



Haselmeier: Injection Pens for Clinical Trials

Terence O'Hagan
General Manager
Haselmeier, Inc

“Working together to inspire your patients”

Fast Facts

- * Established in 1920
- * Self Injection Systems
- * Standard Platform devices
- * Customized Solutions
- * Proprietary Technology
- * Pharma Packaging
- * Connected Devices





Global Design & Manufacturing

- * Manual & Automated Assembly
- * Final Assembly & Drug Packaging
- * IP Development & Ownership
- * Factories
 - Germany
 - Czech Republic
 - India



A personalized injection device with...



- ... one or more preset doses in one device?
- ... flexible dose volume setting not available with fixed-dose injectors?
- ... a mechanism to prevent the setting of unintended doses?
- ... an easy, rapid and cost-effective customization of the preset doses?

Haselmeier has a new solution for you:

It takes **Just one.** The new



Clinical Trial Challenges

➤ Complex

Manufacturing

Ethical/Regulatory

Trial Protocols

Supplier Management

Scheduling

Reporting

Contracts & agreements





D-Flex Self Injection Device



- Flexibility
- Improved Patient Safety
- Clinic to Commercial Simplicity

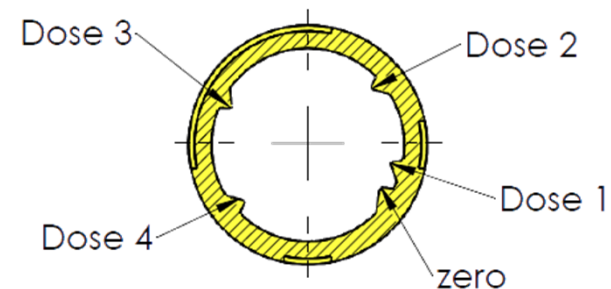


Flexibility



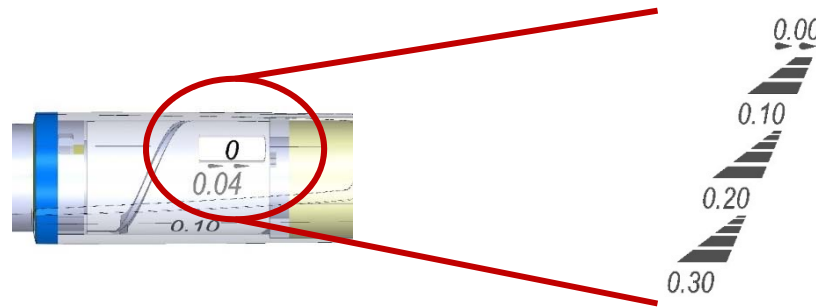
- In D-Flex the **Dose Selector** defines the intended doses
- The dose regimen can be selected upon assembly by choosing the appropriate **Dose Selector**!
- The **same** assembly **equipment** can be used for different variants
- 3 Versions: **Max Dose** of 0.1 ml, 0.3 ml, 0.6 ml

A truly **flexible** platform!



