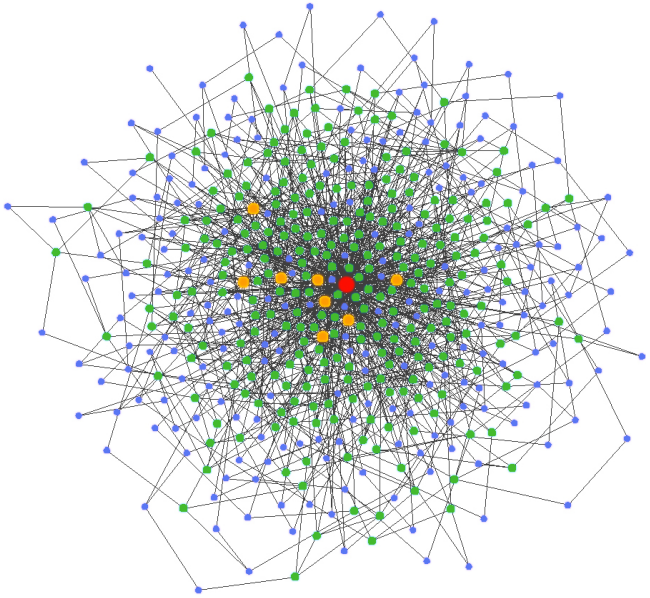
Medicis Promed

Business Bootcamp
Training for the Dragon's Den
Leman School, University of Geneva
March 2018

What is the purpose of non-science training

- cross-disciplinary understanding, economic context, co-creation of the next stage

- understand the contextual development of the science as well as each others' work.
- Understand the needs of business as partners, collaborators and investors (organisational behaviour, negotiation, innovation as part of strategy)
- Institutional frameworks (regulatory, intellectual property, policy) that most strongly affect Medicis
- Concepts of innovation, entrepreneurship and investment



The Medicis Dragons' Den'

- Lisbon 4-9th June you pitch for funding for the 'next stage' of the radiopharmaceuticals development; resources to take the next steps towards positive patient outcomes
- One panel, you have choice of "audiences" to pitch to
- Develop a case for investment between Geneva and Lison
- Group formation, instructions, research on targets and incentives between now and June
- A competition, with prizes!

BUSINESS BOOTCAMP

What is the purpose of Business

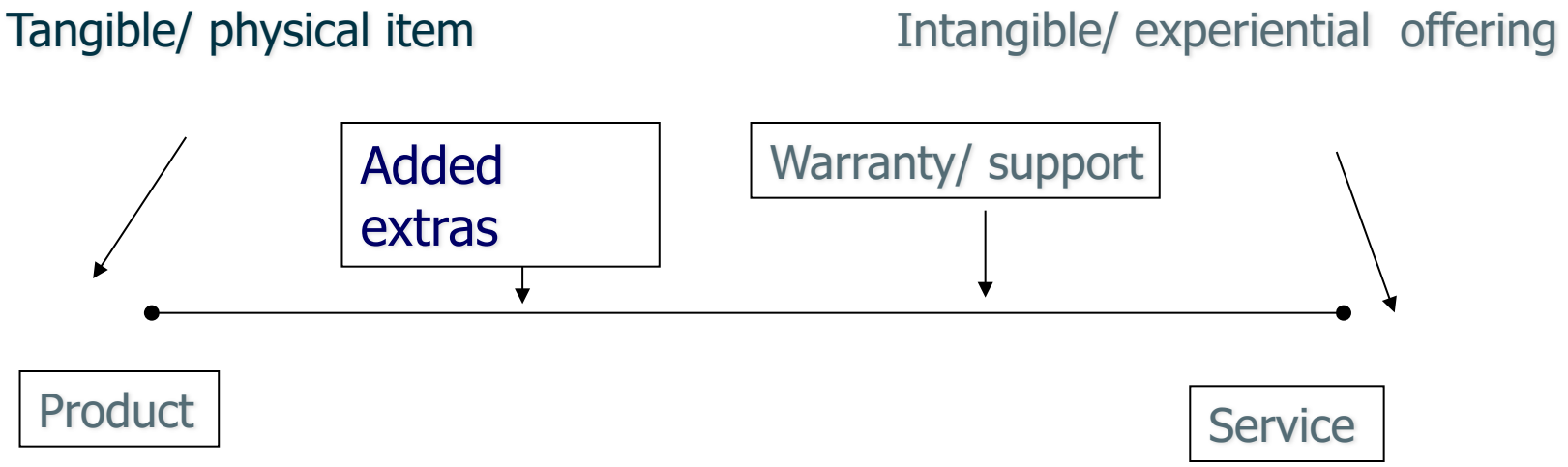
- Create financial value for owners
- Shareholders, Directors, employees
- Business acts as vehicle for other purposes, eg social impact, R&D and more
- The necessary and sufficient condition for business is customers
- Difference between end-users; who are the customers, how change or innovation creates value for customers, or new customers

What is a Market – Global markets

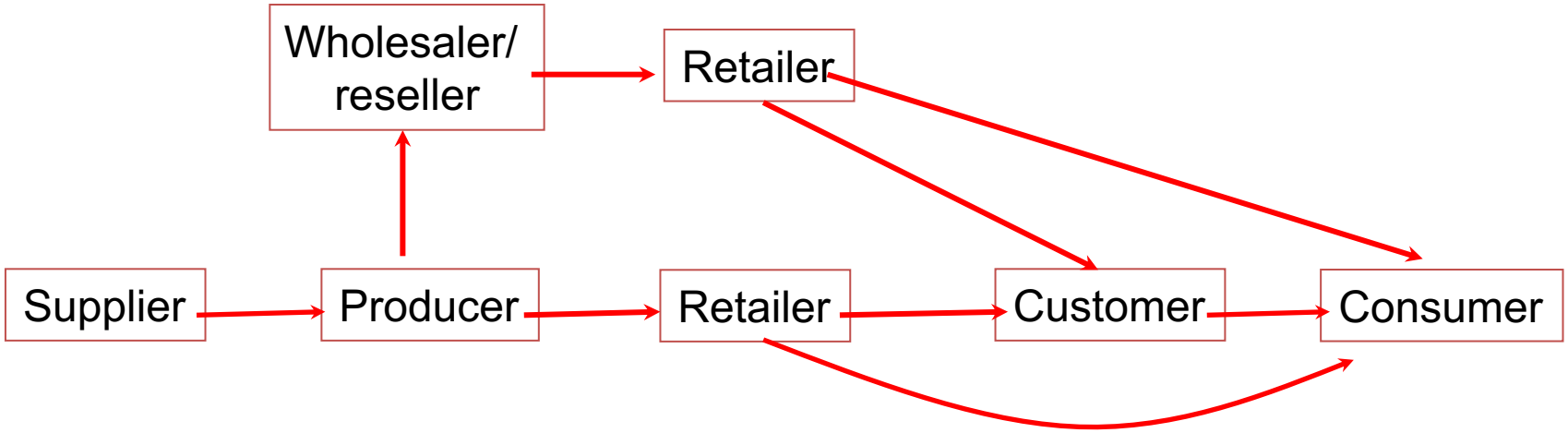
- Set of actual or paying buyers of a product process or service
- Market economics – Market forces
- Product – Service continuum

Product-Service continuum

- Services get added to the core offering to gain competitive advantage, and vice versa.
- **By adding services to products you can make them more 'valuable' to the customer**

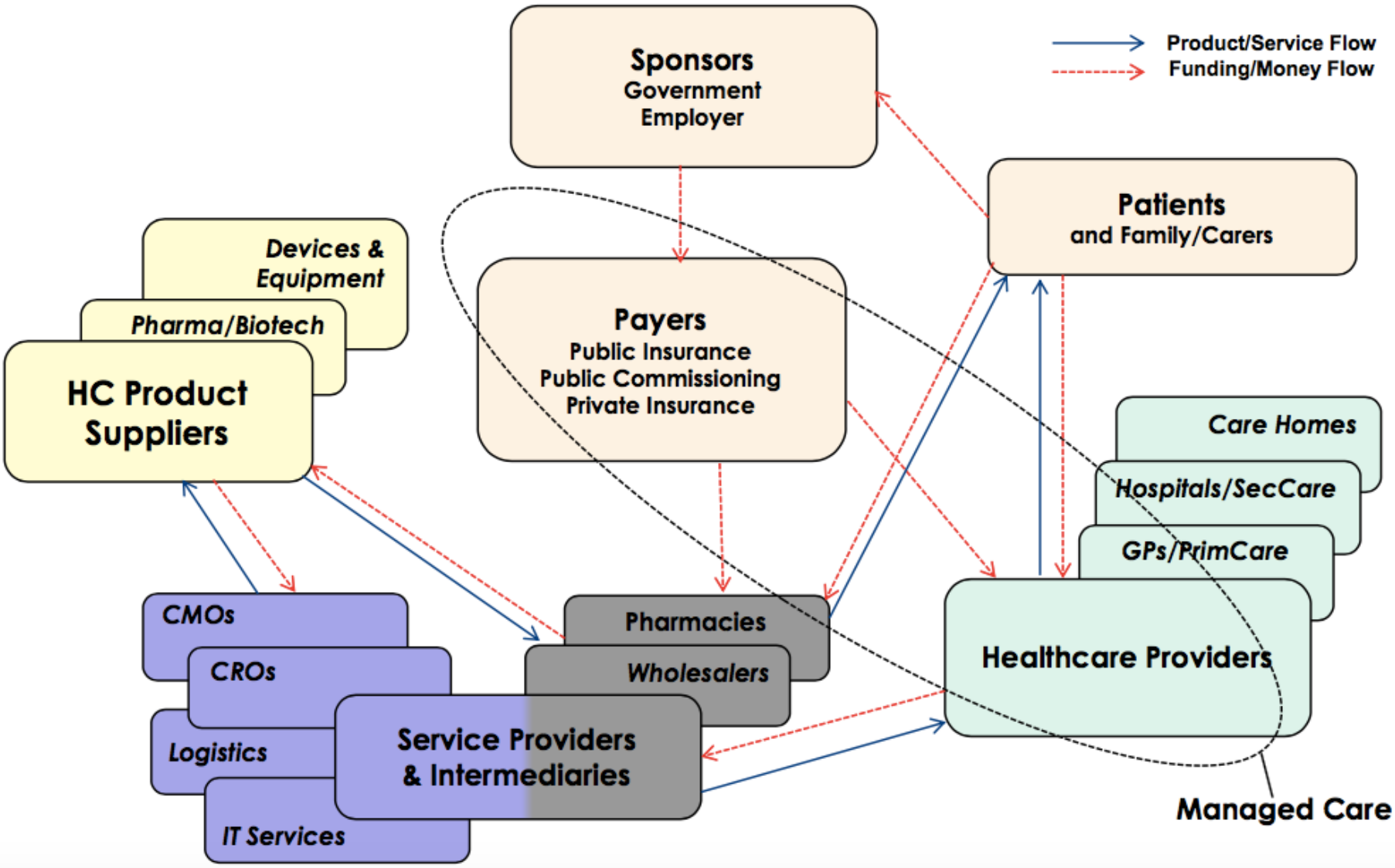


Reminder - supply chain



Supply chain. Knowing this chain intimately determines where the opportunity or entrepreneurial value lies

