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viable network of evidence for recommended treatments. Heterogeneity was assessed for study and population characteristics that were potential treatment effect modifiers. The research was conducted in a Bayesian framework and fixed and random effects models were considered. Subgroup analyses were performed on programmed death-ligand 1 (PD-L1) defined populations and scenario analyses were conducted based on the heterogeneity assessment. PD-L1 populations were defined by complete positive response (CPS). Results: The network contained 28 RCTs reporting OS and 23 RCTs reporting PFS, grouped into 10 therapeutic class-based nodes. In the all-comers population, nivolumab plus FP chemotherapy had 55% probability of being best treatment for OS and PFS. In the PD-L1 CPS=5 subgroup, nivolumab plus FP chemotherapy had 72% probability of being best treatment for OS and 74% for PFS. The heterogeneity assessment showed moderate to major heterogeneity in almost all variables including potential treatment-effect modifiers. However, only one scenario analysis, a meta-regression correcting for age, showed different results, and these were not accounted for alone. No inconsistency between direct and indirect evidence was observed across multiple analyses. Conclusions: Nivolumab plus FP chemotherapy showed better estimates of efficacy in comparison to all other treatments, with 55% probability of being the best treatment, in terms of both OS and PFS. This probability increased in a PD-L1 enriched subgroup.

POS8277 EVALUATION OF THERAPIES LAUNCHING WITHIN A SPACE WITH NO APPROVED STANDARD OF CARE

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Objectives: This research explored health technology assessment (HTA) outcomes for orphan therapies launching in therapeutic areas with no approved standard of care to identify optimal evidence development strategies. Methods: The EMA website and peer-reviewed articles were scanned for 45 orphan therapies approved in 2011-2020, which were screened for mention of no alternative treatment options in the HTA decision summaries from 6-20 in Germany, HAS in France and NICE in the UK. This identified 15 therapies to explore the trial design, efficacy outcomes and supplementary evidence. Results: 5 of 15 prioritized therapies launched with open-label, single-arm trial data, while in 10 of 15 cases randomized evidence vs. placebo was presented. In 4 of the 5 cases with non-randomized trial design, historical control data was used for estimates of relative treatment effects. While a non-quantifiable added benefit rating was assigned to most studied therapies in Germany given the orphan status, French and UK HTA bodies requested more data to confirm the extent of the benefit (e.g., data from indirect treatment comparisons (ITCs) or post-treatment follow-up). Despite the lack of randomized evidence, in France, an ASMR II or III was granted for therapies with ITC data (3 of 4), while an ASMR IV was assigned to 5 of 10 therapies with randomized data when extent of the benefit was uncertain. In the UK, NICE recommended funding for 6 of 7 therapies assessed; however, a managed access agreement and further data collection has been required for 4 of these therapies to address uncertainties in the clinical evidence. Conclusions: The research demonstrated that, despite the high unmet need, the complexity of trial design for orphan drugs raises several challenges in the HTA process. Evidence strategies, such as follow up data collection or indirect comparison with historic control can be employed to support understanding of the benefit during the HTA process.

POS8278 MODERNISING THE CLINICAL TRIAL: A SHIFT TO DECENTRALISED TRAILS DRIVEN BY ADVANCES IN TECHNOLOGY AND CATALYSED BY THE COVID-19 PANDEMIC

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Objectives: The industry is experiencing a shift from conventional clinical trials to de-centralised trials (DCTs) driven by unprecedented access to anonymised patient data, increases in computational power advancing analytical capability and accelerated by the COVID-19 pandemic. DCTs offer the opportunity to run patient-centric trials, reduce the duration and cost of clinical trials, and improve data quality. This research aims to explore the opportunities of DCTs in a post-COVID environment for accelerating patient access and driving innovation. Methods: A primary research programme was conducted with HTA and budget-holding stakeholders in the EU4, UK and US to explore perceptions of the acceptability of the methodology of DCTs compared to conventional clinical trials and the key opportunities and challenges associated with trials of this nature for communicating value within payer evaluations. Stakeholders provided insights on the extent to which the COVID-19 pandemic has increased the acceptability of DCTs in payer evaluations across key global markets. Results: Despite variability in the awareness of DCTs as a methodology for clinical development, this approach is generally well accepted by payers. Most payers agreed that the COVID-19 pandemic has changed the requirements for clinical trials, potentially increasing the acceptability of DCTs. This was seen to the greatest extent in the UK. Accelerating access, increasing engagement in trials, and an increased patients’ experience were identified as the most important opportunities associated with DCTs. However, challenges with this methodology also exist, including reluctance from regulatory authorities, implications of lack of contact with clinicians, and lack of control over clinical trials. Conclusions: Although conventional clinical trials remain the gold standard, HTA and budget-holding stakeholders in the EU, UK and US recognise the potential that DCTs have in clinical development and value demonstration for new medicines, particularly in a post-COVID-19 environment driven by remote working and regulatory response to the pandemic.

