The economics of personalised medicine: threat or opportunity?

Andrew Briggs

Professor of Health Economics, LSHTM, UK

Visiting Senior Research Scientist, MSKCC, New York, USA

Memorial Sloan Kettering Cancer Center

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The economics of personalised medicine

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  - Opportunity costs (indication specific pricing)

Cancer Treatment Trends

- Precision medicine approaches are becoming more commonplace:
    - 60% of the new active substances approved in the US in 2018 were associated with predictive biomarkers.

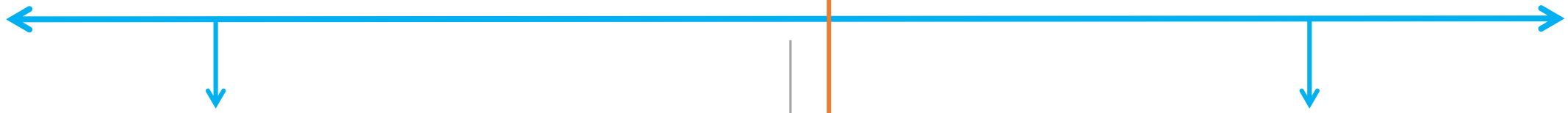
- Innovative oncology therapies are moving quickly through R&D and regulatory filling:
    - 40% of them were approved based on Phase I or II trials and 20% of them included single-arm trials.

IQVIA. Global Oncology Trends 2019. https://www.iqvia.com/institute/reports/global-oncology-trends-2019.

What is tumor-agnostic?

CURRENT/HISTORIC view of cancer treatment

EMERGING/EVOLVING view of cancer treatment



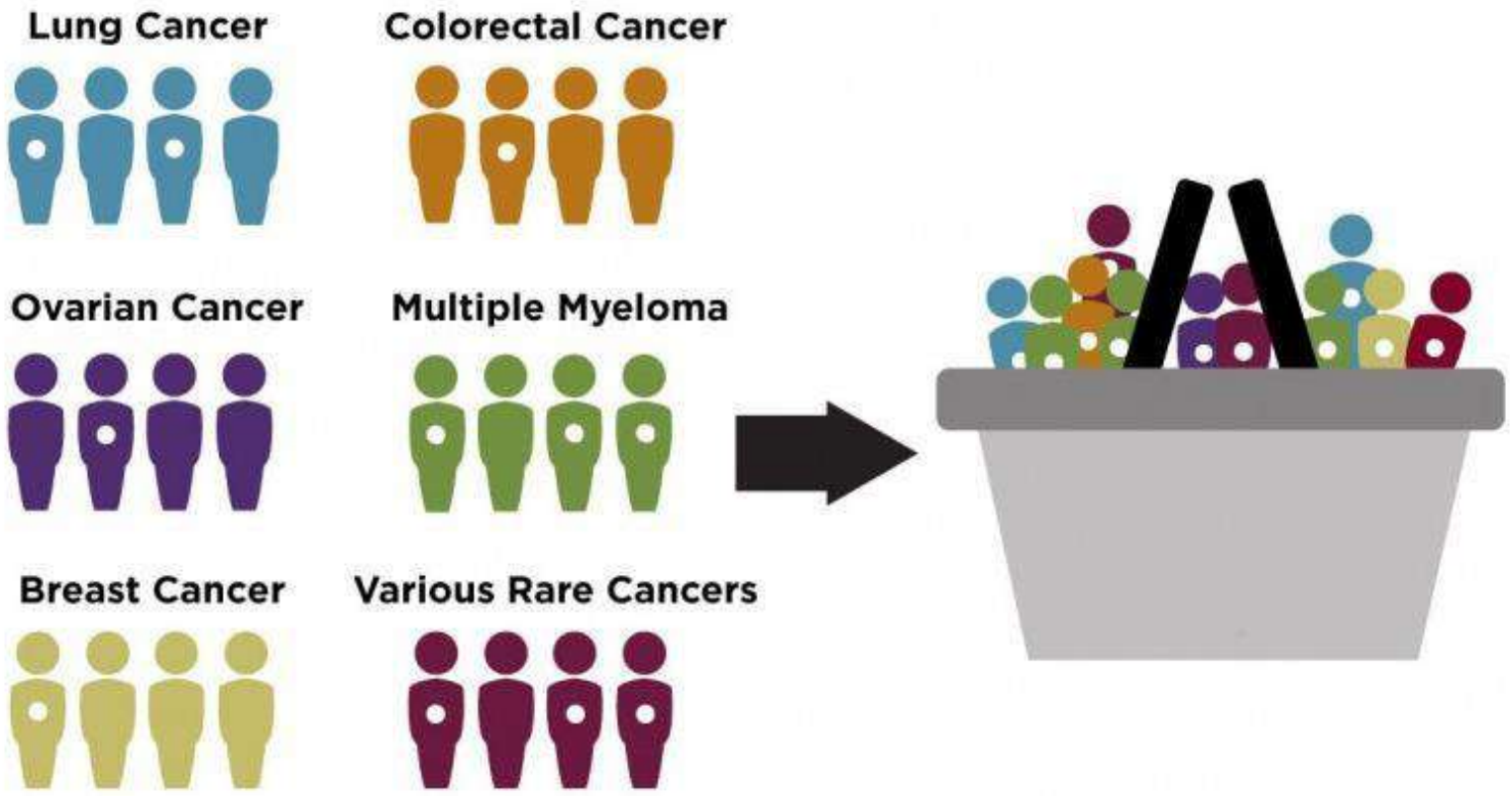
Focus on <u>where</u> cancer presents in the body

