

CANCER ECONOMICS: BALANCING ACCESS, QUALITY AND AFFORDABILITY



MSD

INVENTING FOR LIFE

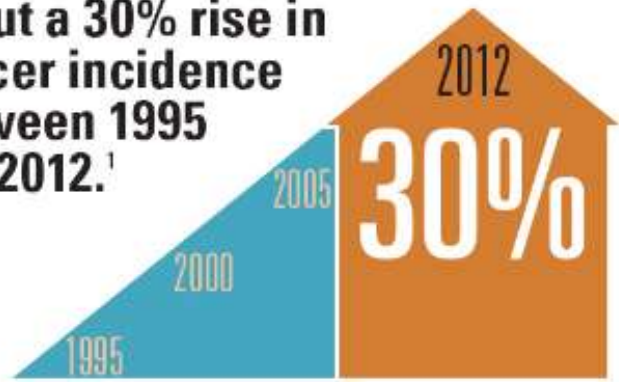
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Policy and Economic Conference Cancer & Personalized Medicine

Antonios Karokis

The cancer challenge: How to balance burden of disease, access, and incentives for innovation

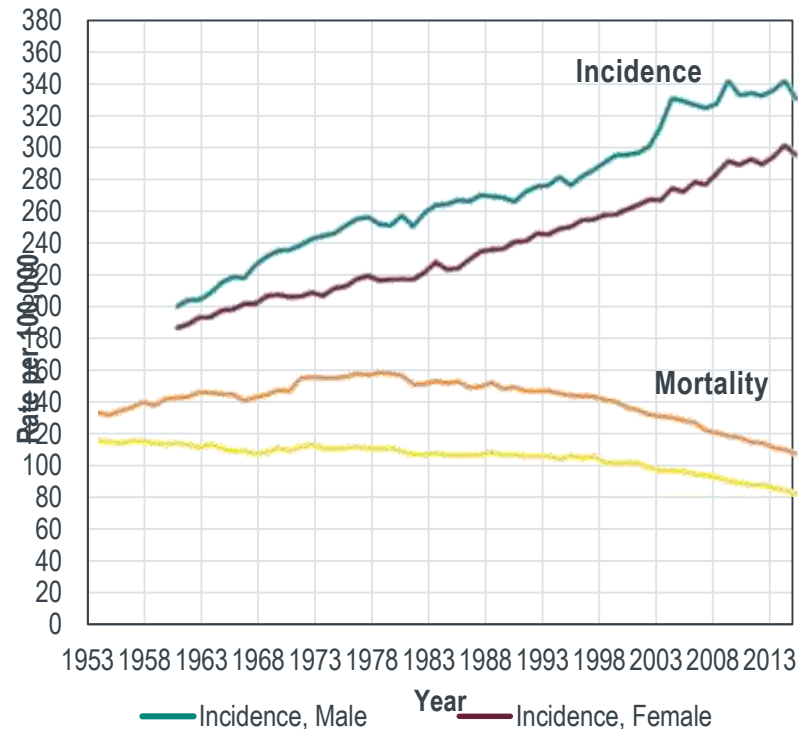
About a 30% rise in cancer incidence between 1995 and 2012.¹



THE PHARMALOT VIEW
At \$475,000, new cancer drug raises thorny questions about drug pricing — and value
By ED SILVERMAN @Pharmalot / SEPTEMBER 4, 2017

- In 1996, a physician had only **4** medicines to treat lung cancer
- In 2016 there were **19** different medicines available [2]

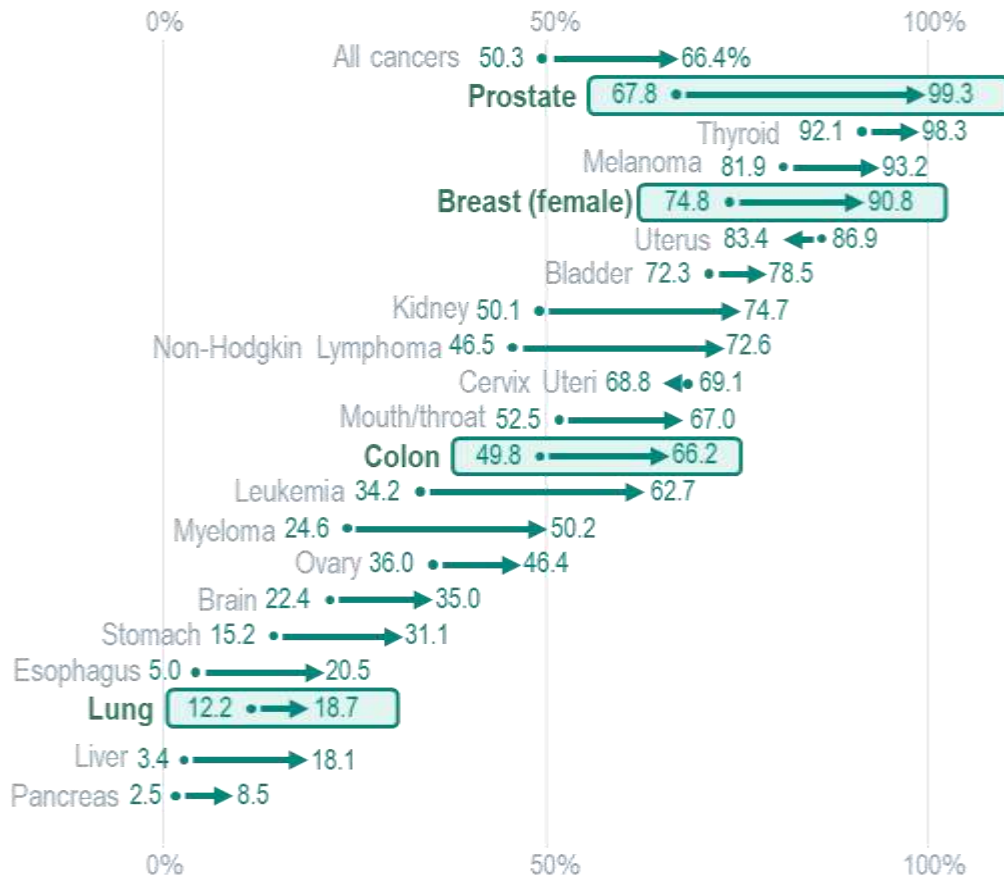
Despite increasing cancer incidence, there is decreasing mortality due to advances in prevention, screening, diagnosis and treatment



