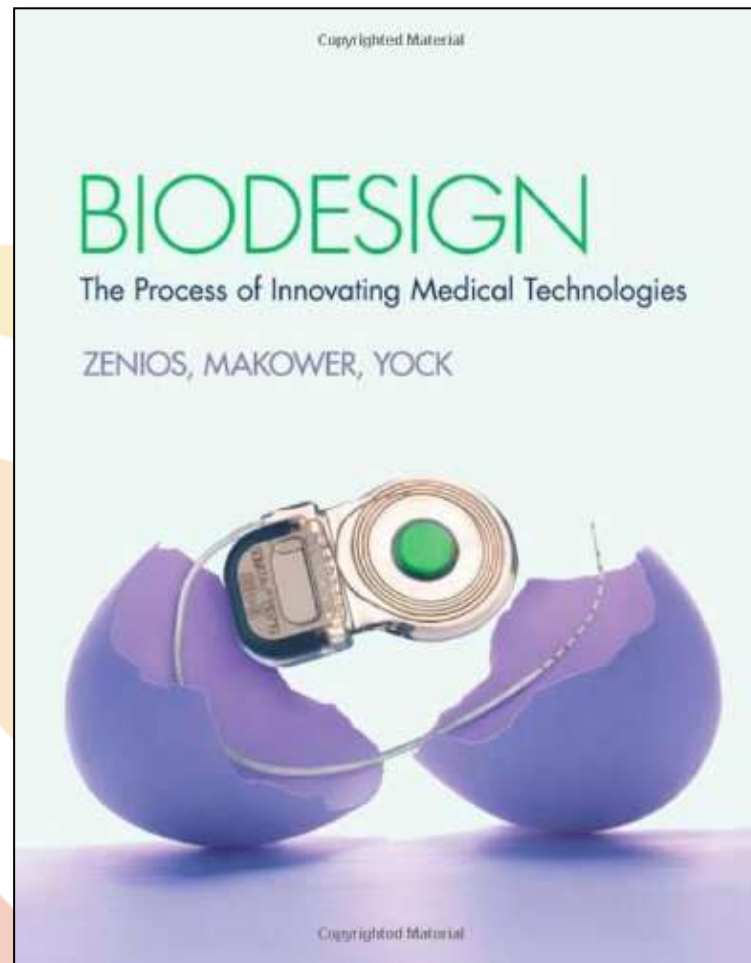


SH1.4 IL PROCESSO DI INNOVAZIONE DEI DISPOSITIVI MEDICI: DAL CONCEPT AL MERCATO

Irene Lasorsa

30/07/2019 - ore 15.00

L'approccio



METHODOLOGY

Processo di innovazione dei dispositivi medici

- Ricerca dei bisogni
- Selezione dei bisogni
- Generazione del concept
- Selezione del concept
- Strategia e Pianificazione
- Integrazione

IDENTIFICAZIONE
INVENZIONE
IMPLEMENTAZIONE

IDENTIFICAZIONE

1. Ricerca dei bisogni
2. Selezione dei bisogni

1. Ricerca dei bisogni

IDENTIFICAZIONE

- 1.1 Focus strategico
- 1.2 Osservazione e identificazione dei problemi
- 1.3 Sviluppo del “Need Statement”

1.1 Focus strategico

«An engineer with a needle-phobic mother decides to design an alternate method for administering the daily insulin she takes to control her diabetes»

«A business student observing a birth at a hospital in Africa is struck by the need for a technology to prevent blood spary during the process to protect healthcare workers when the mother is infected with HIV»

Esempio focus strategico

Desiderio di esplorare miglioramenti nelle procedure di impianto della protesi dell'anca

1.2 Osservazione e identificazione dei problemi

Process	Description	Example
Set up observations	Target patient, providers, payers, and representatives from the facility	Make arrangements to spend a week performing observations in two different orthopedic surgery centers. Plan to observe full cycle of care across stakeholders
Prepare for observations	Perform background research on procedure/treatment, as well as the facility and its policies. Be prepared to ask educated questions	Research hip implant procedure and standard of care. Investigate track records, policies, and attitudes of the facilities and physicians to be observed. Make note of questions to ask and things to watch for during observations
Conduct observations	Become embedded in the team. Maintain an open mind. Watch for clues that signal a potential problem	Arrive early. Shadow the team, Be helpful (when appropriate). Stay out of the way (when appropriate). Identify clues and watch for their recurrence. Talk with stakeholders, but be careful to recognize opinions, dogma...
Document observations	Create an innovation notebook. Record only what is seen - do not editorialize	Observation = Elderly patient with degenerative hip disease who had received elective hip replacement surgery needed hip implant removed due to infection
Name the problem	Summarize critical data. Prioritize what has been learned. Articulate the most compelling problem	Problem statement = Elective hip implants to treat degenerative hip disease in the elderly can become infected and require removal
Test and refine	Conduct additional observations. Perform secondary research of the literature in the field. Refine problem statement, if needed	Find out the answers to important questions, e.g., how often does infection occur in elderly versus the general population? What causes infections? ...

