

EU Cancer Plan: Data, Technology and Human Touch

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**LET'S
DIFFERENTLY
TALK ABOUT CANCER**

Please join our efforts to "end with cancer as we know it" during 2019 Romanian Presidency of the European Union.



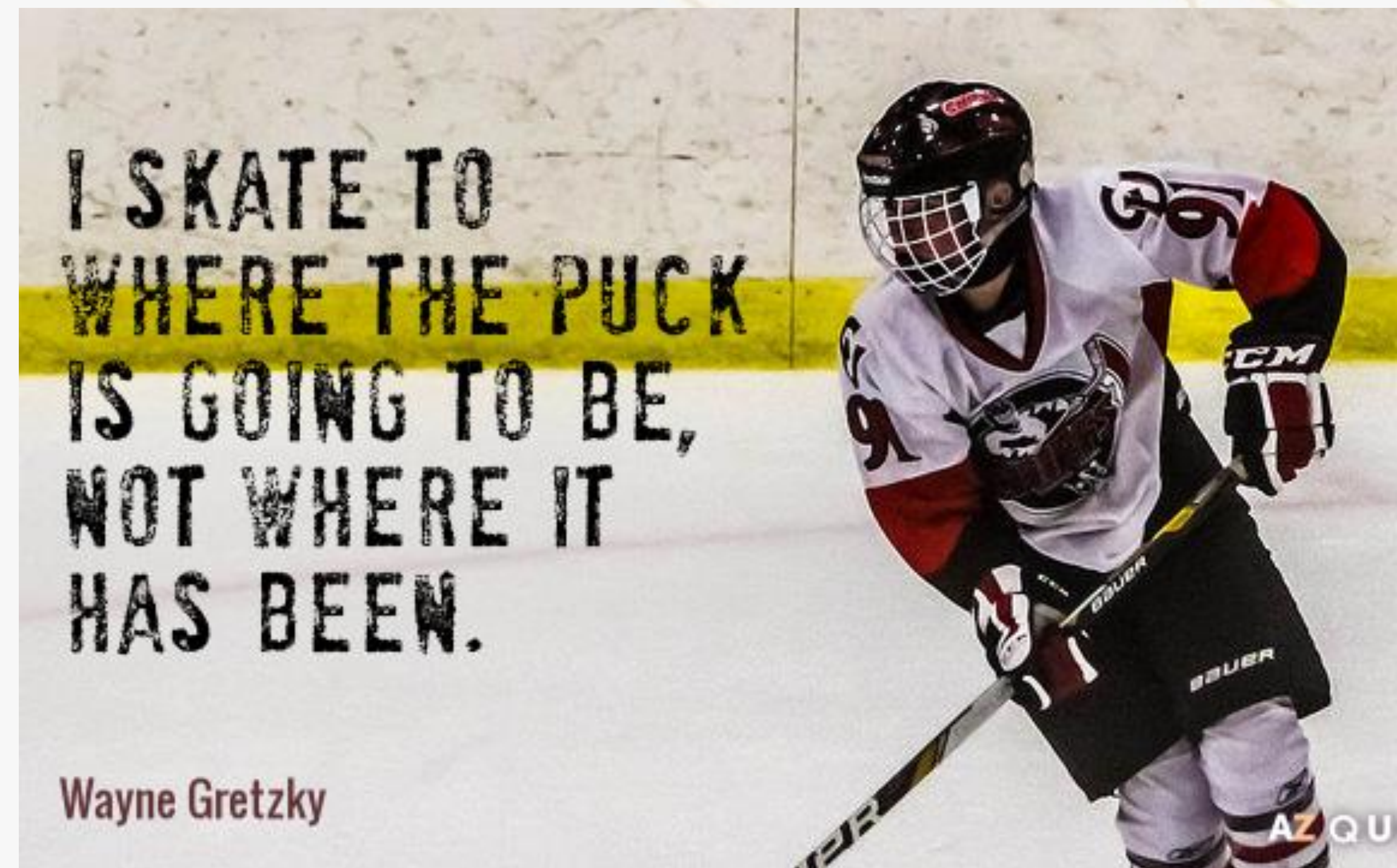
2019

Pioneering the healthcare transformation

Expertise : personalised healthcare, biotech, digital medicine, cancer policy, health literacy, patient empowerment, health communication

Advocacy and agenda setting activities:

- Personalised Medicine Committee at MoH (2017)
- e-Health Agency (2019)
- health priorities of Romania at Presidency of the Council of the EU (digital medicine, cancer)
- Innovation Fund (2017-2019)
- HepC elimination National Plan (2017-2019)

