



**pmi**  
**Pharma Summit 25**  
evolving through change

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## Sharon Rice

### Incoming President

**pmi** THE PHARMACEUTICAL  
MANAGERS' INSTITUTE

*On behalf of the Committee of the PMI, it is my great pleasure to welcome you all to our 2025 Pharma Summit – Evolving through Change.*

*Those of us who've been in this sector for a good number of years would say that change has always been part of our industry. New innovations and new medicines move us forward and challenge the status quo, always we hope, to the benefit of patients. As a result, we've all become good at innovating and collaborating to ensure patients are getting the treatments they need when they need them, and the PMI has always been a great forum for sharing ideas and learnings about how best to manage through that change.*

*I don't think I'm exaggerating when I say that the current pace and extent of change in the industry has never been greater. We need to learn from each other, connect with each other and collaborate across disciplines and companies more than ever before. The pharmaceutical industry in 2025 and beyond will be characterized by rapid innovation and significant shifts in how drugs are developed, delivered, and accessed.*

*With advancements in personalised medicine, digital health, sustainability, and global health equity, the industry is clearly moving toward a more patient-centric, efficient, and sustainable healthcare system. As managers and leaders in the industry, we will be at the forefront of that change.*

*This transformation is driven by breakthroughs in technology, evolving regulatory landscapes, and a growing demand for solutions that prioritise the needs of patients. As we navigate this period of change, the pharmaceutical industry's unwavering commitment to improving patient outcomes remains at the core of what we do, ensuring that every advancement contributes to a healthcare system that benefits those who rely on our medicines.*

*Cell & gene therapies that cure diseases that would once have been a death sentence, the use of GLP-1 drugs to reverse diabetes and obesity, chronic illnesses that have traditionally put huge burdens on health systems worldwide, are just two examples of the new hope but also new complexities that come with innovations in the industry. We're seeing substantial change to how patients access therapies but also changes in the how payors need to consider their cost/value calculations. Our jobs as leaders in the healthcare industry is to evolve with this change, to highlight the potential of new treatments for patients and to help to manage the complexities surrounding their incorporation into the healthcare framework in Ireland.*

*As ever, the PMI is focused on giving our members the opportunity to learn, connect and grow. I'd like to take this opportunity to thank the speakers and sponsors, whose generosity enables the PMI to run this event.*

*And of course, I'd like to thank you all for taking a day out of your busy schedules, to share your knowledge, meet your colleagues and counterparts and maybe learn a little about how to deal with the demands of the current environment.*

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# Session One: Industry CHANGES



**Sarah Rickwood,**  
Vice President, EMEA Thought Leadership



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**Professor Kingston Mills,**  
Professor of Experimental Immunology &  
Director of Trinity Biomedical Sciences Institute



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**Fionnnuala King,**  
Chief Pharmacist - Access & Integration  
Drug Management Programme



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# Sarah Rickwood

Vice President,  
EMEA Thought Leadership



Sarah has 30 years' experience as a consultant to the pharmaceutical industry, having worked in Accenture's pharmaceutical strategy practice prior to joining IQVIA.

She has an extremely wide experience of international pharmaceutical industry issues, having worked most of the world's leading pharmaceutical companies on issues in the US, Europe, Japan, and leading emerging markets, and is now Vice President, European Thought Leadership in IQVIA, a team she has run for 14 years.

Sarah holds a degree in biochemistry from Oxford University

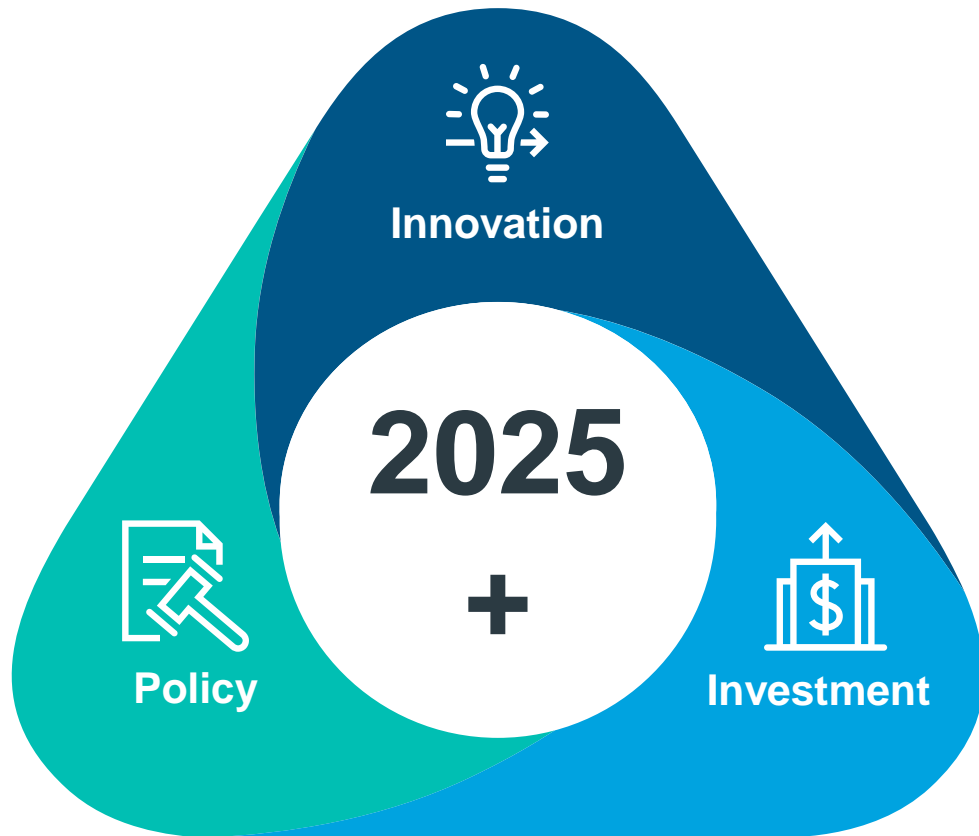
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# Opportunity, uncertainty and risk- a prescription for change in an evolving environment?

Sarah Rickwood, VP, EMEA Thought Leadership, IQVIA

# The world is changing...



## Policy

- **Globally** protectionist shift, feeding forces of divergence for life sciences
- **Trump Administration** full spectrum impact on Life sciences and health care

## Innovation

- **New Obesity medications transformative**, lead to wider Cardiometabolic renaissance
- **New cancer modalities:** bispecifics, ADCs, radioligand, mRNA

## Investment

**Uncertain environment** for investment in early assets and biotech

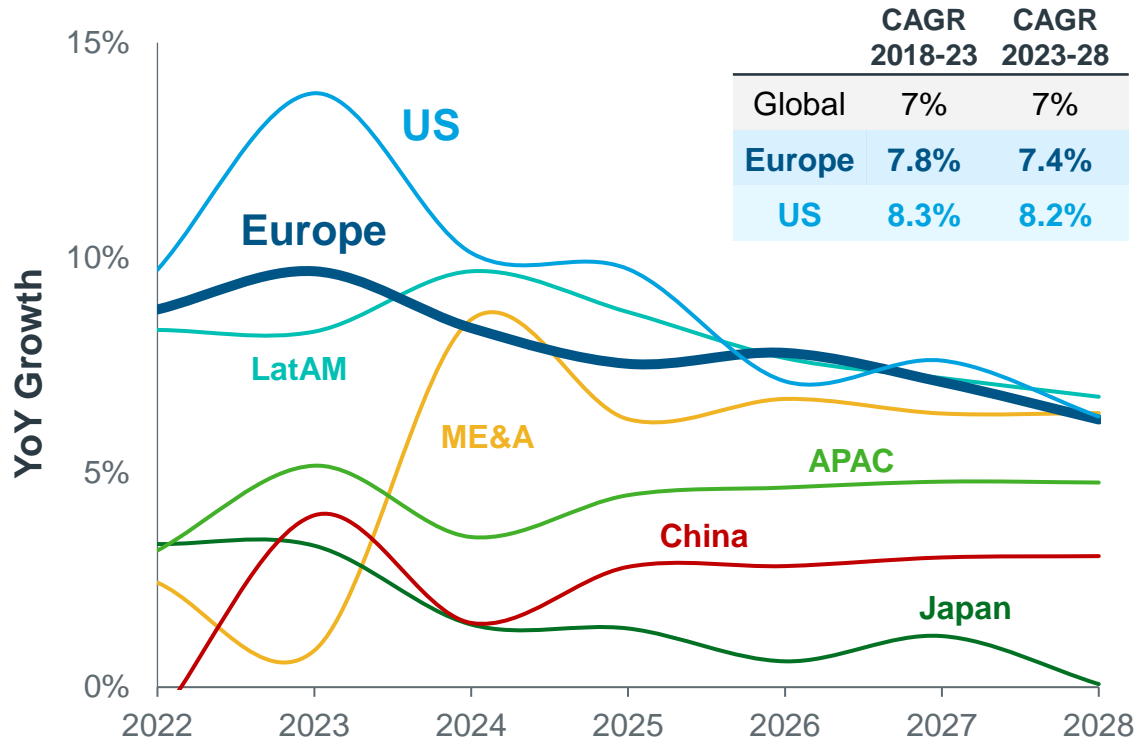
**Scramble for manufacturing capacity** driven by tariff threat, medicines security and obesity demand



# The global prescription medicines market will deliver over \$0.6Tn of value growth in coming years, but prepare for a patent cliff

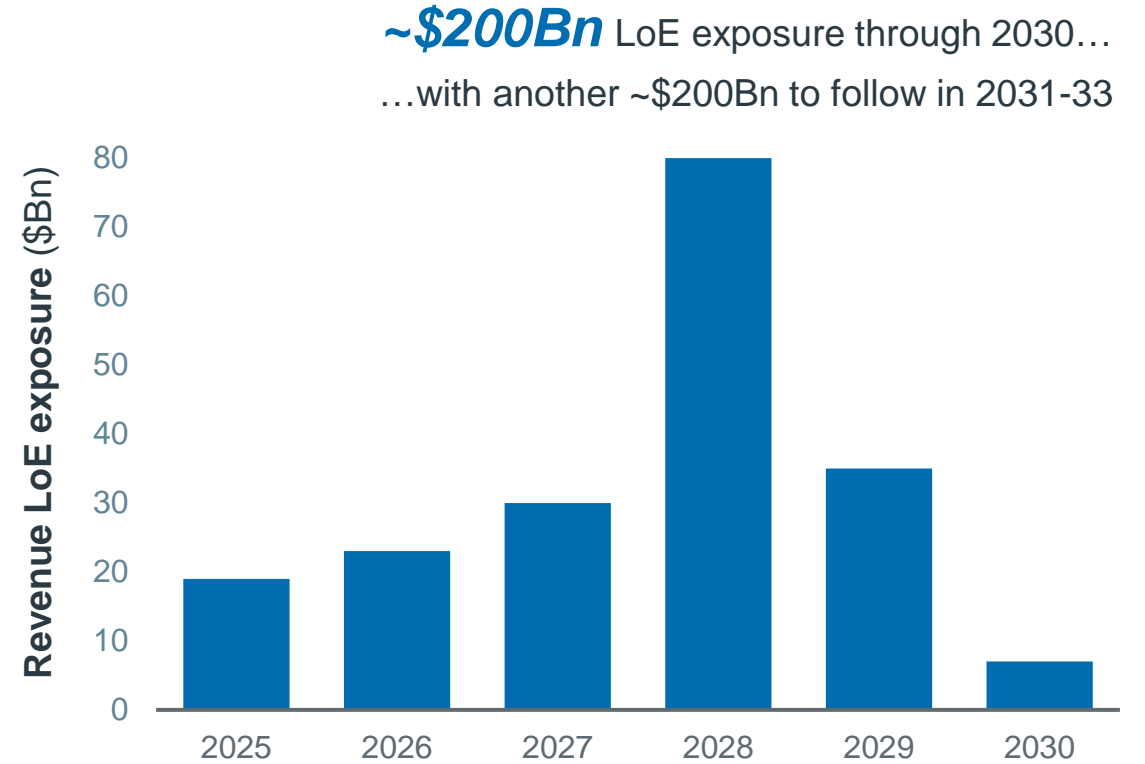
## Developed markets growth slowing down...

(Global spending growth by region, at list prices, ex. Covid vaccines, constant \$)



## ...while major LoE exposure looms

(Estimated projected revenue at risk from LoE; \$)

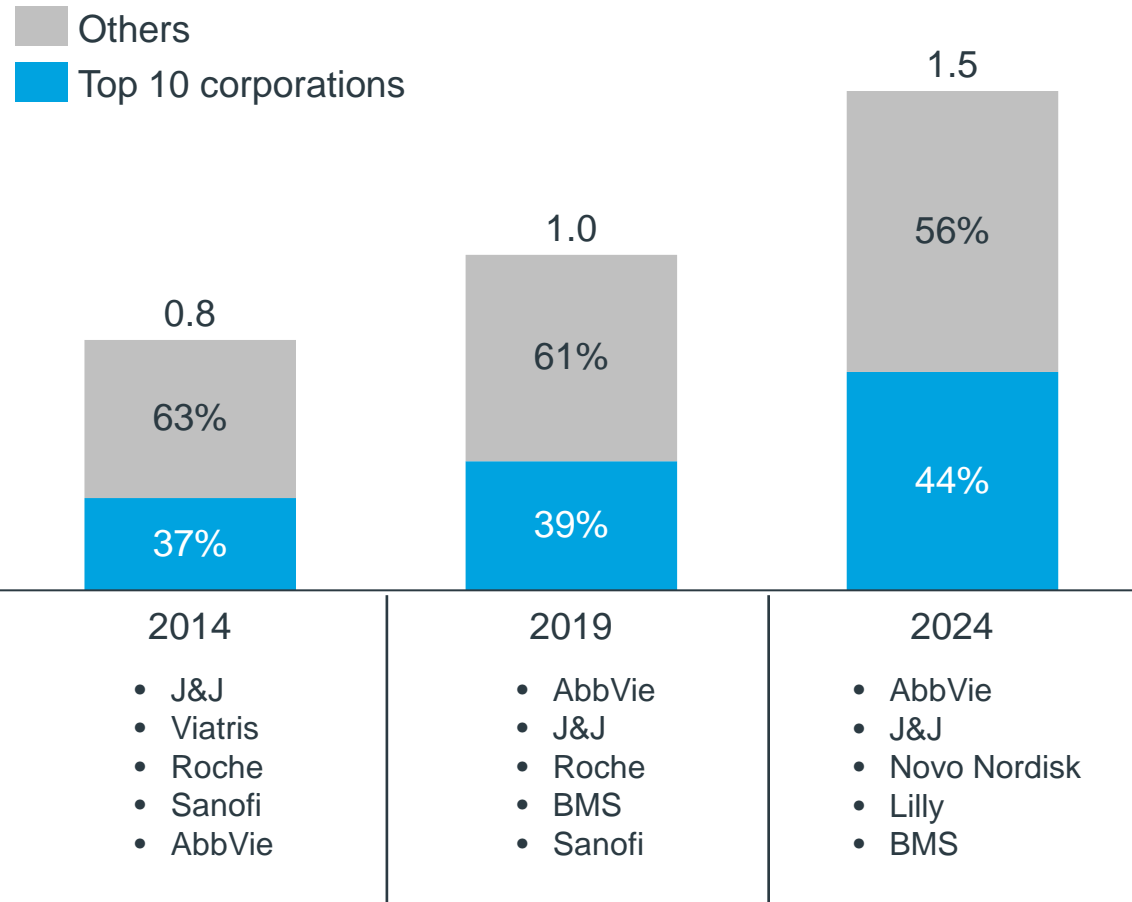


Source: IQVIA Market Prognosis, Sep 2024; company filings; IQVIA EMEA Thought Leadership analysis; Copyright © 2025 IQVIA. All rights reserved; Abbreviations: Bn – Billion, Tn – Trillion, CAGR - Compound Annual Growth Rate, LoE – Loss of Exclusivity

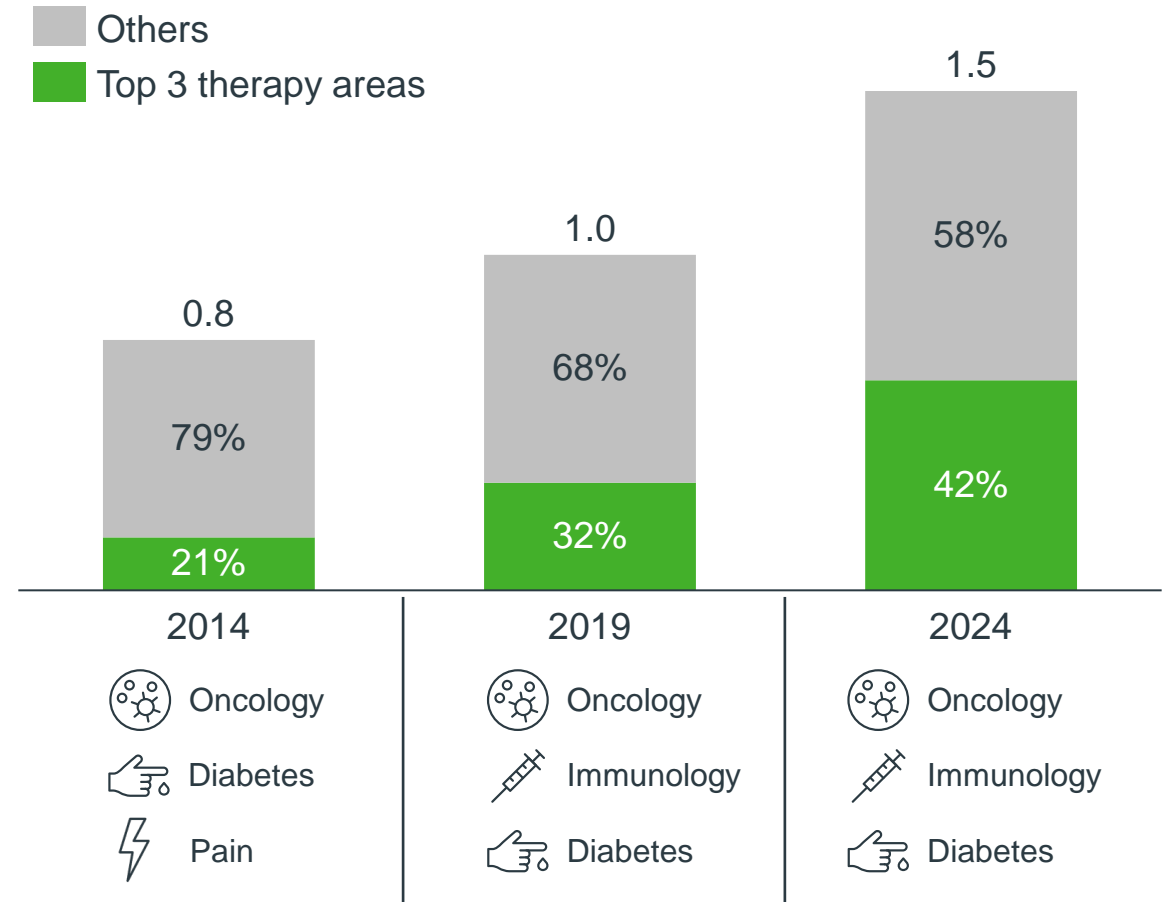


# The global pharma market is concentrating more than ever

## Top 10 Pharma Companies by Global Sales (Tn USD)



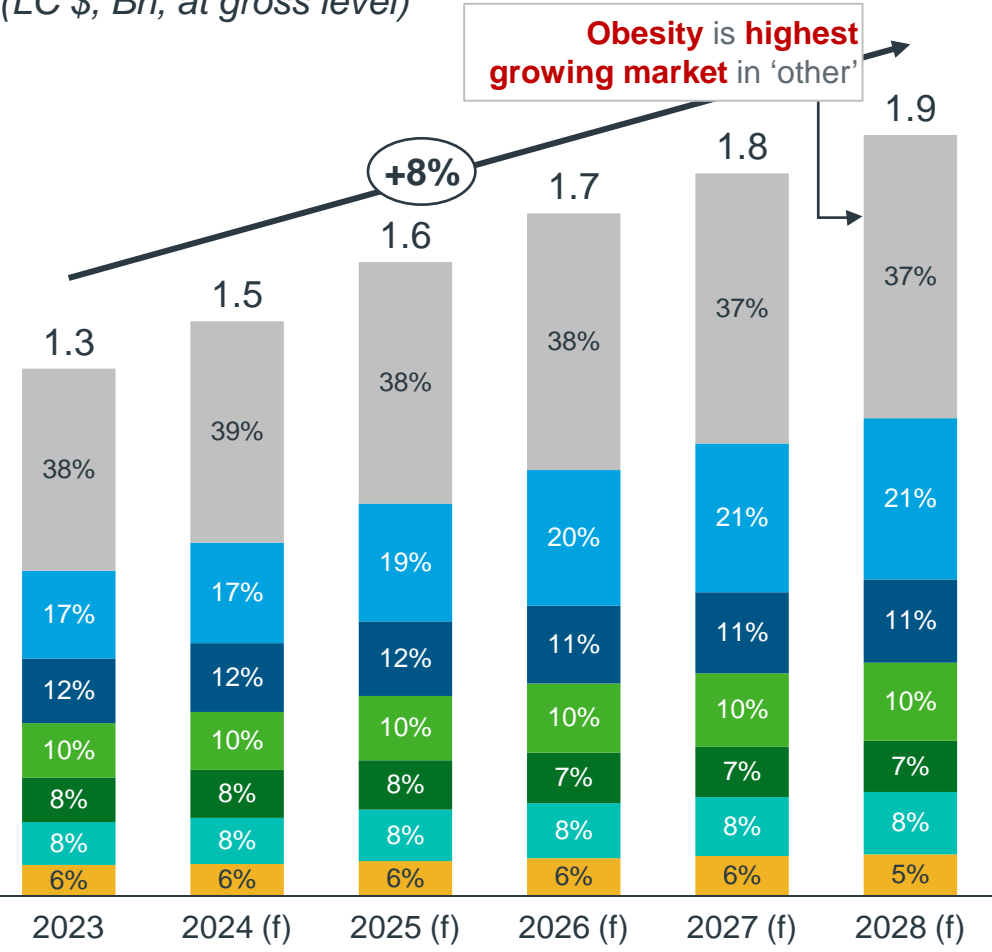
## Global Top Therapy Area (Tn USD)



