



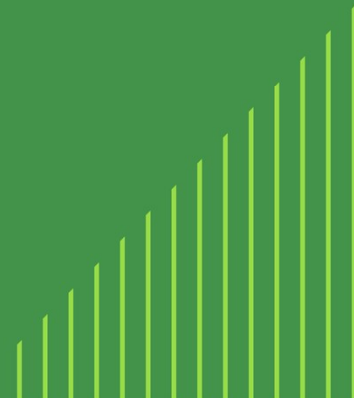
**User Experience in Medical Devices:**  
Combining **Smart Design**  
with Regulatory Requirements

MDI EXPO 2025

Cognit.co.il



**Gal Nir-Cohen, PhD**





**UX/UI Design** - UX strategy & architecture - **UX Research** - Global recruitment & research operations - **Usability for Medical Devices** - **Full support for FDA / CE approval**

20+

Years of experience

25+

Experts (MSc, PhD)



Tel Aviv, Yokne'am

## Usability for Medical Devices



 Take Home Message

# Integrating Design with Usability

- 1 Save effort, Save time**

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- 2 Create better medical devices**

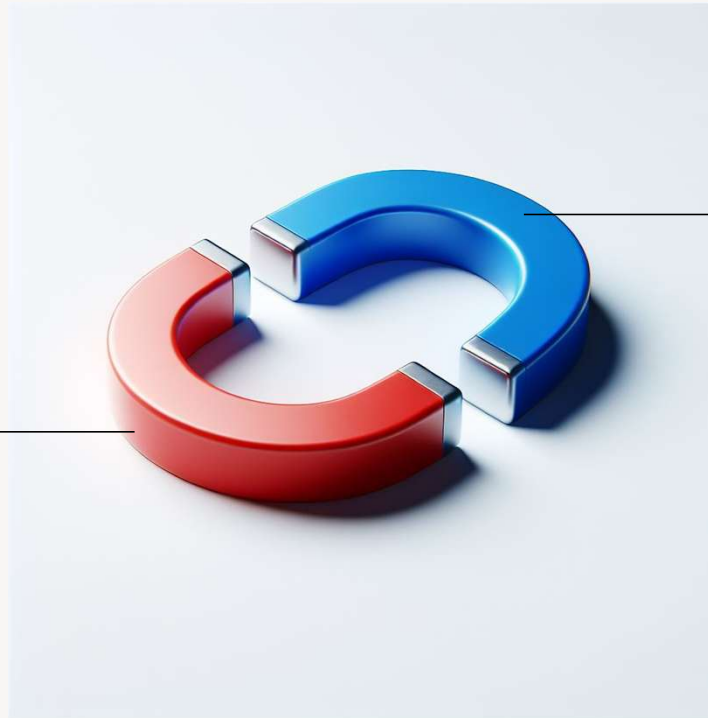
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- 3 FDA / CE approvals**

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## Most of the time

**Design and  
Development**

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**Usability  
Requirements**

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# Design and Development vs. Usability Requirements

