An inclusive approach to the development of a platform medical device when the intended therapy area is not yet known

Introduction

Regulatory Human Factors (HF) guidance and international best practice advise safe and effective use of a medical device must be tested on the intended users.
Recruiting study participants that are truly representative of the intended users is especially challenging when the intended therapy area is not yet known in the case of platform development. Further, prospective customers will understandably seek assurance that their intended user has been adequately considered throughout the design process and iterative user testing.

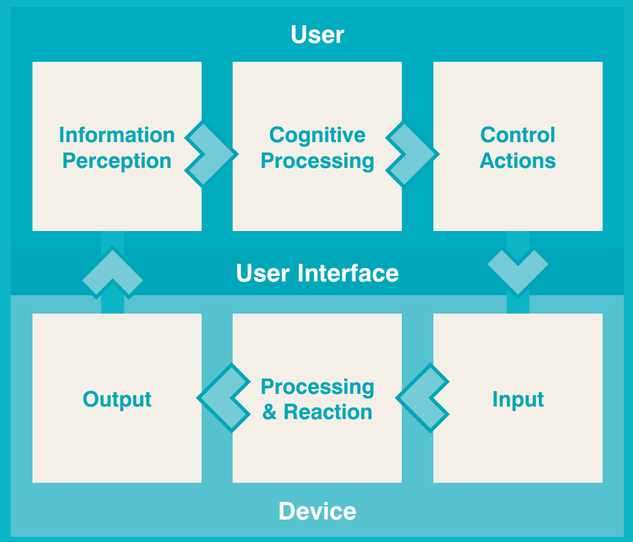
This HF Sampling Strategy was established to inform user centered design decisions and give confidence to future business partners that the needs of their intended users been covered during early stage platform development.

Rationale **The strategy adopts a practical, yet robust framework based upon 7 user groups.**

A. Reflect intended user capabilities

The strategy adopts the Perception, Cognition, Action (PCA) framework in sample recruitment. PCA is a method of understanding root cause of user error in user interface design and was formally recommended by FDA in their HF guidance[1].

Targeting users that are impaired in each of these functions, ensures that each facet of user interaction is covered insofar as practicable with measured sample sizes.



Device User Interface in Operational Context (adapted from Redmill and Rajan, 1997)

B. Reflect specific user types

FDA states that caregivers, healthcare professionals, younger users and adults should be considered as distinct user types[1]. These categories have been included as four groups in the sampling plan.

The HF Sampling Strategy

This sampling strategy identified the following seven user groups:

Group	Description	Minimum sample size	
		Small study	Large study
Adults	Adult aged 18 years plus; no upper age limit	3	7
Juveniles	Persons aged between 8 and 17 years – with representative age spread	2	7
Caregivers	Lay caregivers who help another person to administer their injected medication	2	7
HCPs	HCPs who administer injected medication to patients (e.g. nurse, pharmacist, GP)	2	7
Perceptual ability	Persons with visual impairment and auditory impairment. Other senses targeted where especially relevant – e.g. skin sensitivity	2	7
Cognitive ability	Persons with a range of moderate cognitive impairment (e.g. ADHD, autism, dyslexia, learning disability)	2	7
Action ability	Persons with a range of physical (upper limb) impairment (e.g. RA, Parkinson's, MS). Group size modified to recruit biomechanical impairment versus neurological impairment.	2	7
	Total	15	49

Further adjustments can be made to sample size to incorporate a representative range of secondary characteristics such as hand dominance, gender, and ethnicity.
For commercial purposes, the size of each group can be adjusted in line with projected needs of the business, seeking to recruit (for example), a minimum representation of users with a specific diagnosis and or comorbidity. This is especially useful where market trends and insights are available.

Conclusion

As long as the intended therapy area is not yet defined, the medical device developer must assume a hugely diverse target population. This HF sampling strategy provides a framework for effective user evaluation planning in the absence of user data, to ensure best practice standards are applied, and the needs of prospective customers can be met.

References: 1. FDA. Applying Human Factors and Usability Engineering to Medical Devices. 3 February 2016.

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Parenteral Drug Association (PDA) Universe of Prefilled Syringes and Injection Devices conference, Oct. 2020

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