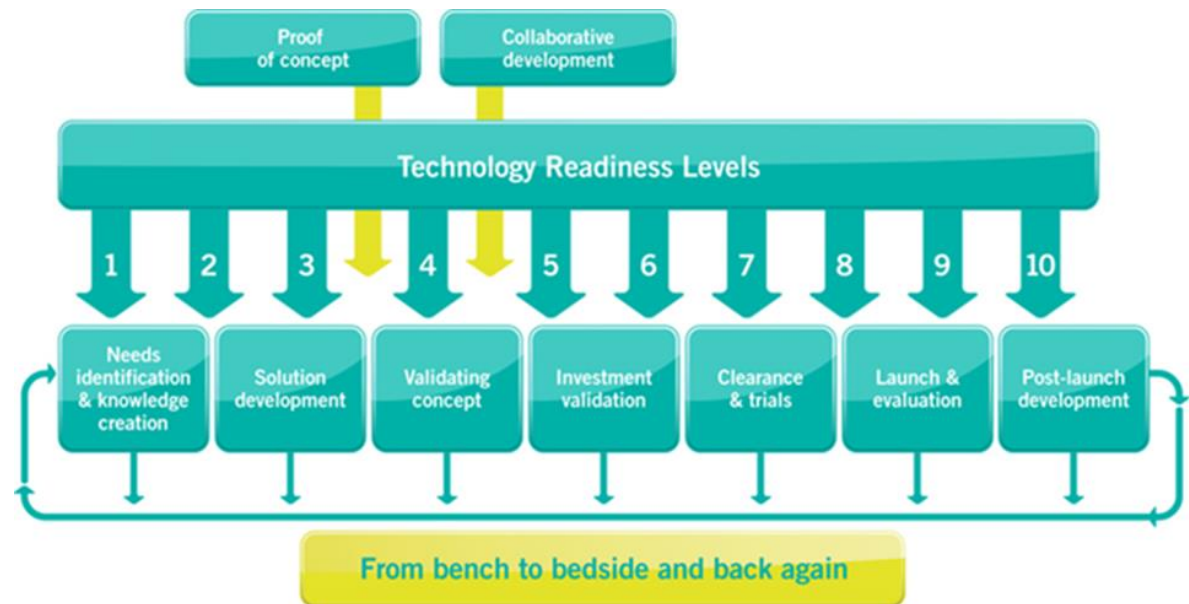
Refresh from Session #2

Requirements:

- Resource (core team, people, skills, consultants)
- Supply Chain, materials, equipment (capital)
- Facilities (lab, manufacturing, other?)
- Funds
- Advisory Board
- IP
- Strategic partner(s)

