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Patient-Centred R&D & 'Real World Development'

Presentation to PRISME SIG

Andy Black, CEO Kinapse

Alderley Park

22 May 2012

Personal perspectives

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- Patient
- Relative
- Healthcare Practitioner
- Regulatory Consultant
- Pharma Consultant
- Pharma Service Provider

Pharma perspectives

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- Patient at the Centre?

- Patent at the Centre

Pharma ‘market access’

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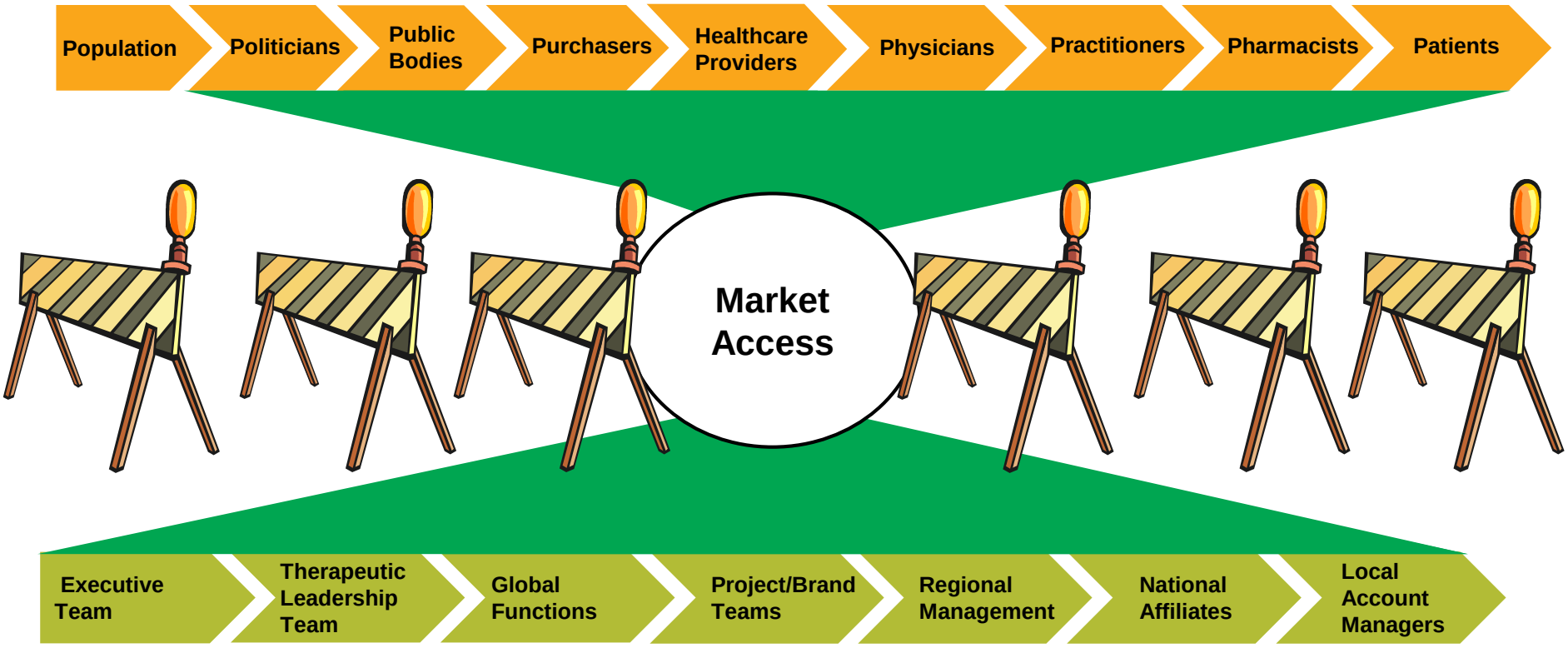
External stakeholders



Internal pharma stakeholders

The outcome for big pharma?

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With thanks to Defined Health

Where is their ‘Market Access’ department?

