

gerresheimer

# Facilitating Subcutaneous Self-Administration of Biopharmaceuticals for Enhanced Patient Experience

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## FDA Perspective on VOP

... only patients live with their medical conditions and make daily choices regarding their health care. Their voice and perspective are critical to understanding the impact of medical devices."

FDA (CDRH)



# Subcutaneous drug delivery of biologics



# Growing need for injection of biologics



In a CT with 200 patients switching to SC delivery of trastuzumab at home:

© Savings of more than \$2 million<sup>1</sup>

<sup>1</sup> Tetteh, E. K. et al. Health Econ. Rev. 4, 26 (2014).



# Switching IV to SC

## Benefits of SC self administration<sup>2</sup>



- Per body weight
- Injection time: 30-90 min
- Active HCP time: 67.6 min
- Drug preparation at hospital pharmacy 9.8 min

- Fixed dose
- Injection time: 1-5 min
- Active HCP time: 13.9 min
- No Drug preparation at hospital pharmacy



# Subcutaneous Self-administration

Reduces the burden on the health care sector

Generally preferred over IV administration as it:

- Enables **at-home injection**
- Improves **quality of life**
- Reduces **health care costs**<sup>3</sup>



<sup>3</sup> Dychter, S.S. et al. Journal of Infusion Nursing: May/June 2012 - Volume 35 - Issue 3 - p 154-160

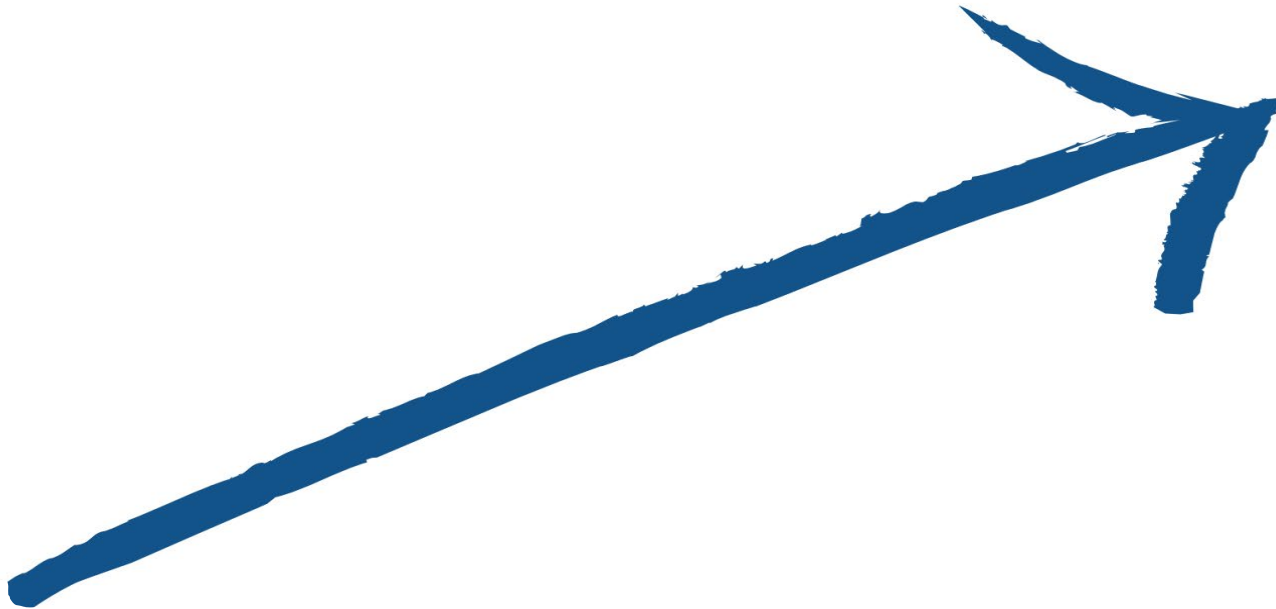
# SC Injection of Large Molecule Drugs



Current Solutions by Gerresheimer

# Device Development

Expectation...

