OPHTHALMOLOGY: THERAPY TRENDS IN EUROPE BASED ON CLINICAL TRIAL REGISTRY DATA
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OBJECTIVES: Ophthalmology pharmaceutical market is growing worldwide due to rising aging population, new delivery technologies and changing lifestyle. However, challenges like patent expiry of major brands and lack of awareness still persist. Therefore, it is important to understand the upcoming therapy options, changing patients’ needs and requirement of cost effective therapies. This analysis provides an overview of the recent trends and future scenario in Ophthalmology. Method: Results: Conclusions: The described systematics methodology for the construction of treatment pathways may be used by manufacturers in early drug development decisions to identify unmet clinical needs, understand which treatment positioning may provide the most value, and identify future treatment comparators in the same indication. Guidelines to inform such commercial strategies may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. Between 2010–2011 high-risk human papillomavirus (HR-HPV) DNA test was used as primary screening. The cohorts were compared in terms of acceptance rate of invitation, cytological results, molecular results including HPV genotype, detection rate of histological lesions.

RESEARCH POSTER PRESENTATIONS - SESSION V
DISEASE-SPECIFIC STUDIES
Cancer – Clinical Outcomes Studies
PCN1
TREATMENT PATTERNS AND HEALTH OUTCOMES AMONG PATIENTS WITH RADIATION-REFRACTORY DIFFERENTIATED THYROID CANCER IN THE UNITED STATES AND WESTERN EUROPE
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OBJECTIVES: Most patients with differentiated thyroid cancer (DTC) have an excellent long-term prognosis and survival with modern treatment options. However, patients with radiation-refractory (RRDTC) are limited. This study investigated the treatment patterns and health care resource use among patients with radiation-refractory differentiated thyroid cancer (RDTTC) and identifies key differences in patients managed with WW vs. PCR. Results: Conclusions: We observed a trend toward more days hospitalized from disease-associated complications was observed for patients managed with WW (Mean = 2.4, respectively) and non-systemic treatment (Mean = 8.27) than patients treated with chemotherapy (Mean = 7.25) or TKIs (Mean = 8.22). CONCLUSIONS: Among patients diagnosed with RDTTC, watch and wait and non-systemic treatment appear to be cost effective. The direct cost burden may be observed given the frequent and long hospital stays.

PCN2
APPROVING DRUGS BASED ON EARLY STAGE DATA – HOW PHASE II TRIAL DATA CORRELATES WITH PHASE III OUTCOMES. CASE STUDY: NSCLC
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OBJECTIVES: There is increasing pressure on regulators from patients, physicians and industry for earlier access to pharmaceuticals for serious diseases. In reaction, in March 2014 the European Medicines Agency (EMA) and the National Institute for Health and Care Excellence (NICE) adopted adaptive licensing, and the Medicines and Health Care products Regulatory Agency (MHRA) unveiled their Early Access to Medicines Scheme. Nevertheless, there are questions over how, and if, Phase II trial benefits can be predictive of clinical advancements in Phase III studies, which this research aims to address. METHODS: Phase II data of any Non-Small Cell Lung Cancer (NSCLC) oncologic appraised by the EMA, or that had failed Phase III clinical trials, since 2002 was extracted along with its corresponding Phase II data. Statistical tests were conducted using Pearson’s coefficient correlation. Results: Conclusions: Of the 12 oncologics identified with both Phase II and III readouts, 6 of which met their Phase III trial primary endpoint, Overall Response Rates (ORRs) reported in Phase II trials varied from 0%–61% (mean 24%). 42% of patients with Phase II ORR ≤30% met their primary endpoint vs. only 2/8 (25%) with ORRs ≥30%. Phase II ORRs were strongly correlated with Phase III Progression-Free Survival (PFS) (r = 0.864, p < 0.0005) and Overall Survival (OS) outcomes. The study of 12 oncologics is consistent with the hypothesis that Phase II data can predict future Phase III outcomes. Nevertheless, 6/12 drugs that failed their Phase III primary endpoints had comparable Phase II data indicating benefits versus these same comparators, most notably onatuzumab, whose Phase III trial was terminated early due to unacceptable survival, and brivanib, whose Phase II trial was stopped due to serious adverse events.

PCN4
CERVICAL HUMAN PAPILLOMA VIRUS (HPV) DNA PRIMARY SCREENING TEST RESULTS OF THE EXPERIENCE OF A REGIONAL LABORATORY IN CENTRAL ITALY
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OBJECTIVES: To investigate feasibility and effectiveness of a cervical screening program with DNA tests as preliminary assay versus usual cytology protocols in Umbria Region. METHODS: A large cohort of 35-64 aged women afferent to the unique regional laboratory was considered. The usual algorithm with cervical cytology test in first instance and HPV test in the case of uninvited cytology test results was followed (10/2009–08/2011). Between August 2010–October 2011 high-risk human papillomavirus (HR-HPV) DNA test was used as primary screening. The cohorts were compared in terms of acceptance rate of invitation, cytological results, molecular results including HPV genotype, detection rate of histological lesions. RESULTS: A total of 31,228 women were invited: 21,249 (68.2%) were accepted to the cervical screening test while 9,983 (31.8%) were refused. Conclusions: Age-related differences were evidenced, with younger women (35-49) more prone to specifically request molecular screening as primary screening. A similar rate of adhesion (56.6% vs. 56.5%) was observed.

PCN5
COMPARATIVE EFFECTIVENESS OF TREATMENTS FOR RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA (R/R MCL), USING MATCHING ADJUSTED INDIRECT COMPARISON
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OBJECTIVES: For prognosis or relapsed or refractory (R/R) MCL patients with existing treatments is poor; most patients progress within ~4 months. Ibrutinib, an oral once daily Bruton’s tyrosine kinase inhibitor (BTK), has demonstrated a good response rate in 111 R/R MCL patients and a median progression free survival (PFS) of 13.9 months. Ibrutinib received breakthrough designation and United States Food and Drugs Administration approval for use in MCL patients who received at least one prior therapy (R/R MCL). This indirect analysis aims to compare the efficacy signifi-
of ibritinib to available treatments for R/R MCL patients. METHODS: A systematic literature review was conducted to identify randomized trials containing ibritinib versus controls. Methods for extracting and analyzing data for R/R MCL. Matching adjusted indirect comparison (MAC), described by Signorovitch et al 2012, was utilized to obtain indirect relative treatment effect for ibritinib compared to other treatments. Using individual patient level data (IPD), baseline characteristics, outcomes, numbers of patients, and survival. The primary endpoint was overall survival (OS) at 3 years and OS at 5 years (between first and last ipilimumab doses); post-regimen; and pre-death (within 90 days of the last ipilimumab dose). Pre-death period. Of 808 records reviewed, 17 trials in the R/R MCL population were included in the SLR, 10 were phase II trials, 4 were phase III trials, and 3 were phase IV trials. Of these trials, 12 were randomized controlled trials (RCTs), 1 was a retrospective chart review, and 4 were observational studies. The findings suggest that most HER2+ breast cancer patients in the advanced setting benefit from trastuzumab and treated continuously with trastuzumab for a median of 1.2 years post-regimen. For both outcomes at all time points, there was no significant difference between dasatinib and nilotinib.