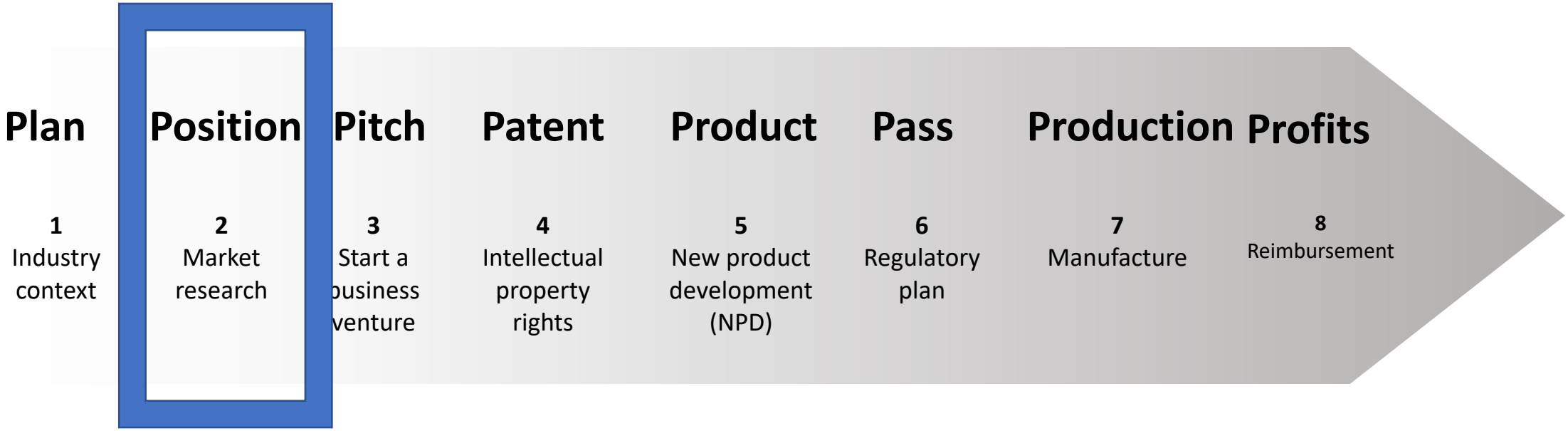
Commercializing Successful Biomedical Technologies 2nd Ed.

Shreefal Mehta



Markets of interest and market research steps

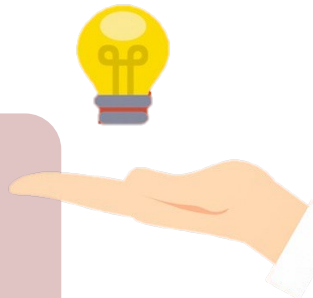
Shreefal Mehta

Chapter 2

First Identify Market Need and Specific Customer (Indication)

The product development process must begin and end with the market need / customer as a clear goal or focus of the effort.

- ✓ Technology becomes a product the day the first customer touches it
- ✓ Consider strategic partners as first customers



Initial questions about the technology and resultant product

- Can you manufacture it?
- Is it safe and effective?

Market-focused questions

- Who Cares?
- Why?
- The Why question should be asked repeatedly until you get to the core point
- Identify the specific problem and clinical need to be addressed by the new product or service.

Product Development Starts With MARKET RESEARCH

Start by defining a target product profile (TPP) with following inputs to TPP:

- Specific TPP characteristics are derived from understanding:
  - ✓ The biology
  - ✓ Pharmacology or the material's interaction with the body
  - ✓ The specific market
  - ✓ The desirable clinical outcome from addressing this market/problem,
  - ✓ Competitive positioning
  - ✓ Other internal and external factors
- TPP requires detailed market research
- TPP includes analysis of the market needs and the economics of the application
- TPP requires prioritization and optimization of counter-balancing product features obtained from customer inputs as part of market research
- Priority-rank the product features as inputs to product design process