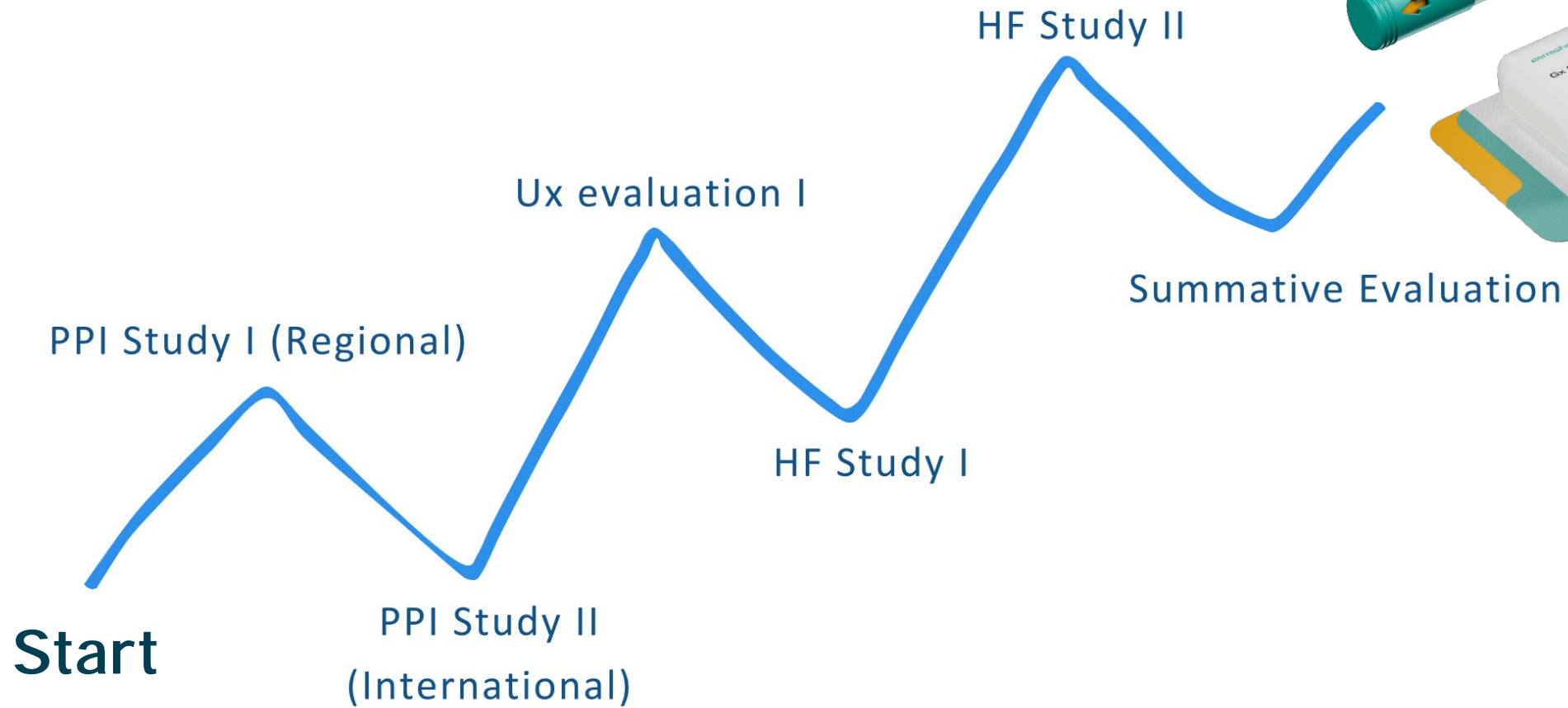


Start



# Device Development

Vs Reality...





