



How to Navigate the Usability Journey?

# Hard-Won Lessons for Israeli Med-Tech



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# Hello, We are Cognit

**+20**

Years of experience

**+25**

Experts (MSc, PhD)



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RAFAEL

FORTINET



Perion

WIX

proofpoint.

maytronics

Simply



# HFE & Usability for Medical Devices

Unique expertise in usability & HFE processes for regulatory approval of medical devices

- **Use Related Risk Analysis (URRA)**
- **Design for mitigation** of use-related hazards
- **Formative & Summative** (validation) testing
- Documentation for **FDA/CE clearance**



# ► The Impact of **Distance** on the Usability Process

## Challenge

Local innovation operates at a **distance** from users, work environments, context of use, and regulators

## Consequence

In many cases, **user interface development happens internally. Usability and users come in late**

## Risk

Usability **problems** are **identified late** in the process.  
Costly modifications and submission delays

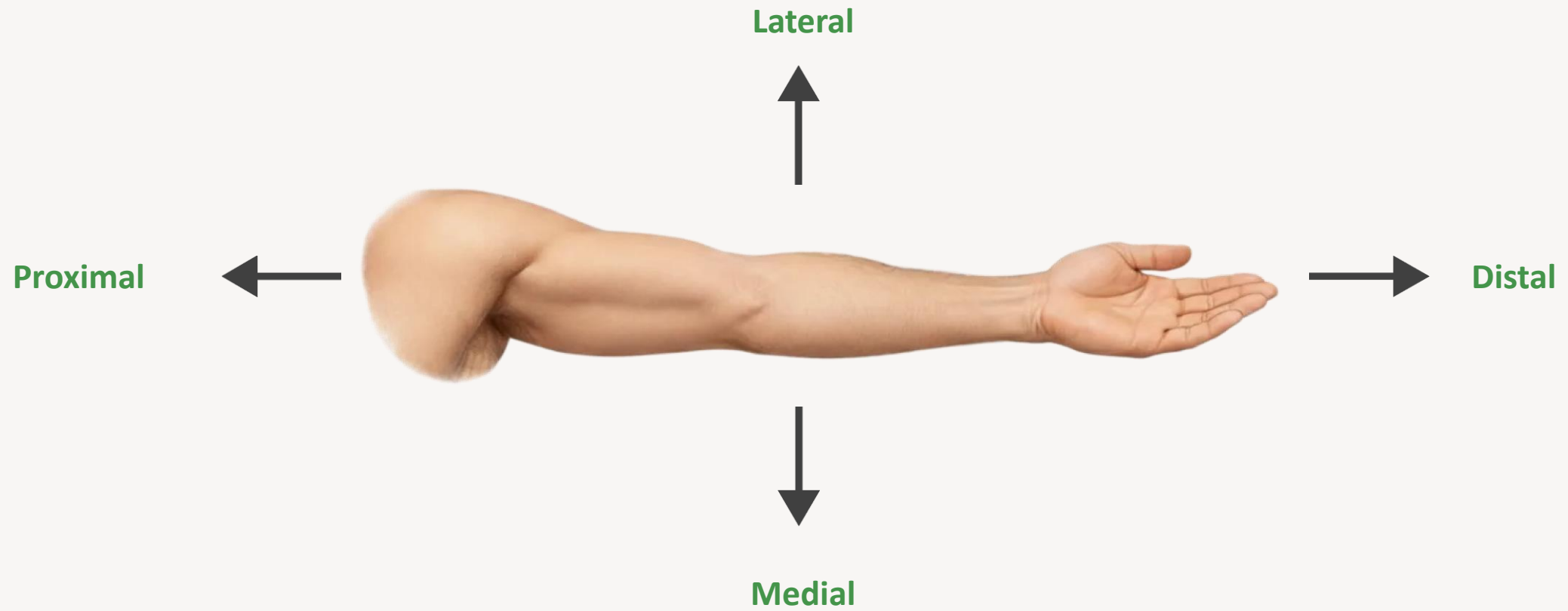
# 5 Lessons for **Effective Usability**

You Don't Need a Flight Ticket to Start a **Usability Process**



# Home-Use Device for Lay Users





## Lesson 1

# Don't Skip the **Expert Evaluation**



### Human Factors

Does it align with cognitive principles?



