Can greater transparency on public funding received by pharmaceutical companies make new medicines more affordable?

David Epstein

Professor of Applied Economics

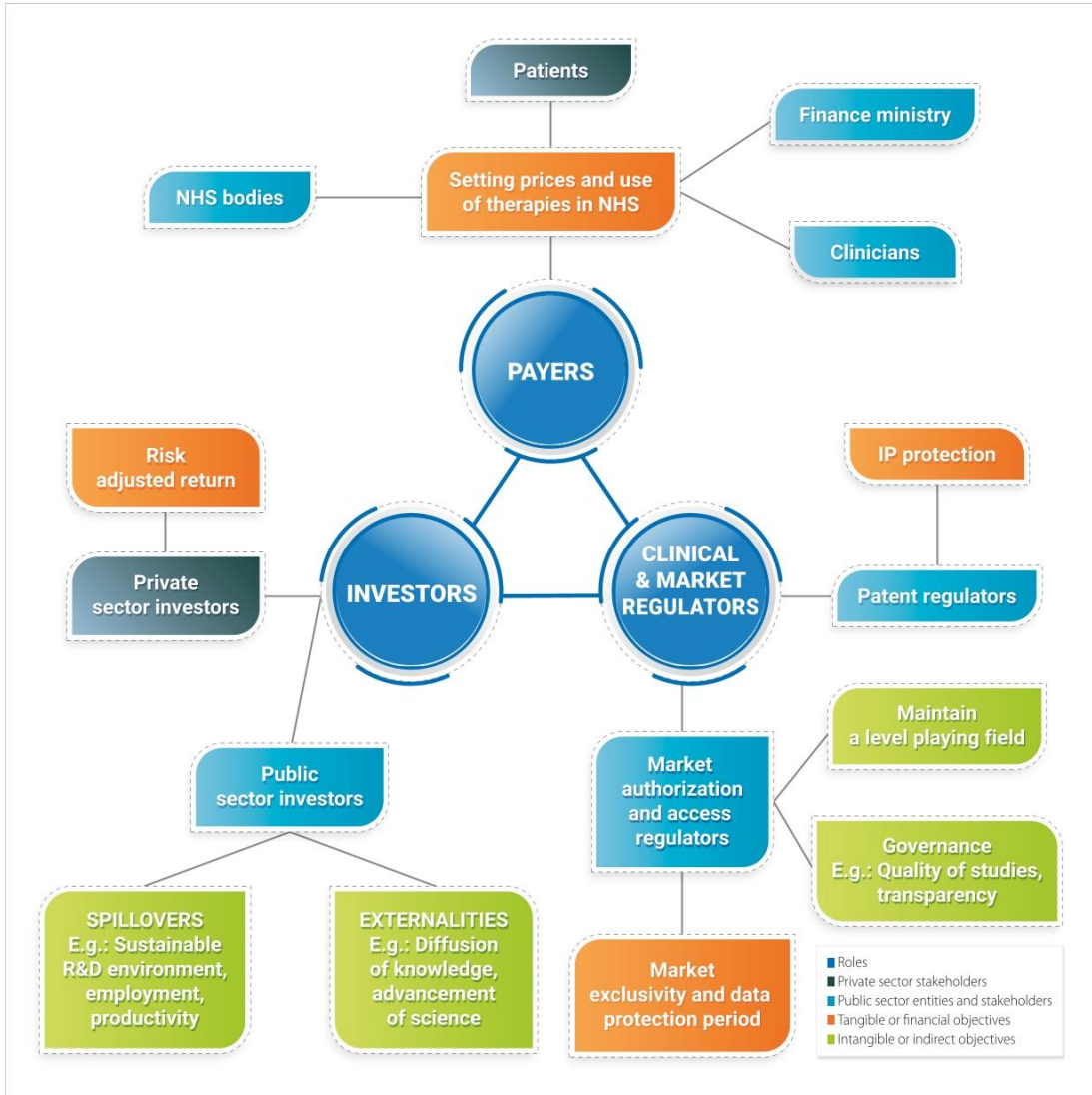
University of Granada, Spain

Financed by Horizon Europe project HI-PRIX Grant agreement ID: 101095593

Overview

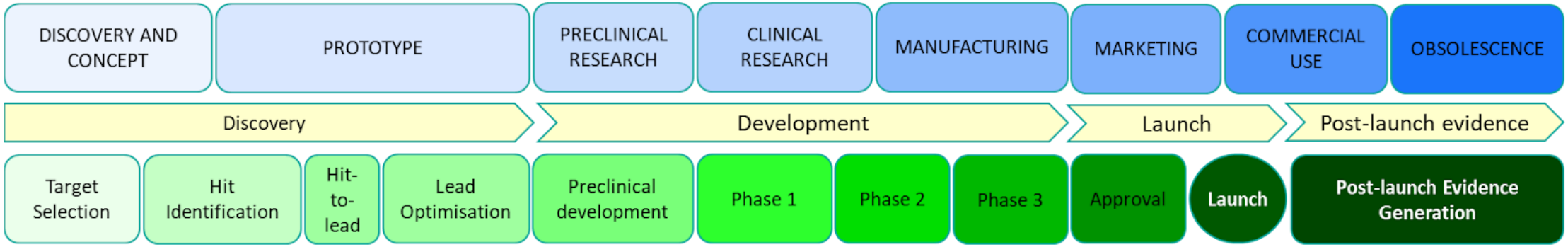
- In what ways does the public sector fund (or influence) medical R&D?
- What can greater transparency about public funding of pharmaceutical R&D expect to achieve?
- Should health service payers try to recover these R&D investments by setting lower prices?