- **Cancer is set to become the #1 disease burden**, especially given trends in demographic changes and lifestyle
- As drug prices and incidence continue to grow, **payers are concerned with the burden of innovation** on the healthcare system
- **However, cancer mortality is decreasing due to innovation**
 - i.e. advances in prevention, screening, diagnosis and treatment

Survival has increased for three out of the four high incidence tumour types Lung Cancer is the last frontier

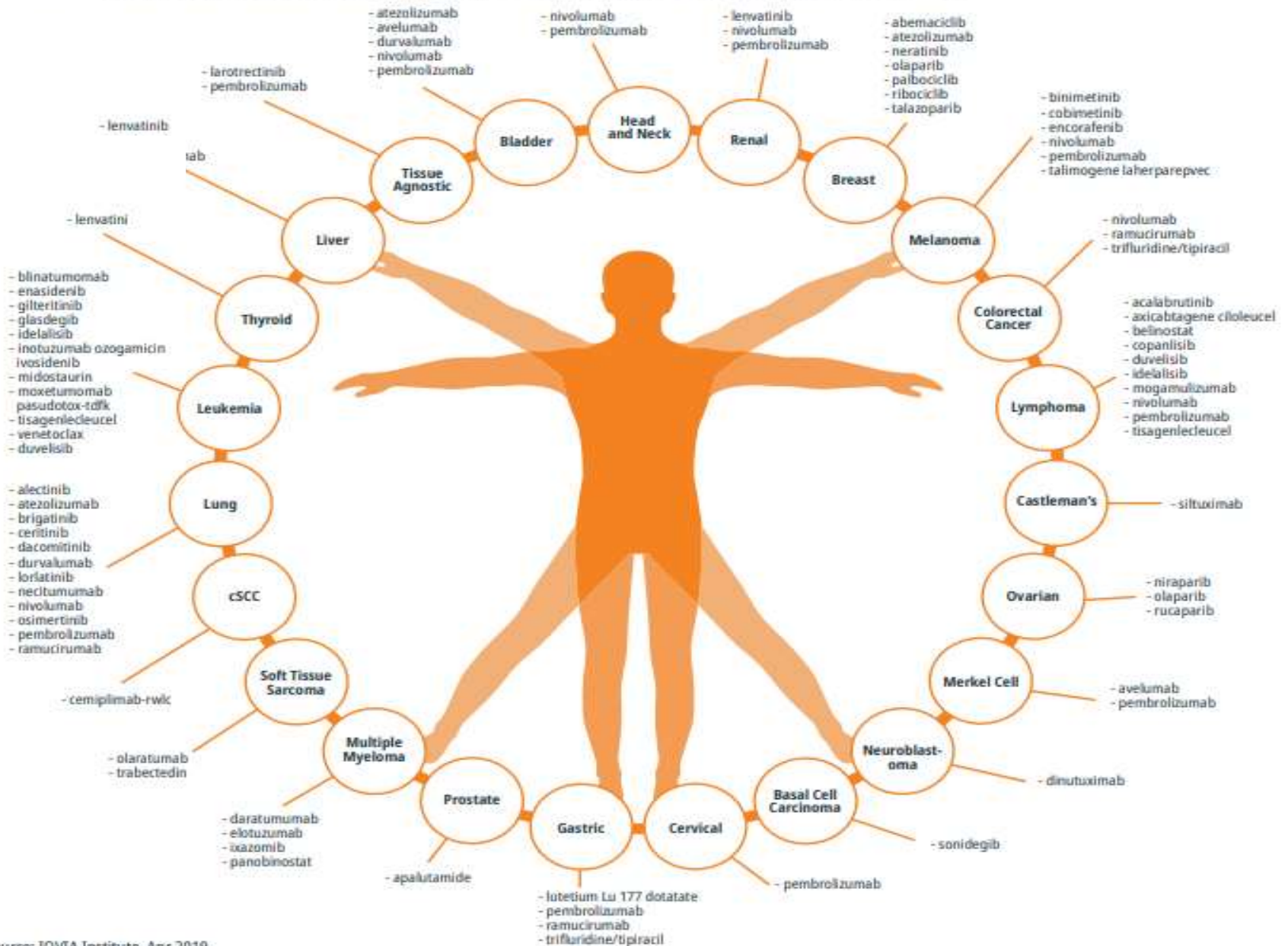
Evolution of Five-Year Survival Rates for Most Common Cancer Sites¹



Immuno-oncology
is revolutionizing
this sector.

Lung cancer is the
last major killer,
with very poor
survival rates.

