Utrecht University

Pharmacoepidemiology
and Clinical Pharmacology

HPR10

Added Benefit and Revenues of Oncology Drugs Approved by the European Medicines Agency Between 1995 and 2020

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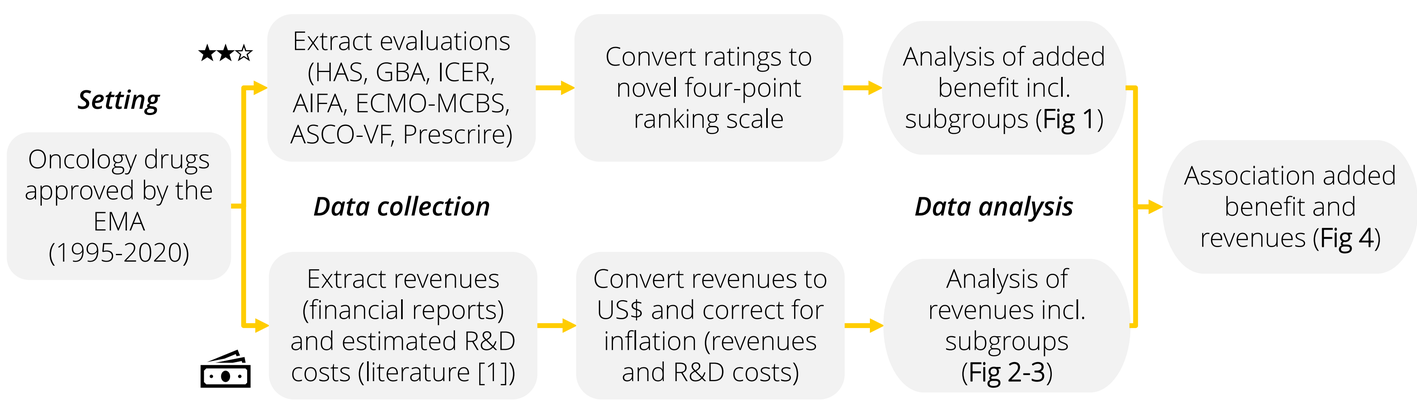
INTRODUCTION

- This study assessed the added benefit and revenues of oncology drugs approved by the European Medicines Agency (EMA) between 1995 and 2020.
- Study objectives:
  i. Evaluate added benefit
  ii. Evaluate (cumulative) revenues
  iii. Evaluate association added benefit and revenues
- Subgroup analyses were performed to examine potential disparities among drugs approved via standard marketing authorization (SMA), conditional marketing authorization (CMA), and authorization under exceptional circumstances (AEC).

METHODS



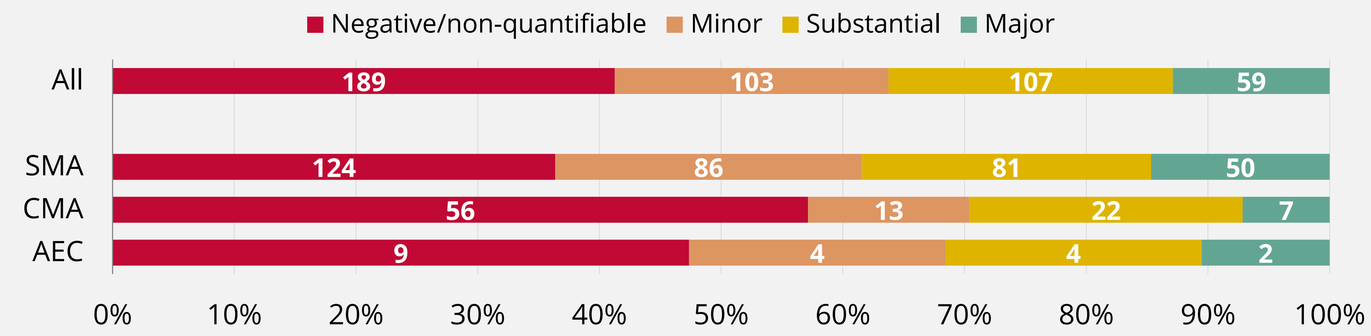


Fig 1. Distribution of the extracted ratings (n=458) among the four levels of added benefit.

RESULTS

i. Added benefit:
- 189 (41%) added benefit ratings were negative/non-quantifiable (Fig 1).
- Negative/non-quantifiable added benefit ratings were more frequent for CMAs and AECs than for SMAs (RR 1.53, 95%-CI 1.23-1.89) (Fig 1).

ii. Revenues:
- Median time to offset median R&D costs of $684 million was three years (Fig 2).
- 90% of drugs recovered these costs within eight years (Fig 3).
- CMAs generated lower revenues and took longer time to recover R&D costs than SMAs (four versus three years) (Fig 2).

iii. Association added benefit and revenues:
- Drugs with higher added benefit ratings generally had greater revenues (Fig 4).

