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# End of PhD! What's next?

@softjournal



Ideation Phase

Proof of Concept

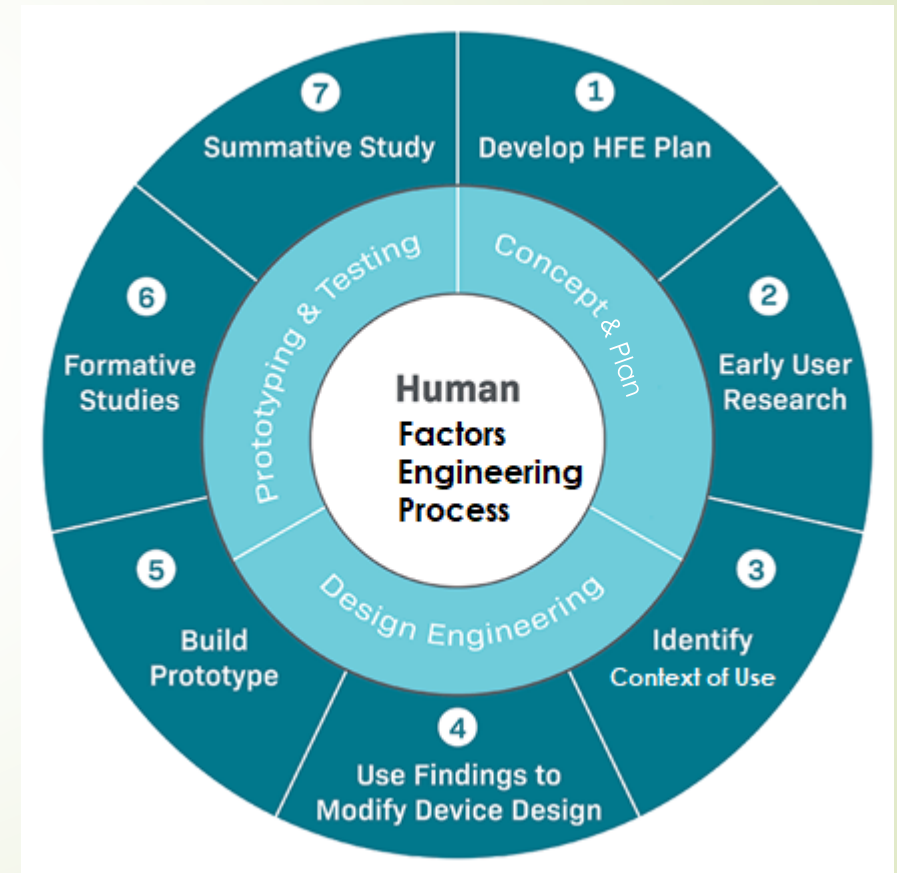
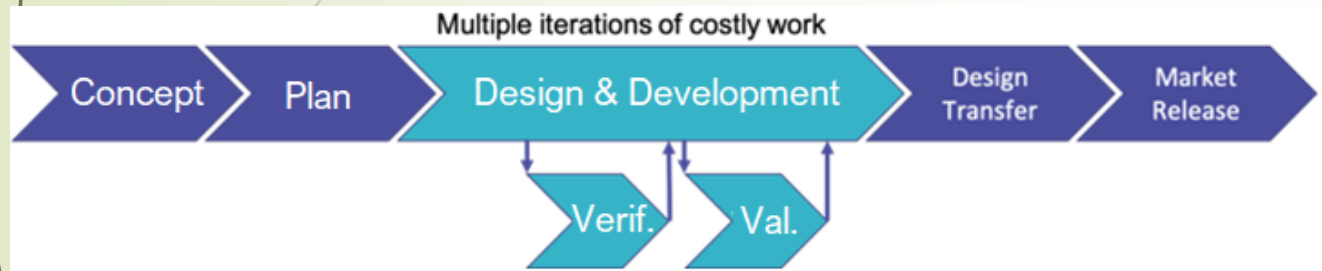
Prototype

How do I get from my Proof of Concept to the first marketable prototype?

How to get on market?