New Active Substance Approvals in Oncology by Tumor Type, 2014-2018

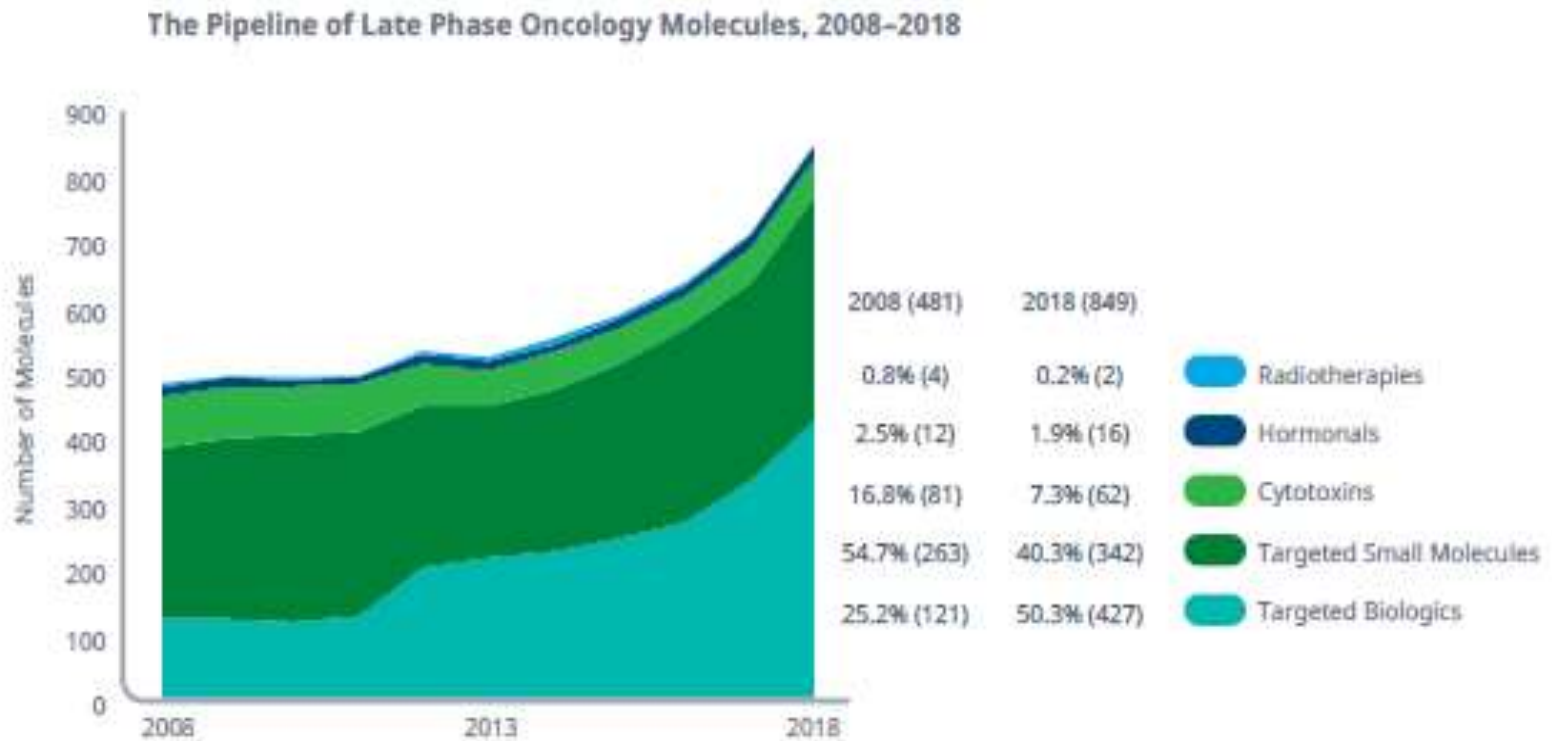


Source: IQVIA Institute, Apr 2019



INVENTING FOR LIFE

The late-stage oncology pipeline included 849 molecules in 2018, up 77% since 2008, due to the increasing number of targeted therapies

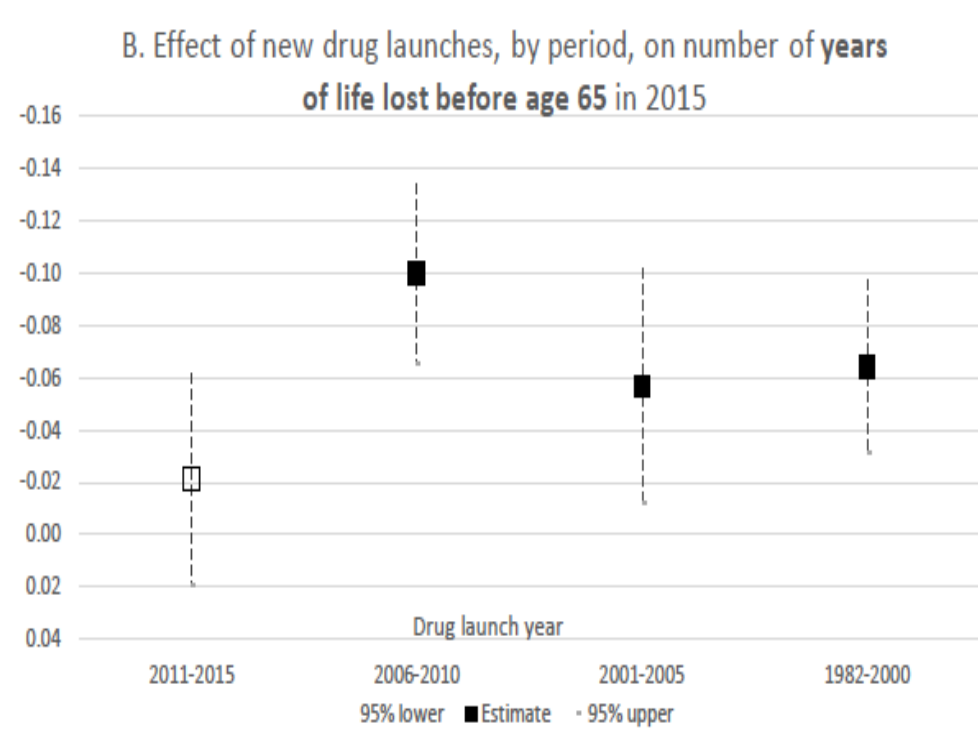
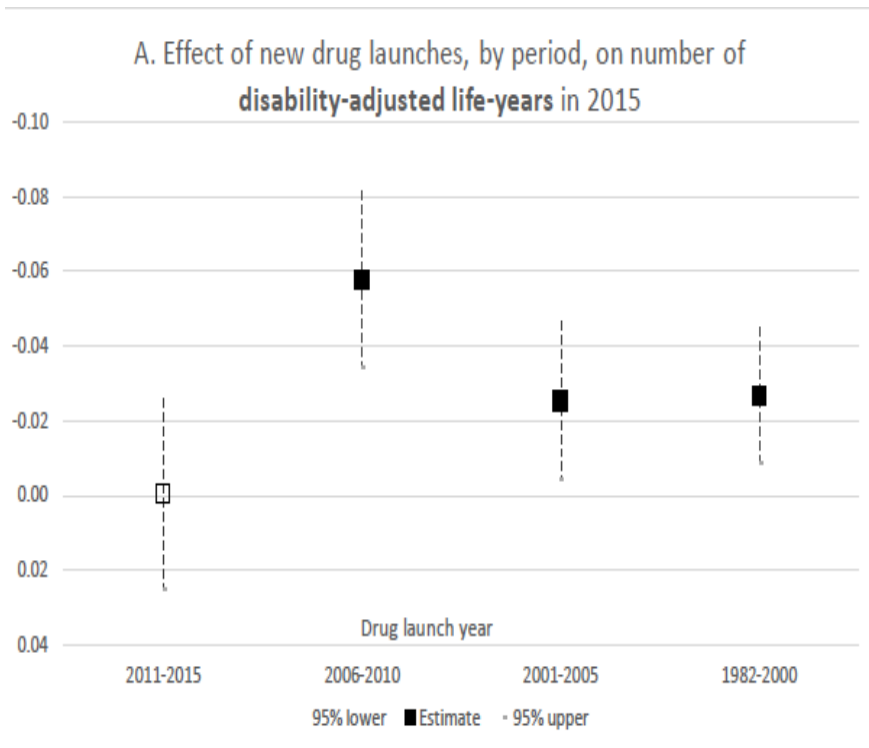


Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, May 2019

Drugs launched during the entire 1982-2010 period reduced the number of cancer DALYs lost in 2015 by about 23%.

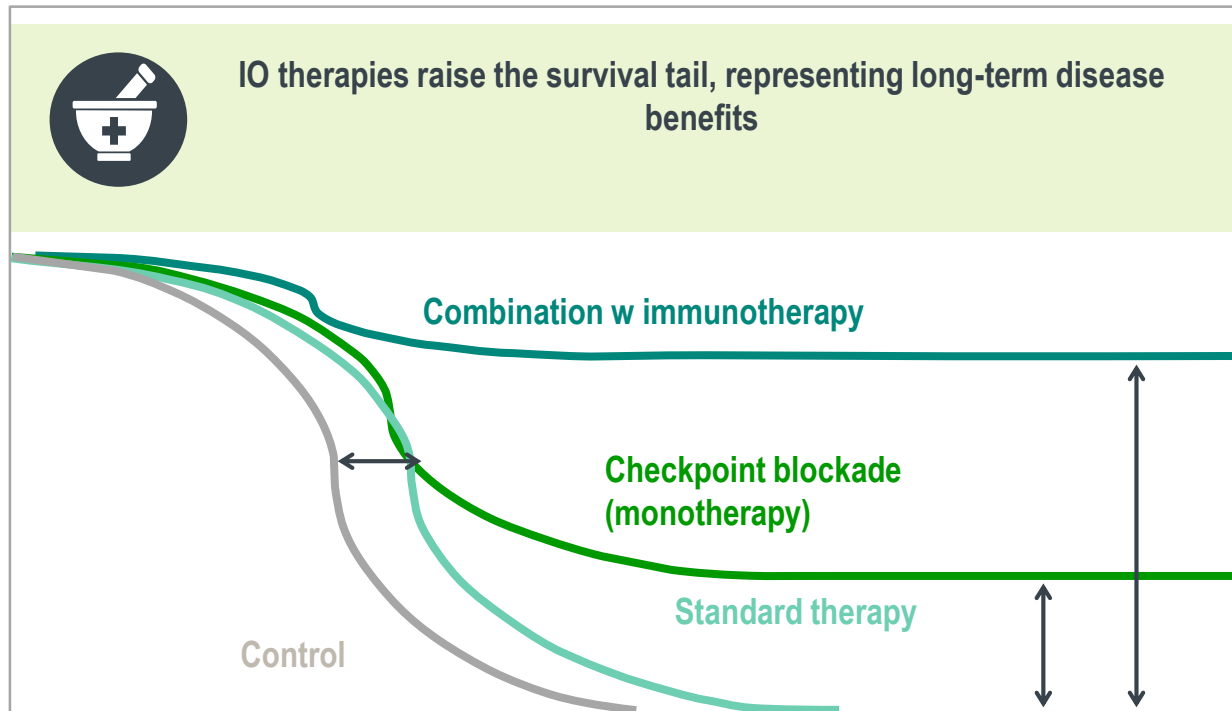
In the absence of new drug launches during 1982-2010, there would have been 26.3 million additional DALYs lost in 2015.

Estimated effects of new drug launches on DALYs and YLL65 in 2015



Vertical scale is inverted. Solid markers indicate significant (P-value < .05) estimates; hollow markers indicate insignificant estimates.

Immunotherapy represents an important health innovation providing durable response and long term survival

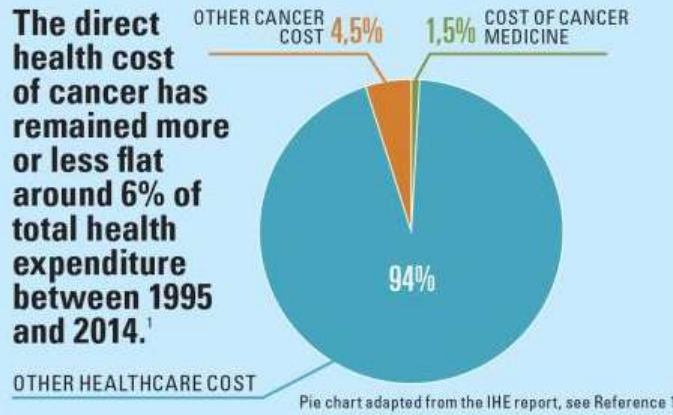


The share of health expenditure devoted to cancer has been mostly constant over 20 years

Table 1
Health expenditure on cancer in the EU (current prices), 1995 and 2014.