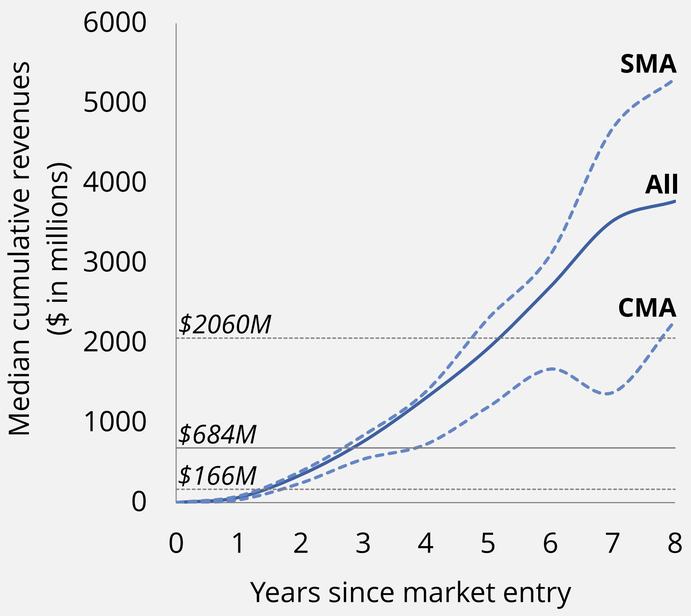


Fig 2. Median cumulative revenues between year 1 (n=109) and year 8 (n=55) since market entry in relation to estimated R&D costs (min-med-max) [1].

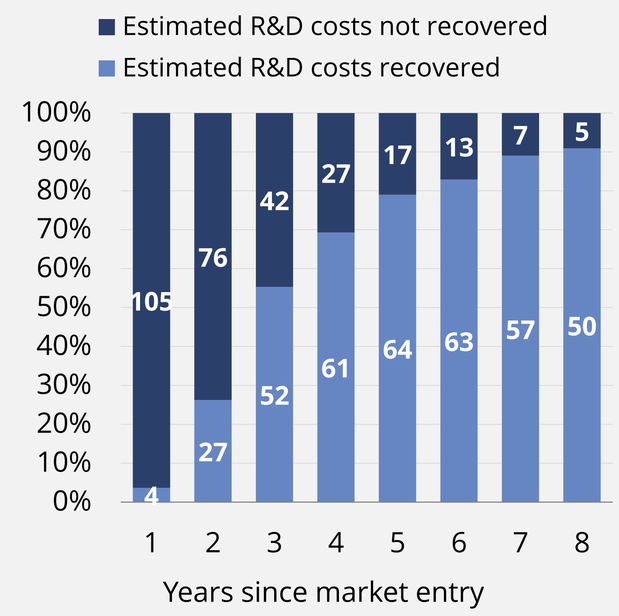


Fig 3. Number of drugs per year that had recovered median R&D costs ($684 million [1]).

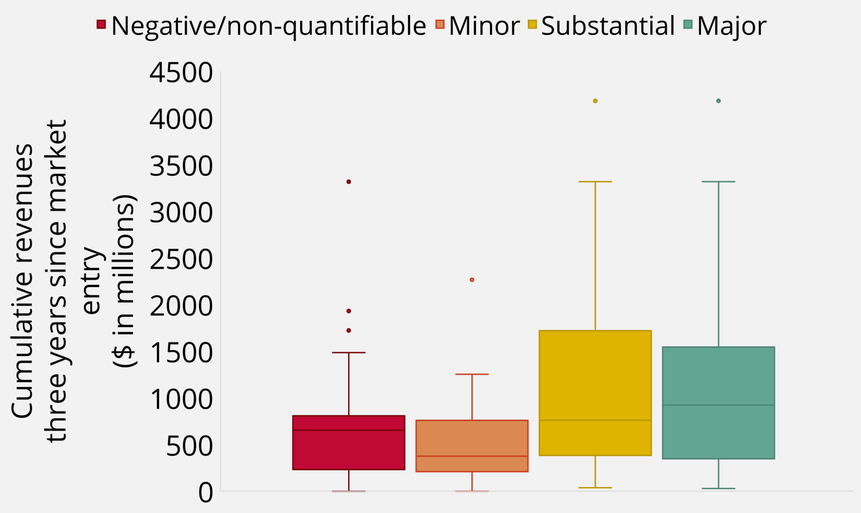


Fig 4. Median cumulative revenues of oncology drugs three years since market entry (n=43), with ratings of negative/non-quantifiable (n=50), minor (n=32), substantial (n=38), or major added benefit (n=29).

CONCLUSION

- Our study shows that many oncology drugs approved by the EMA (1995-2020), especially those via expedited pathways, provide minimal or no added benefit.
- We found alignment between added benefit and revenues, but even drugs with low added benefit are able to recover estimated R&D expenses within a short period.
- Further collaboration on the interface of drug regulation and reimbursement could create opportunities to incentivize the development of highly beneficial drugs that address unmet needs more effectively.

REFERENCES

1 — Prasad V, Mailankody S. Research and development spending to bring a single cancer drug to market and revenues after approval. JAMA Intern Med 2017; 177: 1569–1575.

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