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



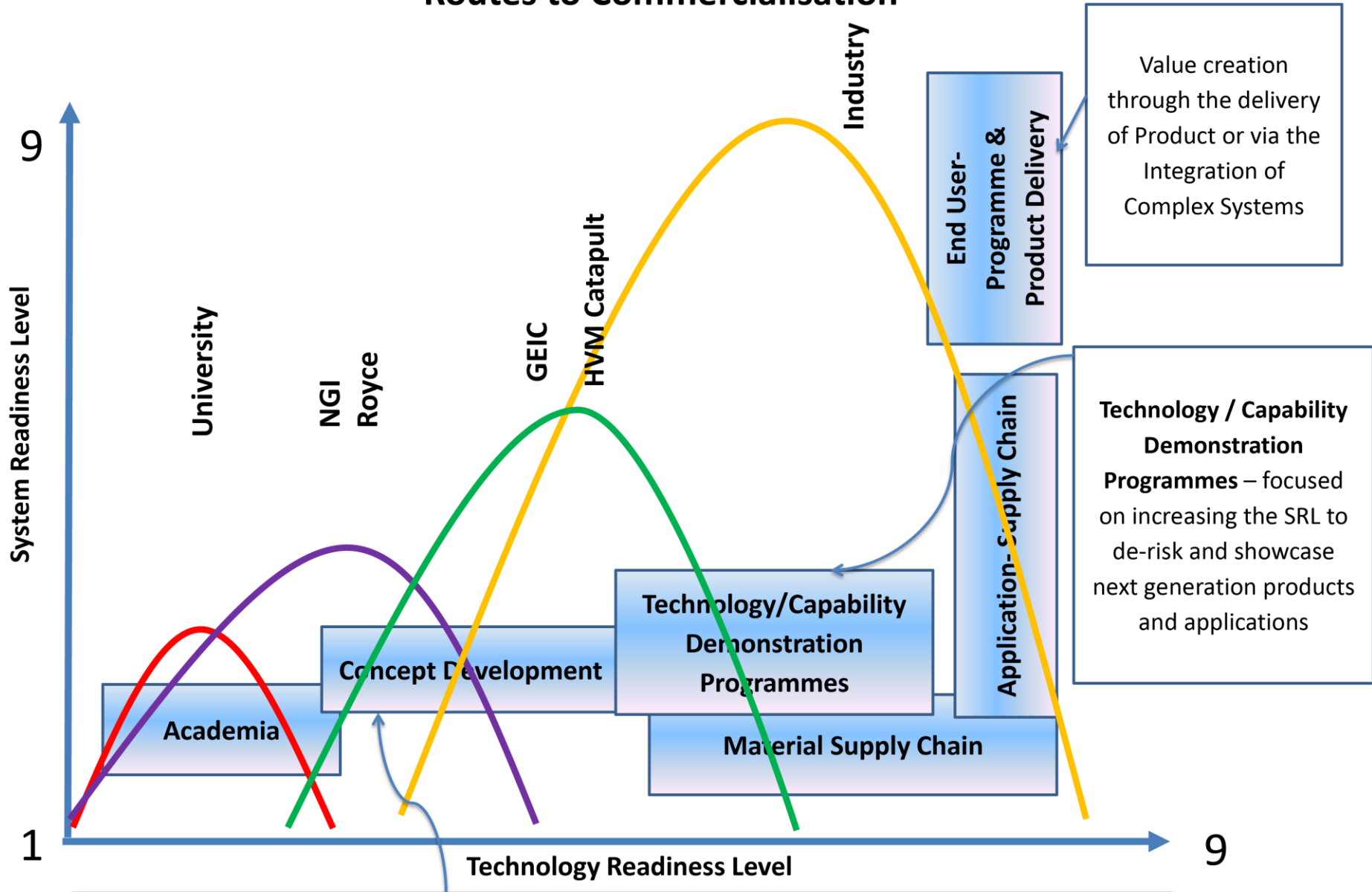
Example of Technology Readiness Levels (TRL) using in medical device development