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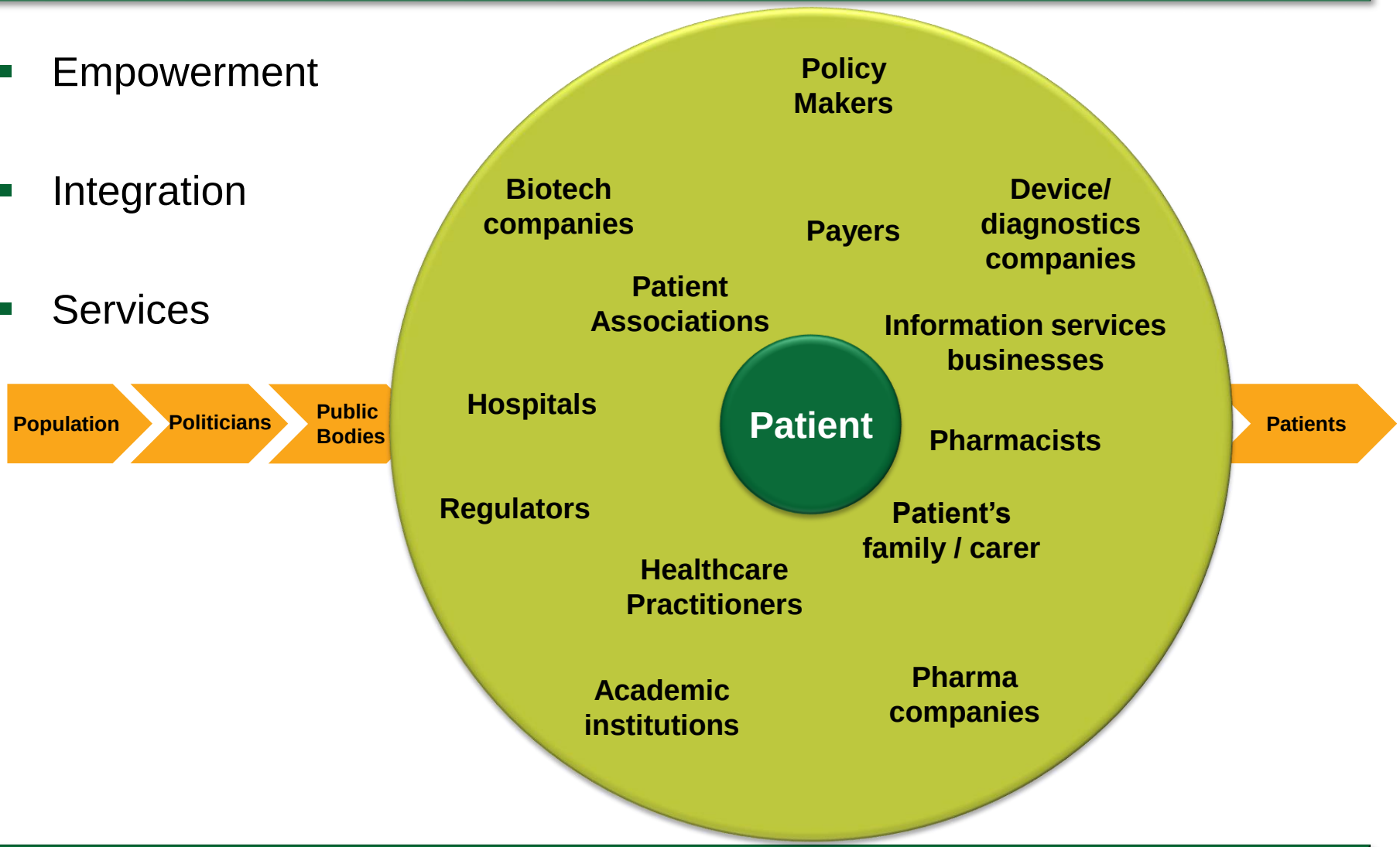
Google

Pain in calf and short of breath

Google Search | I'm Feeling Lucky

Patient access

- Empowerment
- Integration
- Services



Pharma putting the 'patient at the centre'