- Trials and guidelines by tumor type and location

Focus on <u>what causes</u> cancer within a given patient

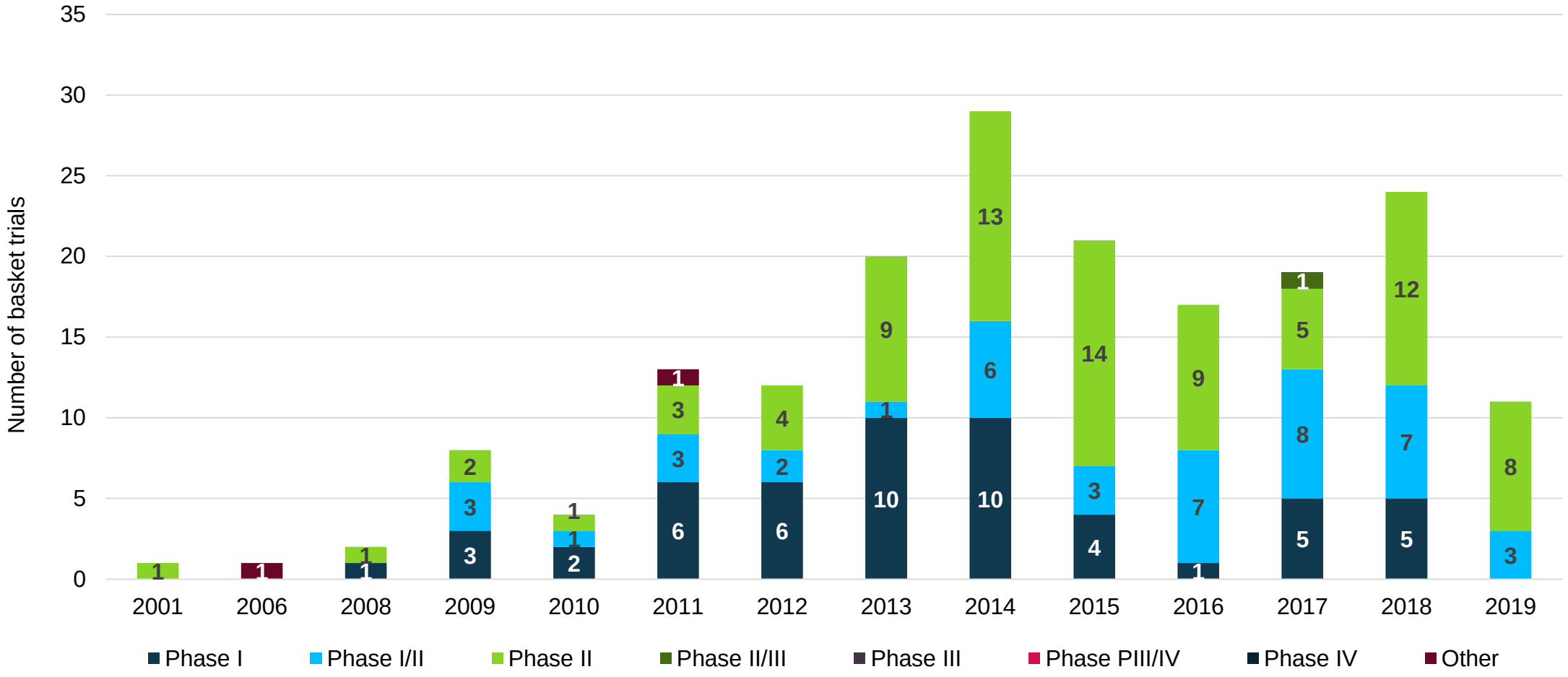
- Pan-tumor or histology-independent
- Primary oncodrivers
- Therapy based on biomarkers or genetic characteristics of patients tumor
- Examples: Keytruda (MSI-H and dMMR), Vitrakvi (NTRK fusions)