Healthcare System as a Whole

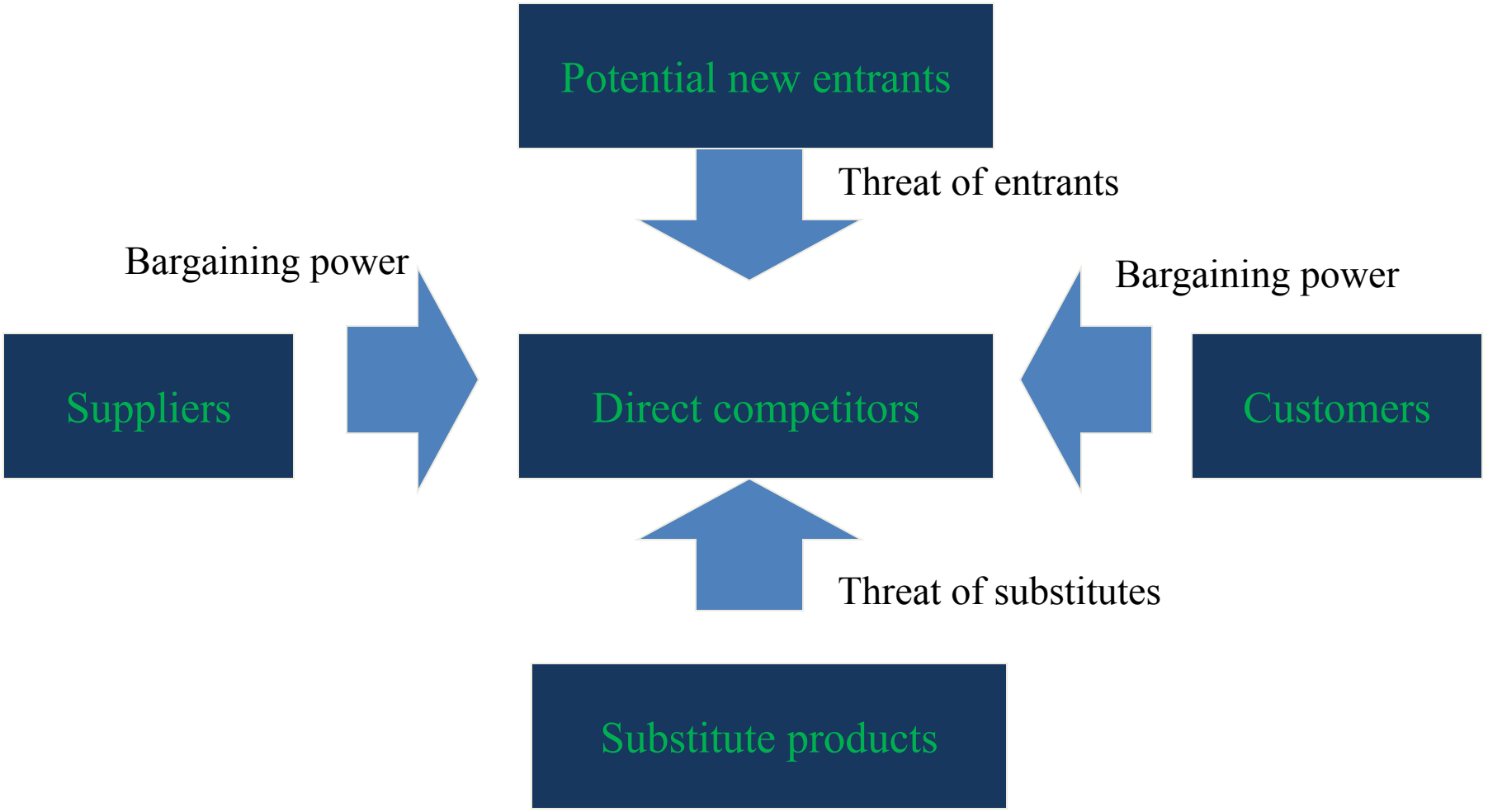


WHAT ARE THE WAYS THAT BUSINESSES USE TO EVALUATE INNOVATION INVESTMENT

Businesses map innovation investment according to…

- Strategy – Competitive position
- Alignment with internal portfolio/customers
- Integration into familiar product development processes
- Commercialisation routes
- Reputational assets

1) Strategy - Porter's Five Forces – looks at a market sector

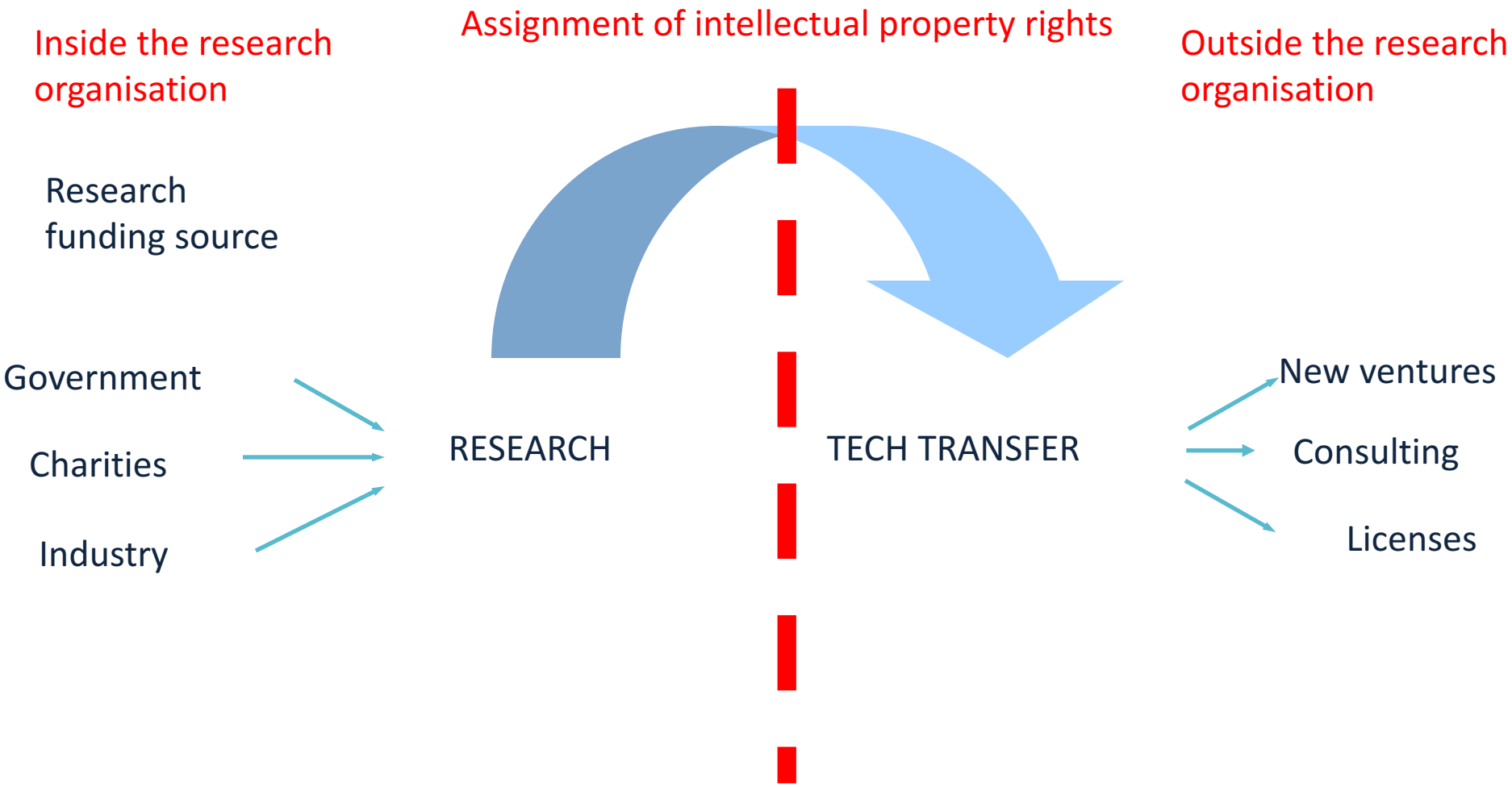


2) Commercialisation routes from science

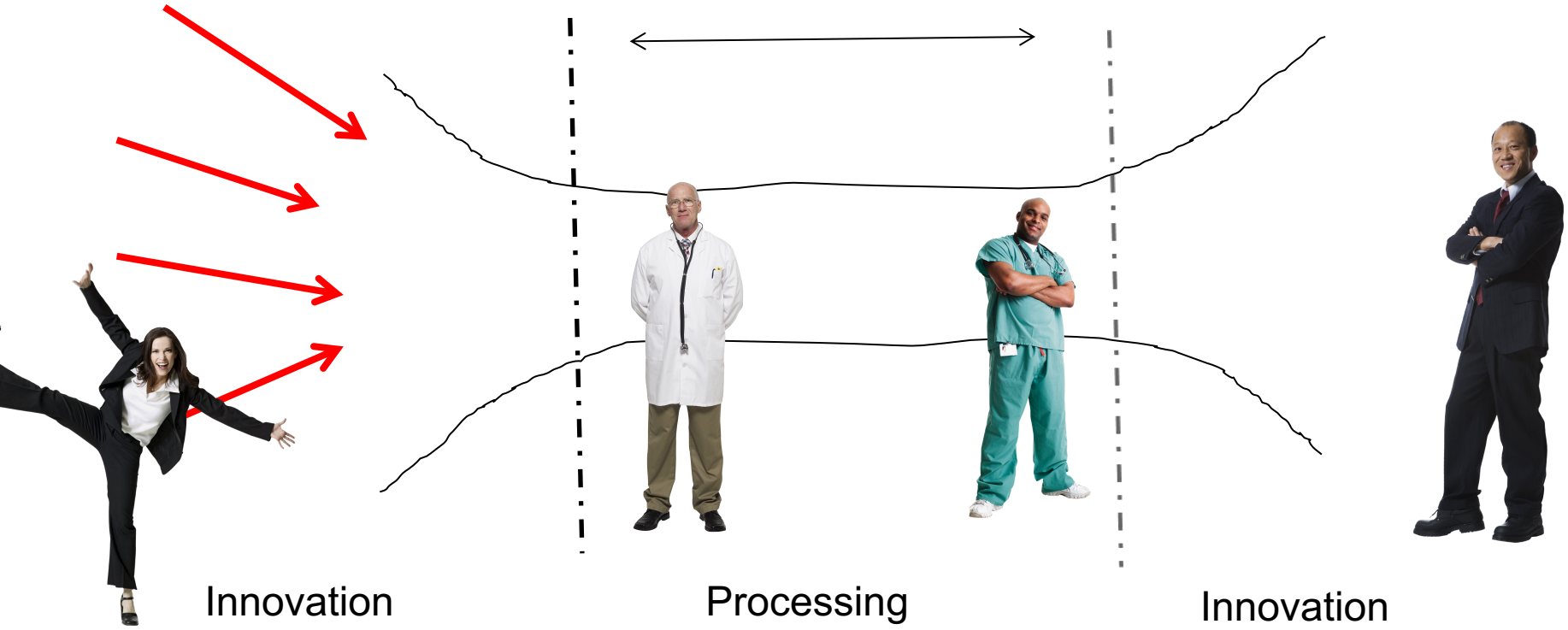
- Licensing
- Creating a company using a research organisation's intellectual property (spinout)
- Creating a company not from within an organisation, where there is no intellectual property, or you own it (start-up)
- Consultancy
- Joint venture

What are you doing

Ownership change of Intellectual Property when transferred



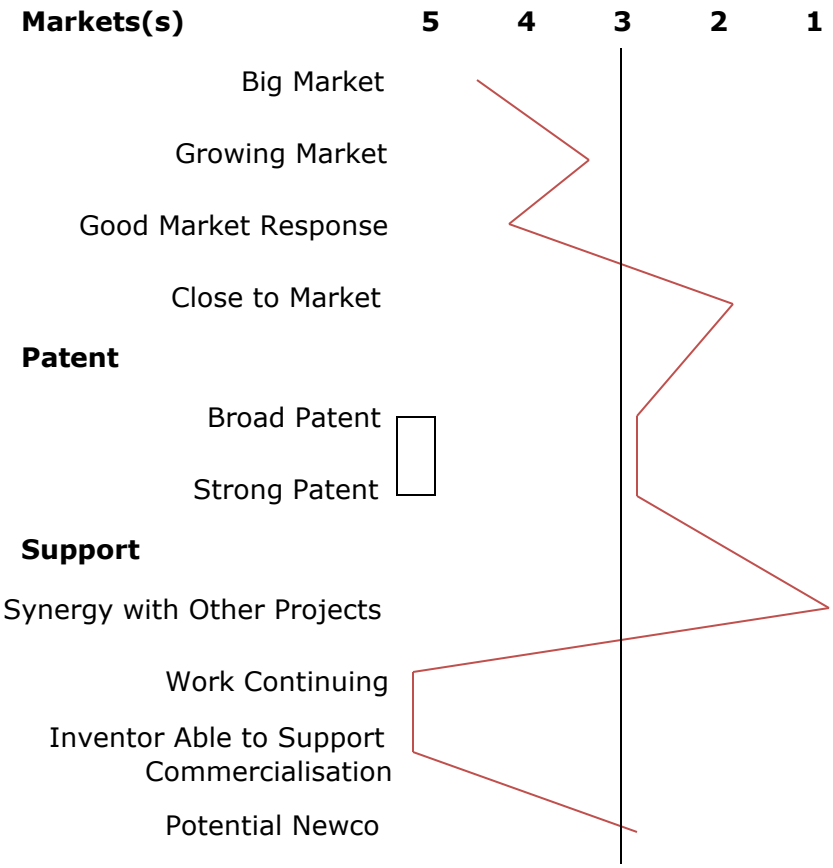
3) Integration with their own product development processes



