recommendations. Its Dutch counterpart, ZI, issued only 8% of negative decisions to TCTs. The mode for a success rate in the Netherlands was special policy that enabled reimbursement of TCTs without CA.

PCN251  THE CANCER DRUGS FUND: A SYSTEMATIC ANALYSIS OF THE REQUIREMENTS FOR INCLUSION ON THE ENGLISH NATIONAL LIST OF DRUGS FOR PRIORITY FUNDING McNamara L, McNamara S Roche Products Ltd, Welwyn Garden City, UK OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access therapies that are not routinely available on the National Health Service (NHS). In April 2013, NHS England became responsible for the management of the CDF with a single national list of drugs for prioritised funding. As the CDF has recently been extended to 2016, it is increasingly important to understand the key clinical characteristics of drugs on the CDF list to guide future drug submissions. Therefore, we decided to define: METHODS: CDF appraisal reports were sourced from the NHS England website (April 2013 – March 2014) and the date, decision, and key rationale were extracted. RESULTS: 56 CDF decision summaries were available, 14 (25%) received full approval, 10 (18%) received conditional/restricted approval, 28 (50%) were rejected, and 4 (7%) were referred to commissioning. The key clinical attributes of each oncologic were given a numerical scoring that sum to a possible maximum of 21 and minimum -4. The maximum score of any drug appraised was +8 and the minimum was -1. Excluding appraisals referred to commissioning, 16/18 appraisals scoring ≥2 were rejected (89%) compared to only 5/25 (20%) scoring ≥2 (65% primarily due to trial comparator choice). Of these 9 were not scored due to a lack of appropriate (SACT) data in the submission. The maximum score of any EMA oncologic (with no submissions, efficacy scores were halved), 5 of which were approved. CONCLUSIONS: A score of ≥2 seems to be the key clinical threshold above which most drugs are accepted whereas few approval are rejected. Given that 43/47 scoring 5 or more were approved.

PCN252  TESTING THE UTILITY OF THE NHS’S SYSTEMIC ANTI-CANCER THERAPY DATA SET FOR MULTICENTER PREDICTION McNamara L, McNamara S Roche Products Ltd, Welwyn Garden City, UK OBJECTIVES: The price of a new medicine should reflect the value it offers to patients, the health care system and society more broadly. However, with current pricing, manufacturers can only set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as being too high. This paper seeks to identify where a restricted criteria set can lead to patients being denied access to medicine in certain indications. METHODS: The implementation of a pricing model where there is differentiated value of a medicine across indications, line of therapy or if used as a mono/combination therapy requires the use of real world drug utilisation data. The Personalised Reimbursement Models project is at the forefront of the development and implementation of innovative pricing approaches in the UK. This project includes identifying and developing the indicative criteria in order to introduce Multi-Indication Pricing (MIP) into the NHS in the UK. We have worked alongside NHS Trusts and national bodies in a joint working project to validate and test the utility of the Systemic Anti-Cancer Therapy (SACT) data. RESULTS: This joint working project demonstrate that SACT has the potential to allow implementation of MIP in England. CONCLUSIONS: Following completion of this work we hope SACT will be used to introduce MIP in England - this will administer the economic burden of data collection for commercial schemes for oncology or cancer medicine and for the value they provide in each of their uses and ensure that patients are not disadvantaged due to having a condition potentially treatable by a product with multiple indications.

PCN253  ONCOLOGY PRODUCTS IN THE AMNOG PROCESS – LEARNING FROM A SUCCESSFUL DOSSIER SUBMISSION Dehnen J, Goldhagen K IMS Consulting Group, Munich, Germany OBJECTIVES: Since AMNOG reform has taken effect 3.5 years ago, 78 dossiers have been evaluated by the G-BA. Especially with oncology agents, 28 products have started the process and G-BA has finalized decisions for 25 dossiers. In 20 cases additional benefit was granted. Therefore, the success rate of oncologic products is 80% and much higher than the success rate of non-oncology products (29%). METHODS: An analysis of all oncology assessments will reveal key drivers responsible for the positive assessments by IQWiG and G-BA. Besides the study design (R2G vs. indirect comparison), and comparator choice the analysis will focus on submitted end points. It will be evaluated which endpoints contribute most in oncology indications to additional benefit. RESULTS: Additional benefit is assessed based on patient relevant endpoints (mortality, morbidity, quality of life & safety). More than 55% of submitted endpoints fall in the safety category, followed by morbidity (approx. 30%), mortality (approx. 10%) and quality of life (approx. 5%). The most important endpoint for the additional benefit (58%), where the G-BA granted additional benefit in 18 out of 20 dossiers primarily based on OS data. In terms of morbidity, FFS, ORR and “Time to Pain Progression” are the top three most submitted morbidity endpoints; however, only “Time to Progression” lead to additional benefit in 2 out of 3 cases. In conclusion, quality of life contributing endpoints are required in order to evaluate additional benefit. CONCLUSIONS: OS will continue to be the most additional benefit contributing endpoint in oncology. In the absence of OS, FFS will not be helpful in the overall additional benefit decision by G-BA, whereas the MIF can justify FFS to be patient relevant according to IQWiG methodology. Although QoL is an accepted endpoint by G-BA, due to the high methodological standards set by G-BA and IQWiG, manufacturers should de-prioritize this endpoint.

PCN254  MEDIA COVERAGE OF THE NICE FIRST DRAFT CONSULTATION GUIDANCE FOR TRASTUZUMAB EMANASITUBE (KADCYLA) IN BREAST CANCER Macaulay R HERON Commercialization, London, UK OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criteria. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncology). The goal of our study is to examine how the media currently report NICE decision-making, focussing on the NICE appraisal of KADCYLA in breast cancer. METHODS: A systematic review of the criteria for accessing drugs under the CDF and how this compares to access under NICE. OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable cancer patients to gain access to therapies that are not routinely available on the NHS. However, this fund has been critised for providing funding for therapies that have not been shown to be cost-effective by the National Institute for Health and Care Excellence (NICE). This review aims to define how the media currently report NICE decision-making, focussing on the NICE appraisal of KADCYLA in breast cancer. RESULTS: CT fully recommended 14/14 (100%) oncologics appraised on the basis of pivotal Phase II data, with 10/14 obtaining ASMR I (50%). 6/6 (100%) oncologics appraised on this basis were deemed to offer some added benefit, avoiding reference pricing (5/6 were orphan drugs which are not subject to a benefit assessment). NICE approved 5/7 (71%) and 2/7 (29%) for Phase I and II, respectively. For any oncologic approved by the EMA on the basis of pivotal Phase II data (up to March 2014) and the decision and key rationale were analysed. CONCLUSIONS: CT fully recommended 14/14 (100%) oncologics appraised on the basis of pivotal Phase II data, with 10/14 obtaining ASMR I (50%). 6/6 (100%) oncologics appraised on this basis were deemed to offer some added benefit, avoiding reference pricing (5/6 were orphan drugs which are not subject to a benefit assessment). NICE approved 5/7 (71%) and 2/7 (29%) for Phase I and II, respectively. For any oncologic approved by the EMA on the basis of pivotal Phase II data, favourable ASMR and benefit ratings can be awarded on this basis. CONCLUSIONS: For any oncologic approved by the EMA on the basis of Phase II data, favourable ASMR and benefit ratings can be awarded on this basis. CONCLUSIONS: For any oncologic approved by the EMA on the basis of Phase II data, favourable ASMR and benefit ratings can be awarded on this basis. CONCLUSIONS: For any oncologic approved by the EMA on the basis of Phase II data, favourable ASMR and benefit ratings can be awarded on this basis.