Human factors approach to platform device development

Finola Austin[1] & Miranda Newbery[2]

[1]Owen Mumford Ltd, [2]Inspired Usability

SUMMARY

Medical device manufacturers may enjoy some freedom to operate during platform device development. However, the absence of a specified drug means that there is a lack of predetermined limits and guidance with regards to various human factors that pertain to intended use, including user characteristics. This paper presents a best practice approach adopted by one manufacturer that aligns with the regulatory process and helps to anticipate the needs of a diverse group of potential end users. An inclusive approach to sampling both intended users and device variants is described alongside the resulting design decisions.

KEYWORDS

Medical device design

Background

Owen Mumford sought to introduce a 2-step autoinjector platform called Aidaptus® that has a similar mode of operation to several on market predicates. The autoinjector can house a range of different designs of 1ml or 2.25ml pre-filled syringes, with different fill volumes (0.3 to 2.0ml) and drug viscosities of ~20cP to deliver a drug formulation within a 3 to 10 seconds delivery time. As a platform product, it is intended that the product be suitable for use as a combination product by a wide range of intended users, but these are not yet defined and subject to onboarding of customers. Some of the initial design parameters are commercially driven. A human factors programme that aligns with international standards is planned and implemented to ensure that the needs of the unknown target audience are defined and supported throughout the design and development process. This also serves to manage use related risk and provide assurance to prospective customers about the product's suitability for their intended use case.

Human Factors Process

The human factors process dovetails with the manufacturer's design process and is aligned to medical device directives, international and best practice standards (see Figure 1).

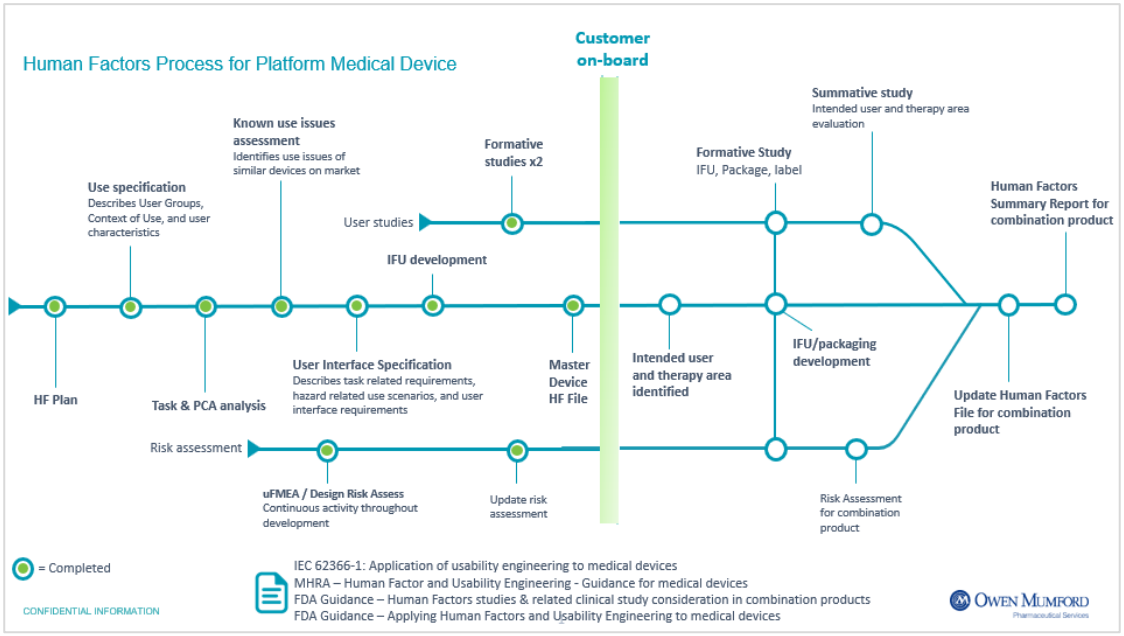

Figure 1: Human Factors Integration Process

Whilst the manufacturer assumes responsibility for the device, it will ultimately become part of a combination product, and the regulatory submission will fall to the pharma owner. As neither the regulatory pathway nor territory is known at that stage, the human factors process adopted a 'new product' approach, helping to mitigate the late identification of use related difficulties and risk for the intended user. The process uses a blend of activities from regulatory sources to ensure that there are no gaps in the human factors data that is generated; terms such as 'critical tasks' from the FDA guidance (FDA 2016; FDA 2018) are used, whilst the human factors file also includes a 'user interface specification' based on IEC 62366-1 (IEC 62366-1, 2020).