Integration within product development processes

CORPORATE EVALUATION OF INNOVATION

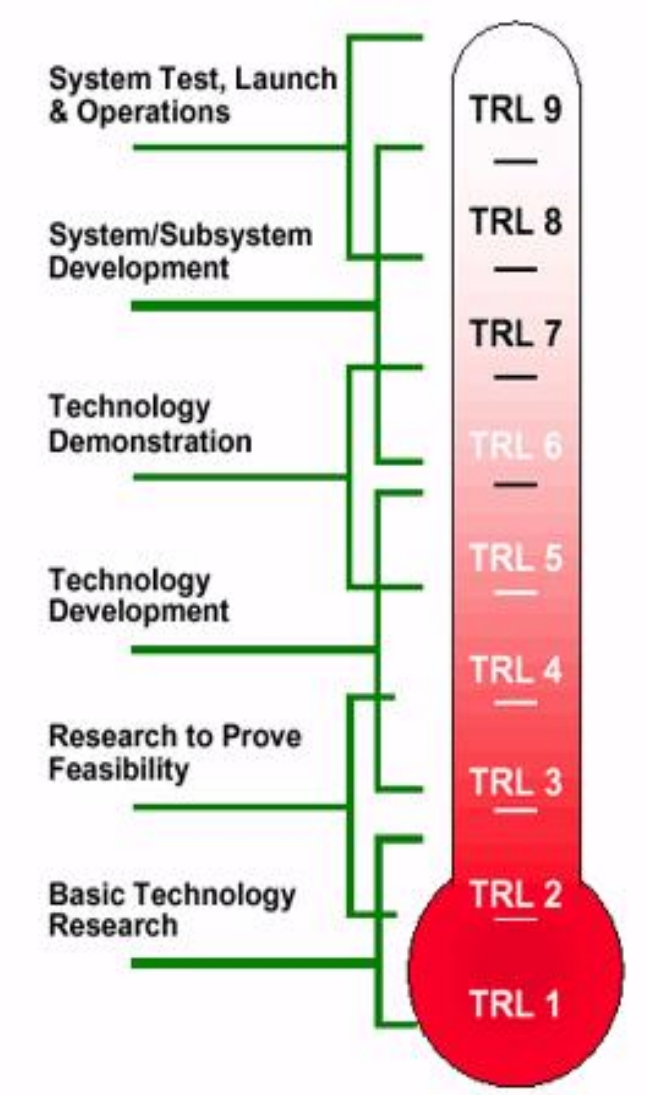
Project Evaluation – a decision sheet



Parameter	Score (1-4)
Disclosure	1
Prior art	1
Patent strength	1
Commercial potential	1
Technology readiness	2
Academic motivation	1

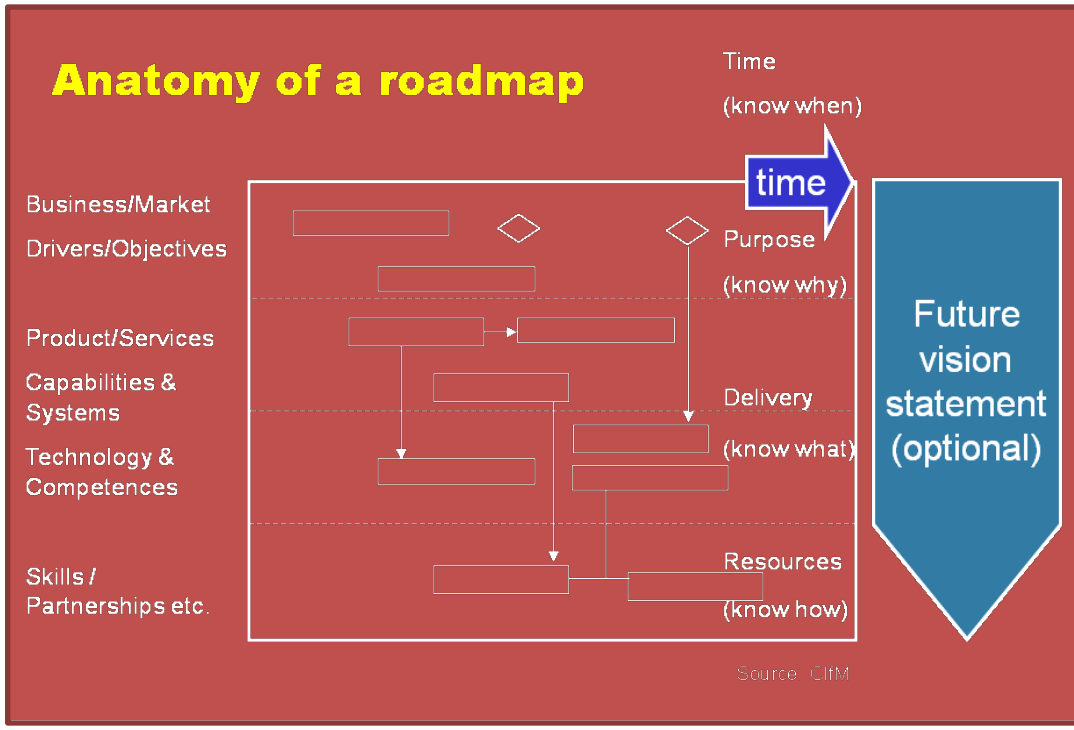
Technology Readiness Levels

- Invented by NASA, used widely in US government agencies, and industry.
- Describes the de-risking - and confidence-building process - from concept, through proof of concept, testing, prototype, operational testing to proven system



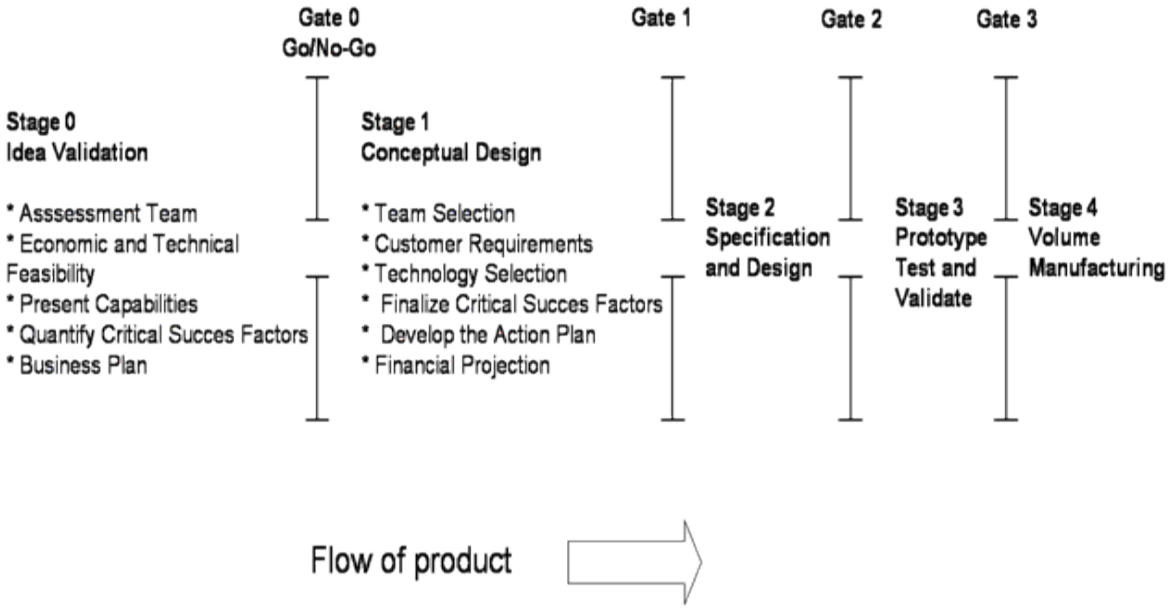
Technology/Roadmap

- Characteristics of a roadmap
  - Time based
  - Works towards a stated vision
  - Indicates a response plan
  - Contains checks and measures
- Levels of roadmaps
  - Individual businesses
  - Specific technologies
  - National roadmaps



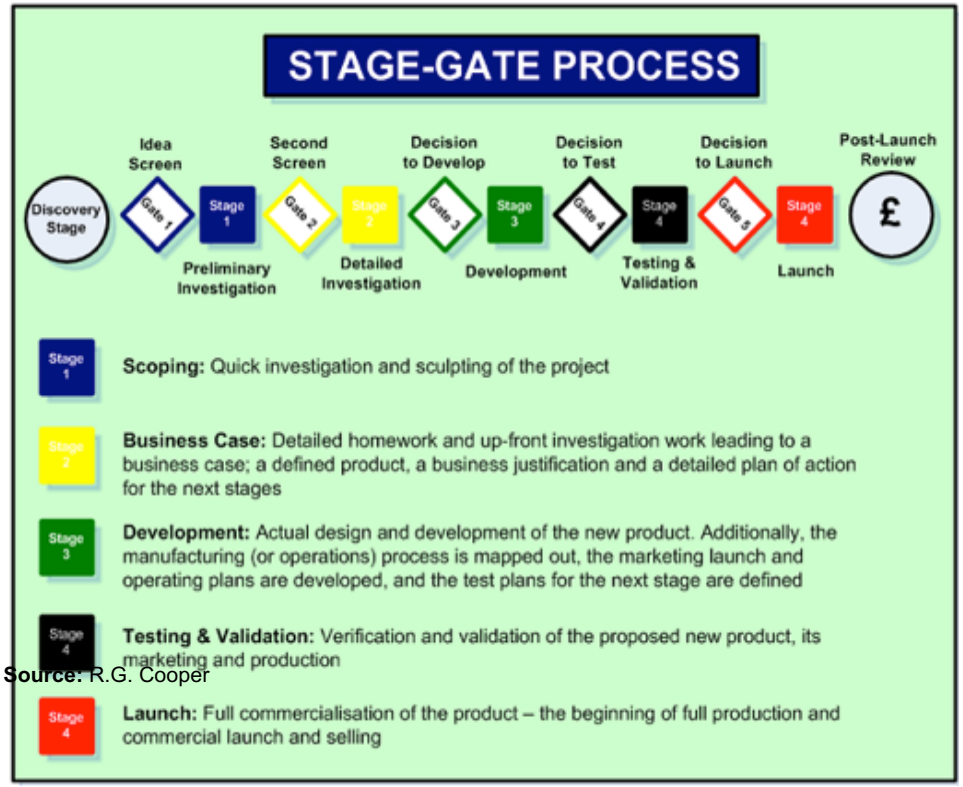
Stage Gate Systems

- **Stage:** Where the work is done;
- **Gate:** A set of criteria that the product must pass before moving to the next stage;
- **Gate keeper**: Senior management team.



