MedTech BEST
Session 4
21 February 2018

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

Market Analysis
Understanding the Customer
Enablers (IP, Medical Device Regulations)
Company roles

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

MedTech BEST
Today

Info sessions on

- Markets, market analysis, trends } Giles Proffitt,
- Understanding the customer } (Ortheia)
- IP and Medical Device Regulations } Mike Raxworthy
- Company roles }

Team sessions on

- Product concept/value proposition refinement
- Company identity, mission, vision and strategy
- Business plan

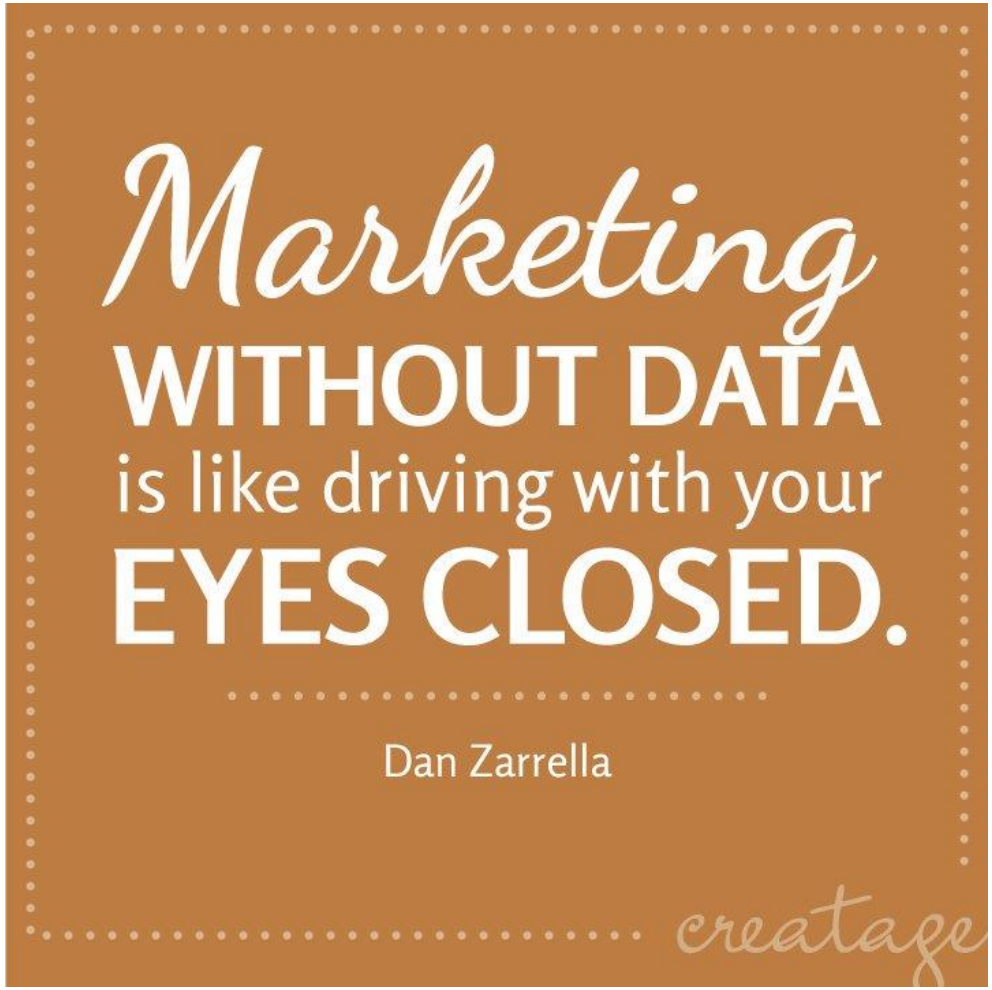
MedTech BEST
Session 4
21 February 2018

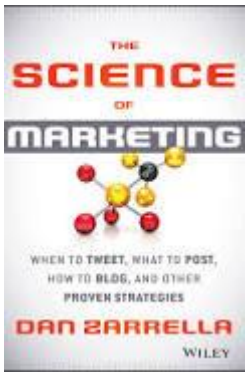
Business and **E**ntrepreneurial **S**kills **T**raining

Website:
https://regenerative-medicine.leeds.ac.uk/medtech-best/

Final event (pitch competition): Thursday or Friday?
(3 May starting at 17.00 or 4 May starting at 16.00?)