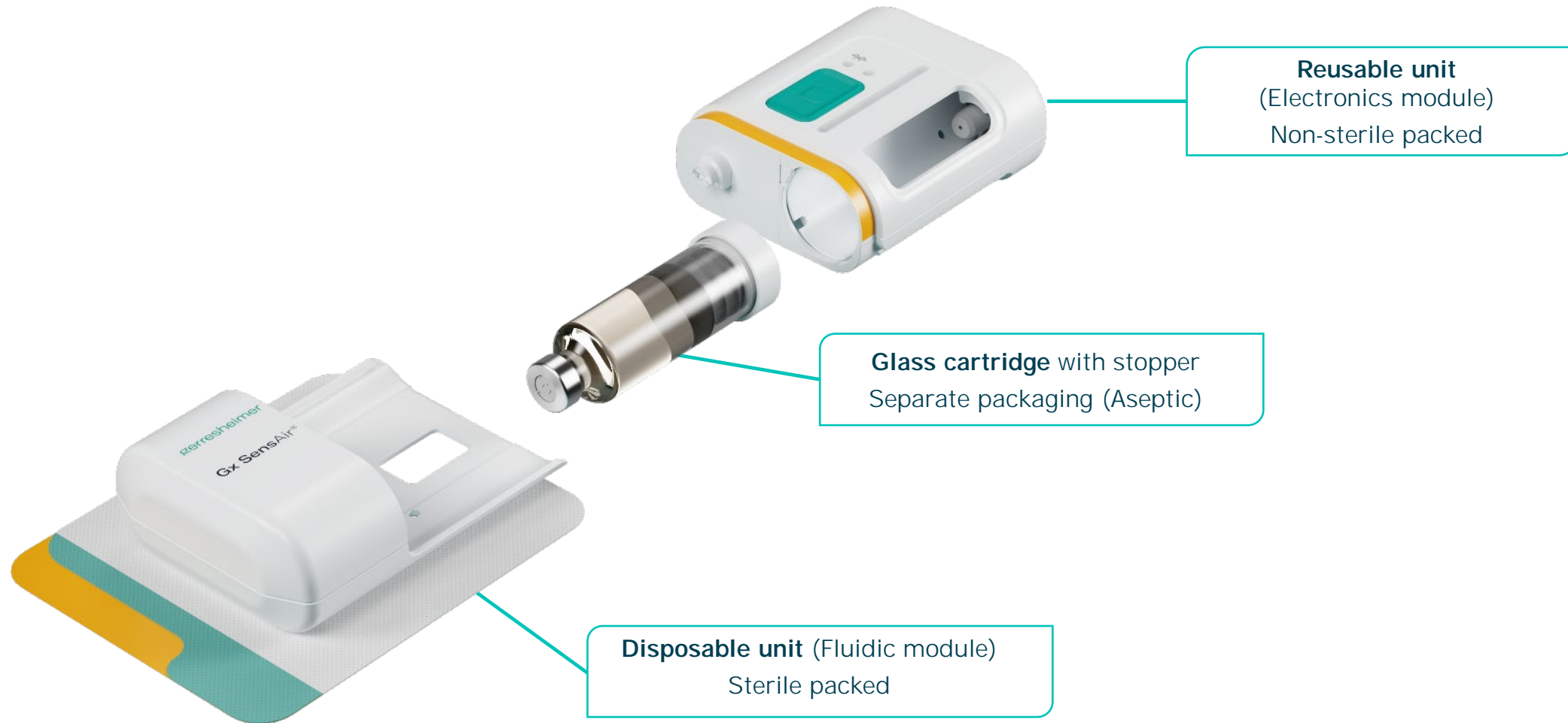
# Gx SensAir® On-body Injector

For SC self-administration of large volume biologics



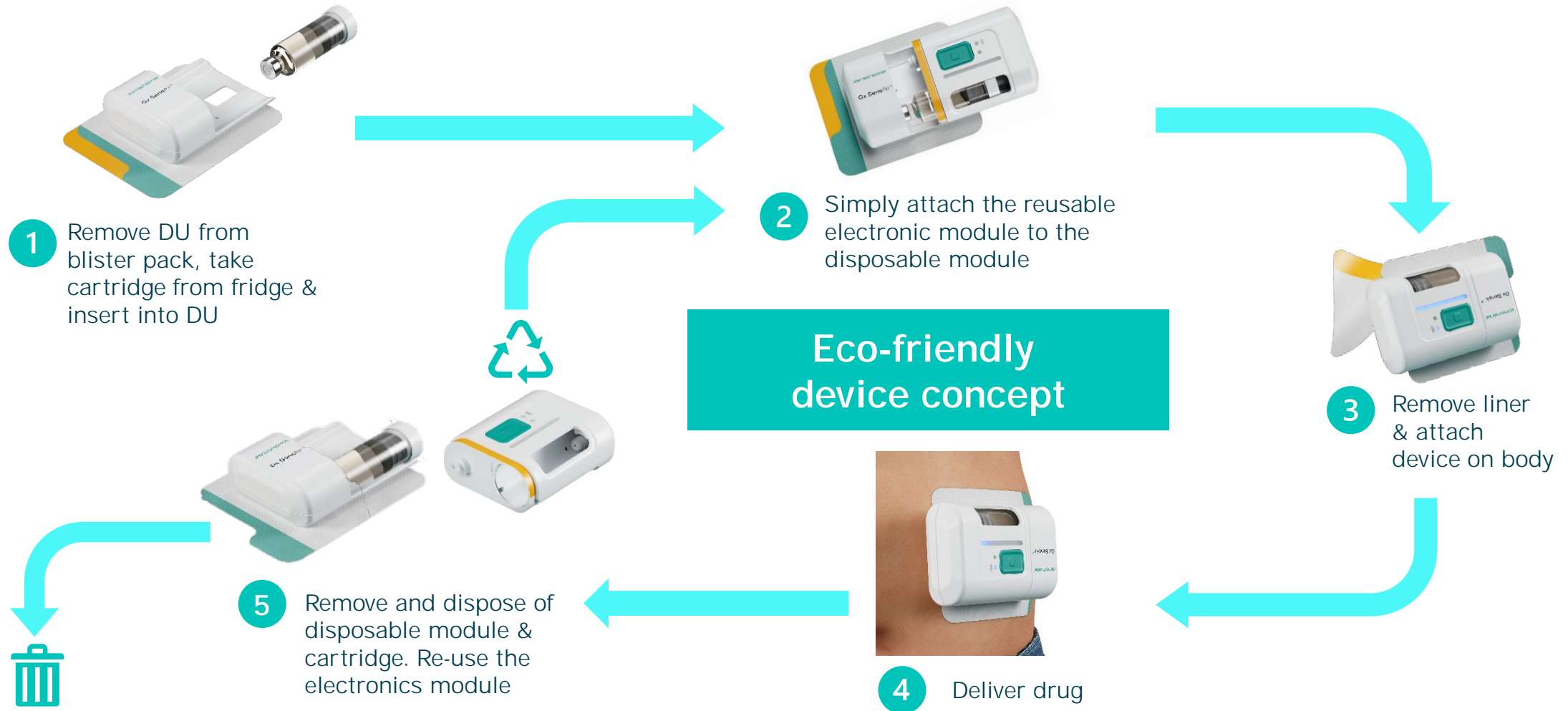
# SensAir® Device Platform

Re-usable and disposable concept



# Ecodesign Concept

Simple 5-step approach for home use



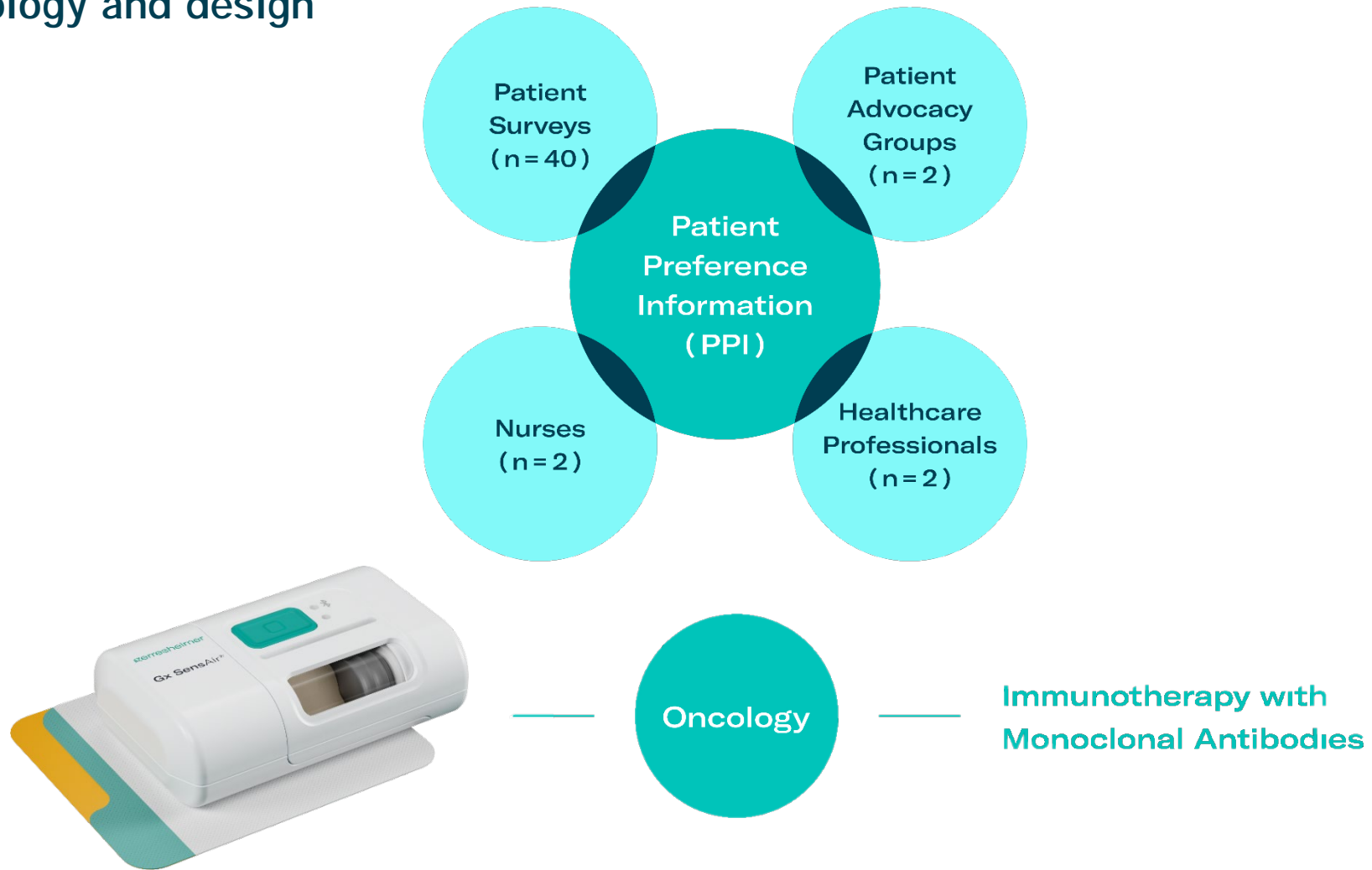


# Early-stage PPI study



# Research Method

## Study Methodology and design





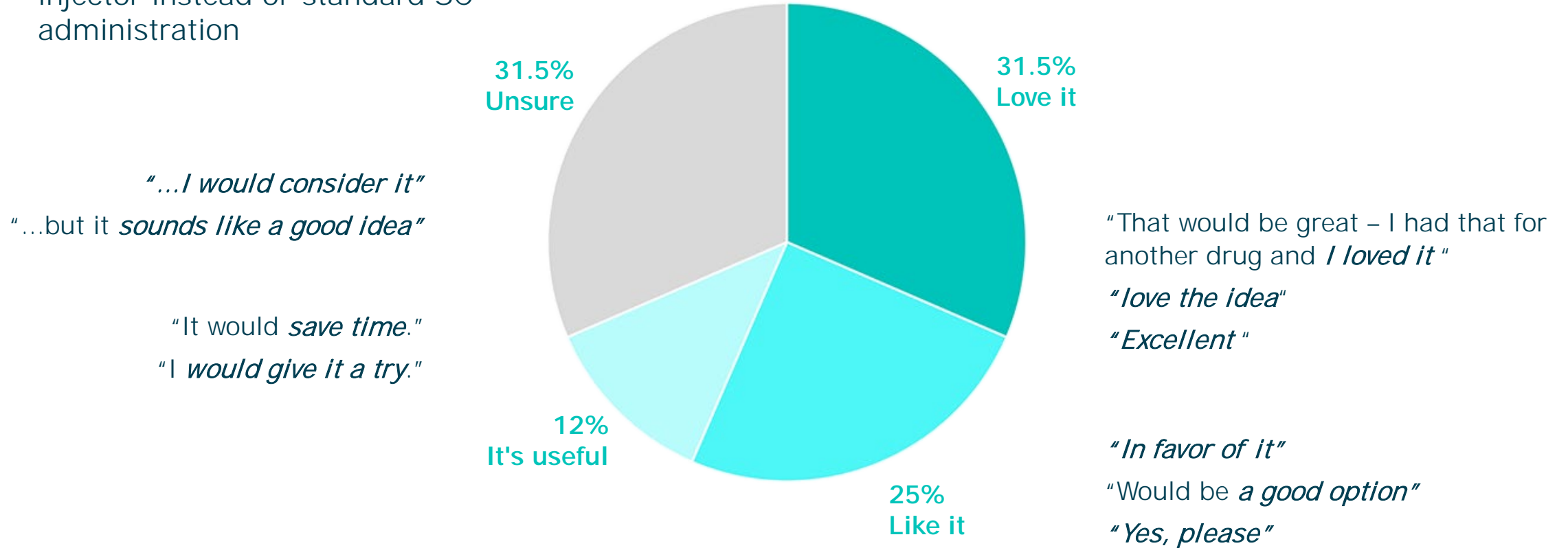