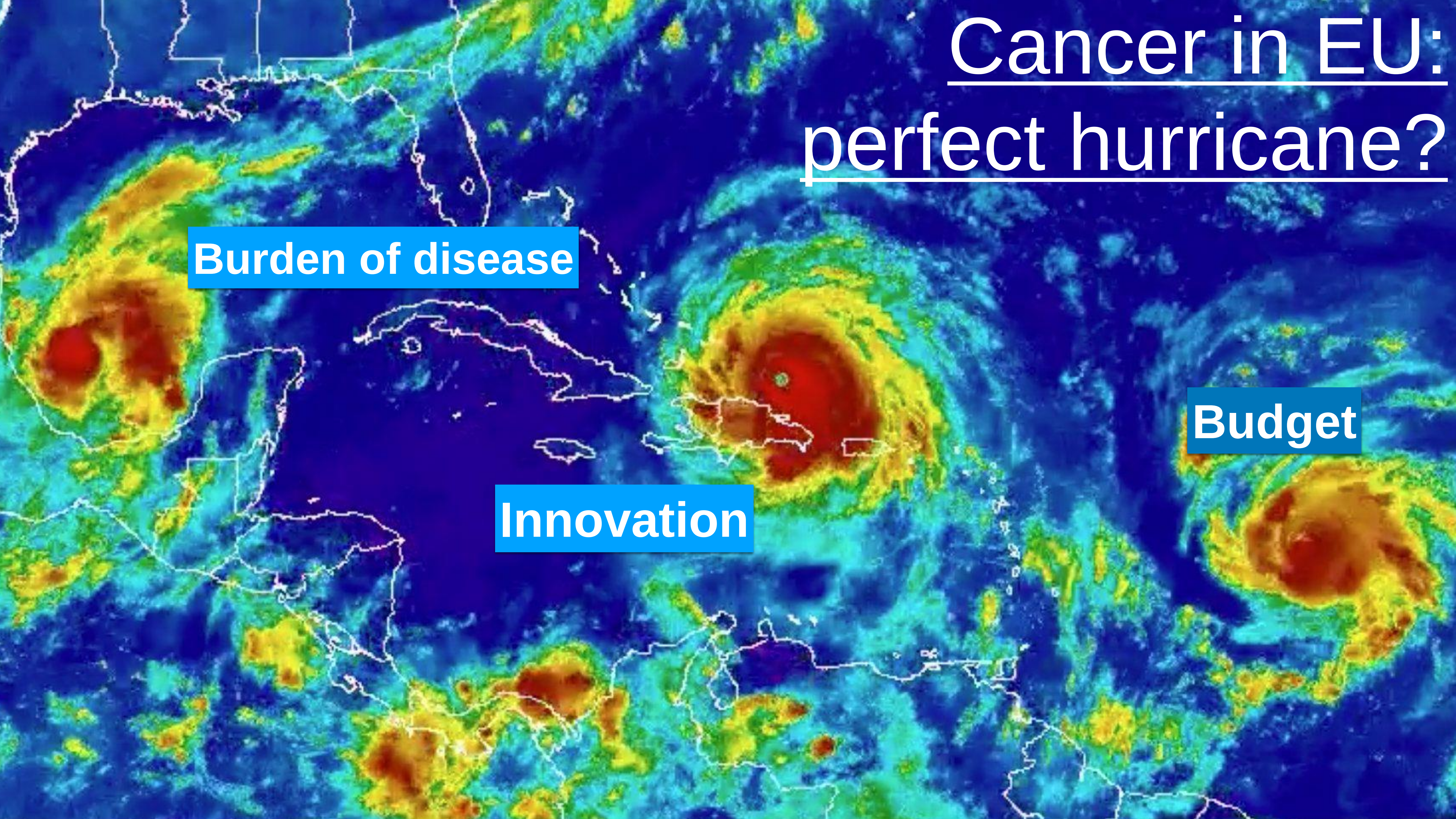


Cancer in EU: perfect hurricane?