MedTech BEST Entrepreneur





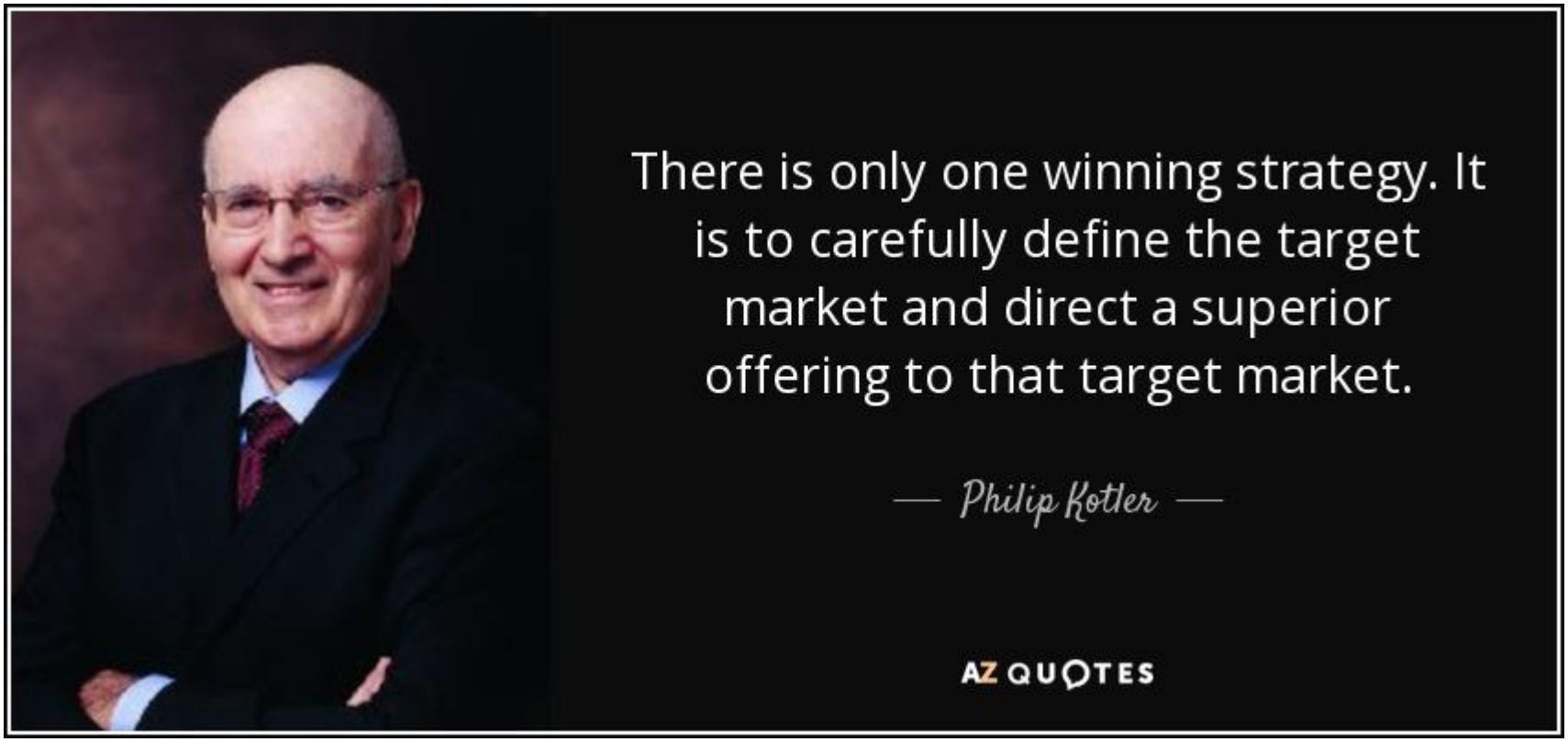
MedTech BEST

Markets, market analysis and trends

You are developing a product to address a clinical need – but need to find out:

- What the customer does/uses today
- What the customer pays
- How many procedures are performed and/or which products are used (and how many)
- How well these products do the job
- Who supplies these products
- How this practice differs in different countries
- What are the trends (growth, contraction, value)

MedTech BEST Entrepreneur



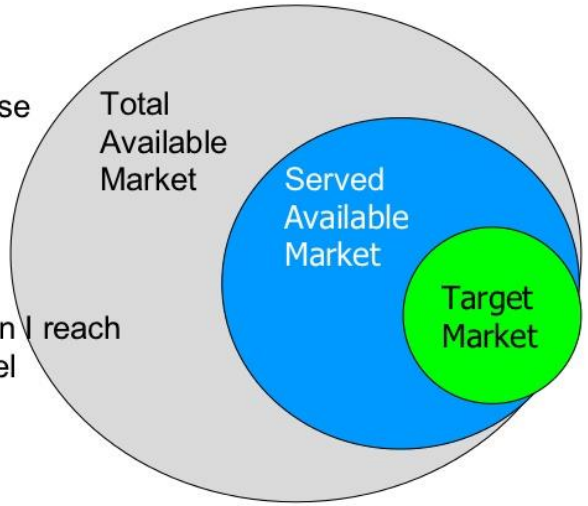
Sector Specialist
- Giles Proffitt (JRI Orthopaedics/Ortheia)

- 20+ years' commercial experience within the MedTech sector, primarily focused on marketing, NPD/NPI and new business development
- Worked with both start-up and established healthcare businesses
- Appreciation of the health technologies landscape ranging from NPD to market access
- Has developed and managed collaborations and projects with major universities and hospitals, with a focus on orthopaedics, woundcare, assistive technologies and endoscopic surgery

Total Available Market, Served Available Market, Target Market

TAM = how big is the universe

SAM = how many can I reach with my sales channel



Target Market (for a startup) = who will be the most likely buyers

MedTech BEST Entrepreneur

MedTech BEST
Understanding Customer Needs

Difficult to do!

