the most common bone disease and its incidence is rapidly increasing with the aging population. Even if curable, it is often left untreated causing a moderate use of economic resources that could be avoided.

PMS129

JOIN PROGRESS A EFFICIENCY PARTNERSHIP PROGRAM ON KNEE JOINT REPLACEMENT

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OBJECTIVES: Hospital Parc Taulí and Johnson & Johnson, partnered in a program to design and implant a fast track program for knee joint replacement. The objective was to decrease morbidity, functional convalesce, length of stay and increase patient and professionals satisfaction efficiently. **METHODS:** The implementation included 3 phases and two multidisciplinary Workgroups. Clinical aspects based on evidence, combined with organizational optimization, resources distribution and process redesign. Phase I: evaluation, nourished by Kaizen methodologies, Lean and 6 Sigma processes, Blum and Taylor laborer environment and Alex Faicknet Osborn group dynamics were taken under consideration. Phase II: Implantation, using Taylor dynamics to define the strategies to produce improvement on target indicators. Phase III: Monitoring, both from length of stay, security aspects such as morbidity, mortality, readmission rates, patient and professional satisfaction, and economic impact. **RESULTS:** The length of stay is influenced by factors such as patient profile and organizational aspects. Empowered patients are more active. A new patient pathway was developed, initiated when admitted to discharge and post-operative follow up. Improvement on healthcare results, increasing patient and professional's satisfaction, and reducing 50% length of stay, resulting on significant economical savings. **CONCLUSIONS:** Analyzing the patient pathway through an analysis methodology, reingeniery and diagnosis healthcare process (in outcomes and in direct cost), the patient involvement in the whole process can result not only in important efficiency improvement, but also improve the working environment and enhanced team work culture for a continuous process improvement.

PMS130

ESTABLISHING THE VALUE OF EMERGING BIOSIMILARS

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OBJECTIVES: The emergence of biosimilars for blockbuster therapies such as Remicade, Humira, Enbrel and Rituxan/MabThera is changing the paradigm by which traditional market access decisions are made for biologics. Furthermore, the regulatory pathway in Europe and the U.S. has raised uncertainties among clinicians regarding both the efficacy and safety of biosimilar molecules. The objectives of our research were to (1) understand the evolving mechanisms for biosimilar market access, (2) identify the key stakeholders involved in access decisions or influence and (3) determine the value drivers of biosimilars across diverse stakeholder groups. **METHODS:** A large sample of stakeholders (n=271) were engaged, including clinical specialists, payers and patients, across Europe and in the U.S. We performed in-depth qualitative interviews to gain an understanding of the current landscape for biologics and expectations for biosimilars, focusing on RA, Ulcerative Colitis, Crohn's Disease and Psoriasis. **RESULTS:** Our research indicates the fundamental understanding of biosimilars is inconsistent both within stakeholder groups and across different groups. Furthermore, for clinicians, a lack of accurate understanding of biosimilars can be a substantial driver of negative perception and a key barrier to anticipated adoption. Overall, each stakeholder group that will influence biosimilar market access has different value needs and expectations from biosimilars. **CONCLUSIONS:** Our findings highlight the need for a more consistent definition of biosimilar and clinical data requirements and a tailored approach to value communication for key influencers and stakeholders in the biosimilar value chain.