What are essential features of a basket trial?



Dubuque C et al. Trinity Partners. Oncology Basket Trials: An Emerging Paradigm Shift in Trial Design & Treatment Approaches? Available at: http://www.trinitypartners.com/files/6115/2656/9438/Oncology_Basket_Trials_-_Trinity_Partners.pdf

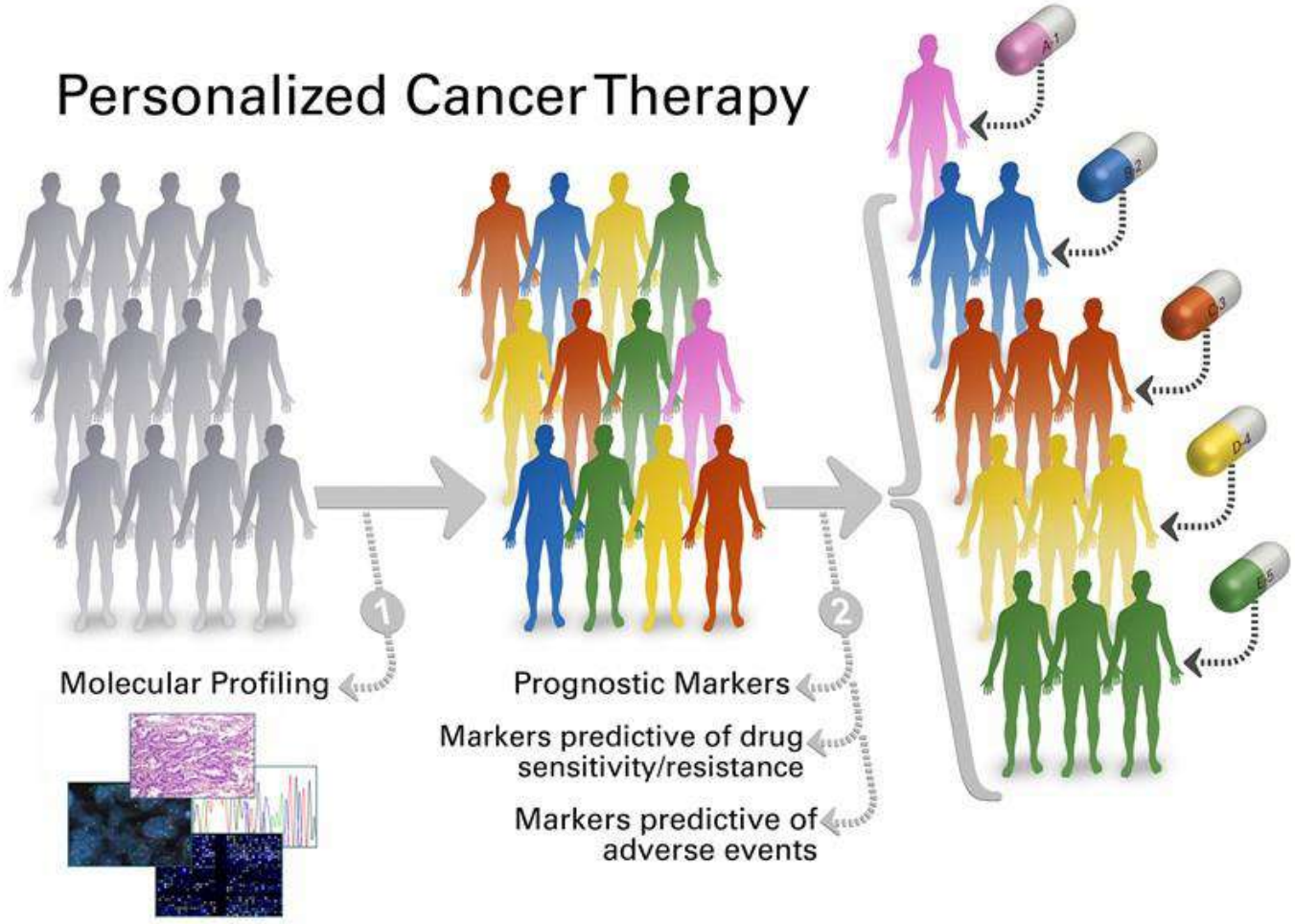
Advances in the science of oncogenes drives increase in multi-indication trials and potential for pan-tumor indications