Market research

- Defines the target market
- Validates the business plan and overall market potential

Investors rarely invest unless there is:

- ✓ Distinct market need being addressed
- ✓ Clear path to market

Market research goals

- To identify and segment markets for a new technology in building a business plan
- To identify new product and sales opportunities
- To define the required product characteristics from an understanding of market needs and context
- To understand the competition
- To project sales revenues and profits and appropriate pricing for a robust business plan
- To spot current and upcoming problems in the industry
- To identify and evaluate/test hypothesis or assumptions about market need, and better define the target product profile (TPP) – product form, fit, and function

Opportunity recognition

How do you recognize an opportunity to build a business?

- **Technology breakthrough** – new insight into biology, new materials or production methods
- **From involvement in the end market –** personal experience of a pain point or need. Or a fresh set of eyes sees a way to solve a problem that others are just used to working around

Strong personal context involved in making a decision to pursue an opportunity to commercialize technology

- ✓ Personal passion and motivation
- ✓ Life situation of the individual founders

Action steps in opportunity recognition

- *Define the assumptions and beliefs that must be fulfilled for the idea to be a commercial product.*
- *Market research to test the beliefs or assumptions*
- *Given what we know **and** what we don't know, is the development and financial risk worth taking for the clinical impact and market reward?*

Queries - useful in helping to shed light on the underlying assumptions and beliefs:

- Does the innovation solve a problem for a large enough market?
- What are the assumptions that need to be satisfied in order for the product to be adopted in the market over what competitors are offering or the current alternatives?
- What are the assumptions that need to be satisfied in order for revenues to grow to reach the market potential?
- Specific technical hurdles and assumptions for this technology to go from laboratory prototype to reliable device, diagnostic, or drug product?
- Can we quantify the impact of introducing the product or service arising from the technology in the existing disease referral chain
- Do I (scientist, technopreneur) understand and accept the risks

Value of technological innovation is its product market

The value or commercial opportunity of a new technical innovation that can create a product or service offering is defined by the market segment addressed by the product and the potential revenue stream from that market

Understand and specifically identify market need and target market segment

To identify the target problem, generate and test hypotheses iteratively :

Methods commonly utilized:

1. Observation and analysis of stakeholders and referral chains
2. Hypothesis testing of prototypes or concepts with real customers

The result of this market research with hypothesis testing is:

I. Identification of a target market segment (**indication**)

II. Definition of the unique characteristic features (**target product profile**)

III. Target customer among all the stakeholders (**market segment and size**)

Primary market research

Collected by the researcher through first-hand experience or interaction with the source of information

Observational

- Observation of the course of treatment from diagnosis to amelioration of problem ("**referral chain**")
- Provides rich context to gauge the real needs of the market, the actual behavior of patients, and the potential for adoption in the application context of interest
- May include the collection of data from a focus group through professional market research firms if you have a physical product or software.

Experimental

- Testing a prototype
- Most reliable way to get assessments

Secondary market research

Collected from data recorded by someone else and is obtained by reviewing and analyzing reports and published information.

Third party reports, papers, and historical market data are common sources

- Past records of product sales
- Compile characteristics of successful products
- Identify and collect data on specific market segments
- If the innovation is radically different from historical products , one could use
  - Data on methods of treatment of the disease,
  - Growth rates of procedures or costs of existing treatments, or past incidence/prevalence rates of the disease

Output of market research for product development

Figure 2.3

Surveys to collect information

- Survey methods involve posing a number of questions to the stakeholders in the markets of interest
  - ✓ Nurses, patients' family members, doctors, therapists, hospital administrators etc.
- Survey design and appropriate statistical analysis are key to obtaining valid results
- A challenge is to get responses to a survey from busy professionals
- Typical response rates for
  - ✓ Direct mail surveys - 1 to 10%
  - ✓ Telephone surveys - 20 to 60%
  - ✓ Personal interviews - 70 to 100%
  - ✓ Web and email surveys - 30 to 50%
- Surveys sent by email or mail require additional follow-up by phone

How big is the market for my technology/innovation?