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## A case study



# Precision medicine

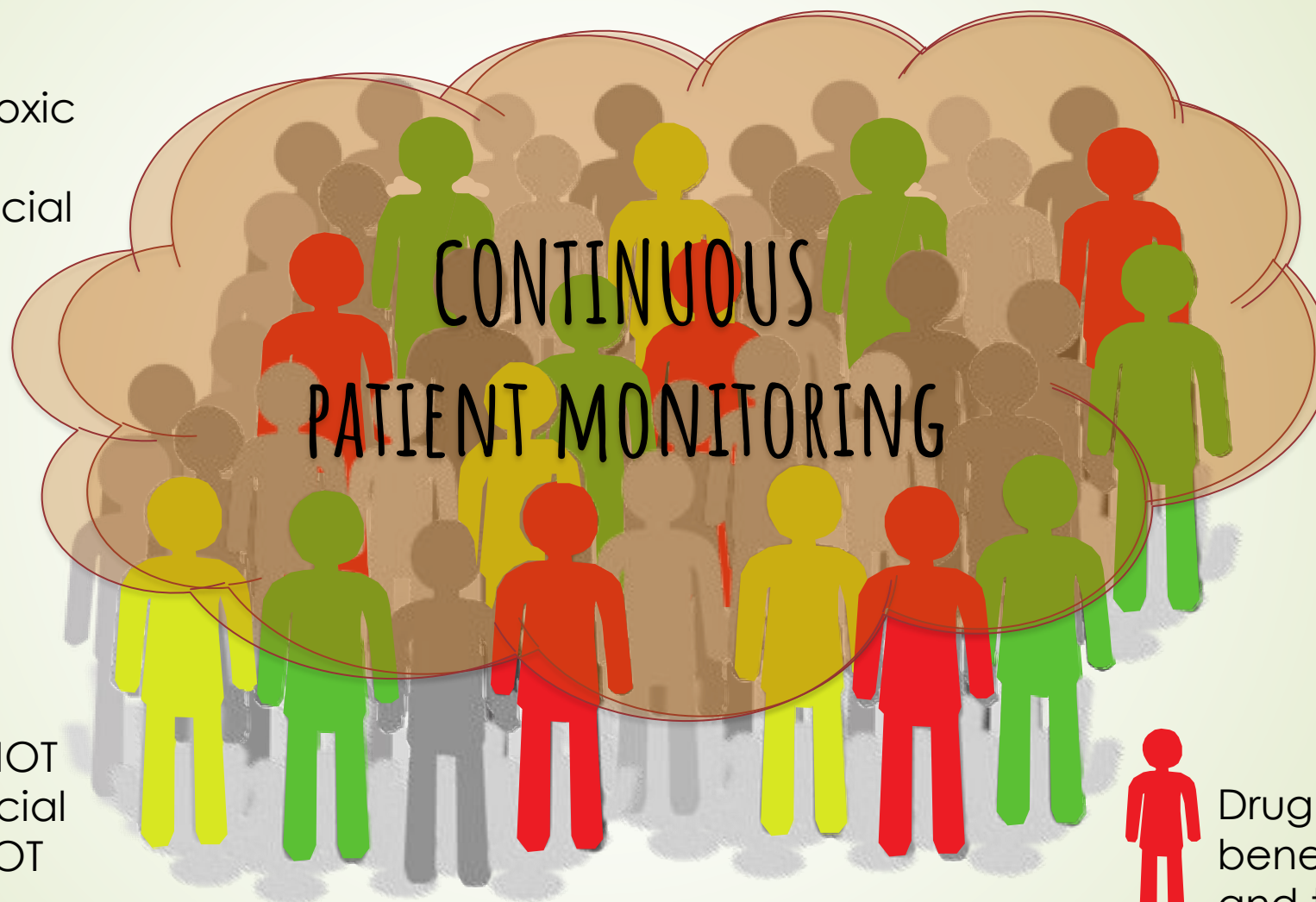
Target product: Point of Care System for  
Personalized Anesthesia delivery