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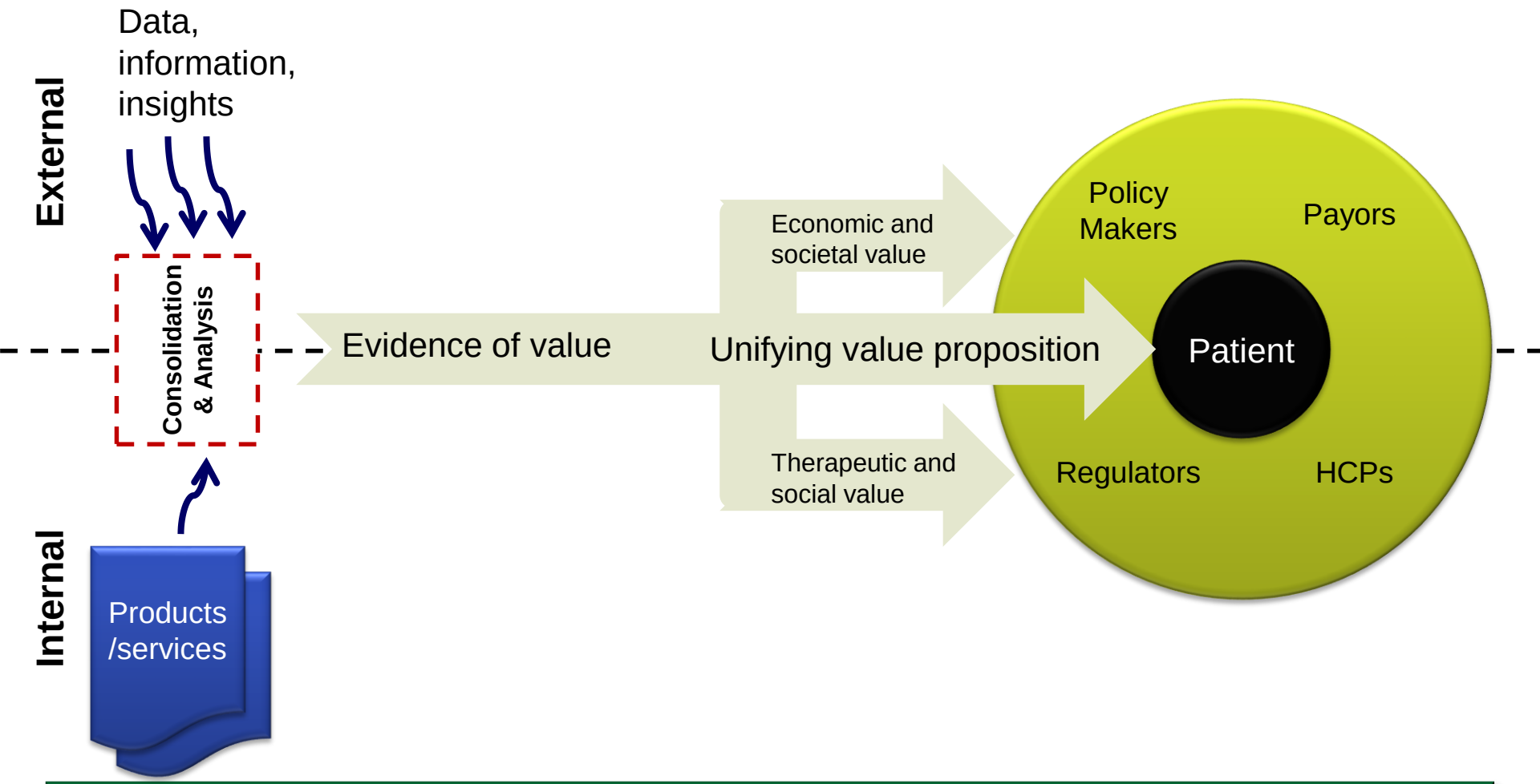