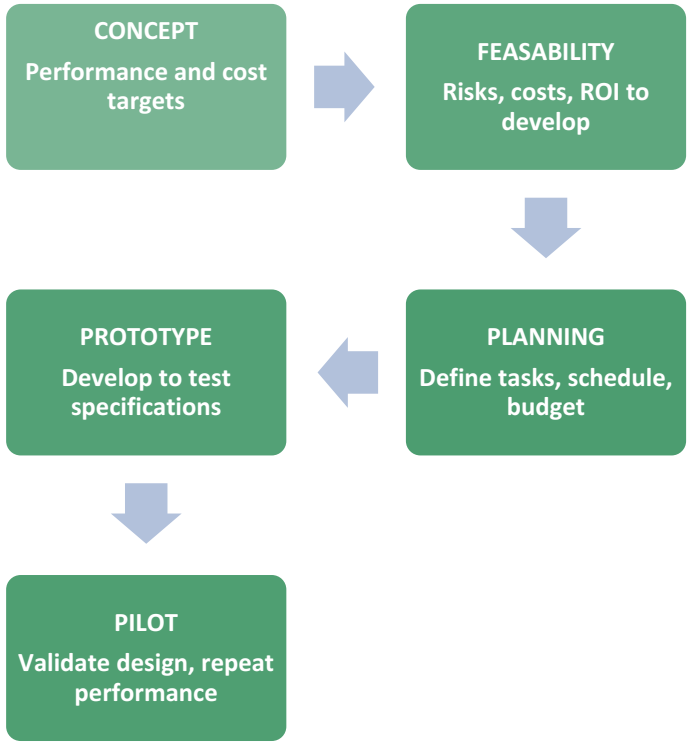
Source: Northern Telecom, Inc.

Innovation processes – Stage Gate



Source: R.G. Cooper

Sample DEVELOPMENT STAGE



5) Reputational assets

- Rock the share price
- Pipeline dreams
- Social impact
- Research-based multinationals
  in charge, cutting-edge, experimental

Using market principles to evaluate Medicis

MARKET-END EVALUATION

Medicis - value to customers

- Who are the customers for Medicis products?
- Innovation – what does it allow someone somewhere to do, what does it deliver
- Different
- Better

Good starting questions i

?

How might we?

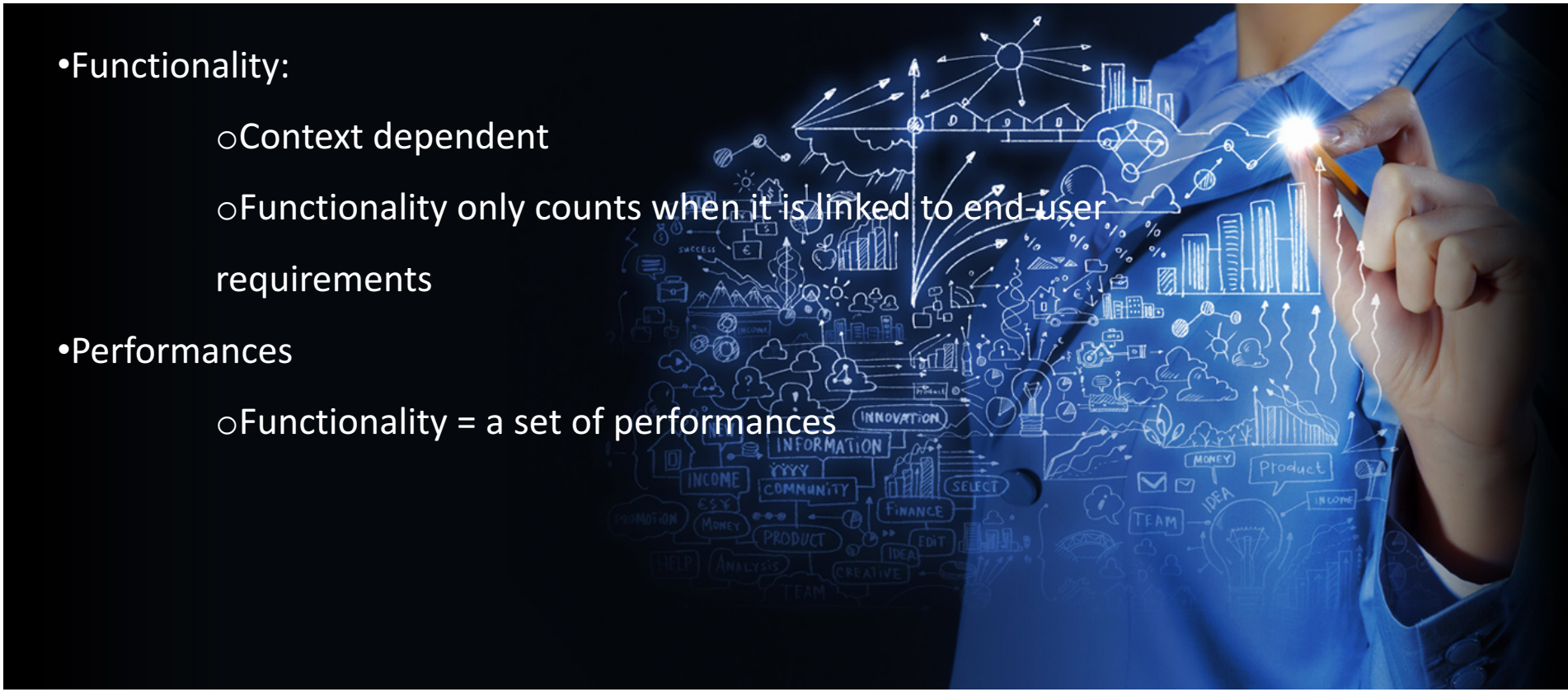
How has this been done before?

What does technology now allow us to do that was not possible before

Good starting questions ii

Not how does it work, what does it do?

- Functionality:
  - Context dependent
  - Functionality only counts when it is linked to end-user requirements
- Performances
  - Functionality = a set of performances



Summary – market value depends *critically* on the context in which that value is created

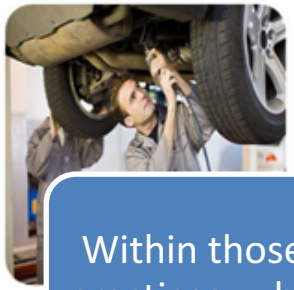
- The value of much intellectual property depends on the value of an underlying business or businesses:
  - ➔ Understanding the ecosystem is critical to understanding the value of Medicis innovations and intellectual property rights (IPRs)

- All businesses involve value chains.
  - ➔ Understand who is involved and who else can capture value from the Invention

Four tech transfer steps: sourcing customer benefit from innovation

What is the innovation we could commercialise

What practices provide potential applications



Within those practices, who are the end users

Who will buy the innovation for them?

EVALUATING AND INTEGRATING THE END USERS IN INNOVATION

End-Users

- How will they engage with the product, process or service
- Integration with current practice & machinery
- Professional practice, treatment protocols, equipment
- End user requirements are an integral part of innovation and developing products for the market
- Perception of end-user/customer barriers

End-users: Adaptive AI for anaesthesia infusion control

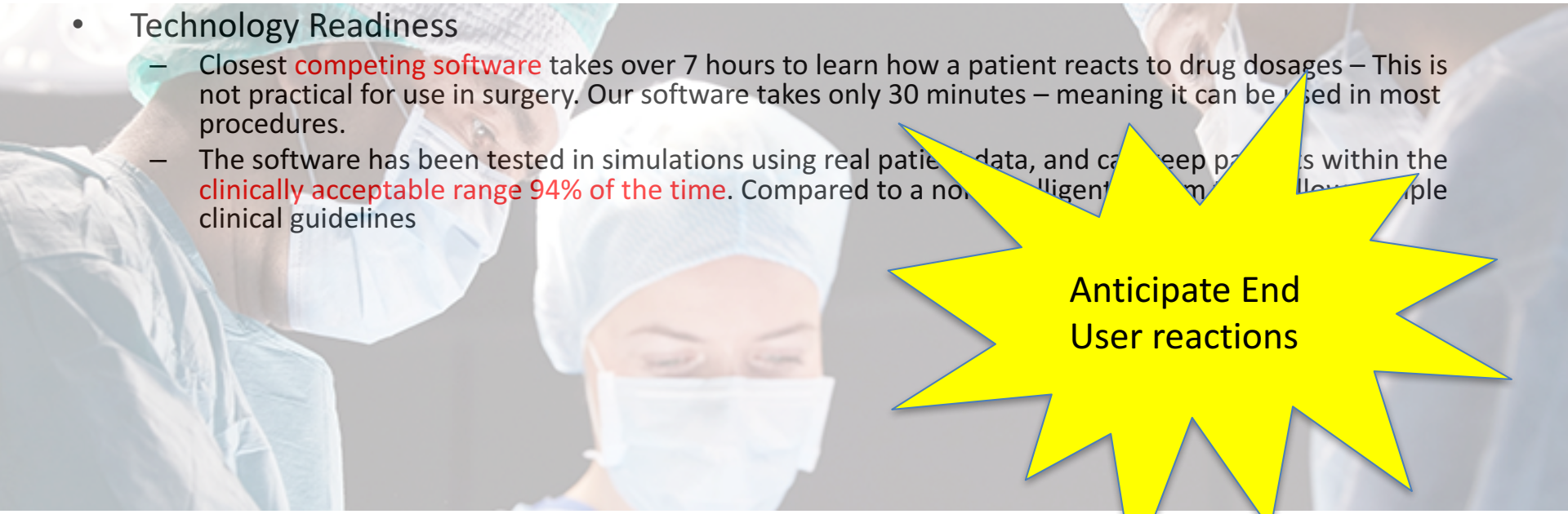
Technology

A team at Imperial College London has developed reinforcement learning algorithms that can lower the risks of general anaesthetic and incidences of patients regaining consciousness in-surgery.

•

What does it allow someone to do?

- “More accurate in keeping patients within acceptable range than a controller following basic clinical guidelines in simulations.
- Proactive rather than reactive control.
- Learns how a patient responds to changes in dosages during surgery.
- Initial settings based on data collected from a large number of patients - so can constantly update the more it is used.
- • Algortihms can be applied across a range of monitoring techniques.



- Technology Readiness
  - Closest competing software takes over 7 hours to learn how a patient reacts to drug dosages – This is not practical for use in surgery. Our software takes only 30 minutes – meaning it can be used in most procedures.
  - The software has been tested in simulations using real patient data, and can keep patients within the clinically acceptable range 94% of the time. Compared to a non-intelligent algorithm following simple clinical guidelines

Anticipate End User reactions

End users – Medicis

- Integration with:
  treatment protocols
  assessment of safety, tolerance, patient sub-sector
- Equipment:
  space, cost, additional layers
- Proof:
  safety, efficacy, regulatory approval

End users are not customers

Welcome Back!

Understanding the Investment process

Preparation for Dragon's Den

Preparation for the Lisbon Medicis Dragons' Den'

- Stand outside the bubble of science, work with different sets of values and accountability
- Making an investment case
- For Medicis phase ii
- Triple M (MMM)
- → short guide to investment philosophy
- → Investment Case & Medicis investment case
- → working on what to say
- → practice thinking entrepreneurially!

Business learnings from statistics talk – How to choose a mouse and other stories

- Meaning behind numbers
- Perceptions
- Bias
- Randomness

  - ➔ Human behaviours behind particular actions
  - ➔ Cultural behaviours and common action

Medicis – Managing perceptions of complexity

The challenge is to manage complexity so that it isn't complicated

Investor perspectives illustrated during the Leman training week

- AAA story
- The EC Medicis budget/project plan
- Horizon 2020, Fellowships

  - → bureaucracy around accountability
  - → timing, projections and project mngmt
  - → return & risk on that return

AAA learnings i

Strategic:

- Novartis investment of $4 billion in RPs space
- Rock the share price: pipeline news
- 13 Acquisitions (M&A)

Under promise and Over deliver:

"AAA exceeded its budget forecast for the five years before floation"

Assumption: Path dependency on pharma:

"We need big pharma distribution, that's the only way to operate"??