PMS131

STRATEGIES -BASED ON EVIDENCE- TO RATIONALIZE THE HIGH COST DRUGS NATIONAL LIST IN THE DOMINICAN REPUBLIC

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OBJECTIVES: In 2014, the budget for high cost drugs in Dominican Republic (DR) was USD 107 million, accounting for 51% of the MoH budget for medicines. Resources allocated for the 2015 budget were USD 49 million, leaving a shortfall of USD 62 million. The MoH requested technical assistance from the USAID funded SIAPS project to conduct an evidence based analysis of the 98 products included in the list. **METHODS:** Stage 1. Gathering of Evidence and Analysis; SIAPS consultant analyzed the therapeutic benefits and cost, and proposed 4 priority levels: Priority 1: Medicines included in the WHO Essential Medicine List; Priority 2: Included in the list of a Central America and DR procurement mechanism (COMISCA); Priority 3: Not included in the preceding groups but with scientific evidence of therapeutic benefits and approved by EMA and FDA; Priority 0: Medicines for which evidence on benefits was insufficient or for which better/cheaper alternatives were available. Stage 2. Review and approval by national scientific committee. During a two-day workshop, clinical specialists reviewed the proposed priority groups, consulted literature and proposed modifications supported by scientific evidence. **RESULTS:** In the plenary session, the scientific committee, agreed by consensus on the final version of the high cost drugs list to be procured in 2015. Of the 98 medicines, 22 were on the WHO list and 17 were on the COMISCA; 14 of the remaining 59 medicines were also included because there was scientific evidence of its benefits. Total of 45 medicines were removed by consensus, with a budget decrease of 53 % and savings of USD 21 million. **CONCLUSIONS:** A review -based on evidence- followed by a consensus reached with clinical specialists allowed to select the number of products to be procured, provides alternatives to adjust the budget available and release financial resources for cost effective and sustainable interventions .

PMS132

GRAND-4: THE GERMAN RETROSPECTIVE ANALYSIS ON PERSISTENCE IN WOMEN WITH OSTEOPOROSIS TREATED WITH BISPHOSPHONATES OR DENOSUMAB

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OBJECTIVES: To be effective, osteoporosis (OP) therapy must be taken consistently and as prescribed. Persistence is critical for successful outcomes, including fracture risk reduction. Few studies compare the persistence of oral bisphosphonate (BPs), IV BPs and denosumab beyond 1 year. This retrospective database analysis evaluated 2-year persistence to oral BPs, IV BPs and denosumab following treatment initiation and the risk of treatment discontinuation. **METHODS:** From the German IMS®LRx database, we included women aged ≥45 years who initiated an OP treatment after 1-July-2010 (index date = treatment initiation) with ≥2 years of follow-up until 31-Dec-2014. Persistence (prescription refill gap ≤ 60 days and no drug switch) was measured for 2 years from index date, and a Cox proportional hazard regression model was used to estimate the risk of treatment discontinuation (i.e. non-persistence). **RESULTS:** Data from 159,993 women were included in the analysis. Two years after treatment initiation, 39.8 % of those receiving denosumab (n=21,154), 24.8 % receiving IV ibandronate (n=20,472), 21.2 % receiving IV zoledronic acid (n=3,966), and 16.7 %„Ÿ17.5 % of those receiving oral BPs were persistent. Compared with those receiving denosumab, women receiving IV ibandronate or IV zoledronic acid were at higher risk of treatment discontinuation (HR [95% CI]: 1.65 [1.61-1.69] and 1.28 [1.23-1.33] respectively; p<0.001 for both). Moreover, women treated with oral BPs vs denosumab showed a two-fold risk of treatment discontinuation (HR [95% CI]: 2.02 [1.98-2.06] for alendronate, 2.02 [1.95-2.09] for ibandronate and 1.96 [1.91-2.01] for risedronate; p<0.001 for all). **CONCLUSIONS:** In our database study of women initiating BPs (oral or IV) or denosumab in routine clinical practice, 2-year persistence was highest for denosumab (1.5-2 times higher). Moreover, compared to denosumab, women treated with oral or IV BPs were at higher risk of treatment discontinuation. Such improved persistence may improve clinical outcomes, including increased fracture risk reduction.