Step 1

In the context of the larger market, start by segmenting the target market

Step 2

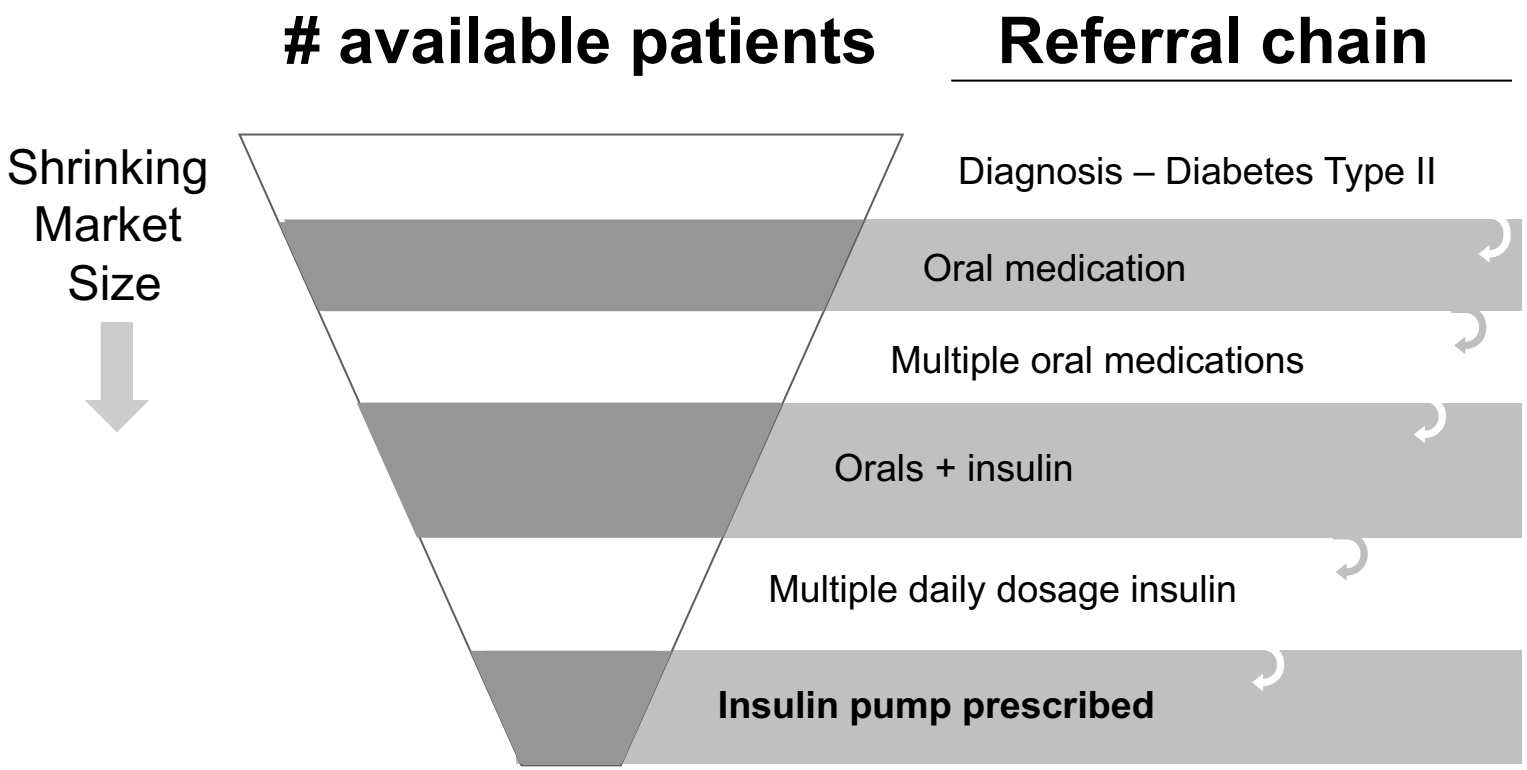
- How much of the (segmented) market can I capture and how soon?
- Industry segment can give an acceptable benchmark
- clearly state all assumptions
- Evaluate competitors
- Identify issues of market acceptance, reimbursement, and hurdles to growth