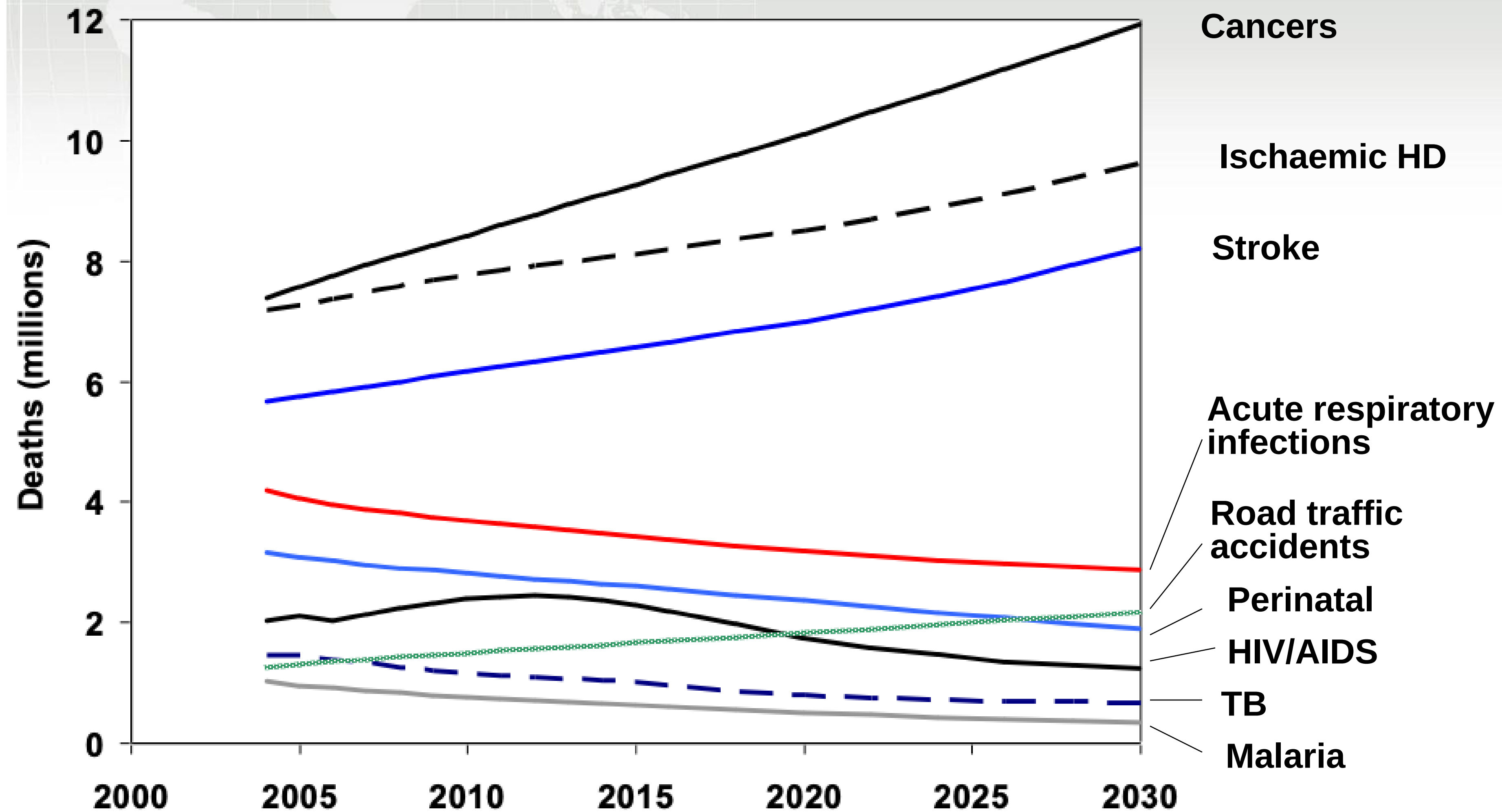
Burden of disease

Budget

Innovation

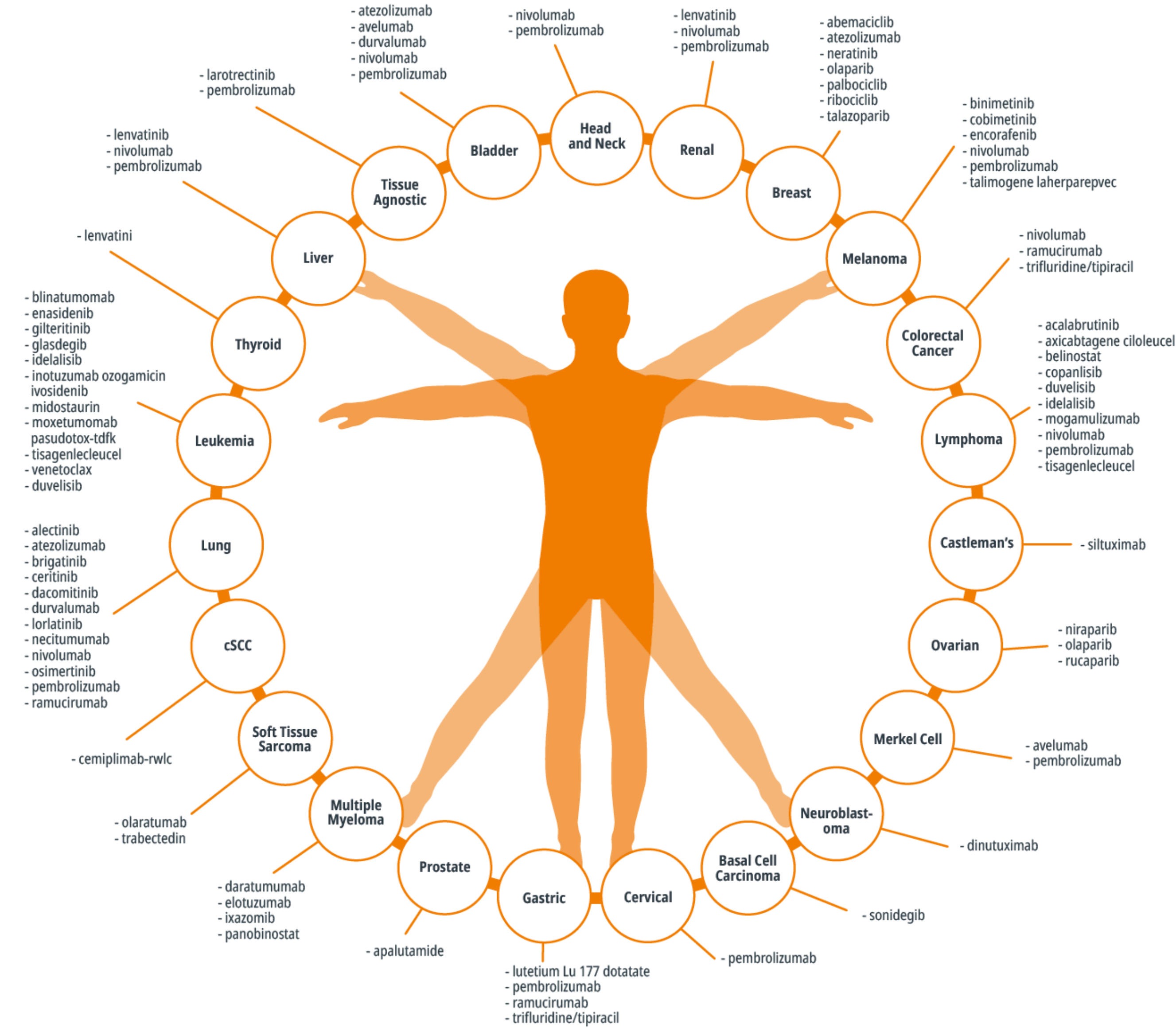


Global projections for selected causes, 2004 to 2030



Updated from Mathers and Loncar, PLoS Medicine, 2006

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

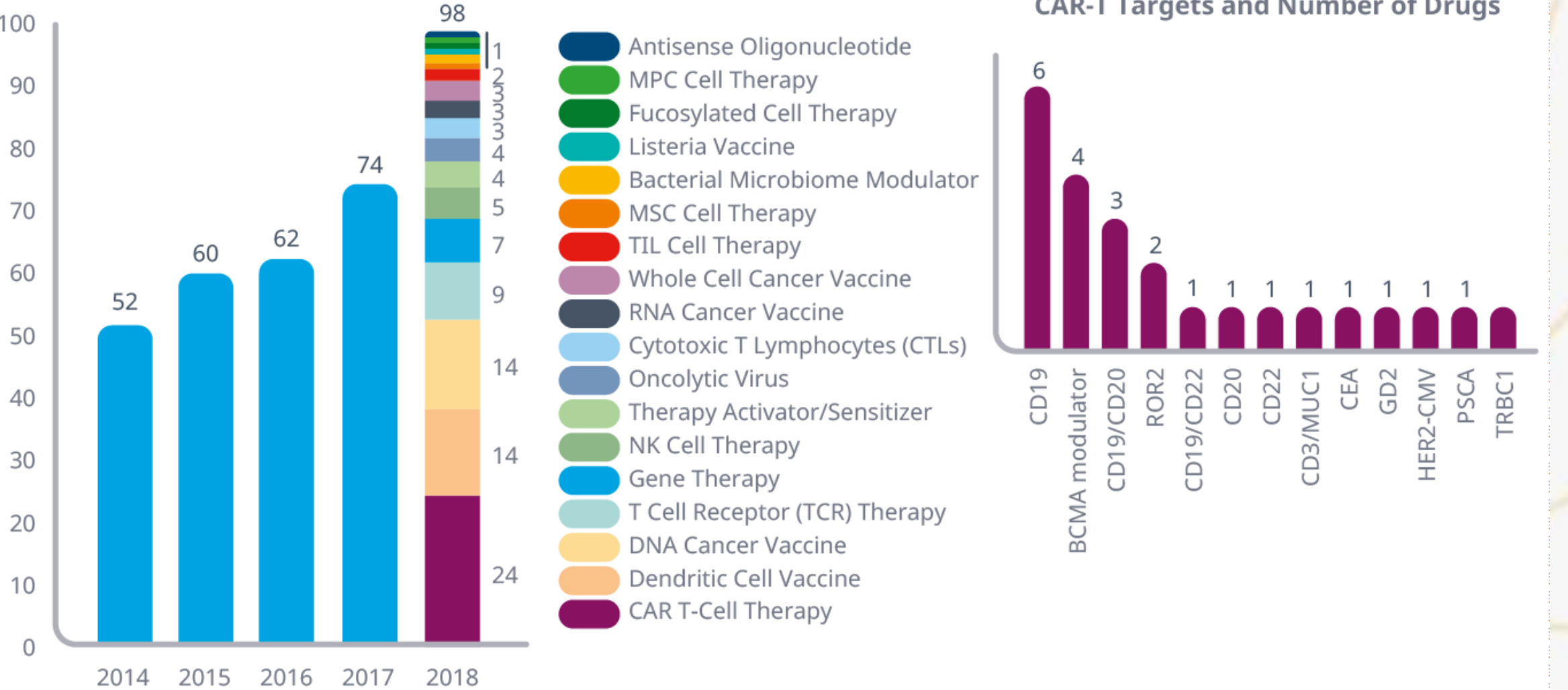


Source: IQVIA Institute, Apr 2019

Chart notes: Excludes supportive care. cSCC = Cutaneous squamous cell carcinoma; mogamulizumab is approved for multiple lymphoma indications: Mycosis fungoides and Sézary syndrome. Pembrolizumab is approved for multiple lymphoma indications: classical Hodgkin lymphoma (cHL) and primary mediastinal large b-cell lymphoma (PMBCL). Chart includes three indication approvals that occurred for NAS candidates within the time frame of launch within 2014 to 2018 that had subsequent indication approvals as of May 2019: pembrolizumab, trifluridine/tipiracil and atezolizumab for renal, gastric and breast, respectively.

Report: Global Oncology Trends 2019 – Therapeutics, Clinical Development and Health System Implications. IQVIA Institute for Human Data Science, May 2019

Number of Next-Generation Biotherapeutic Pipeline Products in Late-Stage Pipeline, 2014-2018

