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Title: Use of a new dry powder inhaler to deliver umeclidinium/vilanterol in the treatment of COPD

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Body: Introduction Simultaneous delivery of compounds to the lungs via an inhaler, simplify treatment and improve patient compliance. This dry powder inhaler (DPI) enables delivery of two compounds without need for co-formulation and was used to deliver umeclidinium (UMEC)/vilanterol (VI) to COPD patients in phase 3a studies. Methods In two 3 month crossover exercise studies (DB2114417,DB2114418) patient use of the DPI was observed. Ease of use and ease of determination of the number of doses left in the DPI were collected using two patient questionnaires. In two 6 month studies (DB2113360,DB2113374) where the DPI and the HandiHaler® were used, a subject device preference questionnaire was administered. The COPD device preference questionnaire was developed with patient input using two rounds of cognitive interviews to refine content. Questions on the number of steps and time needed to use each inhaler and overall preference were included. Results In the exercise studies, 98% of patients used the DPI correctly following instruction. At six weeks 98 to 99% used the DPI correctly without receiving additional instruction.98-99% of patients found the DPI to be easy or very easy to use, 99% found the dose counter easy or very easy to read. In the 6 month studies, 59-65% preferred the DPI, 18-26% showed no preference and 11-21% preferred the HandiHaler®. Conclusion The DPI is easy to use following training and is not forgotten. The dose counter is easy to read and COPD patients showed a clear preference for the DPI compared to the HandiHaler®. This DPI has potential to reduce the number of handling errors seen with inhalers and increase compliance. GSK Funded,NCT01328444,NCT01323660,NCT01316900 and NCT0131691.