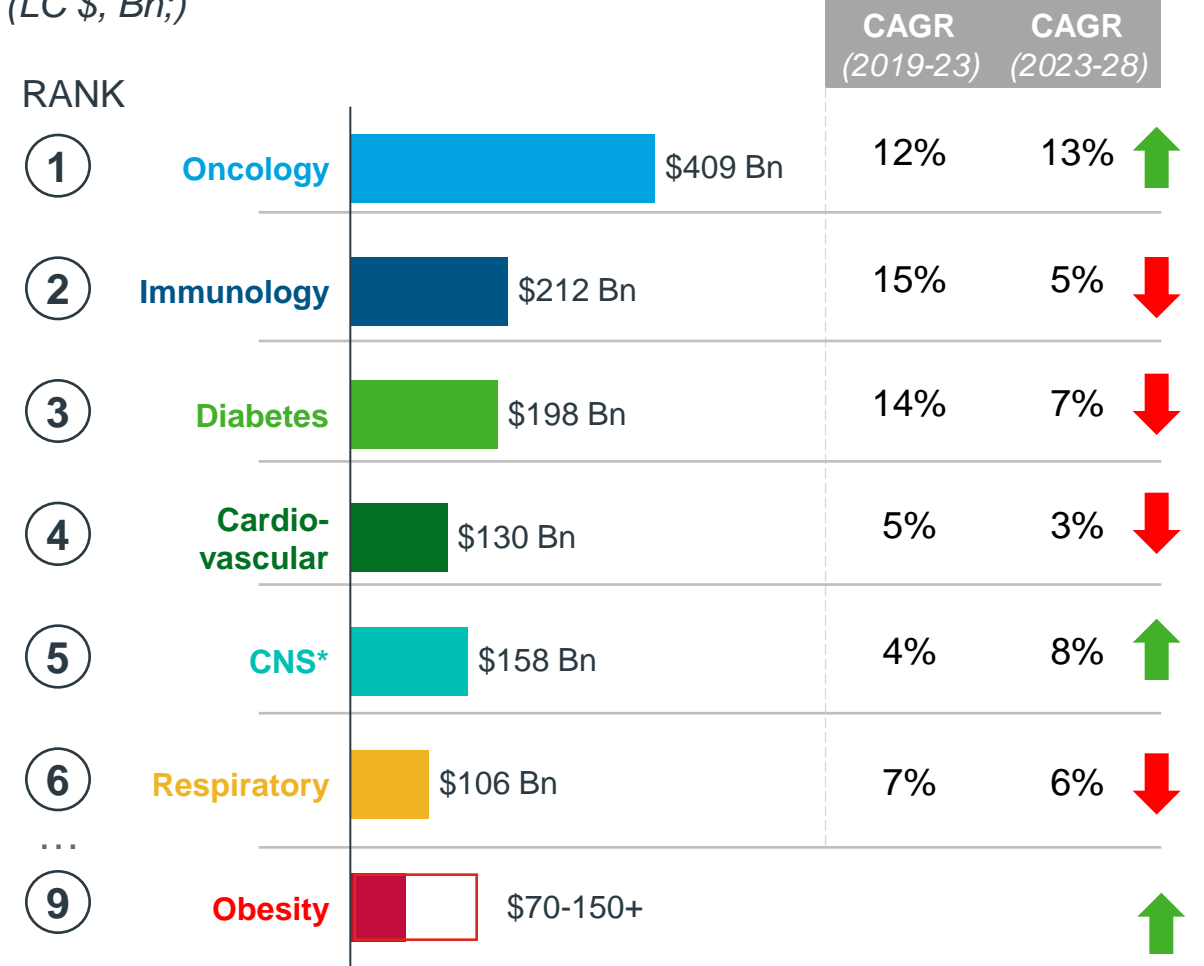
Notes: Excludes COVID-19 Vaccines and Treatments; Companies are arranged from left based on the rankings  
 Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS MAT Q4 2024; Rx-only

# Oncology will continue to grow at historic rates, CNS growth will double, and Obesity will join the top 10

**Global, forecasted top therapy areas by spending<sup>1</sup>**  
(LC \$, Bn; at gross level)



**Global, forecasted top therapy areas 2028 spending<sup>1</sup>**  
(LC \$, Bn;)



\*Includes Pain products  
Abbreviations: Therapy area  
Sources: IQVIA Analytics Link (accessed Jan 2025); IQVIA Institute Global Use of Medicines (2024); IQVIA Institute Oncology Trends (2024)  
DCAT March 17<sup>th</sup> 2025 | Pharma to 2030: Challenges and opportunities in uncertain times



# Trump administration has US and global impacts beyond pharma

## Geopolitical tension

- Isolation under Trump's 'America First' policy
- Potential for pharma tariffs to start
- Calls for reshoring pharmaceutical manufacturing

## Public health and vaccines

- US WHO withdrawal
- USAID shutdown
- Defunding of global health
- Vaccines scepticism

## Agencies turnover

- Political change, funding/workforce cuts, deregulation of health agencies
- *Major job cuts under way and planned for HHS, including FDA, CDC and NIH*



## Drug price controls

- Potential rescoping/expansion of the IRA
- Ongoing preparations for 2<sup>nd</sup> wave of Medicare drug price negotiations
- Potential International Referencing Pricing risk

## Drug transparency

- Health plans to disclose the actual prices they or their PBMs pay for prescription drugs
- In parallel, legislation in Congress is under consideration to improve transparency

## Tax reform

- FTC more facilitating of M&A under Andrew Ferguson
- Plans to lower corporate tax to boost US appeal

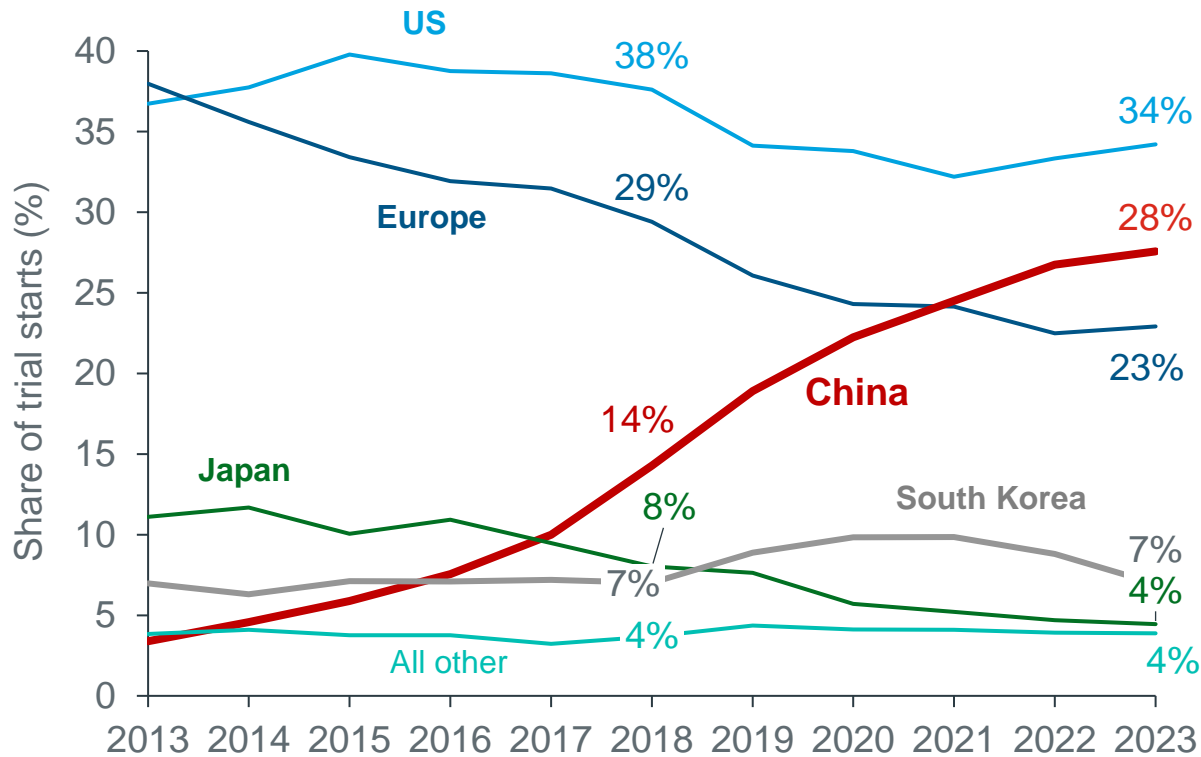
# China emerges as a source of best-in-class innovation; European pharma could benefit from growing US-China tensions



28% trial starts from China-HQ companies

The rise of Chinese innovation

Phase I to III trial starts by sponsor HQ



>30%

In-licensed assets by big pharma in 2024 sourced from China

4,100

New assets added to Chinese companies' pipelines (2022-24)



## High quality assets and solid clinical data

Ivonescimab (VEGF/PD-1 bsAb, Akeso/Summit) beats Keytruda in NSCLC H2H trial



## Example high-profile licencing deals

- MSD-LaNova, VEGF/PD-1 bsAb (\$3Bn)
- Novartis-Shanghai Argo, RNAi CV (\$4.1Bn)
- MSD-Hansoh, oral GLP-1 (\$2Bn)
- AZ-Eccogene, oral GLP-1 (\$2Bn)

Source: IQVIA Institute, R&D Outlook 2024; IQVIA EMEA Thought Leadership analysis; Copyright © 2025 IQVIA. All rights reserved; Abbreviations: HQ – Headquartered, H2H – Head-to-head, Bn – Billion, bsAb – bispecific antibody, CV – Cardiovascular



# Over the horizon: what innovations will headline to 2030?



## New modes of action

- **Personalised mRNA cancer vaccines** join ADCs, bi & multispecific antibodies and radioligands to grow *new oncology areas*
- **New obesity MoAs include orals and new indications**, e.g. *Alzheimer's*
- **Immunology launches in smaller indications + untapped opportunities**, e.g., *urticaria, SLE, HS, BP, nasal polyps*



## Route of Administration

- **Subcutaneous formulations:**
  - PD-1 inhibitors pembrolizumab & nivolumab
  - EGFR and MET bispecific antibody amivantamab
- **Oral, at home delivery of previously hospital based treatments-** eg MS
- **Off the shelf (allogeneic) cell therapies**
- **Self-administered vaccines, thermostable vaccines**



## Technology/AI

- **Consumer availability of clinical grade diagnostics**, e.g., *Continuous Glucose Monitors*
- **AI increasingly prevalent in drug discovery and design**
  - 34 pipeline products with known AI/ML platform use to 2023
  - 75% use in drug design and target ID
  - 8% in trial simulation
- **AI in patient diagnosis/care decisions increasingly important** but exposed to regulation

# The prescription obesity market continues extremely rapid evolution

2024

*AOM market takes shape*

>19Bn

Net sales for key Rx obesity meds

**Supply shortages** for Zepbound/Mounjaro and Wegovy; rush to build manufacturing capacity

Unprecedented willingness to pay OOP in European countries; start of limited reimbursement in some

2025

*More than a transition year*

**Jan 2025:** Lancet Global Commission distinguish between obesity as a risk factor versus standalone disease

**Feb 2025:** FDA declares Zepbound/Wegovy **shortages over**, starting wind down of compounding

Expected read-out of **evoke, evoke+** investigating semaglutide in early Alzheimer's

Expected approval of **semaglutide** in **MASH?**

2026 and beyond

*Next wave of AOMs*

**Lilly's orforglipron**

- first oral, possibly alongside oral semaglutide
- first small molecule

**BI's survodutide**

- first new competitor beyond NN and Lilly

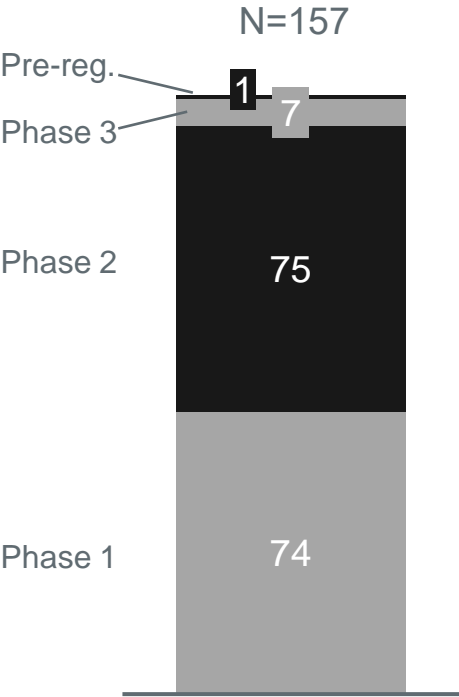
**Novo Nordisk's REDEFINE 4**

- H2H trial of CagriSema (GLP-1/amylin) against tirzepatide

# The gold standard of Obesity care will evolve fast: 157 Anti-Obesity medications, 50+ MoAs are in the pipeline

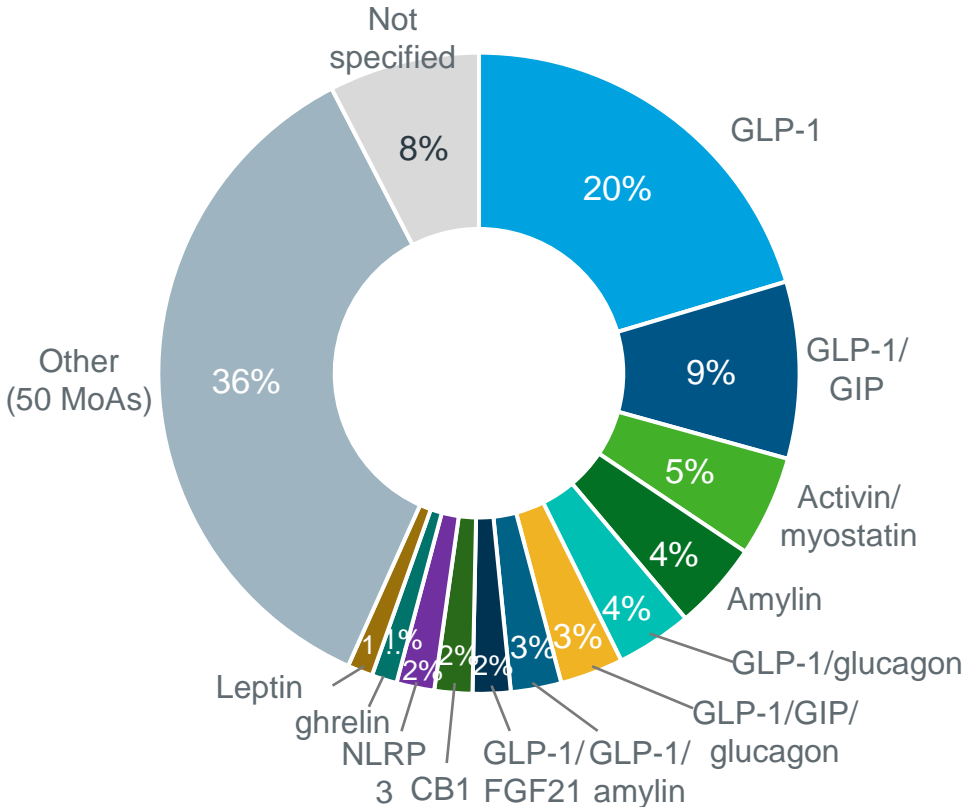
**By phase**

(Number of active assets)



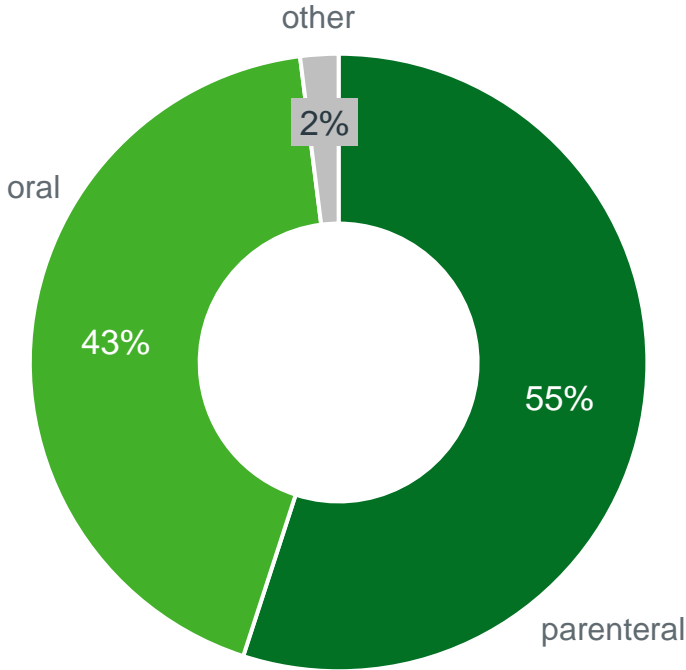
**By mechanism of action**

(phase 1-pre-registration; N = 157)



**By route of administration**

(phase 1-pre-registration; N = 157)



**GLP-1s are the current standard of care, but will rapidly be joined by new MoAs, including orals, with new claims including improvements on speed and quality of weight loss, as well as increasingly compelling data and labels on health benefits beyond weight loss**

Source: IQVIA Analytics Link; Clinicaltrials.gov; company reports, press releases, desk research; IQVIA EMEA Thought Leadership analysis; December 2024, Note: List of companies is not exhaustive.


# Clinical trial readouts have proven that AOMs provide benefits across extensive range of CV-met indications

## Trial readout: 2023

## Trial readout: 2024

	CV-outcomes	Chronic kidney disease	Pre-diabetes	Heart failure	Knee osteoarthritis	Obstructive sleep apnoea	MASH
<b>Semaglutide</b> (Novo Nordisk)	SELECT Risk reduction in MACE-3	FLOW Risk reduction in renal impairment, renal-/CV mortality (in T2D patients)	STEP-10 Reversion to normo-glycaemia	STEP-HFpEF Functional benefits	STEP-9 Reduction in OA-related pain; functional benefits		ESSENCE MASH resolution, fibrosis improvement
<b>Tirzepatide</b> (Lilly)			SURMOUNT-1 (104-wk extension) Risk reduction of progression to T2D	SUMMIT Risk reduction in HFpEF outcomes; functional benefits		SURMOUNT-OSA Reduction in apnea-hypopnea index	SYNERGY-NASH* MASH resolution, fibrosis improvement
<b>Survodutide</b> (Boehringer Ingelheim)							Survodut.-NASH* MASH resolution, fibrosis improvement

\* Indicates phase 2 trial; all others are phase 3 trials  
Source: IQVIA EMEA Thought Leadership, desk research; company press releases

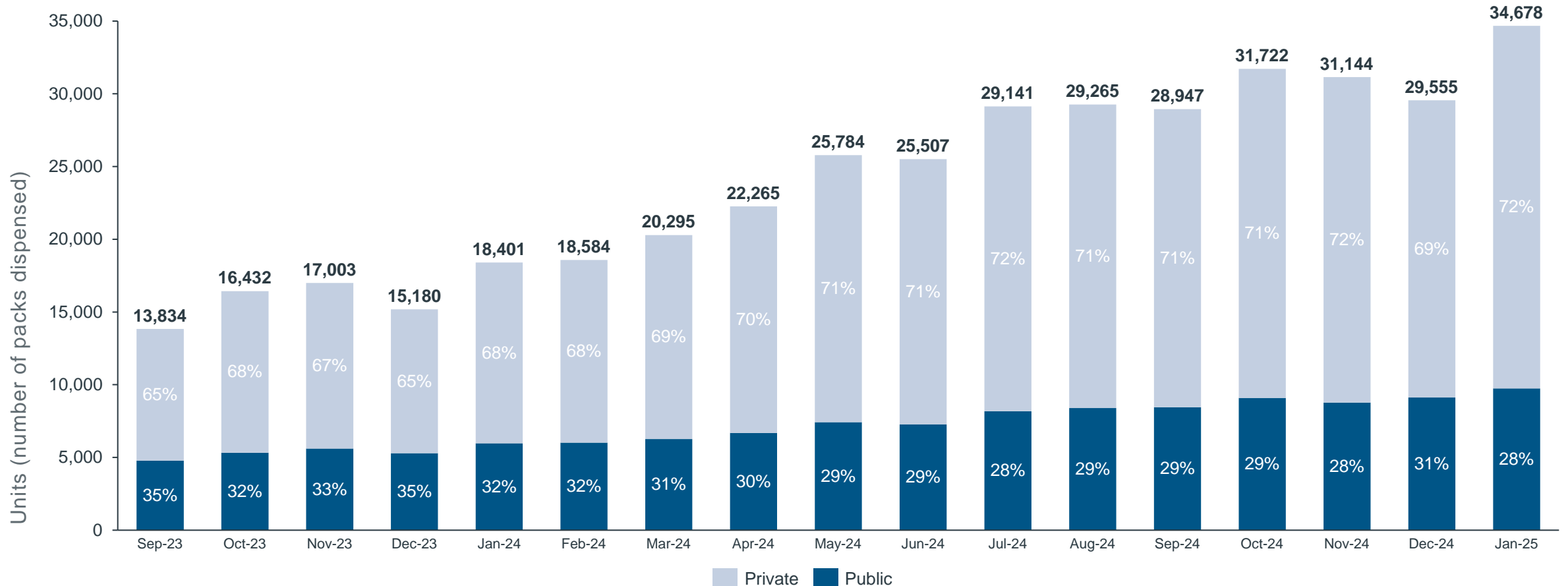
 CV risk reduction, OSA approved by FDA in 2024 as additional indications for Wegovy, Zepbound, respectively

# In Ireland citizens are making their own decisions about their battle with obesity - but what is this doing for Health Inequalities?



Ireland's GLP-1 Weight management market\* has seen an average monthly volume growth of 6% since October 2023

Public/Private Ireland's GLP-1 Weight Management Uptake - (Sep 23 – Jan 25)

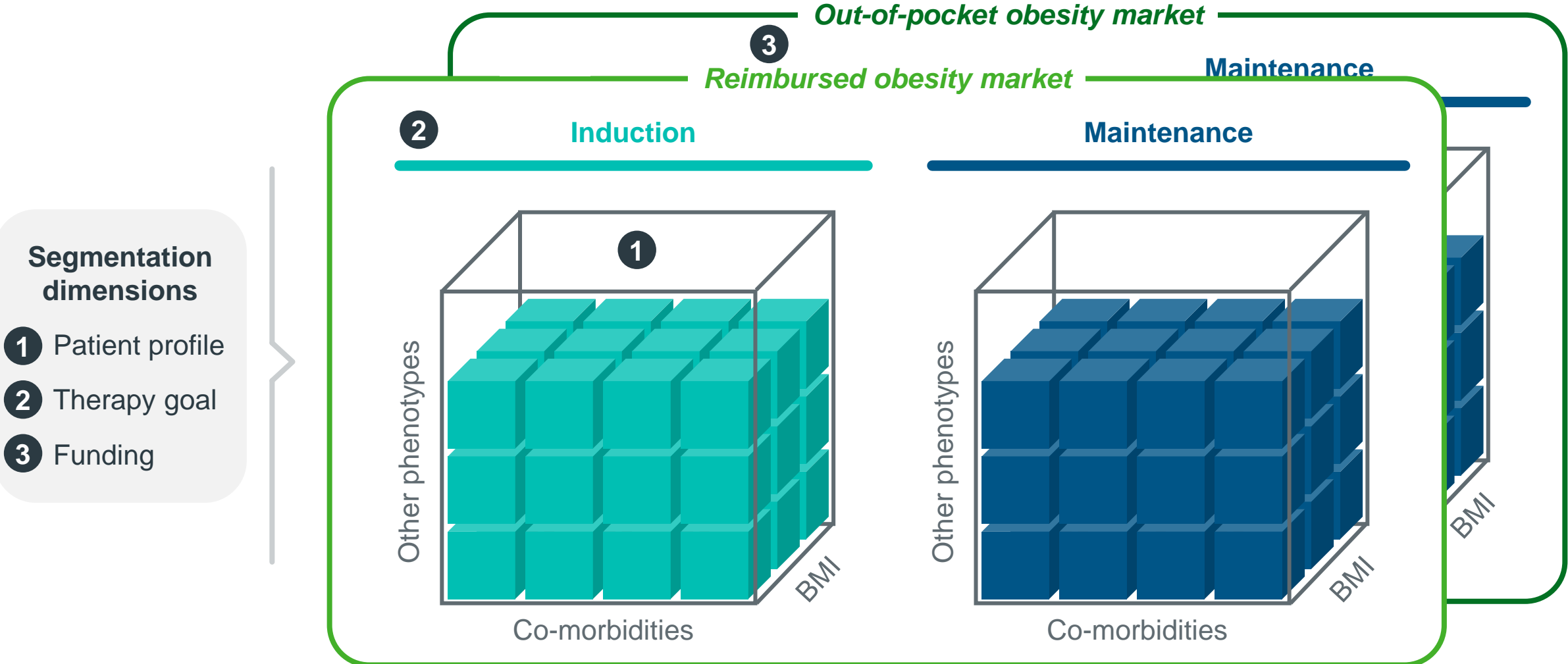


Pubic includes all Community Drugs Schemes, including DPS

\*GLP-1 Weight Management Market defined as any patients on Saxenda or other GLP-1 treatments (OZEMPIC, TRULICITY, VICTOZA) that have no history of collecting other Diabetes medicines and medical devices.