# Study results and insights



# Opinions of an On-body Injector

## Some Patient Testimonials

- ~68% have a positive opinion of an on-body injector instead of standard SC administration

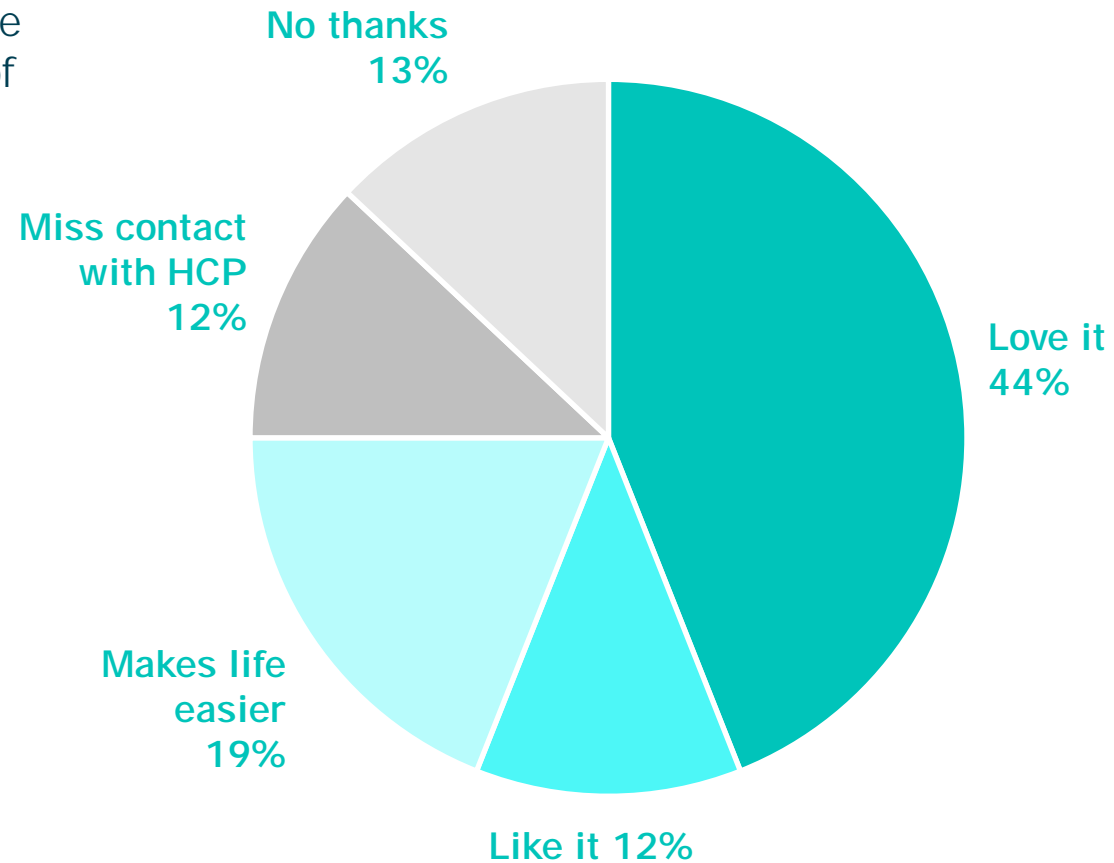




# Opinions of Home Use

## Some Patient Testimonials

- Over 70% of patients are in favour of the aspect of home use (n=32)