TRLs in MedTech

Used in project proposal, scoping and management by MedTech IKC

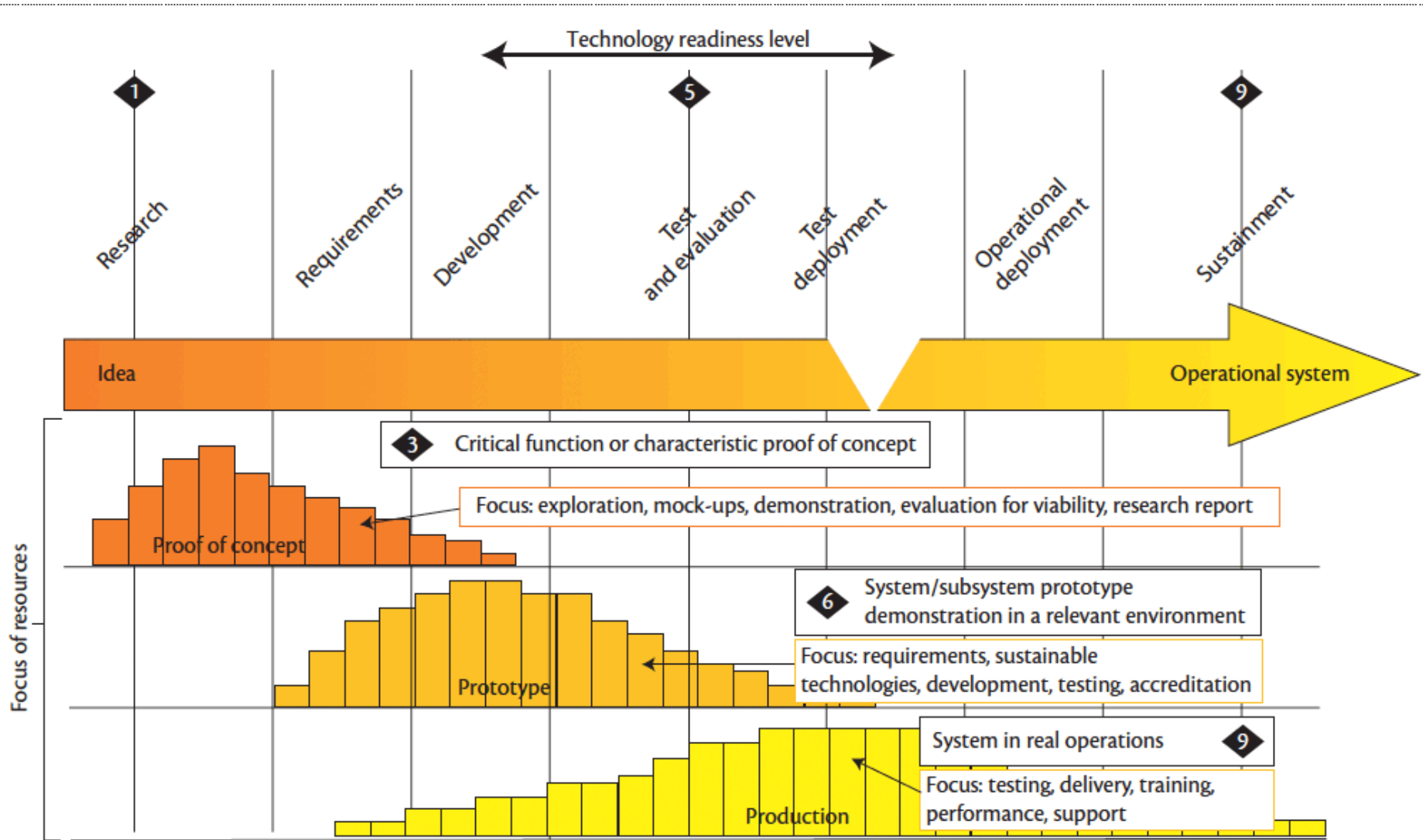
Technology Readiness Level (TRL)							
1-2	3	4	5-6	7-8	9		10
Clinical need defined & knowledge created	Solution Generation	Investment Validation	Development & Validation	Clearance & Clinical	Outputs	Outcomes	Post Launch Market Support
Define clinical need/relevance Develop/refine solution IP	Generation 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

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.

Resources & TRLs



Development Process

Stage	Description/Activities	
0: Idea creation/gathering	<ul style="list-style-type: none"> Brainstorming Internal R&D Technology scouting 	<ul style="list-style-type: none"> Literature review Companies/Universities
1: Initiation/Feasibility	<ul style="list-style-type: none"> Initial proposal & business case 	<ul style="list-style-type: none"> Initial proof-of-concept and prototypes
2: Concept/Definition	<ul style="list-style-type: none"> Full business case & project plan Research Customer Requirements Market evaluation IP Review 	<ul style="list-style-type: none"> Initial regulatory plan Manufacturing plan Further develop/test prototypes
3: Design & Development	<ul style="list-style-type: none"> Define design inputs Verification & Validation Plan Further testing/development Risk assessment Develop/review manufacturing process 	<ul style="list-style-type: none"> Develop/test final prototype Design packaging/labelling Update market, IP, regulatory reviews etc.
4: Transfer to Manufacturing	<ul style="list-style-type: none"> Establish and validate process Approve suppliers 	<ul style="list-style-type: none"> Document procedure Train operators
5: Regulatory	<ul style="list-style-type: none"> Prepare Technical File Regulatory submission 	<ul style="list-style-type: none"> Obtain regulatory approval
6: Post Launch	<ul style="list-style-type: none"> Surgeon training Product/Process improvements 	<ul style="list-style-type: none"> Complaints Post-market surveillance