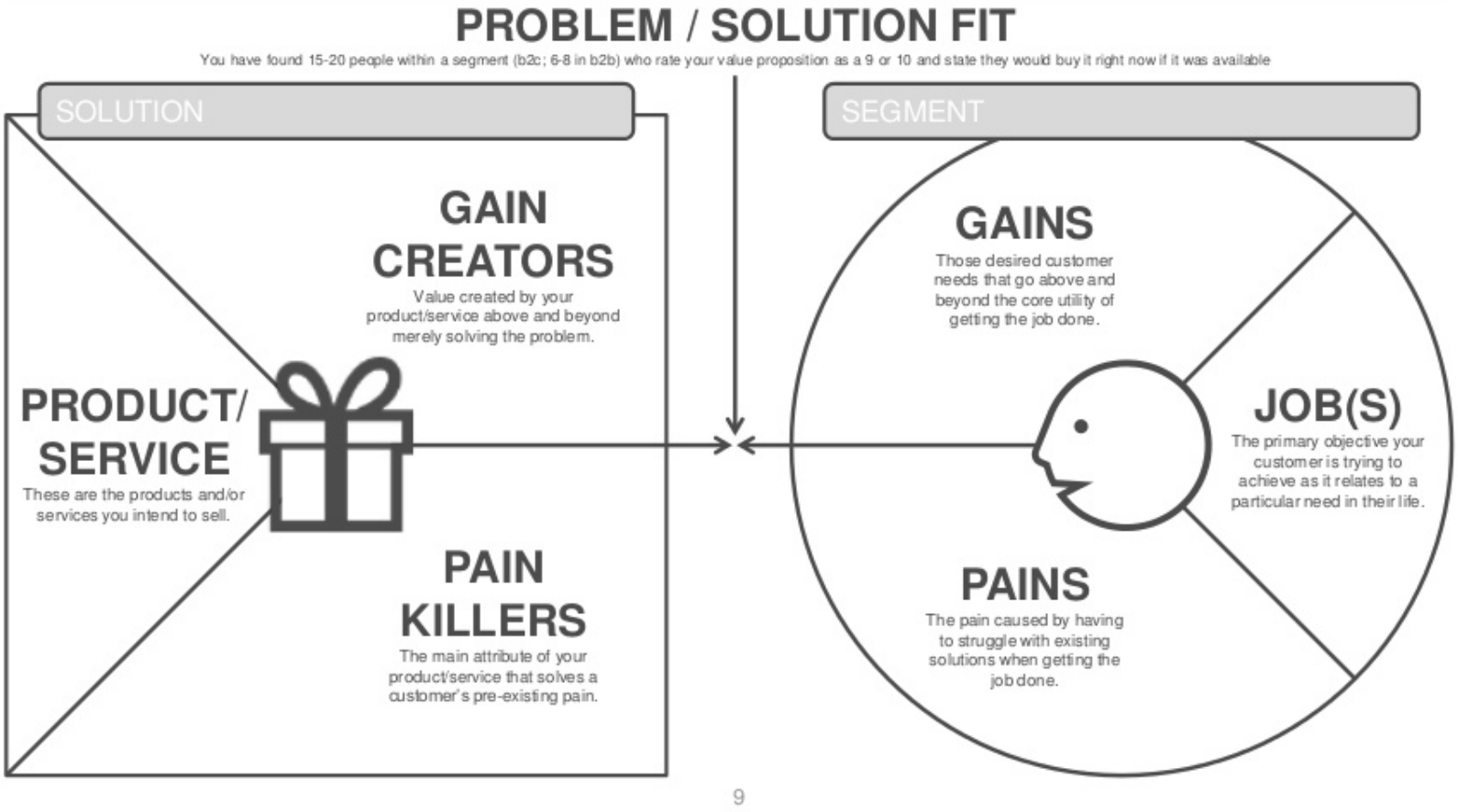
- Who is your customer? (You will have several)
- What do they use today?
- How satisfied are they with this?
- Is there a better way to get the job done (that the customer hasn't thought of/isn't aware of)?
- Think back to the Value Proposition canvas – what did this tell you?
- How will you find out?

MedTech BEST Entrepreneur

MedTech BEST Entrepreneur

Quick recap:

VALUE PROPOSITION DESIGN EXPLANATION

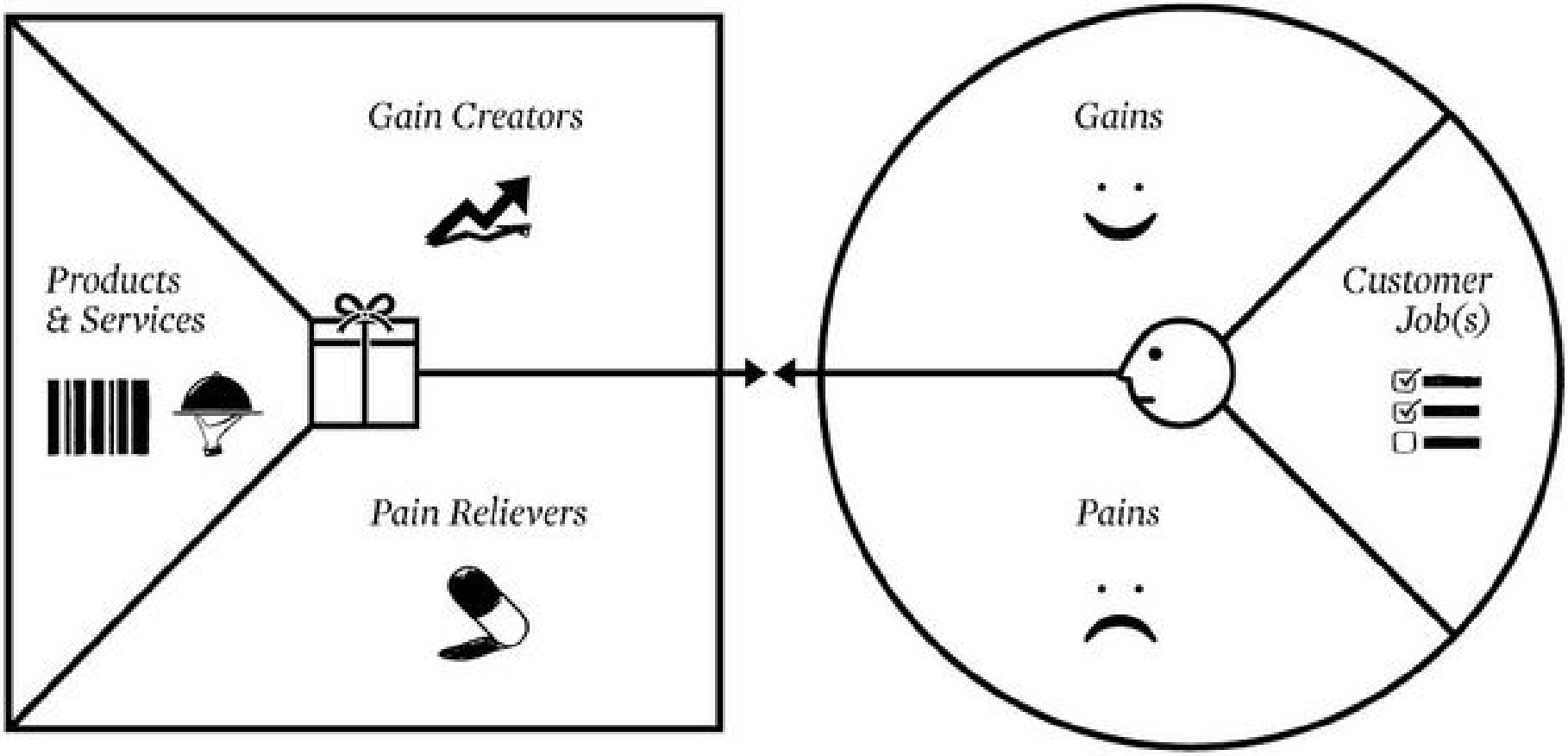


Value Proposition Design, Alexander Osterwalder

Value Proposition Canvas – Modified #2

Product:

Customer:



Substitutes:

Value Proposition Design, Alexander Osterwalder

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.

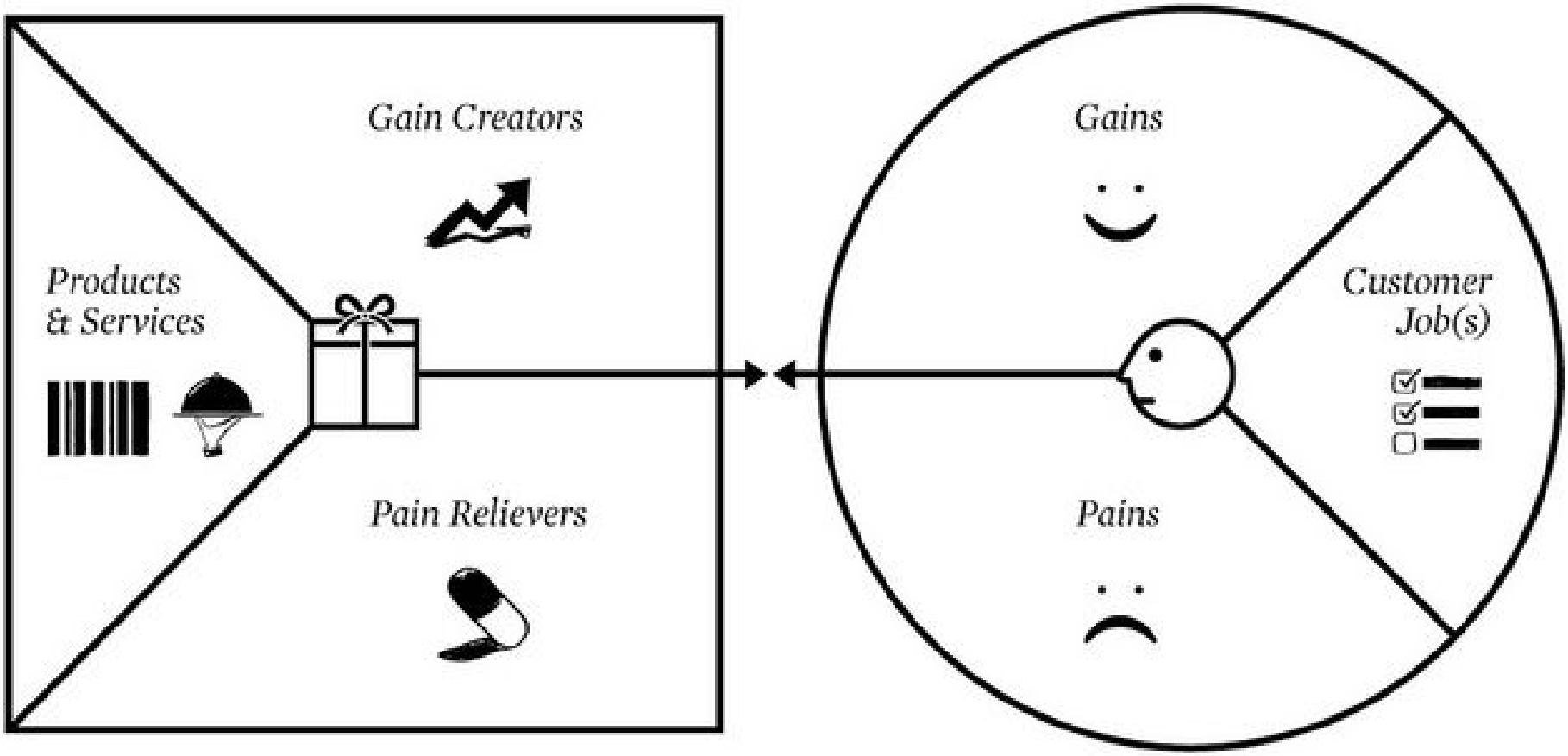
Value Proposition Canvas

Refine for your product concept

30 minutes working in your teams

Product:

Customer:



Substitutes:

Value Proposition Design, Alexander Osterwalder

Enablers

IP

Medical Device Regulations

Intellectual Property

- MedTech BEST talk December 2016

– Fiona Kingscott, Langleys Solicitors

https://regenerative-medicine.leeds.ac.uk/medtech-best/medtech-best-2016-17/sector-specialist-presentations/

- Medical Device regulations – my talk, November 2015

- To be placed on MedTech BEST site

Introduction to IP

IP is a set of legal rights, in categories such as

- confidential information / know-how
- patents
- copyright
- computer programs
- databases
- designs
- passing off & trade marks

Confidential information / know-how

- The law of confidence says that where:
  - you have information that is (a) important and (b) not in the public domain; and
  - you impart it to someone in conditions of confidence; and
  - they misuse it, i.e. publish it or make use of it;

  you have a cause of action against them.
- To bolster this legal right, we get people to sign NDAs (contracts). These set out the position in more detail.

Patents

- Patents are 20-year monopolies
- Available for inventions (new ideas, which are inventive)
- The deal is you disclose the idea in detail, in return for the monopoly, and you pay fees

Copyright

- Authors have long-lasting rights to prevent the copying of their original works (such as original text, drawings, photos, or compilations of data)
- To enforce this right, you have to prove copying or publishing, of a ‘substantial’ part of the work
- Use of a copyright work for criticism or review, where you acknowledge its source, is permitted

Computer programs

- Copyright protects the source code, but not the underlying ideas
- The Software Directive sets down special rules, but still does not prevent the copying of the ideas behind the program, only the literal copying of lines of code

Designs

- The novel shape or appearance of your product can be protected
- Protection is better for aesthetic designs

Designs which are solely dictated by technical function

- Protected in the UK automatically, for 15 years
- Protected by the copyright in your design drawings in most countries of the world

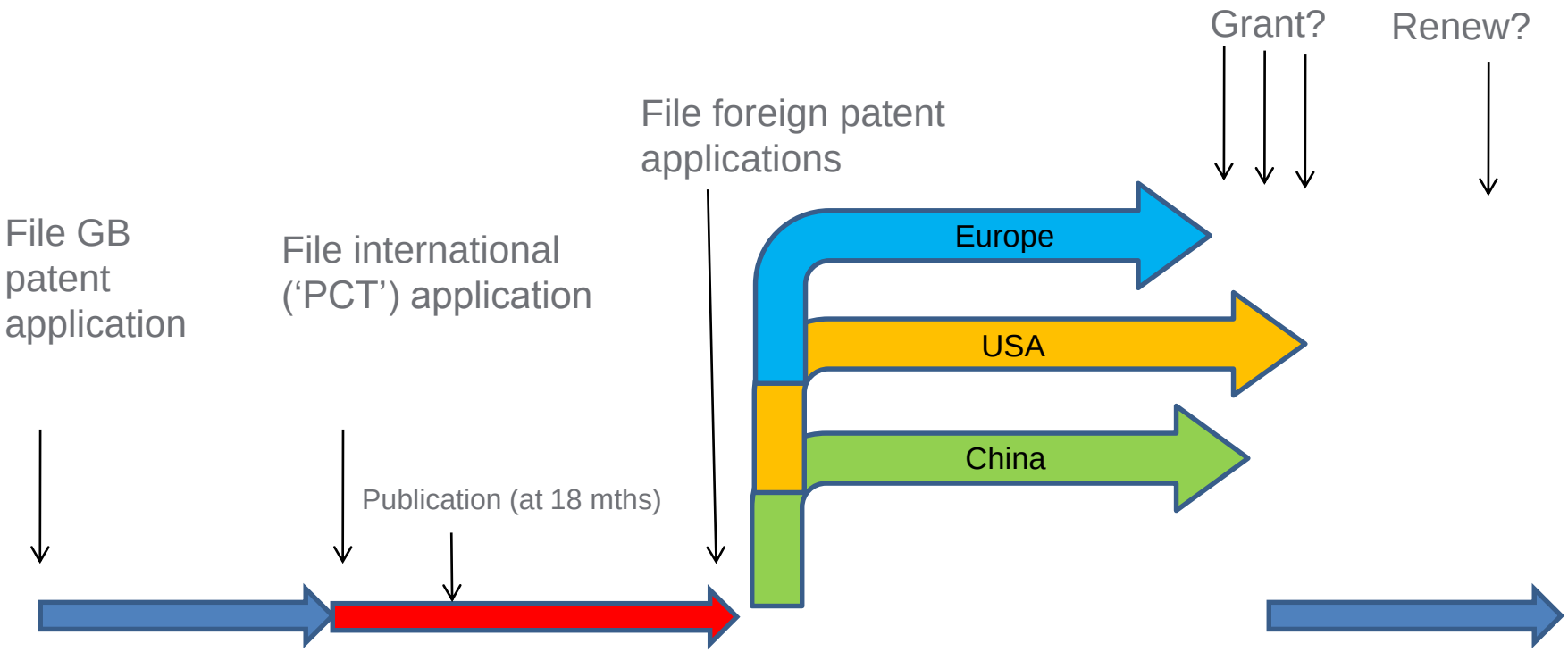
Designs with aesthetic appeal

- Protected across the EU automatically, but only for 3 years from publication date
- Better protected across the EU when you register the design, for up to 25 years, which you can do cheaply and easily

Trade marks

- You can protect IP rights in the name, colour, shape, etc. of your product, where you've built up a reputation
- If you register your trade mark you get a strong right to prevent use of it, in the classes of goods/services for which you register it
- Registered trade marks last indefinitely, as long as you pay the renewal fees
- Unregistered marks are protectable under the law of passing-off

A typical filing strategy



c. £3,500

c. £1,500

c. £2,000 to £6,000 per country

c. £1,000 per country

c. £1,000 per country but rising each year

Freedom to operate ('FTO')

- FTO is the ability to sell a product, or carry out a process commercially, without infringing IP rights
- IP rights include patents, designs, etc., anywhere you might sell the product
- It is difficult to be 100% sure – full FTO searches take many man hours and so cost about £30,000 to £100,000
- Initial FTO checks you can carry out include searching the patent registers worldwide (e.g. using Espacenet.com)
- If you find a patent, but are not sure whether you would infringe it or not, you may decide to consult a patent attorney
- Prior art you are aware of should be notified to the patent office, when you file a patent

Why is it important to have IP in your idea?