Source: IQVIA LRx GLP-1 Tracker Jan 25

# The future obesity market: more choice, more segmentation, increasingly complex to navigate



Source: IQVIA EMEA Thought Leadership blog post "When the dust settles: The future shape of the obesity market" <https://www.iqvia.com/locations/emea/blogs/2024/10/when-the-dust-settles>

# Healthcare challenges are remoulding healthcare delivery

*Capacity constraints vs. innovation demands; implementing mass obesity agents, AI/diagnostics*

## New significance of the private market



- Shift to private/OOP; led by (but not limited to) obesity agents
- Reimbursement challenges: May drive pharma to launch privately first?
- Line between patients/consumers blurs

## Devolved decision making elevates non-physician roles



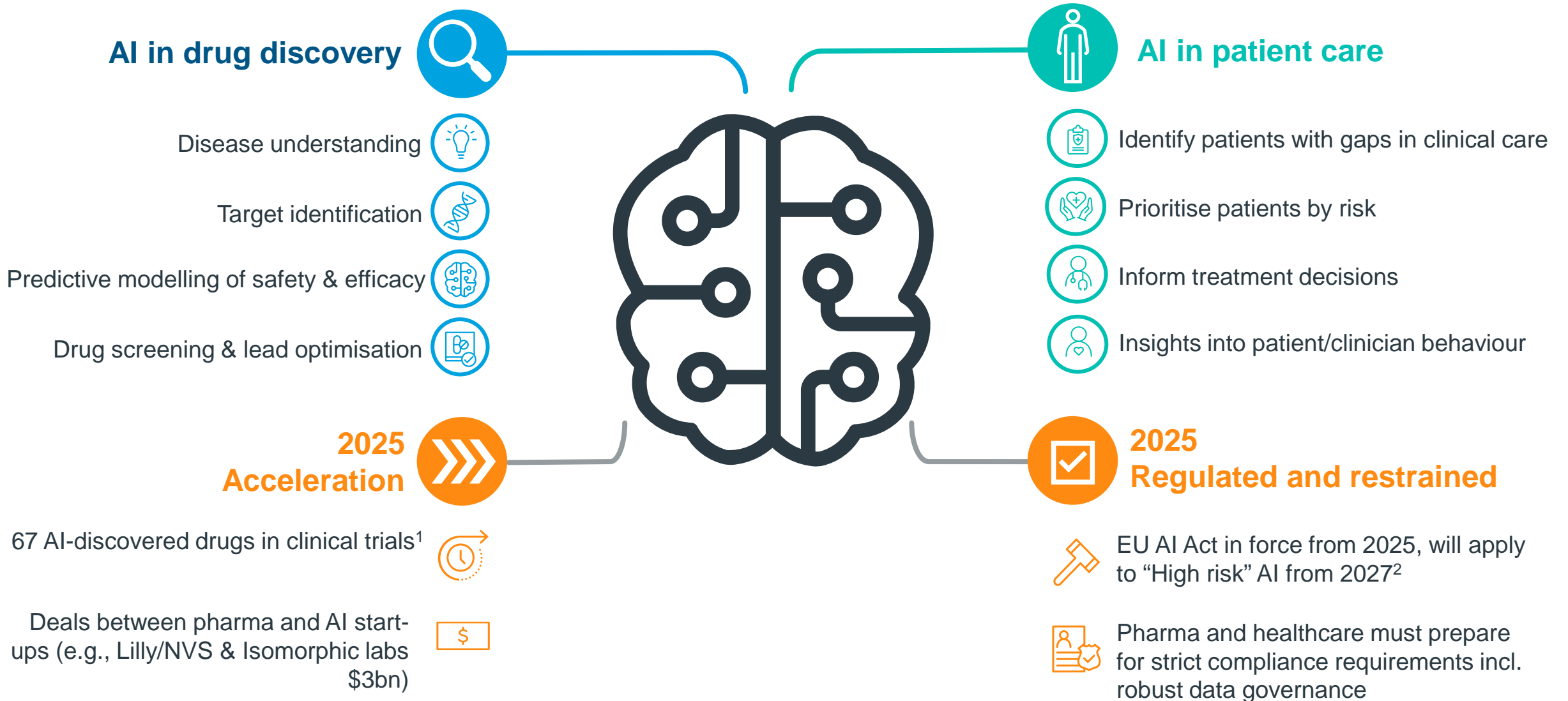
- Expanded roles: nurses, nurse practitioners, pharmacists, physician associates
- Increase in telemedicine, e-prescribing
- AI-based decision support tools becoming reality

## Healthcare systems pulled in different directions



- Conflicting demands: innovation in mass market and highly specialised therapies
- Struggling health systems forced into policy rethink?
- Eg shift to preventative care, individual responsibility, community/home setting?

# A divergence in AI: driving discovery, restrained in healthcare



(1) Drug discovery today 2024: 29 (6) :104009  
(2) IQVIA blog: EU AI Act

# Securing manufacturing supply has never been a more important strategic priority

## Greater capacity required

- **High demand** for chronic diseases targeting molecules, particularly obesity
- **Supply chain impacts** from geopolitics, conflict and climate change.

## Re-localisation and diversification



### US BIOSECURE Act reprise?

- Bans federal funds recipients from contracting with some Chinese firms



### Trump's intentions

- Tariffs on imported finished medicines, APIs



### EU Critical Medicines Act

- Draft published March 2025
- Encourage EU production via state aid, joint procurement, and supply chain resilience



### WHO Pandemic Treaty

- Expected May 2025\*
- Article 10 calls for greater local capacity to reduce global supply chain dependence

## Implications



**Race to understand implications and buy capacity**



**Potential increases in costs**



**Collaborative nature** of supply chain resilience may conflict with national sovereignty

# Evolving through change: four key takeaways for tomorrow's pharmaceutical environment

1

Global challenges creating uncertainty and will reshape the Pharma landscape from manufacturing to commercialisation

2

Healthcare priorities shifting to more efficient patient throughput expanding opportunities in primary care - *Pharma must fit with the strategic objectives*

3

China and emerging biopharma to drive innovation, as large Pharma concentrate their focus on key therapy areas

4

Dynamics of healthcare will change: AI and patient preference will be strong drivers of treatment choice



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# Prof Kingston Mills

Professor of Experimental Immunology  
and Director of Trinity Biomedical  
Sciences Institute



**Trinity College Dublin**  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

Kingston qualified from TCD with a BA(Mod) in Biochemistry and PhD in Immunology. He trained at as a Postdoctoral Fellow at University College London and the MRC National Institute for Medical Research, London. He was lecturer, Associate Professor and Dean of the Faculty of Science and Engineering at Maynooth University.

He was appointed to a Personal Chair at TCD in 2001 and was Head of the School of Biochemistry and Immunology from 2008-2011. His research is the discipline of immunology, where his interests are on the role of T cells in infection and autoimmune diseases. He is lead investigator on the COVID-19 Research Hub at TCD. He is a co-founder of three University spin-out companies, Opsona Therapeutics, TriMod Therapeutics and Parvalis Therapeutics. Kingston received the Science Foundation Ireland Researcher of the year award in 2020.

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How immunology is central to the design of new therapeutics and vaccines for inflammatory disease, cancer and infection

## Kingston Mills

*Trinity Biomedical Sciences Institute  
Trinity College Dublin, Ireland*





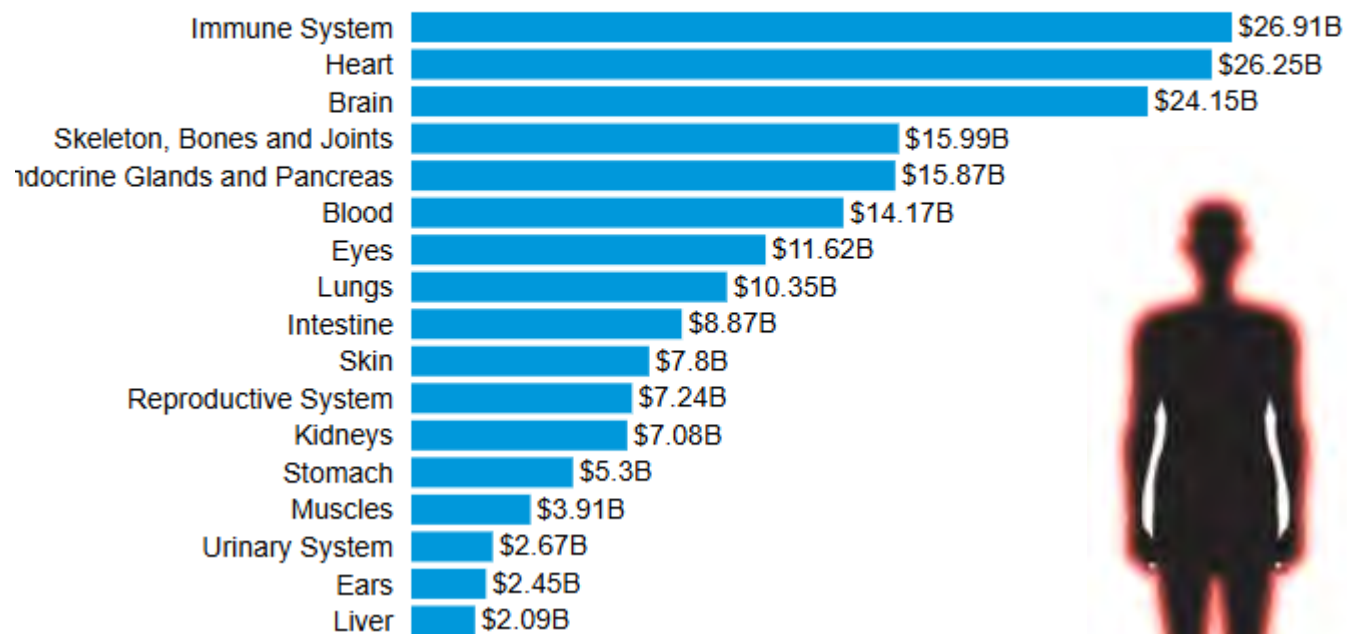
# The Human Body, According to Venture Capitalists

The investors who support emerging medical technologies play an important role in determining which new therapies reach the public. A WSJ Pro analysis of venture investment trends since 1999 reveals which body systems stand to benefit most from their decisions.

By: [Renee Lightner](#), [Christopher Zinsli](#) and [Alberto Cervantes](#)

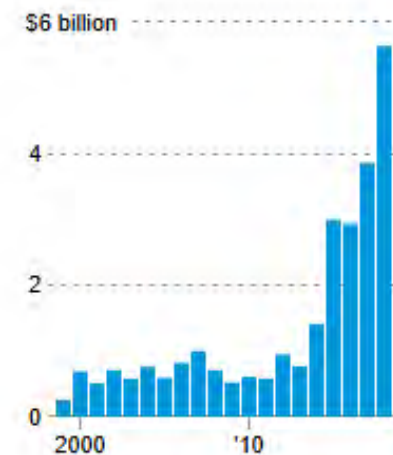
Last updated Feb. 14, 2019 | Published Sept. 14, 2014

## Total amount invested by venture capital deals, 1999-2018



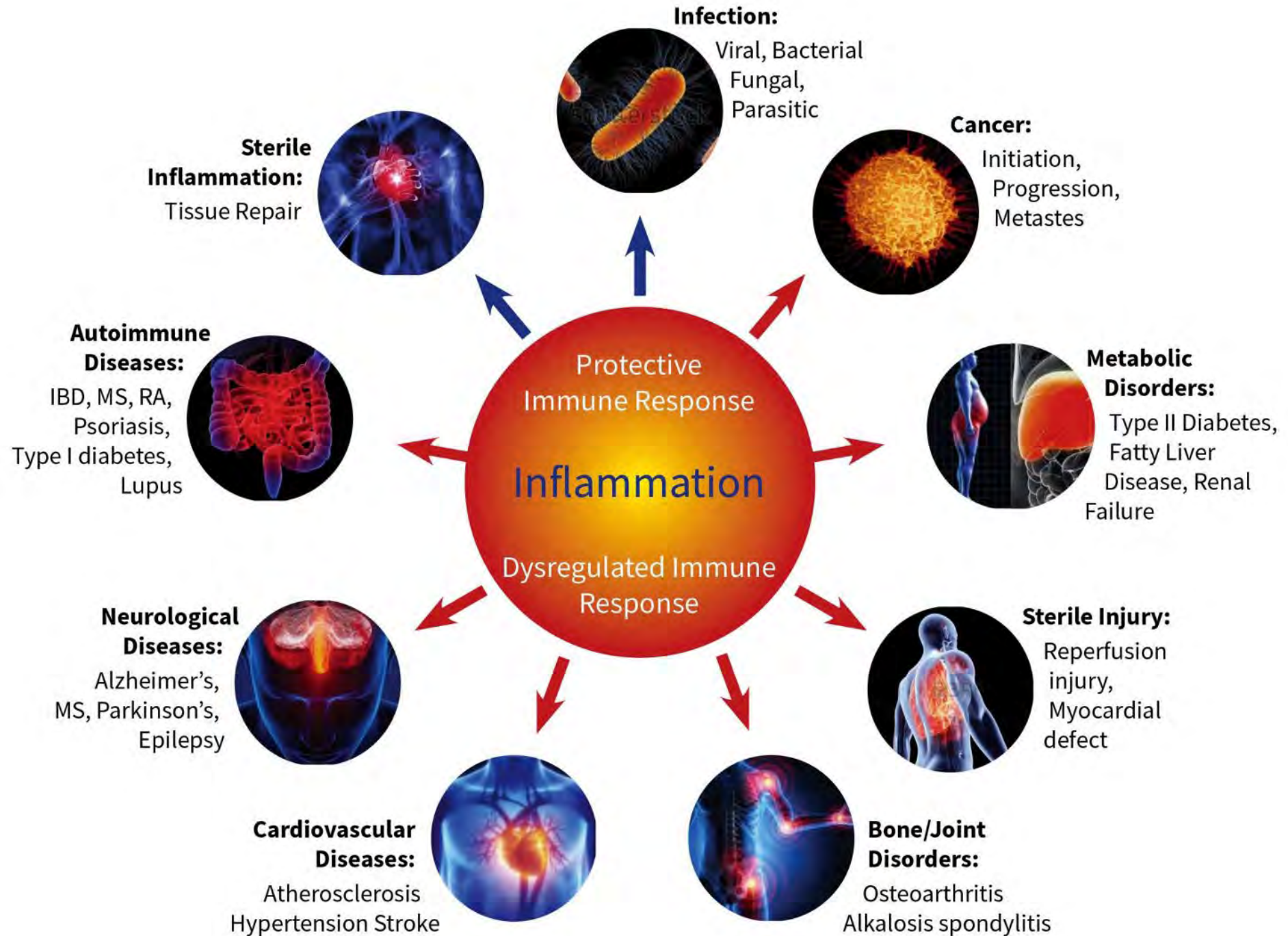
## Immune System

The emerging field of immuno-oncology is driving considerable interest in this sector. The amount of capital invested in immunological startups last year surpassed the amount committed to any medical field in any year on record.

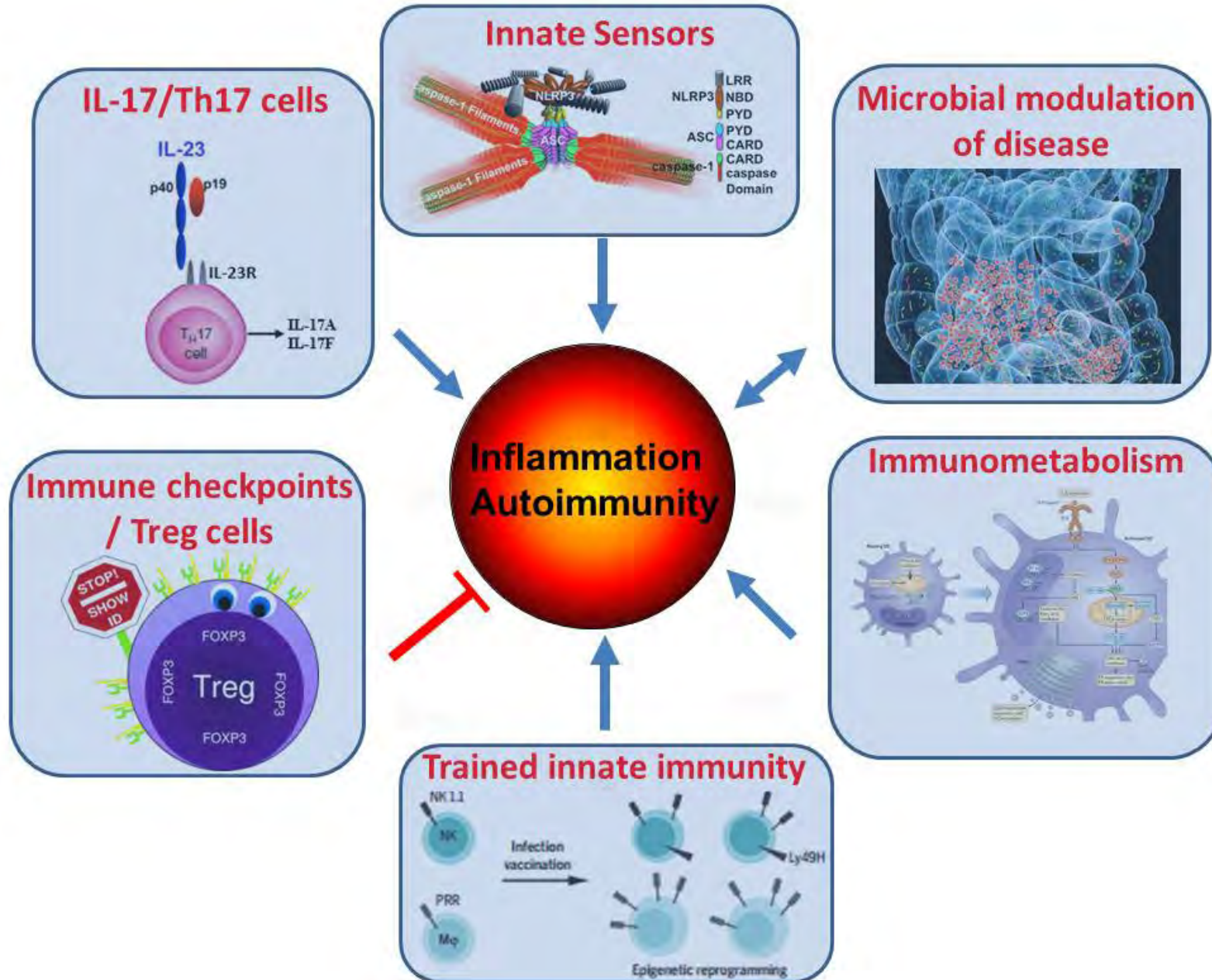


Total 1999-2018:

**\$26.91 billion**



# Frontier areas of immunology



# Precipitating factors in human diseases: Genetic versus environmental

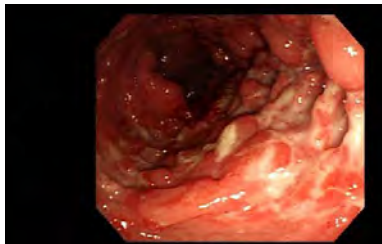
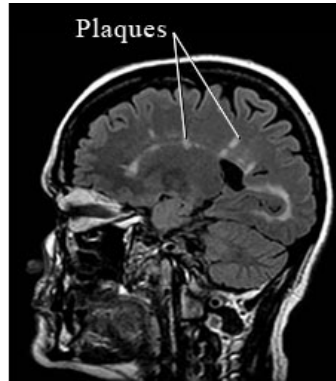
## Variation in the Human Immune System Is Largely Driven by Non-Heritable Influences

Petter Brodin,<sup>1,2,3,11</sup> Vladimir Jojic,<sup>4,11</sup> Tianxiang Gao,<sup>4</sup> Sanchita Bhattacharya,<sup>3</sup> Cesar J. Lopez Angel,<sup>2,3</sup> David Furman,<sup>2,3</sup> Shai Shen-Orr,<sup>5</sup> Cornelia L. Dekker,<sup>6</sup> Gary E. Swan,<sup>7</sup> Atul J. Butte,<sup>6,8</sup> Holden T. Maecker,<sup>3,9</sup> and Mark M. Davis<sup>2,3,10,\*</sup>



Measured 204 different parameters, including cell population frequencies, cytokine responses, and serum proteins, and found that 77% of these are dominated and 58% almost completely determined by nonheritable influences.