Source: Infopharma analysis of Trialtrove: July 2019

Opportunity cost I: Testing (NGS)

- Molecular profiling is expensive
- TRK-Fusion gene is rare
- Specificity is therefore an issue (false positives)



Opportunity cost II: AA erodes evidence base

Research

JAMA Internal Medicine | Original Investigation

Assessment of the Clinical Benefit of Cancer Drugs Receiving Accelerated Approval

Bishal Gyawali, MD, PhD; Spencer Phillips Hey, PhD; Aaron S. Kesselheim, MD, JD, MPH

JAMA Intern Med. 2019;179(7):906-913. doi:10.1001/jamaintern
Published online May 28, 2019.

CONCLUSIONS AND RELEVANCE Confirmatory trials for one-fifth (n = 19 of 93) of cancer drug indications approved via the FDA's accelerated approval pathway demonstrated improvements in overall patient survival. Reassessment of the requirements for confirmatory trials may be necessary to obtain more clinically meaningful information.

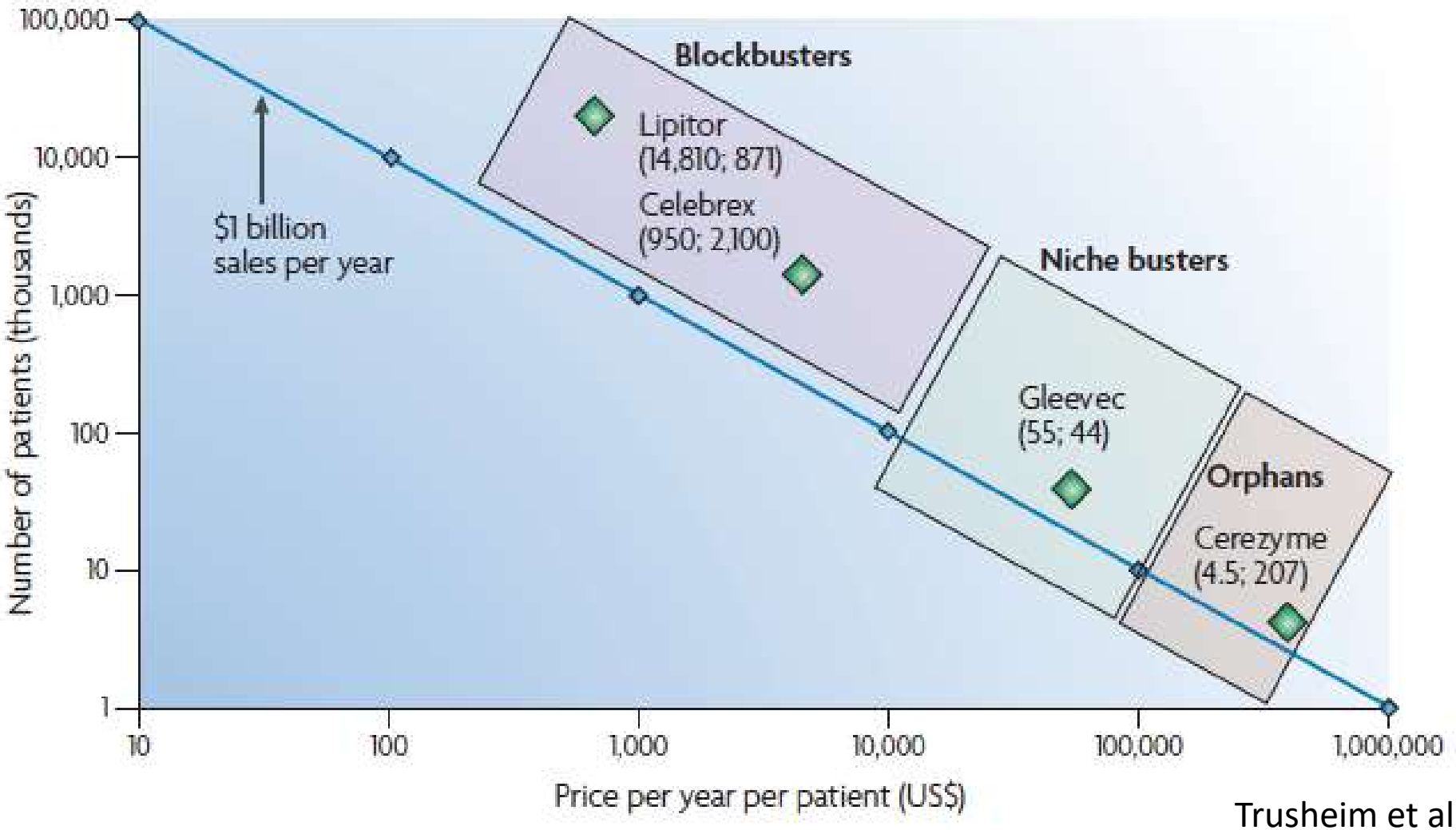
January 18, 2019 08:24 AM EST | Natalie Grover | R&D