- IP gives you exclusivity on the market: it forms a barrier to entry
- Companies aren't likely to invest in ideas which can easily be copied; they tend to look for at least three years' exclusivity on the market
- A patent, for example, gives you up to 20 years' exclusivity on the market in the country it is granted in
- Some patents are easy to work around, but a good patent covers all embodiments of your invention, and improvements to it, or 'second generation' products
- Consider various types of IP: trade secrets, trade marks, copyright in design drawings, etc.; maybe you can rely on one of these, and getting first to market

Intellectual Property

- MedTech BEST talk December 2016
  - Fiona Kingscott, Langleys Solicitors

https://regenerative-medicine.leeds.ac.uk/medtech-best/medtech-best-2016-17/sector-specialist-presentations/

- Medical Device regulations – my talk, November 2015

- Revised version to be placed on MedTech BEST site

What is a Medical Device ?

A medical device is defined as

- Any health care product that **does not** achieve its primary intended purposes by
  - pharmacological,
  - immunological or
  - metabolic means
- Medical Devices are separated into **classes** to include general controls and definition of risk
- **Regulatory** control increases as class or risk increases
- Classification or risk defines the **regulatory requirements** for device type

Medical devices – what is included?

- The **principal mode of action** is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).
- Medical devices may be **assisted** in their function by pharmacological, immunological or metabolic means but this must not be their principal mode of action.
- Accordingly, where a product achieves its principal intended action by pharmacological, immunological or metabolic means, it is a **medicinal product**.

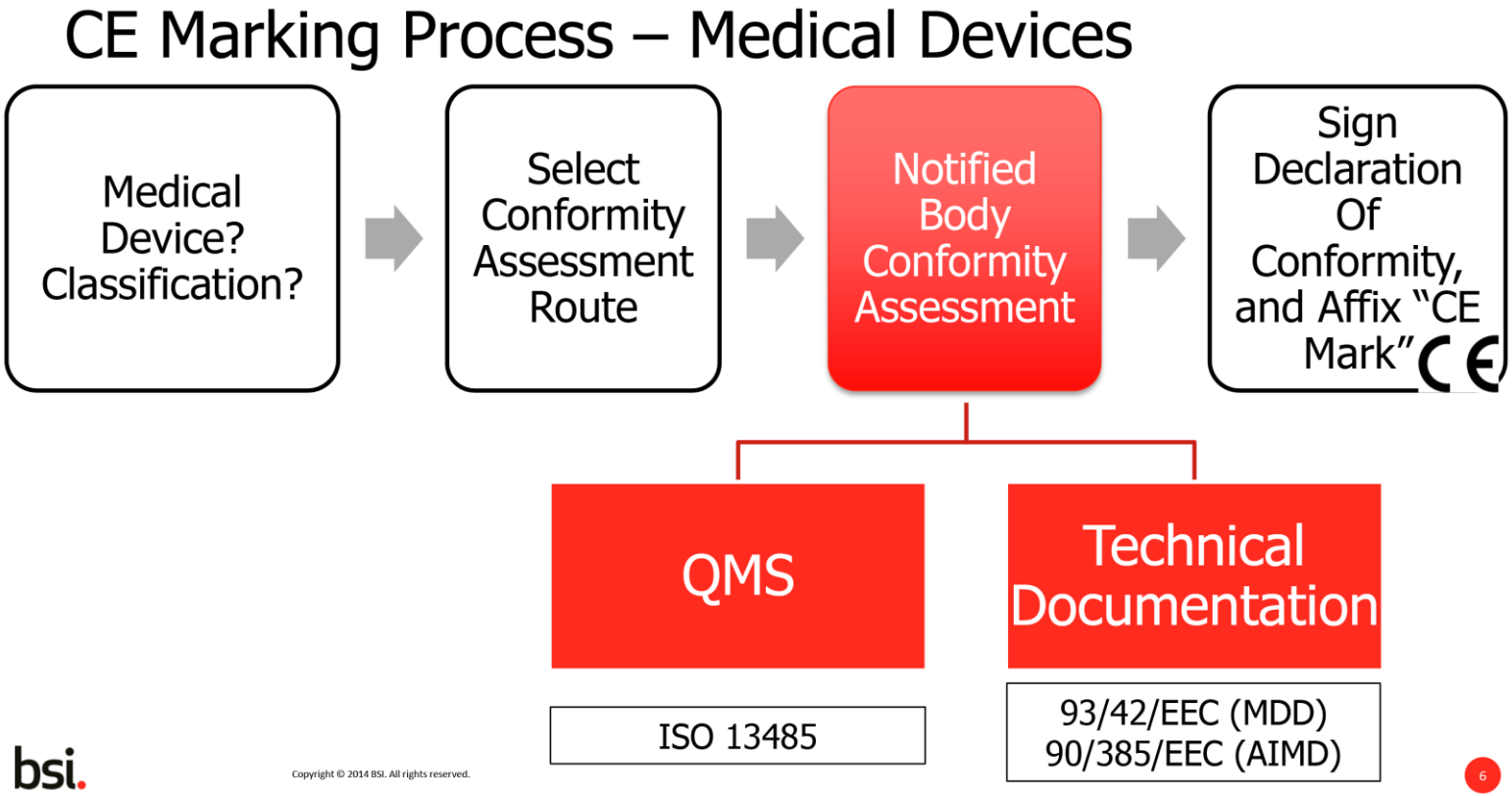
(MHRA)

