

McKinsey  
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# THEMES

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- **Lessons from Covid for the acceleration of innovation**
- **The new era of precision medicine and its implications**
- **Enabling conditions for the innovation ecosystem of the future**
- **Europe's opportunity in the new global order**



# COVID EXPERIENCE COMES AT A PIVOTAL TIME

## The background:

- Eroom's Law of declining R&D productivity
- Slow processes of regulation (European) and reimbursement (national)
- European investment environment much less attractive than US

## The recent developments:

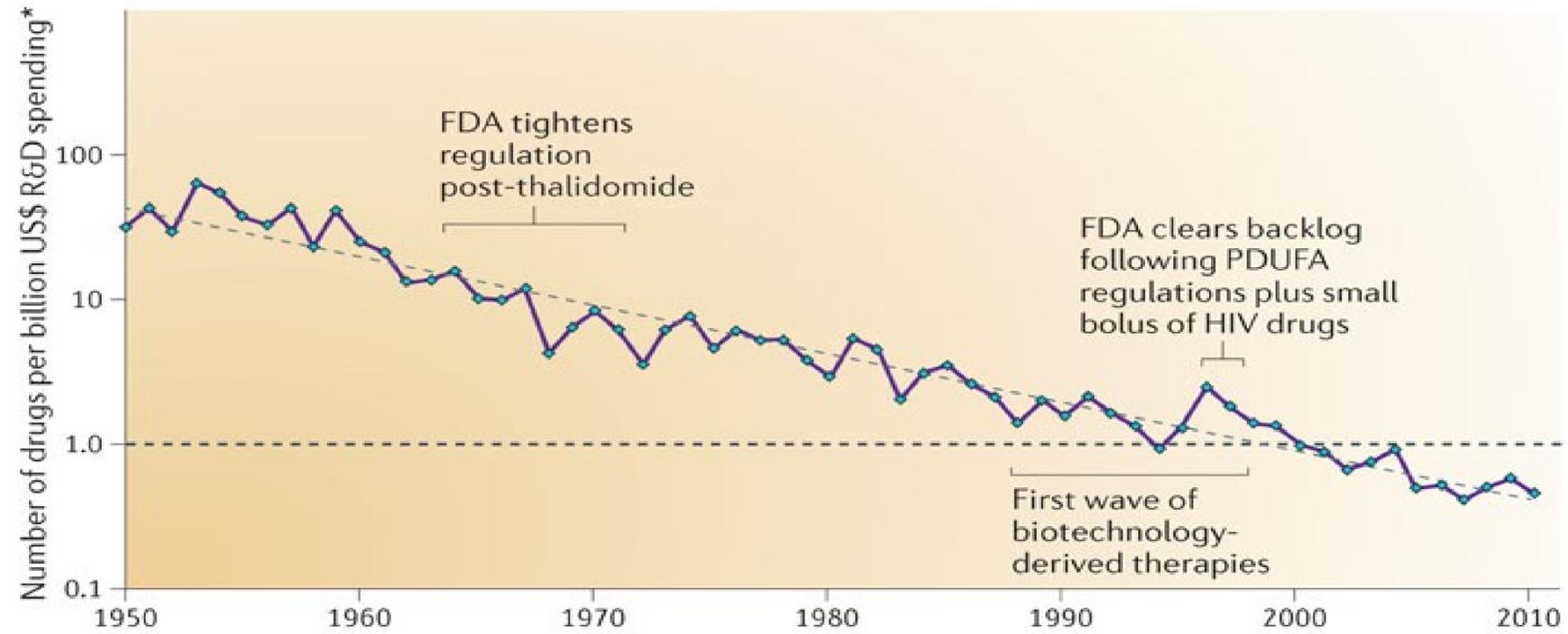
- Experiments with adaptive development/conditional approval and RWE acceptance
- Slow convergence of European HTA
- New highly expensive therapies (cell, gene, etc)
- Experience with Managed Access Agreements
- Emergence of China as a large market with different dynamics

## Covid positives:

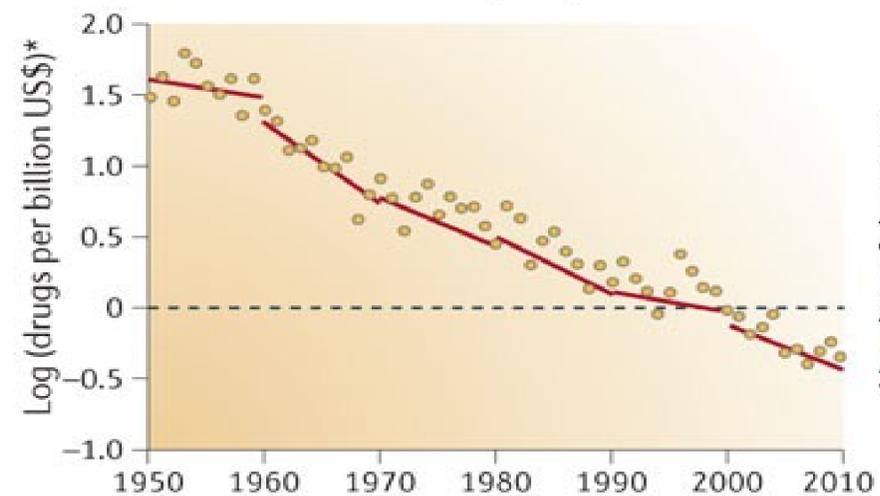
- Vaccine and therapy development in a fraction of the time
- Few arguments about value for money
- Innovation emerging from all 3 major territories
- General (if perhaps temporary) gratitude towards the life sciences sector

