

A course to Experience Medical Device Design: From Business Evaluation to Engineering Design

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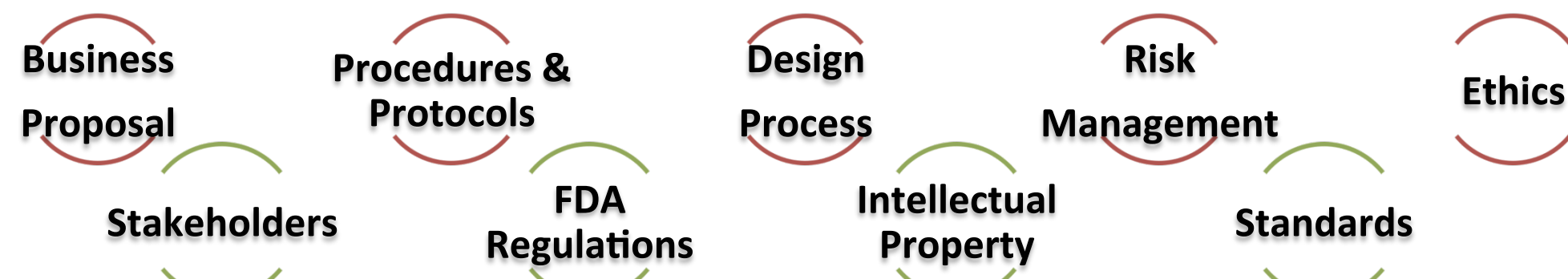
ABSTRACT

The course Introduction to Medical Device Methods (ININ5105) at UPRM provides a discussion of fundamental methods for medical device development, from concept to marketing. The course is interdisciplinary with students from different engineering disciplines, (Industrial, Mechanical, Electrical and Chemical Engineering), that take it as an advance undergraduate course. Through project-based learning (PBL) engineering students are taken out of their comfort zone to learn about entrepreneurship and experience the product definition process required to perform business proposals for medical devices. Project teams are made interdisciplinary based on the expertise needs of the particular medical device (e.g. the neurostimulator must include a student from Electrical Engineering). The first phase of the project is focused on the business evaluation: the clinical needs identification and analyses of the competencies, customer, market, competition, technology, FDA regulations, finances, reimbursement and intellectual property protections. The second phase of the project relates more to technical knowledge by learning and implementing the design process in parallel with risk management. Amongst the innovative features of the course, it includes the use of a web-based application developed by the professor for the students to implements their developments. Furthermore, this course differentiate from others by providing an integrated experience between business and technical knowledge. Students learn the business implications of a new venture with medical devices. They also implement current knowledge (in their engineering field) and acquire new one (of other fields) in order to understand current devices in the market and generate ideas to create new ones.