Routes by which public sector entities fund or influence medical R&D



Rejon-Parrilla et al.2024 Development of a Conceptual Framework for Analyzing the Role of the Public Sector in the Development of New Valuable Health Innovations. Poster HPR75 ISPOR Europe

Influence of public sector on R&D along the life cycle



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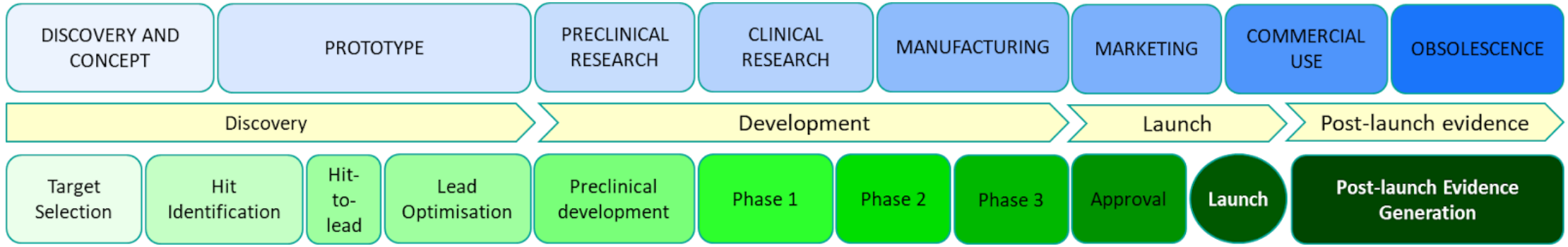

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Investor in preclinical studies

Investor in clinical studies

Real world studies

Repurposing studies

Developer of translational tools including AI & gene editing technology

"Academic" developer of therapies (e.g.CAR-T)

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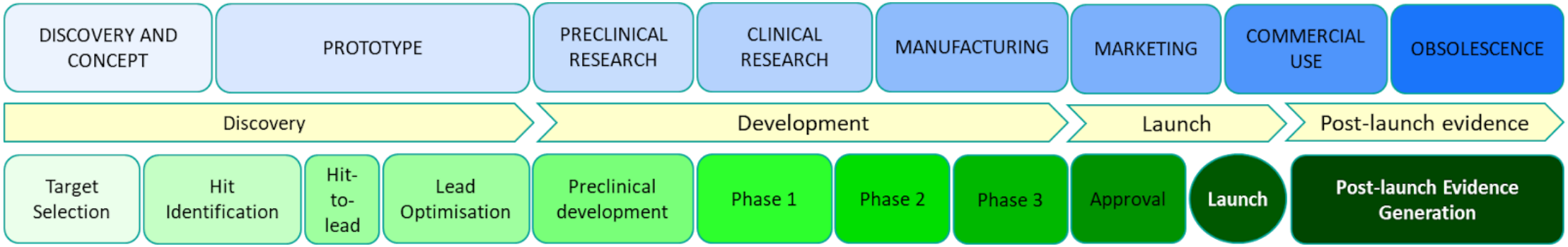

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Governance of clinical trials, orphan drugs, PRIME

Scientific consultation, horizon scanning

Market approval

Market exclusivity and competition

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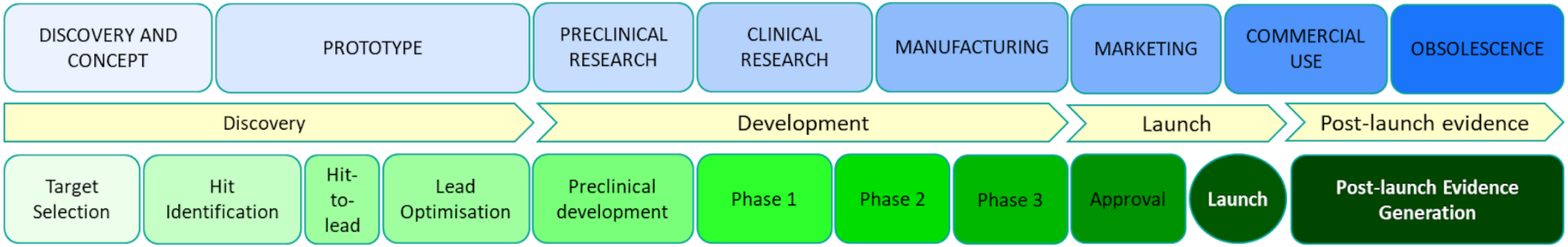

