



Comparative Use Human Factors (CUHF) Studies: An Alternative Approach

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Targeted Devices and Indications

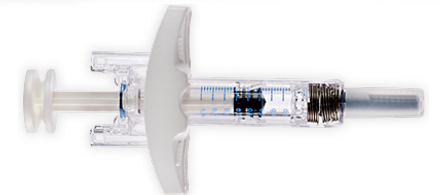
GOAL: Explore device crossover and will seek to challenge the mental models of experienced 4-step and 3-step AI users, PFS users and their ability to use a 2-step AI device safely and effectively without intervention by a healthcare provider (HCP) or training prior to use

	RLD/Reference Device	Indication
3-Step AI		<ul style="list-style-type: none">• Migraines• Arthritis• Lowers LDL
4-Step AI 1		<ul style="list-style-type: none">• Migraines, Cluster headaches• Type 2 diabetes• Psoriasis
4-Step AI 2		<ul style="list-style-type: none">• Arthritis, Crohn's, Psoriasis, UC
PFS with NSD		<ul style="list-style-type: none">• Asthma• Nasal Polyps, Eczema, Dermatitis• Crohn's, Psoriasis, Colitis

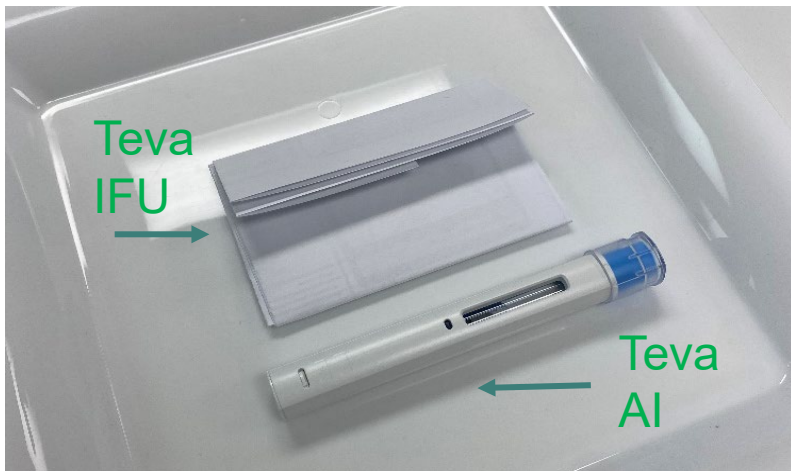
Study Structure

GOAL: Explore device crossover and will seek to challenge the mental models of experienced 4-step and 3-step AI users and their ability to use a 2 step AI device safely and effectively without intervention by a healthcare provider (HCP) or training prior to use

Study Parameters	Description
Intended User Group, Sample Size	<ol style="list-style-type: none">1. Self-administration, 18+ yrs old, Reference Product (RP) experienced2. Self-administration, 12-18 yrs old, Reference Product (RP) experienced
Study Design	<ul style="list-style-type: none">• User's product was substituted at the pharmacy.• Deliver the dose using only the provided IFU.• Threshold Analysis informed design differences for study observation.• URRRA informed critical task and helped reduce use risks as low as possible• Root Cause Investigation informed sources of <u>negative transfer</u>.
Data Analysis	<ul style="list-style-type: none">• Users were NOT asked to use the reference product• <u>Qualitative data</u> will be collected to assess use errors and their root causes• "Use Error Rates" will not be compared• Benefit/risk is compared with reference product for acceptability



Simulated Use Human Factors Studies



Task	Step	Impact to...
1. Preparation	Visually inspect the AI for physical damages, appropriate medication color, and expiration date.	Safety
	Uncap the Pen	Efficacy
	Place the Pen against the skin	Efficacy
2. Inject	Press and hold down the Pen against the skin; you will hear a click.	Efficacy
	Continue to hold down the Pen until you hear a second click.	Efficacy
3. Dispose	Dispose of the Pen in a sharps bin.	Safety

Scenes from the Study

A) User reviews the IFU before use.



B) User simulate injection into pad.



C) User compares the devices after use.



Successful Case Study

Scenario: Users' reference product was replaced with a 2-step AI and a mock IFU



Notable Observations:

- 3-step AI:** Users that identified as rheumatoid arthritis patients noted that it is easier to use an AI without a button due to dexterity requirements for button activation
- 4-step AI 1:** A viscosity difference between RLD DP and glycerol mimic contributed to an observation of negative transfer for two (2) users; users expected the gx to inject in the same amount of time as their RLD.
- 4-step AI 2:** 11/20 users preferred not having a button; five stated that the button's presence or absence did not impact the way they used the device; two preferred having a button
- PFS with NSS:** Two (2) use errors were observed where users lifted too quickly, causing an incomplete dose. One accidentally activated and immediately realized it, a second did not know that pressure needed to be maintained throughout injection.