Drug toxic  
but  
beneficial



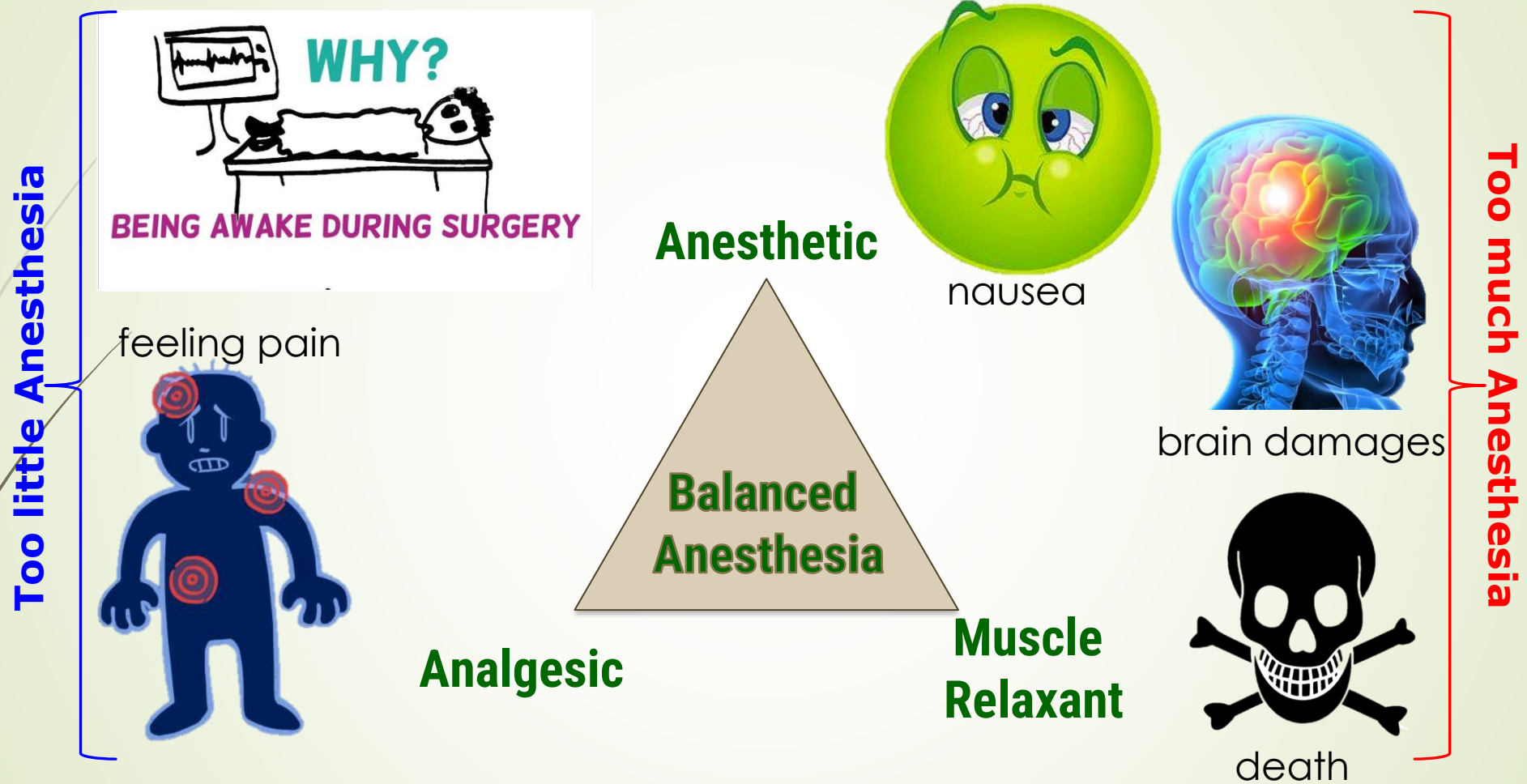
Drug NOT  
beneficial  
and NOT  
toxic



Drug NOT  
beneficial  
and toxic