Step 3

- Run benchmark checks on your assumptions for market penetration (adoption), revenue growth and market segment dynamics.
- Check the output of the projections in the context of the larger market size and historical growth rate.
- How have other innovations/ product launches fared historically in this market?

Market Segmentation Example

Context – diabetic patient



Final indication – diabetes Type II patients who are refractory to insulin or other medications

Figure 2.4

Market drivers and hurdles

Drivers

- Demographics - Population growth trajectory
- High levels of investment in biotech – government and venture capital
- Research breakthrough leading to innovations and new products
- Approvals and streamlined FDA processes
- New laws and regulations

Hurdles

- FDA regulatory delays and inconsistency
- Increasing buyer power
- HMOs, Medicare, insurance
- Pricing pressures
- Generic competition
- Pipeline of blockbuster products
- Development costs and low success rate

The referral chain: developing market context and understanding customer needs

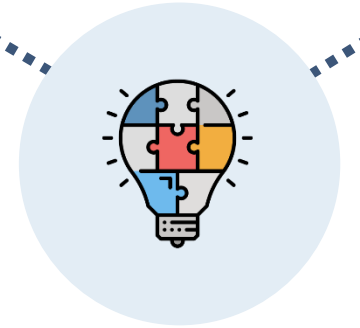
- Evaluate all transactions that start with the patients' first awareness of a health problem and end with the fulfillment/resolution of that problem or need given current standard of care – this is the "referral chain"
- identify the components for products and services and payments for delivering patient care
- Identify the point of intervention in this referral chain by your new product/service and resulting downstream impact
- What do patients need at that point of intervention?
- What do caregivers need?
- How does the product meet the needs of these groups involved in the referral chain?
- Who is the decision-maker and customer for your product?
- What is the impact on the life of the patient?

The referral chain analysis helps evaluate the economic impact of the new product/service

The referral chain

Step 1

Determine the condition that drives the first interaction with medical care



Step 2

Identify the point of intervention with the innovative product

Step 3

Identify the altered referral path (diagnosis and treatment path) for the patient post-intervention until resolution

Step 4

Document, savings

Step 5

Identify and explain benefit

These steps will result in an identification of the key value proposition for the new product for multiple stakeholders and a clear economic benefit

