

Mind the Gap

Assessing the different data requirements between regulatory approval and health technology assessment for oncologics

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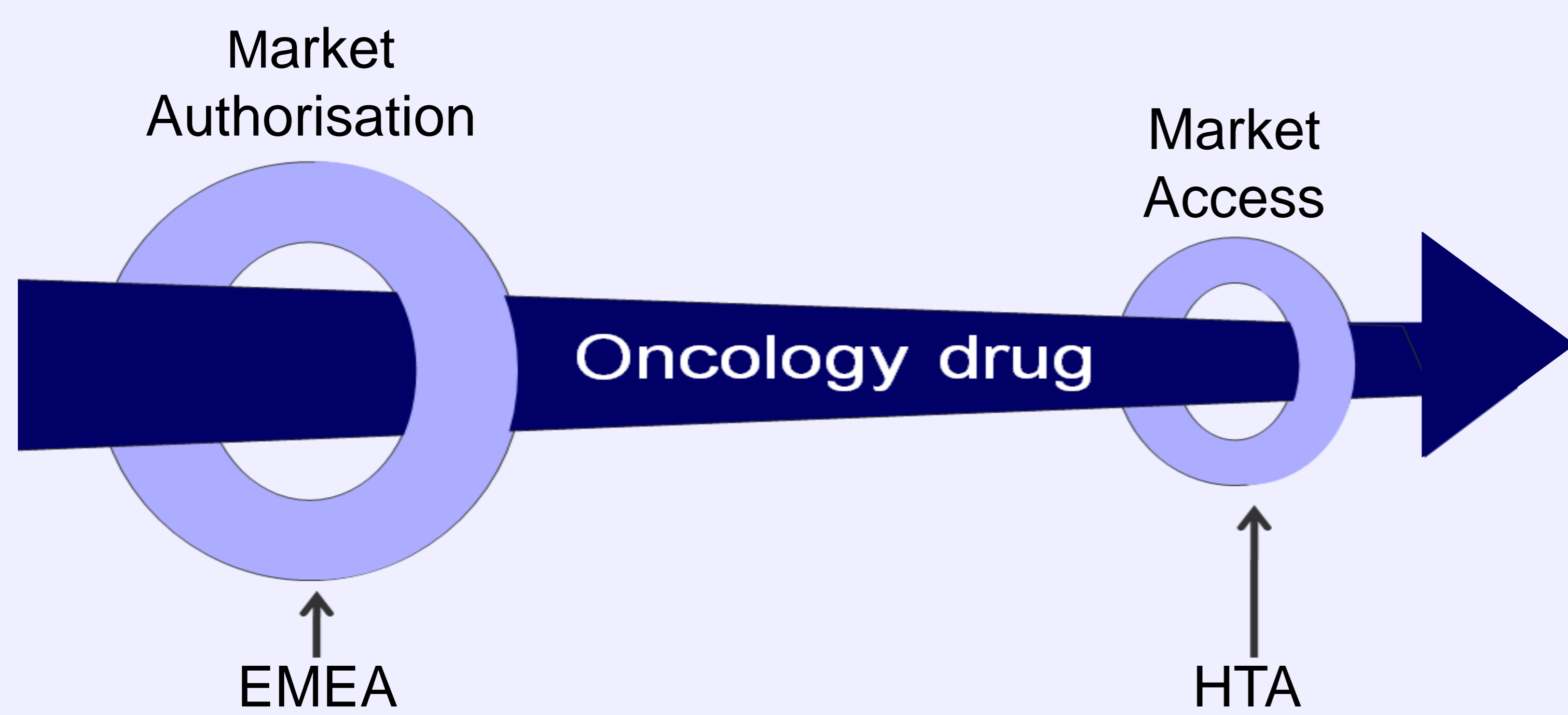
Objectives and Methodology

Objectives: Across Europe, health technology assessment (HTA) and post market authorisation bodies are requesting more clinical evidence before allowing market access. These raised expectations create an imbalance between what clinical trial data is required for market authorisation and what is required for market access and has implications for equity of access to oncology drugs for patients. To address the growing gap between regulatory and market access requirements, this research seeks to provide a better understanding of what payer expectations are and what is driving those expectations by examining the differences in data requirements, as well as trends on which data are required for market authorisation and access.

Methodology: A review was made of twelve EMEA (European Medicines Agency) approved oncology drugs (Tyverb, Tassigna, Torisel, Atriance, Revlimid, Sprycel, Sutent, Nexavar, Evoltra, Tarceva, Velcade and Glivec) and their EMEA European Public Assessment Reports (EPARs), Transparency Commission (TC) reports, National Institute for Health and Clinical Excellence (NICE) technology appraisals, Scottish Medicines Consortium (SMC) and All Wales Medicine Strategy Group (AWMSG) reports. France and the UK market systems were selected because of the stark contrasts between their drug assessment processes.