# We have had exponential decline in pharmaceutical products produced per unit of investment

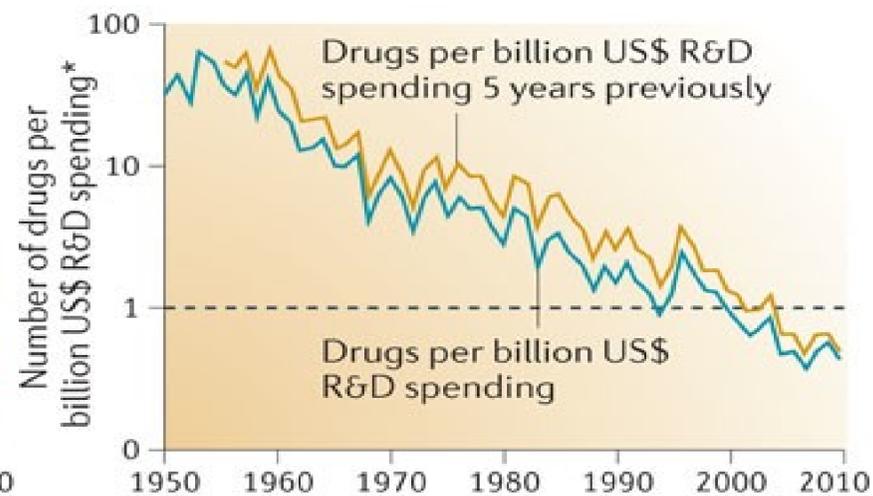
**a Overall trend in R&D efficiency (inflation-adjusted)**



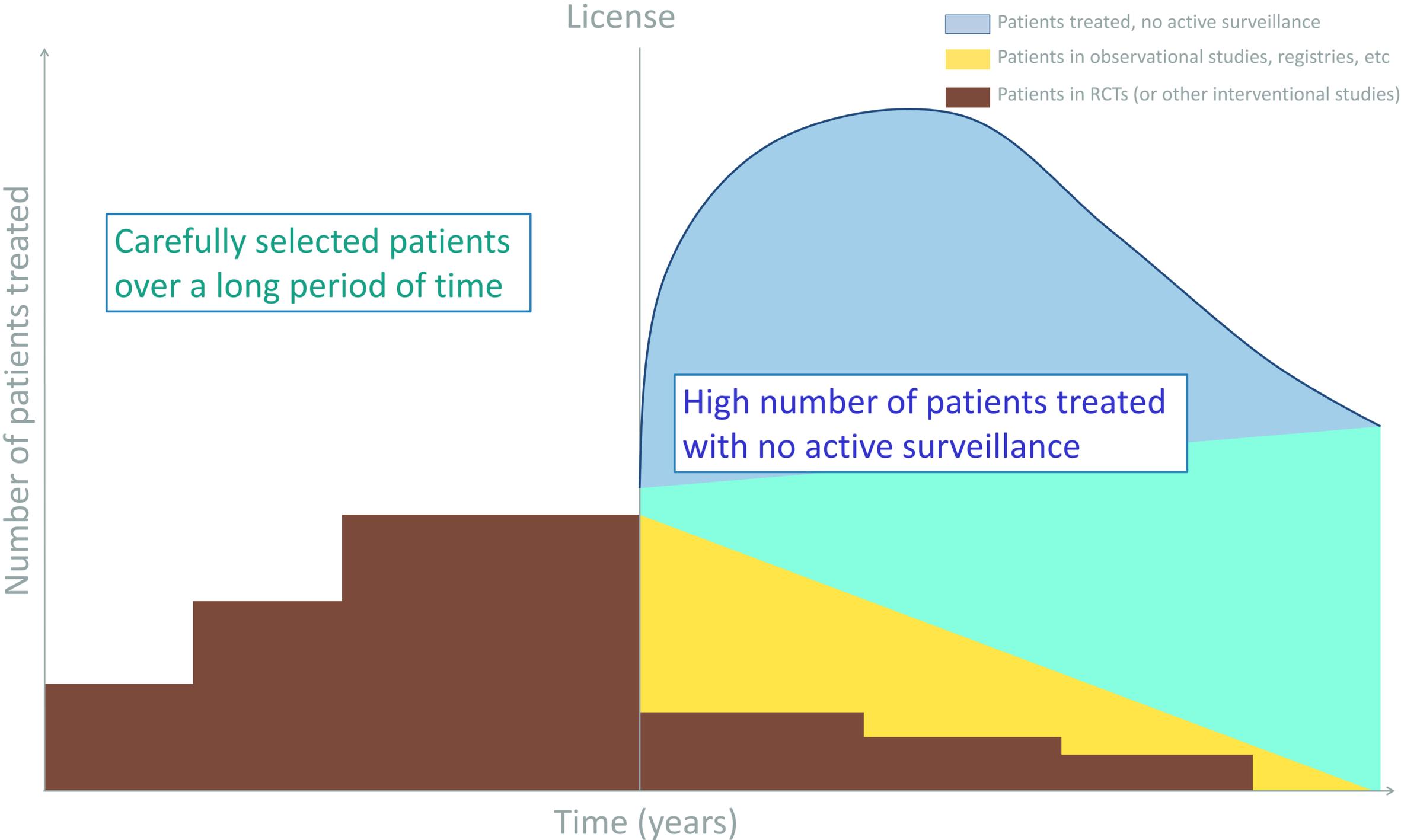
**b Rate of decline over 10-year periods**



