Objectives: The objective of this study was to identify the most common clinical endpoints used for assessing treatment efficacy in nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH) by analysing ongoing, completed, and early-stage clinical trials related to these conditions. ***Methods:*** Clinical trials focusing on NAFL/NASH were analysed using data from ClinicalTrials.gov. Trials in the third, fourth, or undetermined phase with over 50 participants where included while device testing, diet restriction, surgeries, and diagnostics were excluded. Trials were tagged and grouped based on outcome measures and the most common primary and secondary outcomes across all trials were identified. ***Results:*** The initial search has provided 505 results for pre-screening. After filtering towards adopted criteria, the spectrum was limited to 76 trials out of which 51 concerned mainly NASH/NAFL and in remaining 25 NASH/NAFL was considered in the background. The investigated studies included 27 phase IV and 29 phase III clinical trials. 35 studies were completed with total 4233 participants and average follow up of around 27 weeks. After the review process, 86 unique primary and 174 secondary endpoints were identified. All of the enlisted endpoints were connected towards measuring the fat content of the subject or its liver. The most common primary endpoints were lowering NAFLD Activity Score NAS (21 trials), improvement of fibrosis (11 trails),-resolution of NASH/NAFL (8 trials); and secondary endpoints: BMI (16 trails) , alanine transaminase level ALT (13 trials), measure of aspartate aminotransferase AST (11 trials). ***Conclusions:*** Many clinical trials investigating various treatments for NASH are ongoing. They differ in terms of the considered outcomes. Awareness of this diversity and knowledge of the most common endpoints will allow for more efficient clinical comparisons and economic modelling in the future.

CO159
A BAYESIAN NETWORK META-ANALYSIS (NMA) FOR EVALUATING THE RELATIVE EFFICACY OF DUAL THERAPY COMBINATIONS OF DAPAGLIFLOZIN AND METFORMIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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Objectives: This study aims to utilize Bayesian network meta-analysis (NMA) to assess the relative efficacy of dapagliflozin add-on to metformin as a dual therapeutic strategy for managing T2DM. The main emphasis is on comparing the outcomes of this dual therapy approach with both placebo and other SGLT2 inhibitors used in combination with metformin. ***Methods:*** A Bayesian NMA with random effects model has been conducted to estimate the relative efficacy of dapagliflozin when administered at various doses and frequencies in combination with metformin. Pertinent data related to changes in HbA1c levels from the baseline were extracted for analysis. The assessment of relative efficacy was conducted by evaluating the mean differences (MD). ***Results:*** Following a systematic review of the existing body of literature, the study encompassed a selection of 20 randomized controlled trials, all of which provided outcomes for a minimum duration of 16 weeks. The reduction in HbA1c levels demonstrated a significant increase when dapagliflozin at doses of 2.5mg QD, 5mg QD, and 10mg QD was administered alongside metformin, as compared to the combination of metformin with a placebo. The mean difference between the three treatment regimens compared to placebo were -0.388 (-0.625, -0.158), -0.507 (-0.682, -0.340) and -0.523 (-0.683, -0.382). However, no statistically significant difference was observed in the efficacy endpoint of HbA1c reduction compared with other SGLT2 combined with metformin. ***Conclusions:*** This study synthesized direct and indirect evidence to establish indirect comparisons of dual therapy combinations of different SGLT2 inhibitors and metformin. The result indicates that irrespective of the medication's dosage and frequency, the therapeutic impact of dapagliflozin in conjunction with metformin exhibited a considerably superior efficacy compared to metformin as a standalone treatment. The variance in effectiveness among distinct SGLT2 and metformin regimens may be discernible in facets beyond HbA1c.