# Sedation Cocktail

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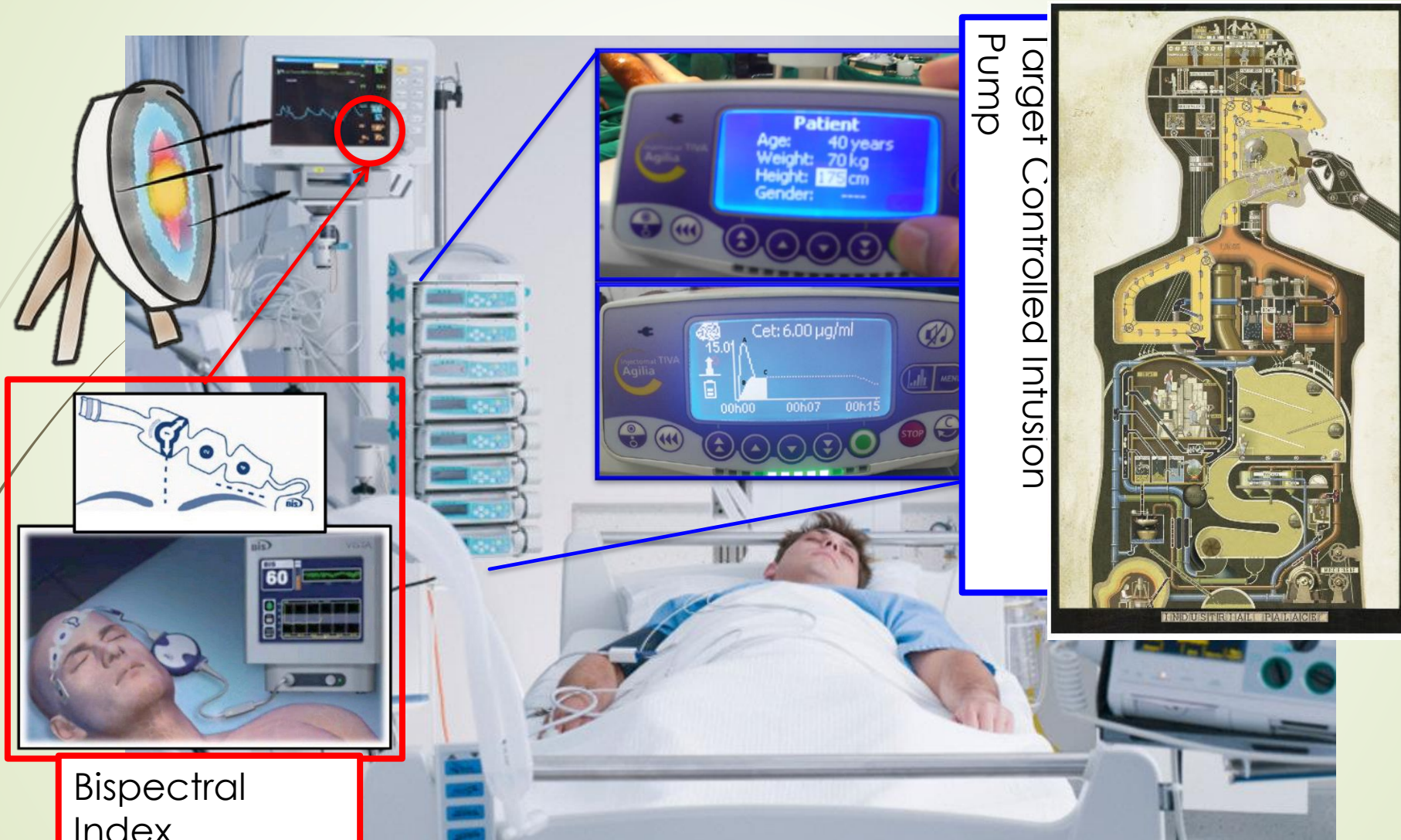
**Vital Importance: the right personalized balance!**