Country	1995				2014			
	% of THE	Total (M€)	Total (M€, PPP)	Per capita (€)	% of THE	Total (M€)	Total (M€, PPP)	Per capita (€)
Austria	6.0% ^a	1049	901	132	6.8% ^a	2396	2154	281
Belgium	5.6% ^a	927	814	92	6.2% ^a	2722	2415	244
Bulgaria	6.6% ^a	35	135	4	6.8% ^a	210	466	29
Croatia	6.9% ^a	79	147	17	6.9% ^a	213	337	51
Cyprus	6.3% ^a	21	25	32	6.3% ^a	74	88	96
Denmark	6.3% ^a	110	148	22	6.3% ^a	44	57	10
The Netherlands	4.6% ^a	1228	1069	79	5.7% ^a	4517	4046	264
Poland	6.2% ^a	301	814	10	6.7% ^a	1737	1031	46
Portugal	3.9% ^a	261	332	26	3.9% ^a	639	795	61
Romania	6.6% ^a	61	230	3	6.8% ^a	554	1048	27
Slovakia	6.3% ^a	56	140	11	6.2% ^a	376	764	99
Slovenia	6.7% ^a	80	108	40	6.7% ^a	223	283	109
Spain	5.6% ^a	1903	2303	48	5.8% ^a	5319	5961	116
Sweden	6.3% ^a	1030	876	119	6.3% ^a	2746	2119	283
United Kingdom	5.1% ^a	3082	3338	53	6.1% ^a	9554	8298	148
EU	5.9% ^a	35,747	35,747	74	6.1% ^a	83,184	83,184	164

M = million; THE = total health expenditure; PPP = purchasing power parity; EU = European Union.
Notes: cancer is defined as ICD-10 C00-D48.
The sum of all PPP-adjusted estimates does not equal the estimate for the EU because the different shares of cancer-specific health expenditure change the weighting of the national estimates.
^a Estimated share based on data from similar countries; see Ref. [1].



- Health expenditure on cancer increased continuously from **€35.7 billion in 1995 to €83.2 billion in 2014 in the EU.**
- Spending on cancer drugs has also increased from **€7.6 billion in 2005 to €19.1 billion in 2014 (current prices).**
- However, the share of total health expenditure devoted to cancer **was mostly constant (~6%).**

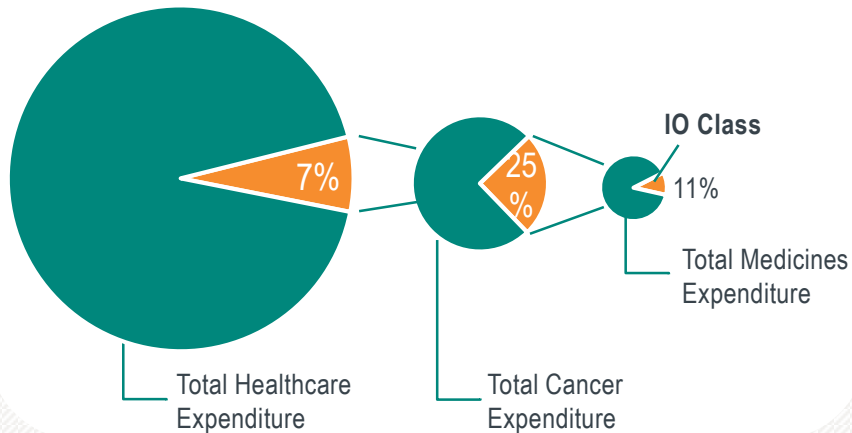
More than 11,000 life years could be gained with IOs in the next 5 years, with manageable healthcare expenditure

The budget impact of the IO class may only be a small portion of healthcare expenditure...

Example



**Budget impact of the PD-1/PD-L1 class in Austria:
0.2% of the total healthcare expenditure**



...but offer significant health benefits vs. SoC over 5 years

Example



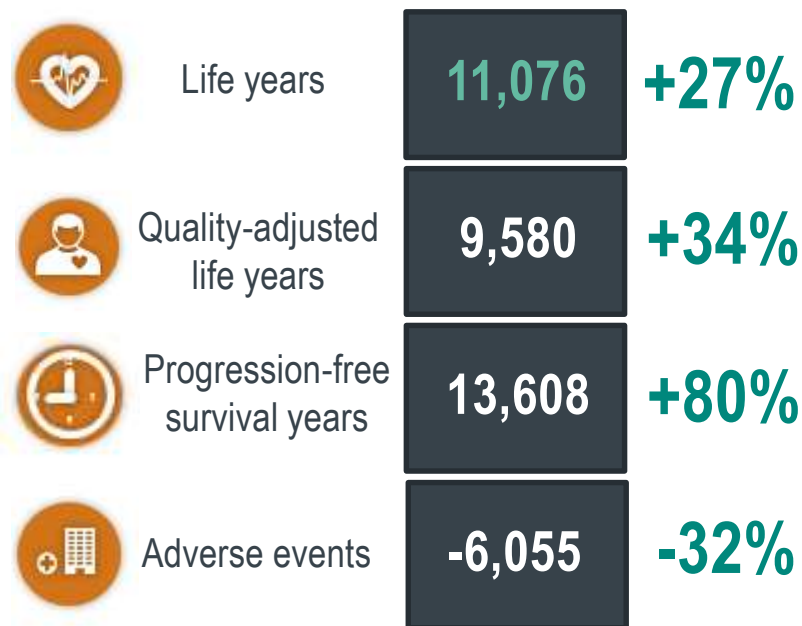
Health benefits gained by introducing anti-PD-(L)1 vs. SoC over 5-years



Source: Van Bavel J et al. (2018), Modelling the Budget Impact and Health Outcomes of the Anti PD-1/PD-L1 Class in Cancer Care in Austria; Poster at EUPHA 2018; Van Bavel J et al. (2018), Modelling the Budget Impact and Health Outcomes of the Anti PD-1/PD-L1 Class in Cancer Care in Belgium; Poster at EUPHA 2018;

In Belgium anti-PD-(L)1 therapies provide patients with significant benefit by increasing life years gained by 27%