POS8279 A COMPARISON STUDY OF PRICES AND MARKET ACCESS DELAYS FOR ATUC DRUGS IN FRANCE VERSUS EU4 & UK

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Objectives: Autorisation Temporaire de mise en Cohorte de Cohorte (ATUC) is a French early access programme dedicated to promoted innovative treatments before marketing authorization, and limited to patients with the highest need. These treatments are funded by the National Health Insurance at a price freely set by pharmaceutical companies. This research aims to compare ATUCs prices versus launch prices in France, Germany, Italy, Spain and the United Kingdom, and to observe market access delays. Methods: Between January 1st, 2017 and December 31, 2019, 42 ATUC drugs were assessed by the Haute Autorité de Santé (HAS). The ATUC prices were available for 39 of these drugs in the French Ministry of Health database, and launch prices and dates were taken from PricercentreOne by Eversana (cut-off date on June 1, 2021). Appropriate statistical analysis was used. Results: ATUC price in France is usually one of the first available. The first country publishing prices after ATUC France was Germany mainly due to its free pricing policy, followed by the UK and Italy. Subsequently, any company published negotiated prices after a year which was followed by Spain. And France was the last country to negotiate a public reimbursed price. Compared to ATUC prices, observations show that prices in Germany are significantly higher (+11.9%, P=0.02) when they were freely set. And in Italy and Spain, there was no statistical difference in listed prices (P=0.08 and P=0.36) while in the United Kingdom (-7.5%, P=0.03) and France (-16.5%, P=0.01), the prices are significantly lower. Prices negotiated in Germany, one year after the launch were also significantly lower than ATUC (-11.1%, P=0.03). Conclusions: In France, where ATUC provides early access to a small part of the target population, high price expectations from companies may lead to longer delays in access, for the rest of the target population versus its reference countries.

POS8280 REVIEW OF REAL-WORLD DATA USE IN FRENCH ECONOMIC AND PUBLIC HEALTH ASSESSMENT COMMITTEE (CEESP) EFFICIENCY OPINIONS FOR ANTI CANCER DRUGS

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Objectives: Lowering the uncertainty is becoming more important in CEESP's economic evaluation of therapies in France so RWDs may prove increasingly useful. This work aims to describe the use of RWD in the economic evaluation of anticancer drugs. Methods: All efficiency opinions in oncology and onco-hematology published on HAS website from 2018 to 2020 were reviewed. In each opinion, every mention of RWD was identified as the most important for OS (75%) for RWD. And in Italy and Spain, there was no statistical difference in listed prices (P=0.08 and P=0.36) while in the United Kingdom (-7.5%, P=0.03) and France (-16.5%, P=0.01), the prices are significantly lower. Prices negotiated in Germany, one year after the launch were also significantly lower than ATUC (-11.1%, P=0.03). Conclusions: In France, where ATUC provides early access to a small part of the target population, high price expectations from companies may lead to longer delays in access, for the rest of the target population versus its reference countries.

POS8281 DO HTA BODIES HAVE AN ISSUE WITH DIVERSITY?

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Objectives: There is increasing recognition of the power of diverse working environments in bringing people from different backgrounds and ways of thinking together to encourage innovation, reduce discrimination and increase productivity. General diversity in healthcare decision-making may be particularly important, given the number of conditions and healthcare technologies that are associated with a single gender. This research evaluates the gender balance across several Health...