Case study

Human factors testing – impact of device modifications

Case Study - Scenario

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The company commissioned a human factors test to evaluate the performance of the modification based on a threshold of the number of ‘correct’ injections performed as a result of the modification.

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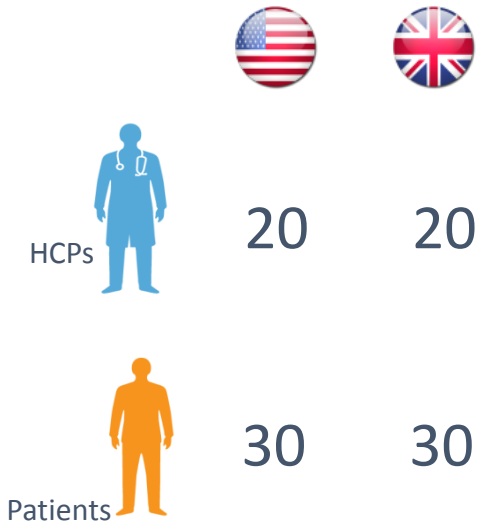


Case Study - Methodology

A formative quantitative study was conducted
45 minute face-to-face interviews

Two devices were tested – Current (Device A) and New (Device B). Respondents were asked to perform an injection with each device into a cushion

Order of devices rotated between interviews

The moderator made observations as respondent carried out the injection before asking rating & performance-related questions regarding the devices and the IFU

HCPs	20	20
Patients	30	30

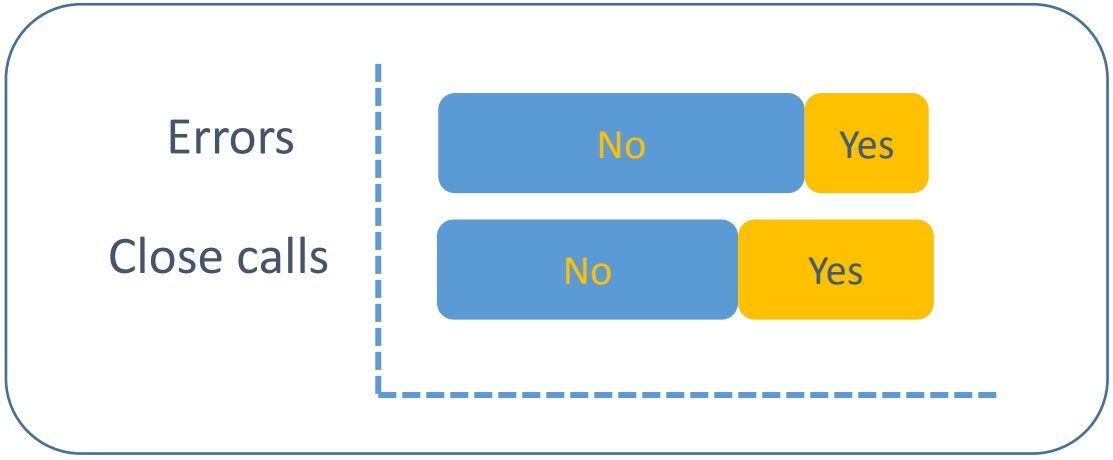
Case Study – Client Value

Reliable, robust data that was used to form part of the FDA submission

Had the success criteria not been met it would have been a useful ‘early warning sign’ for the client to go back and further develop the prototype but, in this case, the findings were very positive

The ability to conduct a ‘human factors’ test on their devices in lieu of conducting clinical trials costs less and takes less time