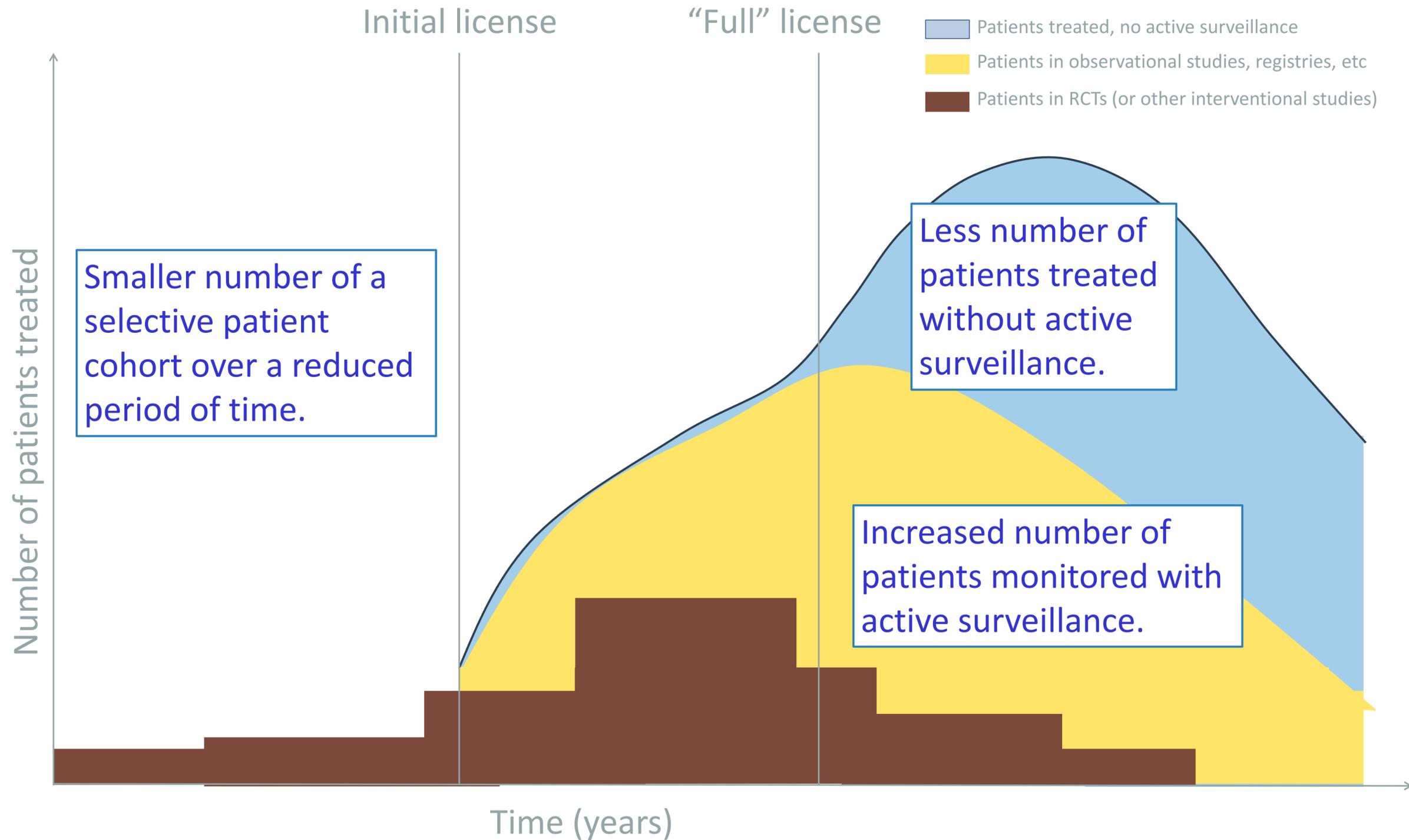
**c Adjusting for 5-year delay in spending impact**



# CURRENT PATHWAY



# APPLYING ADAPTIVE THINKING TO THE PATHWAY



# LESSONS FROM COVID

Time from identification of infectious agent to vaccine:

Ebola: 43 years

HPV 25 years

Hepatitis B 16 years

Measles 10 years

Coronavirus 0.8 years

# COVID-SPECIFIC FACTORS

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- Universal recognition of unmet need
- Willingness to advance purchase (vaccines) and so subsidise development
- Grants for manufacturing facilities
- Rapid set-up of comparative trials (therapies)
- Rapid set-up of trials in high prevalence settings (vaccines)
- Fast-track regulatory review
- Grant emergency use approvals
- Waive normal cost-effectiveness analysis
- Over-purchase against need
- Strike international collaborative purchase agreements
- Set up dedicated product distribution/administration systems

# THE NEW ERA OF PRECISION MEDICINE

## Technology:

- Better targeting through biomarkers, beginning with cancer
- New highly personalised treatments for rare diseases
- Molecular redefinition of some diseases
- Cell and gene therapies moving into the mainstream

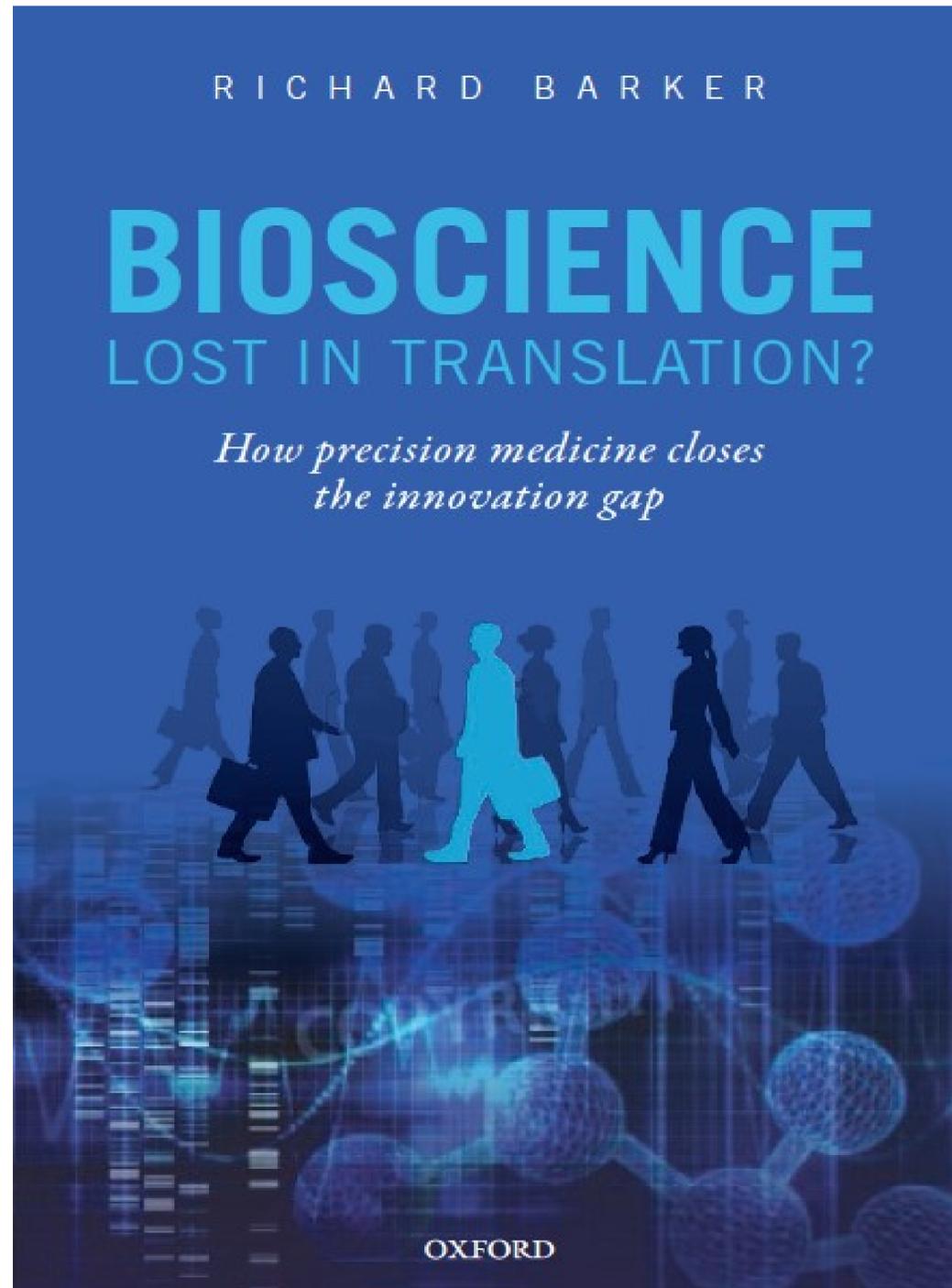
## Issues:

- Clinical education and uptake
- Biomarker business models
- Affordability question as curative yet expensive therapies arrive
- Continuing reluctance in some companies to narrow product markets