CO160
BURDEN OF ILLNESS AND TREATMENT PATTERNS OF ADULT PATIENTS WITH ADVANCED OR METASTATIC GASTRIC/GASTROESOPHAGEAL JUNCTION CANCER: A SYSTEMATIC LITERATURE REVIEW

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Objectives: Gastric and gastroesophageal junction cancer (G/GEJC), represents the fifth most common malignancy and the fourth leading cause of cancer-related death worldwide. This study aimed to identify published evidence on treatment patterns, real-world clinical and economic outcomes, and humanistic burden in previously untreated, unresectable, locally advanced and/or metastatic G/GEJC patients. ***Methods:*** A systematic literature review was conducted following the PRISMA 2020 guideline. The MEDLINE, Embase, and Cochrane Library were searched electronically for articles on 24 June 2022, supplemented by hand searches of congress abstracts, health technology assessments, relevant regulatory documents, and treatment guidelines. Searches included all interventions regardless of regulatory approval and were limited to English language. Interventional or preclinical studies, case series, case reports, and editorial articles were excluded. Reporting focused on publications published since 2012, with large sample size (n≥150). ***Results:*** Of the 1721 identified publications, data from 53 publications were extracted and included in this review. Majority of the publications (n=49) reported data from single-country studies; 25 from Asian countries and 8 from the US. Treatment patterns were reported in 37 publications, with combinations of fluoropyrimidines and platinum being the most commonly used regimens. S-1 was almost exclusively used in Asian countries. Most studies (n=40) reported real-world clinical outcomes with an estimated median OS ranging from 6.4 to 18.9 months. Economic burden was reported in 5 studies which showed a significant financial impact of advanced G/GEJC on patients, caregivers and healthcare providers. ***Conclusions:*** Across studies, patients with advanced or metastatic G/GEJC had poor survival outcomes. There is limited real-world data available on the humanistic burden of advanced G/GEJC. Due to the search timeframe, the identified studies did not capture real-world outcomes of recently approved immuno-oncology therapies.

CO162
MORE SERBIA: MOLNUPIRAVIR REAL WORLD UTILIZATION AMONG COVID-19 PATIENTS IN SERBIA

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Objectives: Molnupiravir is currently available under an import license which is approved the agency of drugs and medical devices of Serbia (ALIMS), following the decision of the Government of Serbia (CLI05:00-566/2021), for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult patients who are at high risk of progression to severe disease. This study describes the patient characteristics and clinical outcomes of molnupiravir users in a real-world setting in Serbia, where molnupiravir has been available since the end of 2021. ***Methods:*** In this chart review study, non-hospitalized adults (≥18 years) with COVID-19 treated with molnupiravir between January 1 to April 30, 2022 were included from five outpatient health centers. Patients' characteristics at the time of molnupiravir initiation and clinical outcomes within 28 days after molnupiravir initiation were collected. ***Results:*** In this analysis, 1172 patients were included. Mean age was 57.5 years and 58.2% were female. At the time of molnupiravir initiation,38.5% of the patients had 2 or more co-morbidities, with hypertension (55.9%) and obesity (18.7%) being the most common. The majority (72.4%) had at least one comedication other than molnupiravir and 20.1% had ≥5 comedications. 65.9% received COVID-19 vaccination. Within 28 days of initiating molnupiravir, 4 (0.3%) patients were hospitalized due to COVID-19. Of the hospitalized patients, 3 were older than 60 years, 2 were admitted to an intensive care unit, and one required mechanical ventilation. No death occurred among the patients in our study. ***Conclusions:*** The current study describes the patient profile and clinical outcomes of individuals treated with molnupiravir in a real-world setting in Serbia. Patient population was on average younger and had fewer co-medications and comorbidities than in other published retrospective studies of molnupiravir-treated patients, reflecting a less restrictive use of the medication in Serbia. Hospitalization was uncommon after treatment with molnupiravir, and no death occurred.

CO165
VALIDATION OF HIGH RISK CRITERIA IN MEDICATION RECONCILIATION IN MAJOR ORTHOPEDIC SURGERY: A DELPHI STUDY

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Objectives: Medication reconciliation(MR)is relevant in the transitional care, however, given the limited resources, it is necessary to identify the patients who can benefit most from this activity. Our aim was to validate the criteria that identify patients at high risk of experience medication errors and error-related adverse events undergoing major orthopaedic surgery. ***Methods:*** The Delphi technique was used through a questionnaire carried out in 3 phases (April-June 2023)to obtain consensus on the inclusion criteria. These were previously defined by a multidisciplinary team, based on the probability of risk of the adverse event to happen.Each expert rated the criteria according to a 5-point Likert scale, and consensus was assumed if 50% of the mean responses were ≥4 (inclusion) or <2 (exclusion). It was possible to suggest the inclusion of new criteria. ***Results:*** 10 experts from 4 Faculties of Pharmacy and Medicine were invited. In the first phase,9 responses were obtained