Case Study – Highlights from example outputs

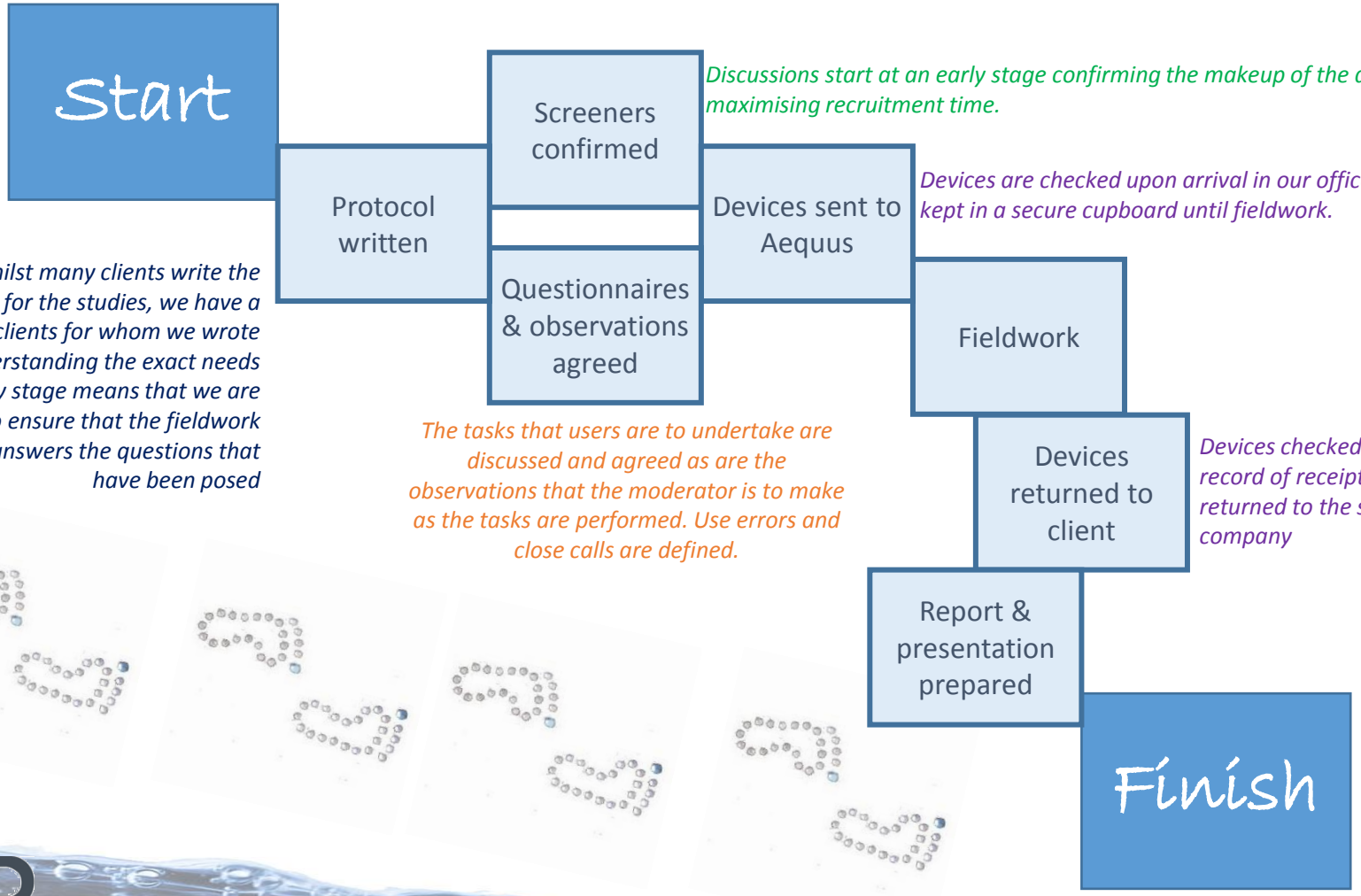


"Larger - clearer - broken down into different steps. Easier to follow, bigger print" UK Carer

"Nice clear drawings on the leaflet. You didn't need to actually read" UK HCP

Significantly higher proportion reported they had difficulties when using the current device compared to the new device

Typical project process



Important factors in a device handling study

Brief / protocol	We have experience of working with research protocols for regulatory approval (FDA)
Methodology	Structured or semi-structured questionnaire Qualitative or open-ended elements for exploration/rationale elicitation
Data collection	Pilots in a central location followed by field interviews
Respondent type	Patients (including children and adults), family members / carers, Practice and Specialist Nurses, Specialists, GPs/PCPs, Technicians, Pharmacists
Resources	In-house expertise / fully trained partner agencies Strict quality control measures to track each and every device throughout the project's life
Deliverables	Key results presentation, sub analysis presentation, statistical analysis summary and in-depth Word report if required for submission purposes

Key personnel

- Basil Feilding, Insight Manager, leads our projects related to devices:
- Basil recently undertook the AAMI ‘Human Factors for Medical Devices’ course and as such is fully aware of the necessary processes required for FDA approval of new devices
  - Basil also participates on an ongoing basis in AAMI training webinars
- The project team is chosen dependent on the therapy area and objectives of the study but will always include another Director