**E' ANCORA TROPPO PRESTO
PER PENSARE ALLA
SOLUZIONE!**



1.3 Sviluppo del need statement

Need Statement

*A way to (SOLVE PROBLEM)
(FOR PATIENT POPULATION)
(IN GIVEN SETTINGS)
in order to (RESULT IN OUTCOME)*

Esempio need statement

Un modo per prevenire o ridurre l'incidenza delle infezioni associate agli impianti d'anca nei pazienti anziani

2. Selezione dei bisogni

IDENTIFICAZIONE

- 2.1 Conoscere la patologia di riferimento
- 2.2 Conoscere le opzioni di trattamento
- 2.3 Effettuare un'analisi degli stakeholder
- 2.4 Effettuare un'analisi di mercato
- 2.5 Selezionare i bisogni

2.1 Conoscere la patologia di riferimento

Possibili fonti:

Medscape

PubMed

Harrison's online

Centers for Disease Control
and Prevention

National Center for Health
Statistics



2.2 Conoscere le opzioni di trattamento

		Reduction in AF recurrence	Limited side effects	Minimally invasive	Non-invasive	Convenient for the patient	Economics
Rhythm control	Electrical cardioversion	-	+	+	-	-	+
	Pharmacological cardioversion	-	-	+	++	-	-
	Catheter ablation	+	-	+	-	--	-
Rate control	Implantable defibrillation	-	--	-	--	--	--
	Pharmacological rate control		-	+	+	+	+
	Catheter ablation of AV node		-	+	-	-	--
Thromboembolic risk	Pharmacological therapy		--		++	-	+

2.3 Effettuare un'analisi degli stakeholder



2.4 Effettuare un'analisi di mercato

- Segmentare il mercato
- Dimensionare il mercato
- Comprendere le dinamiche del mercato
- Comprendere i bisogni di ogni segmento
- Capire quanto il mercato è disposto a spendere
- Definire il mercato target

2.5 Selezionare i bisogni

Esempio Need Statement

A better way to detect potential rhythm disturbances in non-hospitalized patients with suspected arrhythmias

Must have

- *Minimal impact on patient lifestyle and comfort*
- *Accurately allow physicians to determine if patient's symptoms are caused by arrhythmia*
- *Ability to monitor and function over extended period of time until arrhythmia can be ruled out*
- *Inexpensive*

Nice to have

- *External device*
- *Allows diagnosis of arrhythmia if present*
- *Have limited to no patient involvement to function*
- *Ability to correlate symptoms to arrhythmic events*