PMS133

SELF-REPORTED RHEUMATIC DISEASES AND EARLY RETIREMENT IN PORTUGAL

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OBJECTIVES: We aim to examine the association between self-reported RD and early retirement by using large real-world observational data in Portugal. **METHODS:** We used individual level data from the national, population-based EpiReumaPt study (September 2011 to December 2013). 10,661 inhabitants were randomly surveyed in order to capture and characterize all cases of RD within a representative sample of the Portuguese population, which were stratified by administrative territorial units (NUTSII). In this analysis we used all participants aged between 50 and 65 years old, near the official retirement age (N=2,792; females: 1,727). The association of self-reported RD and early retirement was tested using logistic regression. All estimates were computed as weighted proportions, in order to take into account the sampling design. **RESULTS:** 29.9% of the Portuguese population with ages between 50 and 64 years old were officially retired. Among these, 43.2% were retired due to ill-health, which in turn about a third (30.4%) was specifically due to RD. Thus, 13.1% of all retirees self-reported RD as the main reason for early retirement. More than a third (34.2%; females: 46.3%) of all study population self-reported RD, being also more likely to self-report other main chronic disease (OR: 3.4; CI: 2.53-4.65; p<0.001). 35.2% of RD respondents were retired versus 27.2% of those non-RD (p=0.025). Prevalence of self-reported RD seems to be associated with early retirement (unadjusted OR: 1.45; CI: 1.05-2.01; p=0.025). Some other characteristics are also associated with early retirement, in particular older age, male gender and presence of other chronic diseases. RD association tends to be independently associated with early retirement (adjusted OR: 1.41; CI: 1.03-1.95; p=0.031). **CONCLUSIONS:** These results are similar with previous data from the National Health Survey conducted in Portugal nearly a decade ago and confirms the impact that self-reported RD still have on early retirement.

PMS135

CHARACTERISTICS OF PATIENTS STARTING BIOLOGIC TREATMENTS FOR RHEUMATOID ARTHRITIS IN THE REAL WORLD: SYSTEMATIC REVIEW

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OBJECTIVES: To assess demographic and disease characteristics of rheumatoid arthritis (RA) patients starting treatment with biologic disease-modifying anti-rheumatic drugs (DMARDs) in observational studies. **METHODS:** Systematic review of published observational studies in adult patients with RA treated with one of three biologic DMARDs (etanercept, rituximab, tocilizumab). We identified eligible studies through electronic searches of the MEDLINE and EMBASE databases. Two reviewers screened the articles independently. We extracted study characteristics such as location and calendar period, demographics of study populations, dose, frequency and concomitant therapies, and baseline characteristics such as disease duration,

disease activity and lab measurements. **RESULTS:** 106 papers met our inclusion criteria. Studies were published between 2003 and 2015 and mostly from Europe; 39 included patients starting etanercept, 36 included patients starting rituximab and 32 patients starting tocilizumab. Mean age ranged between 42.9 and 63.3 years, 78.2% were female. The drugs were given in combination with methotrexate and/or other traditional DMARDs in over two thirds of the studies. Mean disease duration varied between 4 and 17.5 years, baseline disease activity 28 scores between 4.3 and 7.0, and baseline health assessment questionnaire values between 1 and 2.9. The mean percentage of rheumatoid-factor positive patients was 76.4%. Reporting of comorbidities and smoking status was generally poor, with only few studies providing detailed data. **CONCLUSIONS:** This systematic review of data from observational studies and clinical databases indicates that the characteristics of RA patients starting biological DMARDs outside clinical trials in the real world varied widely. These observational data will now be compared with clinical trial data but it seems likely that some patient groups were not well represented in the trials.

PMS136

EFFECTIVENESS OF A REFERRAL PROGRAM FOR EARLY ARTHRITIS DIAGNOSIS AT PRIMARY CARE CENTERS IN PORTUGAL - PRELIMINARY RESULTS FROM THE SIARA STUDY

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OBJECTIVES: Early diagnosis and treatment of inflammatory arthritis can limit the impact of disease outcomes. We aimed to evaluate the effectiveness of a referral program on the identification of patients with suspected inflammatory arthritis. **METHODS:** SIARA (Referral Strategies and Disease Education Impact on Diagnosis and Referral of Axial Spondyloarthritis and Rheumatoid Arthritis Patients) is an observational prospective, randomized (by clusters of primary care centers) study to analyze the impact of Referral Support Actions (RSA) consisting of physician educational sessions about the disease and implementation of referral recommendations. The participating primary care centers (n=24) were randomly assigned to RSA or control group (with no intervention). Both RSA and control groups identified and referred patients with suspected inflammatory arthritis to the rheumatology unit of the reference hospital (n=6). The main studied outcome is the correct diagnosis of inflammatory arthritis / rheumatoid arthritis confirmed by the rheumatologist of the reference hospital. **RESULTS:** A total of 125 patients were referred to a rheumatologist (considering 4 hospitals): 61 RSA patients and 64 control patients. Mean age was 48.9 years (range: 19-73) and 88.8% were female (differences not statistically significant between groups). About 14.8% (n=9) of RSA patients and 4.7% (n=3) of controls had a confirmed diagnosis of arthritis (any type) by the rheumatologist (OR=3.5; 95%CI, 0.9-13.7; Chi-square p=0.056). Rate of confirmed rheumatoid arthritis was 4.9% in RSA patients and 1.6% in controls (p=0.287). The majority of the patients (82.0%) were referred in the 4 months after educational session (month 3:63.9%; month 6:96.7%). **CONCLUSIONS:** Although the study results still lack statistical significance, this preliminary data already suggests a positive impact of a referral program on the early identification of inflammatory arthritis, especially after the first few months. This should be further analyzed and considered by healthcare deciders in order to improve health outcomes in inflammatory arthritis.

