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 EU.

**PDB124**

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

Trimmer D1, Hancock E1, Robinson F1, Dale P1, O'Reilly K1, Gisy M2

1Decision Resources Group, London, UK, 2Otsuka Pharmaceutical Europe Ltd, Wexham, UK

**OBJECTIVES:** Hyponatremia (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 trials. The objective of this study was to evaluate HRQL responses from SALT I & II to EQ-5D using a publicly 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 function which used to estimate changes in EQ-5D from baseline at day 30 using ordinary least square regression (OLS) as a function of baseline characteristics, tolerability, and treatment arm. 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 day 7 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 increase in simulated mean EQ-5D of 0.04 (n=244, p=0.54). No other consistent predictors of HRQL were observed at day 7 (n=76, p=0.99) 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 demonstrated statistically significant improvements in HRQL associated with tolvaptan use at day 30. Further research is required to test whether sodium correction has an effect on HRQL.

**PDB125**

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

Van Brunt K.1, Ignaut D.A.2, Zimmermann A.G.3, Threlkeld K.J.4, Martin G.5

1Eli Lilly and Company, UK, Windlesham, Surrey, UK, 2Eli Lilly and Company, Indianapolis, IN, USA

**OBJECTIVES:** The 347 million people who live with diabetes face an array of daily 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 objective was to evaluate 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 group and usability studies highlighted the benefit of providing a flexible solution, as well as redesigning the diary from the patient’s perspective, with the aim of improving data capture.

**METHODS:** A diary was designed to capture 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 and results demonstrated a need for a refined solution for use in clinical trials. **RESULTS:** 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 multiple diabetes-related tasks of 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.

**PDB126**

BEST PRACTICES IN INTEGRATING HOME GLUCOSE MEASUREMENTS WITH ELECTRONIC PATIENT REPORTED OUTCOMES (ePRO) IN CLINICAL TRIALS

Garrard P1, PDB129

1CRF Health, London, UK

**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 measurement with ePRO.

**METHODS:** A survey was conducted with stakeholders. Participants were asked if they had integrated in blood glucose measurement data collection and if so, when was the integration implemented and how was it initially implemented? How was the integration maintained? Finally, how was the integration used? All respondents were asked what they considered to be successful integration of blood glucose monitoring and 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, thereby providing clear guidance on how to transfer measurements to the eDiary; a method for managing control test measurements should 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

McEvoy K

CREF Health, London, UK

**OBJECTIVES:** The 347 million people who live with diabetes face an array of daily 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 objective was to evaluate 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 group and usability studies highlighted the benefit of providing a flexible solution, as well as redesigning the diary from the patient’s perspective, with the aim of improving data capture.

**METHODS:** A diary was designed to capture 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 and results demonstrated a need for a refined solution for use in clinical trials. **RESULTS:** 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 multiple diabetes-related tasks of 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

Selhorn H1, Stringer S2, Reinders S2, Schreib K1

1Evoked, Bethesda, MD, USA, 2Evoked, Inc., Bethesda, MD, USA, 3Evoked, London, UK

**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) studies. Our study expands on 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 characteristics among patients 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/gential infection side effects, nausea, gastrointestinal side effects, weight change, weight events, treatment in case of low blood sugar, and blood pressure). Farth-worthy utilities were estimated using multi-log 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/gential 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 better 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

Oakley A1,2, Frier BM1, Hammill MM1, Frier BM3,4

1Novo Nordisk Limited, Gatchor, UK, 2Novo Nordisk Scandinavia AB, Copenhagen, Denmark, 3The Queen’s Medical Research Institute, Edinburgh, UK

**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 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 fingertip tests was very low. **CONCLUSIONS:** Handling and re-use of eDiaries previously used by patients doing fingertip tests poses a low and acceptable risk of contamination to individuals handling and re-using electronic diaries previously used by patients doing fingertip tests.