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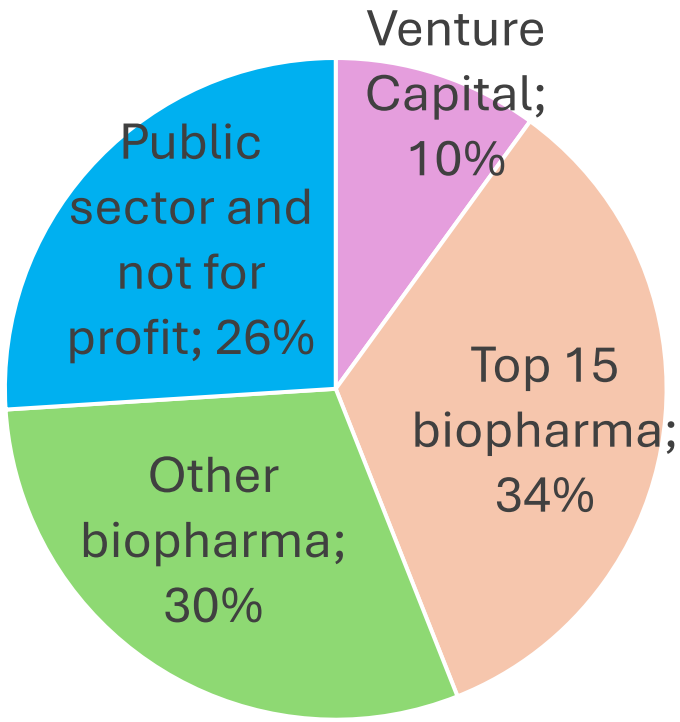
Payer

HTA + P&R

Competition policy

Public sector R&D investment



Estimated R&D spend by investor type in 2020. Total $303bn, excluding costs of capital.

- Academic, public sector and not for profit spent $79bn in R&D in 2020
- Mostly in early stages (basic science to drug discovery)
- 67% in USA, 21% in Europe, 11% in Asia-Pacific
- Private investors come in after drug discovery stage
- But not well documented

SiRM, L.E.K. Consulting & RAND Europe, *The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue*, 2022.

What can greater transparency about funding of pharmaceutical R&D expect to achieve?

- ✓Understand how the R&D ecosystem operates
- ✓Identify gaps and market failures (e.g. translational gaps)
- ✓Support proposals for public sector subsidy / intervention / policy
- ✓Promote level playing field for competition
- Need to balance need for information with the costs to manufacturers of compliance with that regulation (Shaw & Mestre 2020)
- There is an argument that the public sector is "paying twice" (Shipper 2019)
  - Once for the investment in R&D, and again in the high price of the medicine
- **Can** and **should** transparency about public sector funding for R&D help payers negotiate lower prices for medicines during P&R?

Shaw B & Mestre J. 2020. Talkin' about a resolution. Pharmacoeconomics 38:125-134
Shipper I, de Haan E, Cowan R. 2019. Overpriced: drugs developed with dutch public funding. SOMO / WEMOS

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- Appeals to concepts of “fair” and “affordable” pricing (Zhou 2024)
- But supposes that pricing of medicines follows a “cost-plus” model
  - Not usually recommended: asymmetric information; complex to unpick; incentive to pad-out costs
- Economists usually recommend that prices should be “value-based” (e.g. Ramagopalan 2024, although also see e.g. Paulden 2024)
- Setting prices below a “value-based” price for a particular indication could weaken incentives for competitors to develop alternative therapies for that market

Paulden M 2024. A framework for the fair pricing of medicines. Pharmacoeconomics 42:145-164
Zhou, Edward et al. Considering Returns on Federal Investment in the Negotiated “Maximum Fair Price” of Drugs Under the Inflation Reduction Act: An Analysis (February 28, 2024). Institute for New Economic Thinking Working Paper Series No. 219
Ramagopalan et al. 2024. Is the price right? Paying for value today to get more value tomorrow. BMC Medicine 22:45

Alternative models for sustainable public sector R&D

- Basic science: should the public sector aim to monetise this investment? Traditionally viewed by economists as a public good (Stiglitz 1999)
- Public investment in preclinical studies (e.g. “translational gap”)
  - Investment can be recovered by royalties e.g. MRC Technology “LifeARC” retained IPR for pembrolizumab
  - No influence on the price of the product (although also see Shipper 2019)
- Public sector R&D investment could have greatest impact in creating generalizable tools (gene editing technology, AI, platform manufacturing etc)
  - Potential applications in development of wide variety of therapies
  - Greatest societal impact can be leveraged if licensing is non-exclusive and affordable (Storz 2024)
  - Suggests need for self-funding public/private consortiums with a public interest mission (Mazzucato 2017)

Stiglitz J. Knowledge as a global public good. In Inge Kaul, Isabelle Grunberg, Marc Stern, Global Public Goods, OUP, New York, 1999
Shipper I, de Haan E, Cowan R. 2019. Overpriced: drugs developed with dutch public funding. SOMO / WEMOS
Storz, U 2024 The CRISPR Cas patent files, part 1: Cas9 – Where to we stand at the 10 year halftime?,Journal of Biotechnology,379
Mazzucato M, Semieniuk G. 2017 Public financing of innovation: new questions. Oxford Review of Economic Policy 33:1