# Autoimmune / chronic inflammatory diseases

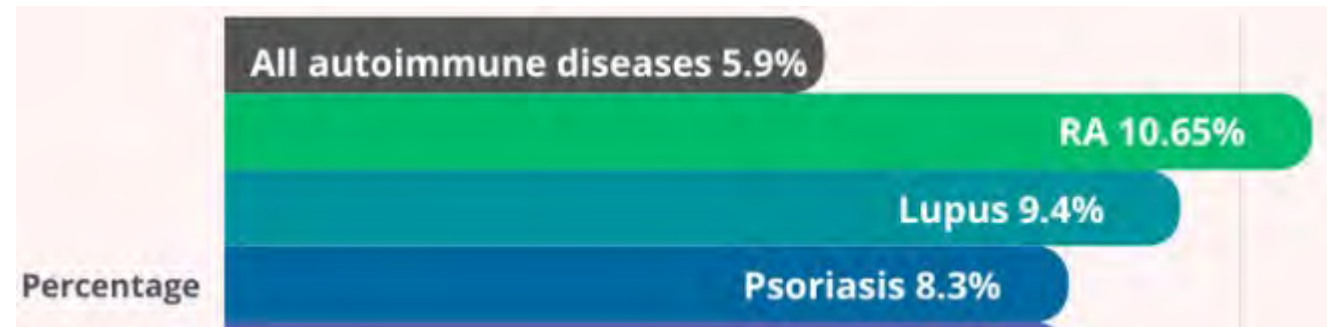


- Affect over 300 million people worldwide and increasing

- **Rheumatoid arthritis** (RA): 1/100, 20m people in US
- **Psoriasis** 1/50-1/1000; 5.5m in US
- **Multiple sclerosis** (MS): 1/700,
- **Crohn's disease and Ulcerative colitis**: 1/500-1/2000
- **Type 1 Diabetes**: 1/100,000 – 1/2000

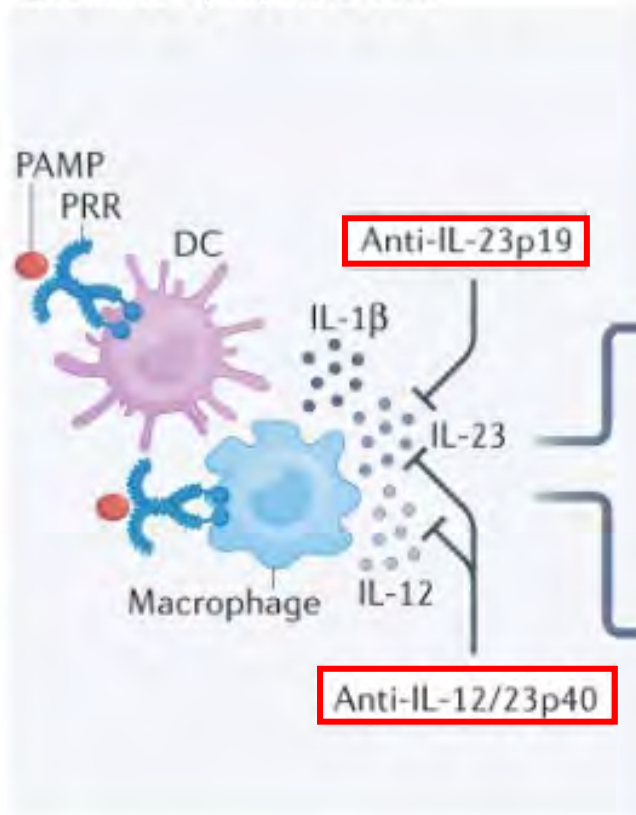
- Pharmacological drugs, including traditional chemotherapy, still major first line treatment, but biologics increasing use and market share

## % patients prescribed Biologics at time of diagnosis

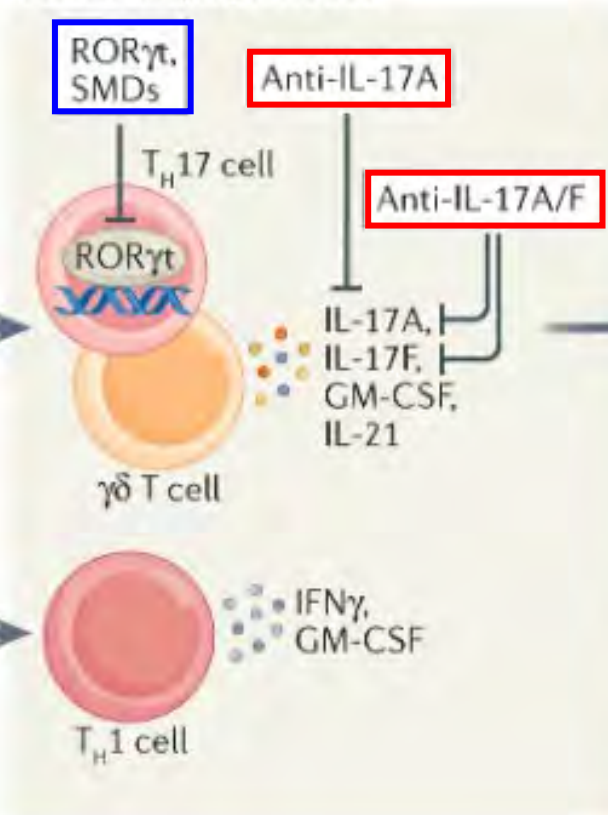


# Drug targets in IL-23-IL-17 pathway

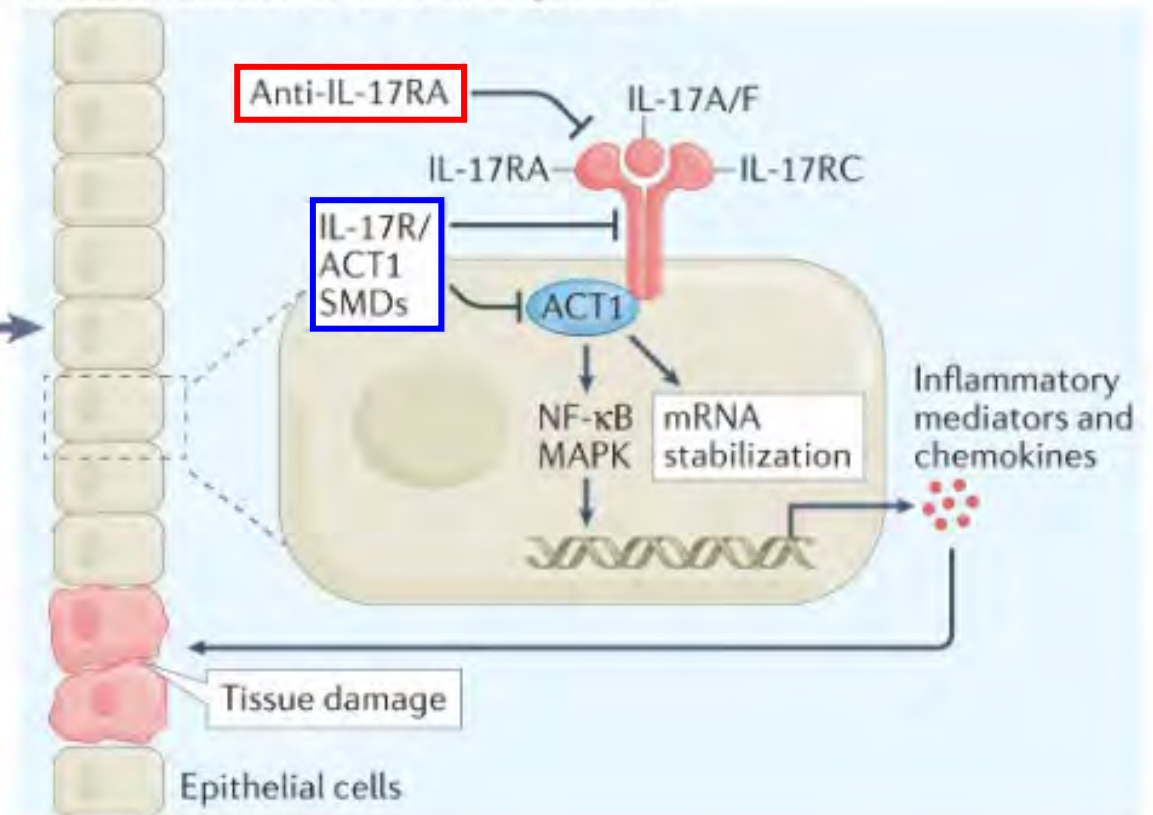
## Production of T cell-polarizing cytokines by myeloid cells



## Activation of pathogenic T cells in lymph nodes

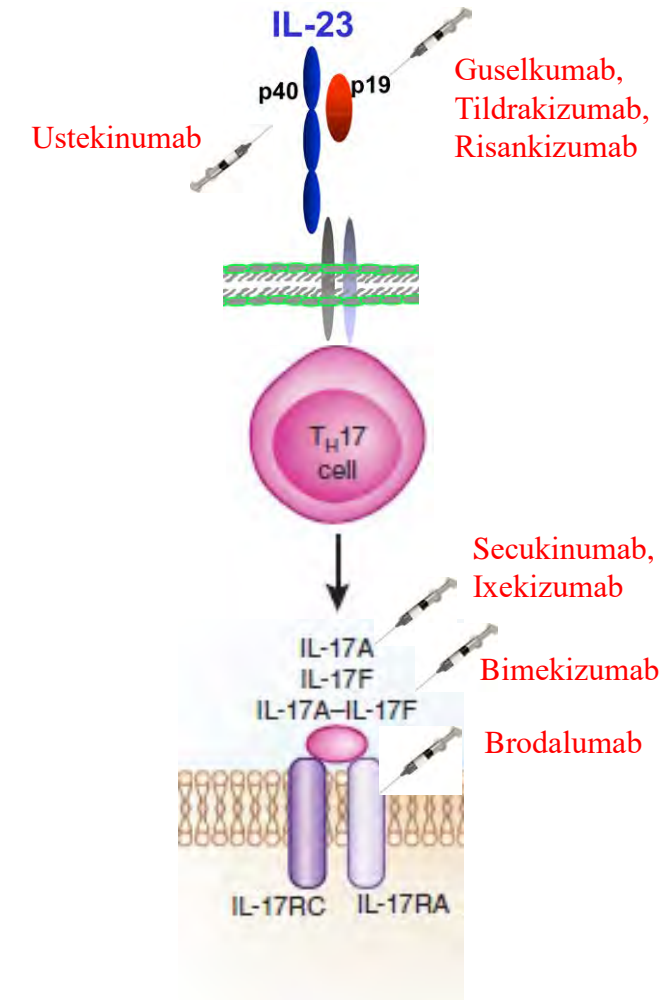


## Effector function of IL-17 in target issue



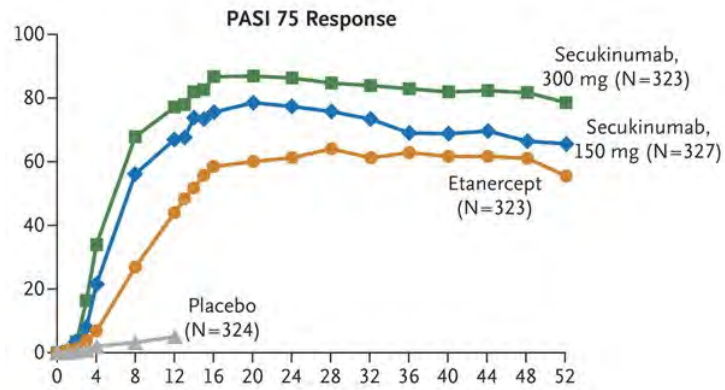
# IL-17/IL-23 therapies for autoimmune/inflammatory diseases

Indication	Evidence of role for IL-17 pathway	MoAb to IL-17 pathway in clinal trials / human use
Psoriasis	IL-17RA SNP association. Th17 and $\gamma\delta$ T17 in skin lesions	ustekinumab, secukinumab, ixekizumab, bimekizumab, brodalumab guselkumab, tildrakizumab, risankizumab approved
Psoriatic arthritis	Th17, Tc17, $\gamma\delta$ T17 and ILC3 in skin lesions and synovial fluid	ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, risankizumab, approved
Ankylosing spondylitis	IL-23R, STAT3 & CARD9 SNP association	secukinumab, ixekizumab, brodalumab approved
Rheumatoid arthritis	IL-17 in synovial fluid.	ustekinumab or guselkumab no efficacy secukinumab low efficacy
Multiple sclerosis	Th17 and $\gamma\delta$ T17 in brain lesions	secukinumab some efficacy phase 2
Inflammatory bowel disease	IL-23R SNPs association. Th17 enhanced in CD and UC	ustekinumab approved, secukinumab, brodalumab $\uparrow$ disease
Type 1 diabetes	Th17 expanded in blood in T1D	ustekinumab and ixekizumab phase 2/3 recruiting
Uveitis	Elevated IL-17 and IL-23 in blood	secukinumab phase did not meet primary endpoint.
Atopic dermatitis	IL-17A $\uparrow$ in skin lesions, $\uparrow$ Th17 in blood	secukinumab phase 2 completed
Neutrophilic asthma	IL-17A SNPs association, Th17 cells $\uparrow$ in blood	secukinumab and broadalumab phase 2 trials terminated
Graft versus host disease	$\uparrow$ Th17 in blood of GVHD patients	Ustekinumab Phase 2 completed, some benefit
Hidradenitis suppurativa	Substantial skin infiltrating CD161 <sup>+</sup> Th17 cells	bimekizumab, secukinumab phase 3 ongoing
Alzheimer's disease (AD)	$\uparrow$ Th17 in blood in mild cognitive impairment	ustekinumab in pre-clinical Alzheimer's diagnosis.
Fatty liver disease	IL-17 $\uparrow$ in obesity / liver disease.	Secukinumab completed



# IL-23/IL-17 pathway biologics – a ‘cure’ for psoriasis

## Secukinumab (anti-IL-17A)



Langley, N Engl J Med. 2014; 371:326-38



Baseline  
\*Before treatment  
GLDEMAN457A/0549

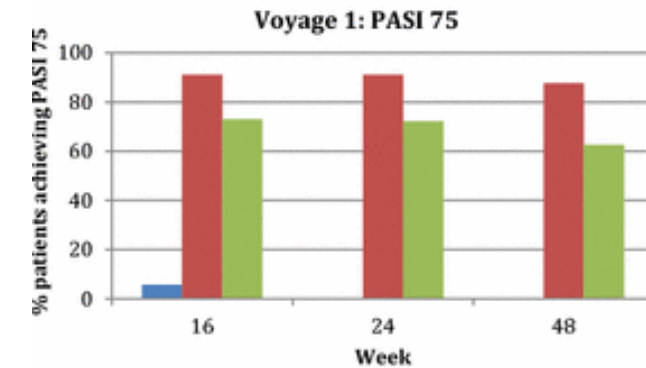


NOVARTIS

- 89% PASI 75 response rates at Year 5.
- 44% of psoriasis patients completely clear skin (PASI 100) at Year 1, maintained to Year 5 (41%).
- 21% of psoriasis patients - skin clearance for up to one year without treatment

(Step in Trial; P2223 26th EADV Congress 2017)

## Guselkumab (anti-IL-23)



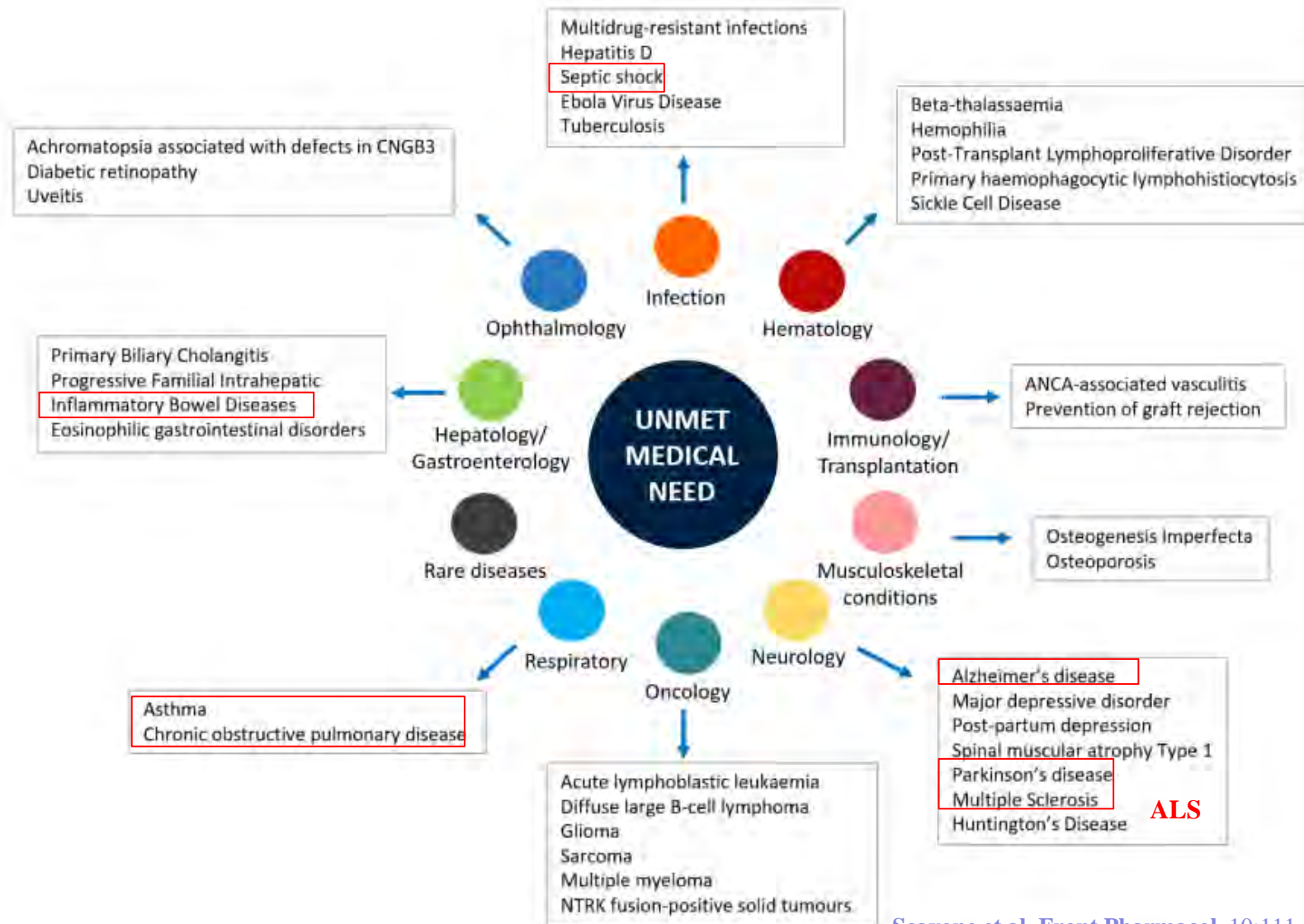
Nakamura et al Dermatol Ther. 2017, 7 (3) 281.

# Future immune-based drugs for inflammatory diseases

## Key target to block inflammation

- IL-23/IL-17
- Inflammasome / IL-1 $\beta$
- Endogenous anti-inflammatories
- Autoantigen-specific Treg cells
- Multiple undiscovered

## Indications



# Inhibition of IL-11 signalling extends mammalian healthspan and lifespan

<https://doi.org/10.1038/s41586-024-07701-9>

Received: 18 April 2023

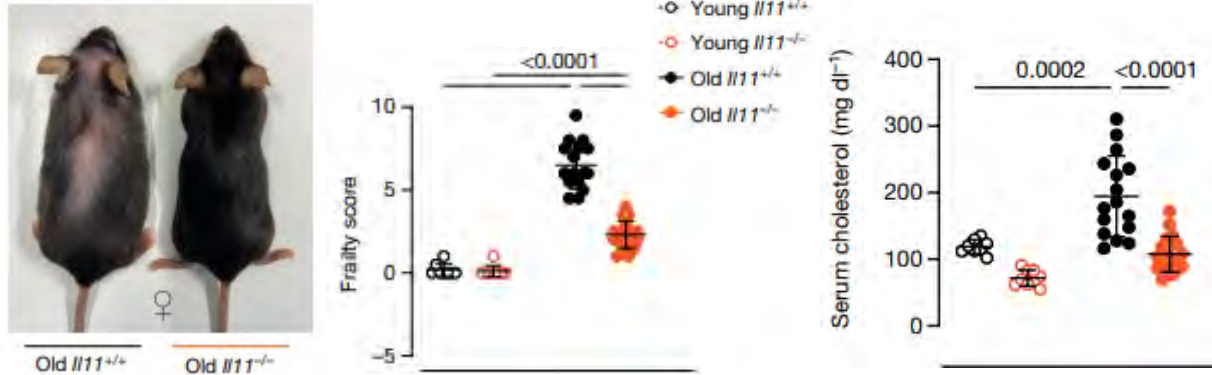
Accepted: 11 June 2024

Published online: 17 July 2024

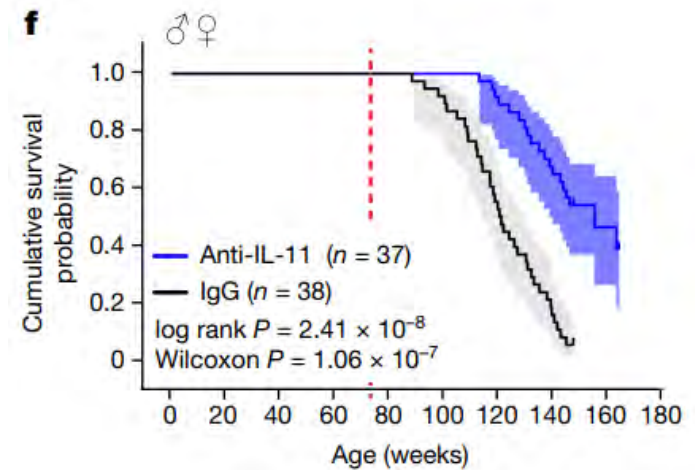
Anissa A. Widjaja<sup>1,2,13,14</sup>, Wei-Wen Lim<sup>1,2,12</sup>, Sivakumar Viswanathan<sup>1</sup>, Sonia Chothani<sup>1</sup>, Ben Corden<sup>2,3</sup>, Cibi Mary Dasan<sup>1</sup>, Joyce Wei Ting Goh<sup>1</sup>, Radiance Lim<sup>1</sup>, Brijesh K. Singh<sup>1</sup>, Jessie Tan<sup>2</sup>, Chee Jian Pua<sup>2</sup>, Sze Yun Lim<sup>1</sup>, Eleonora Adami<sup>4</sup>, Sebastian Schafer<sup>1</sup>, Benjamin L. George<sup>1</sup>, Mark Sweeney<sup>5</sup>, Chen Xie<sup>2</sup>, Madhulika Tripathi<sup>1</sup>, Natalie A. Sims<sup>6,7</sup>, Norbert Hübner<sup>4,8,9</sup>, Enrico Petretto<sup>1,10</sup>, Dominic J. Withers<sup>5,11</sup>, Lena Ho<sup>1</sup>, Jesus Gil<sup>5,11</sup>, David Carling<sup>5,11</sup> & Stuart A. Cook<sup>1,2,5,13,14</sup>

Nature | Vol 632 | 1 August 2024 |

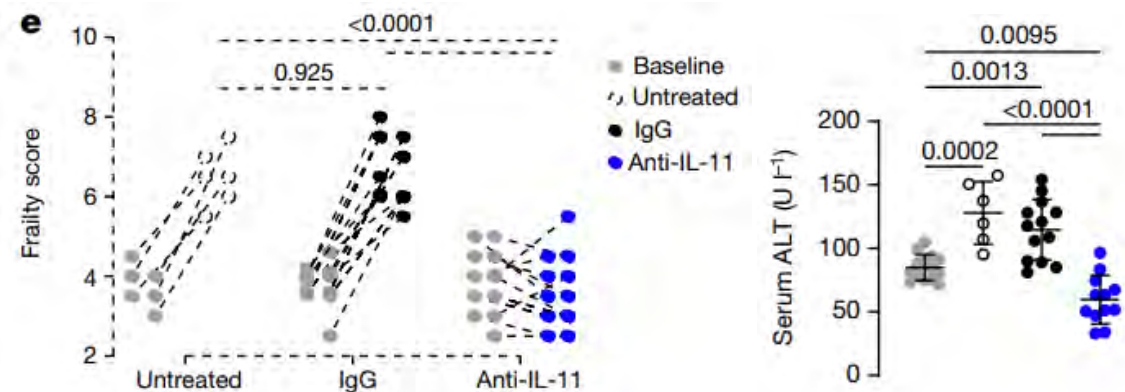
Female IL-11-deleted mice are protected from age-associated obesity, frailty, and metabolic decline.