# Nowadays Practices

MEDICAL APPLICATION: SEDATION

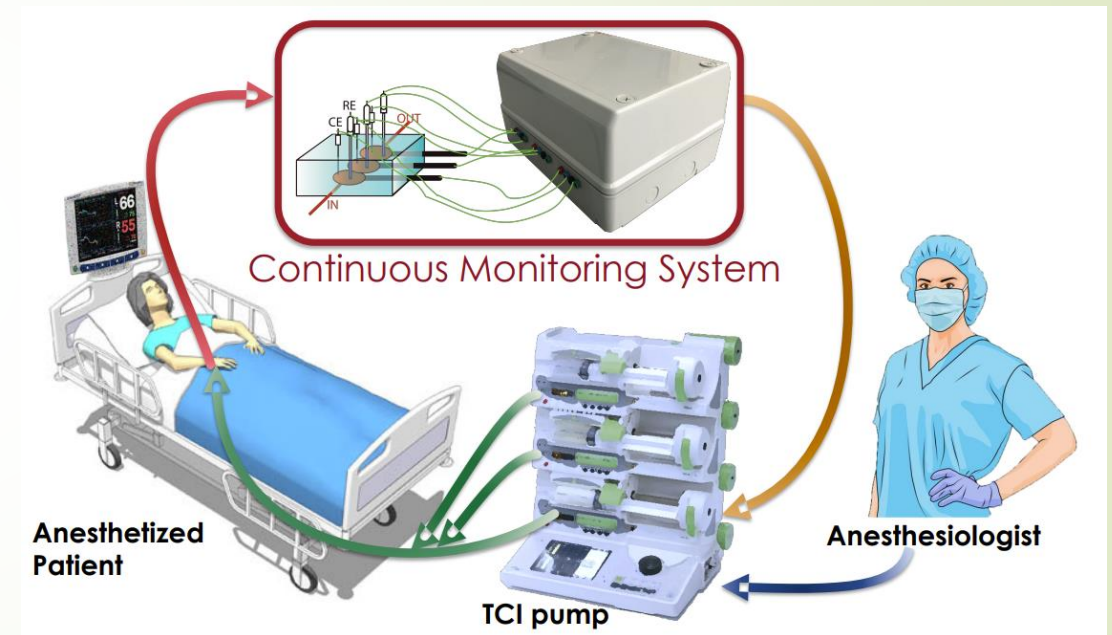
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Bispectral  
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# Define the context of use

- What is the intended use?
  - Monitor the level of anaesthesia in the blood of the patient
- Who are the intended users?
  - Anaesthesiologists
- What is the intended use environment?
  - Operating Room



# Collect the user needs

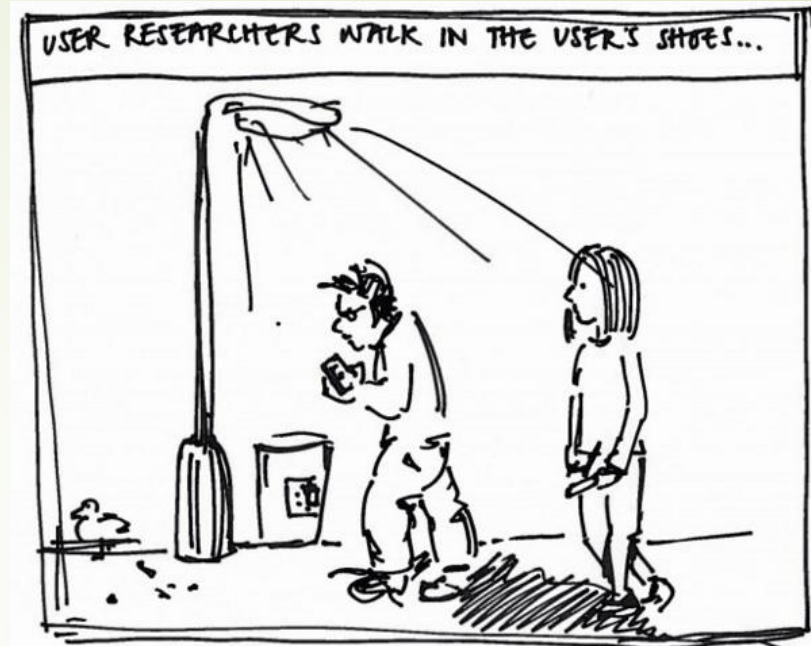
## Early User Research

Different methods:

- Contextual Inquiry
- Interviews
- Surveys
- Focus Groups

## To define:

- User needs
- Task analysis → workflow of use, what are easy tasks/what are the difficult ones? Where can we act to facilitate the flow?