Generating evidence for the value proposition

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Clinical trial data

Patient Reported Outcomes

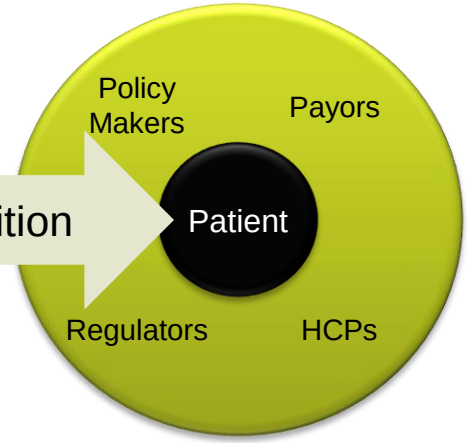
Epidemiology data

Health economic studies

Meta-analyses

Evidence of value

Unifying value proposition



Local market insights

Registries and observational dbases

HA/HTA Scientific advice

Patient surveys

Ad Boards/ Key Opinion Leaders

Integrating and delivering the value proposition

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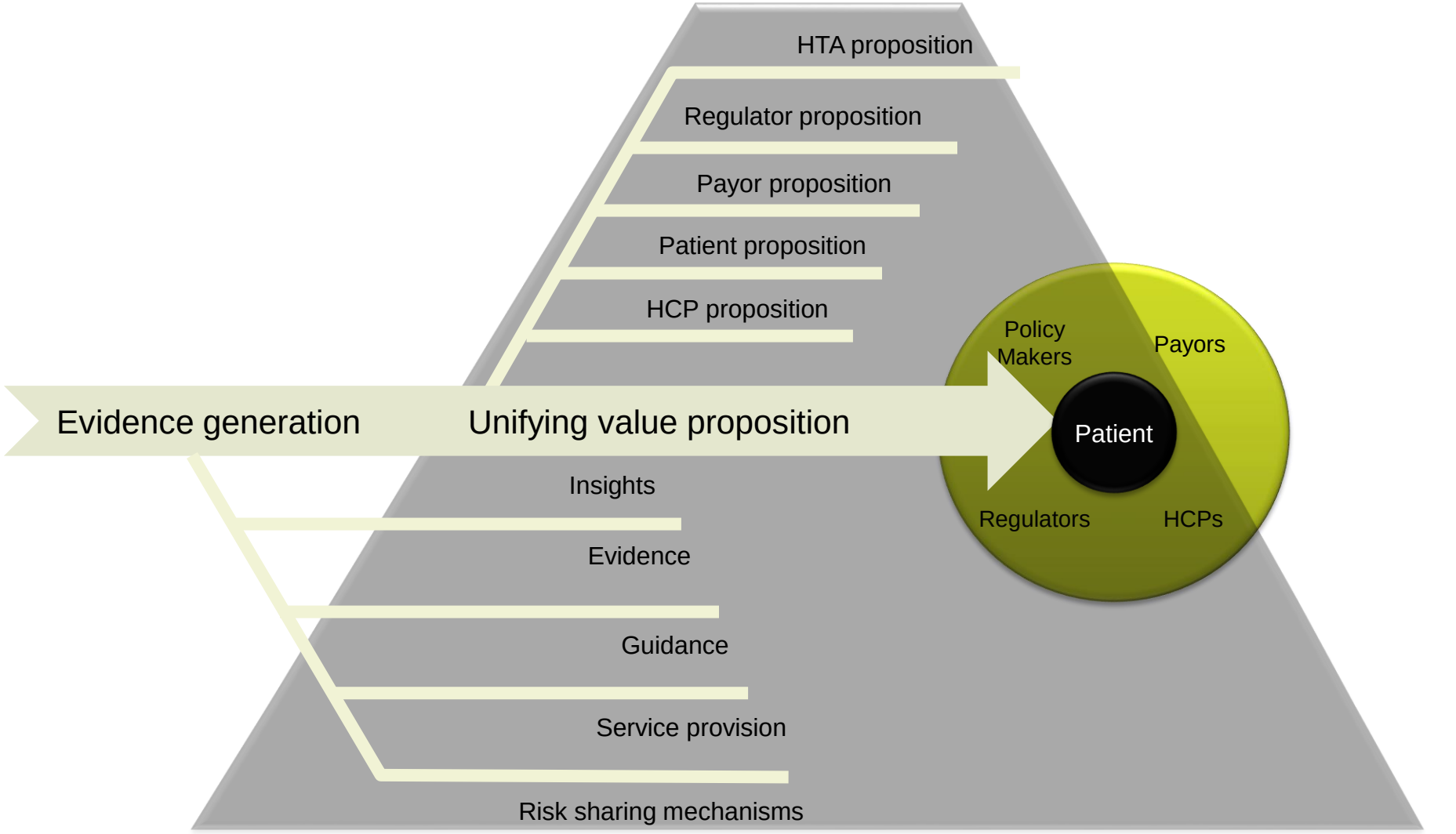

The standard drug development model needs to change

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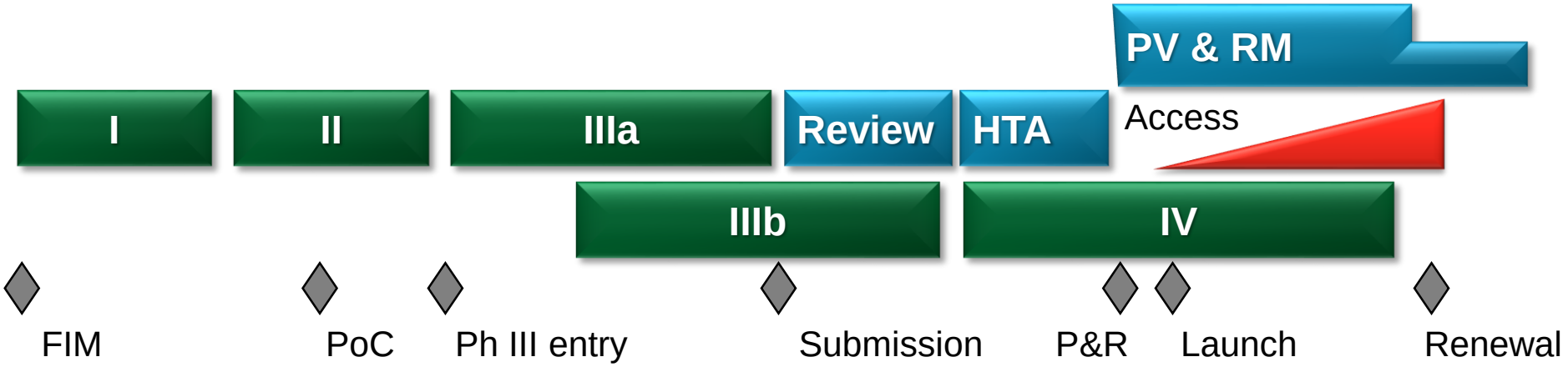