Lilly's approved cancer drug Lartruvo fails confirmatory study, setting the stage for withdrawal of regulatory endorsement

Back in 2016, Lilly won FDA accelerated approval for its soft tissue drug olaratumab on the basis of encouraging data from a small 133-patient mid-stage study, but on Friday a larger, confirmatory trial meant to cement the approval showed that the treatment failed to help patients live longer, which means the US health regulator can rescind its endorsement of the drug.

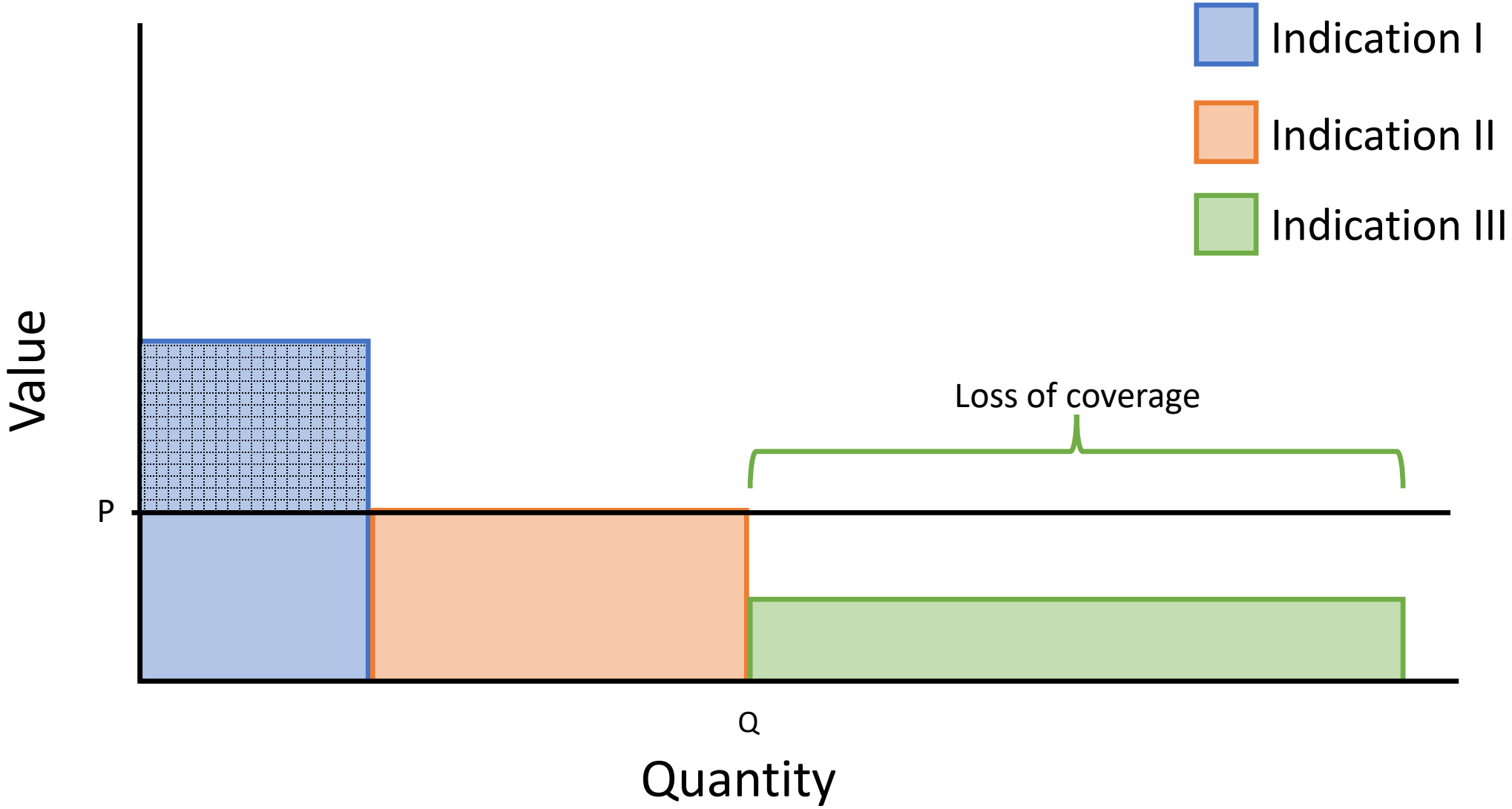
The drug, sold as Lartruvo, had won the FDA nod in combination with the chemotherapy doxorubicin as a first-line treatment for a subset of patients with the disease, which had seen no new approvals in decades. By the third quarter of 2018, Lilly had raked in $221.2 million in Lartruvo sales last year.