Inhibition of IL-11 extends life expectancy of male and female mice.



Therapeutic inhibition of IL-11 reduces age-associated metabolic dysfunction, pathogenic signalling and sarcopenia in male mice.



Anti-IL-11 currently in early-stage clinical trials for fibroinflammatory diseases

# Certain cancer can now be cured in certain patients - exploiting fundamental discoveries in Immunology

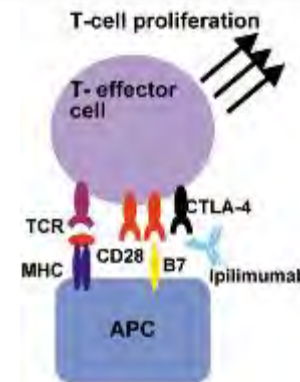


Jim Allison

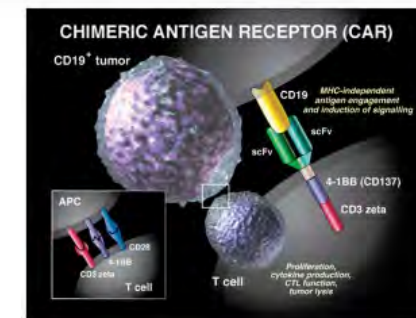


Tasuku Honjo

**Nobel Prize** in Medicine, 2018



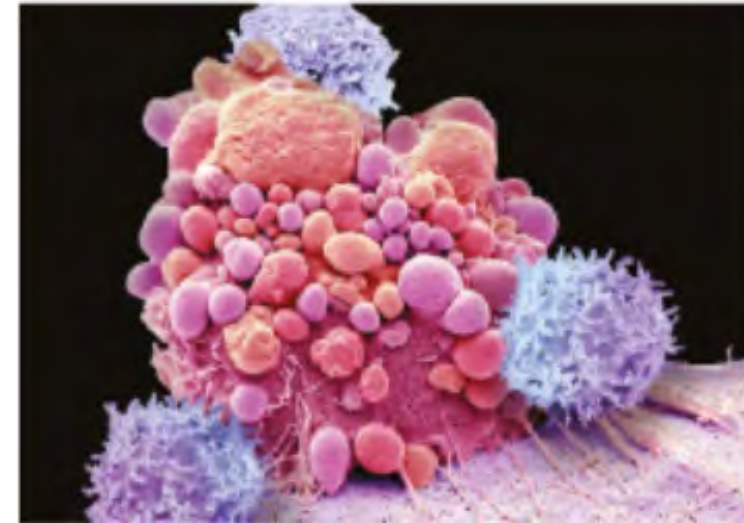
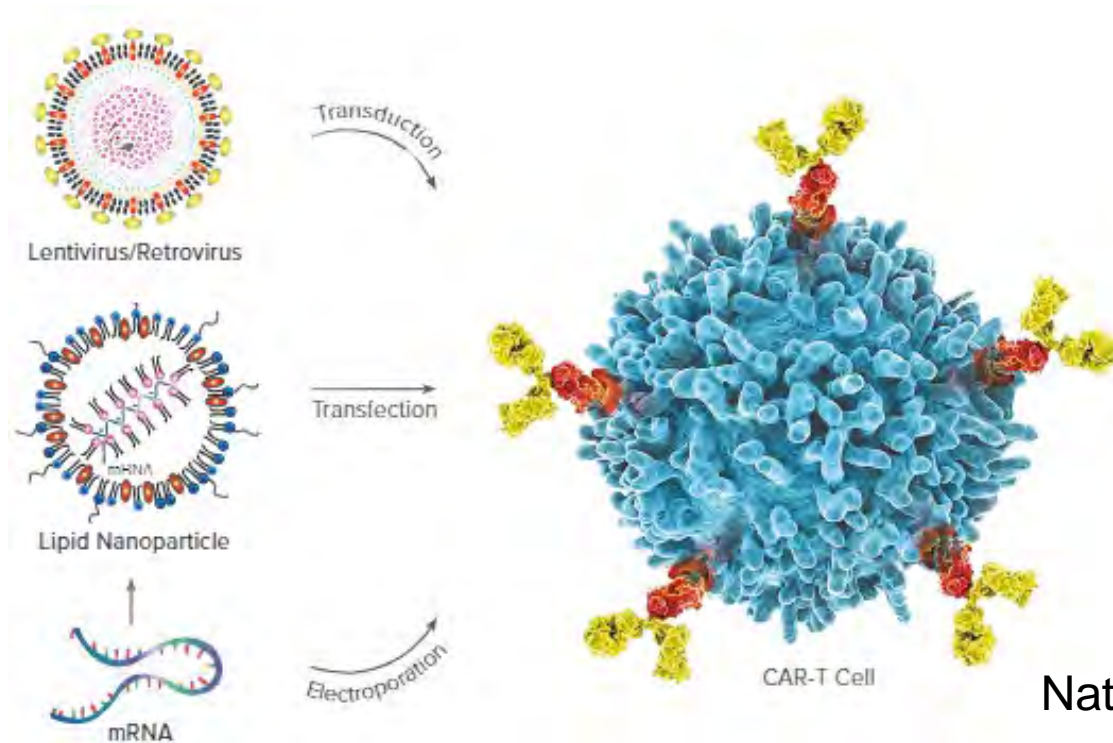
**Immune checkpoint inhibitors**  
Removing the block on T cell activation and survival



**Chimeric antigen receptors (CAR) T cells**  
A living drug – re-infused genetically engineered T cells from cancer patients

# CAR-T cells

approaches for modifying T cells to recognize & attack cancer cells



T cells attacking a cancer cell

Nature, Feb 2022

Developed for use in treatment of acute lymphoblastic leukaemia (B cells lymphoma, CD19<sup>+</sup>)

Complete remission (CR) rates as high as 90% have been reported in children and adults with relapsed and refractory ALL treated with CAR-modified T cells

Safety issues: Cytokine release syndrome. Cytokine storm after T cells blast. 3 people died in trial by JUNO (reported 2015)

Switch to turn on/off CAR-T cells?

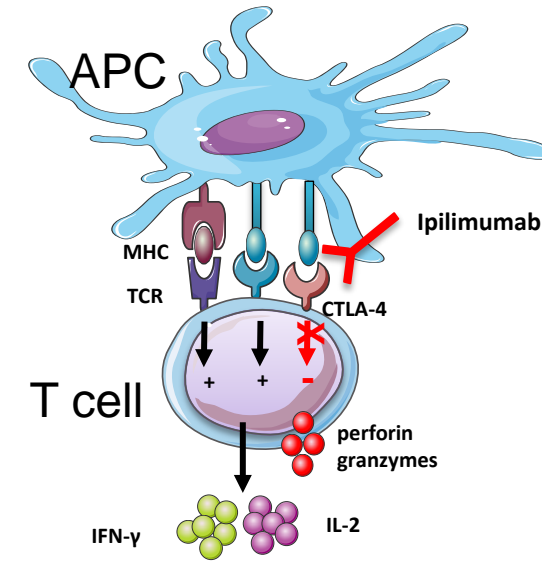
# Immune checkpoint inhibitors: Anti-CTLA4 (ipilimumab + others)

## Cancer regression and autoimmunity induced by cytotoxic T lymphocyte-associated antigen 4 blockade in patients with metastatic melanoma

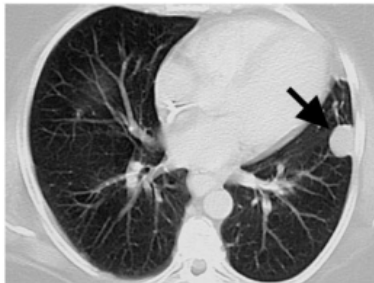
Giao Q. Phan<sup>†</sup>, James C. Yang<sup>†</sup>, Richard M. Sherry<sup>†</sup>, Patrick Hwu<sup>†</sup>, Suzanne L. Topalian<sup>†</sup>, Douglas J. Schwartzentruber<sup>†</sup>, Nicholas P. Restifo<sup>†</sup>, Leah R. Haworth<sup>†</sup>, Claudia A. Seipp<sup>†</sup>, Linda J. Freezer<sup>†</sup>, Kathleen E. Morton<sup>†</sup>, Sharon A. Mavroukakis<sup>†</sup>, Paul H. Duray<sup>†</sup>, Seth M. Steinberg<sup>‡</sup>, James P. Allison<sup>§</sup>, Thomas A. Davis<sup>||</sup>, and Steven A. Rosenberg<sup>†,††</sup>

PNAS | July 8, 2003 | vol. 100 | no. 14 | 8375

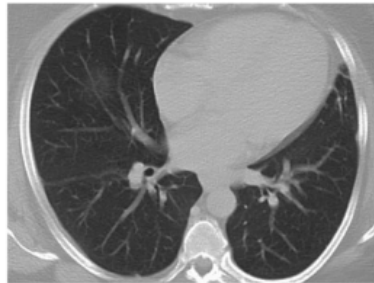
- Removes CTLA4 blockade on T cell activation
- Advanced melanoma – 22% survival after 3 yrs
- Approved in 2011 for melanoma
- Efficacy in other indications
- A significant proportion of recipients develop immune-associated adverse reactions



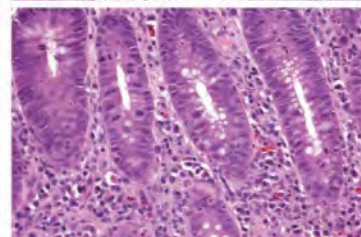
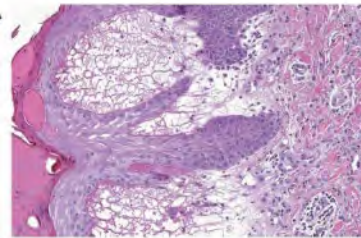
Pre-



Post-treatment



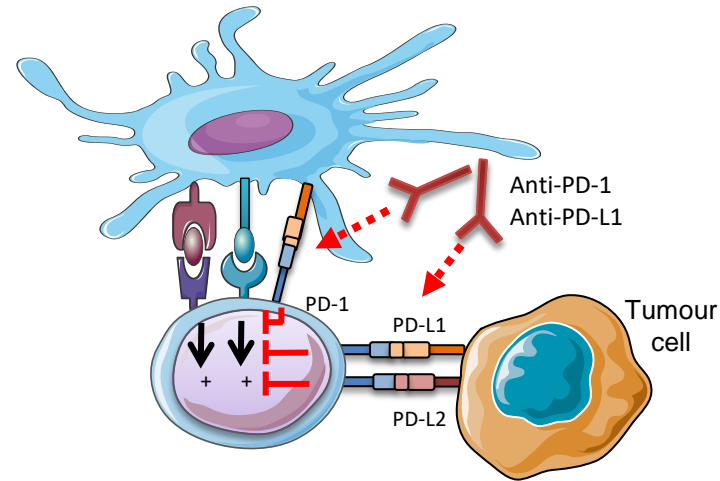
Dermatitis and colitis



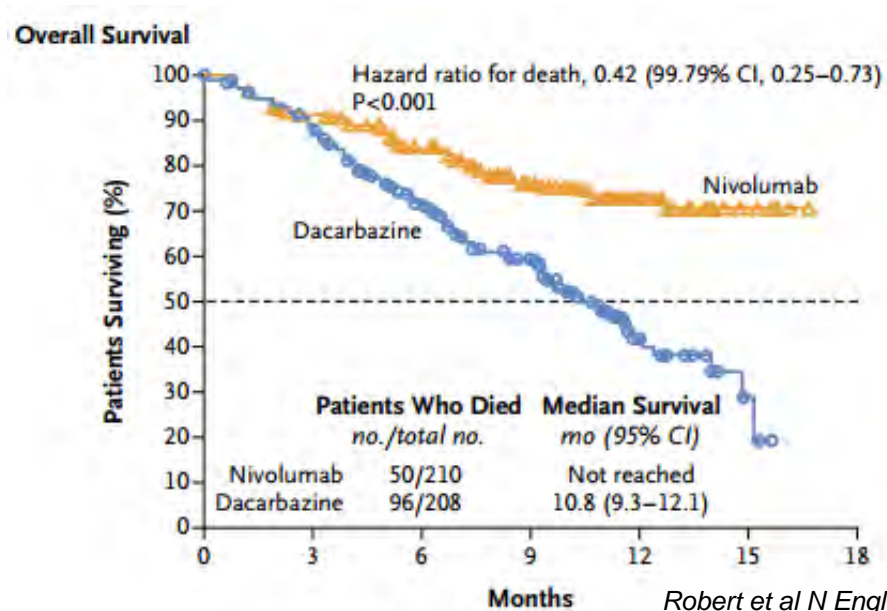
# Immune checkpoint inhibitors: Anti-PD-1/anti-PD-L1 and combinations

Nivolumab/ Pembrolizumab + others

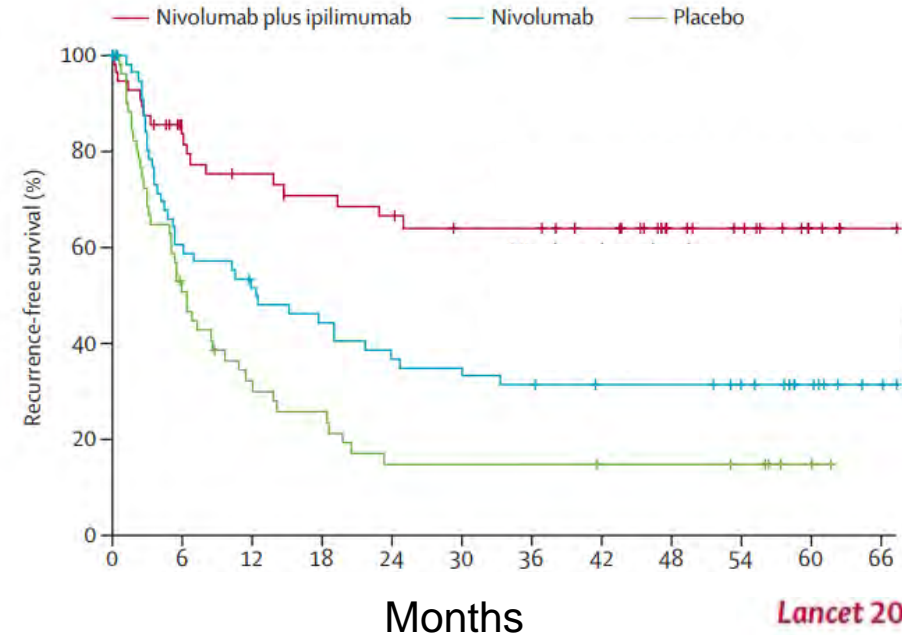
- Anti-PD-1 antibody
- Negative signal to T cell
- Blocking PD-1 enhances effector T cells
- Increases CTL and reduces Tregs
- 200 trials anti-PD-1 or anti-PDL-1 completed or underway in a variety of cancer indications



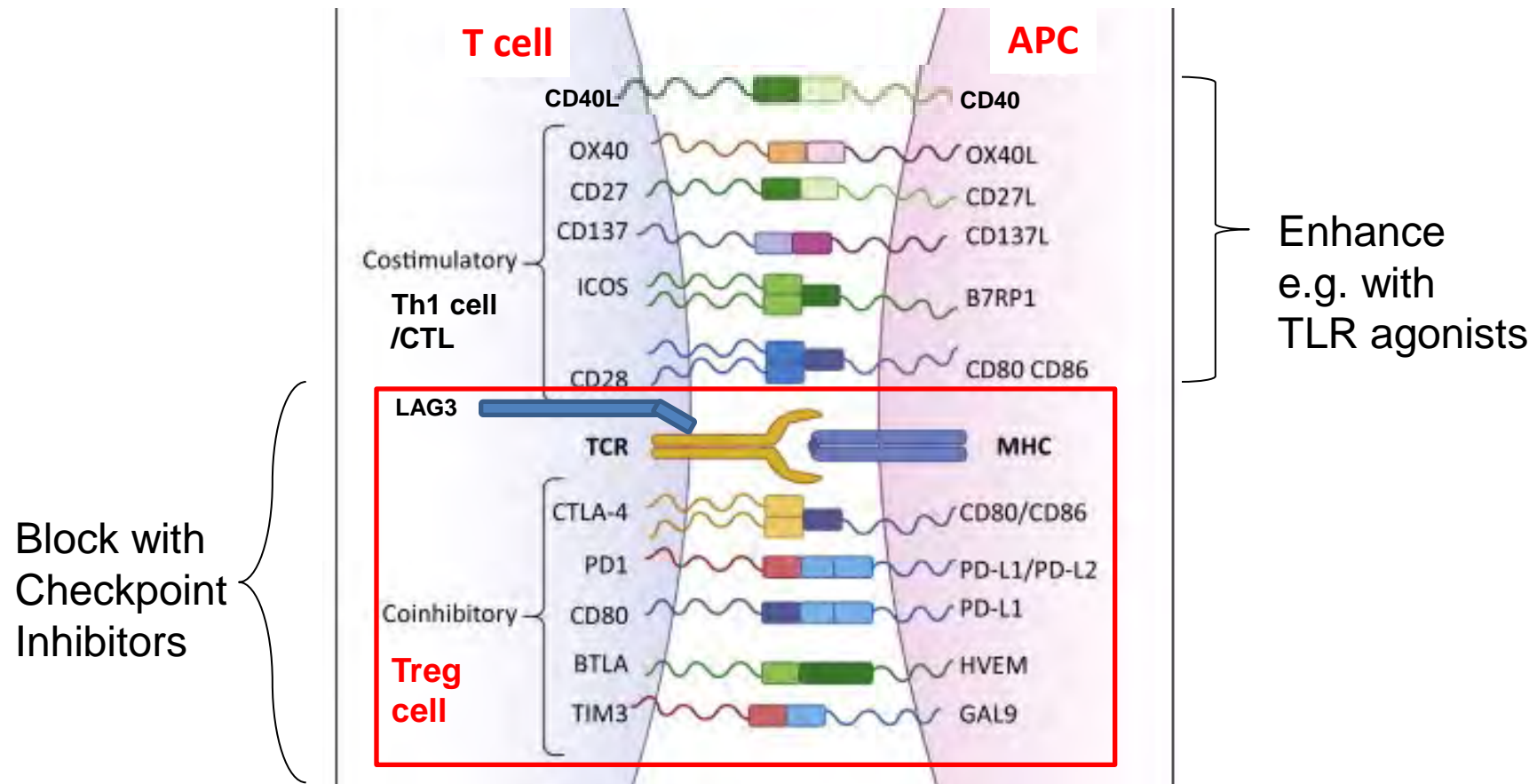
Previously untreated Melanoma  
without *BRAF* mutation



Combination of CTLA4 + PD-1 inhibition in stage 4 melanoma



# Multiple new targets in the immunology Synapse – enhancing T cell responses to tumours



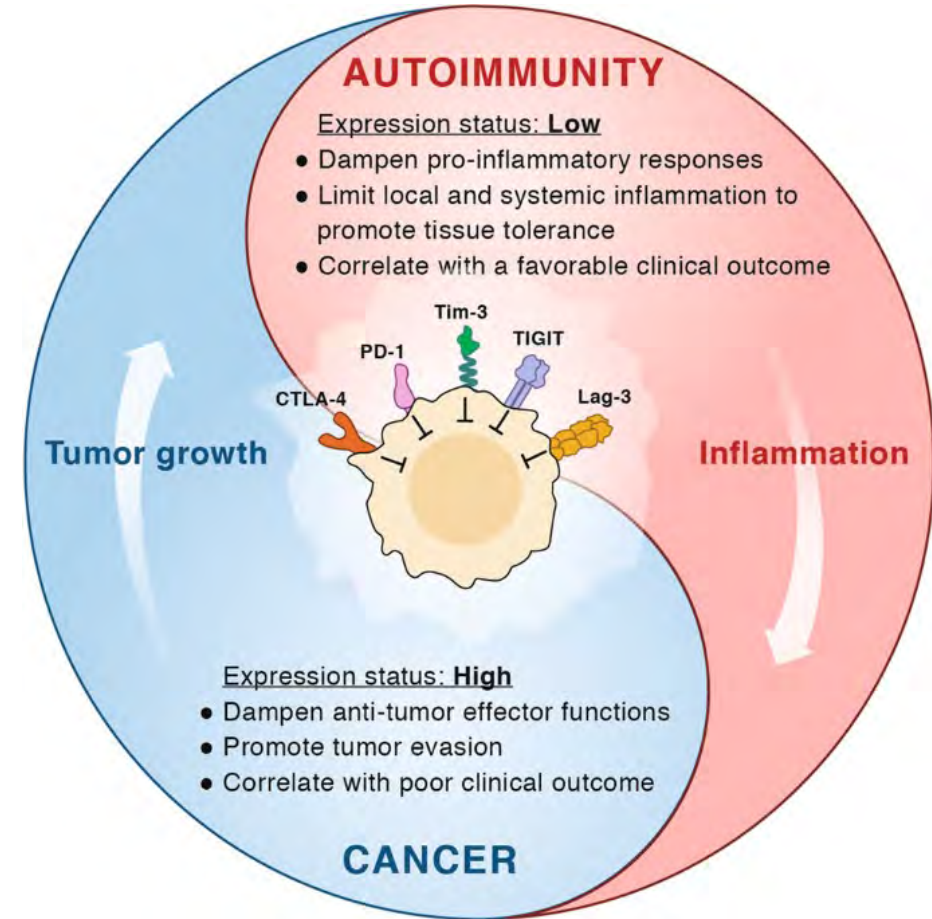
## Clinical trials

IMP321	Dimer of LAG3, APC activator	I/II	Breast, prostate
IMP701	Monoclonal antibody to LAG3	I	Cancer
M7824	Bi-functional anti-PDI + TGFβ trap	I/II	Prostate
Dacetuzumab/ Lucatumumab	Anti-CD40 agonist MoAb	I	CLL, NHL, MM
TLR agonists	TLR9, TLR7/8	III	NSCLC, various

