of options and requirements by country. The evaluation of market access options for OD-HOM can ease market access and reimbursement and influence international launch sequences of innovative orphan drugs.

PHP293

COST AND DURATION OF REGULATORY PROCESS IN AN OBSERVATIONAL STUDY IN EUROPE AND USA

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OBJECTIVES: Despite the growing interest in observational studies, there is any defined regulatory process unlike clinical trials, which have a defined one. Currently, international observational studies have to deal with each country regulatory process that means to face times and costs very heterogeneous and not regulated yet by the EU. Here we report the experience of MediData in international observational study conduct. METHODS: The start-up process in 7 countries was analyzed as for regulatory process of time and costs. Results: the regulatory process takes 12 weeks (Turkey) and the slowest one takes almost twice as long (Italy 24 weeks), while in the USA they spend almost 16 weeks to conclude the whole process. Usually times and costs have an inverse relationship, but the observationally conducted shows that the second cheaper country is Turkey, that comes after France where the process is free. Another example of this variety is the case of Spain and France in the same duration of the process they have a difference of spending of 1200%.

CONCLUSIONS: These duration and spending really differentiated have a huge impact on the observational study conduct. Especially at the international level, we might run into sponsored studies which could be conducted in countries with cheaper or faster regulation process, with the real risk of a selection bias of the sites of observation. In other word, a very partial collection of data. Inevitably, the result national level, we might run into sponsored studies which could be conducted in another way. Effectiveness of this policy depends on resolving the weaknesses of EPS process. In the UK, it is possible for a reimbursement by the Social Security Institution (SSI) in 2008, Public Procurement Law (PPL) was amended to implement and regulate e-Procurement in Turkey. Non-private, public purchaser hospitals are obliged to enter tender results of their medical device purchases into e-procurement system (EPS) to be eligible for a reimbursement by the Social Security Institution (SSI). Objectives of this research are to examine the impact of the EPS that is currently being used for medical device purchases in Turkey since 2011, and to investigate how the system is being used to define ceiling prices for reimbursement, concurrently assessing the quality and quantity of data uploaded by hospitals. EPS data is downloaded on a GMDB from Turkish National Database for Medical Devices, (TITUB) which is an e-catalogue system that was launched to provide barcode product registration, search and the e-procurement process. In accordance with the objectives, assessment is conducted on more than ten GMDBs and results are utilized to see the effect of EPS on pricing, comparing the prices on officially published SSI positive lists. Our study shows that a lowest price detected on EPS could be set as the reimbursement price, as was the case for the product; aortic stent graft, contralateral limb, where a defined SSI positive list price was reduced after determination of a lower price on EPS, on account of a mispriced tender record. An exploration while searching out the reimbursement prices is needed instead of SSI’s calculations based on merely a retrospective and detection of lowest price practice. Effectiveness of this policy depends on resolving the weaknesses of EPS data in terms of quality and coherence with the tender or a mispriced product could be a ground for an erroneous price setting and tenders that are not recorded at all or deferred might lead to incomplete EPS data to define reimbursement prices.

DISEASE-SPECIFIC STUDIES

MENTAL HEALTH – Clinical Outcomes Studies

PMH1

THE RISK OF METABOLIC DISORDERS IN PATIENTS TREATED WITH ASENAPINE OR OLANZAPINE: A REAL WORLD DATA STUDY CONDUCTED IN ITALY AND SPAIN

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OBJECTIVES: Second-generation antipsychotic drugs, known as Atypical Antipsychotics, have a better tolerability than conventional antipsychotics but it has reported that its usage to a substantial weight gain, an increase risk of dyslipidemia and type 2 diabetes mellitus. In this article authors assessed the risk of metabolic adverse events associated with Asenapine in comparison with those associated with Olanzapine by studying real world data. METHODS: The study was a retrospective analysis based on data extracted from Italian and Spanish Cegedim Statistical Data Linkage Database. Patients were divided in two cohorts (Asenapine and Olanzapine) according to the inclusion criteria and data collected in the period 2009-2012. RESULTS: Results showed that Asenapine was associated with a decreased risk of metabolic adverse events than Olanzapine, demonstrating a better safety profile with regard to metabolic effects.

PMH2

EFFICACY OF THE PHOSPHORYLATED TAU P181 FOR THE ALZHEIMER’S DISEASE DEMENTIA - A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: The purpose of this study was to apply a systematic review of the literature to evaluate the diagnostic effectiveness of the Phosphorylated tau p181 for the Alzheimer’s disease dementia. METHODS: A systematic literature review was used to evaluate the effectiveness of the Phosphorylated tau p181 for the Alzheimer’s disease dementia. The Scottish Intercollegiate Guidelines Network (SIGN) tool was used to two evaluators to independently evaluate the quality of the ten studies. The literature review covered from October 27, 1996 to October 2012, and searched the following databases including Ovid-MEDLINE, EMBASE, and Cochrane Library were used. RESULTS: A total of 9studies (9 diagnostic evaluation studies) were identified to evaluate Phosphorylated tau p181. The results of this test was evaluated based on diagnostic accuracy. The diagnostic accuracy for identifying AD of ELISA was high (pooled sensitivity, 0.843 (95% CI 0.818-0.867), pooled specificity, 0.799 (95% CI 0.768-0.828), summary receiver operating characteristic under the curve 0.908±0.0236. Primary criteria for inclusion were studies which included patients with a diagnosis of AD with confirmed or suspected AD and non-AD dementia, and (ii) assessment of tau levels using appropriate comparative tests. CONCLUSIONS: EasLATED Phosphorylated tau 181 levels are of potential utility in the differential diagnosis of AD versus non-AD dementias and healthy controls.