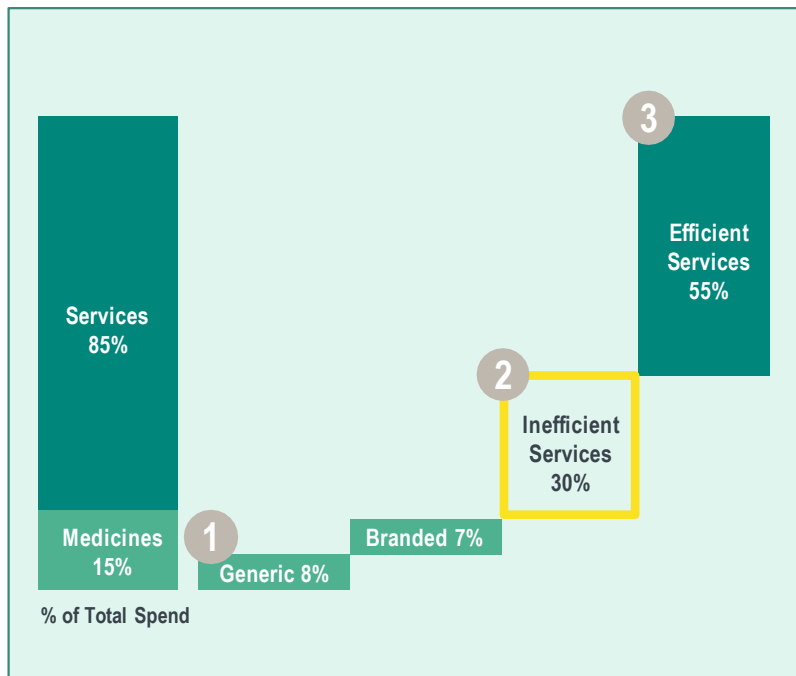
Health benefits gained by introducing anti-PD-(L)1 vs. SoC over 5-years



Conclusions:

1. **22,000 patients** will benefit from innovative life-saving IO therapies over the next 5Y
2. The use of anti PD-1/PD-L1 is estimated to lead to **by approximately 10,000 more qualitative life years** over the next 5 years
3. The **rapid reimbursement decided by the MoH increased the LY gained with 66%** compared to the traditional P&R process
4. The **expected budget impact** of the anti-PD-(L)1 class represents a limited share of medicines expenditure, ranging from around 3% to 8% of total medicines budget (2018-2022)

Creating budget headroom for innovation to promote sustainable healthcare



There are three areas to seek headroom and identify ways to promote sustainable healthcare:

- 1 **More than half of medicines spend are on generics**, but uptake can be poor
- 2 Non-medicines spend carries an estimated 30% inefficiency; **significant opportunity exists** to fund innovation
- 3 Health spend benefits accrue in other areas such as: reduced unemployment, greater tax revenues, and **budget re-appropriation**

Addressing affordability

Medicines cost increase may lead to savings to other parts of the health care system

Innovative contracting agreements can minimize payer risk and ensure predictability

Addressing system inefficiencies can lead to budget reallocation

Oncology is a stable portion of total health care spending

Medicines spending increases coincides with less hospital or other health system use

Prevention and access to medical innovation can save lives and reduce cancer costs

Financial performance agreements can reduce payer risk: (Discounts, PVAs, Multi Year Multi Indication Agreements)

Performance based agreements are difficult to implement because of high administrative costs

Coverage with evidence generation and RWE generation can shape IO reimbursement landscape in the medium to long run

Increasing use of generics can free up space for innovation
Addressing inefficiencies in the non medicines sector can lead to savings up to 30% (i.e. AMR, optimizing resource use, addressing LoS)

Prevention and earlier diagnosis can lead to cost savings. Reducing access may increase costs in the overall economy

However, the average delay between market authorisation and patient access for Oncology products is between 2 months to over 2.5 years

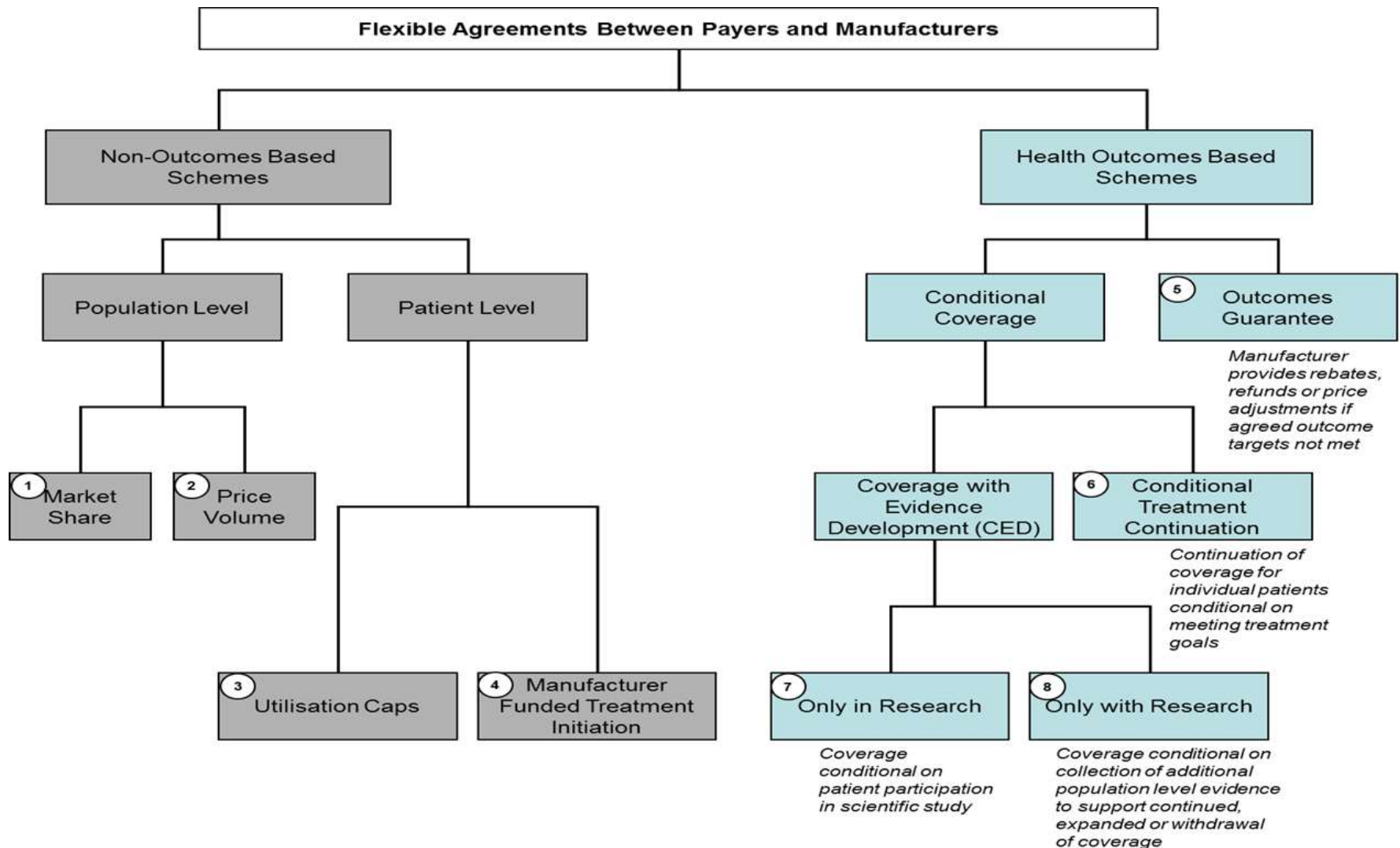
The **average time between marketing authorisation and patient access** - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes



- In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE where some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average.
- In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France is higher than in reality.
- Average of 29 European countries in the analysis (excludes Macedonia)
- Oncology market definition: L1&L2&V3C&Revlimid&Xgeva&Proleukin&Pomalyst

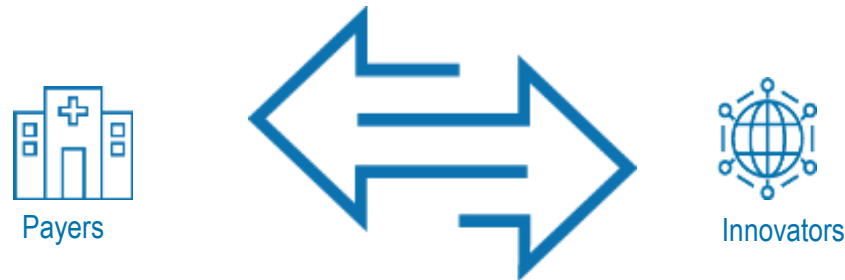


There is a great variety of performance-based agreements to enable affordability in healthcare systems



Multi – Year – Multi – Indication (MYMI) agreements are a new form of agreements that re-define value

New form of agreement between payers and manufacturers that goes across multiple indication and years



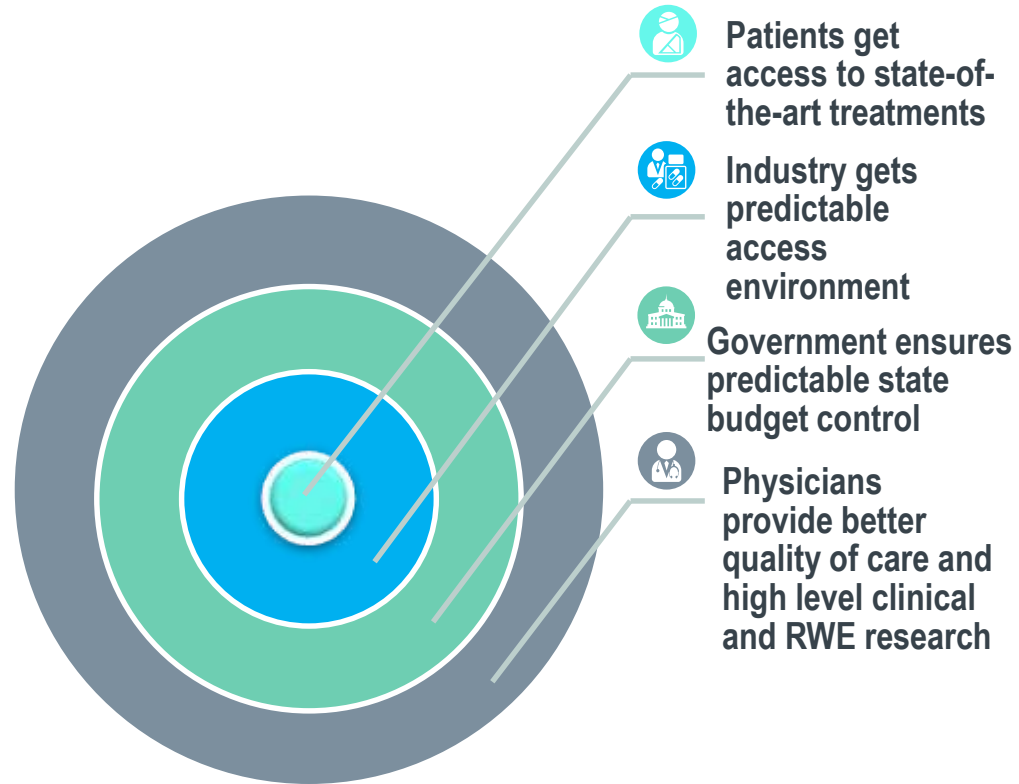
Agreement component	Description
Value assessment	<ul style="list-style-type: none">• Initial agreement anticipates future indications• No or light-touch assessment of subsequent indications• There can be re-assessment using RWE
Access	<ul style="list-style-type: none">• Agreement allows for immediate or accelerated access to indications
Pricing	<ul style="list-style-type: none">• Agreement includes a pricing arrangement that covers all indications and is set for the agreement period
Duration	<ul style="list-style-type: none">• Agreement is for a set duration after the initial P&R approval

The benefits of MYMI agreements span across all stakeholders

Multi-year-multi-indication (MYMI) agreements

- New form of agreement between payers and manufacturers
- Goes across multiple indications and years
- Light-touch or no assessments for new indications
- Price and budget impact of new indications is discussed at the beginning of the agreement

This can help ensure patients have access to state-of-the-art treatments within a **predictable, controlled, and sustainable policy setting**



The implementation of risk-sharing agreements requires collecting appropriate data through registries