### User

Is it intuitive to the intended users?



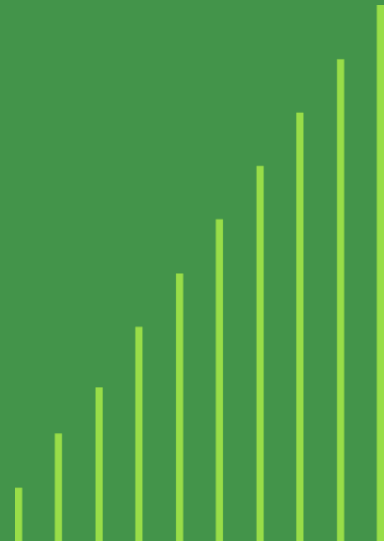
### Regulation

Is design compliant with guidelines?

**Before you test with users, test with experts**

# Expert Evaluation ≠ User Testing

Expert evaluation is important  
but it doesn't replace **real user insight**



## Lesson 2

# Leverage Existing **Opportunities** for **User Research**

VOC  
Marketing

Conferences  
& Exhibitions

Clinical  
Trials

Field  
Visits

User  
Training

No separate budget needed, just **smart planning**.  
Every **user interaction** is a learning opportunity

**Don't forget to document**

# Formative Studies





## Lesson 3

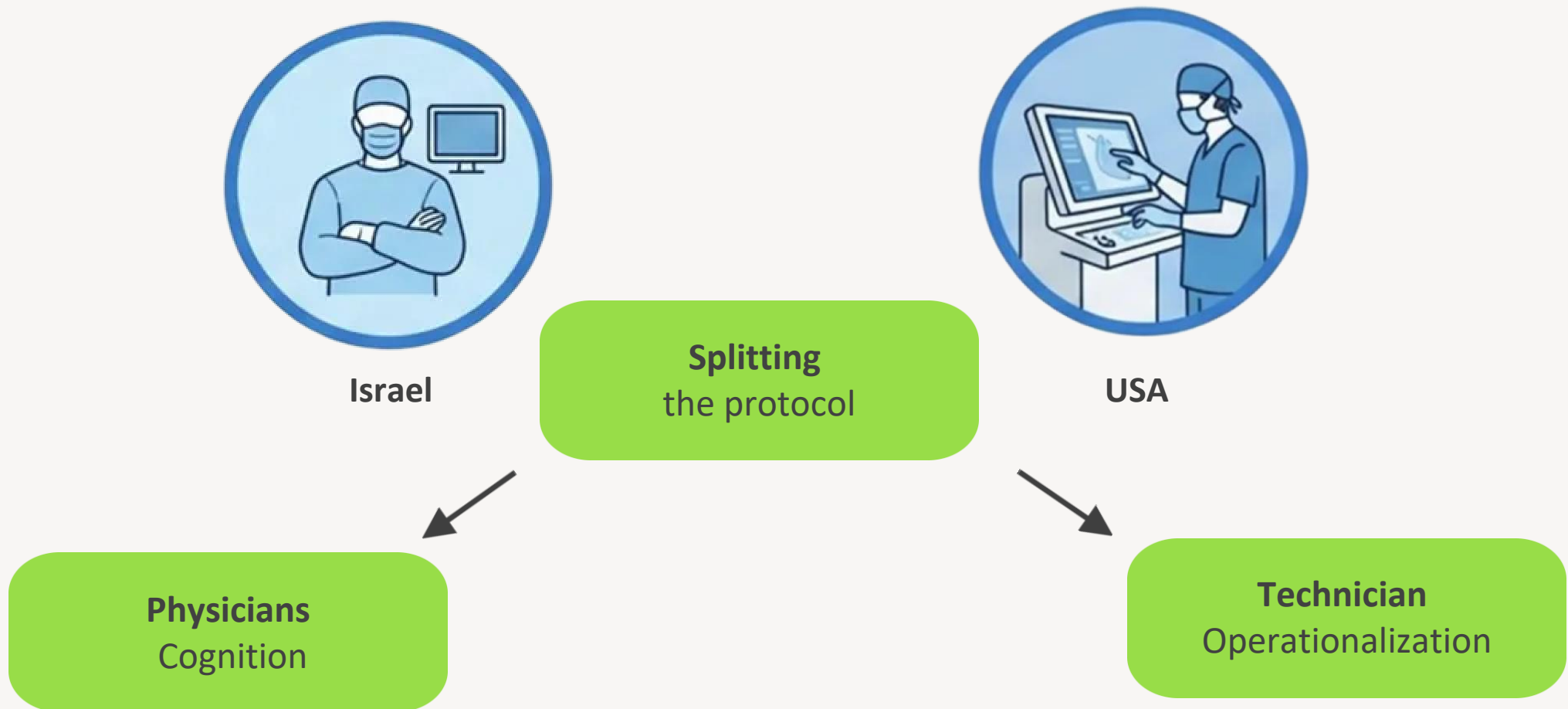
# Conduct Formative Studies early



# Local Formatives



# Map The Differences



# Remote