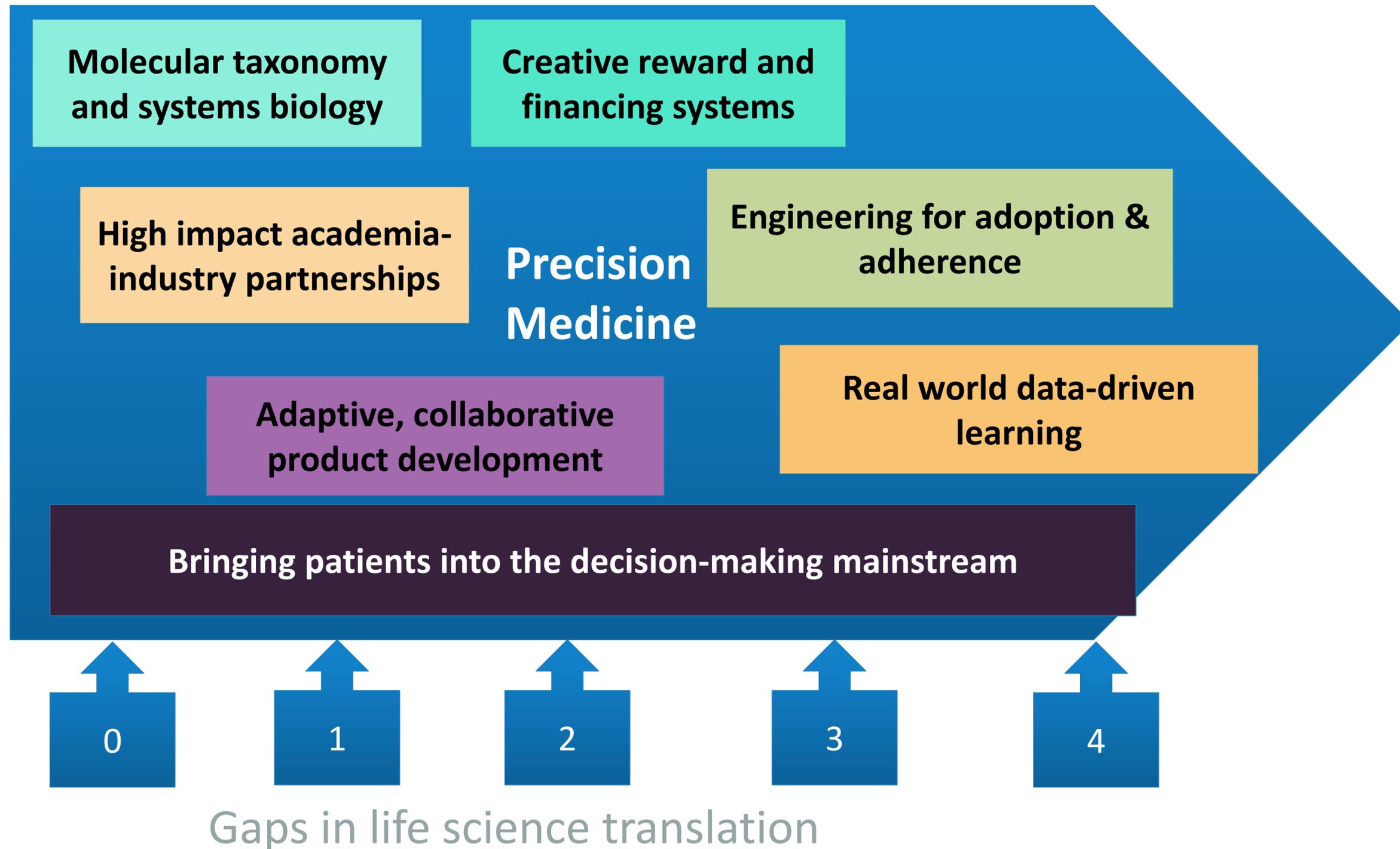
## Useful developments:

- Rx-Dx partnerships
- Clinical decision support systems
- Pricing creativity

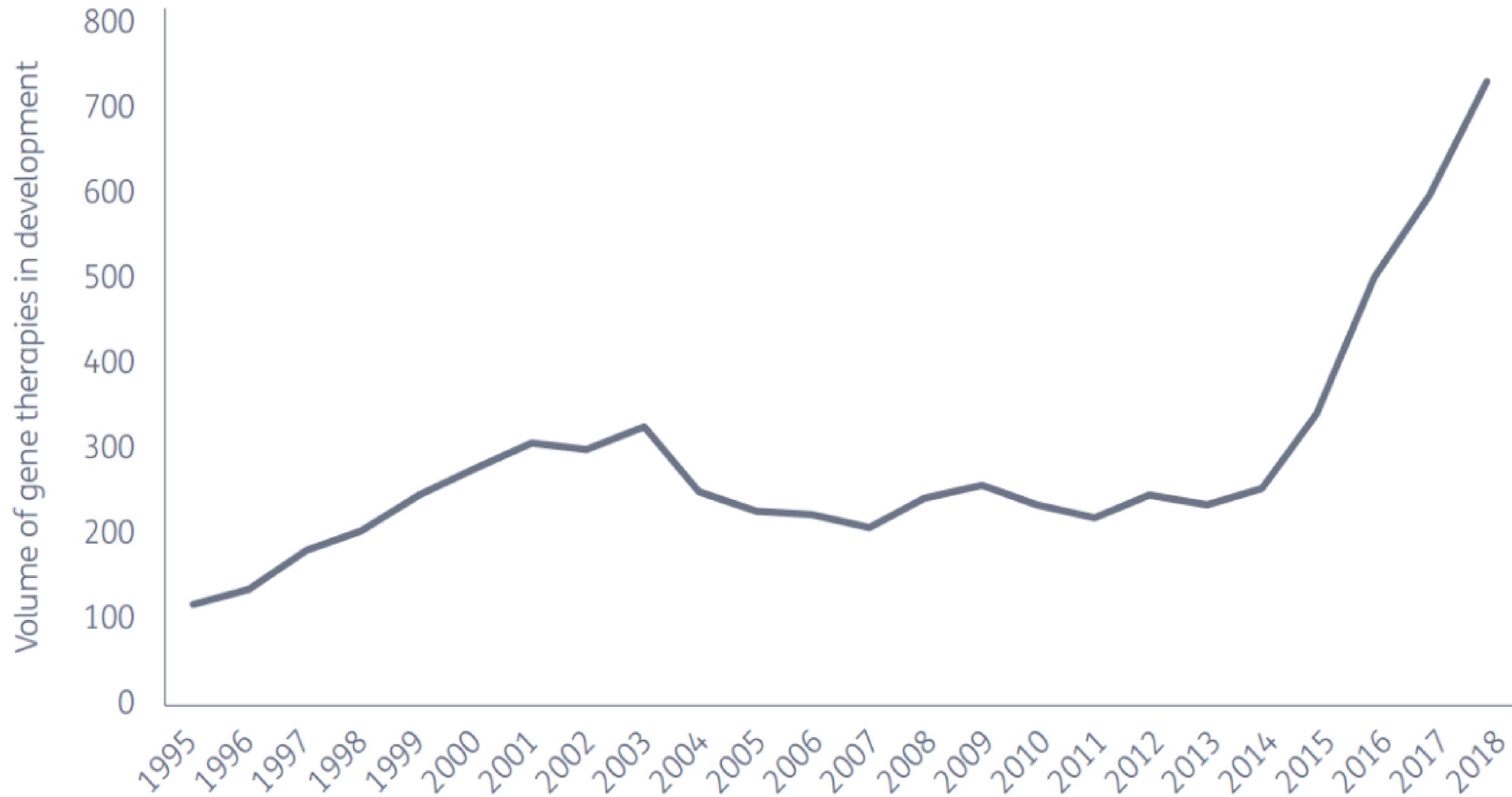
# PRECISION MEDICINE KEY TO TACKLING THE 'INNOVATION GAP'



# Seven steps to sustainable innovation



# Gene Therapy Pipeline Volume, Preclinical through Pre-Registration



# Near-Term Gene Therapy Pipeline

Indication	Projected Launch Year	Prevalence + Incidence 2-5 Years	5-year Total Estimated Cost Impact (2020-2024) \$m	
			Low Market impact	High Market Impact
Haemophilia A	2020	7,360	1,460	5,830
B-thalassemia major	2020	1,050	210	550
Sanfilippo syndrome type A	2021	1,150	90	350
Cerebral adrenoleukodystrophy	2021	6,790	670	1,790
Adenosine deaminase SCID	2021	1,710	130	340
Leber's hereditary optic neuropathy	2021	5,480	1,090	4,340
Choroideremia	2021	4,560	900	3,610
Haemophilia B	2021	2,620	520	2,060
Wiskott Aldrich syndrome	2022	3,350	500	1,340
Metachromatic leukodystrophy	2022	3,420	510	1,370
Sickle cell anaemia	2022	117,020	8,670	23,400