and consensus was reached on 18 criteria: polypharmacy, anticoagulants, oral chemotherapy (not hormone therapy),immunosuppressants,antiretrovirals, (pyridostigmine and neostigmine),insulin, corticoids, neuroleptics, antiarrhythmics, digoxin, carbamazepine, phenytoin, valproate, thyroid drugs, anti-glaucoma therapy, anti-aggregants and urgent surgery. Systemic antifungals and opioids were suggested. In the second phase, 8 experts responded. Consensus was reached on 6 criteria: anti-parkinsonics, beta-blockers, age ≥65 years, length of stay ≥5 days, opioids and systemic antifungals. In the last phase, 6 experts responded and 1 criterion reached consensus: sulfonylureas. At the end,3 criteria did not reach consensus: anxiolytics, angiotensin converting enzyme inhibitor or angiotensin II receptor antagonists and calcium channel blockers. ***Conclusions:*** We developed and validated a list of 25 criteria to identify patients at high risk of experience medication-related adverse events undergoing major orthopedic surgery. These criteria may help improve human resource management for clinical pharmacy activities by prioritizing patients who would benefit most from MR. This methodology could be replicated in other clinical areas.

CO166
EFFICACY OF LECANEMAB IN PATIENTS WITH EARLY ALZHEIMER DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Objectives: Alzheimer's disease (AD) causes a decline in memory, thinking, learning, and organizing skills. It's the most common cause of dementia and usually affects people over the age of 65. AD is characterized by the accumulation of beta-amyloid protein in the brain. We reviewed the clinical evidence for lecanemab, a humanized monoclonal antibody that binds with high affinity to soluble amyloid-beta protofibrils, for treating early AD. ***Methods:*** A systematic search of published literature was performed using Embase® and MEDLINE® from database inception to June 2023 to identify the randomized controlled trials assessing lecanemab in early AD. The outcomes of interest included change from baseline in Clinical Dementia Rating-Sum-of-Boxes (CDR-SB), Alzheimer's Disease Composite Score (ADCOMS), and Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog14) at 18 months. The meta-analysis was performed using Stata 17 software. ***Results:*** Two double-blind, placebo-controlled, 18-month trials (Study 201, and Clarity AD) met the inclusion criteria. Both trials were broadly similar in terms of methodological and clinical characteristics. Lecanemab 10 mg biweekly was associated with statistically significantly better efficacy vs. placebo in terms of reduction in CDR-SB (WMD, 95% CI: -0.44, -0.70 to -0.17), ADCOMS (-0.05, -0.07 to -0.03), and ADAS-Cog14 (-1.55, -2.30 to -0.79) scales. A sensitivity analysis performed using data from different analysis types i.e., MMRM, Bayesian, etc., showed similar results. ***Conclusions:*** Lecanemab demonstrated a decrease in cognitive and functional decline compared to a placebo for the treatment of early-stage AD over an 18-month period. Future meta-analysis studies should also include the safety and tolerability outcomes. Further, longer-term studies are needed to evaluate the effectiveness and safety of lecanemab for the treatment of early-stage AD.

CO168
A PROPENSITY SCORE-BASED COMPARISON OF TEPOTINIB VERSUS IMMUNOTHERAPY WITH/WITHOUT CHEMOTHERAPY, USING REAL-WORLD DATA IN PREVIOUSLY UNTREATED *MET* EXON 14 (*MET*EX14) SKIPPING NON-SMALL CELL LUNG CANCER (NSCLC)