The Use Specification is drafted based on a series of assumptions about the most likely target audience and intended use scenarios. These are informed by:

- an understanding of general practice in the use of autoinjectors such as contexts of use and ambient conditions.
- a working knowledge of the autoinjector market, including existing and predicted therapy areas, and known end user needs related to features such as portability & size.

A broad use case was established to maximise the potential opportunity – with intended user age starting at 8[1], and a high-level summary of the range of intended user symptoms and associated impairments. Emergency use/lifesaving drug is excluded.

The preliminary analysis is designed to inform early design decisions and lay the foundation for any proposed user testing and is underpinned by use related risk analysis. A task analysis is carried out and used to identify which aspects of the user interface have potential to influence intended use at each use step. This not only supports the use related risk assessment, but it drives the scope and content of subsequent formative user testing. A set of generic use related hazards are defined with

[1] A child's psychomotor skills develop with age. A 2010 study of children injecting diabetes medication (Ekim, 2010) found that the success rate for self-injection developed rapidly over a child's age range, from as low as 16.7% in children aged 7-9 years up to 100% in those aged 13-18 years. Given the low success rate for younger children, and the high likelihood that parents would administer their injection, the lower age limit for the Juvenile group can be taken to be the midpoint age in the 2010 study, 8 years.

worst case assumptions for drug related aspects of the device such as drug contact and dosing errors. For completeness, all tasks are assigned 'critical' status, since there is no material advantage in not doing so; all device interactions would be user tested to ensure realistic use scenarios, and to generate data that can be available to prospective customers.

As the technical possibilities for the platform device is established, the breadth of design attributes and variants available to the user is confirmed. User interface specifications are again steered towards inclusivity, in the knowledge that they can be refined as more is understood about possible device constraints, and user capabilities and limitations.

IFU development

A generic instruction for use leaflet is drafted to support user testing. Since the primary focus is device usability at this stage, the size, format, layout and content were designed to get the best possible task outcomes. The manufacturer explored different images and text to communicate use steps effectively, guided by on market samples, and learning from concurrent in-house user testing.

The drafts did not include any level of customisation, branding nor drug related content that one might expect in a patient information leaflet.

Formative user testing

Sampling representative users: In the absence of a defined therapy area, the recruitment strategy used physical and sensory impairment, age, and role (e.g. patient, healthcare professional and lay caregiver) to select and screen participants resulting in 7 distinct user groups:

User groups

1. Healthcare Professionals

Patients/Lay Caregivers:

2. Children (aged 8-15)
3. Older adults (aged 66+)
4. Vision impaired
5. Hearing impaired
6. Musculoskeletal
7. Neurological

The sample was also screened for representation of handedness, gender, and level of injection naivety versus type of injection device experience to ensure a spread of relevant characteristics across each user group. The Cochin Hand Function Scale (Duruöz M.T. et al., 1996) was used to help select participants with a range of impairments that have potential to influence their interaction with the device interface. In addition to general demographic data, the study collected anthropometric measurements, and participants conducted dexterity tests to support the subsequent analysis of user task performance.

Experimental design

The platform device now had a range of attributes with variable potential to influence safe and effective use. The study was designed and executed by Inspired Usability to verify the efficacy of each solution to support design decision making; the range of study variants are presented in Figure 2, and the study design is summarised in Table 1.

Figure 2 - Aidaptus variants used in Formative Study 1

Table 1: Summary of device attributes and formative study 1 objectives

Device attribute	Attribute description	No. of variants	Study objective	Testing method
Syringe size	1ml & 2.25ml	2	The 1ml syringe is further away from the device outer surface than the 2.25ml – how does that affect visibility and user interaction?	Participants were assigned a 1 or 2.25ml variant for simulated use according to study stratification to ensure representation of each user group for each design.
Window size	The device variants include 5 different window sizes. The trial focused on 3 representative window sizes; Small 12mm x 8mm, Medium 25mm x 8mm, Large 39mm x 8mm	3	Window size would be driven by fill volume. Does this affect the user and their ability to inspect the drug and understand injection progress?	Participants were assigned different fill volumes for simulated use according to study stratification to ensure representation of each user group for each design. Drug inspection was also evaluated by comparing participants' ability to see different colour liquid in different prototypes
Window design	The device body concepts were developed – a moulded window, and a window that is created by an aperture in the label.	2	Does window design affect drug/plunger visibility and general handling?	Drug inspection was evaluated by comparing participants' ability to see different colour liquid in different prototypes