INVENZIONE

3. Generazione del concept
4. Selezione del concept

3. Generazione del concept

INVENZIONE

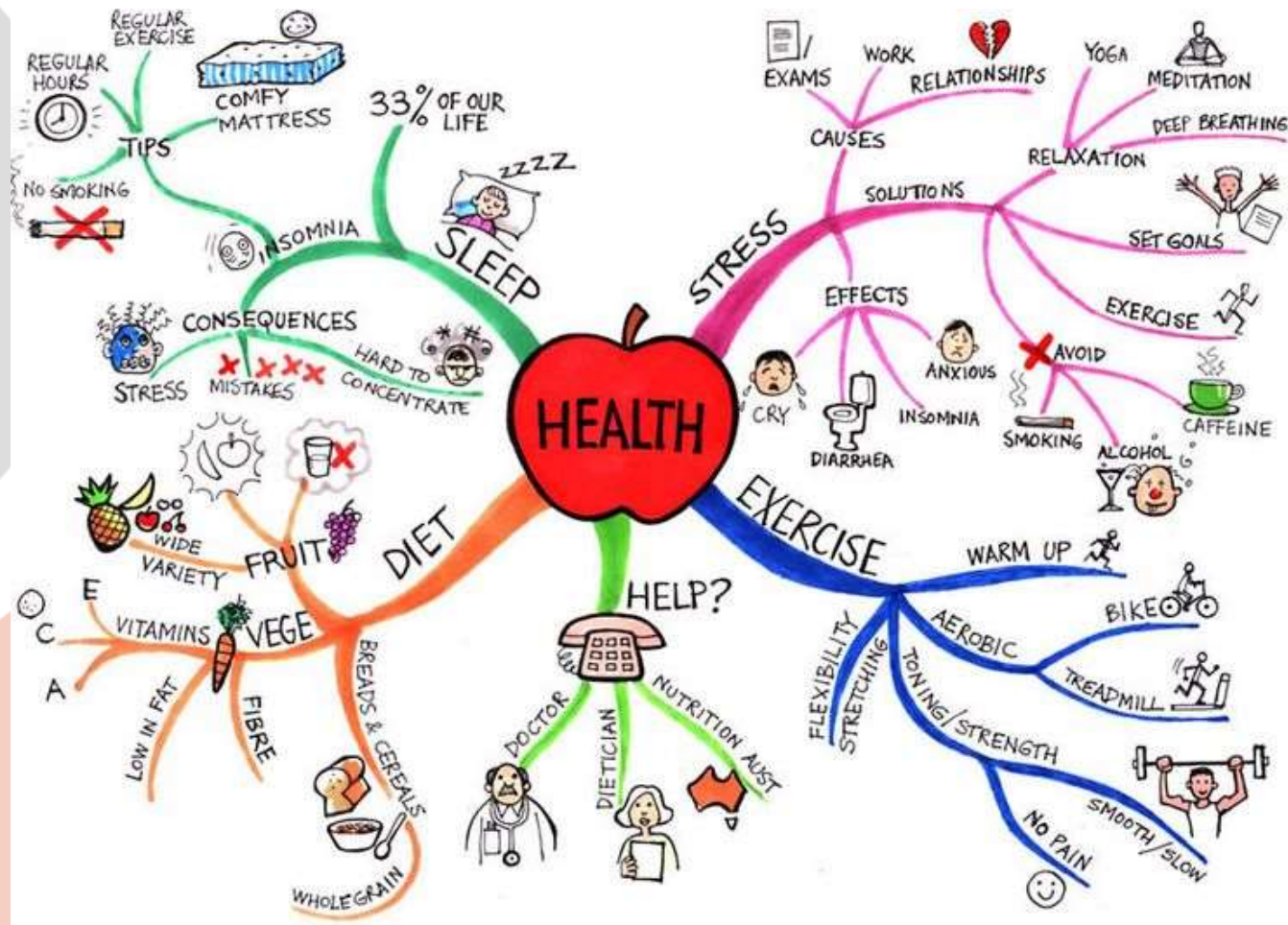
3.1 Ideazione e brainstorming

3.2 Screening del concept

3.1 Ideazione e brainstorming



3.2 Screening del concept



4. Selezione del concept

INVENZIONE

- 4.1 Basi di proprietà intellettuale
- 4.2 Basi regolatorie
- 4.3 Business Model
- 4.4 Prototipazione
- 4.5 Selezione del concept finale

4.1 Basi di proprietà intellettuale

- Recuperare informazioni sullo stato dell'arte dell'invenzione e del dominio di applicazione
- Ricercare le invenzioni pregresse già brevettate
- Identificare gli aspetti brevettabili
- Preparare la domanda di brevetto
- Presentare la domanda di brevetto

4.2 Basi regolatorie

- Identificare le normative di riferimento
- Identificare la classe di appartenenza del dispositivo
- Predisporre un percorso regolatorio da seguire

4.3 Business Model

The Business Model Canvas

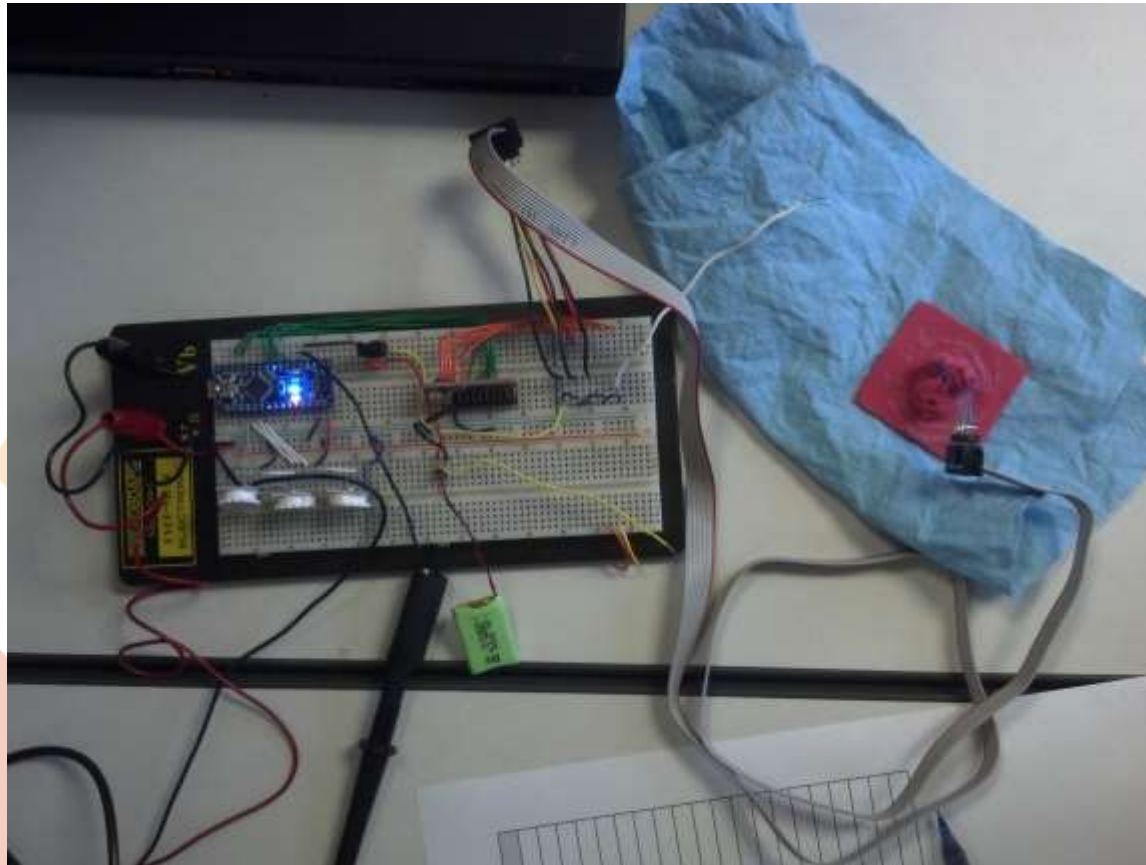
Designed for: _____ Designed by: _____ On: _____