## Design and Development needs

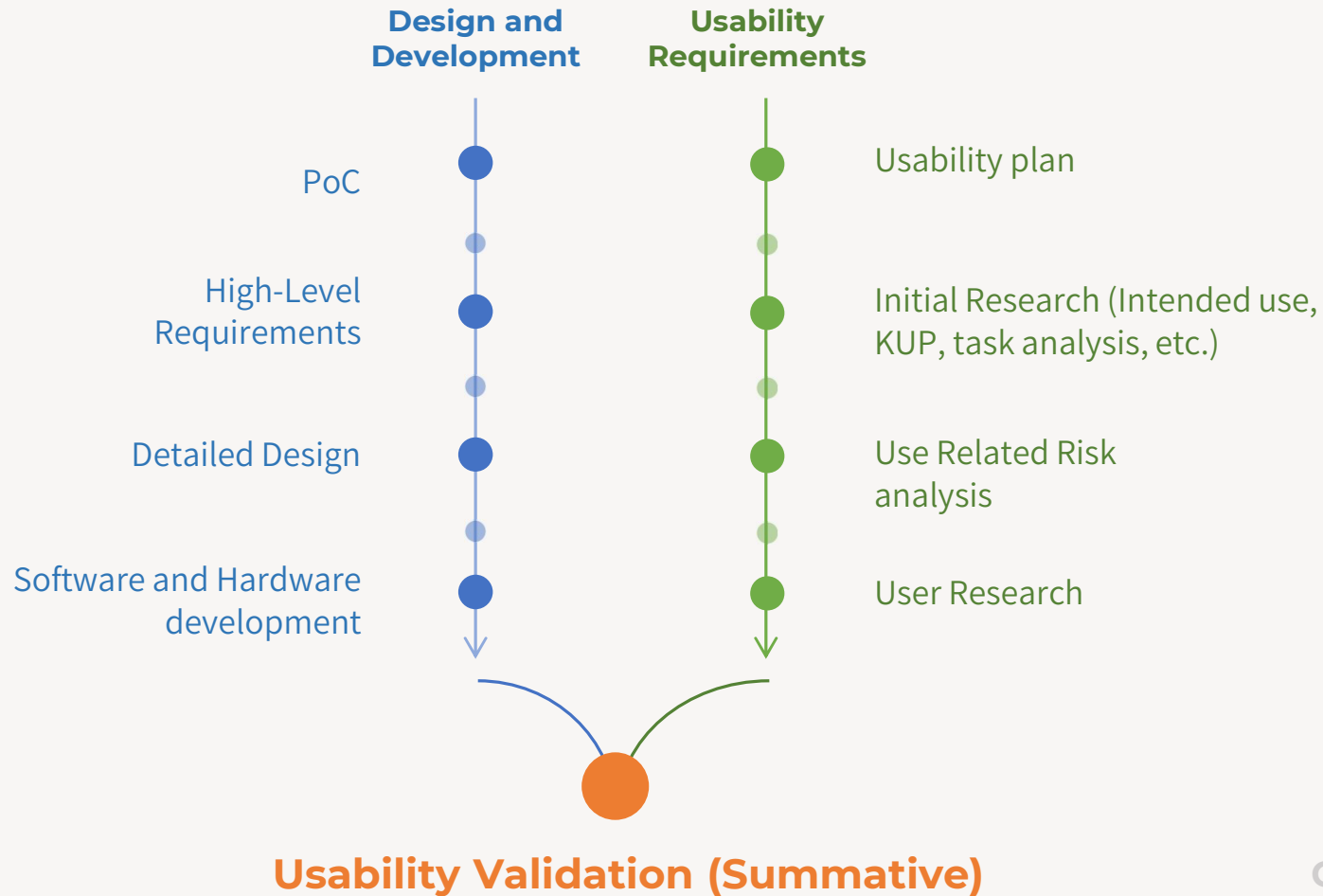
- Get to market fast
- Stay under budget
- Stand out from competition
- Innovation freedom
- Market differentiation



## Usability Requirements

- Follow usability standards
- Risk management and mitigation
- Traceability
- Validate thoroughly

# Design and Development vs. Usability Requirements



**Design and  
Development**

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**Usability  
Requirements**