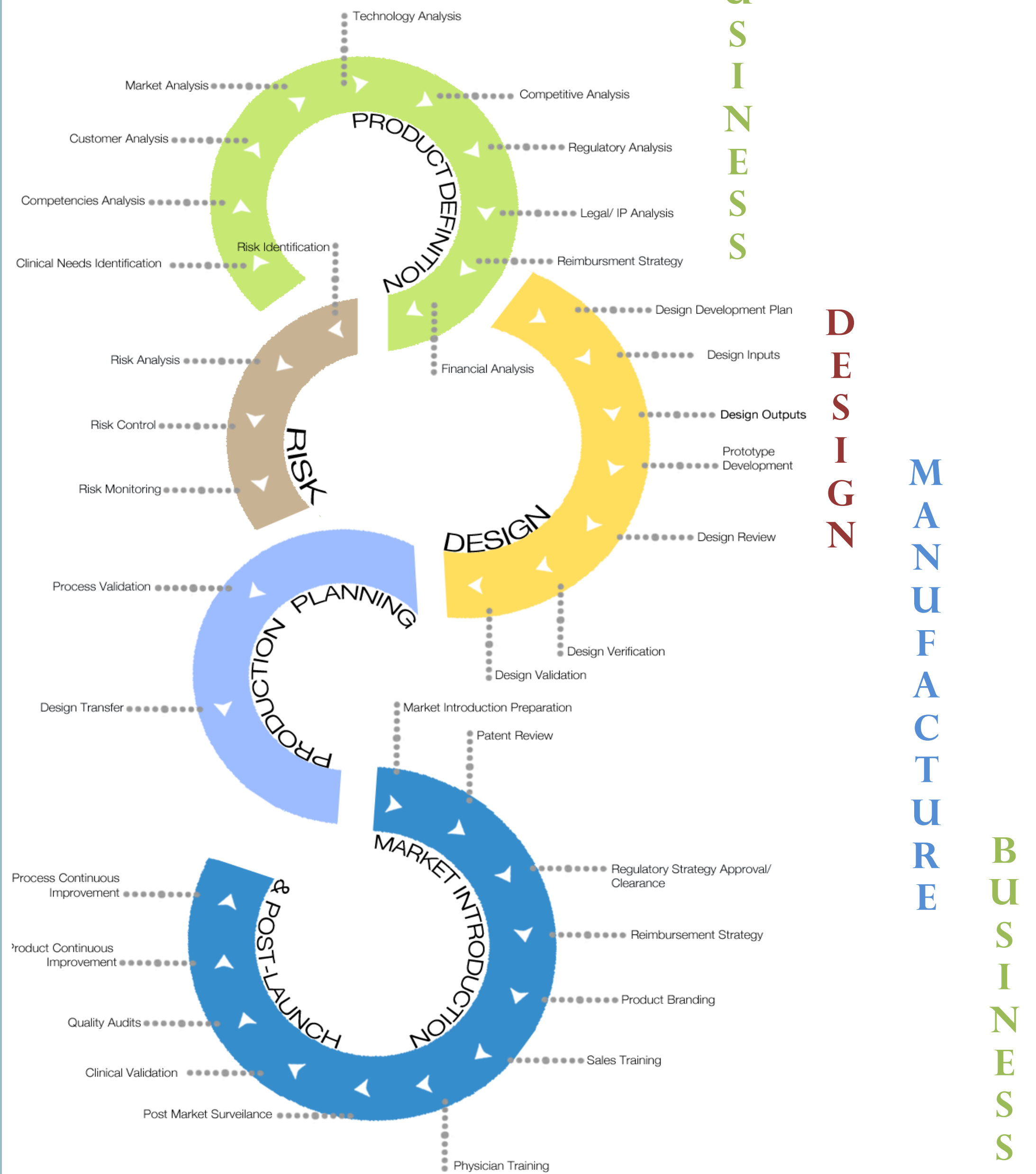
OBJECTIVE

Provide a holistic learning experience of the medical device development process.

What are the fundamental methods to develop a medical device from concept ideation to marketing?
What are associated standards, regulations (FDA), and intellectual property protections?
How to identify, analyze, control, and monitor risks?



METHODOLOGY: THE MDD PROCESS



STATE OF THE ART

Collaboration Platforms for Product Development

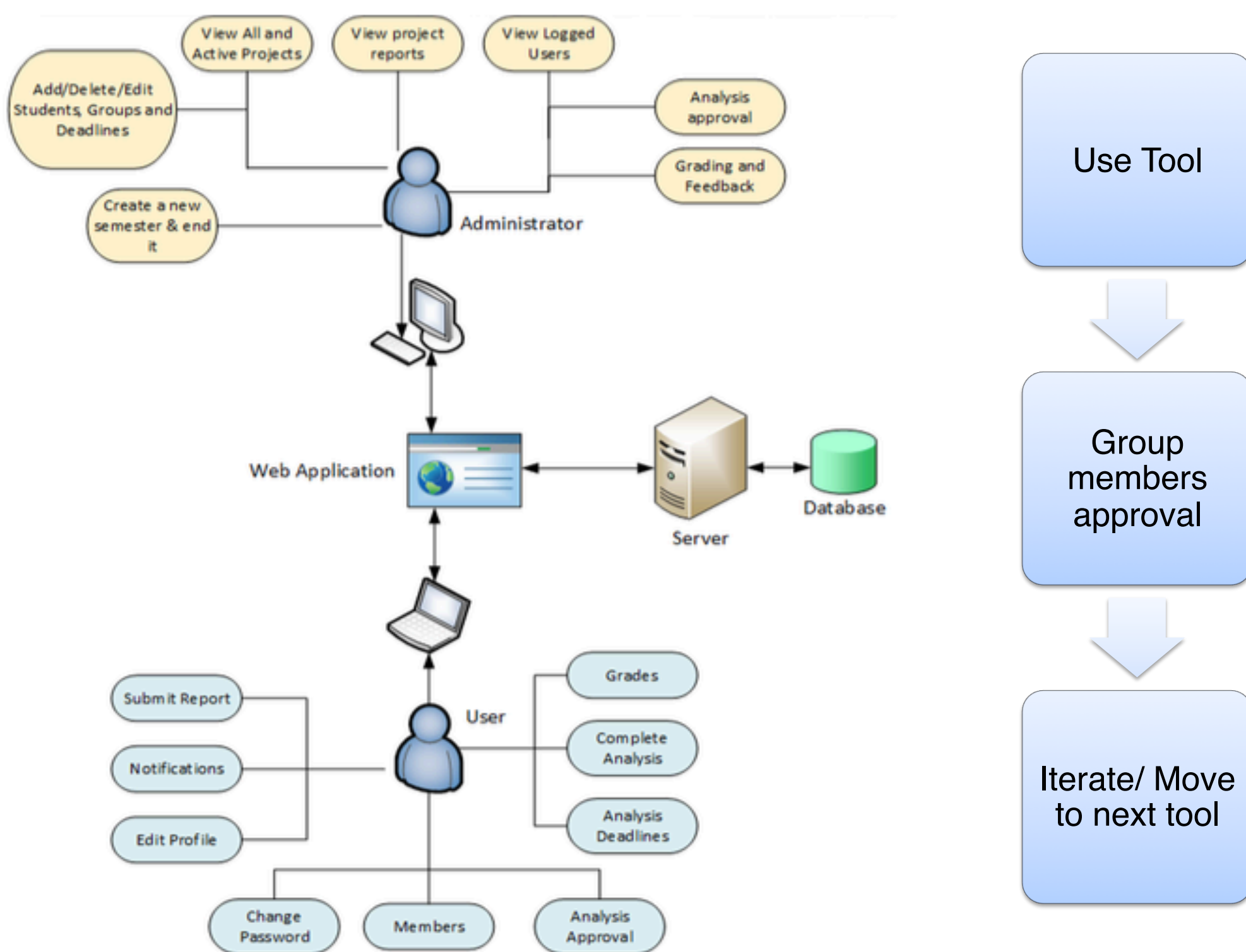
- Decision-making is one of the most important aspects of the product development process. [10]
- Design and development activities' duration can be reduced through collaboration while delivering a high-quality product. [8]
- Good collaboration within the different roles inside the company are crucial determinants of a new product's success. [6]
- Computer and web tools have taken more relevance as IT advances have enabled more possibilities to aid NPD and lifecycle management from its early stages. [12]