Revision: _____

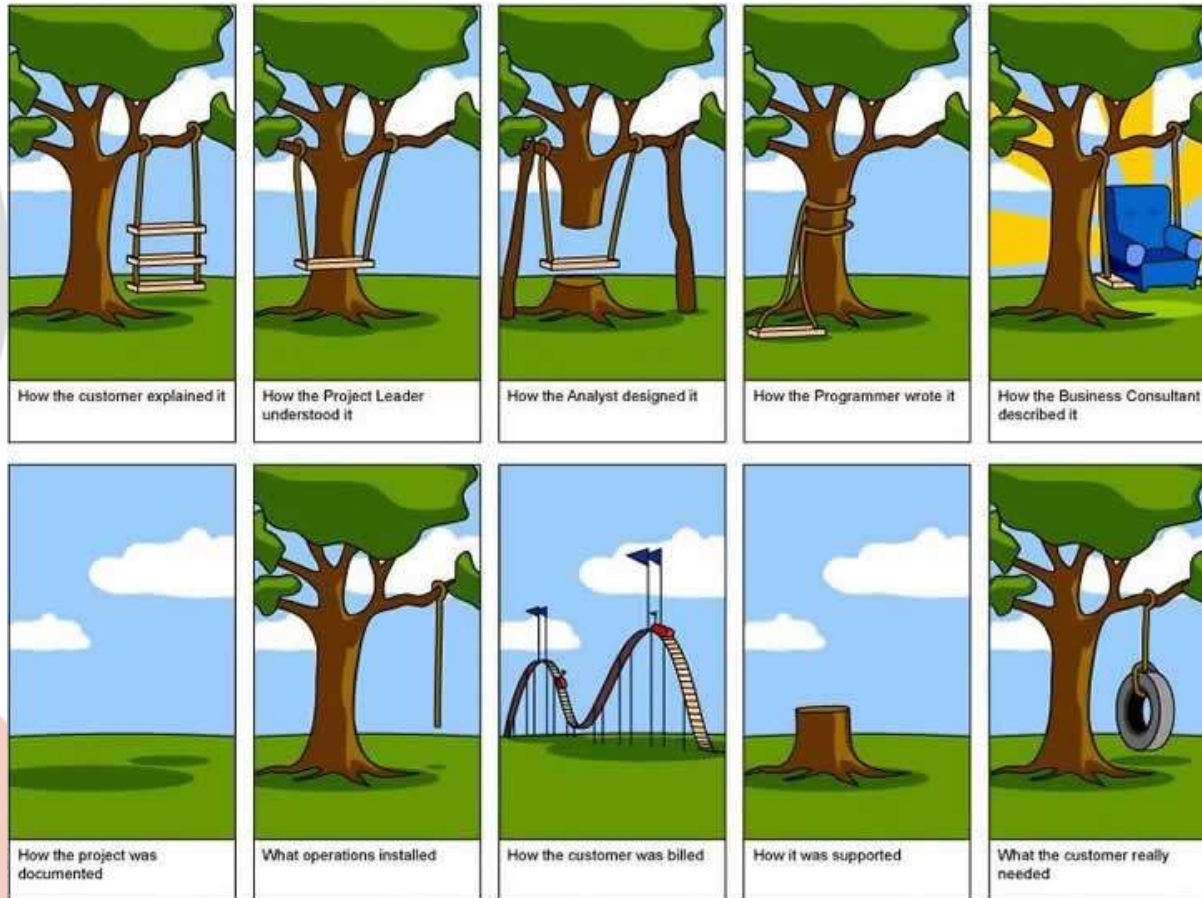
<p>Key Partners</p> <p>Who are my Partners? Who do we rely upon? Who do we buy from? Who do we partner with? Who do we co-create with?</p>	<p>Key Activities</p> <p>What Key Activities do we perform? What do we do? What are our key processes? What are our key tasks? What are our key activities?</p>	<p>Value Propositions</p> <p>What value do we deliver to the customer? What is our value proposition? What are our key benefits? What are our key features? What are our key services?</p>	<p>Customer Relationships</p> <p>What type of relationship do we want to build? How do we interact with our customers? What are our key channels? What are our key touchpoints? What are our key services?</p>	<p>Customer Segments</p> <p>Who are our target customers? Who are our key segments? Who are our key markets? Who are our key demographics? Who are our key geographies?</p>
<p>Key Resources</p> <p>What Key Resources do we need? What are our key assets? What are our key capabilities? What are our key competencies? What are our key strengths?</p>		<p>Channels</p> <p>Through which Channels do we reach our Customers? How do we reach our customers? What are our key channels? What are our key touchpoints? What are our key services?</p>		
<p>Cost Structure</p> <p>What are our key costs? What are our key expenses? What are our key investments? What are our key resources? What are our key activities?</p>			<p>Revenue Streams</p> <p>How do we generate revenue? What are our key revenue sources? What are our key revenue streams? What are our key revenue models? What are our key revenue structures?</p>	