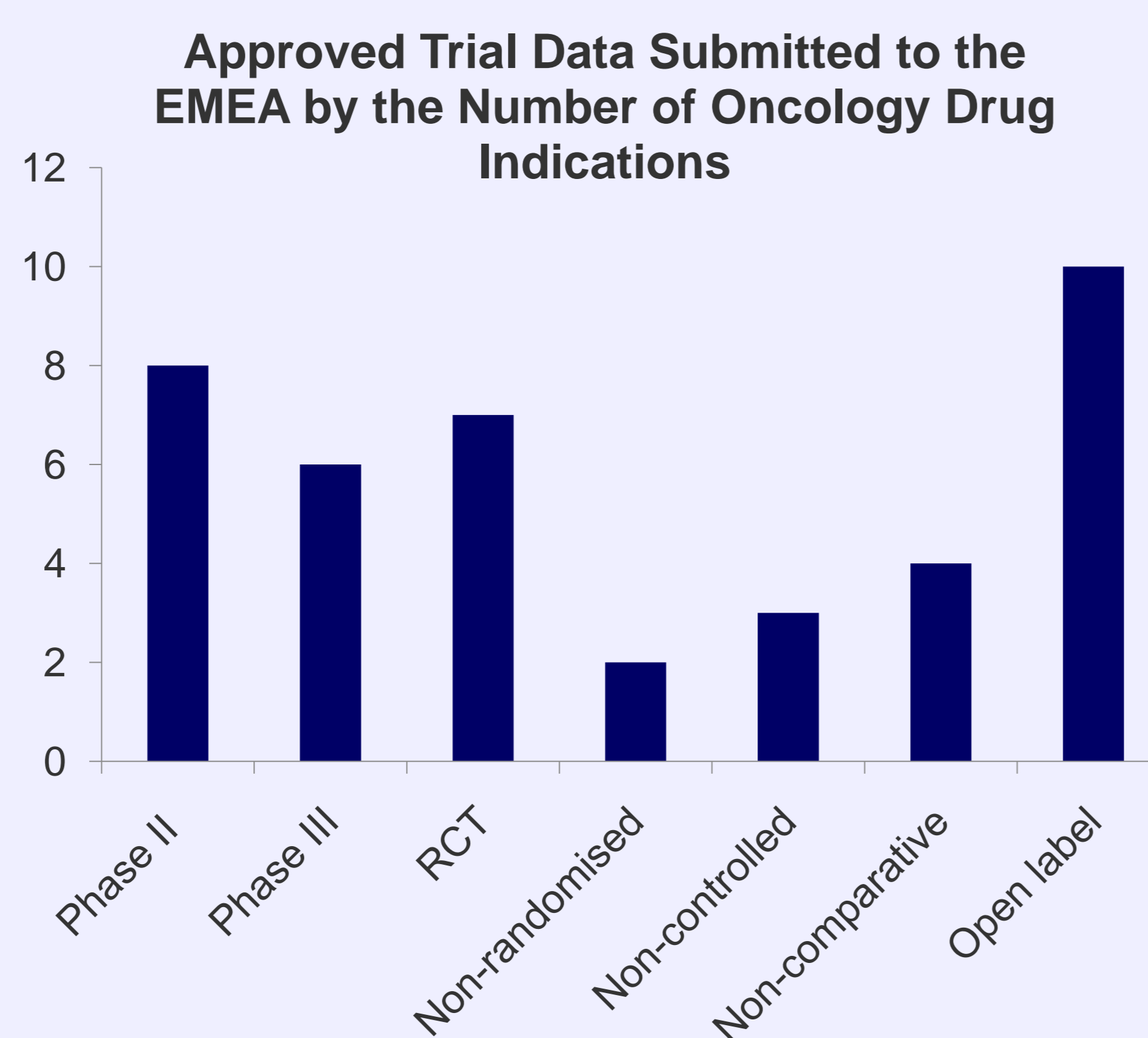
Results

Differences in oncology clinical trial data required for market authorisation and for HTA appraisals present difficulties for market access