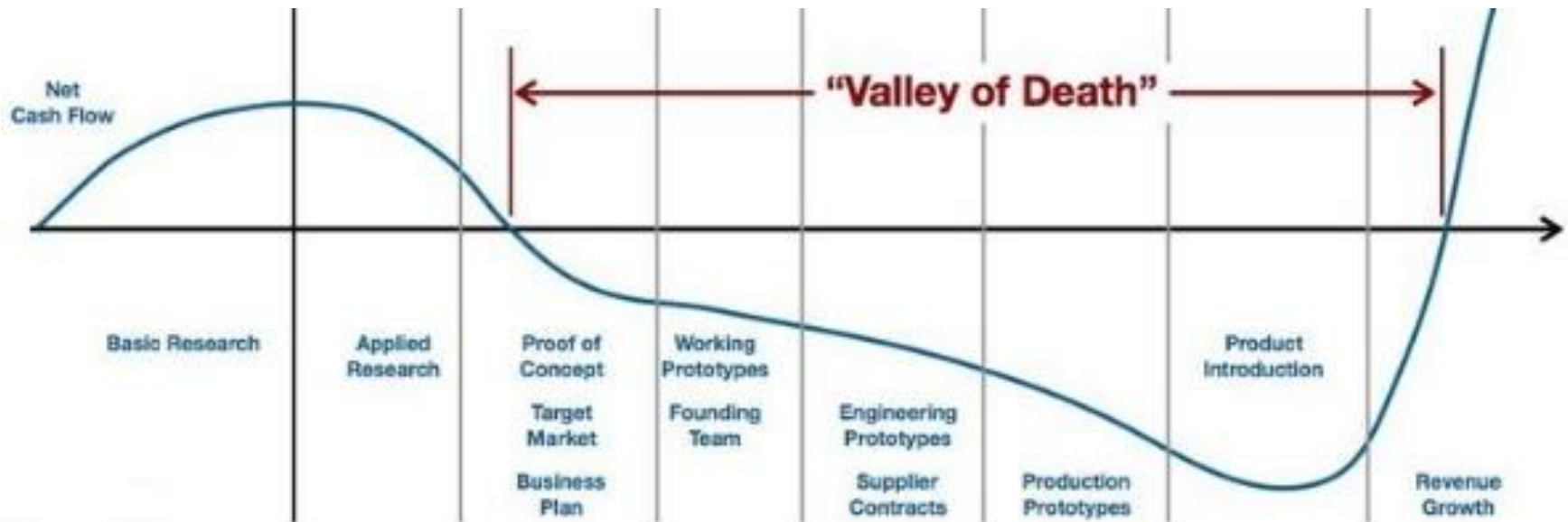
Requirements at different stages of Translation

Requirements – you will need to estimate costs at each stage of new product development process

- Resource (founders, core team, people, skills, consultants)
- Supply Chain, materials, equipment (+/- capital)
- Facilities (lab, manufacturing, other?)
- Funds
- Advisory Board
- IP
- Strategic partner(s)

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.

Start-up Stages

Stage 1: Seed And Development

- This is the very beginning of the business lifecycle, before your startup is even officially in existence. ...

Stage 2: Startup

- Once you have canvassed and tested your business idea, it's time to launch your startup. Important to get this stage right to give best chance of avoiding failure later in company's life. Much time will be spent tweaking products based on the initial feedback.

Stage 3: Growth And Establishment

- Product development, approvals, initial sales. Cash flow should start to improve. Opportunities to expand the team and look at other opportunities. Responsibilities for managing the business become more shared along lines of mission and purpose agree in previous stage.