Key characteristics of the standard drug development model

- Linear processes
- Binary decisions
- Expensive
- Risks deferred
- Delayed access

External activities

Sponsor activities

An alternative patient-centred approach based in the real world

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Characteristics

- Multi-stakeholder collaboration
- Evolutionary trial design
- Use of various existing real-world data sources
- Transparency and shared access to data and analyses

Benefits

- Earlier access to innovative therapeutics by well-informed, consenting patients
- Improved understanding of drug performance, increasing confidence of clinical efficacy, risk/benefit and value
- Earlier and better characterisation of risks and their management
- Elimination of traditional clinical trials in Phase III and IV

A proposed Real World Development model

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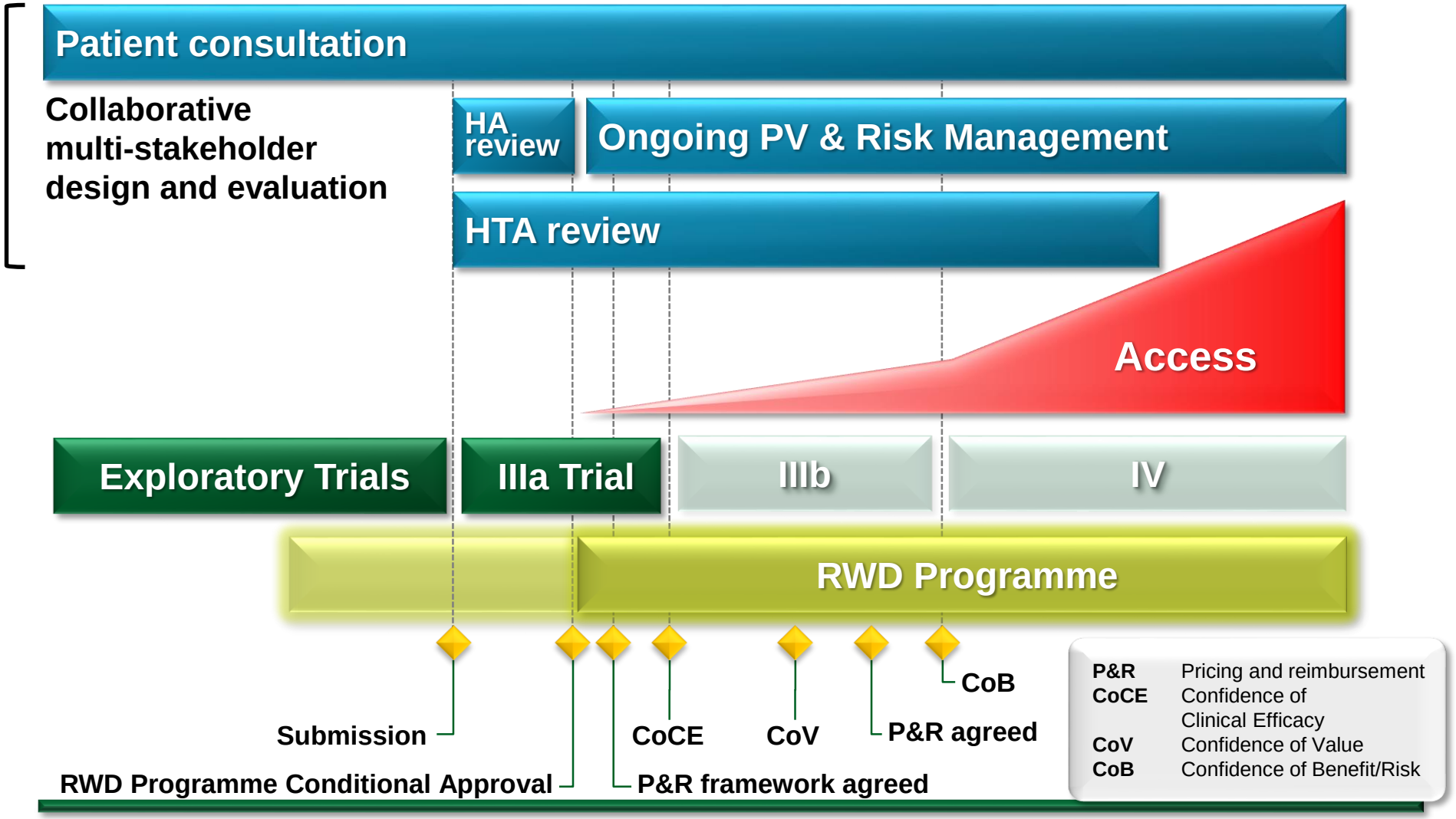