@JENNI DE LUCA, CAREERFOUNDRY



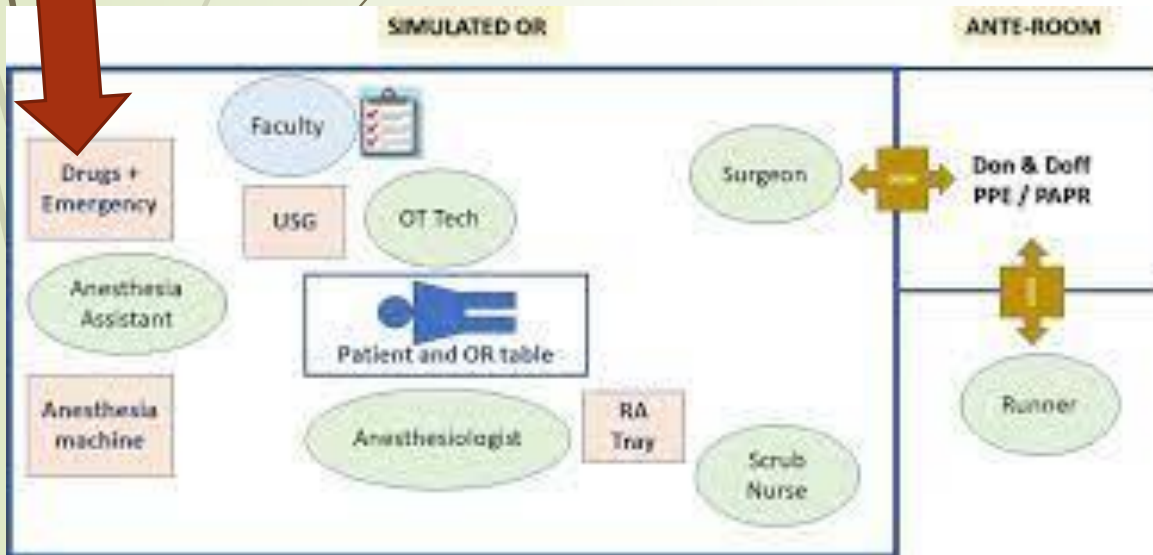
# Example of anaesthesia task analysis



## Some Anaesthesiologist Needs:

- As Anaesthesiologist I need to have free hands
- As Anaesthesiologist I need to keep under eyes parameters of different patients at same time

## Example of simulated OR



Ashokka B, Chakraborty A, Subramanian BJ, et al  
Reconfiguring the scope and practice of regional anesthesia in a pandemic: the COVID-19 perspective  
*Regional Anesthesia & Pain Medicine* 2020;45:536-543.

### Preoperative assessment

1. comorbidity evaluation
2. tumor location
3. PRFA approach and patient positioning

### Anesthetic plan

1. premedication choice
2. general anesthesia vs. loco-regional technique
3. airway management plan
4. acquisition of the informed consent

### Anesthesia and preparation

1. application of monitoring
2. general or loco-regional anesthesia delivery
3. patient positioning

### PRFA procedure

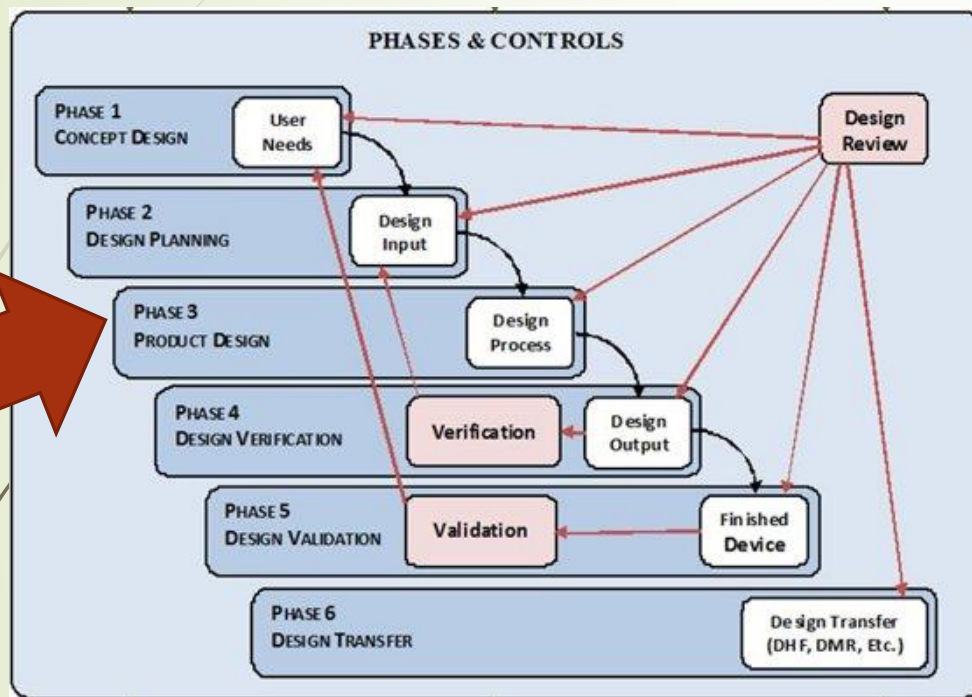
1. antibiotic prophylaxis
2. sterile field set-up
3. radiofrequency ablation