"That would be *awesome!*"  
"that would be *very convenient!*"  
"It will help *reduce travel time!*"

# HF & usability evaluation





# Useability Evaluation

## Assembly and simulated drug administration

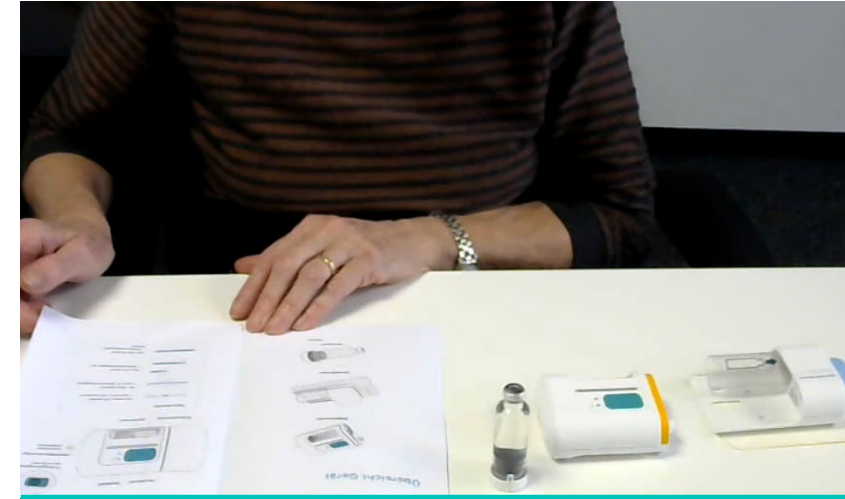
“It's good that there aren't too many buttons”

“Easy to use”

“Can be done before breakfast, half asleep”

“Technically very simple, even for elderly people”

“Lightweight and compact device”



### Participants

- n = 10 subjects
- 6 female, 4 male
- Age 21 – 72
- Device-naïve subjects

# Observed Use Errors & Design Solutions

Vital information for further design development

**Error:** Cartridge inserted into RU & not clicked in



**Error:** RU & DU not correctly assembled



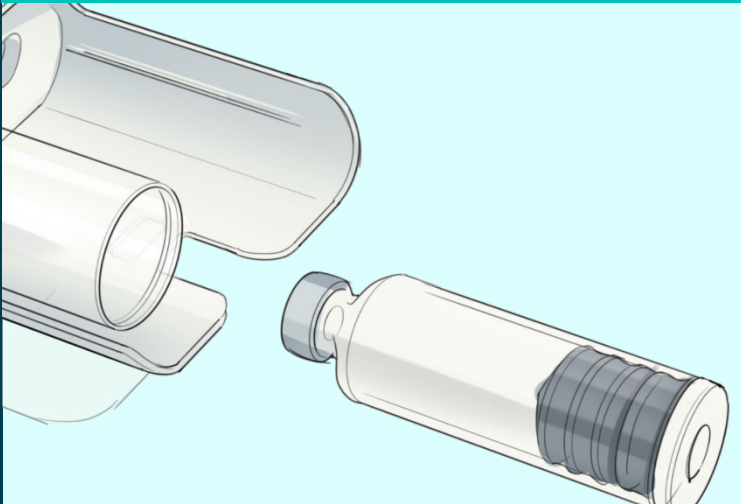
**Error:** Users found it difficult to track injection progress



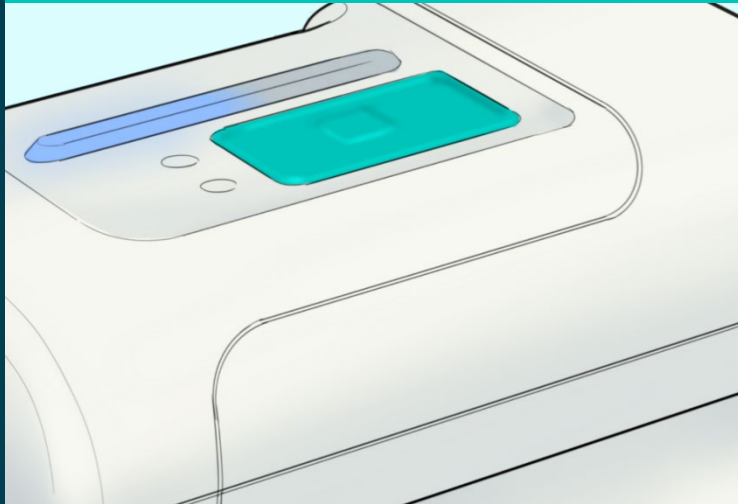
# Observed Use Errors & Design Solutions

