

Designing & Entrepreneurship:

Neuro Technology & Cognitive Technology:

Identification

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SECOND EDITION

BIODESIGN

The Process of Innovating Medical Technologies

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NEEDS FINDING

PART – 1:

Strategic Focus

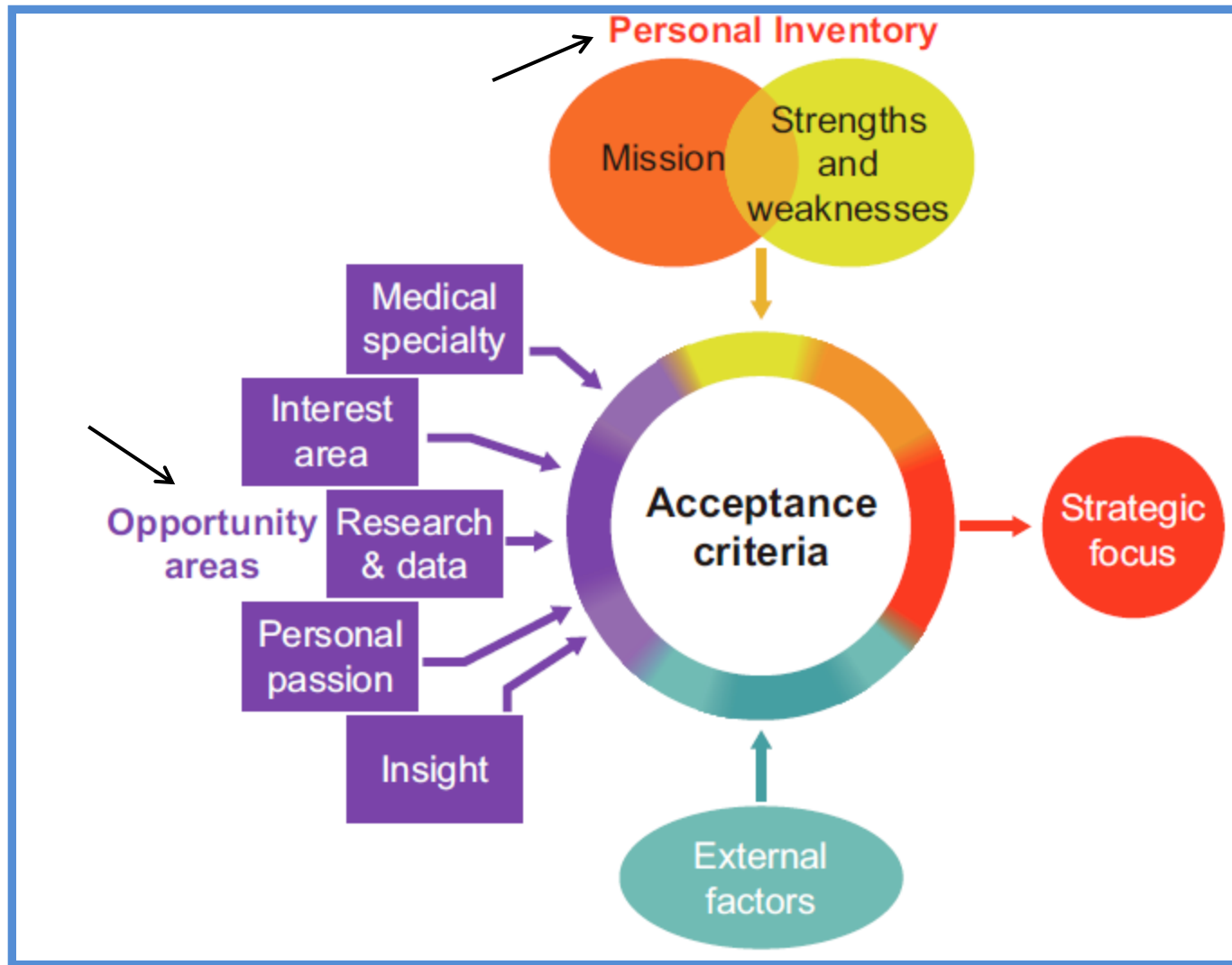
STRATEGIC FOCUS FUNDAMENTALS:

- Deciding what the innovator or organization values or wants to achieve..
- Accurately assessing what competencies the innovator or the organization have (or do not have).
- And then translating these insights into criteria that can be used to objectively evaluate opportunities and decide which problems or focus areas to pursue.

