II (liraglutide, saxagliptin), depression (agomelatine), bipolar disorder (asenapine), and epilepsy (eslicarbazepine). Data of all Phase II and III trials were identified in the European public assessment reports, the WHO Trials Registry, and PubMed. Outcome measures: the number of randomized subjects and the number of those aged 65 and 75 years and older. Trials with missing data were not included in the calculation of that outcome. Rates of trials giving information about the number of older subjects and the proportions of older people were calculated.

**Results:** The number of people aged 65+ and 75+ was available in 39% and 48% of the 116 included trials, respectively. The proportion of older people varied from 0% to 93%. In trials for indications primarily related to aging (n = 7), 47.1% of the subjects were 65+ (median, 268; range, 524–5848); 20.6% were 75+ (median, 1575; range, 216–5348). In trials for indications not specific for, but present in old age (n = 5), 7.5% of the subjects were 65+ (median, 108; range, 14–887); 0.9% were aged 75 and older (median, 26; range, 0–83).

**Conclusion:** This study on the number of older subjects in clinical trials of recently authorized drugs shows that in trials for indications primarily related to aging, almost half of the randomized subjects are aged 65 and older. In trials for indications not specific for, but present in old age, the number and especially the proportion of older subjects is limited. So, serious improvement concerning the inclusion of the older target population is needed for drugs intended for younger as well as for older patients.

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**OCO20—OPTIMAL SAMPLING STRATEGY FOR BUSULFAN IN STEM CELL TRANSPLANTATION PATIENTS**

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**Introduction:** Busulfan, an alkylating agent, is used in combination with other drugs in patients undergoing stem cell transplantation. Busulfan presents a very narrow therapeutic window, which has been linked to various adverse events. Therapeutic monitoring protocols have been developed to allow the individualization of the dose, but the dose selection and the sampling time for pharmacokinetics are based on empirical evidence. Consequently, target exposure cannot be warranted. The aim of this investigation was to determine the optimal sampling scheme and develop a model-based dosing algorithm for busulfan in stem cell transplantation patients.

**Patients (or Materials) and Methods:** Clinical data (n = 29) from an ongoing study were used for the purposes of our analysis. A 1-compartment model was selected as basis for sampling optimization and subsequent evaluation of a suitable dosing algorithm. Internal and external model validation procedures were performed before the optimization steps using ED-optimality criteria. Clearance and volume of distribution were considered as parameters of interest. The final sampling scheme and dosing algorithm were based on the deviation from target exposure range, as determined by AUC_{\text{tot}}.

**Results:** A 1-compartment model was found to describe busulfan exposure after oral administration, with ideal body weight (IBW) and alanine transferase (ALT) as covariates on clearance. A sparse sampling scheme with five samples per patient (t = 0.5, 2.25, 3, 4, and 5 hours after dose) was found to be sufficient for the characterization...