AAA learnings ii

Classification and Boundaries:

Diagnostic drug is a novelty category, the new concept required clear explanation

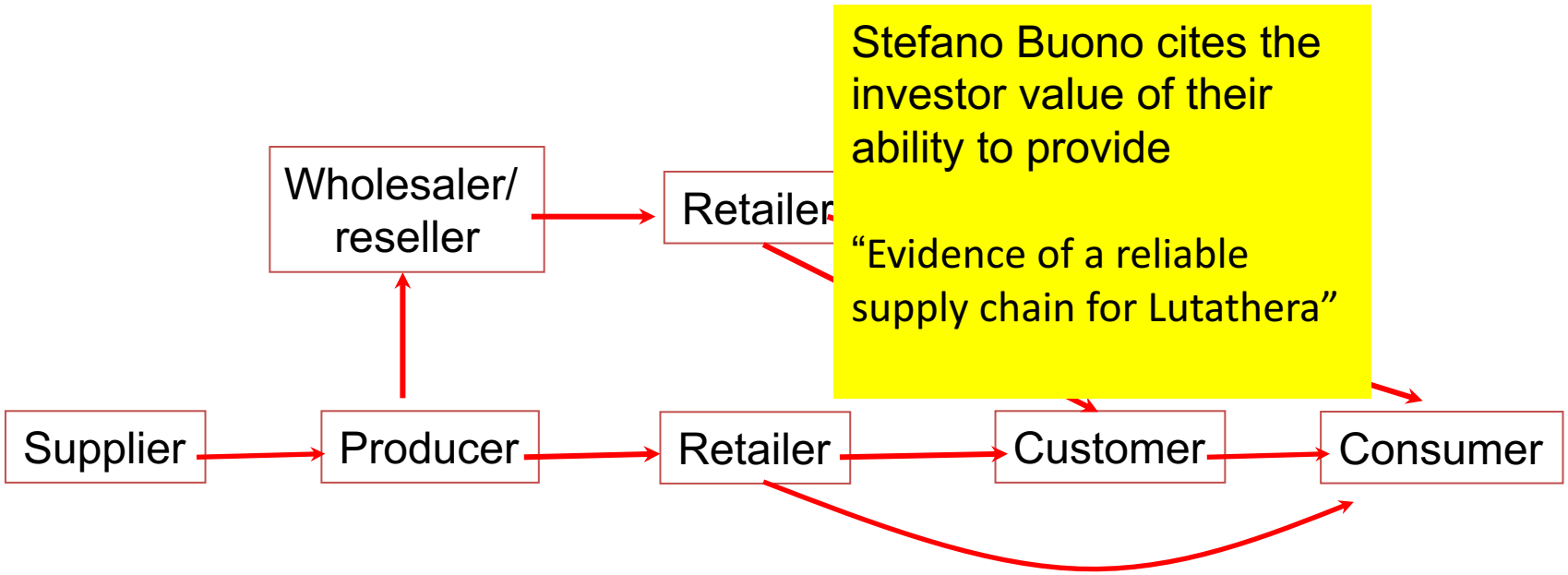
Clarity:

PET was a difficult business for investors to understand

Emphasis

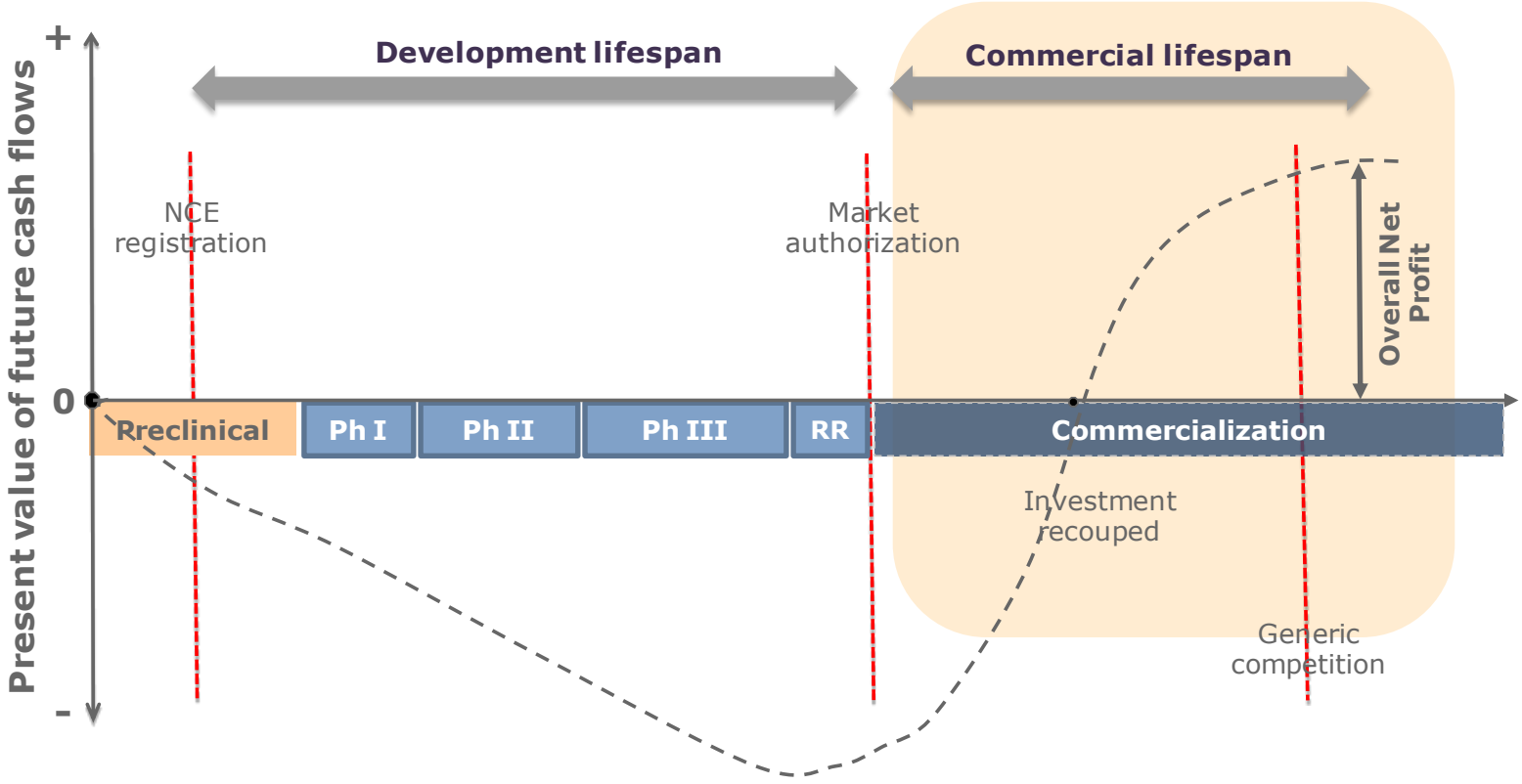
BUSINESS PRINCIPLES FOR MEDICIS CONSIDERATION

Medicis “supply chain” vs value chain?



Pharma–specific: Value drivers in pharmaceutical companies drug lifecycle revolves closely around marketing exclusivity

- Product lifecycle is composed of development and commercialisation stages
- Goal is to reduce development time and extend exclusive time on market
- **This determines the profit potential of a clinical initiative/ investment**



Investor Communication often pivots around ideas of Value

- Transformational headlines:
  - 79% reduction in disease progression
- Innovation described in terms of what it does eg:
  - allows for accurate diagnosis of complex disease;
  - helps improve cost-effective patient management;
  - allows us to target certain types of radio-resistant tumours;
  - overcome deep-seated location difficulty with PET;
  - deliver therapeutic dose to patients and subsequent imagery by PET scanners

Summary – business take-aways from the last three days for future boundary spanners

- Drills
  - What job do they want done?
- Clarity & Classification
  - Specificity of evidence targeted to audience
    don't tell them everything you know, your status speaks already to the scientific expertise
- News management
- Projection – time, goals

INVESTORS

General classification of investors

Equity investors

- Sovereign wealth funds
- Private Equity/Hedge funds
- Venture Capitalists
- Companies
- Business Angels
- Crowdfunding

Public & Philanthropy

- Govt/EC sources (some require industry match funding)
- Foundations/NFPs/3rd sector
- Individuals

Why fund?

- All funding, public sector and commercial is given/ loaned/ invested in the belief…..
  that returns will outweigh costs

- What return is expected depends on the transaction and the funder, for example:
  - Information & Knowledge
  - Money
  - Job creation
  - Macroeconomic or social good

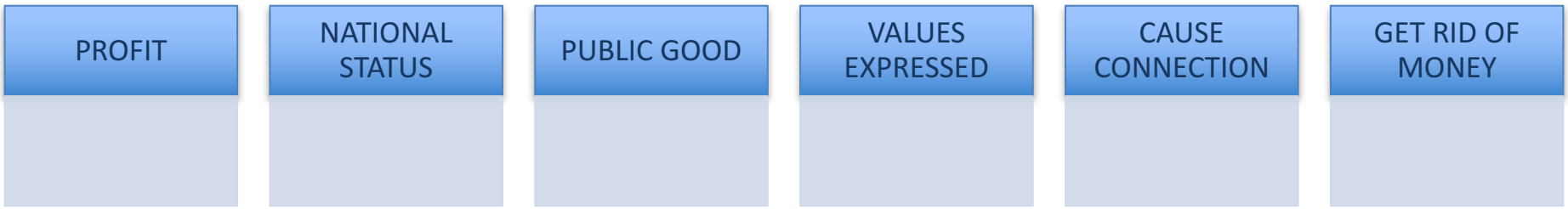
THE ROLE OF RISK & RETURN

Risk

- The funder also factors in the risk that it will not receive the full benefits (or any) from the transaction – this risk requires further compensation

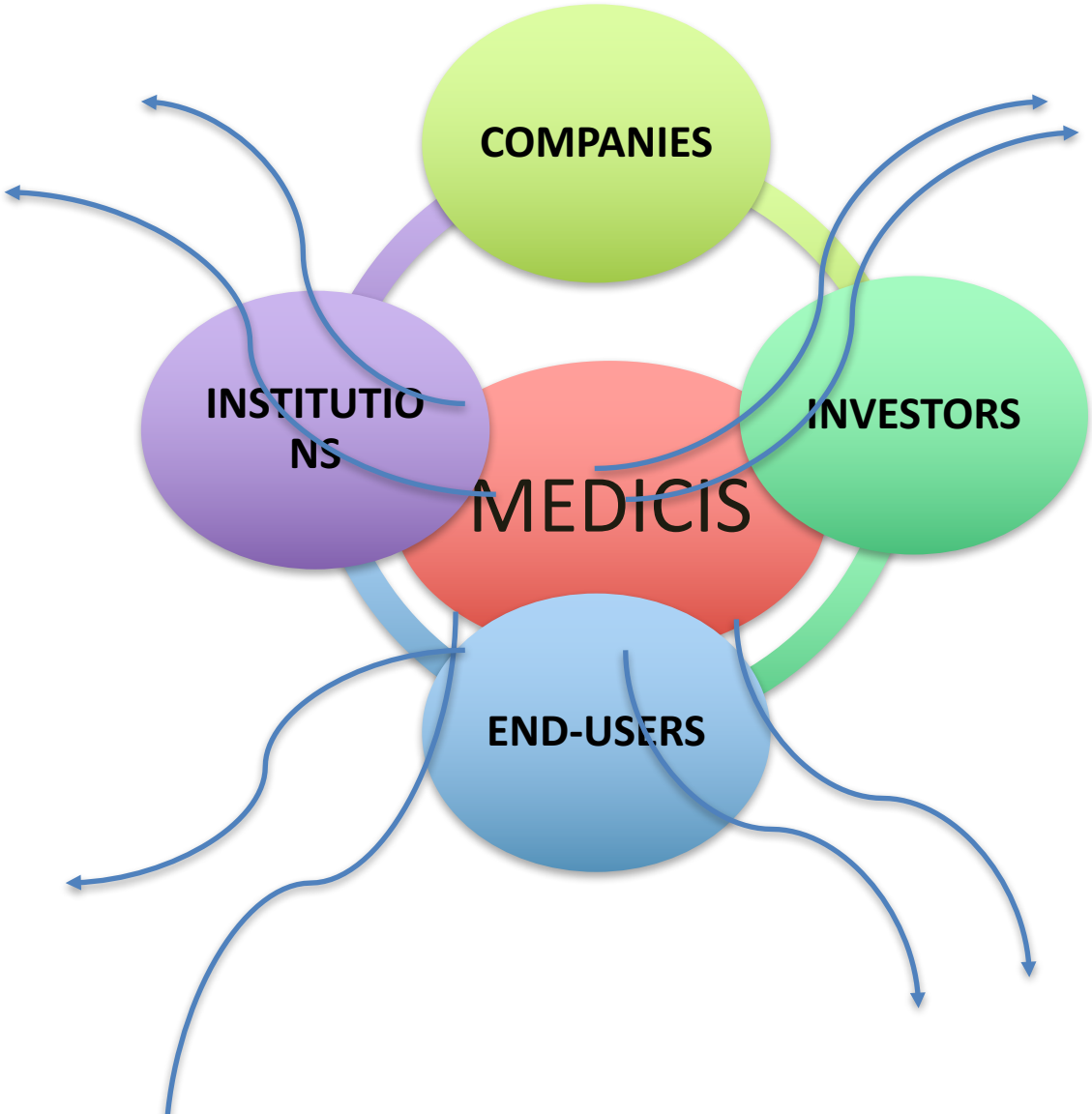
- ➔ A key investment metric therefore is *their* perception of risk
- ➔ This maps to perceptions of people, reliability, reputation, project projections, goals, evidence + alignment to Big Goals like strategy, national roadmap, Horizon 2020