Testing



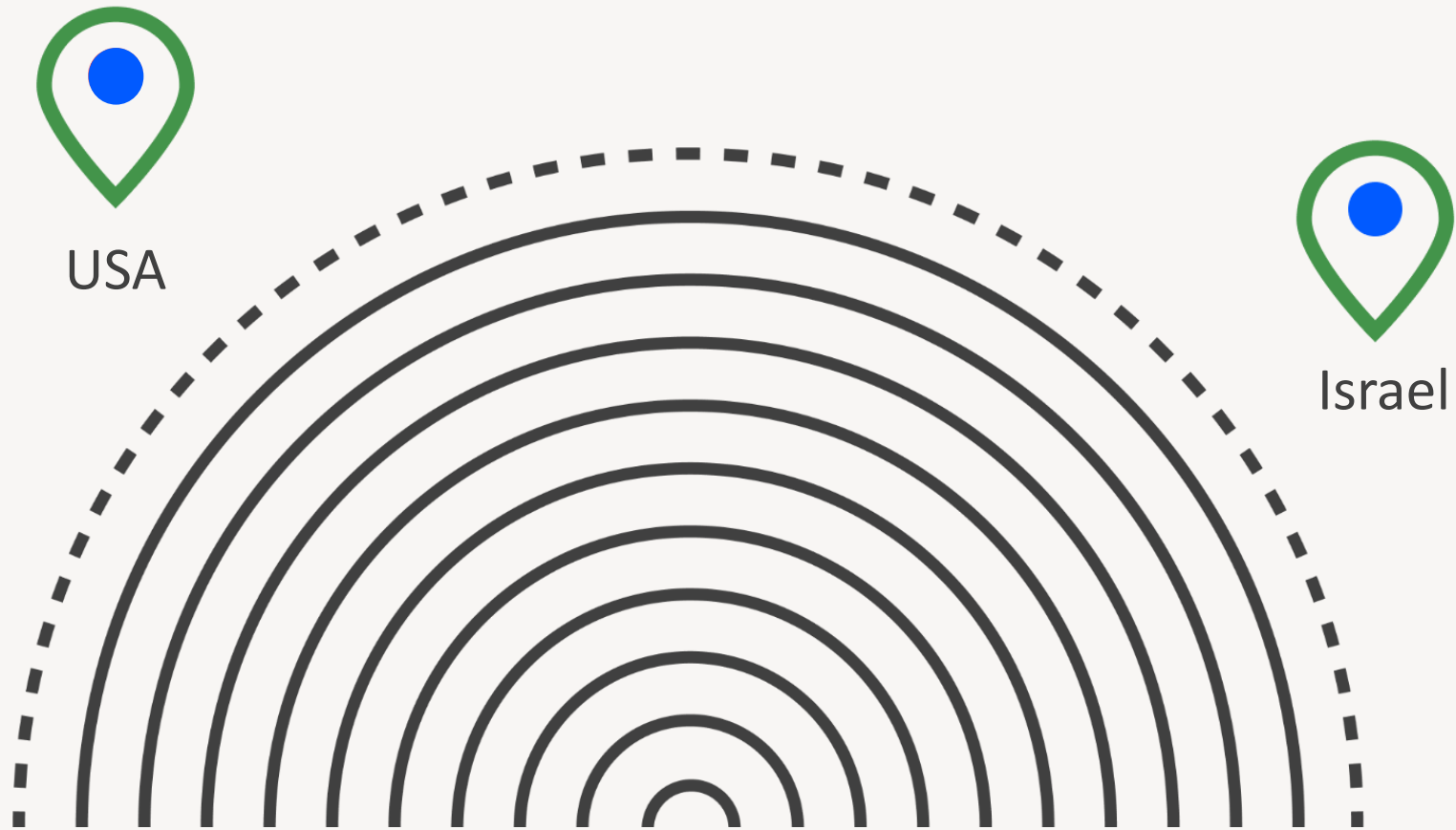
# Remote Testing

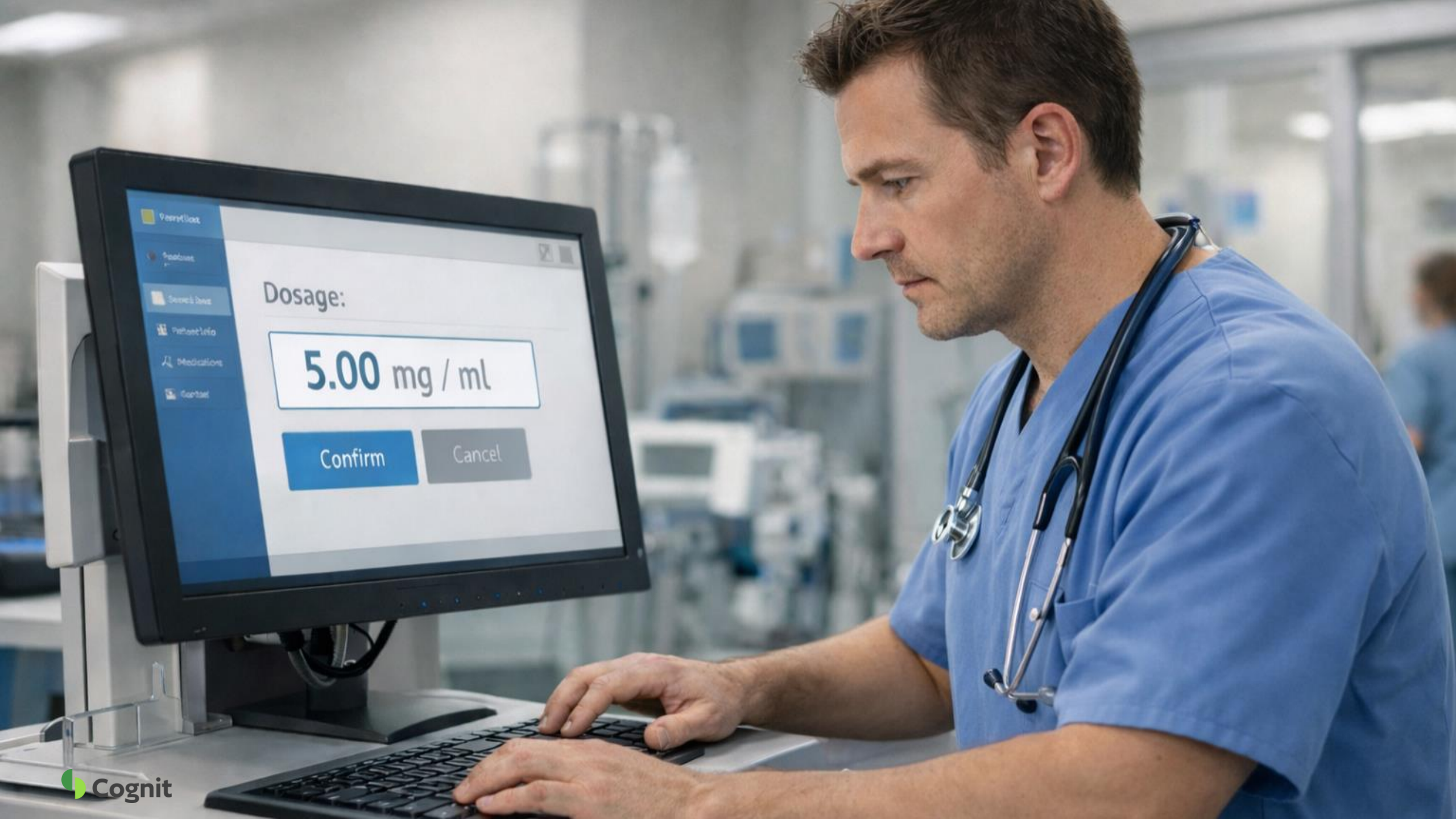


- GUI changes
- Understanding
- Interpretation
- Decision-making
- Label comprehension



# Summative





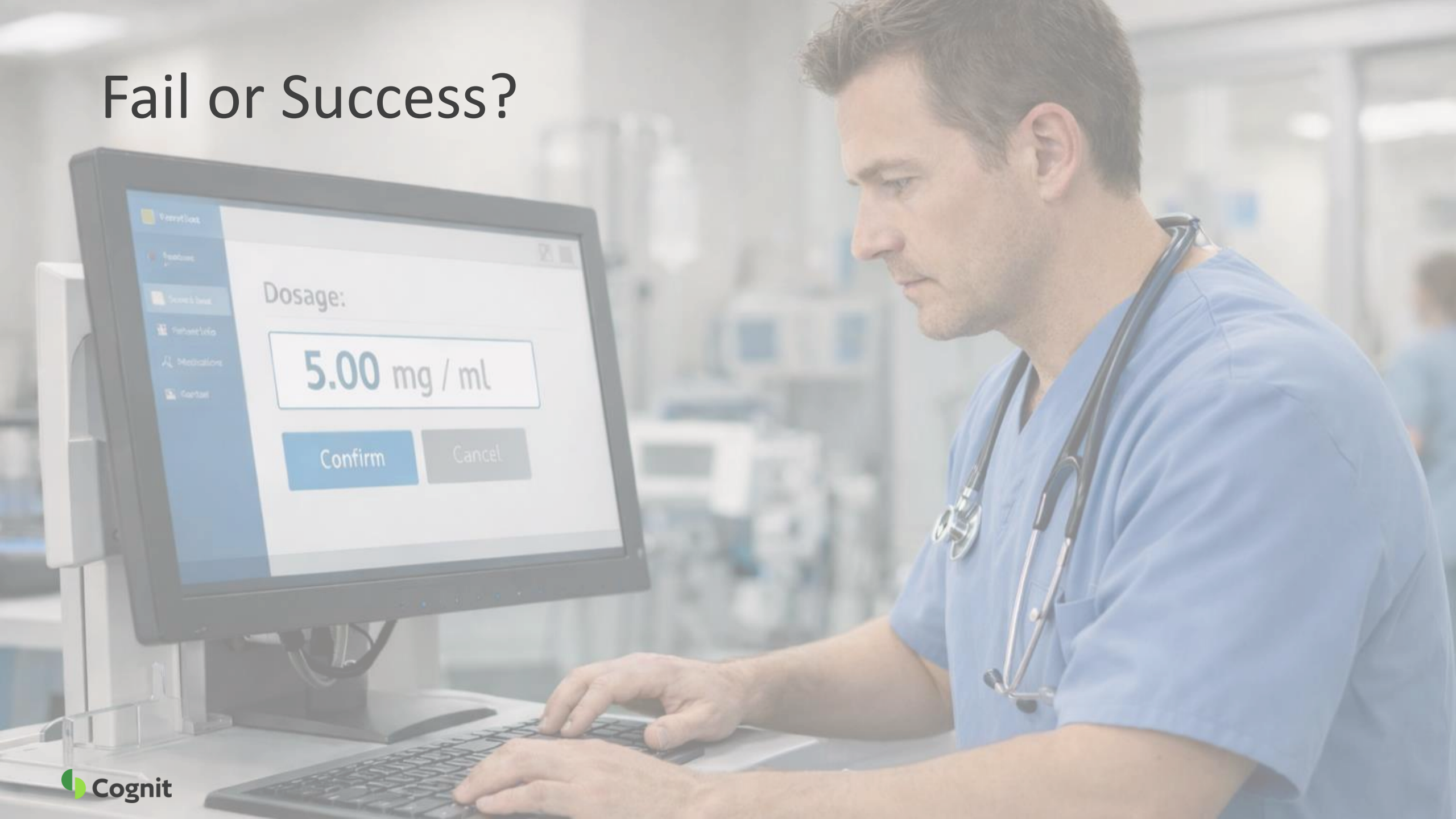
Dosage:

5.00 mg / ml

Confirm

Cancel

# Fail or Success?



## Lesson 4

# Plan Your Summative Carefully

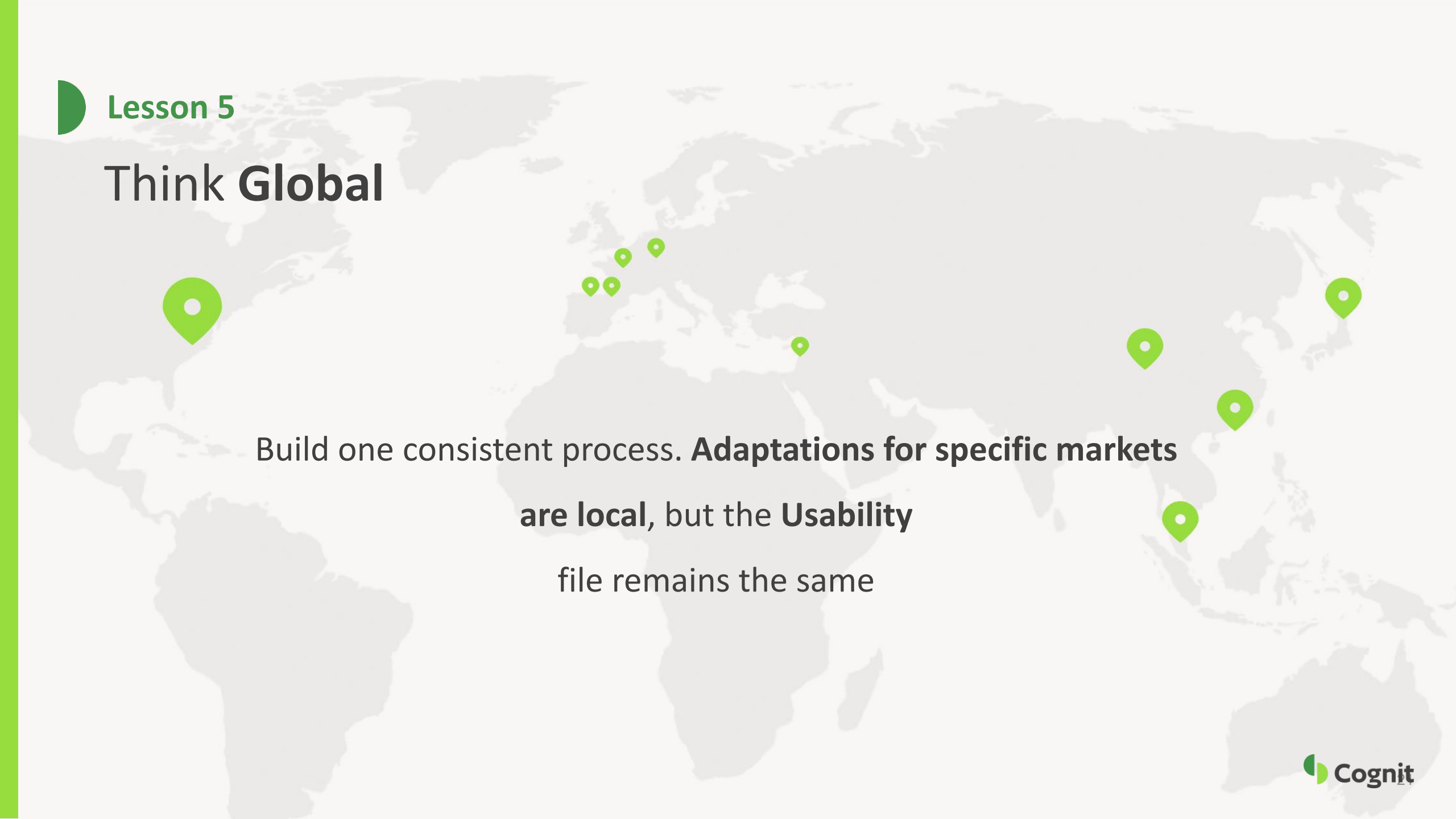
Based on URRRA,  
IFU and Formatives

Conducted by someone who was  
a part of the usability process

**Human behavior is unpredictable**

 Lesson 5

# Think **Global**

A light gray world map is shown in the background. Several green location pins are placed on the map, indicating various global locations: one in North America, several in Europe, one in the Middle East, and several in East Asia and Southeast Asia.

Build one consistent process. **Adaptations for specific markets are local**, but the **Usability** file remains the same