# Immune checkpoints prevent autoimmune diseases

## Immune checkpoints

- Natural brakes on the immune system
- Prevent development of autoimmunity
- But also suppress immunity to tumors
- Immune checkpoint inhibitor (anti-PD-1/PDL-1 & anti-CTLA4 highly effective in treating cancer
- Responders develop autoimmune diseases



# PD-1 agonistic MoAbs in clinical development for autoimmune diseases

- Expression of PD-1 increased in synovium of RA patients
- Strong expression on T cells correlates with disease activity

nature reviews drug discovery

Explore content ▾ About the journal ▾ Publish with us ▾ Subscribe

nature > nature reviews drug discovery > news in brief > article

NEWS IN BRIEF | 02 June 2023

## PD1 agonist antibody passes first phase II trial for autoimmune disease

- Lilly running another Phase II in RA and options for other autoimmune disease
- BMS/Celgene CC-90006 (Moab) licensed from AnaptysBio was in phase I for psoriasis

Features March 4, 2021

**Merck-Pandion acquisition: re-balancing immune response to treat autoimmune disease** \$1.85bn

Gilead Bets \$405M on MiroBio's Checkpoint Agonists for Autoimmune Disease

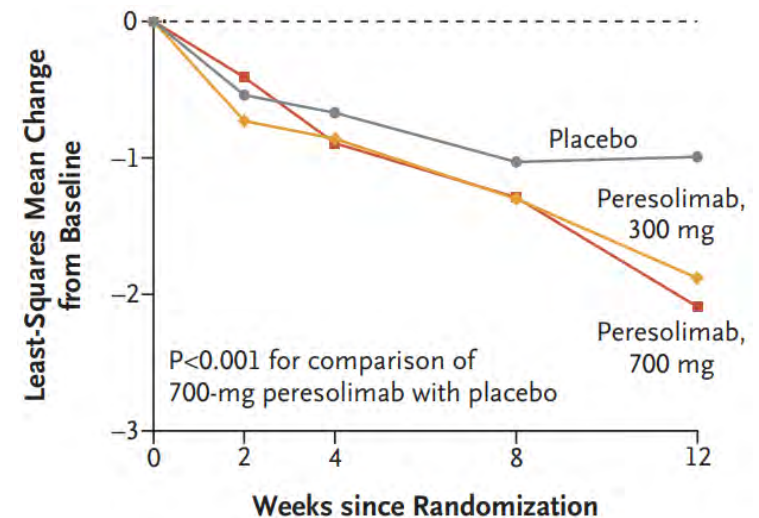
Published: Aug 05, 2022 | By Alex Keown

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## A Phase 2 Trial of Peresolimab for Adults with Rheumatoid Arthritis

Jay Tuttle, Ph.D., Edit Drescher, M.D., Jesus Abraham Simón-Campos, M.D.,





# COVID-19 vaccines developed in 1/10 time of a typical vaccine

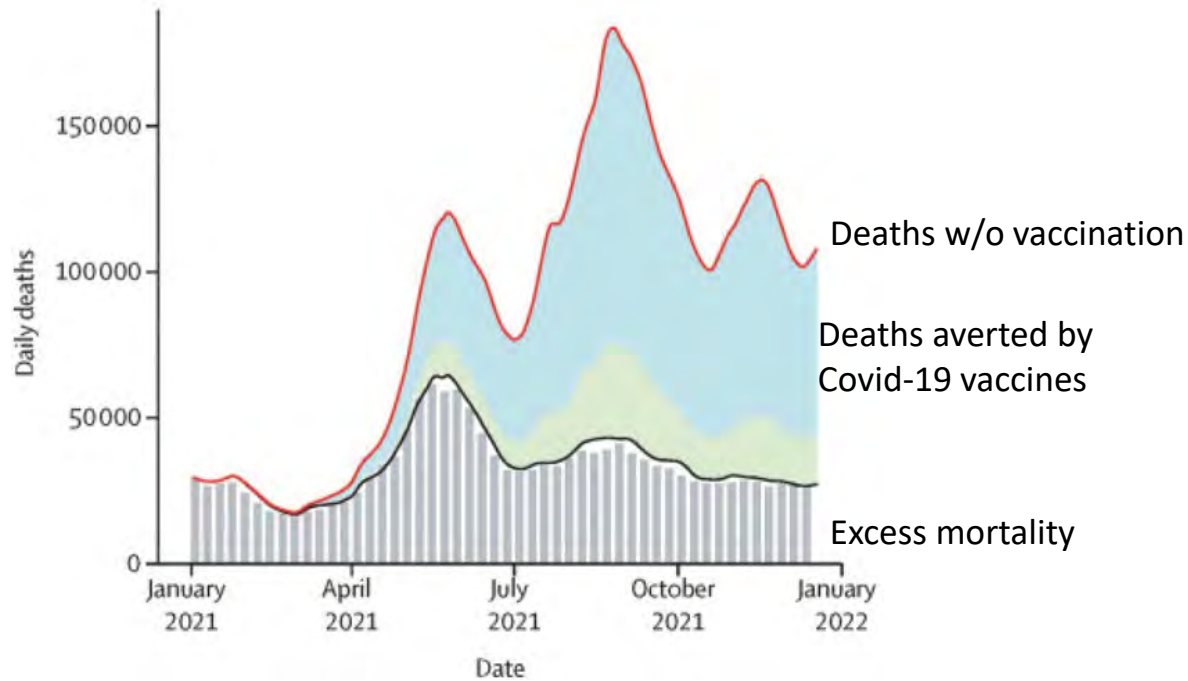
## Traditional vaccine development: One step at a time



## COVID-19 vaccine development: Multiple steps happening at once



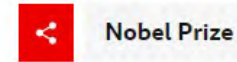
**COVID-19 vaccines prevented an estimated 14.4 million deaths from COVID-19 (19m including excess deaths) in first year of use.**



[J Paediatr Child Health](#). 2022 Sep 20 : 10.1111/jpc.16213.

## Nobel Prize goes to scientists behind mRNA Covid vaccines

2 days ago



Professors Drew Weissman (left) and Katalin Kariko

**By James Gallagher**

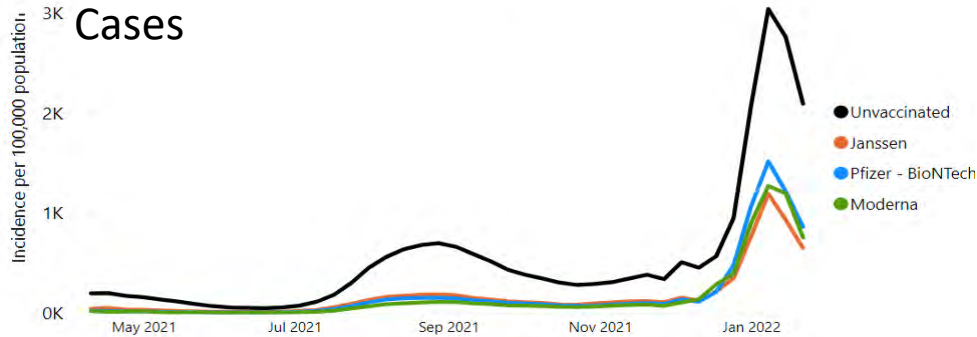
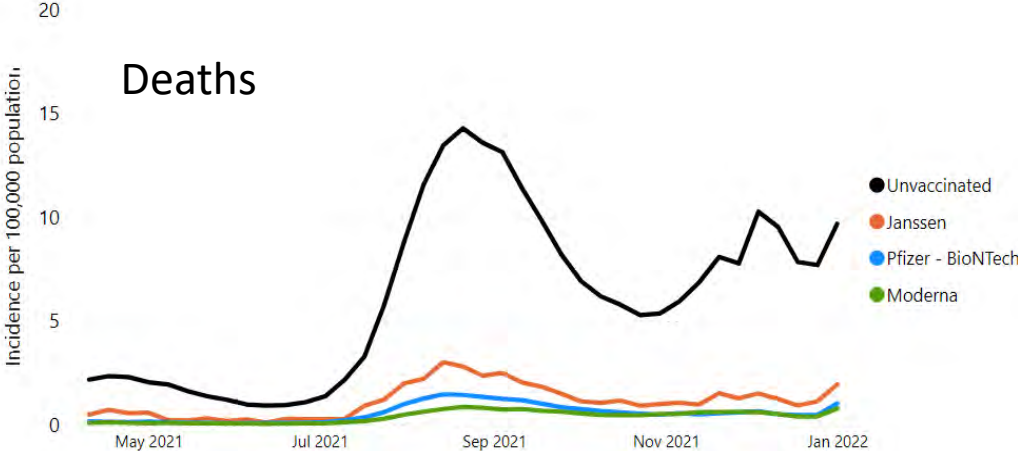
Health and science correspondent

The Nobel Prize in Physiology or Medicine has been awarded to a pair of scientists who developed the technology that led to the mRNA Covid vaccines.

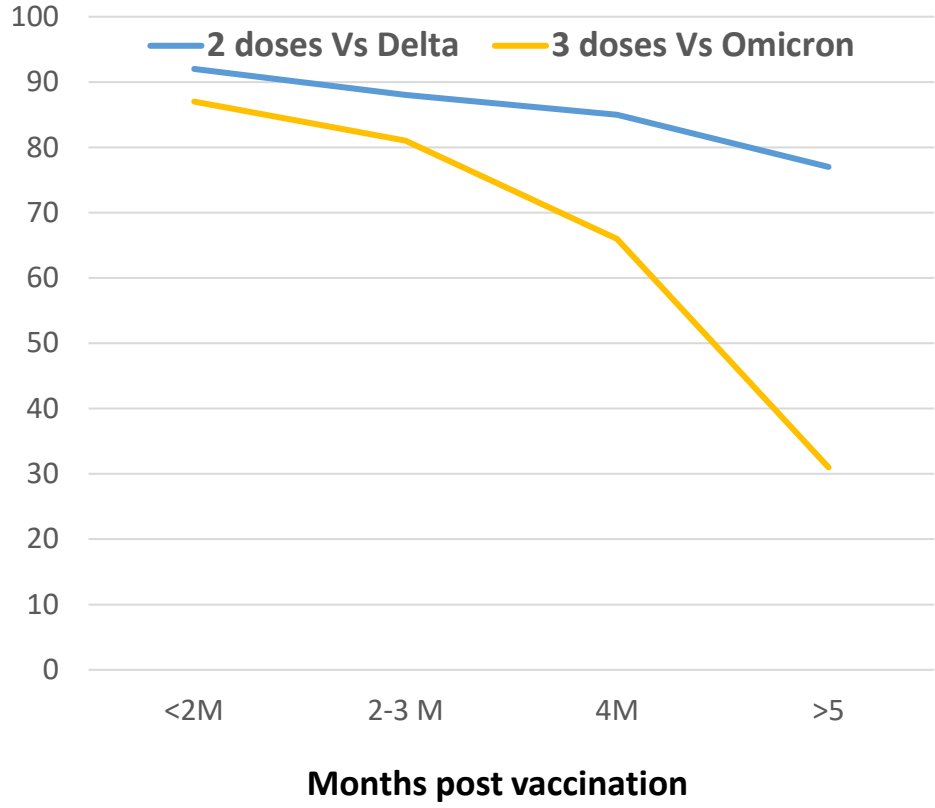
Professors Katalin Kariko and Drew Weissman will share the prize.

# COVID-19 vaccines prevent severe disease but does not prevent SARS-CoV-2 infection or sustain protective immunity

USA April 21 – Jan 22

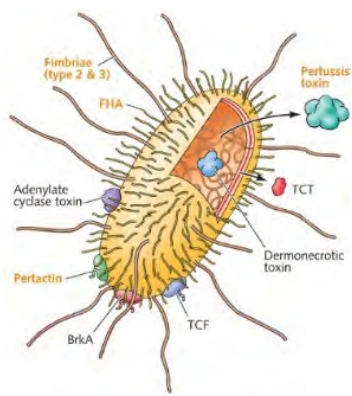


Vaccine Efficacy (%) Versus Symptomatic Infection



Qatar study NEJM Feb 2022

# Bordetella pertussis



- Whooping cough (pertussis) - severe persistent respiratory infection especially in infants
- 24.1m cases, 160,700 infant deaths/yr
- Re-emerging pathogen - despite introduction of a new acellular pertussis (aP) vaccine in 1990s
- aP vaccines do not prevent infection and immunity wanes rapidly post vaccination

## Pertussis cases in UK



## Rising Whooping Cough Cases In The UK Lead To Tenth Child Death

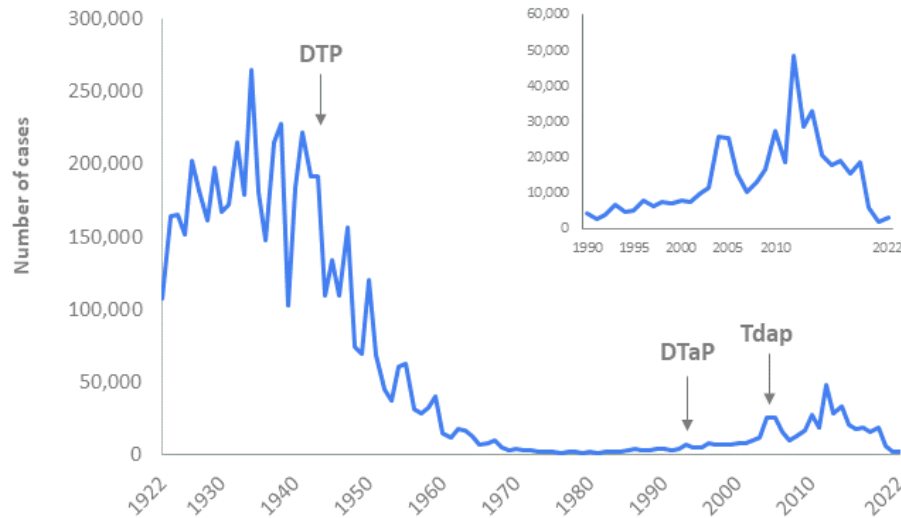
The outbreak is part of a global resurgence of the disease, which has seen cases and deaths in countries like China, Philippines, and the Netherlands.

Edited by: NIKHIL Pandey WorldNews Aug 09, 2024 09:35 am IST

Read Time: 3 mins



## Pertussis cases in US 1922-2022 (CDC)

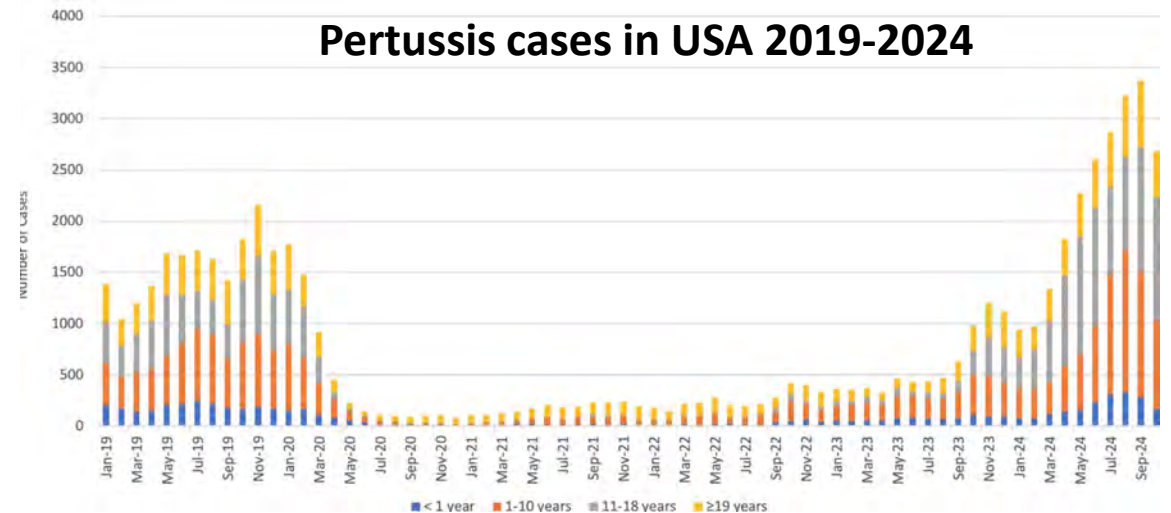


## THE IRISH TIMES

## Whooping cough cases in country increase by 3,000% in a year

Latest figures show 567 cases in Ireland up to November 9th, compared to 18 cases in 2023

## Pertussis cases in USA 2019-2024



# Current acellular pertussis vaccines prevent disease and reduce lung infection but do not prevent nasal infection with *B. pertussis*

## Whole cell pertussis (wP) vaccines (1940-90s)

(killed whole bacteria, including LPS + other PAMPs)

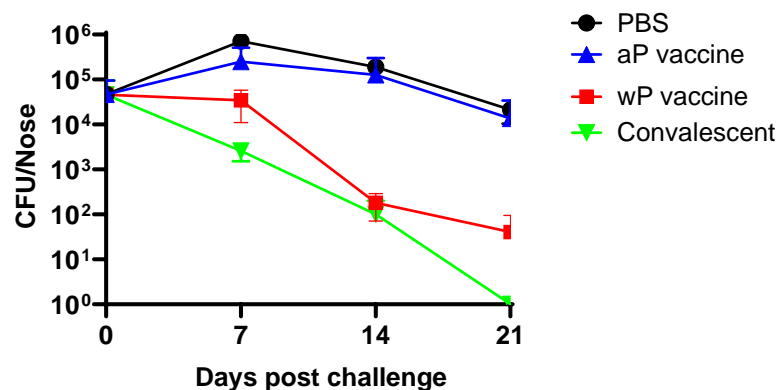
- Effective but had side effects

## Acellular pertussis (aP) vaccines (2000s-)

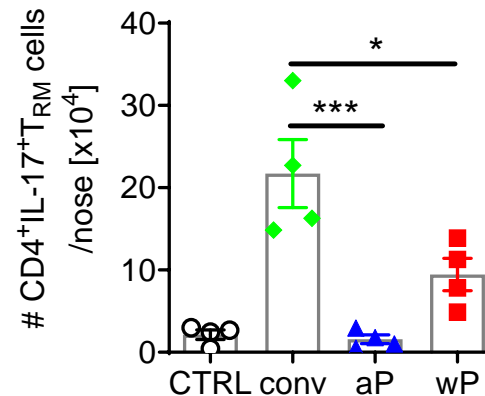
(3-5 antigens with alum)

- Safe, but do not prevent bacterial transmission
- Promote antibody and Th2 responses
- Does not induce respiratory T<sub>RM</sub> cells

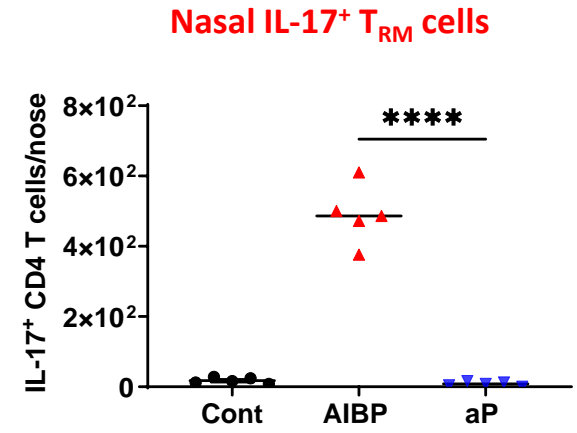
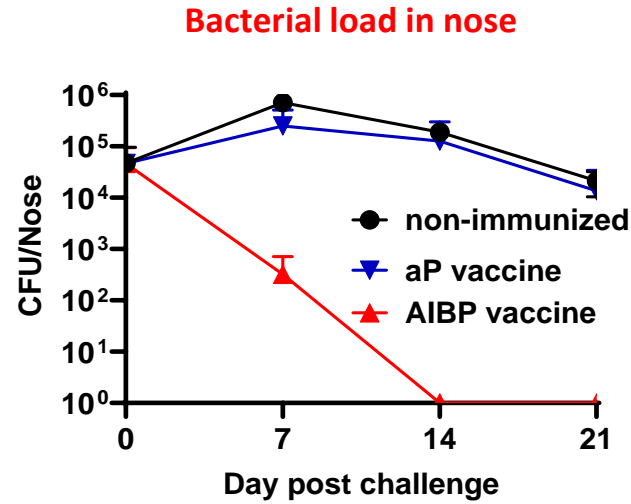
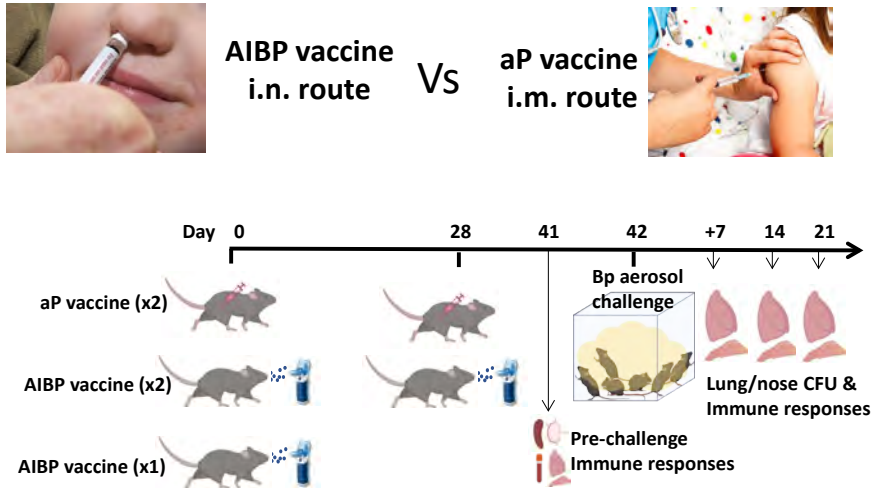
### Bacterial load in nose



### IL-17<sup>+</sup> CD4<sup>+</sup> T<sub>RM</sub> in nasal tissue

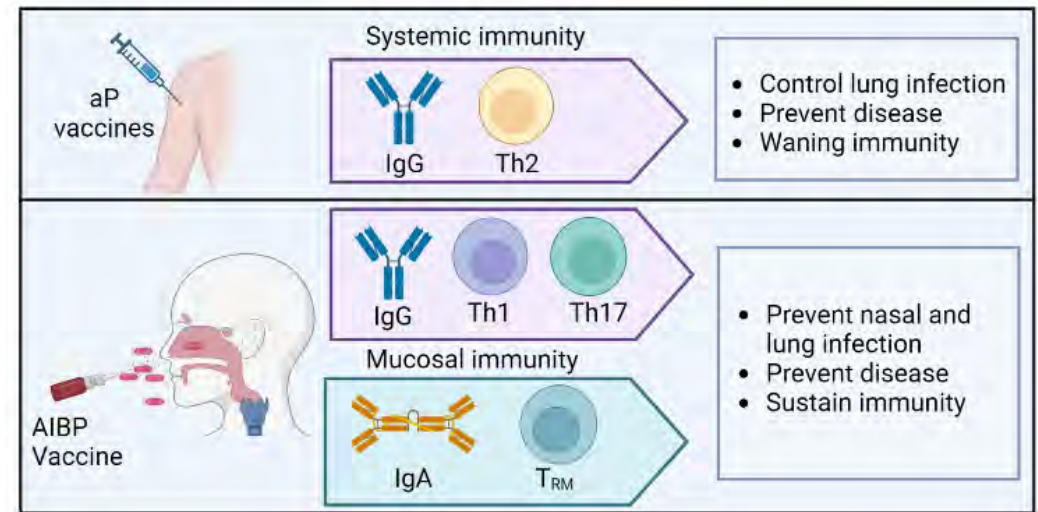
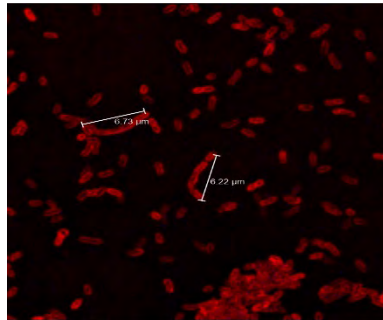
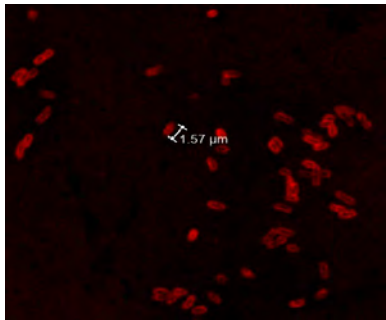


# Aerosol-delivered antibiotic-inactivated *B. pertussis* vaccine (AIBP) induces potent respiratory IL-17<sup>+</sup> T<sub>RM</sub> cells and protects against nasal infection with *B. pertussis*



Un-treated *B. pertussis*

Ciprofloxacin-treated *B. pertussis*



# Impact of mRNA technology on vaccine/treatments for other diseases

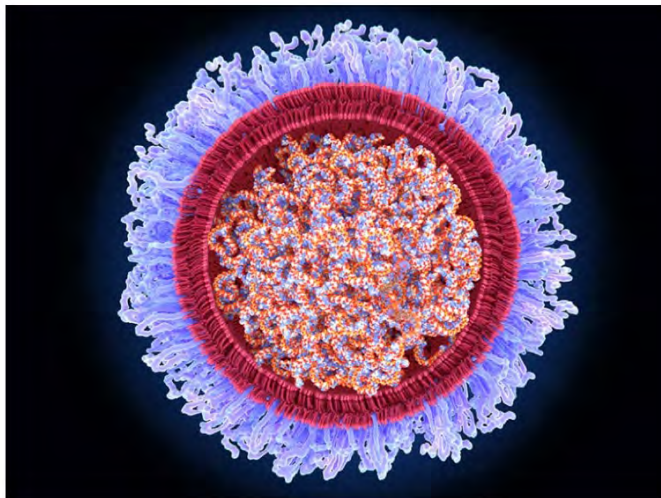
**nature**

NEWS EXPLAINER | 03 October 2023

## mRNA COVID vaccines saved lives and won a Nobel – what's next for the technology?

*Nature* talks to experts about how messenger RNA is transforming medicine.