Vital information for further design development

**Solution:** Design of cartridge rear cap changed so **no cartridge orientation is needed**



**Solution:** Design change of RU/DU interface geometries which **avoids misalignment**



**Solution:** Increased size of LED light guide & observation window for **improved user interface**







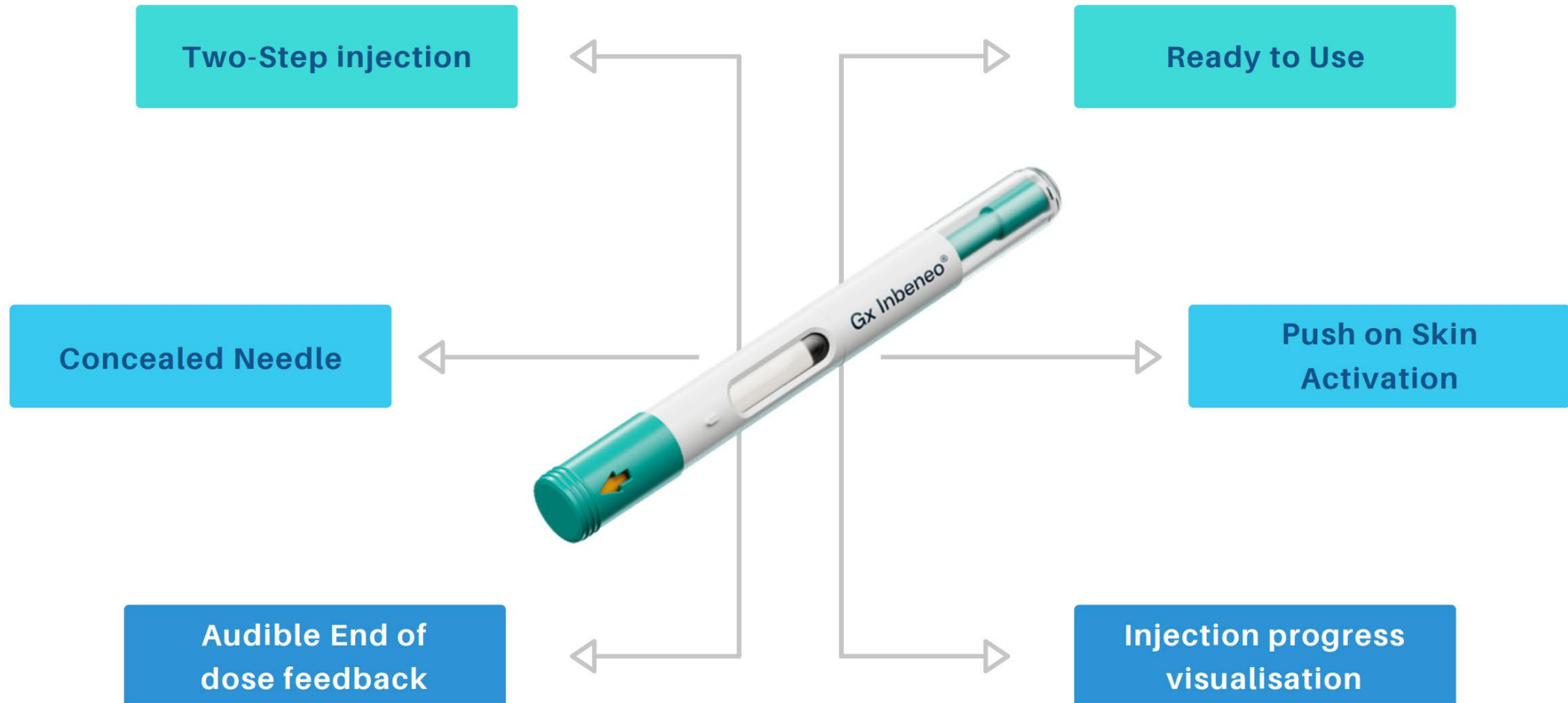
# Gx Inbeneo<sup>®</sup> Autoinjector

For SC self-administration of single-dose biologics

In cooperation with Midas Pharma

# Gx Inbeneo<sup>®</sup>


## Key Device Benefits



# Key Platform Characteristics

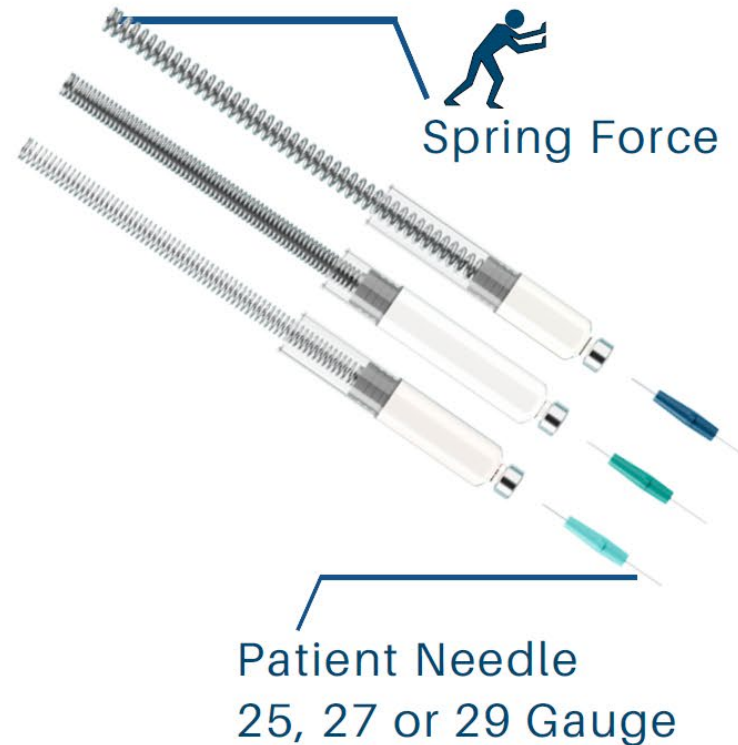
To Address Therapy and Patient Needs