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# When right is left

## **Challenge:**

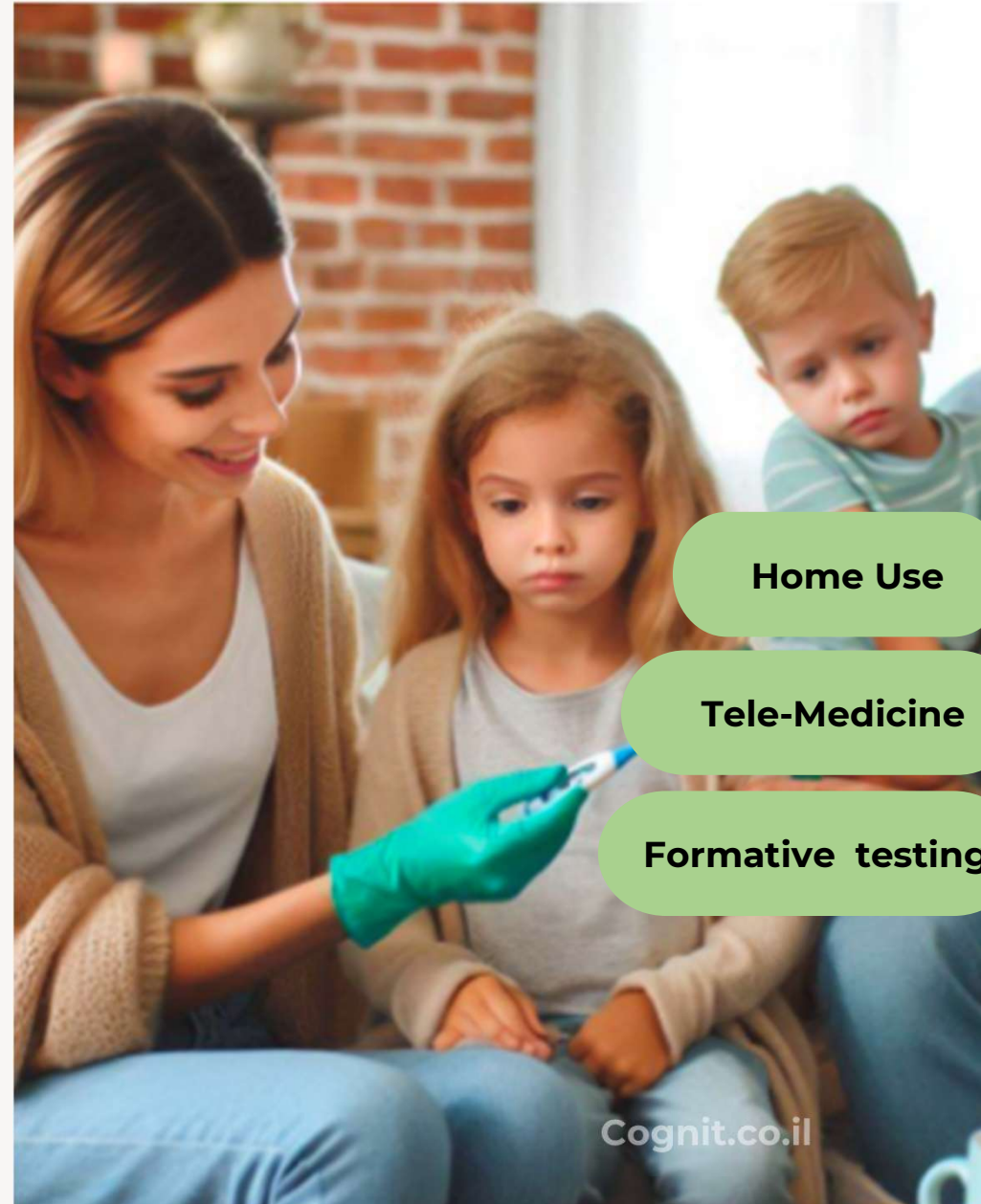
Usability was conducted after product development was completed. Users were unable to complete critical tasks

