Outcomes from our population-based study of older patients diagnosed 1997–2012 appear comparable with recent phase II studies of selected ‘fit’ patients [2, 5]. These single-arm studies again may reflect improved patient health and willingness to treat aggressively, rather than improved chemotherapy regimens. Well-conducted clinical studies for ‘fit’ and ‘unfit’ older patients are required to better understand outcomes in the modern era.

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The ESMO magnitude of clinical benefit scaling tool: from theory to practice

The article by Cherny et al. in this journal presenting the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) provides a very relevant contribution to the discussions how to assess new available cancer therapies in terms of their innovative add-on, clinical benefit and value for patients [1]. The ESMO-MCBS is advancing the critical public policy debate of value in cancer care.

Providing a standardised template for grading clinical benefit, the scaling tool facilitates semi-quantitative clinical benefit assessments. Caution has been taken by the ESMO task force to validate the MCBS through field testing involving more than 300 oncologists and expert statisticians plus subsequent applications of the scale to contemporary and historical controlled clinical trials.

Similarly, by their case-by-case approval decisions, the European Medicines Agency (EMA) has set over many years thresholds for efficacy judgements [2]. The Agency itself is moving forward to a quantitative approach for benefit–risk (BR) evaluations [3], and is in the process to tackle the so-called fourth hurdle of effectiveness through joint evaluations with the national authorities which are responsible for health technology assessment (HTA) and pricing and reimbursement decisions [4]. The nationally acting authorities are attempting, under the roof of the European network for HTA (EUnetHTA), to effectuate more reliable and stringent processes for the relative effectiveness assessments of new therapeutic modalities [5].

In contrast to the regulatory decision-making process—all approvals of new cancer drug are granted since 2006 EU-wide by the EMA—the pace of European integration in terms of HTA and pricing and reimbursement decisions is however delayed resulting in the well-documented lack of equal access to cancer drugs across the EU [6]. Decisions are taken nationally with sometimes limited transparency, and the assessment methodology is still in the stage of refinement. Currently decision patterns just start to emerge, as demonstrated exemplarily by the analysis of early benefit assessments (EBA) done by the German G-BA (Figure 1).

The continuance of the predominantly national HTA policy decisions, often driven by more or less recognisable cost-containment objectives, bears undoubtedly a risk to impede the objective of EU citizens’ rapid and equal access to high-quality medical care. In face of a passionate public debate on the costs and value of novel cancer therapies, the MCBS endeavor can succeed only, if ESMO’s dialogue with the national public policy makers is continued and intensified.

From theory to practice: the ESMO-MCBS may deliver its true significance, if the hitherto undertaken tool validation is pursued by comparisons with outcomes of national HTA decision-making, notably from those EU member states with relevant demographic weight. Gaining external validity would not only help to improve the accuracy of the MCBS, but should allow ESMO to assess in a watchdog-like manner whether and to what extent the actual HTA and value-decision-making across different EU countries and policy makers is well-balanced between access to innovation and pricing efficacy on one hand and adequate resource allocation and cost-containment on the other.
**Disclosure**

The author declares no conflicts of interest with respect to this letter. Outside this work, MH reports having received honoraria from AstraZeneca, Bristol Myers Squibb, ImmunoGen, Onconova, MerckSerono and Roche during the last 3 years.

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**Figure 1.** Outcomes of EBA evaluations by the German Federal Joint Committee (G-BA). In January 2011, the legal Act on the Reform of the Market for Medicinal Products (AMNOG) entered into force. Since, all new medicines marketed in Germany are assessed and graded into six categories: four of them are used if added benefit is shown (major, considerable, minor or non-quantifiable), the two remaining categories relate to no added benefit (no) or even reduced benefit (less). Analysed are all G-BA decisions on new cancer drugs approvals granted from January 2011 to December 2014 by the EMA based on randomized controlled trials with overall survival as (co-)primary endpoint and an estimate for the control arm (placebo or verum) expecting overall survival less or equal to 1 year. In case of split G-BA assessments resulting from the consideration of subgroups, the highest-graded added benefit level is displayed. (Figure modified from Hartmann [7].)