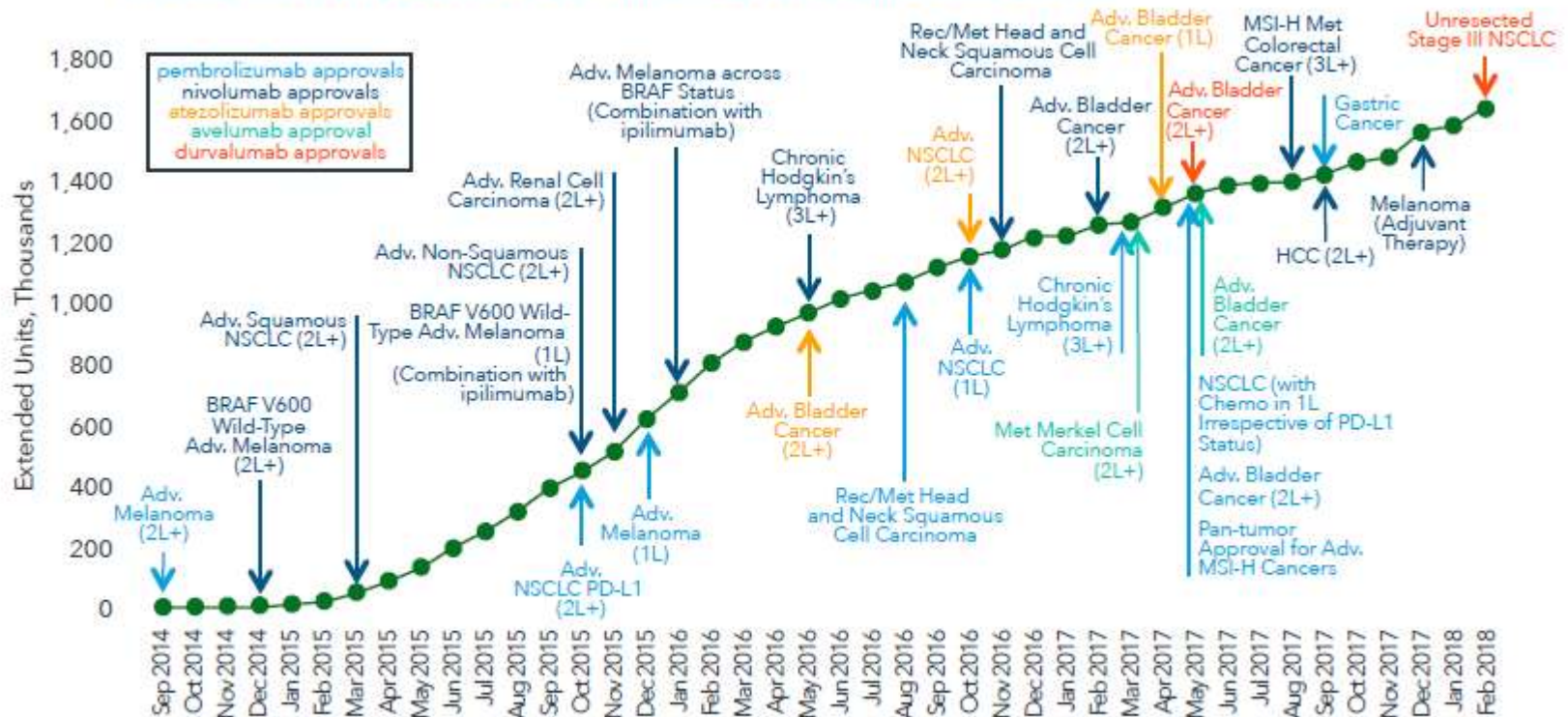
Minimum data required for implementing risk-sharing agreements.

	Field	Description
Patient information	Anonymised patient ID	Unique patient identification, anonymised
Disease information	Identification of disease	Diagnosis (e.g. early disease, metastatic, unresectable, locally advanced)
	Mutational status	The existence of certain mutations can be important to complete diagnosis and/or opt for certain therapy (e.g. KRAS, RAS, HER2, EGFR, BRAF, ALK)
Medicinal product information	Main medicinal product/co-medicinal product	Identification of the medicinal product administered/medicinal product administered in combination
	Amount administered (main medicinal product/co-medicinal product)	Total dose administered in a given cycle
	Date of administration (main medicinal product/co-medicinal product)	Date on which the administration occurred
	Presentation of the medicinal product administered (main medicinal product/co-medicinal product)	e.g. Medicinal product A 150 mg vial
	Number of units administered (main medicinal product/co-medicinal product)	e.g. 2 vials
Treatment information	Line of treatment	e.g. first line metastatic treatment, second line of metastatic treatment, adjuvant, neoadjuvant treatment
	Treatment status*	Not started, ongoing, finished
	Treatment cycle number	e.g. 1, 2, 3, 4,...
	Date of evaluation of response (intermediate or final evaluation)*	Date of evaluation of response to treatment
	Evaluation of response to treatment (intermediate or final evaluation)*	Description of response to treatment (e.g. complete response, partial response, stable, disease progression, death, not assessable)
	End of treatment date*	Date of the end of treatment with a given medicinal product
	Reason for end of treatment*	Reason for interruption of certain treatment (e.g. treatment completed, progression, death, toxicity, patient decision)

*Information required for agreements based on clinical outcomes

The sustained uptake of checkpoint inhibitors demonstrate their remarkable clinical profile and continued expansion of indications

Immuno-Oncology PD-1 and PD-L1 Inhibitor Uptake in the United States



Source: U.S. FDA, IQVIA, National Sales Perspectives, Feb 2018; IQVIA Institute, Apr 2018

The most important benefit of innovative agreements is increasing life year gain by 83% for cancer patients



Life years gained after 5 years

Traditional reimbursement



Innovative agreement



- New cancer treatments may add over **6,000 life years** in the next five years in Belgium
- Innovative agreements, which provide earlier access, **could increase life year gained to 11,000**

Source: Van Bavel J et al. (2018), Assessing the impact of PD-1/PD-L1 inhibitors on health and budget in Belgium; 11th European Public Health Conference: Poster Displays ; MSD HIPP

THANK YOU