[Elie Dolgin](#) & [Heidi Ledford](#)



- Rapid vaccine development against “new” pathogens
- Tackling tough pathogens
  - MRSA, HIV, CMV, TB, universal flu mRNA vaccines
- mRNA vaccine against cancer
- Genome editing: long lasting mRNA to correct rare diseases
  - Cystic fibrosis, Muscular dystrophy, Huntington’s disease, Haemophilia, Cancers



## Mills lab present and recent past

- |                            |                           |
|----------------------------|---------------------------|
| <b>Caroline Sutton</b>     | <b>Sarah Edwards</b>      |
| <b>Lisa Borkner</b>        | <b>Aoife McGinley</b>     |
| <b>Caitlín Ní Chasaide</b> | <b>Niamh McGuinness</b>   |
| <b>Davoud Jazayeri</b>     | <b>Aideen Allen</b>       |
| <b>Sreeram Udayan</b>      | <b>Roisin McManus</b>     |
| <b>Lucy Curham</b>         | <b>Lydia Dyck</b>         |
| <b>Charlotte Leane</b>     | <b>Sauna Quinn</b>        |
| <b>Pauline Schmitt</b>     | <b>Robert Walsh</b>       |
| <b>Béré Diallo</b>         | <b>Lara Dungan</b>        |
| <b>Karen McCarthy</b>      | <b>Stephen Lalor</b>      |
| <b>Paula Kinsella</b>      | <b>Sarah Higgins</b>      |
| <b>Mieszko Wilk</b>        | <b>Pádraig Ross</b>       |
| <b>Kyle Cunningham</b>     | <b>Patrick Kelly</b>      |
| <b>Conor Finlay</b>        | <b>Kevin Walsh</b>        |
| <b>Mathilde Raverdeau</b>  | <b>Anna Stefanska</b>     |
| <b>Alicja Misiak</b>       | <b>Sarah Jones</b>        |
| <b>Martina Gogarty</b>     | <b>Lisa Mielke</b>        |
| <b>Mark Lynch</b>          | <b>James Harris</b>       |
| <b>Joseph DeCoursey</b>    |                           |
| <b>William McCormack</b>   |                           |
| <b>Barry Moran</b>         |                           |
|                            | <b>TCD collaborators</b>  |
|                            | <b>Rachael McLoughlin</b> |
|                            | <b>Marina Lynch</b>       |
|                            | <b>Luke O'Neill</b>       |
|                            | <b>Ed Lavelle</b>         |
|                            | <b>Jean Fletcher</b>      |
|                            | <b>Aisling Dunne</b>      |



## Collaborators

- |                              |                                 |
|------------------------------|---------------------------------|
| <b>CNIO Madrid</b>           | <b>University of Queensland</b> |
| <b>Nabil Djouder</b>         | <b>Matt Cooper</b>              |
|                              | <b>Avril Robertson</b>          |
| <b>Birmingham University</b> | <b>University of Melbourne</b>  |
| <b>Song Baik</b>             | <b>John Hamilton</b>            |
| <b>Graham Anderson</b>       |                                 |
| <b>University of Lisbon</b>  | <b>University of Tokyo</b>      |
| <b>Julie Ribot</b>           | <b>Yoichiro Iwakura</b>         |
| <b>Bruno Silva-Santos</b>    |                                 |
| <b>Cardiff University</b>    | <b>St Judes Memphis, TN</b>     |
| <b>James McClean</b>         | <b>Paul Thomas</b>              |
| <b>Kristin Ladell</b>        |                                 |
| <b>David Price</b>           | <b>Abbvie Inc, Worcester</b>    |
|                              | <b>Anthony Slavin</b>           |
|                              | <b>Jesus Paez-Cortez</b>        |



**Pharma  
Summit 25**

Evolving through change



## Fionnuala King

Chief Pharmacist for the Access & Integration Drug Management Programme



Fionnuala is the Chief Pharmacist for the HSE Access & Integration Drug Management Programme, previously known as the HSE Acute Hospital Drug Management Programme. She was previously business-lead for the implementation of the National Cancer Information System. Fionnuala has over 20 years of clinical experience in oncology and haematology and led the haem/onc pharmacy team in St. James Hospital.

She qualified as pharmacist at Robert Gordon University, completed post-graduate studies in Clinical Pharmacy at the University of London, a Masters in Leadership and Organisational Learning in Royal College of Surgeons Dublin and further post-graduate studies in Cancer Studies in Newcastle University.

Her particular areas of interest are in Pharmacy Practice, Medicines Management and Medication Safety. Fionnuala has published her work in a number of journals and has taught at post-graduate level in TCD, UCC and RCPI.

Proudly supported by:





# **Evolving Landscape of Medicines Management in Irish public hospitals**

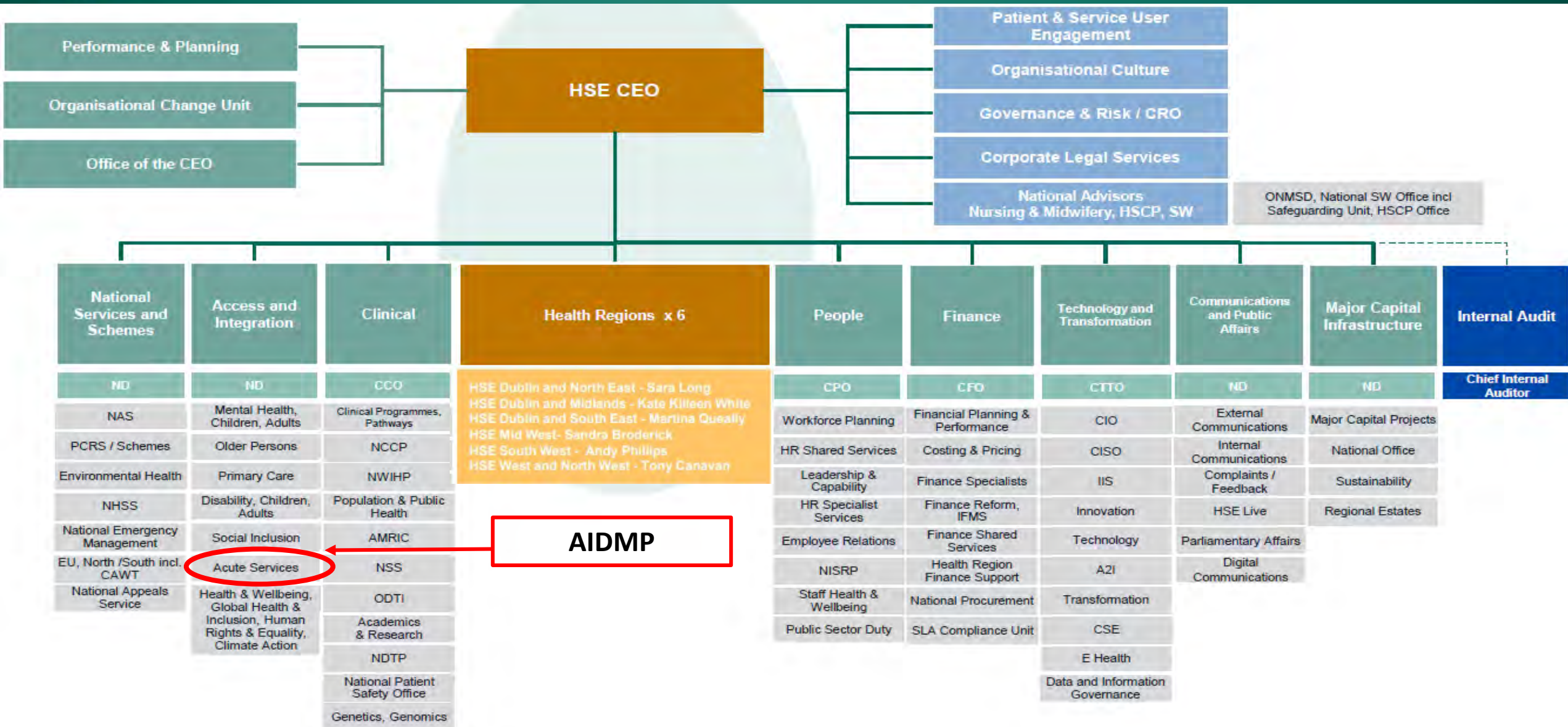
**Fionnuala King**

**Chief Pharmacist,**

**Access & Integration Drug Management Programme**



# HSE Centre New Structure



## Sláintecare Policy

“A healthier Ireland, with improved health and wellbeing for all, and with the **right care** delivered in the **right place** at the **right time**.”

**Key enablers -data, technology, and digitisation,** “advancement in health systems information, is vital in underpinning policymaking that is **person-centred** and **delivers on strategic priorities**”.

Integrated care is only possible with free flow of Data and Information – Right Data and the Right Staff.



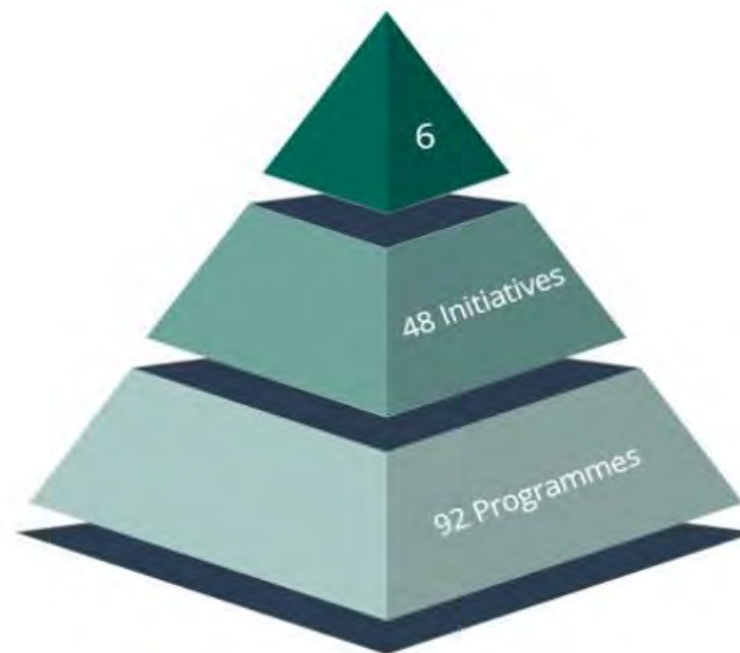
Department of Health – [Digital for Care – A Digital Health Framework for Ireland 2024-2030](#):  
Published 21st May 2024

Health Service Executive - [Digital Health Strategic Implementation Roadmap 2024-2030](#):  
Published 8th July 2024



# Digital for Care 2030

Delivering **Better Health Outcomes** enabled by **Seamless, Safe, Secure, and connected Digital Health Services** which support **Health and Wellbeing** for both our **Patients and Providers.**



# Digital for Care: 48 Initiatives

**Our Vision** Better health outcomes enabled by seamless, safe, secure and connected digital health services and which support health and wellbeing for both our patients and providers.


 <b>Patient as an Empowered Partner</b>	 <b>Workforce and Workplace</b>	 <b>Digitally Enabled and Connected Care</b>	 <b>Data Driven Services</b>
---	--	---	---

- 11 Key Initiatives**
- Patient Portal
  - HSE app
  - HSELive - Contact Centre
  - Patient Feedback Platform
  - Remote Care Monitoring and Digital Therapeutics
  - Benefits and Schemes access
  - Public Facing Engagement and Digital Literacy Development Programmes
  - Public Website Content Management
  - Open Health API Framework
  - Contact Care Platform
  - Telehealth

- 6 Key Initiatives**
- Reliable Secure Connectivity
  - Modern Workspace and Productivity Tools
  - Improve Employee Experience
  - Mobile Ecosystem for Front Line
  - Employee Feedback Platform
  - Digital Finance and HR

- 11 Key Initiatives**
- Shared Care Record
  - Population Health Management
  - Care Coordination
  - Medication Management\*
  - Diagnostics
  - Order Comms and Care Delivery\*
  - Patient Safety and Quality of Care\*
  - EHR Procurement and Delivery
  - Digitisation of Health Care Records\*
  - National Clinical Information Systems\*
  - Medical Device Integration

- 4 Key Initiatives**
- Patient Journey Analytics
  - Healthcare Data Analytics
  - Integrated Referral Management
  - Scheduling, Rostering and Resource Management

 **Digital Health Ecosystem and Innovation**

- 4 Key Initiatives**
- Precision Medicine Support
  - Healthcare Research
  - AI in Healthcare
  - Open Innovation and Ecosystem

 **Secure Foundations and Digital Enablers**

- 12 Key Initiatives**
- Legislation, Regulation, Standards, Governance
  - Patient Identity Management
  - Healthcare Worker Identity and Access Management
  - Architecture, Service Design and Knowledge Management
  - Culture, Change and Agile Delivery
  - Talent Identification and Development
  - Integration, Interoperability, Data Engineering
  - Crisis-Responsive Healthcare
  - ICT Cyber Programme
  - Foundational Infrastructure
  - Regional Strategic Implementation
  - 24/7 Support Function



# What is HMMS?

- HMMS is the national project to **replace the Hospital Pharmacy Departments current legacy pharmacy software** and will also provide a platform for electronic prescribing and electronic medicines administration (EPMA)
- HMMS will **deliver Pharmacy stock control software, within interfaces to PAS, Pharmacy robots, ward ADCs and Finance systems**
- HMMS will be offered to all publically funded acute and non-acute hospital sites in Ireland that are currently paying Pharmacy software license fees
- HMMS was implemented in University Hospital Galway and Merlin Park University Hospital in May 2023 and Rotunda March 2025.



## **NSP 2023: Key Objective**

*“Support the safe and cost-effective use of medicines through health technology and management processes for new medicines and the ongoing clinical management and monitoring, ensuring equity in the provision of existing and emerging medicines / therapies”*



# HMMS and the eHealth Ecosystem

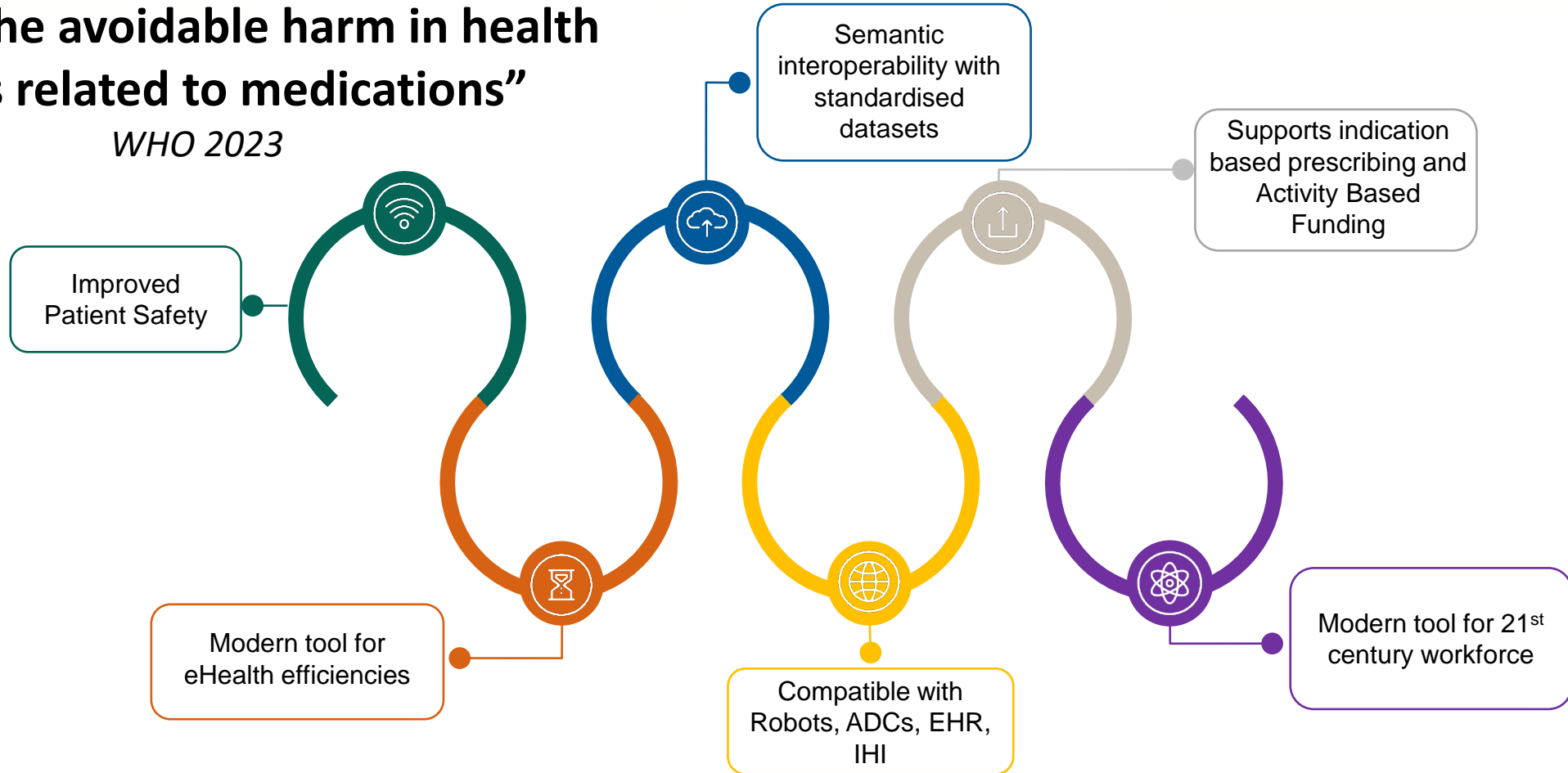




# HMMS Benefits

**“Half of the avoidable harm in health care is related to medications”**

*WHO 2023*





# Drug File Build

- Development of DMAINTW = HMMS National (Common level) drug file
- No comprehensive national drug file
- >15,000 drug lines, >300,000 data points
- Ongoing process – resource intensive
- Includes both:
  - **VMP** (Virtual Medicinal Product) – utilised by EPMA
  - **AMP** (Actual Medicinal Product) – utilised by Pharmacy Stock Control System



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# EAN & GTIN Barcodes

**GTIN codes** are used to decommission products, in accordance with Falsified Medicines Directive

ez\_- FMD provides an interface between FMD software & HMMS, allowing a product to be both decommissioned and moved into stock on HMMS

**GTIN codes** are essential as a product identifier between both these systems.

**EAN codes** are the product/pack size identifiers for HMMS / Robot interfaces.

**EAN codes** can also be used for product search in HMMS software.

**EAN codes** can also be used to scan & deliver products into HMMS in the goods inwards process.





# The Wish list

- Data submitted to HMMS team using the online eforms:
  - <https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/hmms/hmms-drug-file.html>
- Latest product catalogue from Manufacturers/Suppliers – identifying new products & product codes
- Notifications of product description changes – pack size
- Notification of discontinuations – including expiry dates
- Notification of changes in distribution channel – switch of wholesaler



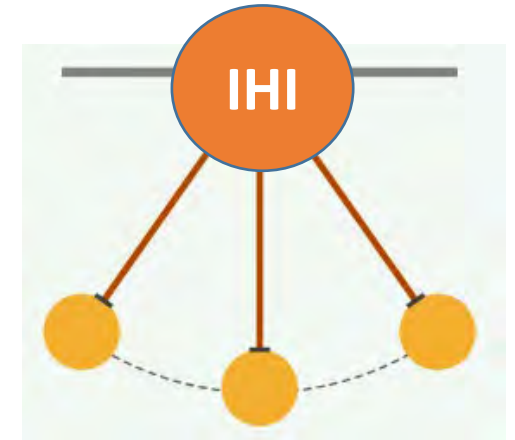
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# HMMS Patient Identifier