PMS137

A WEB-BASED SURVEY TO INVESTIGATE THE EXTENT OF AWARENESS AND UNDERSTANDING FOR BIOSIMILAR AMONG JAPANESE PHYSICIANS AND PHARMACISTS

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OBJECTIVES: Several biosimilar products have been developed and marketed in Japan. However, the degree of understanding of biosimilars among healthcare professionals is uncertain. The objective of this study was to investigate the extent of awareness and understanding of biosimilars among Japanese physicians and pharmacists. **METHODS:** This was a non-interventional, web-based survey conducted in May 2015. Japanese physicians (rheumatologists/oncologists) and pharmacists voluntarily participated and provided their thoughts via questionnaires. Rheumatologists who have seen >= 30 rheumatoid arthritis patients/month on average and have prescribed biologics (Remicade/Humira, etc.) to at least one patient, and oncologists who have seen >= 30 cancer patients/year with use of biologics (Rituxan/Avastin/Herceptin, etc.) to at least one patient were eligible. **RESULTS:** Of screened physicians, about 35% have never heard of "biosimilar", whereas 96% of pharmacists were aware of "biosimilar". One hundred rheumatologists, 120 oncologists (30 each for Hematology/Breast/Gastroenterology/Respiratory) and 90 pharmacists who met the criteria and were aware of biosimilar were analyzed for a further questionnaire. 73% of rheumatologists and 82% of oncologists recognized that biosimilars "are relatively less expensive" and 62% of physicians simply answered "subsequent product/generic". 58% of rheumatologists showed an intention to prescribe future biosimilars, whereas 73% of oncologists showed prescription intention. The main reason behind this was "reduction of burden on patients", followed by "confirmed similarity in efficacy/safety". Physicians with little intention to prescribe biosimilars showed strong concerns for similarity to the innovator (>70%) and insufficient clinical data in efficacy/safety perspectives. Similarities in clinical efficacy/safety were more emphasized compared to structural and functional similarities in biosimilar development pathways. **CONCLUSIONS:** Awareness of biosimilars amongst Japanese physicians was still low with a strong leaning toward burden on patients and sufficient clinical data to confirm the similarity. Providing learning opportunities for general tenets of biosimilarity and its development pathways are vital to increase public recognition of biosimilars.

PMS138

ASSESSMENT OF RISK SHARING AGREEMENTS (RSAS) IN SELECT GLOBAL MARKETS WITH SPECIFIC FOCUS ON ACTIVITIES SURROUNDING IMMUNOMODULATORS

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OBJECTIVES: To understand current Risk Sharing Agreements (RSAs) for immunomodulators for rheumatoid arthritis, psoriasis, and psoriatic arthritis in 11 markets aimed to optimize specific RSA strategies/ payer partnerships. **METHODS:** Review of publicly available health authority websites and peer-reviewed journals. Interviews with payers and stakeholders who influence RSA decisions and ex-pharma executives for validation and gap filling. **RESULTS:** USA manufacturers negotiate RSAs with private health insurers and states. Payers in USA integrate financial risks with manufacturers using outcome based agreements (OBAs). Canada established RSAs with Provinces and use financial based agreements (FBAs) but some are OBAs. France requires volume based FBAs for new high-priced therapies to limit budget impact. Germany uses FBAs at the sickness fund level rather than the Gemeinsamer Bundesausschuss (G-BA) level because sickness funds manage their own budgets. Some OBAs exist with clearly defined outcomes. Italy negotiates RSAs at the national level for new therapies entering the market ranging from FBAs to OBAs depending on the specific therapy and target patient population. Italy may also require manufacturers to incorporate drug monitoring registries in the RSA. In Spain performance based OBAs are used for new therapies with nominal additional benefit at the regional level with clearly established outcomes. Netherlands and Sweden use evidence development (CED) agreements for high priced products to generate cost effectiveness data. In Switzerland, RSAs are new and mostly FBAs and mainly for orphan disease therapies and off-label indications with price capping. In the UK,FBAs with few OBAs are used affecting product price but are not rebate based. Australian RSAs are mostly FBAs and are referred to as "Deeds of Agreement." **CONCLUSIONS:** With high-cost immunomodulators, authorities are shifting towards integrating RSAs in price negotiations to optimize budget expectations prior to launch. Europe prefers FBAs to OBAs which often require clearly defined outcomes.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1