Stage 4: Expansion

- Growth in both revenue and cash flow - blueprint has now established, but be warned about getting too comfortable. Business now firmly established but focus on expanded offerings and entry into new geographies. Risky stage – beware over-reaching and failing.

Stage 5: Maturity And Possible Exit

- Your company should now be seeing stable profits year-on-year. As entrepreneurs you are faced with two choices: push for further expansion, or exit the business. If you decide to expand further, ask
 - Can the business sustain further growth?
 - Are there enough opportunities out there for expansion?
 - Is your business financially stable enough to cover an unsuccessful attempt at expansion?
- Should I stay or should I go? Move on through a sale/exit?

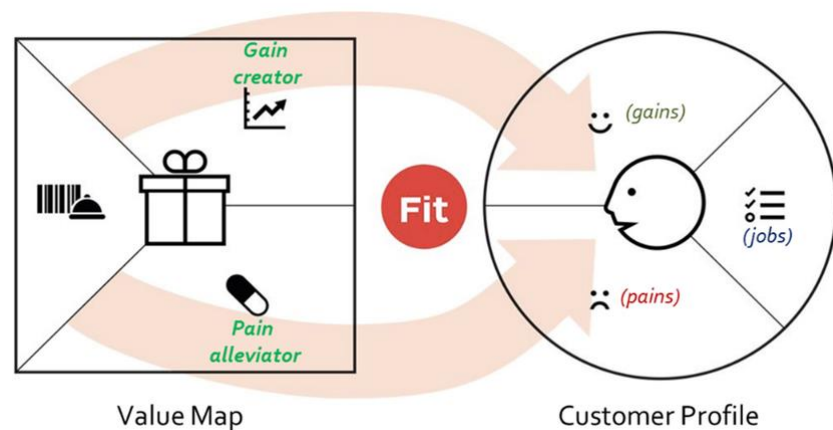
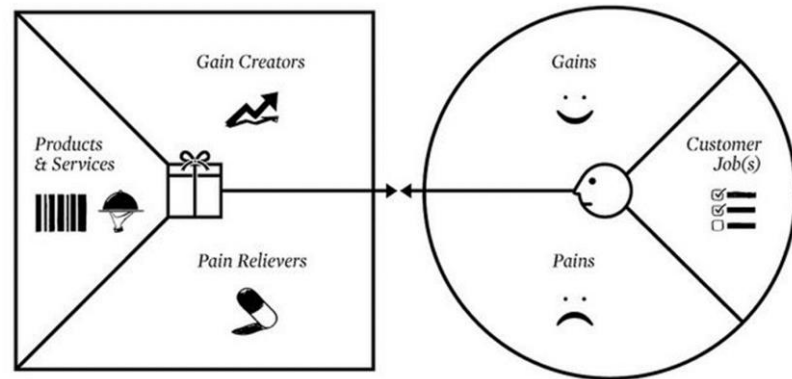
Session #3