- Application supports a **single national** patient record
- Single view of patients national medication history



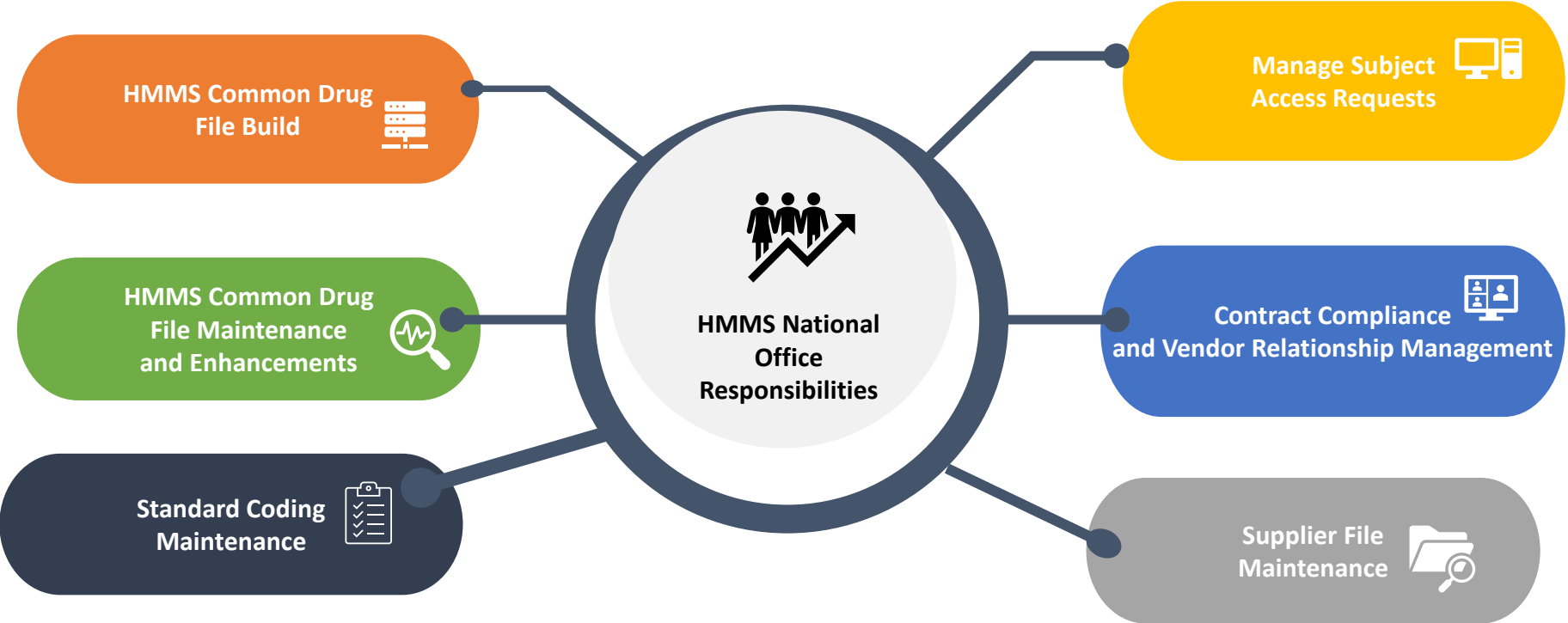
**Patient record  
created at  
common or  
national level**



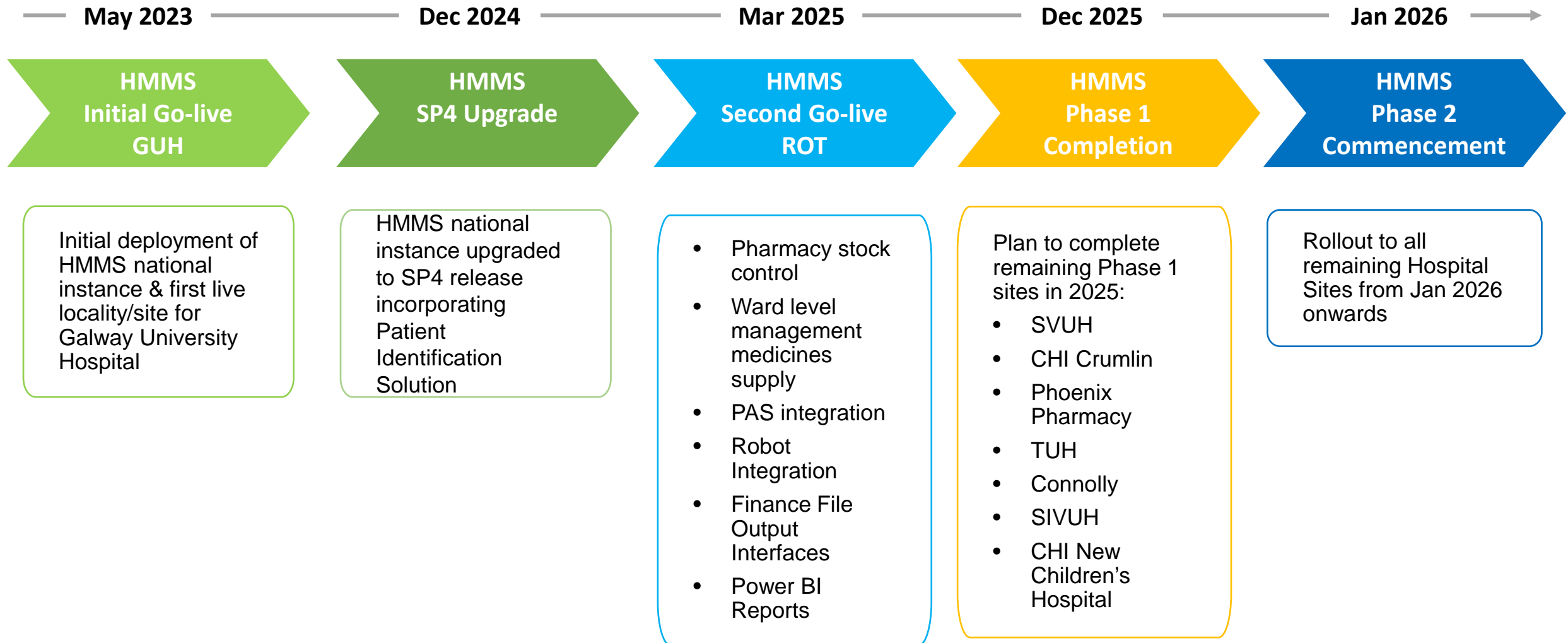
**Patient record  
registered to the  
required Locality**



# HMMS National Office (HMMS.contact@hse.ie)



# HMMS Project Delivery Timeline



# Procurement of Medicines in Acute and non-Acute Hospitals



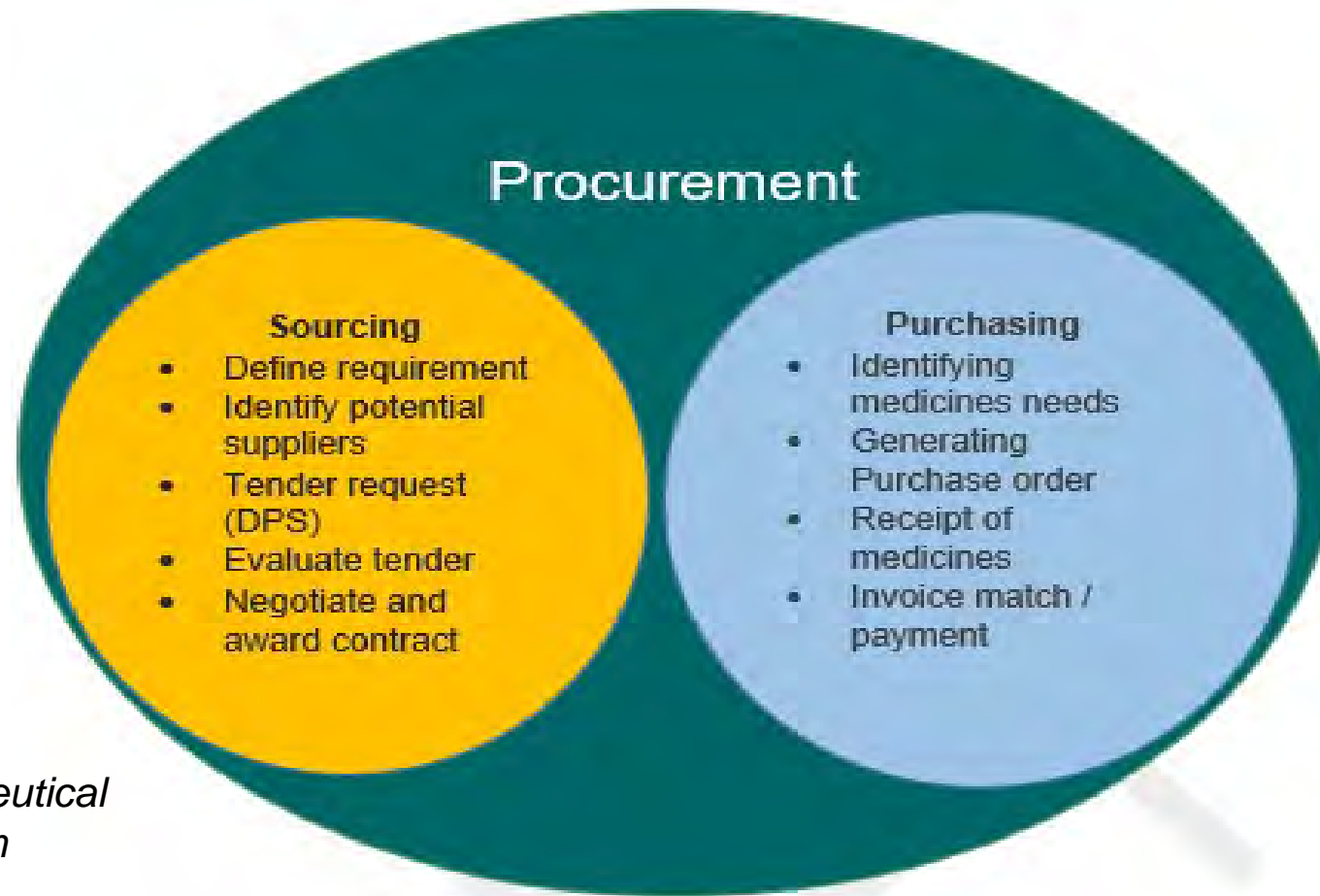


# Current Landscape in Irish Public Hospitals

- Procurement of medicines is an operations activity within the HSE.
- 'Health Region Chief Executive Officer (CEO) or designate (e.g. Hospital Chief Pharmacist / Pharmacy Executive Manager) in each hospital is responsible for the procurement of medicines at the level of their individual hospital and for ensuring that this activity complies with Medicinal Products supply legislation and National/EU Procurement legislation'.
- Majority of medicines are purchased directly by acute & non-acute Hospitals and are funded through individual hospital budgets.
- Certain other medicines are compliantly procured at a national level e.g. vaccines.
- Acute & non-acute hospitals drug expenditure accounts for approximately 20% of the overall HSE spend on medicines.
- Hospital undertake tenders individually or hospitals collaborate through clinical network to tender for medicines.



# Procurement of Medicines



*NPPST: National Pharmaceutical Procurement Support Team*

*Procurement = Sourcing (NPPST) + Purchasing (Hospital Pharmacy department)*



# Background

- [Strategy](#) for the Compliant Procurement of Medicines in Acute and non-Acute Hospitals published in 2019 (updated in 2024)
- Recommendations;
  - Establishment of National Pharmaceutical Procurement Support Team (NPPST) to advise hospital pharmacists on the procurement and contractual knowledge using the pharmacy leadership
  - Establish and utilisation of Dynamic Purchasing System (DPS) (>1 supplier)
  - Establish Sole Source Medicines List (single supplier)
- Aims to ensure legislatively compliance with National Financial Regulations (NFR) and EU Procurement Guidelines, safe and cost effective procurement of medicines.
- The procurement of medicines is clinically led by pharmacy, in collaboration with colleagues in finance, procurement and relevant clinical areas.

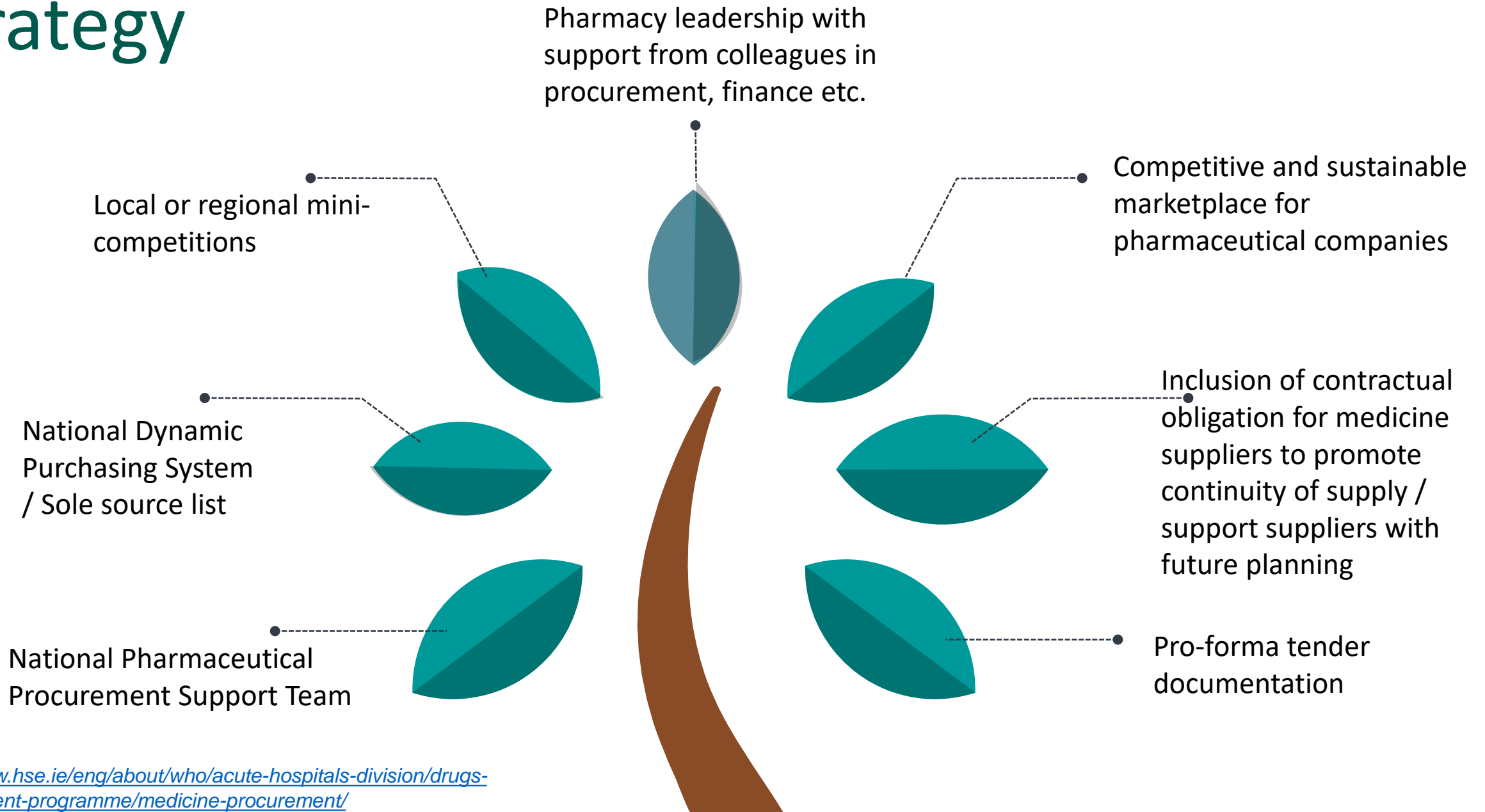


HSE Pharmaceutical Procurement Support Team  
NPPST@hse.ie

## *HSE Strategy for the Procurement of Medicines in Acute & non-Acute Hospitals*

Updated by	Clinical Lead, National Pharmaceutical Procurement Support Team		
Reviewed by	National Pharmaceutical Procurement Expert Advisory Group	Version number	2.2
Approved by	National Director Acute Operations and National Director Community Operations	Date	3rd May 2024

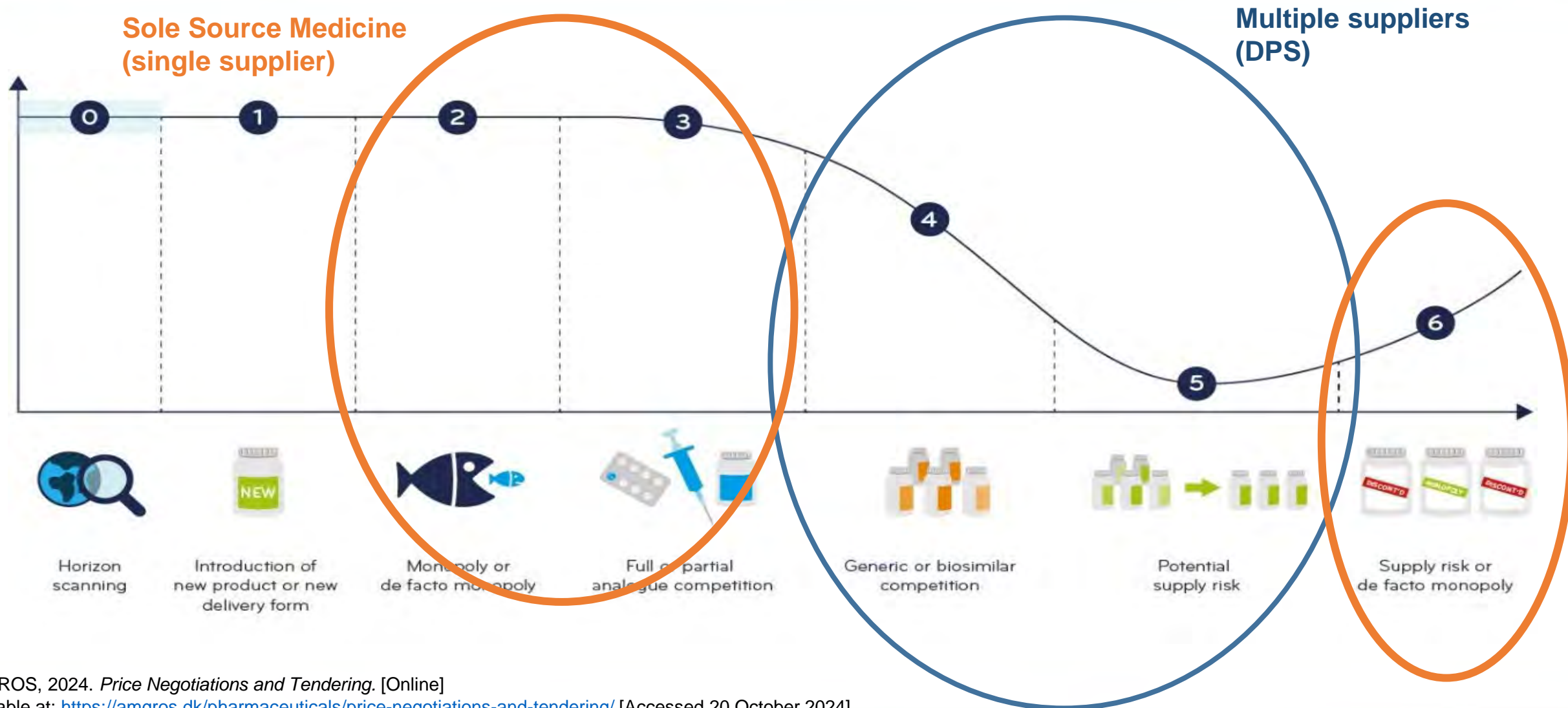
# Strategy



<https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/medicine-procurement/>



# Pharmaceutical Lifecycle





# Sole Source List (single supplier)

## **What is the Sole Source Medicine?**

*A medicine that is available from a single known source in Ireland, with marketing authorisation from the HPRA under the Medicinal Products (control of placing on the market) Regulations 2007 or centrally from the EMA. Published twice a year.*

## ***What is a Preliminary Market Consultation?***

Procurement Legislation permits a contracting authority to directly negotiate with a “sole supplier”. However it is necessary to test the market place to identify bona fide sole suppliers. The “Preliminary Market Consultation (PMC)” outlines how the NPPST will engage with the market place to identify sole suppliers of medicines, thereby enabling a hospital pharmacy to achieve compliance using the exemption available for the negotiated procedure under Article 32 of the EU Procurement Directive.

## ***How can suppliers engage with PMC?***

Suppliers can submit response to PMC through e-tender platform. Latest publication available [here](#).

Closing date for responses current PMC (21<sup>st</sup> March 2025), outcome with updated SSL is expected to be published in Q3 2025.



# Dynamic Purchasing System (DPS) (>1 supplier)

- First established in 2020 for 5 years and replacement DPS in use since Q1 2025
- NPPST engaged with suppliers to transition to new replacement DPS in later 2024
- Opportunity for suppliers to join at anytime during the lifetime of the DPS

*'A dynamic purchasing system shall be operated as a completely electronic process, and open throughout the period of validity of the purchasing system to any economic operator that stratifies the selection criteria'*

## ➤ Two Stage Process



- **Stage 1:** Qualification of Suppliers
- **Stage 2:** Mini-competition for medicines by individual or group of hospitals
- Suppliers **must be successfully qualified to the DPS by HSE to be notified of mini-competitions** when they are advertised
- 3 mini-competitions to date in 2025



# Green Procurement / Sustainability Criteria

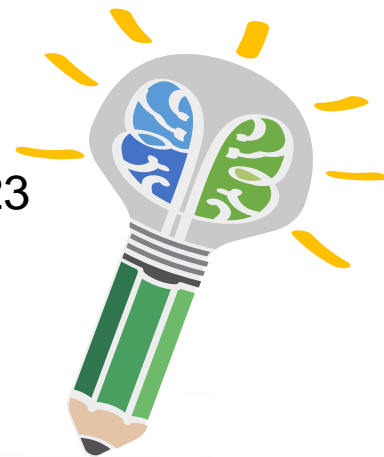
## ➤ HSE Corporate Procurement Plan 2022-2024



### **Climate Action and Sustainability**

The Climate Action Plan 2021<sup>8</sup> provides a detailed plan for taking decisive action to put Ireland on a path to reach net-zero emissions by no later than 2050. The role that the public sector has to play in leading by example is critical. It brings a commitment to developing and implementing a sustainable public procurement policy that ensures that what we are buying and building is consistent with our climate ambition. As the largest purchaser of goods, services and works in the State, the health service will play a central role in delivering greener public procurement. Our suppliers will need to prepare themselves in order to be able to continue to work with us to achieve our sustainability goals.

- Award criteria with a focus on environmental / sustainability introduced in medicines tenders in 2023
- Engaging with European Procurement colleagues to scope the future approach



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