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Objectives: With the approval of immunotherapies (IOs) and IO combinations with chemotherapy (IO+chemo), several IO-based treatment options are available for non-oncogenic NSCLC. However, in specific mutations such as *MET*ex14 skipping, observational studies suggest IOs do not perform as well, and no evidence exists for IO+chemo in this population. By pooling seven real-world datasets of patients with *MET*ex14 skipping NSCLC (the TOGETHER study), we are able to compare IO-based treatments to tepotinib, a selective MET inhibitor. ***Methods:*** TOGETHER includes 289 previously untreated patients, 47 of whom received IO, and 26 IO+chemo, facilitating comparisons with the 164 previously untreated patients from the tepotinib VISION study (NCT02864992). Time-to-event outcomes are compared with the November 2022 data cut-off of VISION, using propensity scoring to account for differences in patient characteristics based on clinical input; reweighting IO treatment data to match VISION. ***Results:*** After weighting, patient and disease characteristics were balanced across groups, with no statistical differences observed. Patients who received tepotinib had longer progression-free survival (PFS, median 8.7 months) than patients receiving IO (median 3.6, Cox Hazard Ratio (HR) 0.56 [95% confidence interval (CI): 0.37, 0.85]) and IO+chemo (median 6.7, HR 0.43 [95% CI: 0.43, 1.12]). Overall survival comparisons marginally favored tepotinib (median 21.3 months) over IO (median 19.0, HR 0.85 [95% CI: 0.57, 1.28]), and IO+chemo (median 19.3, HR 0.97 [95% CI: 0.57, 1.66]). ***Conclusions:*** Although the introduction of IO has led to a step change in non-oncogenic NSCLC, in patients with *MET*ex14 skipping NSCLC, consistent with published observational data, we find time-to-event outcomes to be shorter. Despite limited patient numbers, the evidence presented suggests similarly patterns for IO+chemo. Estimated PFS is longer with tepotinib, while evidence on overall survival remains uncertain and confounded by subsequent treatment use, but does suggest a differential outcome for any treatment in isolation.

CO169
PAN-STAKEHOLDER CORE OUTCOME SET (COS) DEFINITION FOR HEMATOLOGICAL MALIGNANCIES IN THE FRAMEWORK OF THE EU PROJECT, HARMONY: THE HEALTHCARE ALLIANCE FOR RESOURCEFUL MEDICINE OFFENSIVE AGAINST NEOPLASMS IN HEMATOLOGY

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Objectives: Definition of a core outcome set (COS) may improve the interpretation and comparability of future clinical trials. In the scope of HARMONY Alliance a COS, as an agreed set of outcomes for several hematological malignancy (HM) was defined. The HARMONY Alliance is a public-private European network established 2017, which currently includes 51 partners and 73 associated members from 23 countries. ***Methods:*** For COS definition, the Delphi method was used including all stakeholder groups (patients, clinicians, industry, and regulators/HTA bodies). COS were defined for nine different HMs. Conditions and criteria how to define COS were defined in study protocols, which were made publicly available for each HM through the HARMONY and COMET webpages. For outcomes especially valuable to patients, a special "patient-important criterion" was implemented. ***Results:*** For the HARMONY Delphi surveys a total of 365 individuals participated including 177 patients/patient advocates (48%), 126 clinicians (35%), 46 EFPIA/industry members (13%) and 16 regulators/members of HTA bodies (4%). In summary, for the HARMONY HMs 11 out of 59 outcomes met the consensus-in criterion in AML; 8 out of 61 in NHL; 12 out of 51 in MDS; 12 out of 58 in MM; and 17 out of 54 in CLL. For the HARMONY PLUS Delphi surveys, 161 persons participated in total including 20 patients/patient advocates (12%), 93 clinicians (58%), 39 EFPIA/industry members (24%), and 9 regulators/members of HTA bodies (6%). A detailed overview of the HARMONY and HARMONY PLUS COS will be presented at the meeting, additional to results of the latest expert panel meeting. ***Conclusions:*** To the best of our knowledge this was the first multidisciplinary approach to define COS for HMs including the views of all stakeholder groups - with a specific focus on patients' needs – a strong starting point for a harmonized application of core outcomes in future clinical and observational trials.

CO170
TREATMENT EXPOSURE-ADJUSTED EVENT RATES (EAERS) FOR GRADE 3/4 AES ASSOCIATED WITH EMERGING AND EXISTING SYSTEMIC THERAPIES FOR MCRC WITH AT LEAST 2 PRIOR LINES OF THERAPY: INFORMING PAYER AND PATHWAY FORMULARY DECISION MAKING

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