## **Usability Method:**

Formative testing

## **Solution:**

Short and simple videos, served as a user manual with clear instructions



Home Use

Tele-Medicine

Formative testing

# Ducks in a row

## **Challenge:**

Similar components that should be used in a specific order

## **Usability Method:**

Task Analysis and Use related risk analysis

## **Solution:**

Simple, cost-effective Paper Placemat



# Knock on Wood

## **Challenge:**

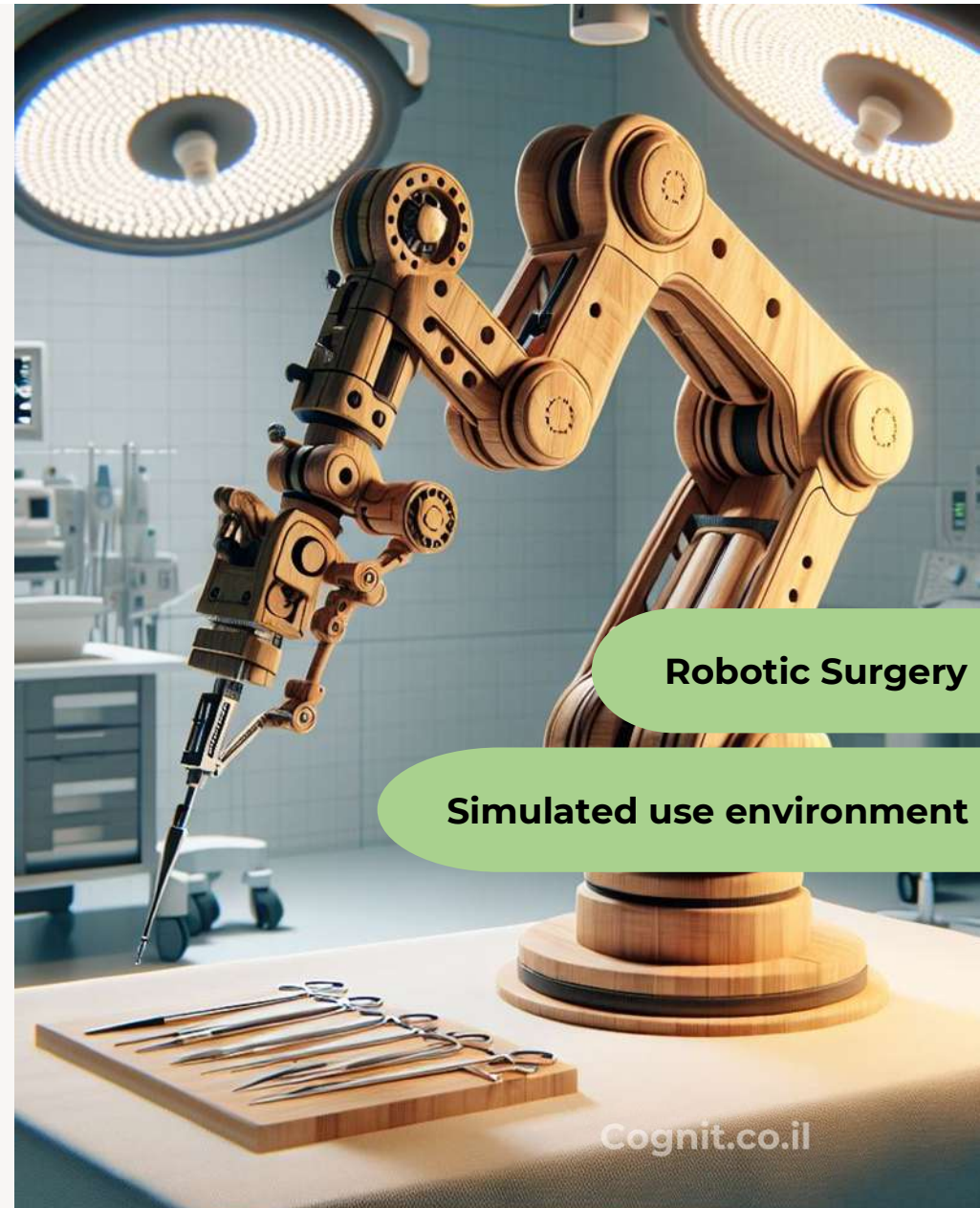
Identify risks for a novel robotic system before development was completed

## **Usability Method:**

Identifying specific scenarios and testing in a real use environment

## **Solution:**

Smart mitigations to avoid use errors









# Teamwork-Centered Design

## Challenge:

Multiple users that are using the systems at the same time

## Usability Method:

Testing of organic dyads

## Solution:

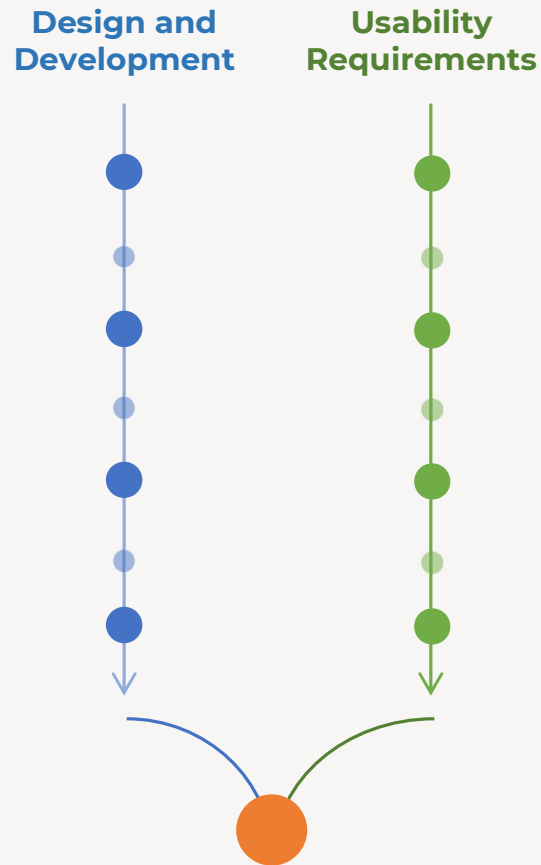
Ergonomics that take into account more than one user