ROI or Return on Investment
Motivation map (nb not strategy)



MODELLING THE NEXT STAGE OF MEDICIS FOR DRAGONS DEN

Next stage – the ECOSYSTEM



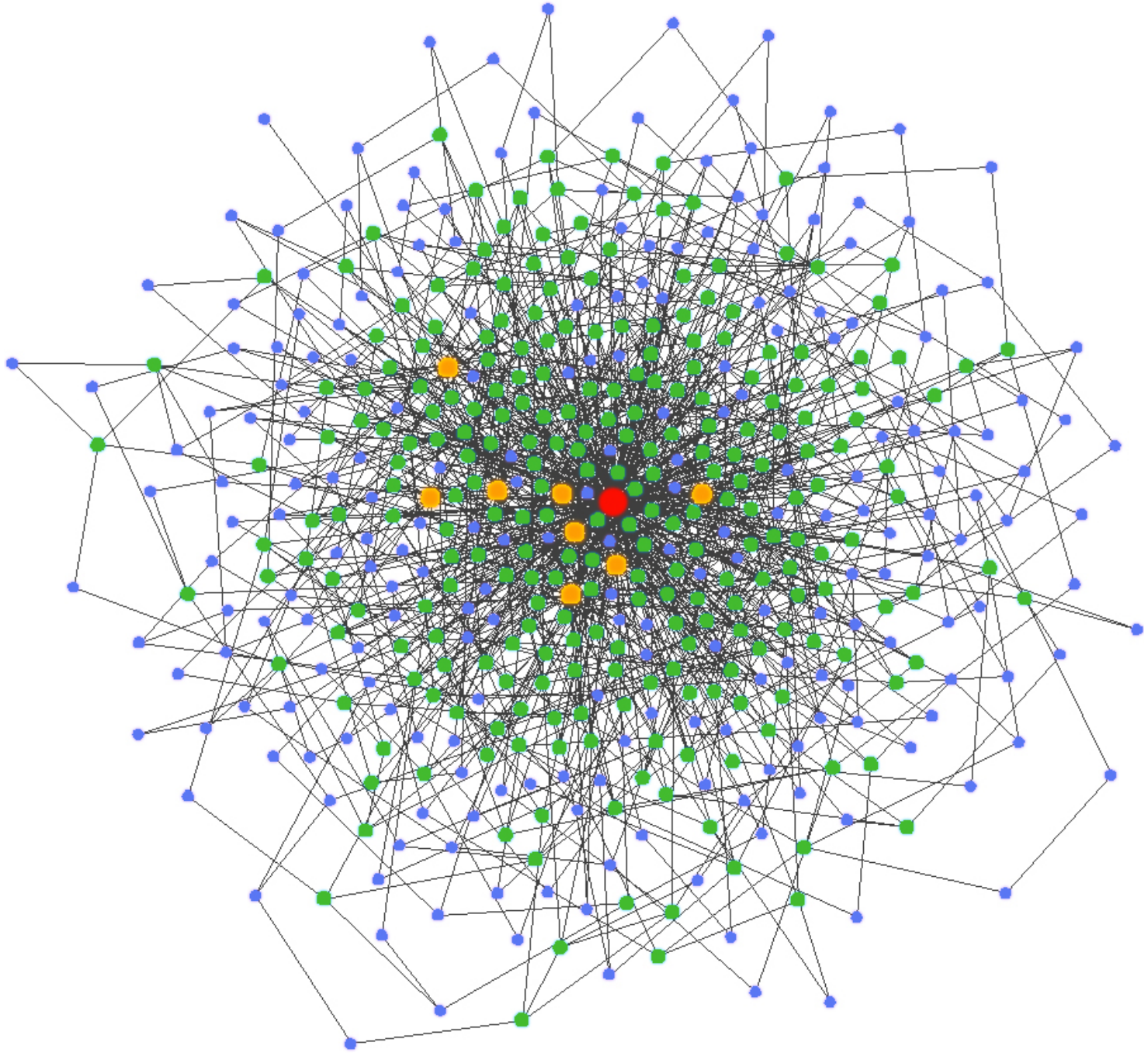
MMM
Model for More Medicis

Specific Medicis Investors & Stakeholders

- CERN
- EC & Research Organisations
- Swiss Hospitals
- Foundations
- Companies
- Individuals

What does 'More Medicis' look like?

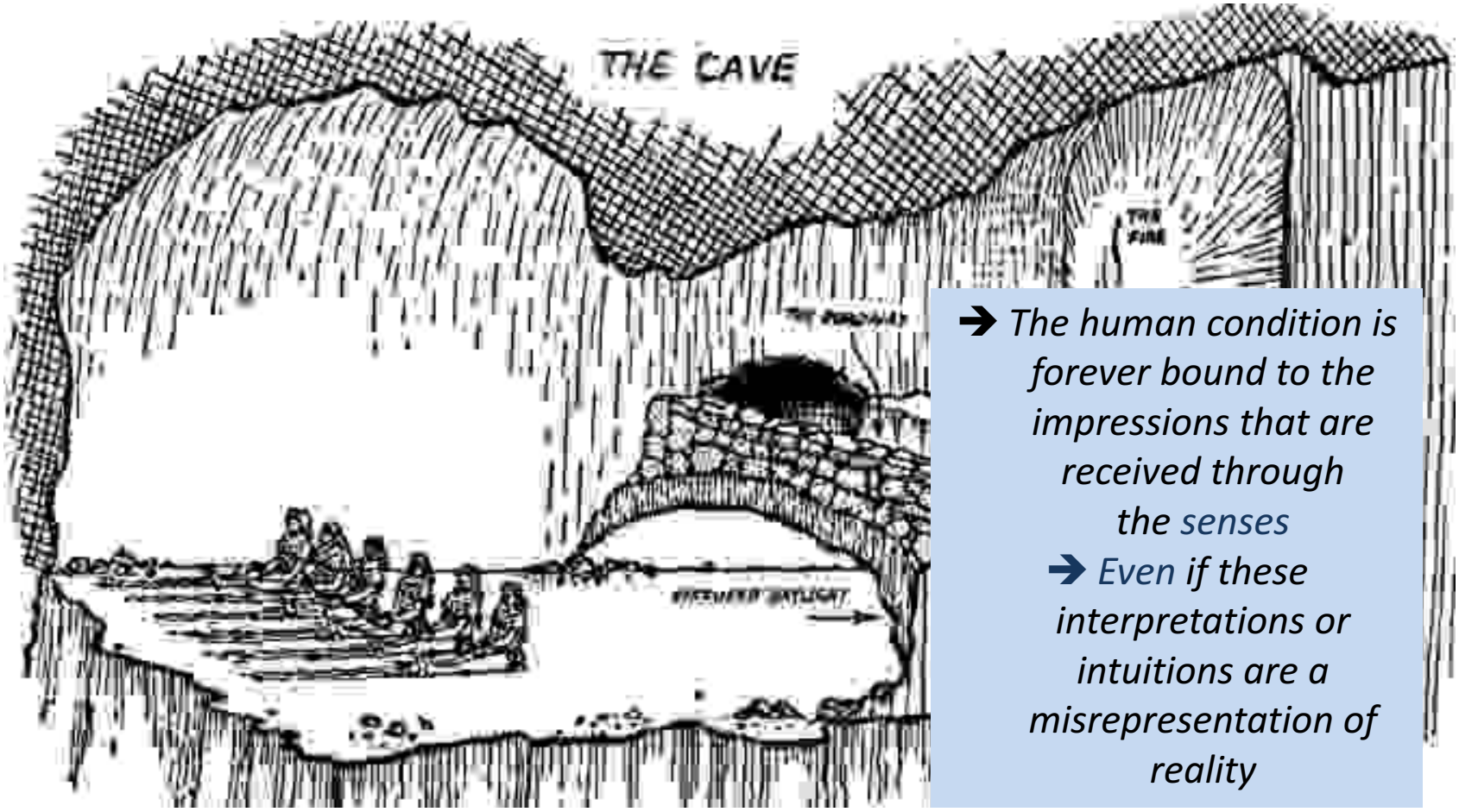
Who has an incentive to fund it?



Plato and Sunflower

TWO TOOLS FOR MAPPING STAKEHOLDER ECOSYSTEM

The Allegory of Plato's Cave



➔ *The human condition is forever bound to the impressions that are received through the senses*

➔ *Even if these interpretations or intuitions are a misrepresentation of reality*

Leadership Tool – for analysis of a stakeholder system

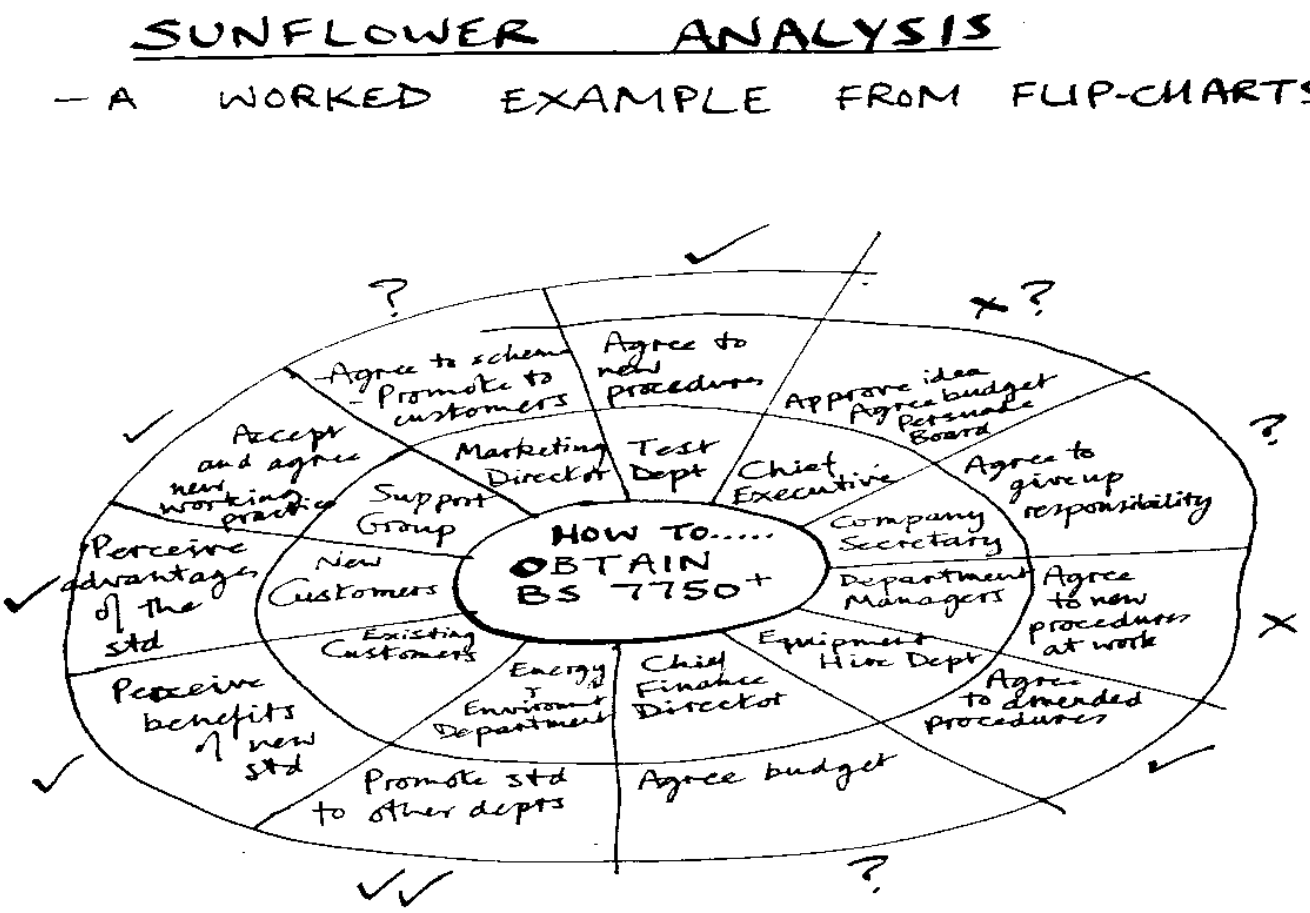
Tool

- Groups
- Objects
- Actions
- Facts
- Affairs

Question to ask

- Who are they?
- What are the objects?
- What actions are being performed?
- What are the known observable facts?
- What is the state of affairs?