Opportunity cost III: Higher prices

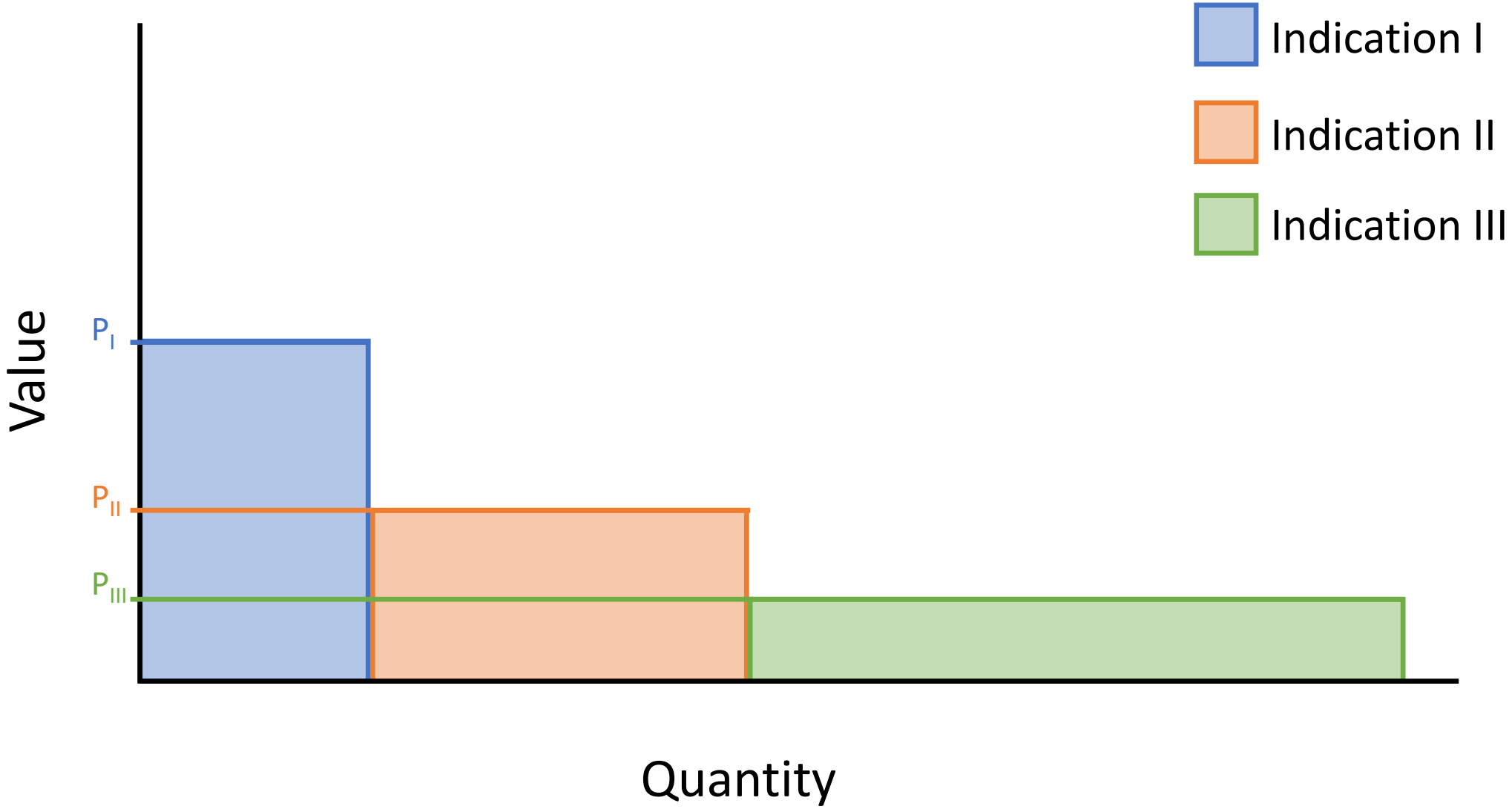


Trusheim et al, 2007 [Nature]

Opportunity cost IV: Indication-based pricing



Opportunity cost IV: Indication-based pricing



Office of Health Economics Consulting

Consulting Report

The Debate on Indication-Based Pricing in the U.S. and Five Major European Countries

May 2018

Adrian Towse, Amanda Cole and Bernarda Zamora

OHE has developed this report, commissioned and funded by AstraZeneca.

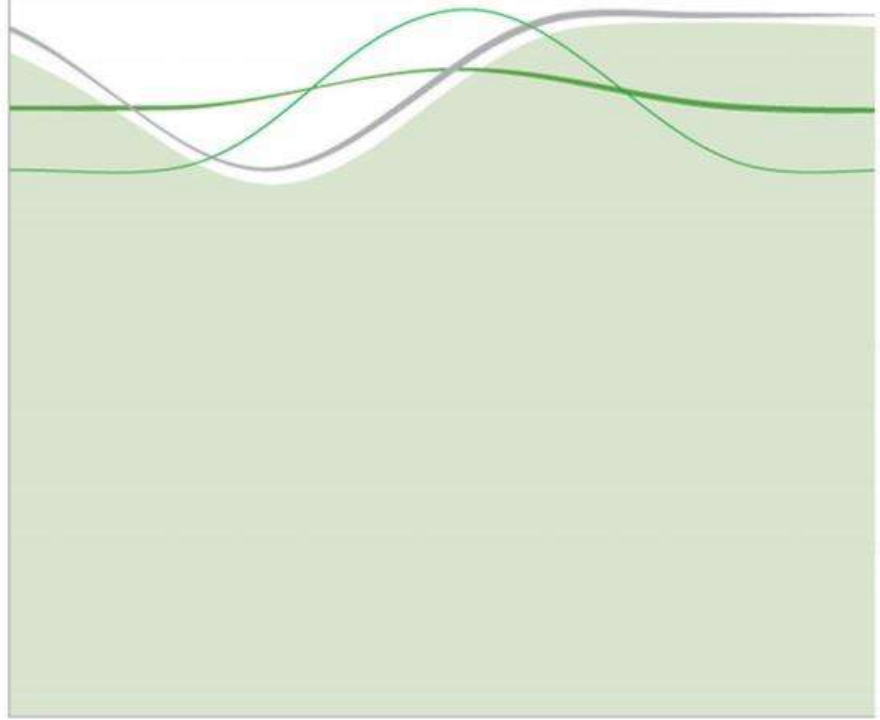
Office of Health Economics Research

Research Paper 18/04

Economics of Innovative Payment Models Compared with Single Pricing of Pharmaceuticals

July 2018

Amanda Cole, Adrian Towse, Paula Lorgelly, and Richard Sullivan



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Value based pricing / paying for results

- Innovative pricing schemes are an area of current interest
- Most of these favour the industry?
- But it should be possible to design schemes to truly deliver value
- This will require collaboration between industry and payers
- Regulators also need to shoulder some responsibility?