Source: CVS Health

## LESSONS WE MIGHT CARRY FORWARD?

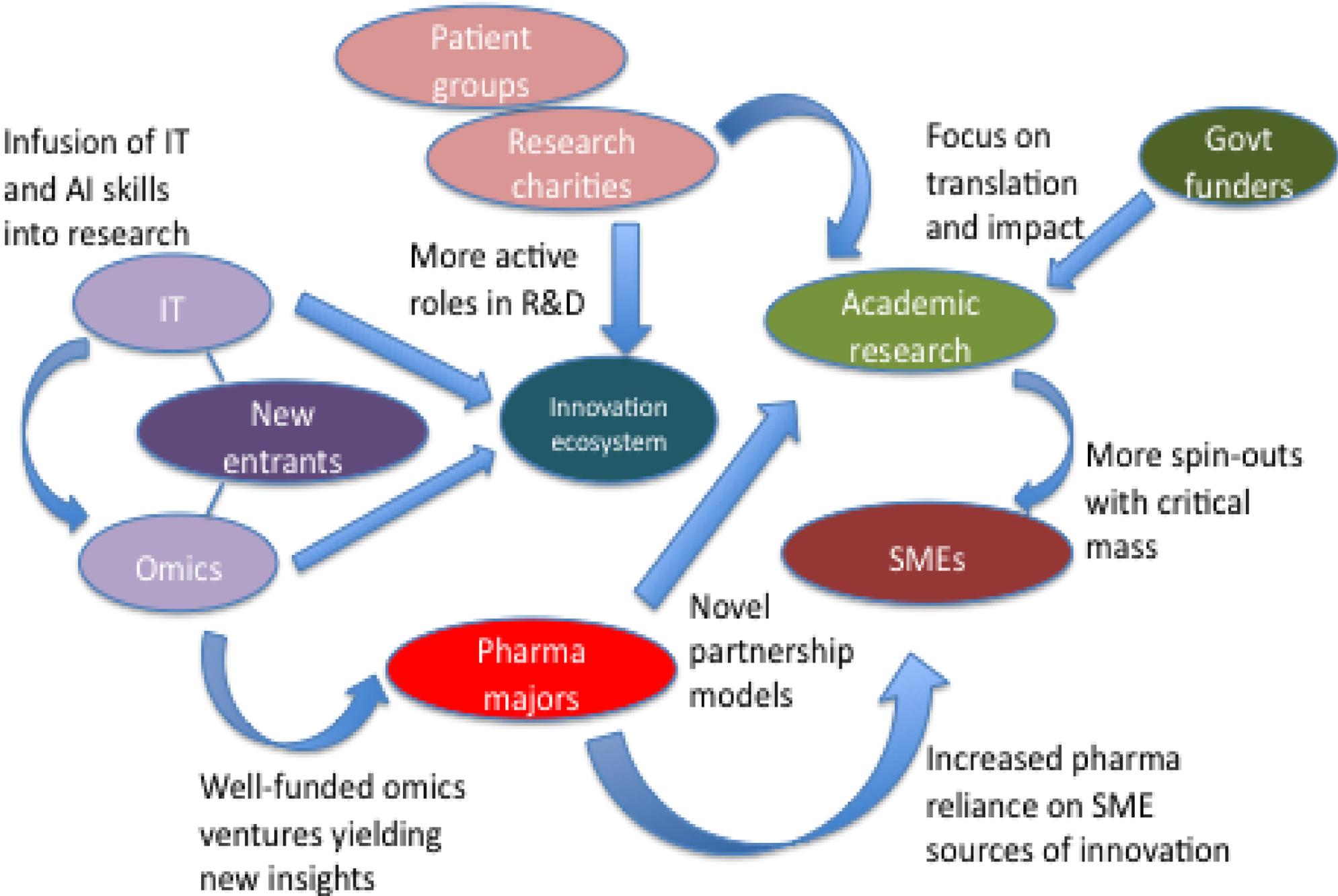
- Universal recognition of unmet need?: **CVD and cancer still killing more than Covid**
- Willingness to advance purchase?: **anti-microbial resistance**
- Grants for manufacturing facilities?: **virus manufacturing for gene therapy**
- Rapid set-up of comparative trials?: **academic opportunities in drug repurposing**
- Rapid set-up of trials in high prevalence settings?: **European disease registries**
- Fast-track regulatory review: **expansion of rapid scientific advice, rolling review, conditional approval etc**
- Waive normal cost-effectiveness analysis?: **unrealistic, but more use of conditional reimbursement with evidence development**
- Over-purchase against need?: **anti-microbial resistance**
- Strike international collaborative purchase agreements?: **could be the pharma future**
- Set up dedicated product distribution/administration systems?: **future pandemics**