Non-union fracture referral chain example

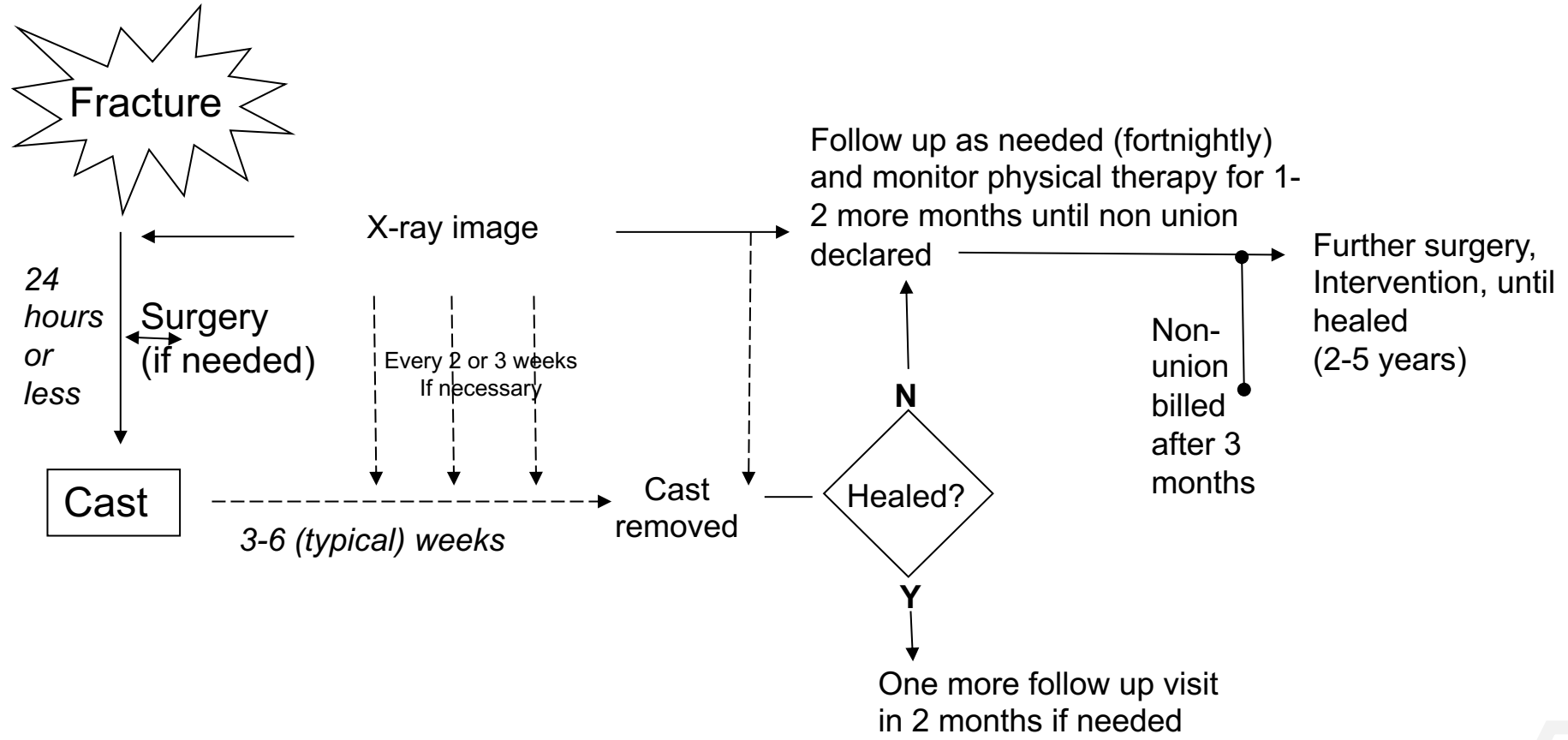


Figure 2.1

Competitive Product Assessment Basis

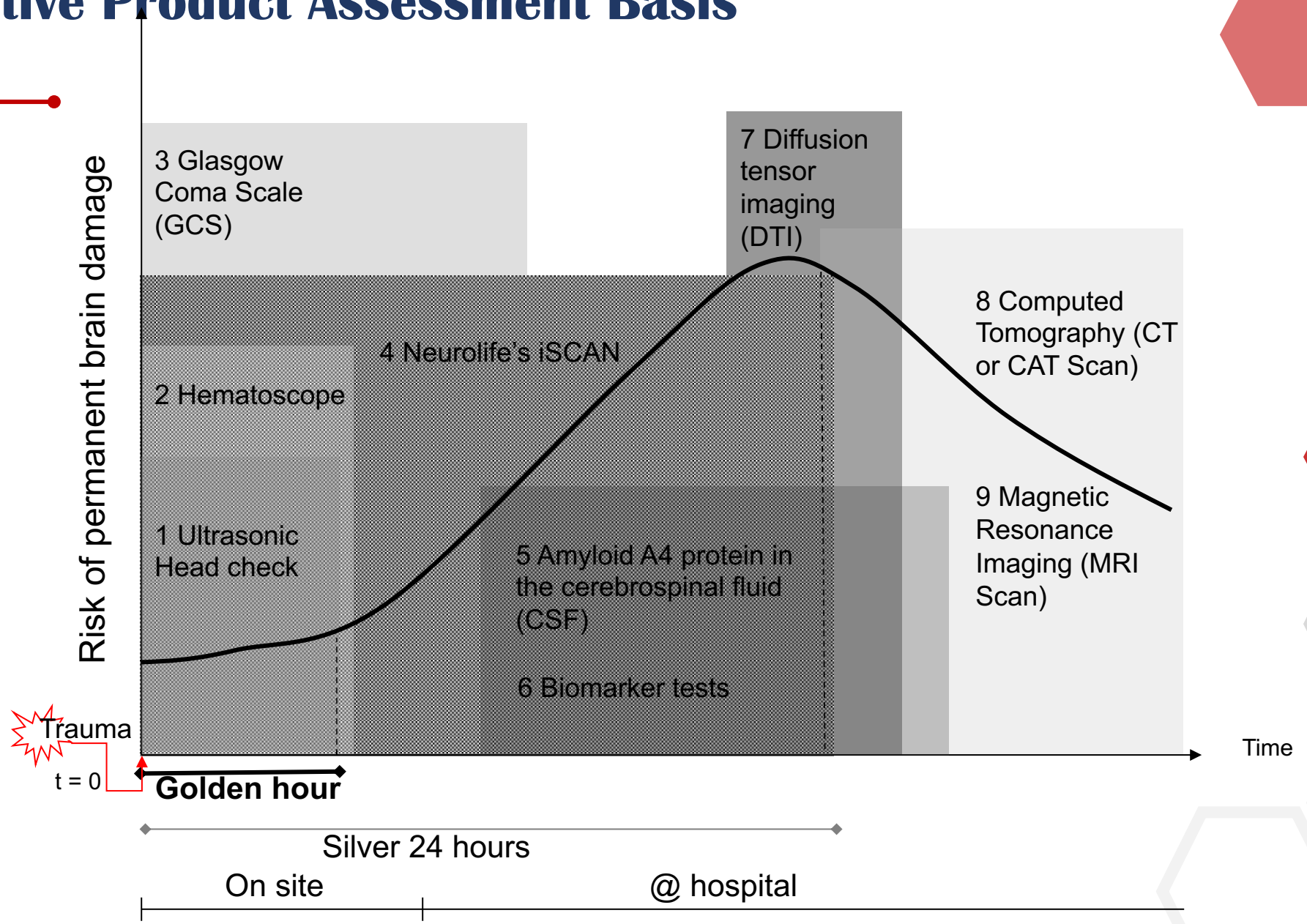
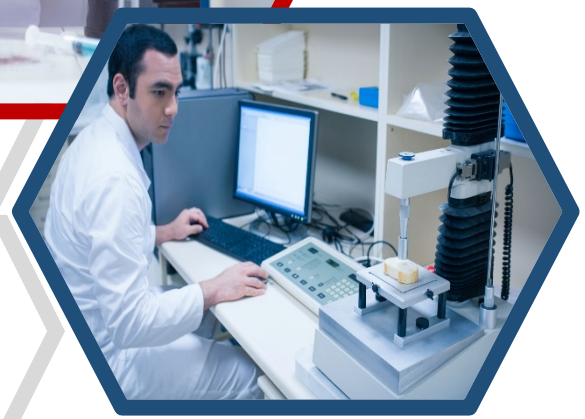


Figure 2.2

Defining the indication

- An “indication” for a drug or device refers to the use of that drug for treating a particular disease
- ***The indication for the product, as worded by the FDA in their approval letter, restricts the marketing, prescription, and sale of the product only to patients with that particular disease condition.***
- ***The wording of the indication is derived primarily from the hypothesis and results of the studies that product developers design***
- Important to define the population and specific benefit of the technology/innovation as best as possible in the early marketing research
- Manufacturer must define the indication as early as possible in the development process in order to guide product development with greatest efficiency



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Thank you…