GPRD

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GPRD

Excellence in Public Health Research

The world's largest database of high quality anonymised longitudinal patient records.

GPRD history

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1987 *Launch*	*1993* *Acquired by Reuters*	*1994* *Donated to DH*	*1999* *Transferred to MCA*	*2012* *Services taken over by CPRD funded by MHRA and NIHR*
VAMP **Research Databank**	**REUTERS**	**DH**	**MCA / MHRA**	**MHRA, NIHR**
Doctors incentivised by access to innovative practice management system in return for data	Briefly owned database on acquisition of VM practice management system, but soon divested to DoH	Transferred and managed within Statistics Division of DH. Managed operationally by ONS.	Established within MCA as operationally independent unit. Database redeveloped for online access	CPRD, new English NHS observational data and interventional research service, took over all activities of GPRD from April 2012

GPRD and CPRD

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GPRD
Excellence in Public Health Research

CPRD
MORE DIMENSIONS TO DATA

Other Real World Development case studies

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	Efficacy (CoCE)	Safety (CoB)	Value (CoV)
Alzheimer's Disease	Evaluation of long-term efficacy and tolerability of Novartis' Exelon among Alzheimer's disease patients		
Women's Health		Assessment of risks associated with short and long term use of Bayer Schering Pharma's Yasmin, a third generation oral contraceptive	
Multiple Sclerosis			The UK multiple sclerosis risk sharing scheme
Cardiovascular	Assessment of comparative effectiveness of AstraZeneca's Crestor vs other statins Statistical methods to overcome unmeasured confounding in observational studies*		

* Statistical methods case study was prepared to highlight the development of methods to improve the use of non-interventional studies in healthcare.

My personal conclusions

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- Healthcare delivery will transform based on increased patient empowerment, improved patient access to useful information and associated services

- A strong consensus exists that the current drug development and commercialisation model must change, focused on patients' needs

- We need to make progress with Real World Development
  - Further definition and communication of acceptable RWD models
  - Selection and approval of pilot programmes
  - Establishment of an operational co-ordinating body, engaging:
    - IMI
    - UK government/DH/ABPI (and other Industry Associations)
    - NEWDIGs/MIT
    - Others?

Thanks for listening

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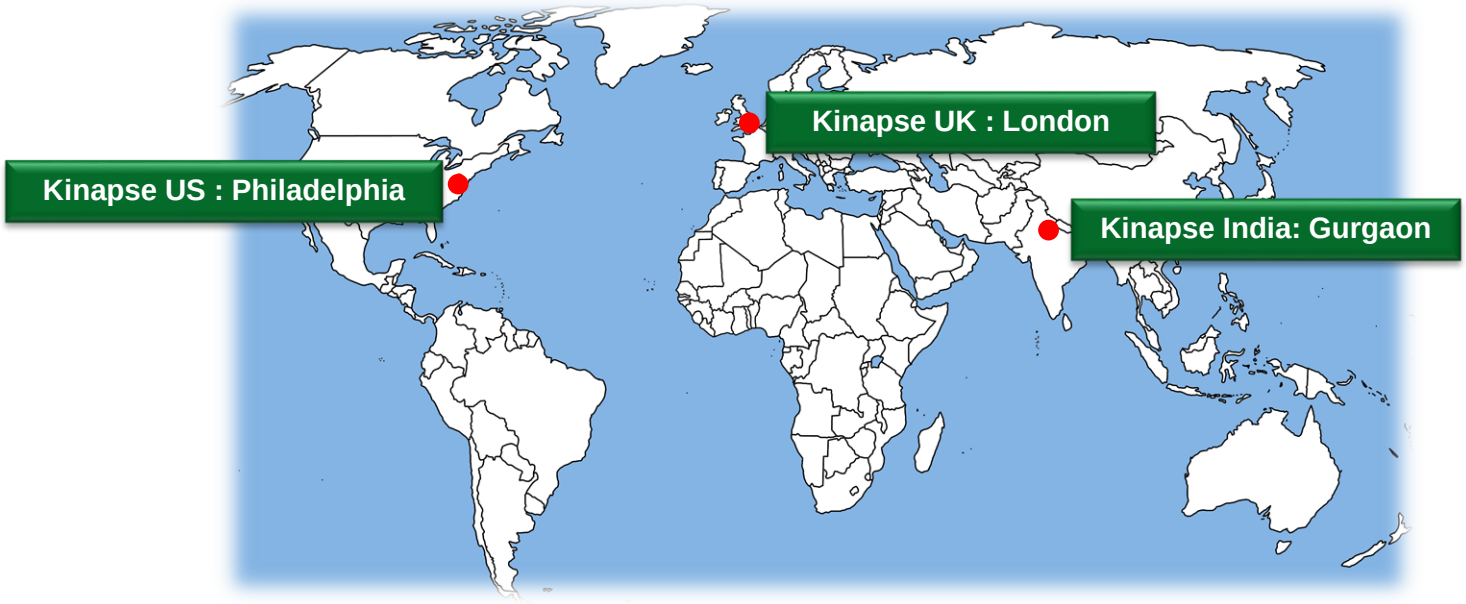