I knew once I found a problem, I could solve it. The biggest challenge for me was which problem to solve.

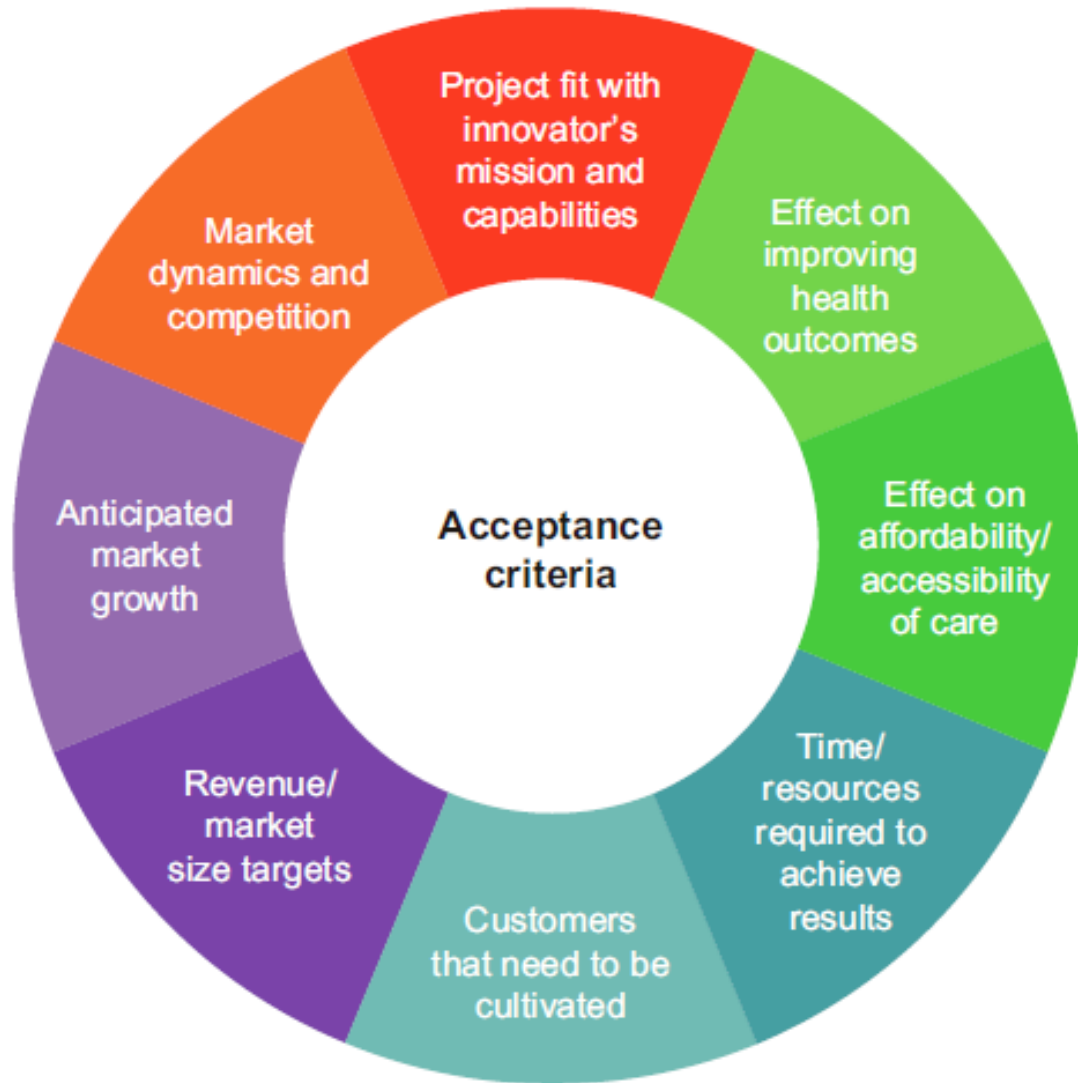
By Mir Imran, CEO of InCube Labs

Developing a strategic focus:



Using a structured approach that takes internal and external factors into account can help lead innovators to a strategic focus that provides a good fit.