www.businessmodelgeneration.com

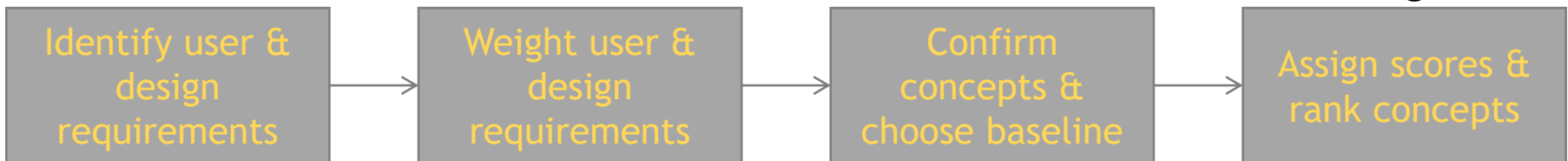
4.4 Prototipazione



4.5 Selezione del concept finale



Pugh Method



IMPLEMENTAZIONE

5. Strategia e Pianificazione

6. Integrazione

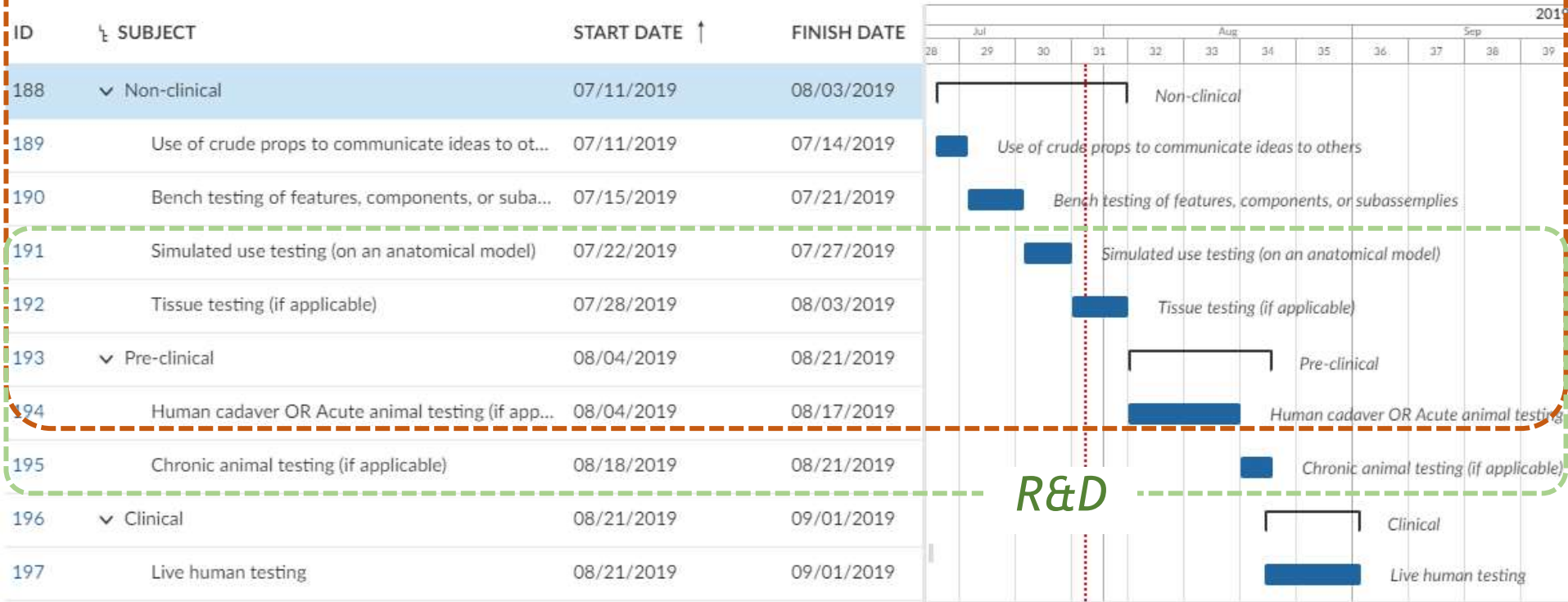
5. Strategia e pianificazione

IMPLEMENTAZIONE

- 5.1 Strategia di Ricerca e Sviluppo
- 5.2 Strategia clinica
- 5.3 Strategia regolatoria
- 5.4 Strategia di mercato
- 5.5 Strategia di vendita e distribuzione
- 5.6 Strategia di business