Sunflower Analysis Example



Sunflower Analysis steps

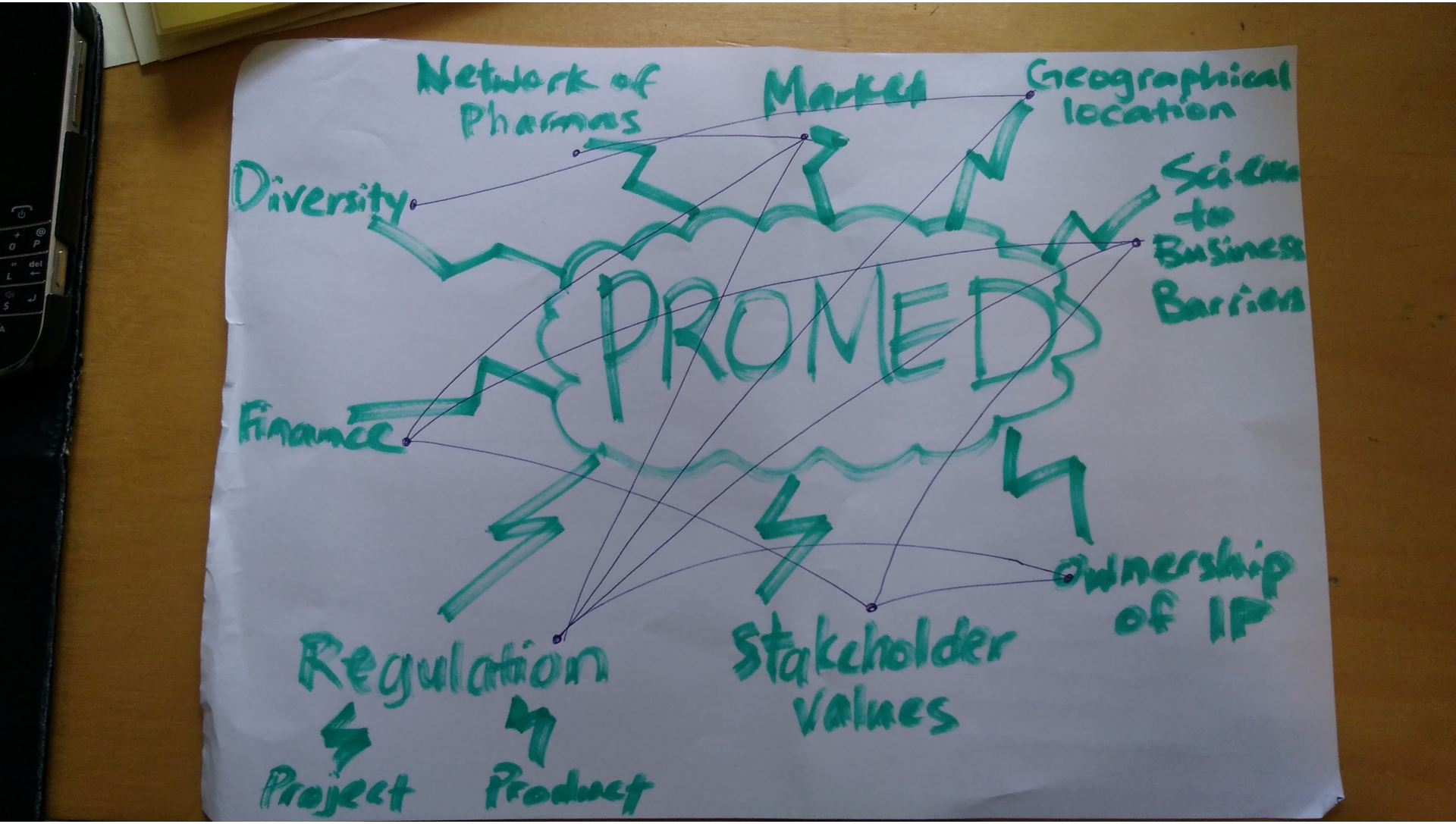
- Identify the change you want to make and enter this in the centre circle – 'eg How to…..adapt the regulatory environment around alpha emitters'
- Draw as many petals as you want to form a sunflower
- Add the names of individuals or groups on the petals
- Is change statement clear?
- Define behaviour required for each person/group on next layer
- Assess each petal for positive/negative content
- Consider the links between each petal and look for levers in the overall situation

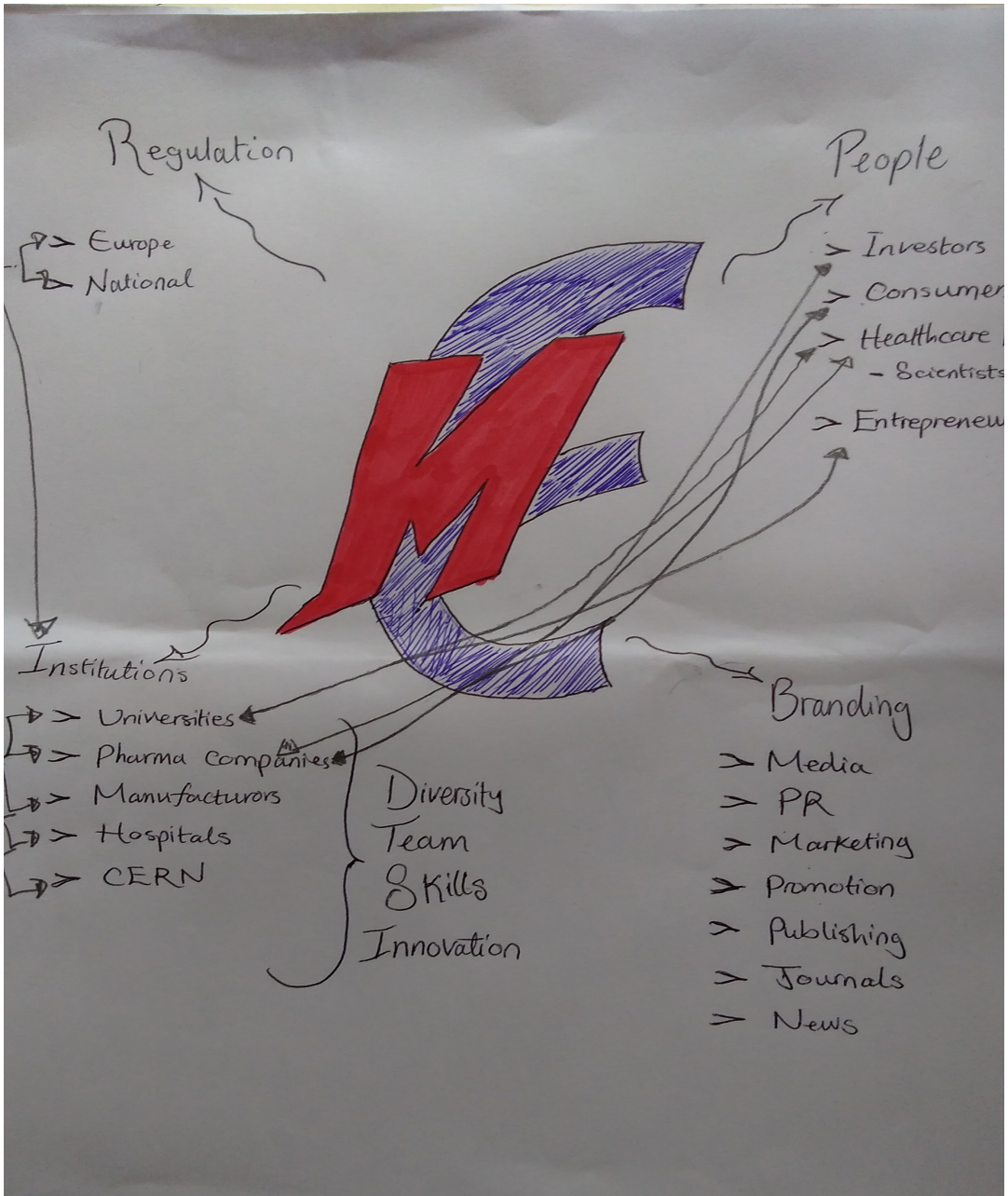
Sunflower Analysis – taking action

- Prioritise a petal to work on - normally the most negative
- Make an action plan to remove restraining forces

Theory of Change

Often used by Public Sector

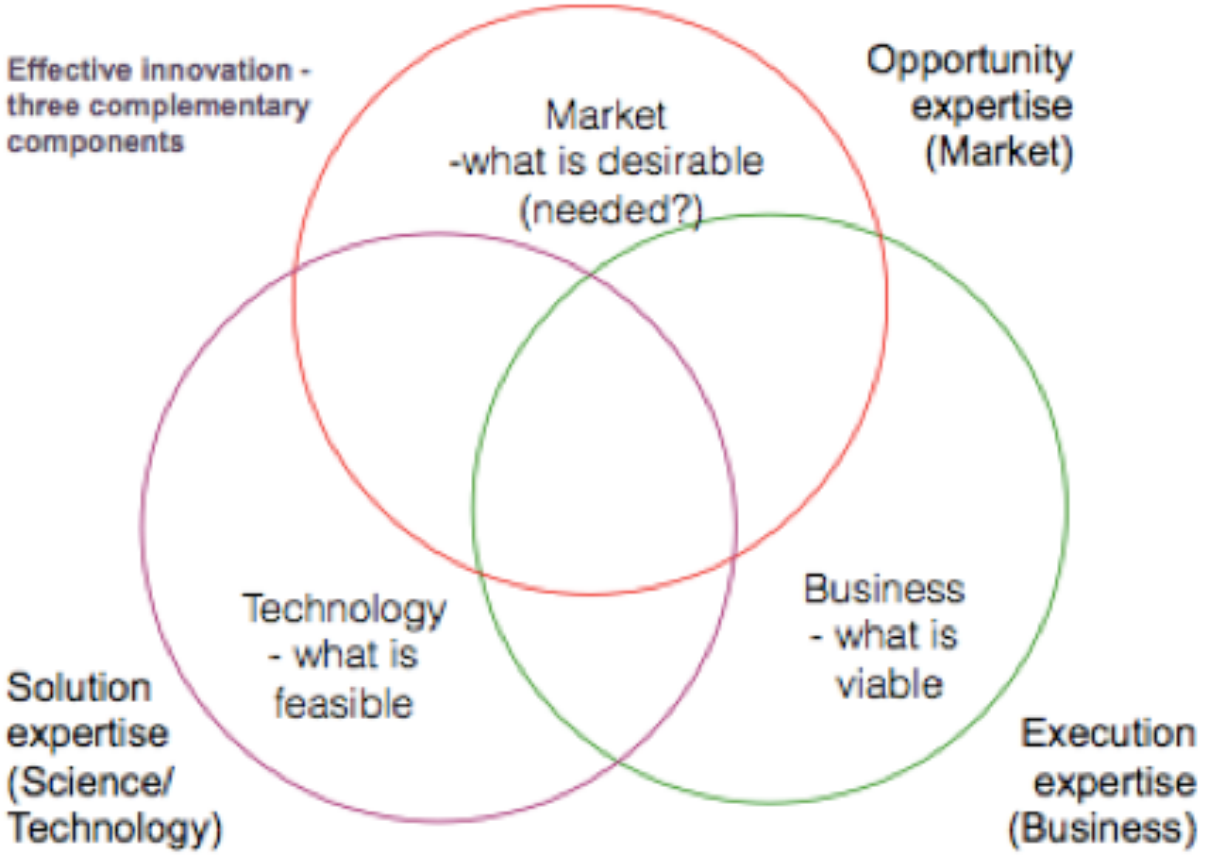

Network of Pharmas
Market
Geographical location
Diversity
Science to Business Barriers
PROMED
Finance
Ownership of IP
Regulation
Stakeholder values
Project
Product


Regulation
Europe
National
People
Investors
Consumer
Healthcare
- Scientists
Entrepreneu
Institutions
Universities
Pharma companies
Manufacturers
Hospitals
CERN
Diversity
Team
Skills
Innovation
Branding
Media
PR
Marketing
Promotion
Publishing
Journals
News

MAKING A CASE FOR INVESTMENT

Commercial investors look at three elements – need a clear picture on at least two usually

Desirability (market demand), the technical feasibility to meet that demand and the viability



Specifically on science & technology…..

