INTRODUCTION
A pre-market tobacco application in the USA requires information to support the appropriateness of a new product for protection of public health. Important elements of this are the risks and benefits of introducing a new product to the population as a whole. To develop tools to collect such data, a suite of questionnaires of subjective measures of individuals’ motivations for, and use of, tobacco and nicotine was collated from the published literature.

OBJECTIVES
• To test subject burden and understanding of a selection of questionnaires and to assess their effectiveness for use in pre-market assessment.
• To determine changes in responses following a short period of electronic cigarette (e-cig) use.

STUDY PRODUCT
Vype estick (blended tobacco flavour, e-liquid, 3.5% v/v nicotine).

SUBJECTS
• 37 smokers who had been smoking for at least six months, with a self-reported consumption of at least ten cigarettes per day.
• Approximately equal numbers of males and females, aged between 19 and 64 years.
• Females who reported to be pregnant or breastfeeding were excluded.
• Subjects were aware of but had never used e-cigs, but were willing to use an e-cig for a period one week.
• Subjects signed Informed Consent Form.

METHODS
• Study was conducted by CDMR in Glasgow, UK.
• Subjects completed a web-based questionnaire (pre e-cig). Each subject was provided with an e-cig and cartridges to use for a week and asked to record their daily e-cig use and cigarette consumption (CPD).
• After a week the subjects completed a follow-up questionnaire (post e-cig) assessing their experiences of using the e-cig.

RESULTS
• Most subjects reduced their CPD during the week of e-cig use (Figure 1). Urge to vape post e-cig use was lower than urge to smoke post e-cig use, which was in turn lower than urge to smoke pre-e-cig use (Figure 2).
• 78% of the subjects perceived e-cigs to be less risky than cigarettes, while only 22% thought e-cigs to be less risky than nicotine patches (Figures 3 and 4).
• Subjects’ perceived risk to health associated with e-cigs was generally lower than cigarettes both pre and post e-cig use (Figure 5).
• More than half of the subjects expressed a future intention to take up e-cigs and smoke fewer cigarettes (Figure 6).

CONCLUSIONS
• Questionnaires successfully collected useful pre-market and follow-up data from this small sample size.
• Demonstrated that they could be used to investigate effects of the introduction of a novel product.
• Follow-up six months later would give better insight into whether subjects’ perceptions have changed or not.
• Further exploratory work with larger subject numbers and different populations, and with additional items to collect data from never and former smokers is planned.