5.1 Strategia di Ricerca e Sviluppo

Prototyping



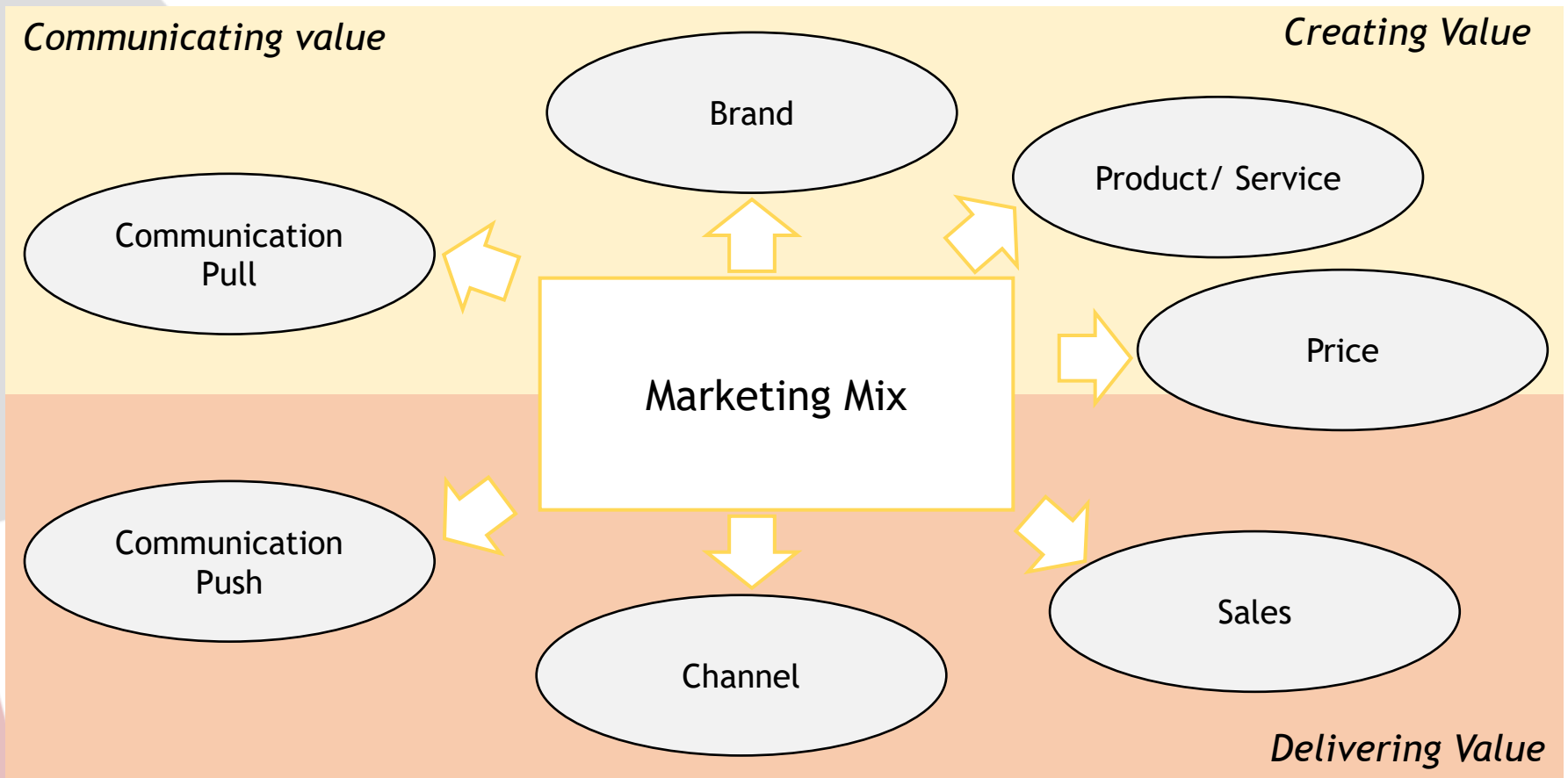
5.2 Strategia clinica



5.3 Strategia regolatoria

- Validare la classificazione e il percorso regolatorio definiti precedentemente
- Esternalizzare l'attività di sviluppo della strategia regolatoria
- Monitorare l'aderenza al percorso regolatorio

5.4 Strategia di mercato

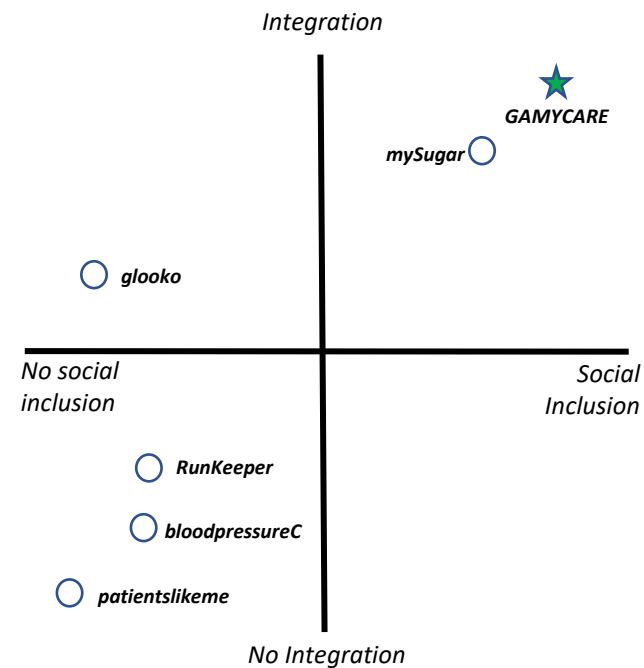


5.5 Strategia di vendita e distribuzione

- Valutare l'impatto del modello di business per raggiungere i consumatori
- Valutare l'impatto degli intermediari sulle vendite e la distribuzione
- Scegliere un modello di vendita e distribuzione
- Coordinare il marketing, la formazione e le attività di supporto

5.6 Strategia di business

	validated clinical knowledge		data processing		interfacing and interaction		interoperability		social inclusion		awareness and self-management	
	integration with clinical evidence and guidelines	Prediction of health status	personalized data-processing	Health status monitoring	multichannel delivery and interaction	education on how to use	with external medical device	with Electronic Patient Record	Social Network	Social Inclusion Real World	methods for increasing awareness	mechanisms for Self-management enhancement
patientslikeme	✗	✓	✓	✓	✗	✓	✗	✗	✓	✗	✓	✓
glooko	✓	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✓
mySugr	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
bloodpressurecompanion	✗	✗	✗	✓	✗	✗	✓	✓	✗	✗	✓	✗
RunKeeper	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓
Gamy Care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