Patentability

- Novelty
- Utility
- Non-obvious

Science

- How strong it is?
- Is it incremental or breakthrough?
- Need/potential for further development?

Customer

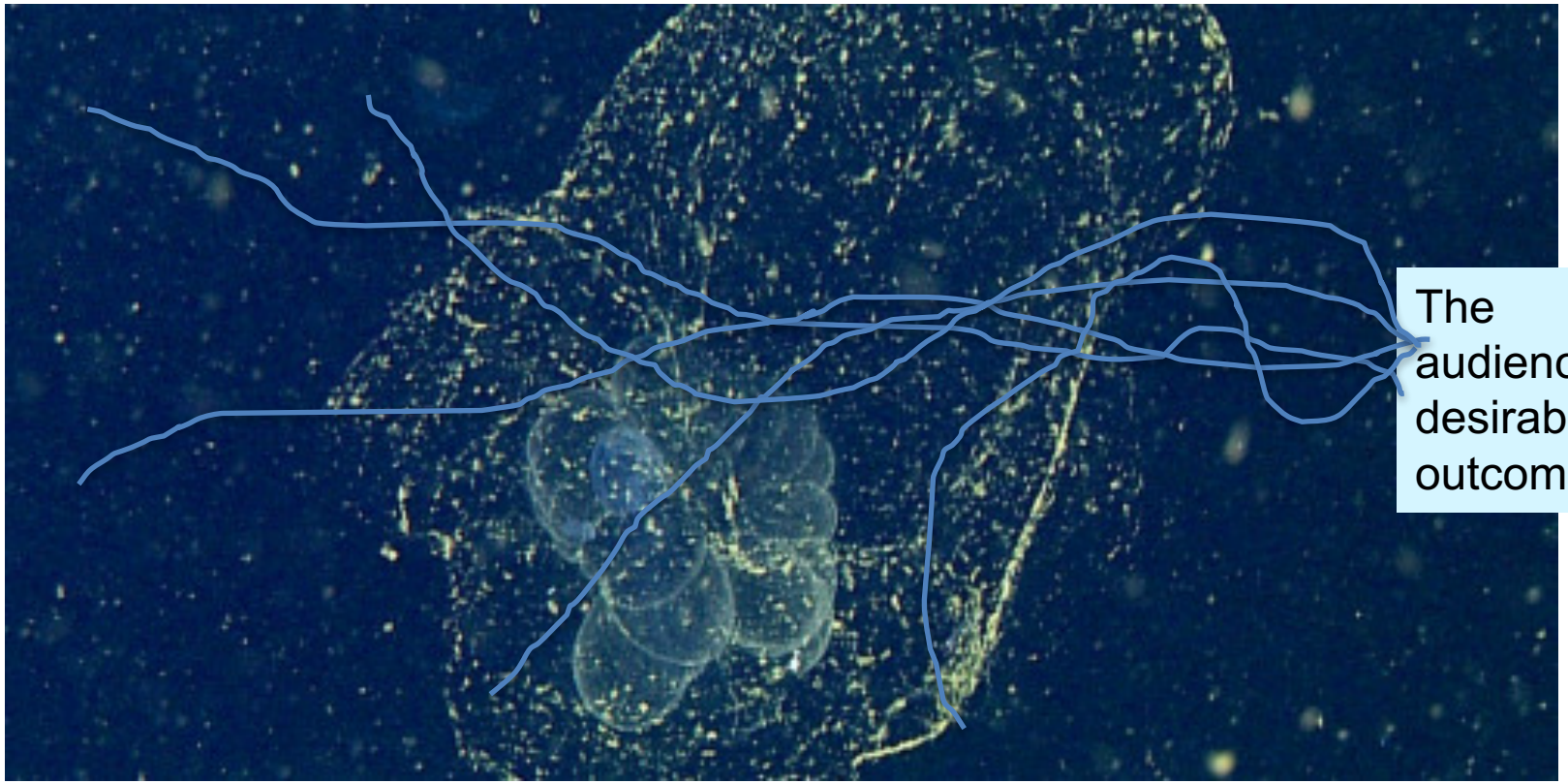
- First customers
- Customer value proposition – different & better?

Anatomy of a normal commercial Business Plan

- Executive summary
- Brief History
- Product or service
- Market and competitors
- Marketing plan
- Production and operation
- Management and its objectives
- Finance + appendices
- Risk, return, exit

Appendices might include: Cashflow, Profit & Loss, timelines, patent details, market research, CVs.

Draw threads from your blob of science to their desirable outcomes



THE MEDICIS INVESTMENT CASE

Evidence

Global Trends to integrate?

- Personalised/Precision Medicine
- Healthcare costs & Insurance
- Focus on Innovation, Impact & accountability
- Drive to build a knowledge-based economy
- Pharma pipeline failure
- Global centre of value creation moving East
  - Networked R&D now the norm
    - 2/3 of NMEs licensed by the FDA now come from academia & small bio tech

Pharma investment success stories
Investment story of Xofigo
‘the bone seeker’

1997 Oyvind Bruland + PhD Student Roy Larsen establish Algeta (spinout?) to commercialise alpha—emitting treatment for prostate cancer from R&D on RPs; Tromso/Oslo

2005 Series A financing €23m; HealthCap, Advent, SR One; first clinical experience reporting

2007 Went public, trading on Oslo stock exchange; Algeta raised $41m

2009: deal with Bayer sized $800m

2013 Bayer makes full acquisition of Algeta for $2.9 billion; largest shareholder Healthcap pre-approved deal, finished 2014.

Xofigo first marketed alpha emitting RP for cancer treatment, fast-tracked by FDA and EMA in 2013;

Barriers: MMM investment case should address real and perceived constraint considerations for investors, supervisory and healthcare

- Cost-benefit
- Public-private
- Partnership/risk management
- Skills, maintenance
- Alignment with existing practice, machinery
- Few customers
- Cost of sales
- Existing behaviours/safety considerations

MMM
Movement for more Medicis

- The Ask?
  - Lobby group for regulatory change
  - Medicis facility phase ii
  - Animal/clinical trials for new radioisotopes
- Evidence
  - For example, Sale of AAA, Xofigo, Medicis facility, production of new radioisotopes, connectivity with hospitals, research integrated around the supply chain, new funding models (Innovative Medicines Initiative)

Communicating Value

- What does it allow someone somewhere to do?
  - Deliver therapeutic dose to patients + subsequent imaging by PET scanners
  - Provide evidence that the supply chain can work
  - Avoid the need for brain tumour patients wearing a cap that burns the skull
  - Target radio-resistant tumours
  - Target deep-seated tumours with PET ions
- Target audiences
  - A swiss hospital
  - A medical insurer
  - CERN
  - Head of DG Research
  - SV Life sciences (VC)
  - Toshiba

A Collective Brainstorm

EVIDENCE POOL FROM THE ESRS

ESR-MMM Evidence Brainstorm

- Facts, Results and Supporting evidence to make an investment case for MMM
- Phrased in terms of "value" the evidence delivers
- Multiple audiences

- Brainstorming
- Gather lots of ideas
- Quality as well as quantity
- Be specific in your phrasing

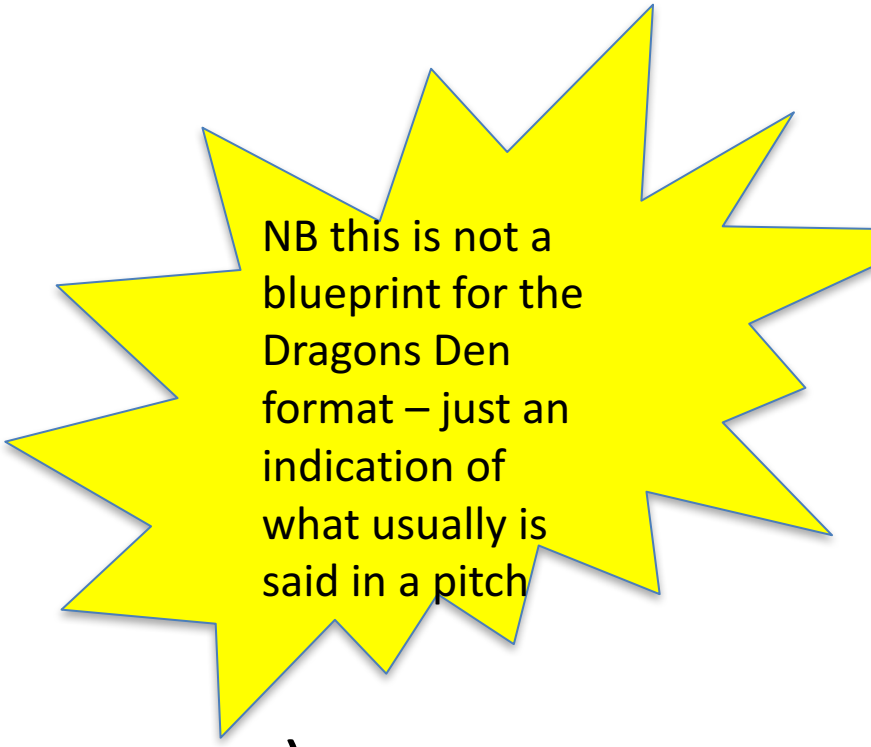
- ➔ synthesise value rather than summarise

One minute of delivery

PITCH PRACTICE

One ‘standard’ pitch format

1. The problem
2. The solution
3. Competitive advantage
4. The team
5. Milestones to date
6. Route to market
7. The financial forecast (summary)
8. The investment and exit



Another standard

1. The Idea
2. The Problem (how big?)
3. What Milestones
4. What is in it for the investor
5. Call to action

Dragon Den's Prep: Evidence Brainstorm

Group 2

Challenging project

TRIUMF / NIRST are doing similar things

We have a strong collaboration in Europe

We have a facility at CERN and simulations / design studies for 11C treatment

Small animal synthesis is already done

We have the right input for the next step

Group 3:

Radioisotopes never studied before and we can now create value with them

Now focused on ovarian cancer but readily expended to other cancers and even other disease

Can do better than others

Better separation and selectivity through new materials and techniques

Improve radioprotection

Personalisation of patient care

Group 1:

Thanks to MEDICIS, we can produce new isotopes, with new sources for new treatments

Larger access

Share the technology with the world to benefit the world

Thanks to increase in production efficiency and to engineering effort for enhance production rates

Great purity has been reached

Will help in Europe and the world for new opportunities in Physics and Chemistry and beyond

Feedback

Feedback:

Lots of positive things said but lacking specificity: How is it going to be better?

What is the actual *value* of the various achievements?

Progress & results must be made relevant to a specific case.

Big picture is a very important aspect to also emphasise (e.g. other cancers and other diseases)

➔ Use the right brush size; big brush for projection, long-term value, smaller for the detailed evidence of progress so far

➔ Be specific, not vague

➔ Avoid assumptions