### Recovery

1. awakening of the patient
2. pain management
3. monitoring until complete recovery (at least 30 minutes)

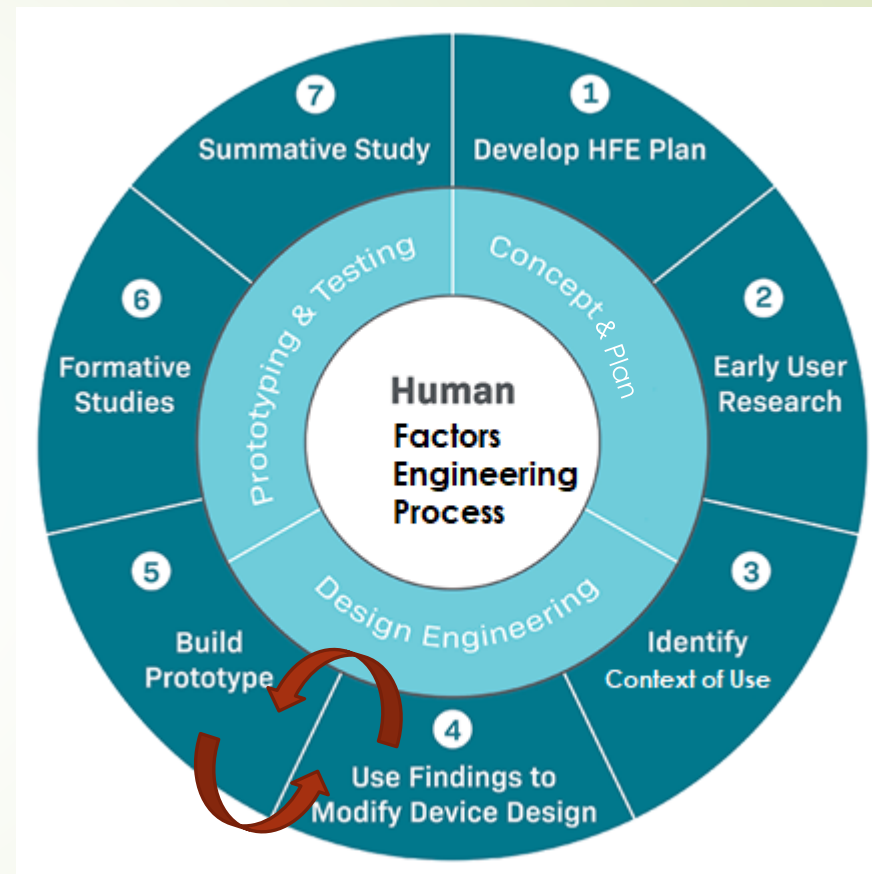


# A case study



And yes...now you are again in design! ☺

Because you have to focus on the user needs & human factors aspects, differently from the technology focus only