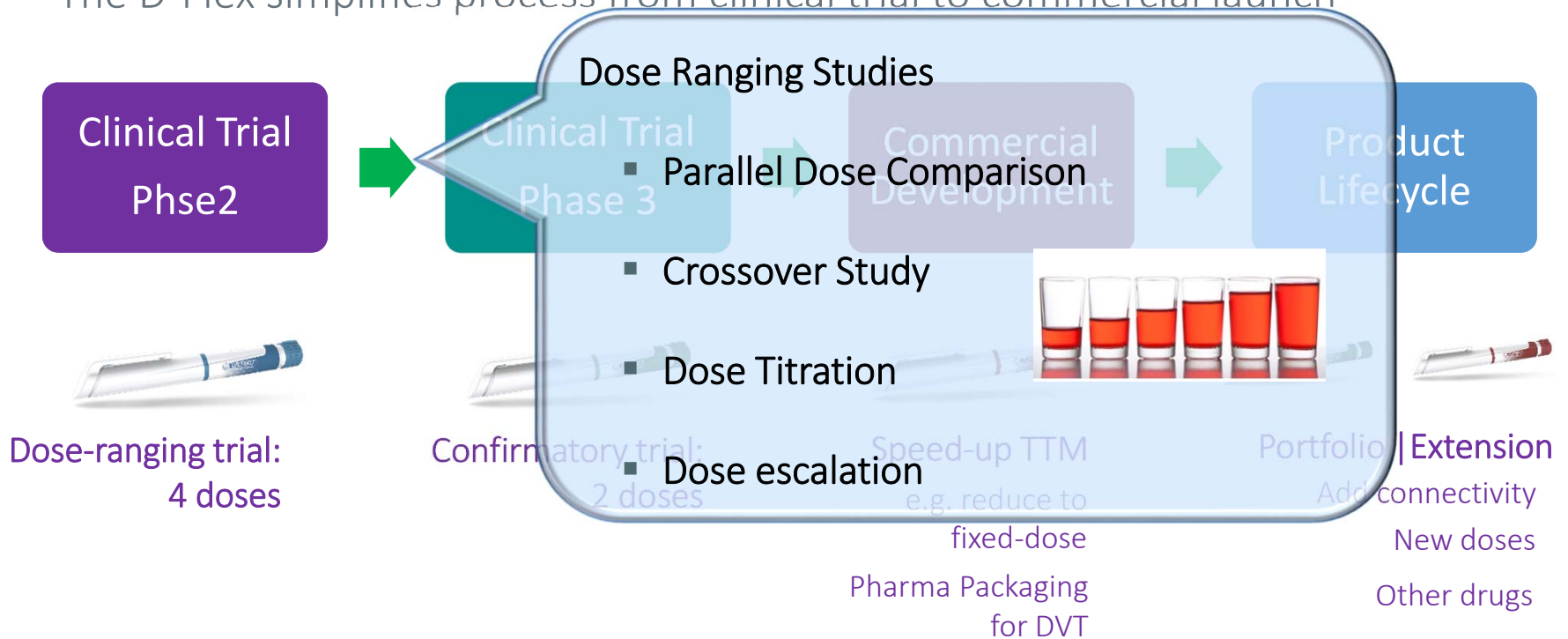
Patient Safety

Patients cannot set the dose in between the preset fixed doses



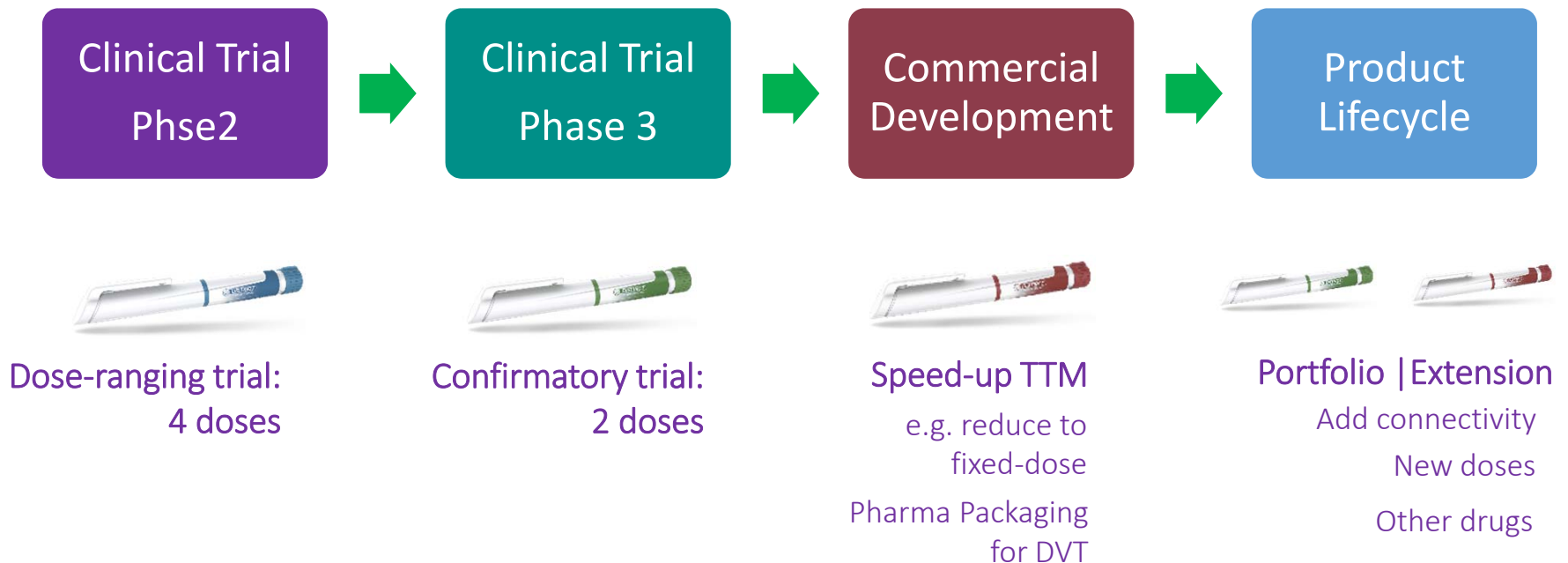
Clinic to Commercial Simplicity

The D-Flex simplifies process from clinical trial to commercial launch



Clinic to Commercial Simplicity

The D-Flex simplifies process from clinical trial to commercial launch



Benefits of For Clinical Trials

❖ Simplify Dosing Studies

Parallel Dose Comparison

Crossover Study

Dose Titration

Dose escalation

❖ Improve Patient Compliance

❖ Facilitate Low Cost Phase Transfers



 **D-Flex**
Product Range



Fixed Dose Pen



Automatic Injection w/
Speed Control



Connected Devices





A flexible and powerful platform.

D-Flex adds value to



Patients



A single device instead of several devices.

Preset doses instead of variable dose device

Patient cannot set other than the preset doses.

Pharma companies



Improved time-to-market and CAPEX

One platform for an easy customization of preset doses.

The same platform to cover clinical dose-ranging studies up to commercial product.¹³



Thank you!

Terence O'Hagan

Haselmeier Inc.
126 John Street, Suite 11
Lowell, MA 01852

+1 469.386.6950

t.ohagan@haselmeier.com

Haselmeier.com

Visit us at Booth X35