Defining acceptance criteria:



Acceptance criteria are frequently built around some combination of these common themes.

Economic Scope: Disease Load

United States, 2010		Percent distribution
Conditions	Total expenses (millions)	Hospital outpatient of office-based visits
Heart conditions	107,186.40	18.0
Trauma-related disorders	82,303.57	43.2
Cancer	81,734.62	50.2
Mental disorders	73,060.24	24.1
COPD, asthma	63,782.99	23.5
Osteoarthritis and other non-traumatic joint disorders	62,362.98	40.3
Diabetes mellitus	51,310.57	21.9

Table: Data such as total expenses for selected conditions and percent distribution by type of service, as shown in the table, can be an interesting source of ideas regarding areas that might meet the innovator's acceptance criteria.

* Relative standard error equal to or greater than 30 percent; total percentages do not always add to 100 due to rounding

Global Medical Devices Market: Segmentation by Product Class, 2012

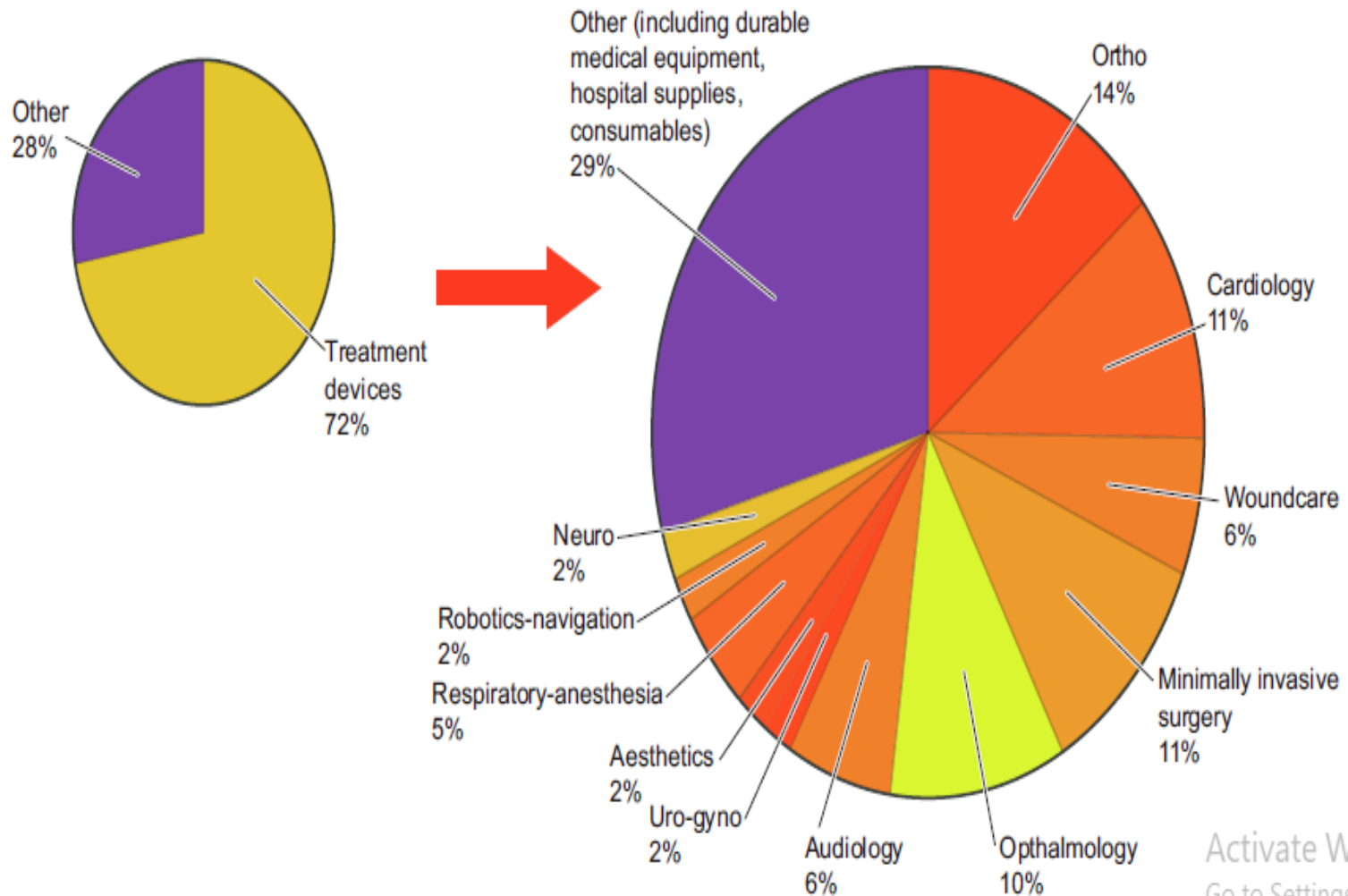
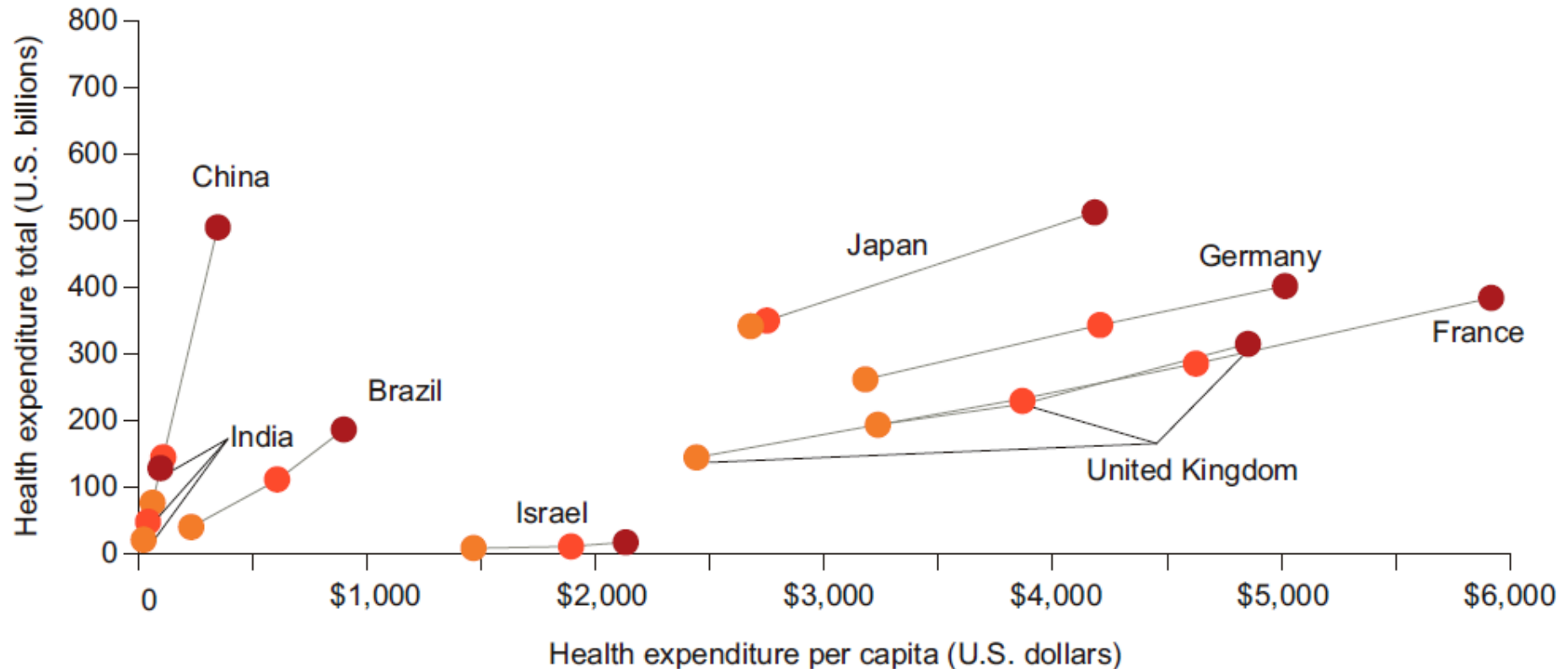


FIGURE : Market segmentation by product class can vary by geography, so innovators may wish to consider data for different locations.