## Customer Needs

  
Drug Viscosity  
up to 100 cP  
  
Up to 3 ml



## Platform Concept



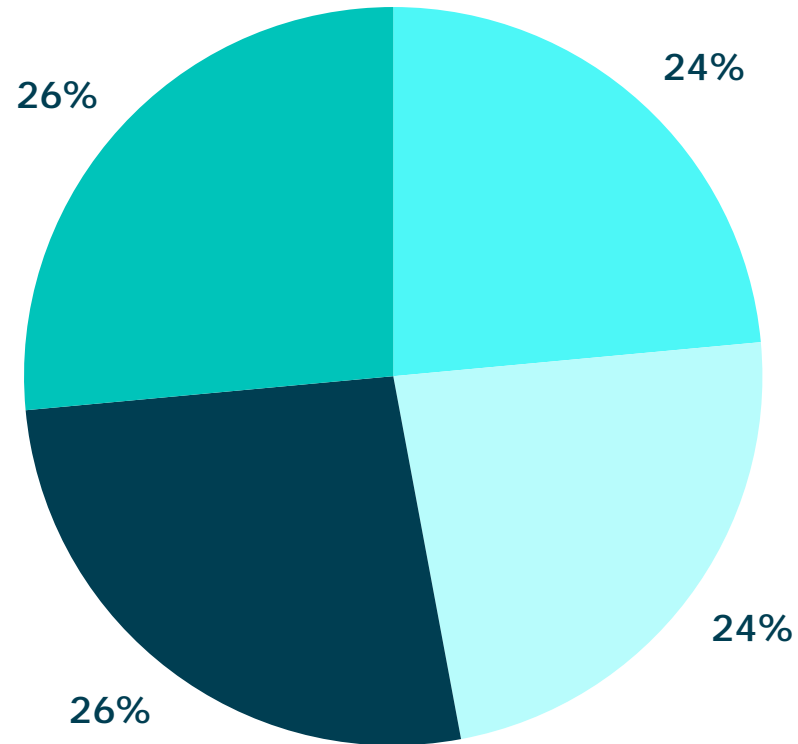
## Therapy Needs





# Gx Inbeneo® - Formative Study\*

## Study Population Breakdown



- Naive adults with mild/moderate dexterity
- Patients with experience injecting themselves with an AI/PFS
- Lay caregivers who are naive to using AI/PFS
- HCPs (4 med doctors, 5 nurses) who have experience using /have been trained to use an AI

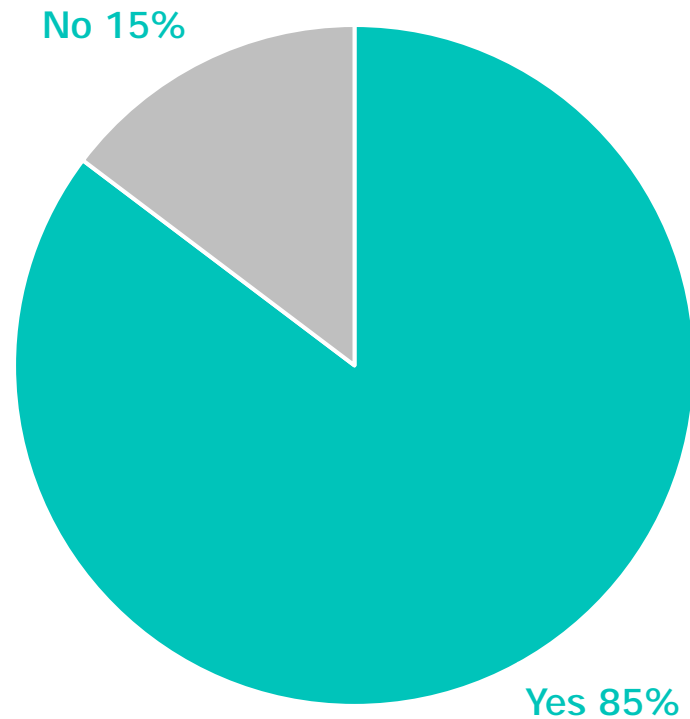


\* Study was performed by 3rd party

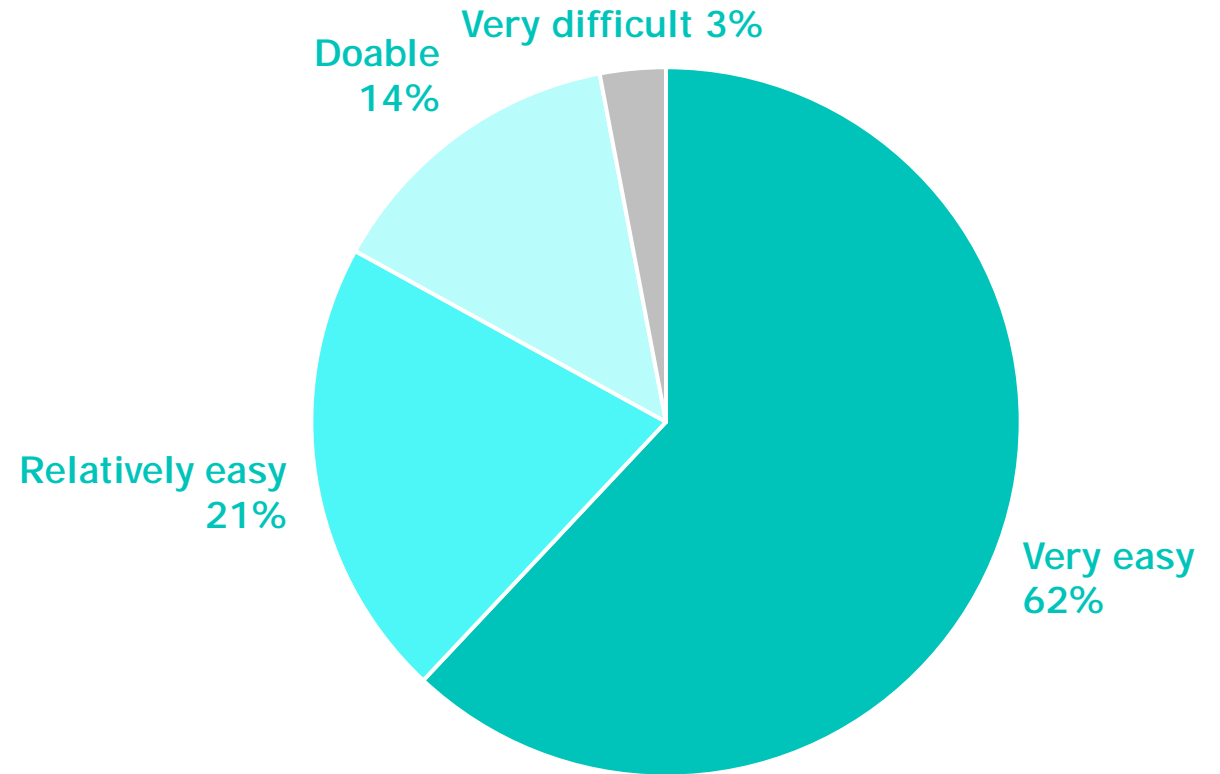
# Patient-centric Design

## Ease of Use

Did you monitor the injection progress?  
(n=34)