Education and Innovation

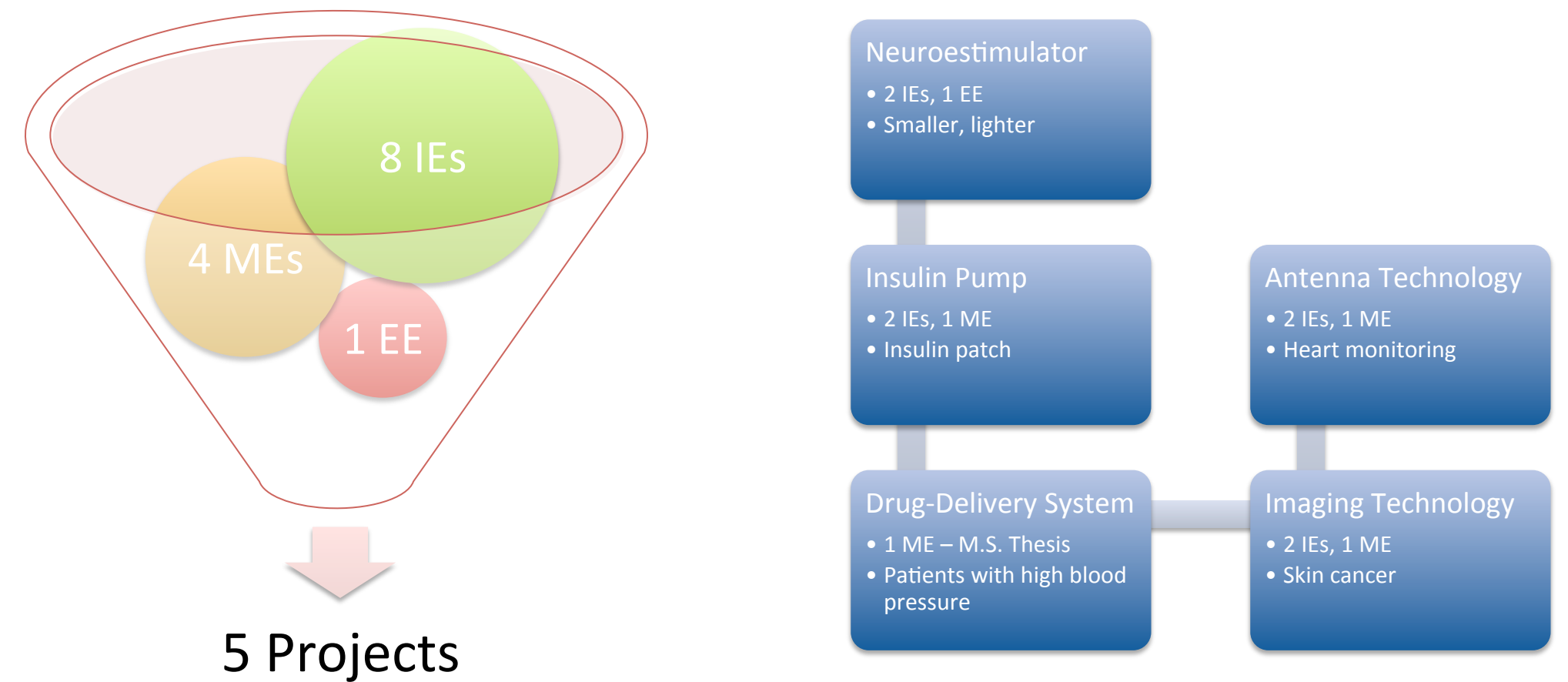
- ININ5015 syllabus is designed so the students end up with the required skillset to develop a medical device.
- Providing a robust tool like the one proposed is key in order to bring organization in terms of planning and development activities needed to launch a start-up company.
- Promoting new ventures that evolve from an academic environment should come hand in hand with removing road blocks, and facilitating design and development activities, adding to the long term goals of the MDD Process Web-based Collaborative Platform

ENVIRONMENT:

A COLLABORATIVE PLATFORM FOR MDD



IMPLEMENTATION: PROJECTS



THE BIG PICTURE