Global consideration in choosing a strategic focus:



The World Bank, World Health Organization, and PwC analysis

FIGURE: This global trend analysis highlights how countries vary in their appetite for cost- versus outcome-driven innovation per capita. As a benchmark, US per capita spending on healthcare was \$7,285 in 2007, compared to per capita spending shown in the chart, which ranges from \$40 in India to \$4,209 in France for the same time period. Total US spending on healthcare in 2007 was \$2,159 (in U.S. billions).

Ethics in the BioDesign:

Similar Ethics for Scientists like Ethics for Physicians:

American Medical Association's Principles of Medical Ethics

A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

Table : An example of a medical ethics (from the American Medical Association's "Principles of Medical Ethics").

The following four principles are widely accepted as ethical standards in the medical field:

- **Respect for autonomy:** Respect for autonomy refers to others' rights to make their own choices.
- **Beneficence:** Beneficence is the practice of doing good.
- **Non-maleficence:** The mandate of non-maleficence also is captured by the phrase "First, Do No Harm."
- **Justice or fairness:** All those in the medical field have an obligation to fairly decide among competing concerns and interests.

NEEDS FINDING

PART – 2:

Needs Exploration

OBJECTIVES:

- Learn how to perform effective background research, observations, and interviews.
- Identify the types of problems that are likely to result in significant opportunities.
- Appreciate the importance of value exploration and recognize the “signposts”.
- Understand the relationship between problems, populations, and outcomes.



FUNDAMENTALS OF NEEDS EXPLORATION :

To understand a need fully, it is useful to consider it in three dimensions

- First, there is the core problem.
- The second dimension of the need is the population affected by the problem.
- The third dimension is the desired outcome.

The 3 most common techniques for performing needs exploration :-

- 1) Background Research**
- 2) Observations**
- 3) Interviews**

These 3 factors will now be analyzed

1) Interviews:-

When conducting the actual interviews, keep these guidelines in mind:

- ✓ Ask why
- ✓ Never say “usually” when asking a question.
- ✓ Encourage stories.
- ✓ Look for inconsistencies.
- ✓ Pay attention to nonverbal cues - Be aware of body language and emotions.
- ✓ Do not be afraid of silence - Interviewers often feel the need to ask another question when there is a pause.
- ✓ Do not suggest answers to questions.
- ✓ Avoid binary questions - Binary questions can be answered in a word.
- ✓ Be prepared to document - Always interview in pairs or use a voice recorder.