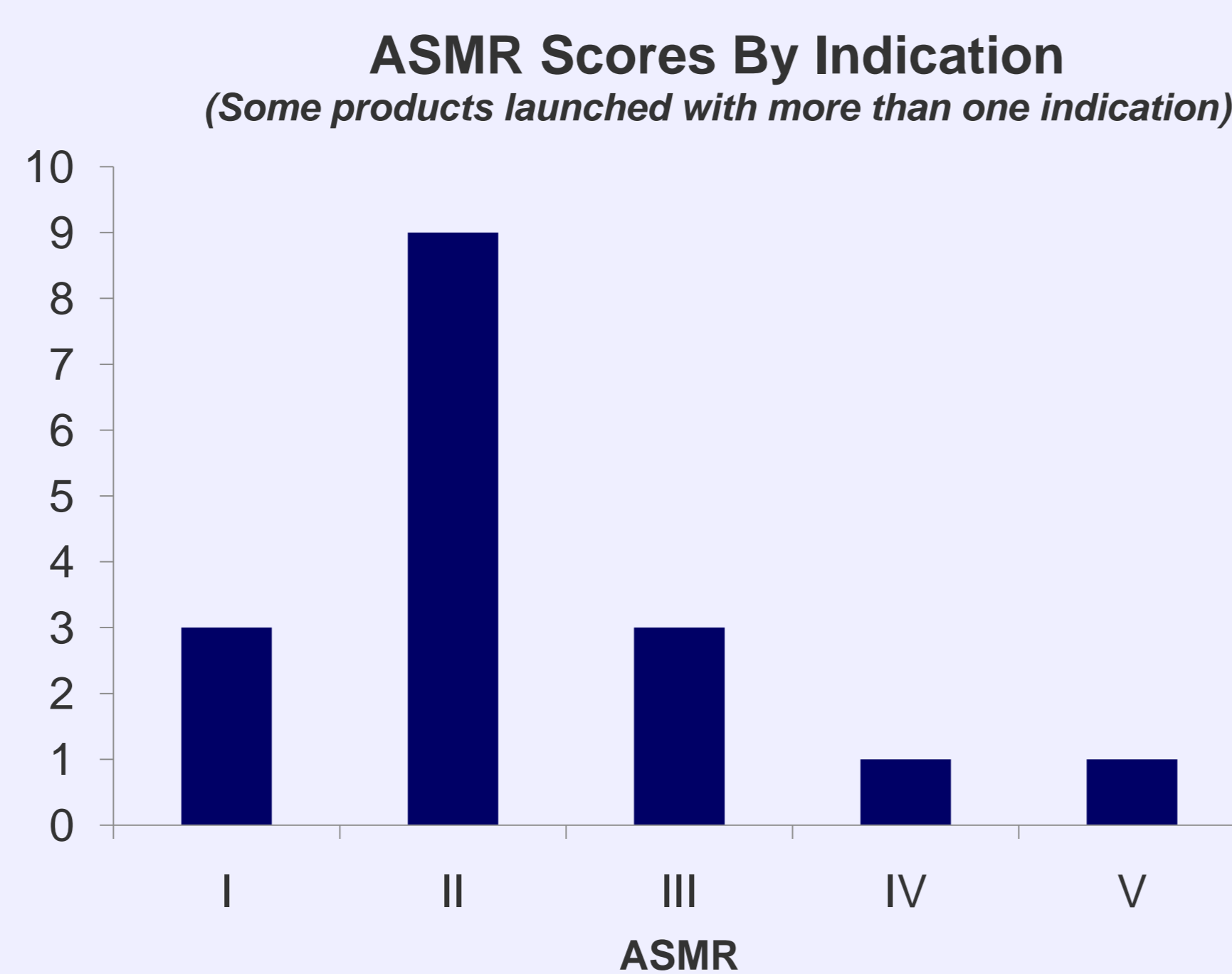
Market Authorisation

- The EMEA is, in some circumstances, willing to grant market authorisation based on phase II clinical trial results
- The EMEA takes into account high unmet need or exceptional efficacy data
 - Atriance and Evoltra were licensed under exceptional circumstances due to sufficient phase II clinical effectiveness and the difficulty of gathering data in a small patient population