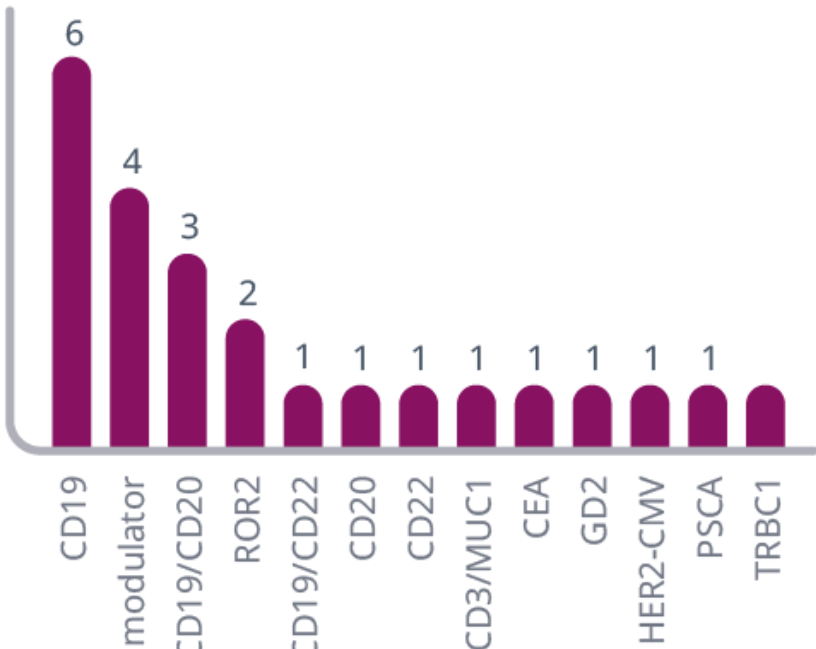


Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, Mar 2019

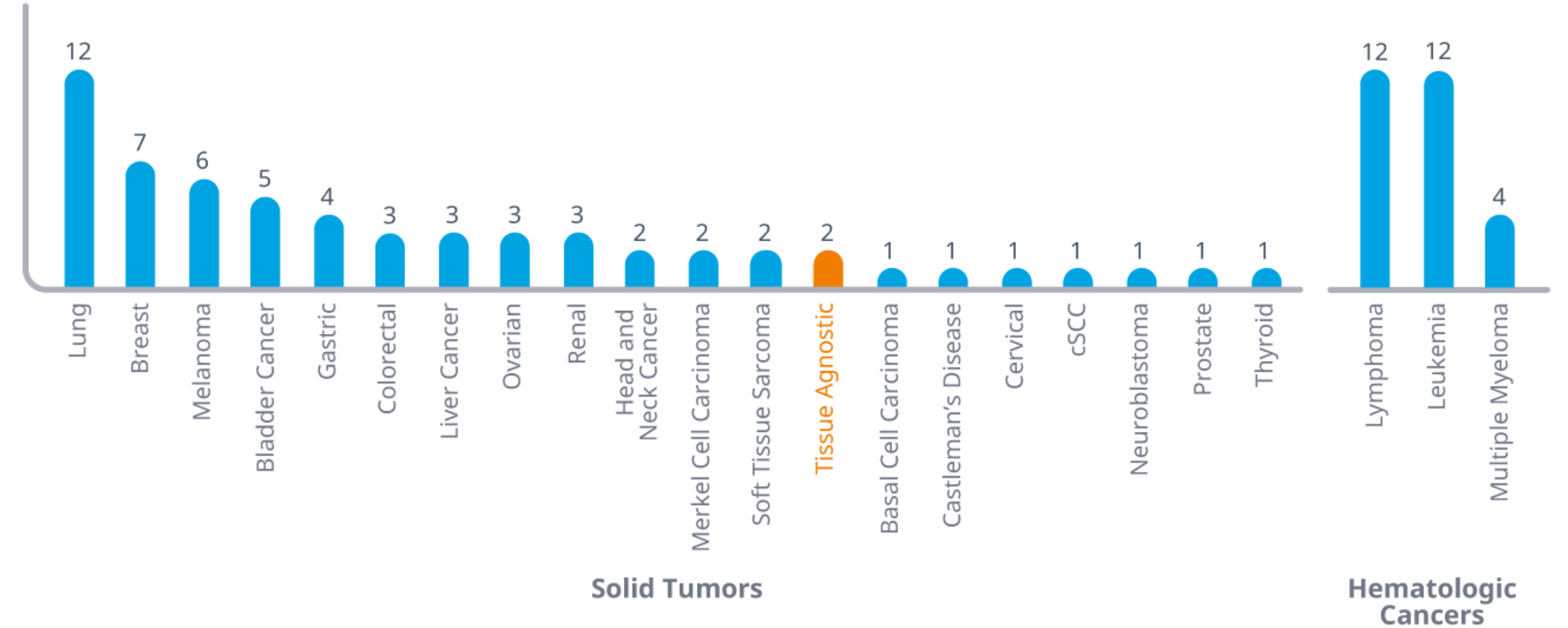
Chart notes: Next-Generation Biotherapeutics are defined as cell, gene and nucleotide therapies. Late-stage pipeline is defined as active programs (activity in past three years) in Phase II through Registered. Defined as cell and gene therapies or nucleotide therapies with mechanisms including: cell therapy; dendritic cell therapy; NK cell therapy; T-cell therapy; CAR T-Cell therapy; T-cell receptor therapy; stem cell therapy; bacterial cell therapy; CIK cell therapy; CIK-CAR therapy; whole cell vaccine; dendritic cell vaccine; bacterial cell vaccine; DNA vaccine; RNA vaccine; exon skipping; nucleic acid based; gene therapy; oligonucleotide; antisense; RNAi; microRNA mimic; gene editing; CRISPR-Cas9; zinc finger nuclease; RNA therapy; mRNA therapy.

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CAR-T Targets and Number of Drugs