Device attribute	Attribute description	No. of variants	Study objective	Testing method
Injection speed	Injection speed is driven by drug volume and viscosity. Three nominal injection speeds of 3, 6, and 10 seconds were selected for evaluation	3	What, if any, effect on intended use and hold times?	Participants were assigned different fill volumes and injections speeds for simulated use according to study stratification to ensure representation of each user group for each design.
Audible feedback	Timing of audible feedback correlates with start and end of injection and therefore varied according to injection speed.	2	Establish the efficacy of audible feedback	Participants were asked specific questions related to their ability to hear and comprehend the audible feedback.
Cap design	A single concept was preferred. Several cap shapes were evaluated using a rig to simulate 25 and 30N pull force.	4	How easy or difficult is it to remove the range of cap variants. What is the impact of cap design on pull force ability.	A bespoke rig was created to evaluate different cap designs and different removal forces.
Plunger/ Window	Plunger inspection in different window designs and sizes	6	Establish whether participant is able to identify a used vs unused device	Participant inspects window in a range of devices that are used/not used to see if device is suitable for use
IFU	Instructions for use	1	Establish whether the device instructions are understood.	Observe use of IFU during simulated use. Further simulated use when directed to read IFU and comment on clarity. Knowledge based questions.

Two formative studies were conducted. The first study sample was controlled along with careful experimental design to ensure that a minimum of 5 participants in each user group e.g. older adult, or people with musculoskeletal impairment were exposed to each device attribute. The study sample was stratified and rotated across different configurations to ensure that each variant was evaluated by all user types represented in the sample. A similar approach was taken on a second study later in the development process as the device development was refined and updates to the user interface were made – notably the instructions for use. The sample size was significantly smaller but the group representation was maintained to optimise the study coverage. User testing was reduced where no further data was required.

Formative study testing was scheduled to ensure there was a sufficient level of fidelity in the prototypes to generate reliable and useful data. A generic instruction for use was created to support intended use. The study was conducted to the level described in international standards so that use related errors and issues could be quickly identified and mitigated where possible.

Analysis and Reporting

Formative study data was used to inform ongoing device development and continuing risk profiling and management.

The study outcomes showed with confidence that user task outcomes were not negatively affected by any single device design permutation. Experimental design coupled with study sampling means that the findings could be generalised to a wide range of intended therapy areas. None of the study findings lead to a requirement to change or limit the design of the device user interface and the range of variants.

Some changes were made to the instructions for use between studies – notably the steps related to the injection step and hold time. Whilst some improvements were achieved, it is known that users are not inclined to adhere to the correct hold time. No correlation between injection duration and hold time was identified. Some minor edits to instruction content have since been incorporated, but it is considered that there is no real advantage to the manufacturer to pursue this further.

Device Human Factors File

The human factors activities described above have been summarised in a device human factors file for Aidaptus®. It helps to establish its suitability for a wide range of applications and establishes functional limits. It provides assurance that the device design and development has been subject to a comprehensive human factors programme, in spite of the absence of a specified drug and intended use case.

The sampling technique has provided commercial benefits; typically pharma clients are keen to understand how their own target user group were represented in user studies during development. Clearly it has not always been possible to include every potential therapy area, but the inclusion of a wide range of sensory and physical impairments has meant that data is available for most applications. It is anticipated that the study variants have covered most foreseeable drug formulations, without evaluating extreme scenarios.

The author does not suggest that the work that has been completed negates the need for further human factors work once a pharma partner is on board. The specification of a drug will allow the use related risk assessment for the combination product to consider new information including but not limited to the specified user, characteristics of the drug, the injection, treatment regime, methods of distribution, training, context of use, and labeling for example.

Conclusion

The methods detailed above are aligned to international standards but go above and beyond that required of the device manufacturer to ensure the best possible outcomes for a wide and unspecified range of intended users. It serves to:

- identify the use related limits associated with what is technically possible in the device variants and
- minimise the gap between the device human factors file and the combination product human factors file.

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