2) Observations :-

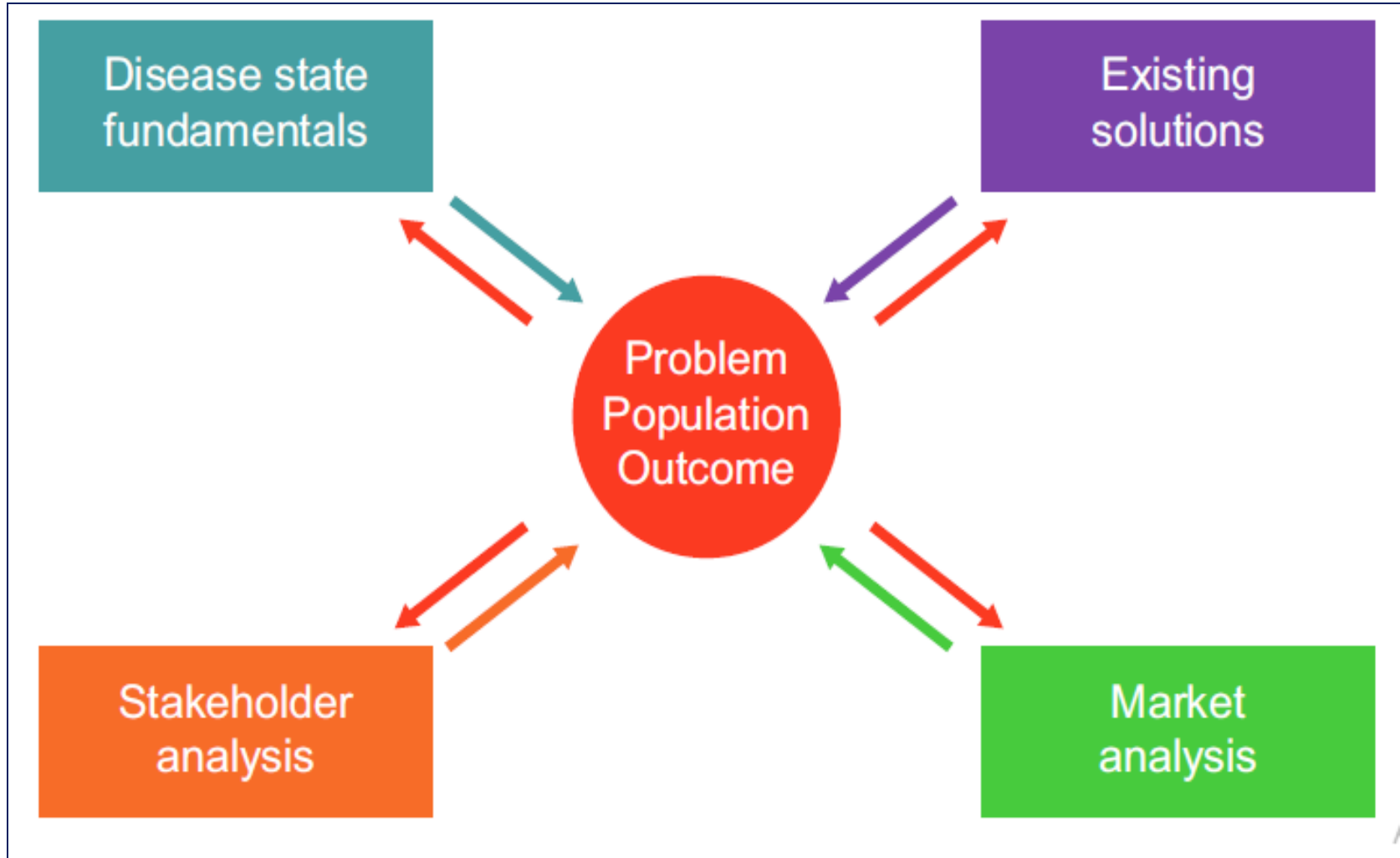
Clinical problems, populations, and desired outcomes come to life through direct observations.

Adopting a beginner's mindset, by following the points listed below, can help innovators set aside their biases :

- ❖ Don't judge
- ❖ Be truly curious
- ❖ Question everything
- ❖ Find patterns
- ❖ Listen

3) Background Research:-

Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.



3) Background Research (Contd)

A checklist of illustrative questions for exploring the patient's perspective across all aspects of their care.



The Patient

- What did the patient have to undergo in terms of pre-operative tests, appointments, etc.?
- What time did the patient have to get up to prepare for the procedure?
- Was s/he allowed to eat the night before?
- What sort of preparation was required?
- Did the preparation have any negative or unintended side effects?
- What did the patient experience when s/he arrived at the hospital?
- How long did s/he have to wait?
- Was the patient taken to the operating room in a wheel chair or on a gurney?
- How long did the procedure take?
- What were the steps of the procedure and how long did each one take?



The Provider

- What training and certification is required to perform the procedure?
- Who prepares the patient for the procedure?
- How many people are present in the operating room?
- What are their various roles?
- Does the same person perform the procedure from start to finish?
- Are practitioner staffing levels and roles the same across different environments?
- Why is work allocated across practitioners in this way?
- How long has this been the standard of care?
- How was the procedure performed before the current approach became standard?
- What are the accepted primary limitations or difficulties associated with the current procedure?
- Do the devices (or other tools used in the procedure) perform as the providers want/need them to?

A checklist of illustrative questions for understanding the provider's perspective across all aspects of patient care.