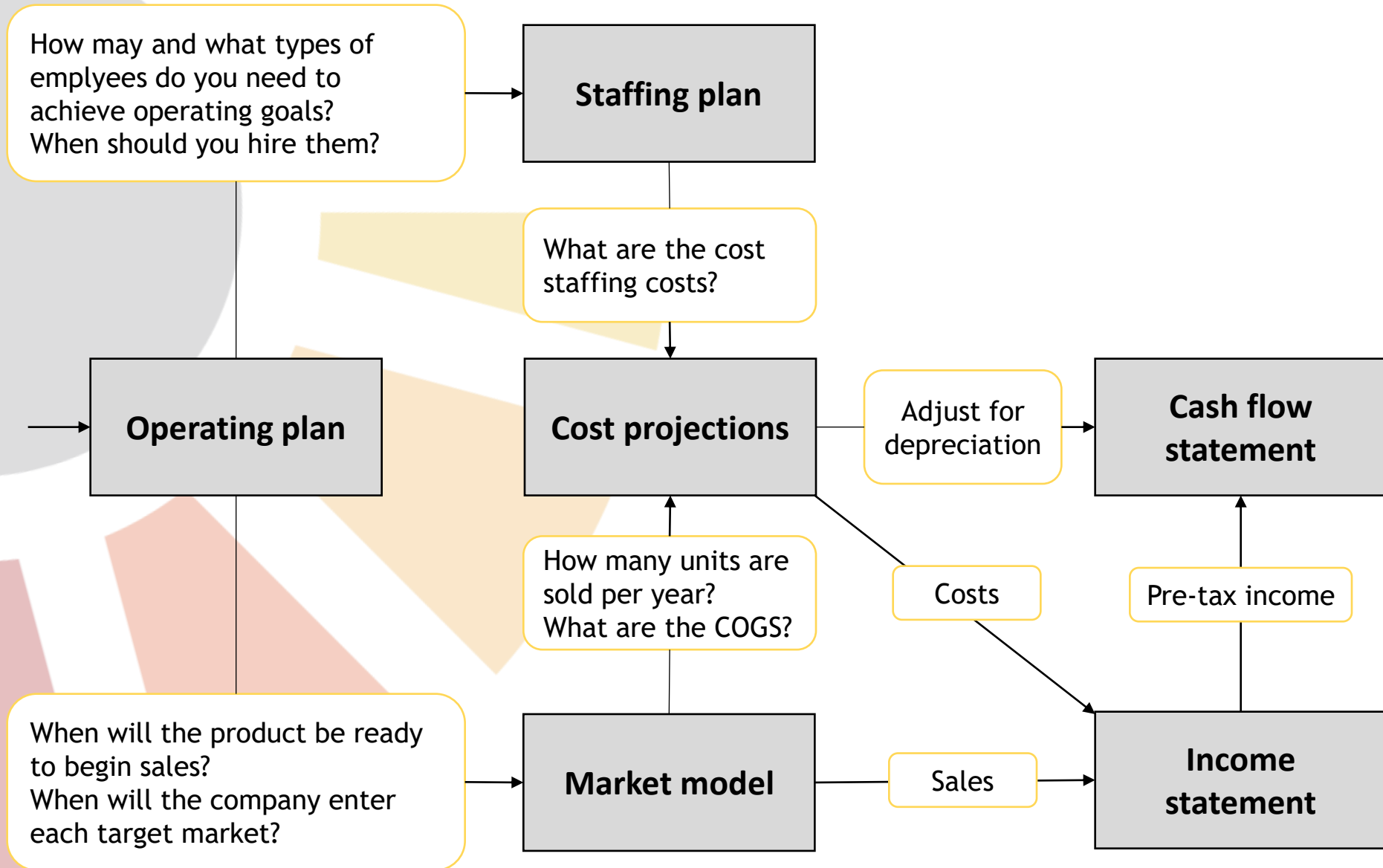


6. Integrazione

IMPLEMENTAZIONE

- 6.1 Piano operativo e modello finanziario
- 6.2 Sviluppo del Business Plan
- 6.3 Ricerca di fondi

