more health care provider visits in the past six months (11.7 vs. 8.9) compared with matched controls (n=286) (all p<.05). **CONCLUSIONS:** DME was more commonly reported by patients with diabetes and its presence was associated with a significant humanistic and economic burden in the 5EU.

PDB124

EQ-5D SCORES IN PATIENTS RECEIVING TOLVAPTAN FOR THE TREATMENT OF HYPONATRAEMIA SECONDARY TO THE SYNDROME OF INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION

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OBJECTIVES: Hyponatraemia (HN) is estimated to occur in 15% of all hospitalised patients with syndrome of inappropriate antidiuretic hormone secretion (SIADH) being one of the most common aetiologies. Patients treated with tolvaptan have demonstrated improvements in health related quality of life (HRQL) in the SALT I & II randomised controlled trials. The objective of this study was to map the SF-12 responses from SALT I & II to EQ-5D using a publically available algorithm and predict the change in EQ-5D associated with tolvaptan. **METHODS:** SF-12 scores from the pooled SALT I & II studies were converted to EQ-5D scores using a mapping algorithm developed by Gray, et. al 2006. Simulated EQ-5D scores were then used to estimate changes in EQ-5D from baseline at day 30 using ordinary least squares regression (OLS) as a function of baseline characteristics, treatment arm and achievement of sodium correction (NA^+) at day 4 (>135 mmol/l). A preferred model was selected based on the highest adjusted R-squared. Secondary analyses looked at change from baseline in EQ-5D at day 7, day 14 and at 7 day follow-up following treatment discontinuation. **RESULTS:** The preferred model included baseline age, gender, sodium level, EQ-5D and a tolvaptan indicator variable. Based on this model, tolvaptan was associated with a positive increase in simulated EQ-5D of 0.10 (n=164, p=0.03) at day 30 vs. placebo. After 7 days follow-up, tolvaptan was associated with a positive, but non- statistically significant effect of 0.04 (n=74, p=0.54). No effect was observed at day 7 (n=76, p=0.90) or at day 14 (n=85, p=0.84). Sodium correction did not appear to be a statistically significant predictor of HRQL. **CONCLUSIONS:** The preferred model indicated a statistically significant improvement in HRQL associated with tolvaptan use at day 30. Further research is required to establish whether sodium correction has an effect of HRQL.

PDB125

PATIENT EXPERIENCE WITH THE SINGLE-USE PEN FOR INJECTION OF ONCE WEEKLY DULAGLUTIDE IN INJECTION-NAIVE PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: This 4-wk, Phase 3b, multicentre, open-label, single-arm, outpatient study evaluated the safe and effective use of the Single-Use Pen (SUP) in patients with type 2 diabetes (T2D) who were naïve to self-injection or injecting others. The SUP contains a pre-filled syringe and automates needle insertion, retraction, and drug delivery; specifically designed for once-weekly glucagon-like peptide-1 receptor agonist, dulaglutide. Patient-reported outcomes (PROs) related to self-injection and to the SUP were important secondary outcomes. **METHODS:** Patients (N=211) were trained on correct injection technique with the SUP containing 0.5 mL placebo prior to initial self-injection. PRO measures were completed by patients after final injection or at early termination to evaluate device ease of use, experience (including satisfaction/confidence), and key device features. Site trainers rated how easy/difficult it was to train the patient to use the SUP. **RESULTS:** 99.0% of patients found the device easy to use. Patients found it easy to hold the SUP when injecting and to push the button to inject (97.6% and 98.1%, respectively). 97.1% of patients were satisfied with the overall injection experience, 96.7% of patients were confident they could identify when the full dose was delivered, and 99.0% were confident in their overall ability to use the SUP. Patients liked not having to attach (99.0%), touch (98.6%), or see (95.7%) the needle. 95.7% of patients also liked hearing the click indicating the dose was complete and 94.8% liked the automatic needle insertion. Finally, 92.4% of site trainers found it easy to train patients on how to use the SUP. **CONCLUSIONS:** This study demonstrated the SUP could be used safely and effectively by injection-naïve patients with T2D; PRO results indicated patient satisfaction with the SUP injection experience. A positive injection experience may be an important factor for some patients and providers when initiating injectable therapy.

PDB126

BEST PRACTICES IN INTEGRATING HOME GLUCOMETER MEASUREMENTS WITH ELECTRONIC PATIENT REPORTED OUTCOMES (EPRO) IN CLINICAL TRIALS

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OBJECTIVES: Monitoring glycaemic control is important in diabetes clinical trials and is also relevant for some oncology trials. It is possible to seamlessly integrate blood glucose measurements with clinical trial data via Bluetooth. This integration reduces transcription errors and improves accuracy and completeness of data, while reducing burden on patients. Our aim was to explore best practices in integrating measurements with ePRO. **METHODS:** A review of best practice and experience in blood glucose measurement data integration was undertaken and the findings were incorporated into a solution for use in clinical trials. A systematic literature review was also undertaken to assess the contamination risk to individuals handling and re-using electronic diaries (eDiary) previously used by patients doing fingerstick tests for blood glucose measurement. We defined search terms and undertook a PubMed and internet search. All documents that were identified as possibly relevant were reviewed and summarised. **RESULTS:** The review revealed key features and activities related to planning, design, testing and delivery that are important for successful integration of blood glucose measurements with ePRO data. The literature review confirmed that the risk in handling and re-using eDiaries previously used by patients doing fingerstick tests was very low. **CONCLUSIONS:** Handling and re-use of eDiaries previously used by patients doing fingerstick tests poses a low and acceptable risk; flexibility for handling measurements should be incorporated in the eDiary design including batch and individual reporting, reporting hypoglycaemic events as part of a meal event or as a standalone event and edit checks should be included to identify where a number of low measurements relate to the same event; there should be clear guidance to patientson how to transfer measurements to the eDiary; a method for managing control test measurementsshould be incorporated; and integrating glucometer measurements decreases patient burden and increases patient engagement.