7 February 2018

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

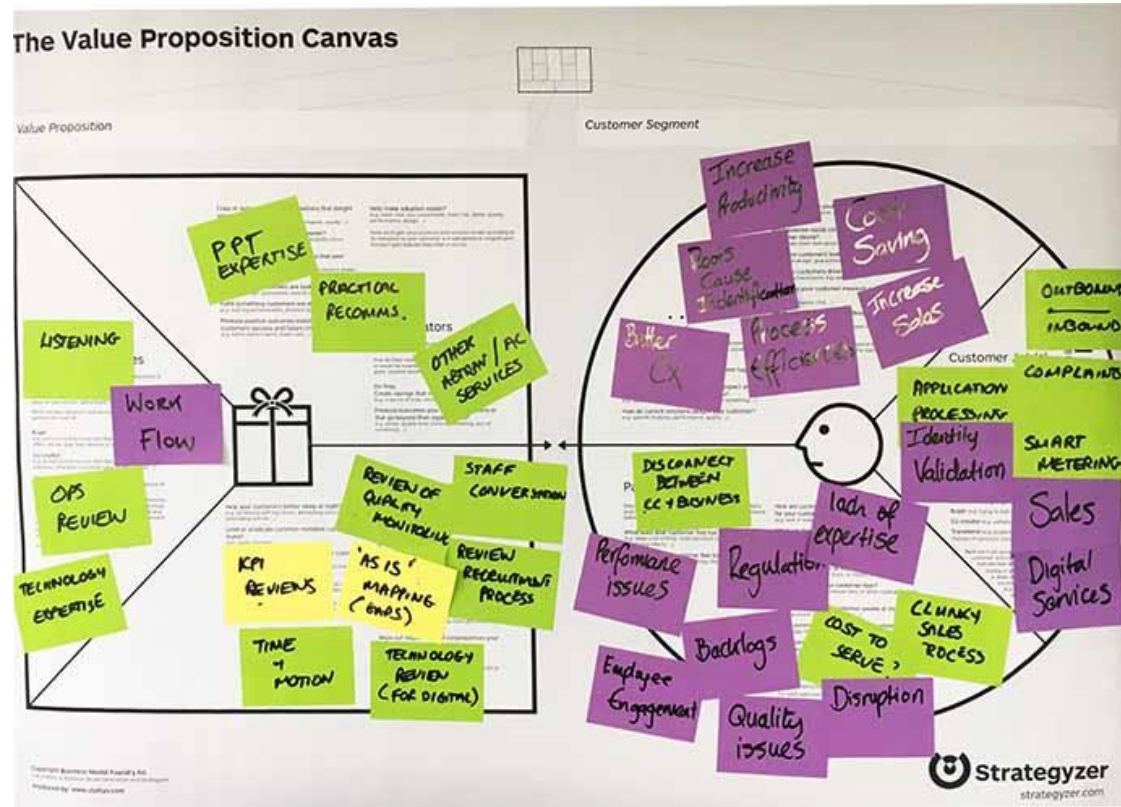
Value Proposition – your turn!

- Templates and definitions in handout
- Start with Features/Pain Relievers then Benefits/Gain Creators
- Move on to Product
- Put to one side and do Customer side – do separate canvases for each customer group
- How well do Problem and Solution match?
- How will you test the fit?



Value Proposition – your turn!