# New prototype



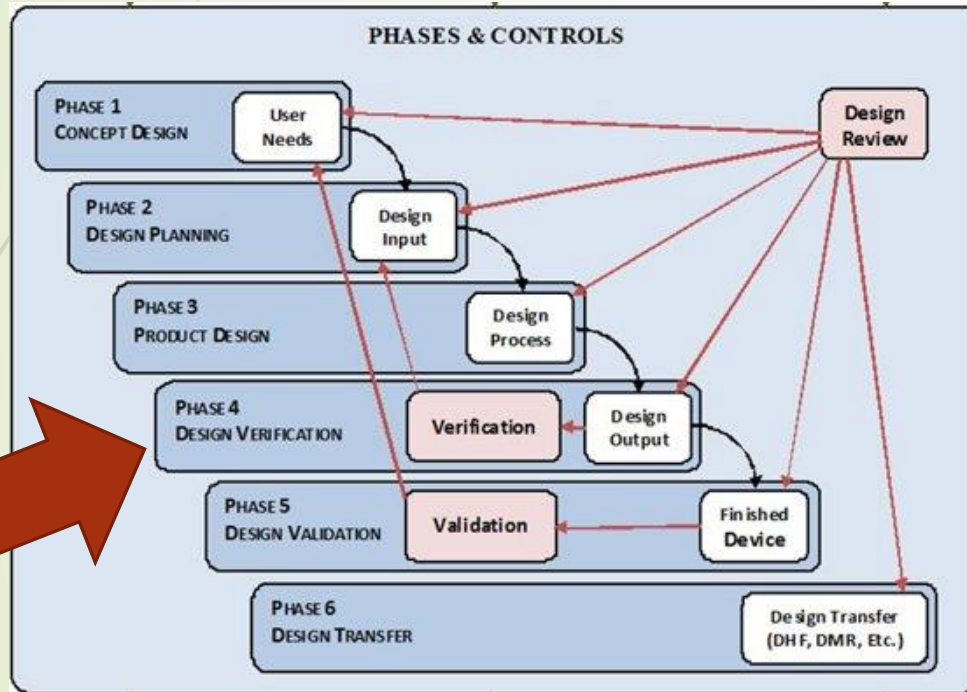
- ✓ Anaesthesiologist needs to have hands free
- ✓ No additional bulky device/monitors in the room
- ✓ Continuous monitoring of all patients connected to the network



You integrated your novel technology within a more usable scenario!

# Plan verif testing

Involve users to observe them interacting with your device



Task Analysis

Use related Risk analysis

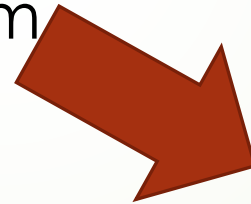
Critical Tasks

Formative Evaluation



# Summative test

- When confident of the design (use error occurrence reduced as far as possible by design)
- Therefore, ready for final validation → Summative
  - All user groups need to test the design
  - Larger user group (15-20 per each group)
  - All functionalities of the system

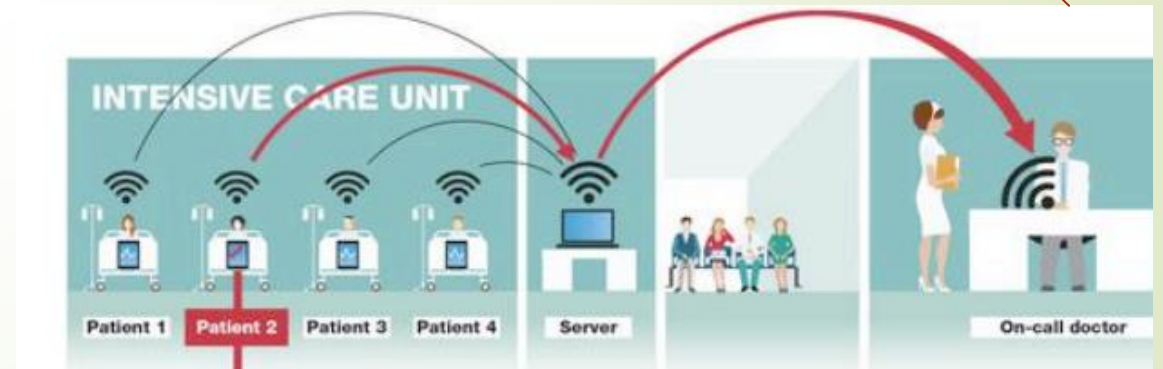
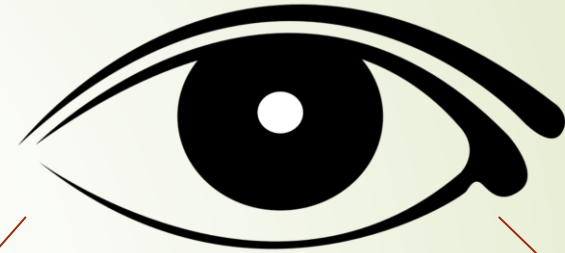


If the device is proven to be safe and effective, then it is ready for the market



# Post-Market activities

- Observe the device in the market in daily use to identify room for improvement
- Where one project “ends” a new one starts ;)



# Backup slide





# Goal: feedback monitoring system

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