Back up slides

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Pressures on Pharma

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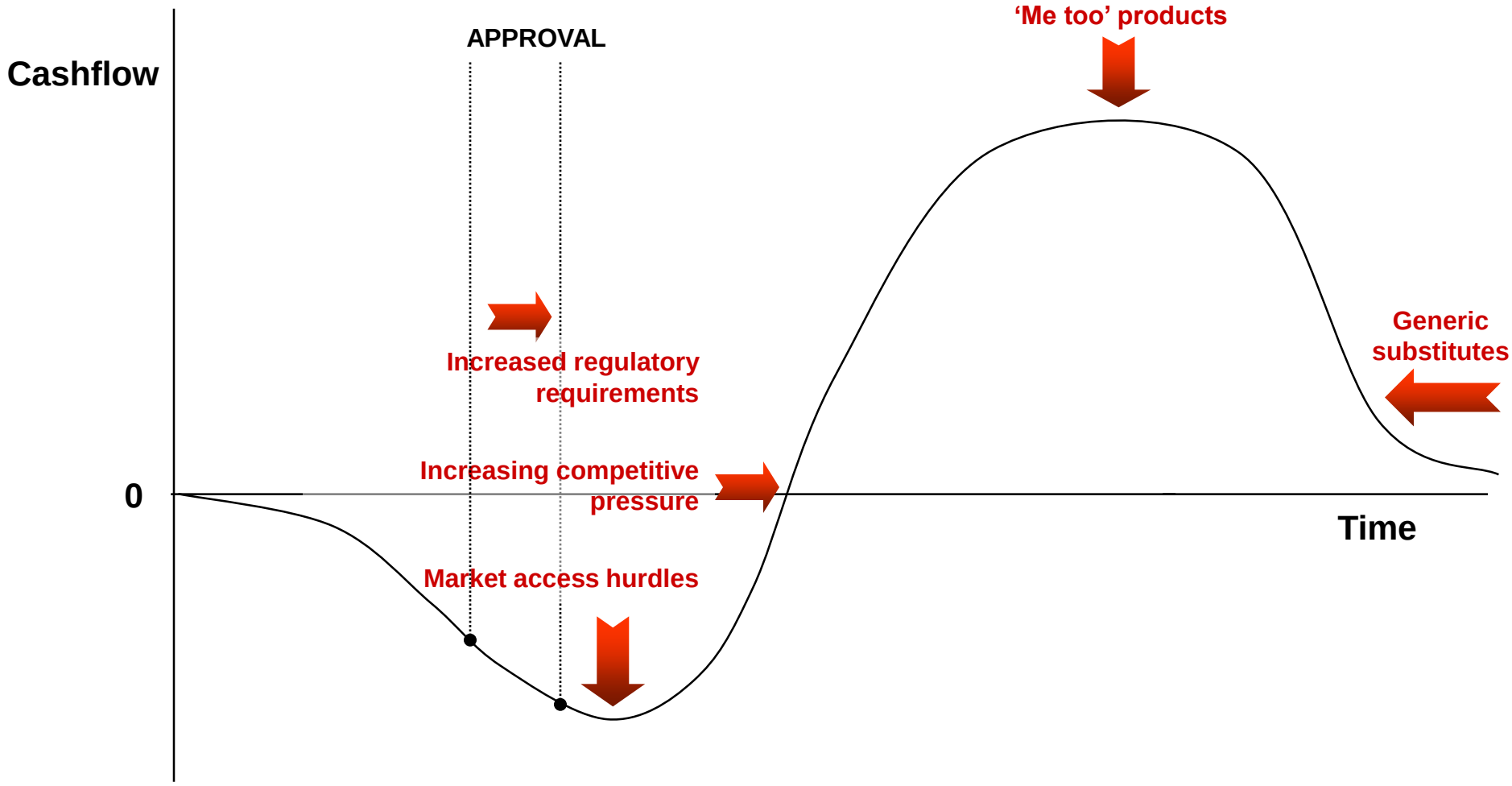