Medical Devices Legislation

Medical Devices are regulated by three Directives:

- 90/385/EEC on Active Implantable Medical Devices (AIMD)
- 93/42/EEC on Medical Devices (MDD)
- 98/79/EC on in Vitro Diagnostic Medical Devices (IVD)
- Movement, placing on the market and the bringing into service of medical devices harmonised throughout the EU Member States
- Design and manufacture of medical devices is subject to **essential requirements** concerning protection of the health and safety of patients and users of these devices

Routes to CE marking



Current/Revised Medical Devices Legislation

Medical Devices are regulated by three Directives:

- 90/385/EEC on Active Implantable Medical Devices (AIMD)
- 93/42/EEC on Medical Devices (MDD)
- 98/79/EC on in Vitro Diagnostic Medical Devices (IVD)

REVISED!

- Medical Device Regulation (MDR) 2017/745 (replaces the MDD and AIMD)
- In Vitro Diagnostic Device Regulation (EU) 2017/746

Changes:

- more scrutiny of technical documentation
- stricter requirements on clinical evaluation and post-market clinical follow-up (addressing concerns over the assessment of product safety and performance)
- better traceability of devices through the supply chain.

In Vitro Diagnostic Device Regulation (EU) 2017/746

The IVD Regulation is significantly different to the IVD Directive:

- changed classification rules and requirements for conformity assessment
- Intended to strengthen the current approval system for in vitro diagnostics, making substantial changes to the existing IVD Directive (98/79/EC) legislation, first introduced in 1998
- Adopted in May 2017; 5 year transition period now in force
- Articles 10-15 outline the roles and responsibilities of the various actors involved in the manufacture and supply of products into Europe
  - Includes concept of the Person Responsible for Regulatory Compliance (similar to Pharma Qualified Person)

Revised Medical Devices Legislation

Now need to ensure:

- the device has been correctly classified against the new risk classification criteria (Annex VIII of the MDR and IVDR)
- general safety and performance requirements are met, including for labelling and technical documentation and quality management systems (Annex I of the MDR and IVDR)
- increased requirements for clinical evidence are met (Annex XIV of the MDR and IVDR)
- manufacturers have a person responsible for regulatory compliance in place (Article 15 of the MDR and IVDR)
- economic operators in the supply chain are compliant
- sufficient financial coverage is in place, in respect of a manufacturer's potential liability (Article 10 of the MDR and IVDR)
- the new vigilance reporting timescales are met and that an annual periodic safety update report is created (Chapter VII, Section 1 and 2 of the MDR and IVDR) https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

Examples of products which are considered to be medical devices include:

- Medicine measuring cups
- Syringes
- Dental instruments
- Stethoscopes
- Thermometers
- Prescription spectacles and contact lenses
- Bandages and splints
- Dental treatment chairs
- Wheelchairs
- Condoms
- First aid kits

Equipment which (in the UK at least) is not considered to fall within the scope of the MDD includes:

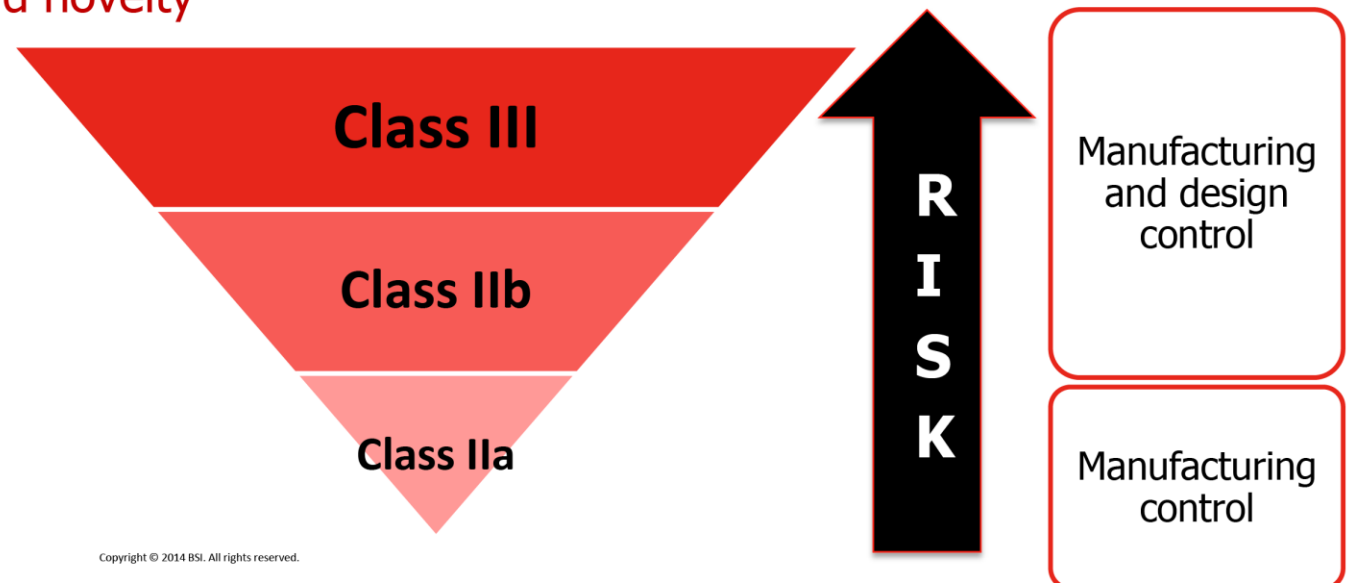
- Toothbrushes
- Baby nappies
- Mouthguards
- Intense Pulsed Light (IPL) therapy for, for example, hair removal.
- Sunglasses (which are covered under the Protective Personal Equipment Directive)
- Breathalysers
- “Consumer products aimed at comfort”
- “Products for sport or leisure”
- Cosmetic products, including tooth whitening products
- Protective gloves - within the scope of the MDD if intended for direct contact with patients; if used in a medical lab are considered to be PPE