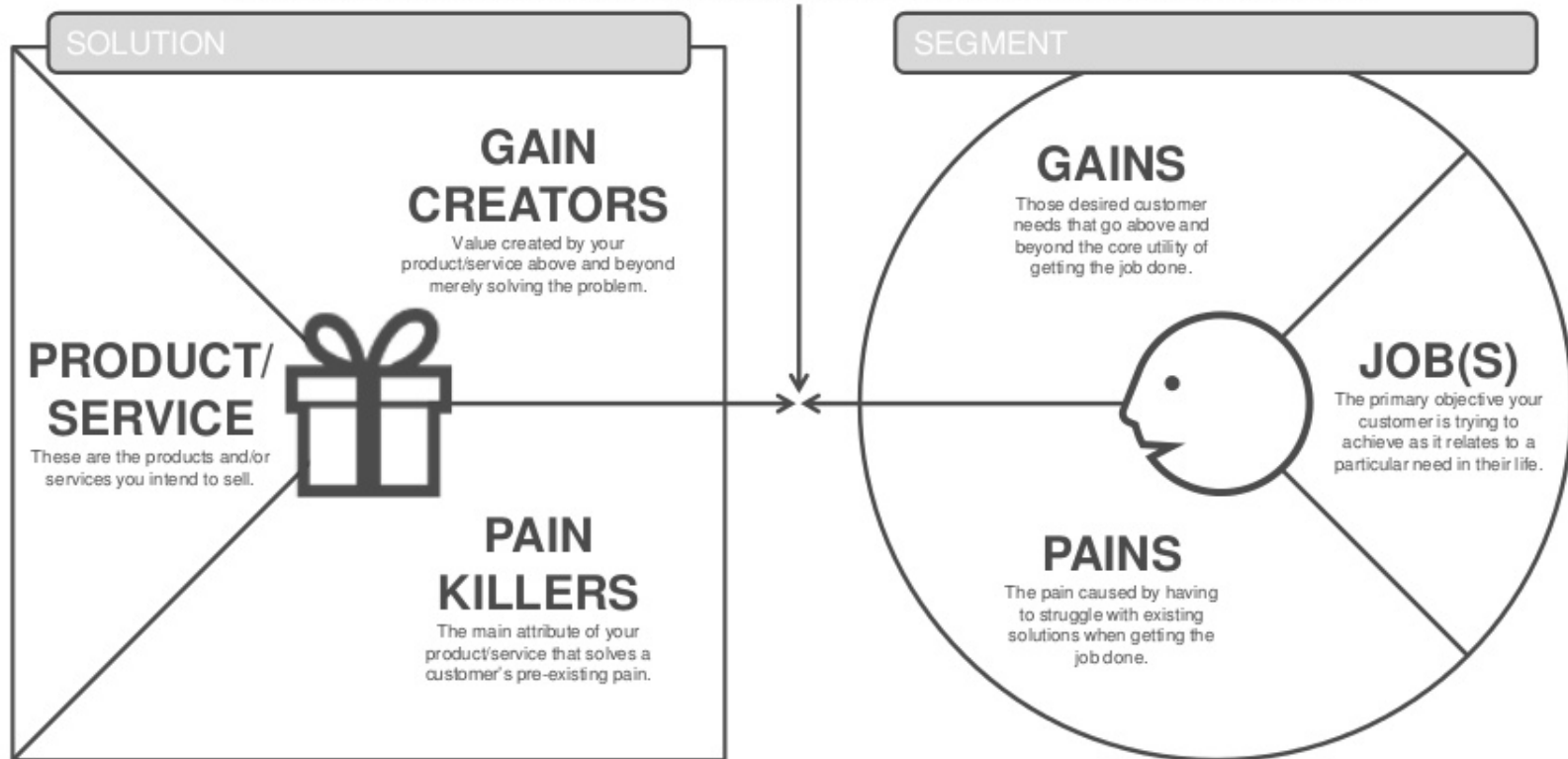
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MedTech BEST Entrepreneur

“I think if you’re going to be a true entrepreneur, you have to accept that some things are going to work and some things are not going to work.”



Sir Richard Branson

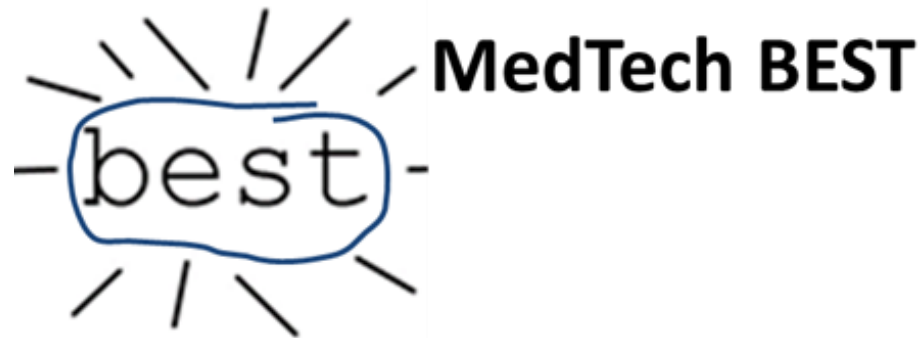
Session #4

21 February 2018 – extended session (13.30 – 17.30)

- MedTech sector markets and trends } Visiting
- Understanding customer needs } Industry
- IP } speaker
- Medical Device regulations
- Company roles

In teams:

- Company roles decided with role description
- Outline business plan assembled



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Professor Mike Raxworthy
x101 Medical Technologies
m.j.raxworthy@leeds.ac.uk