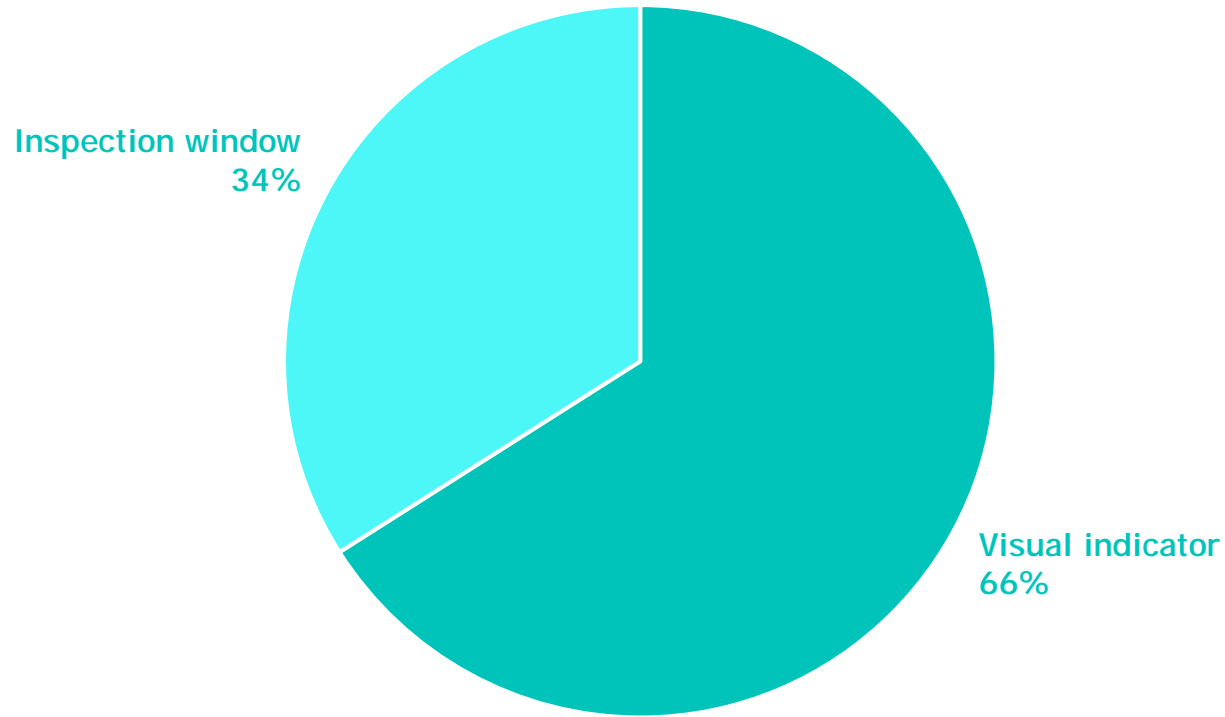
On a scale of 1 to 5, how easy was it for you to monitor injection progress? (n=29)



# Patient-centric Design

## User Preference

Which method did you use to monitor the injection progress? (n=29)





# Patient-centric Design

## Visual Indicator

- 75% gave a positive response

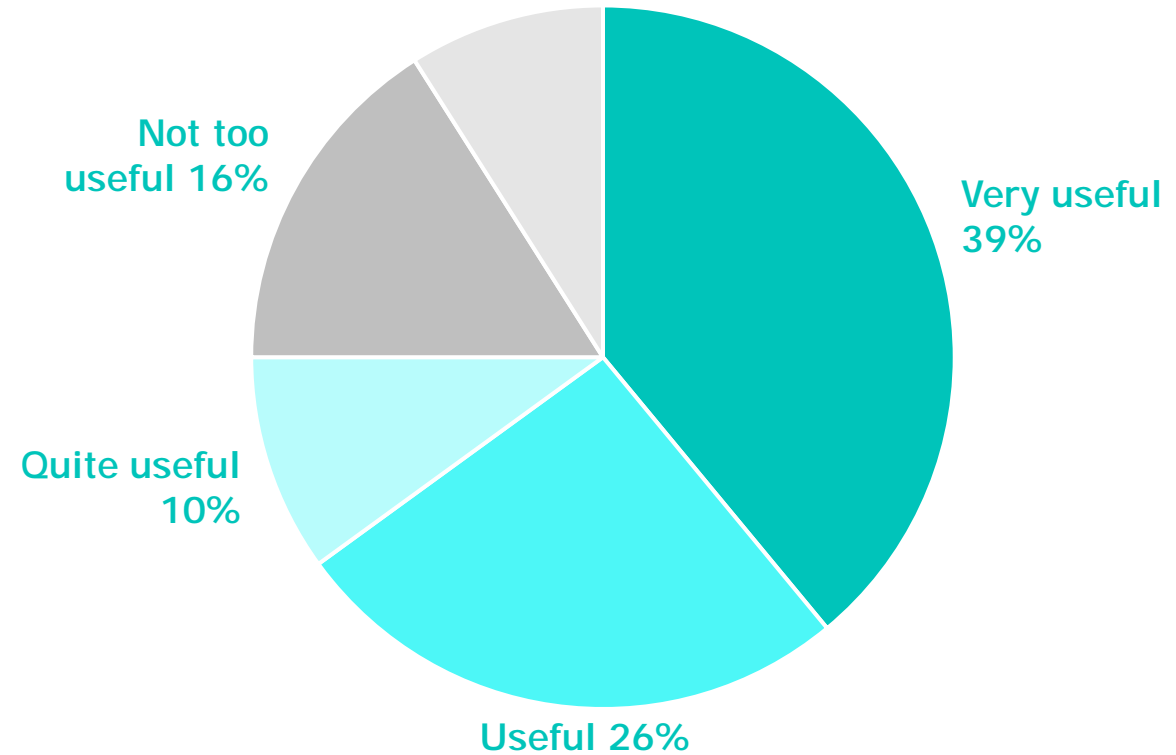


### Visual Indicator

- Partially transparent housing
- Enables tracking of the injection progress

## How useful was the visual indicator (n=34)

Not useful at all 9%



# In Summary

## Early-stage PPI and HF Studies help

- Understand the unmet user needs  
hence,
  - Optimizing device design
  - Avoiding foreseeable use errors
- à Save costs and reduce time to market

## Cancer patients ask for a route of administration which is

- Quick
- Less painful
- Offers more flexibility







Be independent



Wherever you are

Remote drug delivery



Stay connected



In the comfort of your home



gerresheimer

innovating for a better life