(Conformance Ltd)

Routes to CE marking

Technical Documentation: NB Assessment

- NB scrutiny of documentation increases with risk classification
  - ...and novelty



bsi.

CE marking

Products shipped must bear the CE marking to show compliance with the directive. If a Notified Body is involved in the approval, the number of the Notified Body must also appear adjacent to the CE marking.
Additionally, the product must be shipped with a Declaration of Conformity

(601 Help)

EC Declaration of Conformity
Council Directive 93/42/EEC concerning medical devices

We *(Name and address of manufacturer)*
Certify that the product described is in conformity with the applicable provisions of Council Directive 93/42/EEC concerning medical devices.
(Name, type or model, lot, batch or serial no. etc.)
(Description)

(Name of Responsible Person) *(Signature of Responsible Person)*
(Date)

Company Roles

Intellectual Property

- MedTech BEST talk December 2016

– Fiona Kingscott, Langleys Solicitors

https://regenerative-medicine.leeds.ac.uk/medtech-best/medtech-best-2016-17/sector-specialist-presentations/

- Medical Device regulations – my talk, November 2015

- To be placed on MedTech BEST site

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 (KPI's) 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.

Startup Development Phases - From idea to business and team to organization.

Version 3.0 - www.startupcommons.org

Company Roles

Formation

- Visionary/dreamer
- Customer champion
- Innovation architect/technical insight
- Financial nous – assesses viability of organisation

Validation

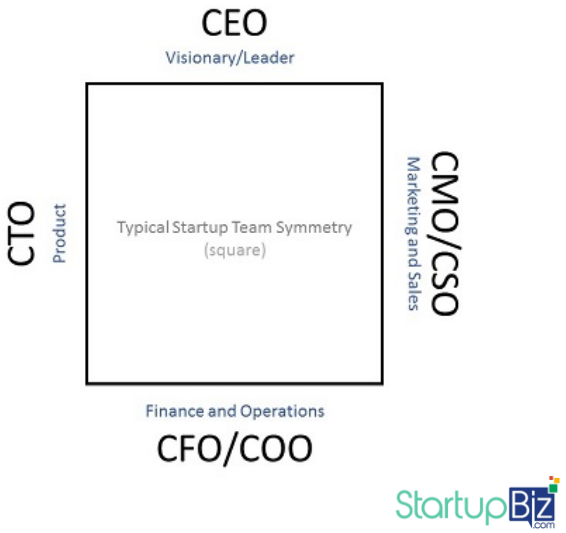
Growth

Company Roles

Validation

Solutions tested – resources added allowing formalisation of roles

- CEO – strategic vision
- Product/technology building (CTO)
- Financial management (CFO)
- Marketing (CMO)
- Operations – systems, processes (COO)
- R&D?

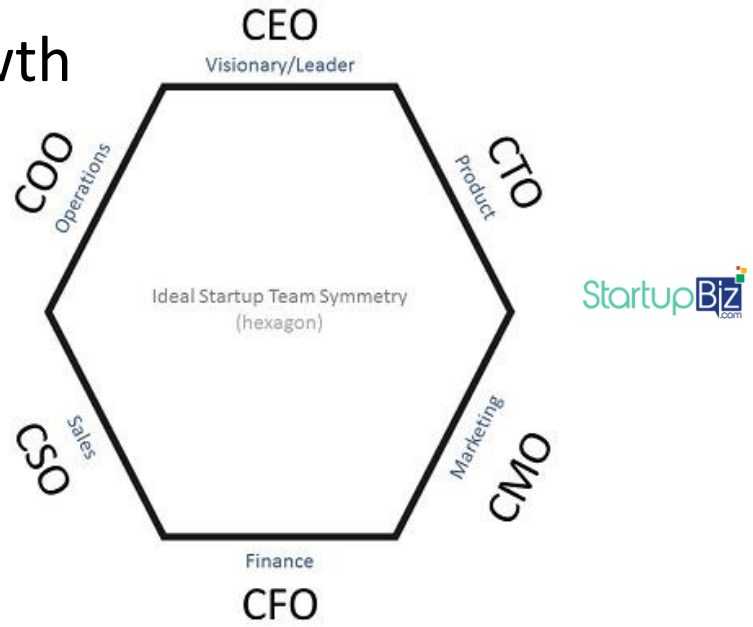


Company Roles

Growth

Scale up and market traction/growth in market share

- Add sales (CSO)
  - Responsible for revenue growth
- Add IP role to CTO



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

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

For next time…….
13 March 13.00 – 16.00

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

MedTech BEST

ROYAL ACADEMY OF ENGINEERING

UNIVERSITY OF LEEDS

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