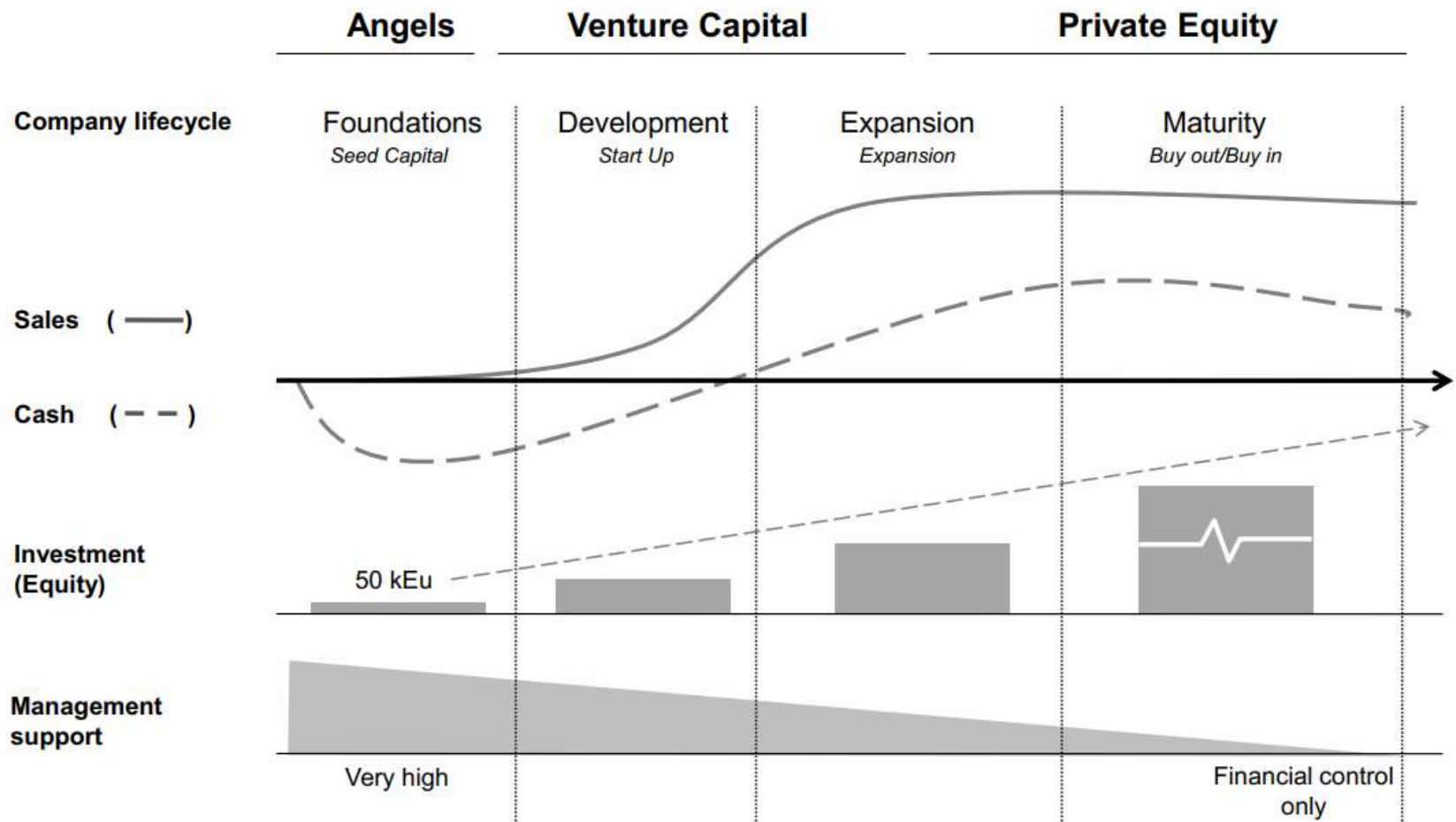
6.1 Piano operativo e modello finanziario



6.2 Sviluppo del Business Plan

Marjor BP sections	Questions to address	
The business	<ul style="list-style-type: none"> • What is the focus of the business and why? • How can the business and its strategy best be described? 	<ul style="list-style-type: none"> • Who is the business intended to serve? • What is the business' competitive advantage?
The Clinical Need	<ul style="list-style-type: none"> • What is the need being addressed? • Why is this need important? 	<ul style="list-style-type: none"> • How is the need currently being addressed? • In what ways are current solutions inadequate?
The product /service	<ul style="list-style-type: none"> • What is the proposed solution to the need? • How will it be used (and by whom)? • How does it better address the need than what is currently available? • What is the Value Proposition? 	<ul style="list-style-type: none"> • How will the company prove that the solution is technically feasible? • What are the most critical technical risks and how will they be mitigated? • How will the product be manufactured and where?
The market	<ul style="list-style-type: none"> • Who is the target customer? • What is the market size? • How fast is growing? 	<ul style="list-style-type: none"> • Who are the primary competitors? • How will the company differentiate itself? • What are the barriers to entry?
IP	<ul style="list-style-type: none"> • How will the company protect its IP? 	<ul style="list-style-type: none"> • How strong is its IP protection?
Regulatory	<ul style="list-style-type: none"> • How will the company get its product approved for the market? 	<ul style="list-style-type: none"> • What will be required to demonstrate safety and efficacy?
Clinical studies	<ul style="list-style-type: none"> • How will the company collect safety and efficacy data? • What other endpoints will be studied (and why)? 	<ul style="list-style-type: none"> • Where will the studies be performed and who will be the key investigator?
Sales and marketing	<ul style="list-style-type: none"> • Why will customers be compelled to use the product? 	<ul style="list-style-type: none"> • How will the company reach customers and generate profit?
Financial	<ul style="list-style-type: none"> • What are the company's financing needs? • What does it intend to do with the money raised? 	<ul style="list-style-type: none"> • How (and when) will it generate a return for investors?
Management team	<ul style="list-style-type: none"> • Who are the key individuals that make up the company? 	<ul style="list-style-type: none"> • What specific qualifications do they bring to bear?

6.3 Ricerca di fondi



Conclusioni

- Il processo di innovazione dei dispositivi medici deve tener conto di **numerose fasi**, ognuna delle quali è fondamentale per il successo dell'impresa
- Qualsiasi soluzione deve partire dall'identificazione di un **problema** e la risoluzione di un **bisogno**
- Perché un'impresa abbia successo occorre identificare con cura il proprio **team**
- Sono necessarie **competenze complementari** e multidisciplinari
- La **passione** è il driver principale (ma non sufficiente..)