PDB127

THE DEVELOPMENT OF AN INTEGRATED ECOA SOLUTION TO IMPROVE THE QUALITY OF DATA CAPTURE IN DIABETES CLINICAL TRIALS

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OBJECTIVES: The 347 million people who live with diabetes face an array of daily disease management tasks, e. g. measuring blood glucose, keeping track of the nutritional value of meals, and monitoring insulin usage. Diabetes trials vary in methodology, level of patient burden, volume of data captured and patient compliance. Our aim was to develop an electronic data capture system for use in clinical trials which would decrease patient burden while increasing compliance and improving data quality. **METHODS:** We developed a diabetes specific, electronic, event driven diary for capturing data relevant for clinical trials. Iterations of the diary were tested in diabetes patients via focus groups and one-on-one usability evaluations. Feedback was analysed to understand the typical day-to-day experience of living with diabetes, and to examine the impact and acceptability of a tailored electronic solution. Feedback was incorporated into a refined solution for use in clinical trials. **RESULTS:** The nature of diabetes means that patients are typically very actively engaged in managing their disease, although a lot of variation was seen in patients and their management routines. The requirement for multiple devices and high volume of data was also reported as burdensome. The focus groups and usability studies highlighted the benefit of providing a flexible solution, as well as redesigning the diary from unstructured blood glucose measurement reporting to event driven reporting. This redesign met the needs of patients, as well as the requirements of clinical trial protocols. Patients agreed that they would prefer this integrated, intuitive solution over traditional paper and electronic solutions. **CONCLUSIONS:** When faced with the task of recording patient data in diabetes, a well-designed and thoroughly tested electronic solution can reduce burden and increase patient satisfaction. This in turn improves compliance, data quality and overall study efficiency, while meeting the needs of all stakeholders.

PDB128

GERMAN PATIENTS' PREFERENCES FOR ATTRIBUTES OF TYPE 2 DIABETES MEDICATIONS

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OBJECTIVES: Treatments for Type 2 Diabetes Mellitus (T2DM) are associated with varying effectiveness and safety profiles. Patients' preferences for each of the medication characteristics that yield these varying profiles can be assessed through discrete choice experiments (DCEs). This study expands on the knowledge from two previous T2DM DCE studies conducted in the United Kingdom (UK) and the United States (US), and was aimed at evaluating the relative importance of medication attributes that influence medication choice among participants with T2DM from Germany. **METHODS:** A web-based DCE was conducted among patients with self-reported T2DM from Germany. The DCE was designed to examine 7 attributes of T2DM medications (efficacy, urinary tract infection/genital infection side effects, nausea/other gastrointestinal side effects, weight change, and hypoglycemic events, treatment in case of low blood sugar, and blood pressure). Part-worth utilities were estimated using multi-logit models, and relative importance [RI] values were calculated for each attribute. **RESULTS:** N=600 Participants with T2DM completed the study (50% male; mean age=58.2 years SD=10.0; BMI=32.4, SD=6.8). The RI values for the attributes in order of importance were: treatment in case of low blood sugar (22.5%), hypoglycemic events (18.1%), weight change (17.5%), efficacy (15.0%), nausea/other gastrointestinal side effects (12.9%), UTI/genital infection side effects (7.9%), and blood pressure (6.0%). **CONCLUSIONS:** The results of this study suggest that hypoglycemic events and the interventions required in the case of such events are of great importance to patients; these two attributes represent over 40% of the variance in patients' medication decisions. Change in body weight as a consequence of treatment was also an important attribute to patients. The results may help treatment providers and payers to understand the preferences of patients with T2DM. Understanding these preferences may be useful in devising strategies for successfully engaging and maintaining patients on T2DM treatments.

PDB129

SELF-REPORTED FREQUENCY AND IMPACT OF NON-SEVERE HYPOGLYCAEMIA IN INSULIN-TREATED ADULTS IN THE UK

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OBJECTIVES: Hypoglycaemia is the main side-effect of insulin therapy and can prevent optimal diabetes management. Real-world data on the frequency and impact of non-severe (self-treated) hypoglycaemic events are scarce. Self-reported frequency of non-severe hypoglycaemic events (NSHEs), their impact on personal well-being, work productivity and health care resource use, and patient–physician communication following non-severe events, were examined in people taking insulin. **METHODS:** Adults in the UK aged >15 years with Type 1 or insulin-treated Type 2 diabetes mellitus (T1DM or T2DM) completed ≤4 questionnaires at weekly intervals (7-day recall). Severe hypoglycaemic events (requiring external assistance) are not