Pharma responses

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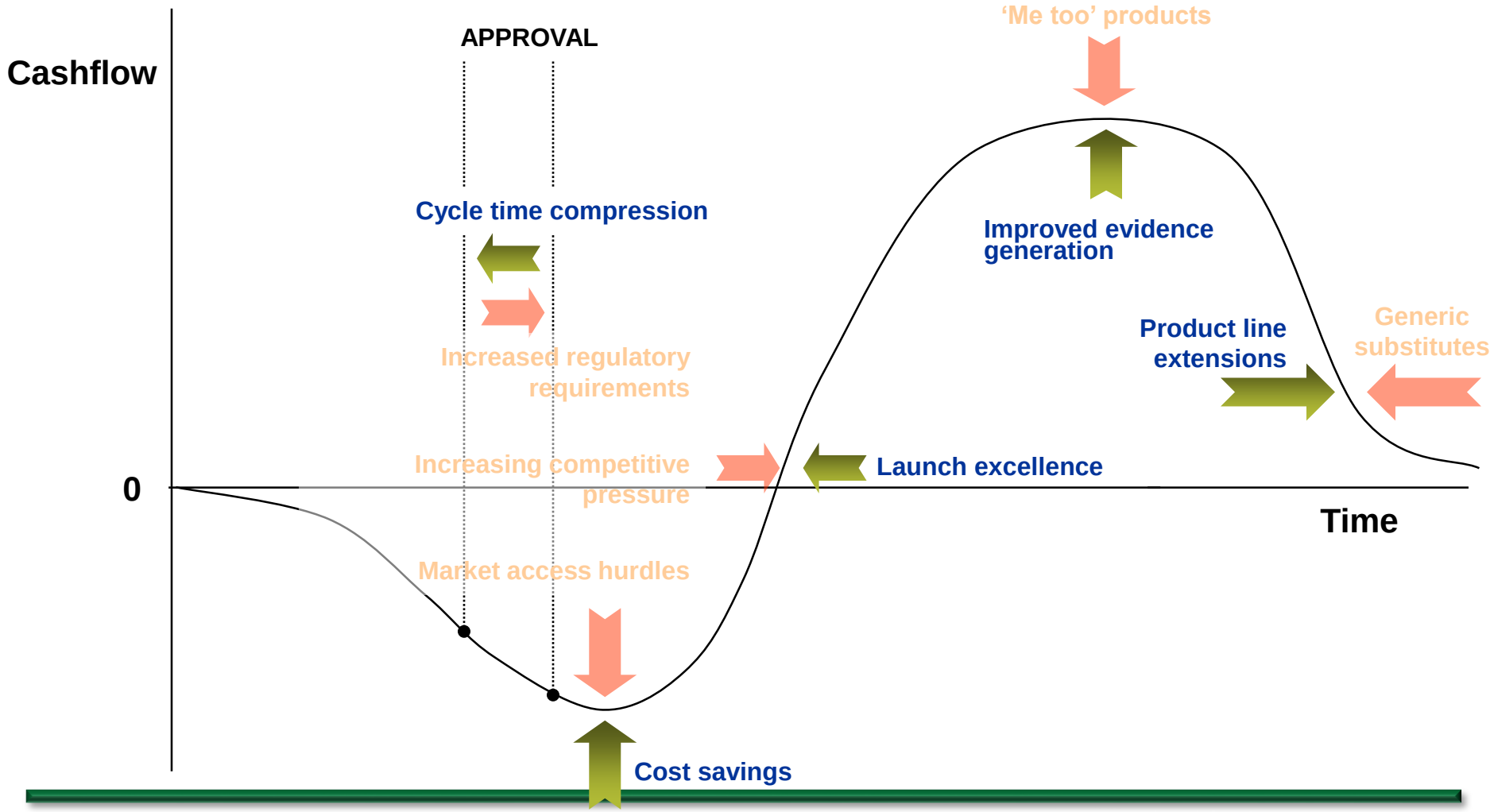

A commercial model based on the patient

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