Number of New Active Substance Approvals in Oncology by Indication

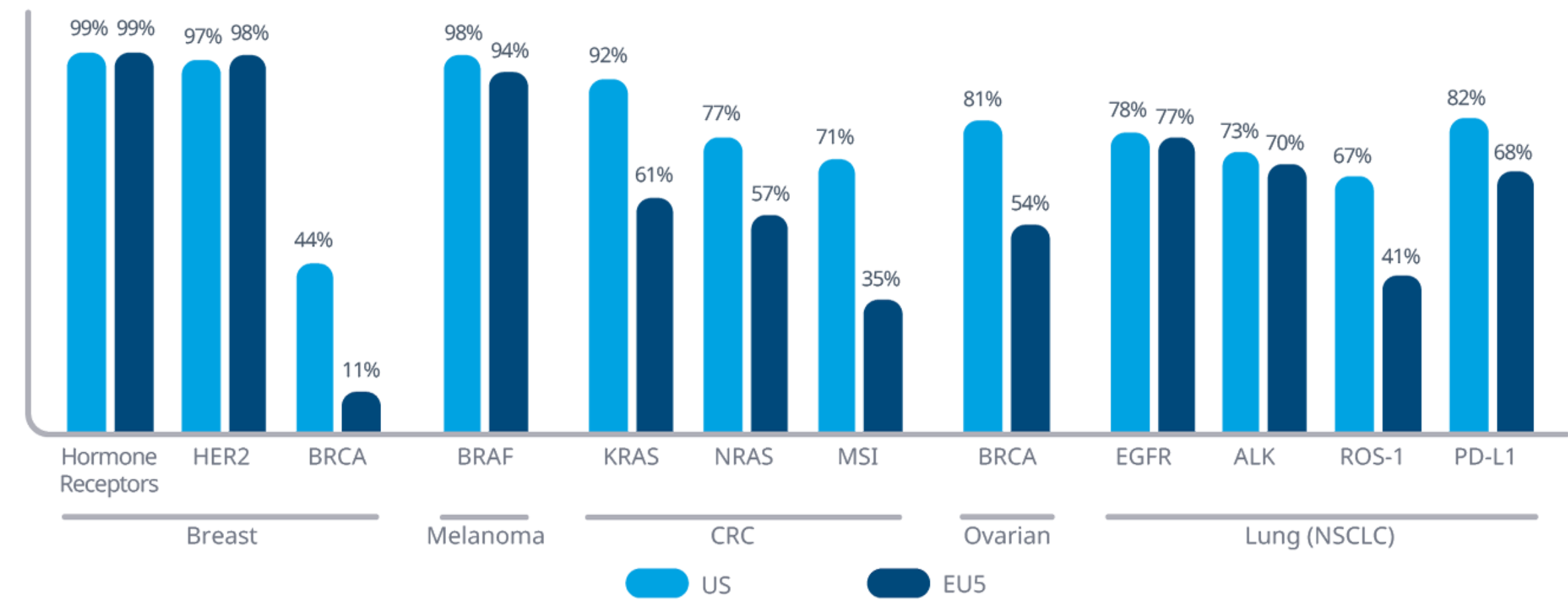


Source: IQVIA Institute, Apr 2019

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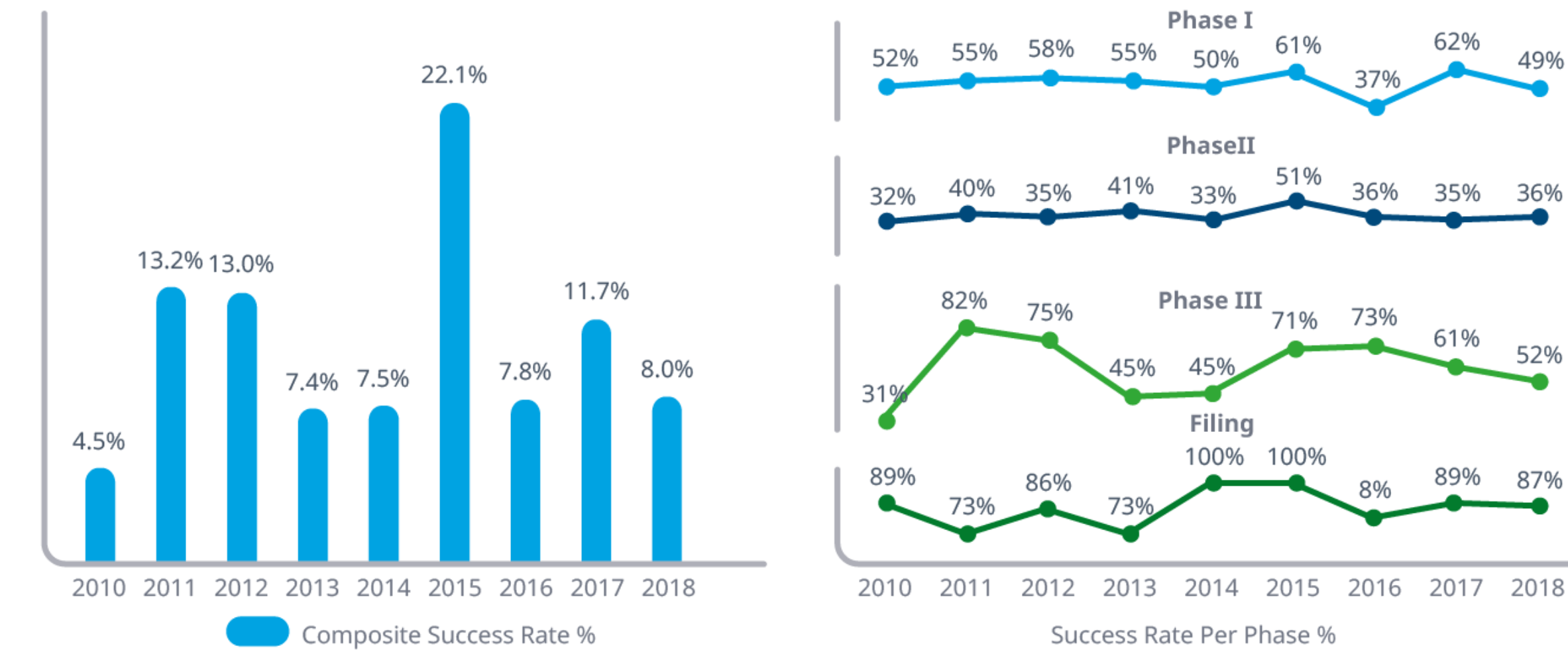
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Percentage of United States and EU5 Patients Tested for Biomarker by Cancer Type



Source: IQVIA BrandImpact, IQVIA Oncology Dynamics, Mar 2019; IQVIA Institute, Apr 2019
Chart notes: Reported as a percentage of knowledgeable respondents; *denotes percentage of metastatic; BrandImpact number of patients covered in the survey: Lung = 13,000–20,000; Breast = 40,000–45,000; Melanoma = 2,726; Colorectal = 11,800–12,500; Ovarian = 7,365. Number of patients covered in the survey: Lung = 12,757; Breast = 16,175; Melanoma = 3,668; Colorectal = 10,167; Ovarian 3,675. PD-L1 = programmed cell death receptor and its ligand; KRAS = gene coding K-Ras protein; ROS-1 = a tyrosine kinase inhibitor encoded by ROS1; NRAS = gene coding N-Ras protein; ALK = gene coding ALK receptor tyrosine kinase; EGFR = gene coding epidermal growth factor receptor protein; BRAF = gene coding B-Raf; Hormone includes PR and ER, which are progesterone and estrogen receptors, respectively.
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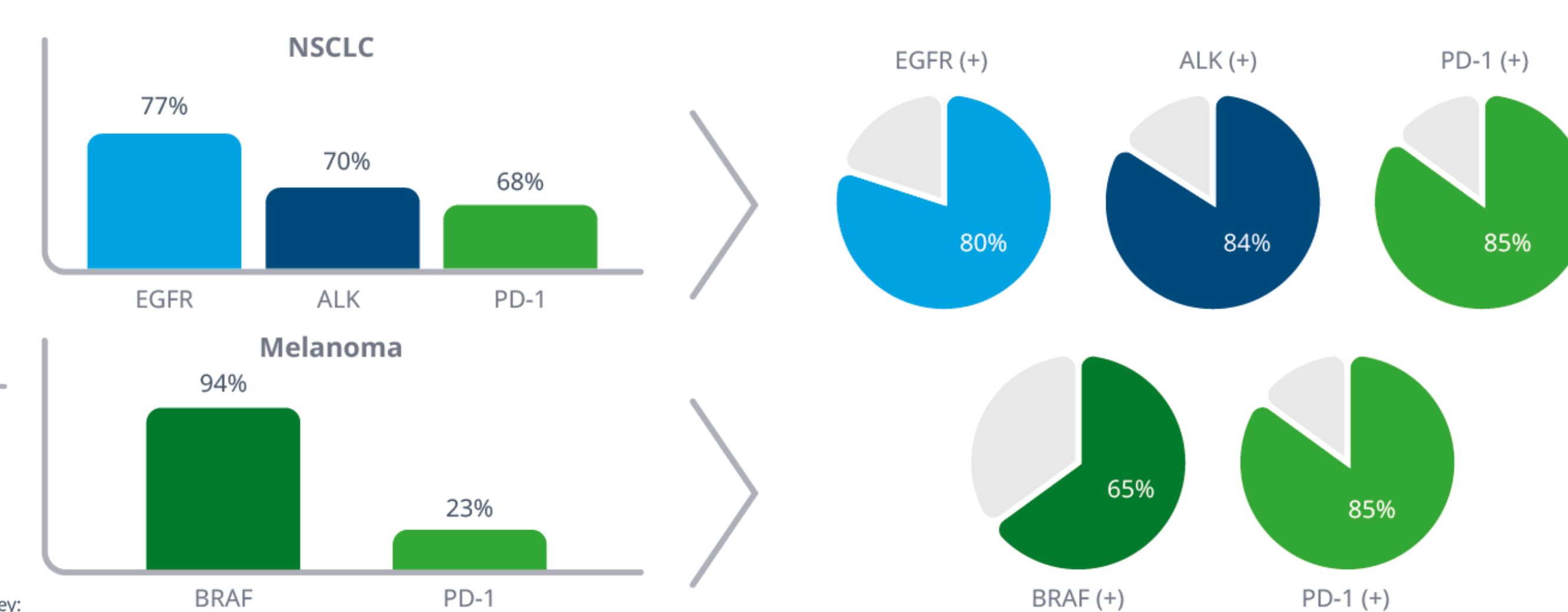
Oncology Trial Phase Transition Success Rate by Phase, 2010-2018