# EUROPEAN ECOSYSTEM OF THE FUTURE

Innovation-friendly  
European  
Ecosystem

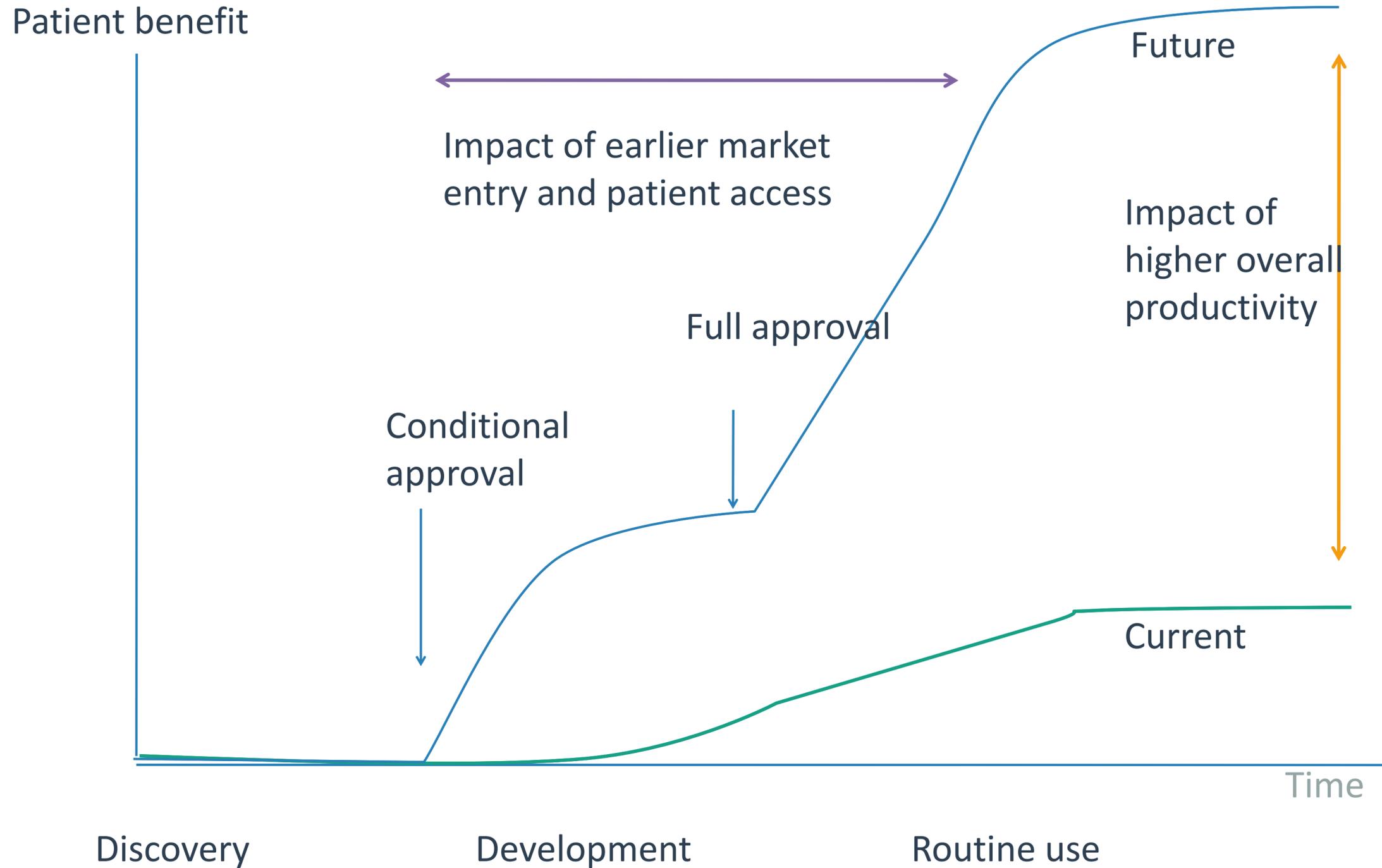
STEP	VALUE	CURRENT STATUS
<b>Clinical trial infrastructure support</b>	Greater level of European trials	A few national initiatives
<b>Adaptive development + regulatory streamlining</b>	Faster access for patients and better returns for companies	Conditional approval experiments
<b>Greater HTA coherence across EU</b>	Simplified evaluation	Some pan-EU agreement re comparative effectiveness criteria
<b>Novel pricing &amp; reimbursement models</b>	Faster uptake of precision medicines	Some Managed Access Agreements, nationally

# Driving forces in the future medical innovation ecosystem





# PRODUCTIVITY IMPROVEMENT COULD BE DRAMATIC



# EUROPE'S ROLE IN GLOBAL LIFE SCIENCES - SWOT ANALYSIS

	USA	Europe	China
Strengths & Opportunities	<ul style="list-style-type: none"> <li>• High public and private sector R&amp;D spending</li> <li>• Highest prices globally</li> <li>• Rapid uptake of innovative products</li> <li>• Significant AI and health data investments</li> </ul>	<ul style="list-style-type: none"> <li>• Strong universities</li> <li>• EU Horizon &amp; IMI programmes</li> <li>• Longitudinal &amp; integrated patient data in some countries</li> </ul>	<ul style="list-style-type: none"> <li>• Rapid market growth</li> <li>• Major national investment in AI</li> <li>• Limited institutional baggage</li> </ul>
Weaknesses & Threats	<ul style="list-style-type: none"> <li>• Vulnerability to future price controls</li> </ul>	<ul style="list-style-type: none"> <li>• Slow reimbursement cycles</li> <li>• Slow uptake of innovative products</li> <li>• Price controls</li> </ul>	<ul style="list-style-type: none"> <li>• Fragmented markets</li> <li>• Residual IP concerns</li> <li>• Strong internal competition</li> <li>• Robust price controls</li> </ul>

## **ENABLING CONDITIONS FOR AN EFFECTIVE ECOSYSTEM**

- **New narrative based on positive Covid experience**
- **Strong investment in science**
- **Innovation-receptive regulatory and reimbursement systems**
- **Capture of - and access to – integrated health system data**
- **Aligned innovation goals and incentives**
- **Recognition of the power of public-private partnership**
- **Full engagement of the patients**
- **Open dialogue!**

## QUESTIONS FOR DISCUSSION

- **Most important Covid lessons?**
- **Missing enabling conditions?**
- **Priorities for political action in Portuguese Presidency?**
- **Better harnessing of EU research programmes?**
- **Stronger focus on next generation therapies?**
- **European health data and AI initiatives?**