

Clinical Problem Selection

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First Steps

- ▶ Have a lab notebook for **assignments**, **readings notes**, **minutes of meetings**, **ideas**, and **drawings**.
- ▶ **Divide** into teams of 1 to 3.
- ▶ Select a **clinical problem** (we will do this together).
- ▶ In your notebook, list your **team members** and **emails**, **team name**, **clinical problem**, and identify your team **strengths** and **weaknesses**.

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Suggestions

- | | | |
|--|---|---|
| <p>1. Allergy</p> <ul style="list-style-type: none"> a. Early detection and treatment of anaphylactic reactions. <p>2. Cardiovascular Diseases</p> <ul style="list-style-type: none"> a. Monitoring and recording engine episodes. b. Arrhythmia monitoring. c. Cardiomyopathy monitoring. d. Minimally invasive treatment methods and tools. e. Pacing and defibrillation. f. Peripheral arterial disease assessment and/or monitoring. g. Stents and other implanted devices. h. Thrombolysis diagnosis and/or treatment. <p>3. Dermatology</p> <ul style="list-style-type: none"> a. Deep learning computer application to diagnosis of skin lesions. <p>A. Ear, Nose and Throat (ENT)</p> <ul style="list-style-type: none"> a. Prosthetics and implants. b. Surgical tools. | <p>5. Emergency Medicine</p> <ul style="list-style-type: none"> a. Applications for trauma. <p>6. Endocrinology</p> <ul style="list-style-type: none"> a. Continuous glucose monitoring. b. Insulin administration. <p>7. Infectious Disease</p> <ul style="list-style-type: none"> a. Rapid diagnosis of pathogens. b. Sample collection. c. Sterilization methods. d. Transport and handling of specimens. <p>8. Gastroenterology</p> <ul style="list-style-type: none"> a. Biopsy instruments. | <ul style="list-style-type: none"> b. Video capsule for visualization of the digestive tract. <p>9. Nephrology</p> <ul style="list-style-type: none"> a. Home dialysis. <p>10. Neurological Diseases</p> <ul style="list-style-type: none"> a. Thoracic back pain diagnosis. b. Parkinson's disease monitoring. c. Peripheral nerve disease assessment. d. Seizure monitoring. e. Sensory and motor function assessment tools. <p>11. Orthopedics</p> <ul style="list-style-type: none"> a. Rehabilitation devices. b. Surgical tools. <p>12. Pharmacology</p> <ul style="list-style-type: none"> a. Enhanced drug delivery systems. b. Infusion Pumps. <p>13. Plastic Surgery</p> <ul style="list-style-type: none"> a. Restorative/cosmetic prostheses and implants. <p>14. Psychiatry</p> <ul style="list-style-type: none"> a. Alert systems for Depression and/or Anxiety. b. Suicide Prevention. <p>15. Pulmonary</p> <ul style="list-style-type: none"> a. Diagnosing drug-induced respiratory depression. b. Low cost sleep apnea monitoring. |
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Investigate the Clinical Problem

- ▶ **Resources**
 - University libraries – topic search, journal articles.
 - Bio-Medical Library in Diehl Hall – medical books.
 - Interview physicians if able – ie. Prof. Saliterman.
 - Interview patients if able – friends & relatives.
- ▶ **Study the disease**
 - What is the clinical presentation and progression?
 - What anatomy and pathophysiology are involved?
 - What are the incidence, prevalence, morbidity and mortality of the disease?
 - What are the causes, treatments, and outcomes?

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Impact

- ▶ **What is the cost/impact of the clinical problem to the patient and society?**
 - Healthcare costs
 - Emotional impact
 - Loss of wages
 - Global issues like opioid addiction
- ▶ **Are there Medicare or other insurance coverage issues?**
- ▶ **Are patient expectations realistic?**

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Formulate a “Needs Statement”

- ▶ **“A process for determining and addressing the gaps between the current situation or condition, and the desired one.”¹**
- ▶ Consider ie. **Chronic Pain Management:**
 - “Lessen the amount and duration of knee pain in elderly adults with osteoarthritis.”
 - “Reduce the number of visits to the emergency room for low back pain.”
 - “Reduce the use of opioid medications for chronic pain among Appalachian residents.”
 - “Improve sleep disturbance due to pain.”

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¹ Needs assessment for medical devices. World Health Organization, 2011

Solutions

- ▶ What are the *existing and emerging solutions* for diagnosis, treatment and management?
- ▶ Do you see an *opportunity* - “gap analysis” to create value within existing solutions?
- ▶ Can you identify a totally *unique solution*, based on yours or someone else’s research?
 - *It is not the discoverer, but the first to patent an invention based on the discovery, that ultimately owns the intellectual property.*

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Stakeholder Analysis

- ▶ Identify the stakeholders, including potential conflicts of interest and alignments.
- ▶ Identify market segments.
 - For example, in *Stroke Management*, this includes:
 - **Pre-hospital** - family and EMS.
 - **Emergency Department** - all personnel.
 - **Hospital** - nurses, doctors, pharmacists, physical therapists.
 - **Recovery** - rehabilitation centers, nursing homes.

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Market Analysis

- ▶ What is your target population/market?
- ▶ What is the current market landscape (for example competitors)?
- ▶ What is the size and demographics of your market (patients, first responders, nurses etc.)?
- ▶ Is the market growing or shrinking?
- ▶ Are there regional or international considerations?

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Clinical Problem Worksheet

Team	Discovery & Ideation	Investigation Phase Invention & Prototype
1. Team members and contact information.	1. Clinical problem chosen.	1. Medical device solution.
2. Team member's individual strengths and weaknesses.	2. Resource list – websites, places and people.	2. Prototype requirements: Costs, timeline and other resources needed.
	3. Understanding of the disease: Clinical presentation and progression, Anatomy and pathophysiology, Incidence, prevalence, morbidity and mortality, Causes, treatments and outcomes	3. Plans for completion and presentation.
	4. Impact of the Disease: To the patient, To society, Insurance coverage, Patient expectations.	
	5. Needs Statement	
	6. Solutions	
	7. Stakeholder analysis.	
	8. Market analysis.	

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Summary

- ▶ Keep a lab **notebook**.
- ▶ Select a **clinical problem**.
- ▶ **Investigate** the clinical problem and its impact.
- ▶ Identify a specific **need**.
- ▶ Consider all **solutions**.
- ▶ Describe the **stakeholders**.
- ▶ Complete a **market analysis**.
- ▶ Propose a **medical device solution**.

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