Source: IQVIA ARK R&D Intelligence; IQVIA Institute, Apr 2019
Chart notes: Composite Success Rate = Phase I x Phase II x Phase III x Regulatory Submission.
Report: Global Oncology Trends 2019 – Therapeutics, Clinical Development and Health System Implications. IQVIA Institute for Human Data Science, May 2019

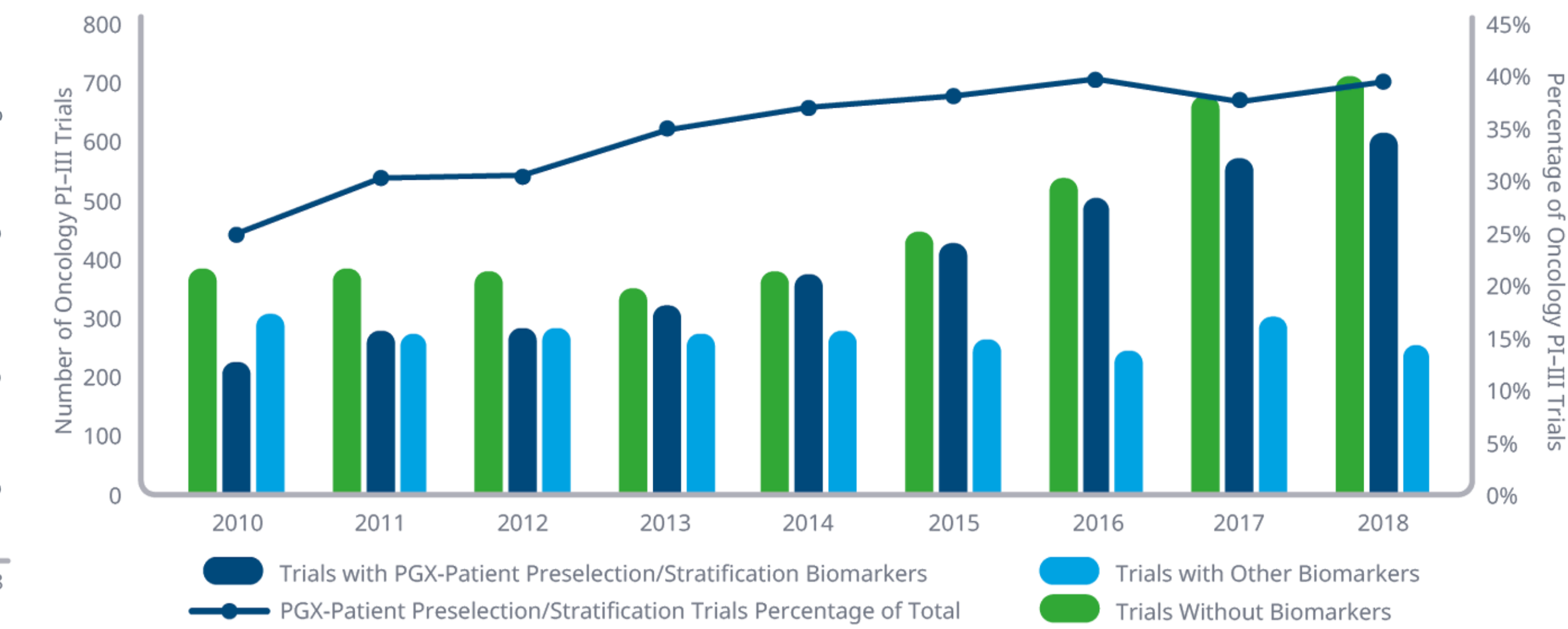
Source: Global Trends in Oncology Report by IQVIA

Percentage of Patients Tested by Biomarker and Cancer in Europe and Patients Receiving Drug Targeting nce Tested Positive



Source: IQVIA Oncology Dynamics, Patient Level Oncology Survey Data, MAT Q4 2018
Chart notes: PD-1 Positive defined as >50% expression; Countries included in analysis: France, Germany, Italy, Spain, UK. NSCLC projected patients = ~150,100; Melanoma projected patients = ~30,200.
Report: Global Oncology Trends 2019 – Therapeutics, Clinical Development and Health System Implications. IQVIA Institute for Human Data Science, May 2019

Number and Percentage of Oncology Phase I-III Trials by Biomarker Type, 2010-2018