# Summary

## 5 Lessons

# for Effective Local Usability

**1. Don't skip expert assessment**

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**2. Talk to users any time you can**

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**3. Run Formatives early (local or remote)**

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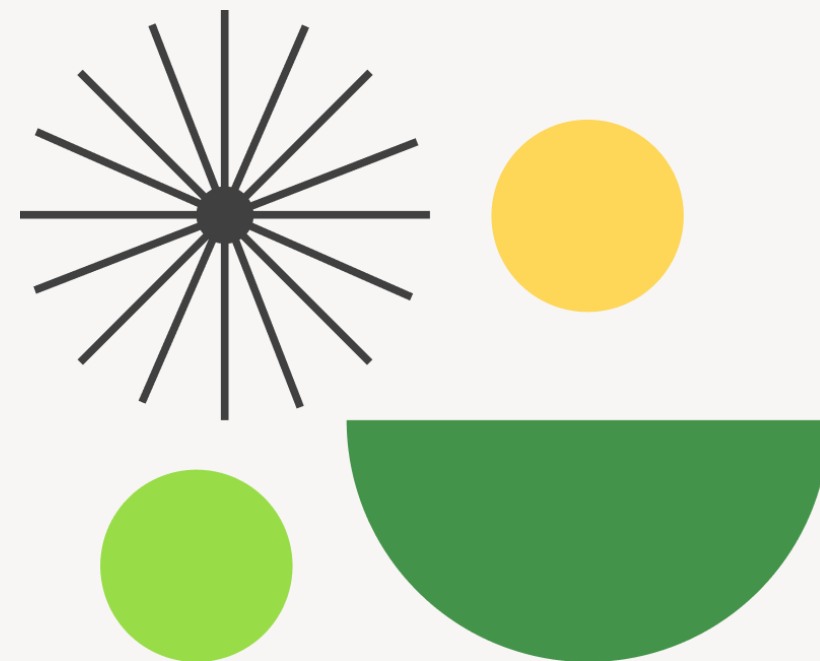
**4. Plan your summative carefully**

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**5. Think Global**

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**Thank you.**



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