of health outcomes. This study aims to find out predictor factors of the public health outcomes at a province level in Turkey.

METHODS:

Life expectancy at birth and mortality are used as public health outcome indicators. Logistic regression and Random Forest classification generated by using 50, 100, and 150 trees were used to compare prediction performance of health outcomes. The results of different prediction methods were recorded changing the "k" parameter from 3 to 20 in k-fold cross validation. The Area Under the ROC Curve (AUC) was used as a measure of prediction accuracy. Prediction performance differences were tested using Kruskall-Wallis analysis and visualized on a heatmap. Finally, predictor variables of public health outcomes were shown on a decision tree.

RESULTS:

Study results revealed that Logistic regression outperformed Random Forest classification. The difference between all prediction methods to predict public health outcome indicators was statistically significant ($p<.000$). The heatmap shows that AUC values to predict mortality have superior performance when compared with life expectancy at birth. Decision tree graphs present that the most important predictor variables were total number of beds for mortality and percentage of higher education graduates for life expectancy at birth.

CONCLUSIONS:

The results of this study represent a preliminary attempt to determine public health outcome indicators. It is hoped that the results of this study serve as a basis to understand the determinants of health care outcomes at province level with focus on a developing country. This study illustrates that there is a need to spend extra effort for future studies to analyze public health outcomes to improve social welfare functions in health systems.

OP135 Confirmatory Versus Explorative Endpoints In Drug Approval Versus Health Technology Assessment

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INTRODUCTION:

The early benefit assessment of drugs in Germany and their preceded market authorization pursue different objectives, resulting in divergent decision-making strategies. This is reflected inter alia by the diverse inclusion of confirmatory endpoints within the assessments of oncological drugs. The pharmaceutical manufacturers are facing the challenge of meeting the requirements for both evaluation processes by the available evidence and avoiding hereby negative early benefit assessments. This is mainly due to the concept of mutually relevant clinical trials.

METHODS:

Identification and gathering of the endpoints is based on a specifically developed guide. The extracted data from the documents of completed assessments up to July 2015 are used to estimate both separately and together the impact of explorative in relation to confirmatory endpoints on the drug approval and early benefit assessment, by contrasting the European Medicines Agency's risk-benefit-ratio and the benefit-harm-balancing of the national Health Technology Assessment (HTA) jurisdiction.

RESULTS:

Twenty-one of fourty-one studies' oncological assessments could be included in the endpoint analysis. From a procedural point of view both the drug approval and the early benefit assessment seem to be not confirmatory since they include explorative endpoints as well. Yet, drug approval is in terms of quality of endpoints more confirmatory than early benefit assessment since it contains a higher proportion of

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primary endpoints. The latter implies only in 67 percent of the assessments a primary endpoint to be relevant for the benefit-harm-balancing. Moreover, explorative mortality endpoints reached the highest agreement and explorative endpoints capturing health-related quality of life no agreement, referring to the mutual relevance of endpoints for the risk-benefit-ratio and the benefit-harm-balancing.

CONCLUSIONS:

The missing information transparency of the assessment reports compared to the information offered within the early benefit assessment makes an assignment of endpoints with respect to the mutually relevant clinical trial sometimes troublesome. To warrant, in the long run, a broader confirmatory basis for decisions in health care supported by HTA, a closer inter-institutional cooperation of approval authorities and German HTA jurisdictions seems favorable.

OP136 Clinical Benefit Of Oncological Therapies At The Time Of Approval

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INTRODUCTION:

In the last decade an increasing number of high-priced, new cancer treatments received marketing authorization in Europe. What is actually known about the clinical benefit of those therapies at the time of approval needs to be elucidated in order to inform decisions about the use and reimbursement of these novel treatment options. Thus, the aim of the current analysis was to systematically investigate oncological therapies approved between January 2009 and April 2016. We extracted, as well as quantified the level of knowledge of the clinical benefit at the time of marketing authorization.

METHODS:

To assess the benefit of new interventions as well as expanded indications, we extracted the median gain of the two study endpoints: progression-free survival (PFS) and overall survival (OS). Information is based on approval documents provided by the European Medicines Agency (EMA) and assessments from the Austrian Horizon Scanning programme (HSO). We included all cancer therapies approved in Europe between 1 January 2009 and 15 April 2016.

RESULTS:

Cancer drugs for 134 new indications approved since 2009 were identified. In the case of thirty-seven indications (27 percent), no data was available for PFS or for OS. A positive difference in median overall survival was reached by seventy-six licensed indications (55.5 percent); twenty-two (16 percent) of them showed a difference of more than three months. Regarding the study endpoint progression-free survival, an improvement was shown in ninety indications (65.2 percent).

CONCLUSIONS:

Scarce knowledge regarding the clinical benefit of anti-cancer therapies is available at the time of approval. In addition, the survival benefit of the approved indications is less than three months in the majority of approved therapies.

OP138 Access To Orphan Drugs In The United Kingdom And Other European Countries

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INTRODUCTION:

Under the Orphan Regulation, the European Medicines Agency (EMA) intended to incentivize the research and development of new treatments for rare and

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