ASSOCIATION OF ADVERSE EVENTS AND HEALTH SERVICE USAGE WITH TAPENTADOL PROLONGED-RELEASE TREATMENT COMPARED WITH MORPHINE CONTROLLED-RELEASE (CR) AND OXYCODONE CR: A UK PRIMARY CARE OBSERVATIONAL STUDY

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OBJECTIVES: This study compared adverse outcomes and resource use in patients treated with tapentadol prolonged-release (PR) with those treated with morphine controlled-release (CR) and oxycodone CR. **METHODS:** Data were from the Clinical Practice Research Datalink, a database derived from UK primary-care. Patients prescribed tapentadol PR between May 2011 and December 2014 were matched to two groups of controls treated with either morphine CR or oxycodone CR on gender, age, pain duration, pain site and aetiology, Charlson index and prior analgesia. Rates of adverse events (constipation and nausea/vomiting) were compared by adjusted hazard ratio (aHR). Rates of primary-care contacts, accident and emergency contacts, outpatient clinic letters and, for a subset of patients linked to Hospital Episode Statistics (HES), inpatient admissions were compared using incident rate ratios (IRRs) derived from Poisson regression. **RESULTS:** 1,176 patients prescribed tapentadol PR were identified; 1,103 (93.8%) had a pain diagnosis. Of these 789 (67.1%) were matched to morphine controls and 557 (47.4%) to oxycodone controls. Compared with controls, adverse events with tapentadol PR treatment were reduced: aHR=0.643 (95% CI 0.459–0.901; p=0.010) versus morphine CR and 0.505 (0.335–0.763; p=0.001) versus oxycodone CR. Compared with morphine CR, primary-care contacts (IRR=0.817; 0.786–0.850), accident and emergency attendance (0.699; 0.560–0.870) and outpatient letters (0.715; 0.543–0.939) were also reduced. For oxycodone CR, the respective figures were 0.776 (0.706–0.840), 0.840 (0.639–1.103) and 0.545 (0.400–0.739). For the subset of HES-linked patients the rates of inpatient admissions were 0.723 (0.590–0.884) and 0.458 (0.357–0.585) vs. morphine CR and oxycodone CR, respectively. **CONCLUSIONS:** Tapentadol PR was associated with significantly fewer adverse gastrointestinal events than morphine CR or oxycodone CR. There was also significantly reduced primary- and secondary-care resource use. As with all observational studies, potential bias due to residual confounding and confounding by indication should be considered.

PSY2

CLINICAL AND ECONOMIC BURDEN OF PULMONARY EXCERBATIONS IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION

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OBJECTIVES: To assess the clinical and economic burden of pulmonary exacerbations (PEx) in patients with cystic fibrosis (CF) and homozygous for the F508del CFTR gene mutation. **METHODS:** Medical chart data from patients with CF ≥12 years old were collected in France, Germany, Italy, Spain, Australia and Canada. Demographics, clinical characteristics, and selected resource utilization were obtained for a 12-month baseline period and a follow-up period ranging from 2-36 months. The frequency of PEx and associated resource utilization was assessed overall and by age (12-17, ≥18 years) and lung function (percent predicted forced expiratory volume in 1-second [ppFEV1] ≥70%, 41-69%, ≤40%). Descriptive analyses were conducted. **RESULTS:** Data for 523 patients were included. Baseline mean ± SD age was 24.8 ± 9.5 years and mean ± SD ppFEV1 was 67.1 ± 22.9%. During