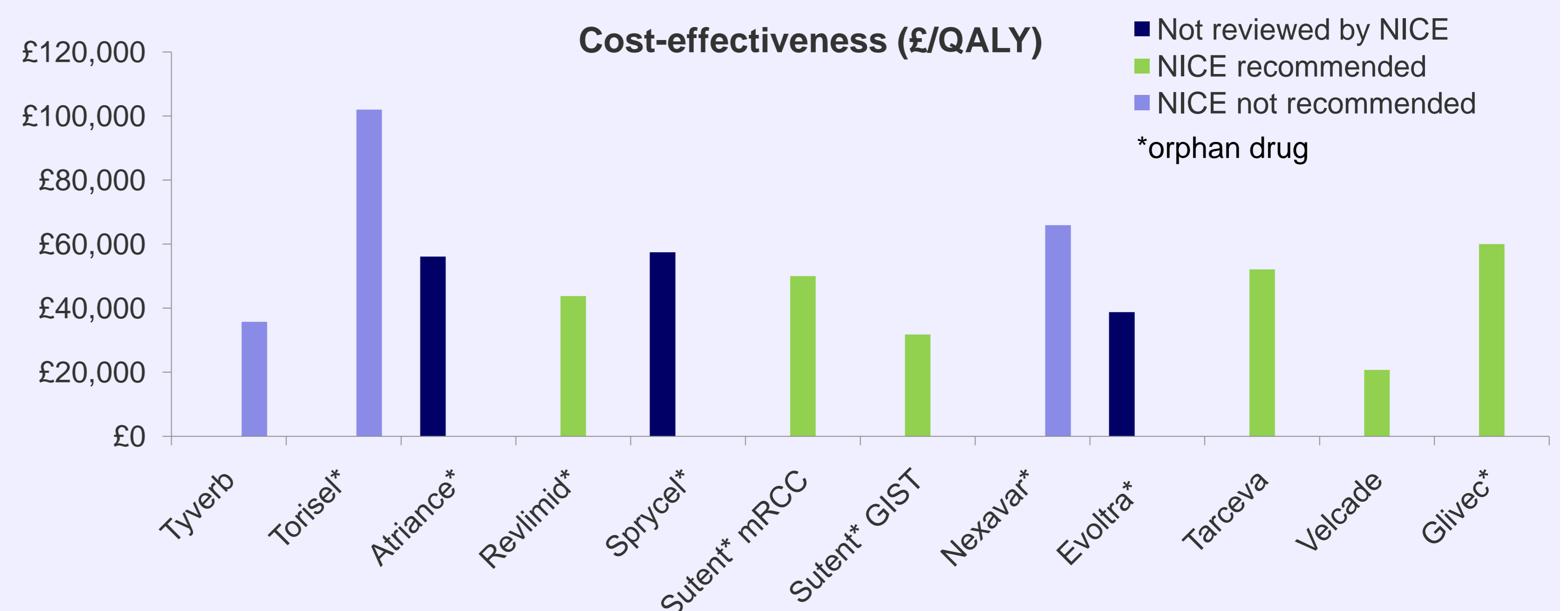
France Driven By Innovation

- The majority of the oncology agents studied were awarded an ASMR score of II, indicating substantial improvement over existing treatments
- Manufacturers are often required to submit post market clinical studies. For example, the TC required a follow up study for Velcade
- Evidence of improved health benefit is also valued
 - Tarceva's metastatic pancreatic cancer indication was not recommended for reimbursement due to insufficient evidence of health gain over its comparator (Gemzar)



Cost-Effectiveness in the UK

- NICE uses cost-effectiveness to try to ensure value for money and equality in prescribing across the UK
- In general, interventions with a cost per QALY above NICE's £30,000 threshold face the risk of negative guidance, but the threshold appears to be more flexible for oncologics
 - Those approved that had a cost per QALY of £60,000 or lower and were generally orphan drugs (4 out of 5 approved)
- To avoid negative guidance (which significantly reduces access), some manufacturers have engaged in risk-sharing agreements with the payer to lower the cost per QALY of their oncology drugs
 - Revlimid, Sutent, Tarceva and Velcade were positively appraised because the manufacturers agreed to provide free goods



Access Inequality

- The EMEA evaluates on efficacy and safety only
- However, market access bodies also assess products in terms of affordability
- The markets' different methods of evaluating new products result in different market access decisions; which contributes to access inequality between the two countries
- According to IMS data, France spends €32 per capita on oncology drugs, while the UK spends €12
- According to Graeme Poston, UK cancer specialist, France spends €8.14 per capita on breakthrough cancer drugs, while the UK spends €0.66
- The EURO CARE working group found that the five year relative cancer survival in France was 56.6% for women and 45.5% for men, compared to 51.4% for women and 41.4% for men in the UK

Market Access Body	✓	✗	?
France TC	All drug indications except Tarceva for metastatic pancreatic cancer	Tarceva (metastatic pancreatic cancer)	---
UK NICE	Revlimid, Sutent, Tarceva (NSCLC only), Velcade, Glivec	Torisel, Nexavar, Tyverb (interim decision)	Tassigna, Atriance (SMC ✓), Sprycel (SMC ✓ / AWMSG x), Evoltra (SMC ✓ / AWMSG ✓)

Improving Access

- To increase access to oncology medicines, France introduced the Cancer Plan which prioritises equity of access to oncology care
- In the UK, authorities have introduced policies to improve access to innovative drugs and help fine-tune the UK's approach to drug assessment (the Cancer Plan, Cancer Reform Strategy, End of Life Guidance and Innovation Pass Scheme), but their impact is questionable

Conclusions

- In France, virtually all of the oncologics were granted market access, contributing to good survival rates that are improving
- In the UK, about half of the oncologics were approved, contributing to poor health outcomes that are not improving
- If improving the UK's record of treating oncology is a measure of NICE's success, then NICE needs to continue to pursue refinements to their assessment methodology
- However, payers and manufacturers need to reassess their oncology expectations
 - While an oncology agent may provide a small incremental benefit to existing treatments, this may still be a significant benefit to the patient