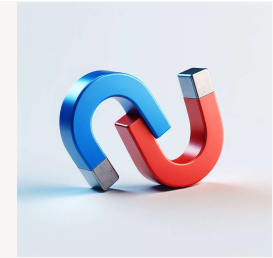


# Design and Development vs. Usability Requirements



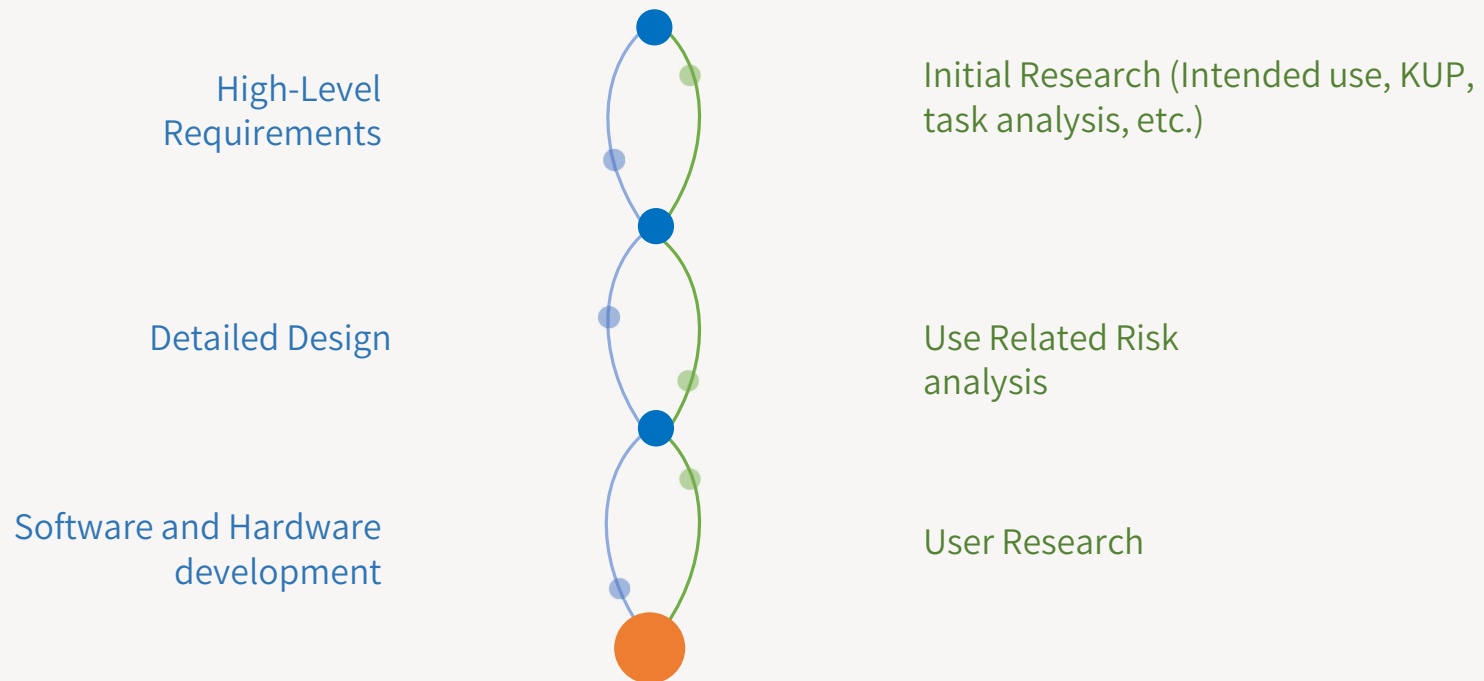
**Usability Validation (Summative)**

# Mutual Journey



**Design and  
Development**

**Usability  
Requirements**



**Usability Validation (Summative)**





As the product evolves  
— **Continue the synergy**

## Take Home Message

# Integrating Design with Usability

**1** Save effort, Save time

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**2** Create better medical devices

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**3** FDA / CE approvals

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Operation Room

Multi - User

Simulated use environment

Home Use

Robotic Surgery

Formative testing

Tele-Medicine

## Take Home Message

# Saving lives.

**Operation Room**

**Multi - User**

**Simulated use environment**

**Home Use**

**Robotic Surgery**

**Formative testing**

**Tele-Medicine**



# Usability at First Sight: **Saving effort, Saving lives.**

# Thank you.



[www.cognit.co.il](http://www.cognit.co.il)



Cognit UX Experts



[gal@cognit.co.il](mailto:gal@cognit.co.il)