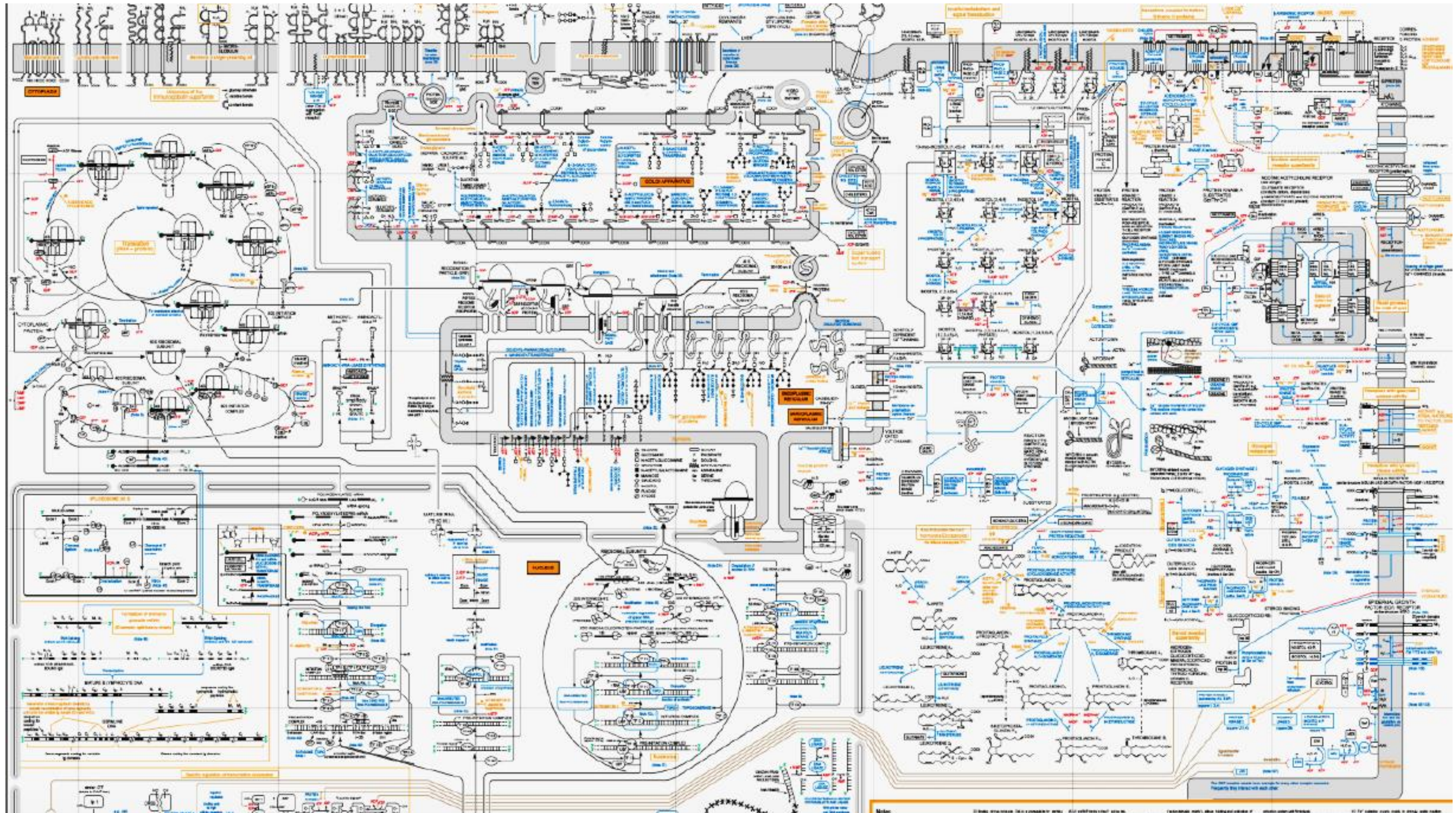
Source: Trialtrave, Pharma Intelligence, Apr 2019; IQVIA Institute, Apr 2019
Chart notes: Citeline's Trialtrave's dataset was used to create a year-over-year analysis for the number of biomarkers in oncology trials. Biomarker trials were identified using the following trial tags: biomarker/efficacy, biomarker/toxicity, PGX-biomarker identification/evaluation, PGX-pathogen, PGX-patient preselection/stratification. PGX trials are those that incorporate pharmacogenomic and/or pharmacogenetic analysis. Trials were industry only and interventional. Terminated and planned trials were excluded. Trials with healthy volunteers were excluded. Phase I through Phase III included.
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Key challenges for cancer in the EU

- Mismatch between the rising burden of disease and a roughly flat spend on cancer care reflective of a sluggish economic recovery and tightening funding constraints
- There are inconsistencies in prioritisation of cancer care on the public policy agenda despite the prevailing disease burden and amplitude of future challenges
- Late diagnosis
- There is a lack of readiness in healthcare systems to adjust to the rate and type of innovation in cancer treatment (e.g. multi-indication medicines, combinations, personalised medicine)
- Inequalities in access add to the burden of disease, and there are large differences in terms of access to and availability of new cancer treatments across the European Union
- There is a disconnect between regulatory and HTA / pricing & reimbursement procedures and restrictive HTA value assessment frameworks
- There are growing disparities in care delivery and outcomes within and across countries
- There is a very diverse and fragmented environment for oncology data in Europe



Cancer: heterogeneous environment



EU Cancer Plan: Data, Technology and Human Touch



**A new vision for cancer
in European Union.**

Data, technology and human touch

- A vision for every citizen and every cancer patient
- A vision at the health system level

Our goal is to promote a visionary EU Plan on Cancer based on human touch, data, technology and modelling approach that empowers citizens.

Various initiatives including the EU Master Plan to Fight Against Cancer and the German Decade against Cancer could provide a strong framework for this vision. (Weber, 2018)

At the centre of our vision is the citizen/patient and the need for a true personalised approach for prevention, early detection, diagnosis and treatment of cancer. Every citizen/patient is unique and deserves the best possible healthcare but this is not always possible due to heterogeneity of the disease (every cancer is unique) and the heterogeneity of the health systems.

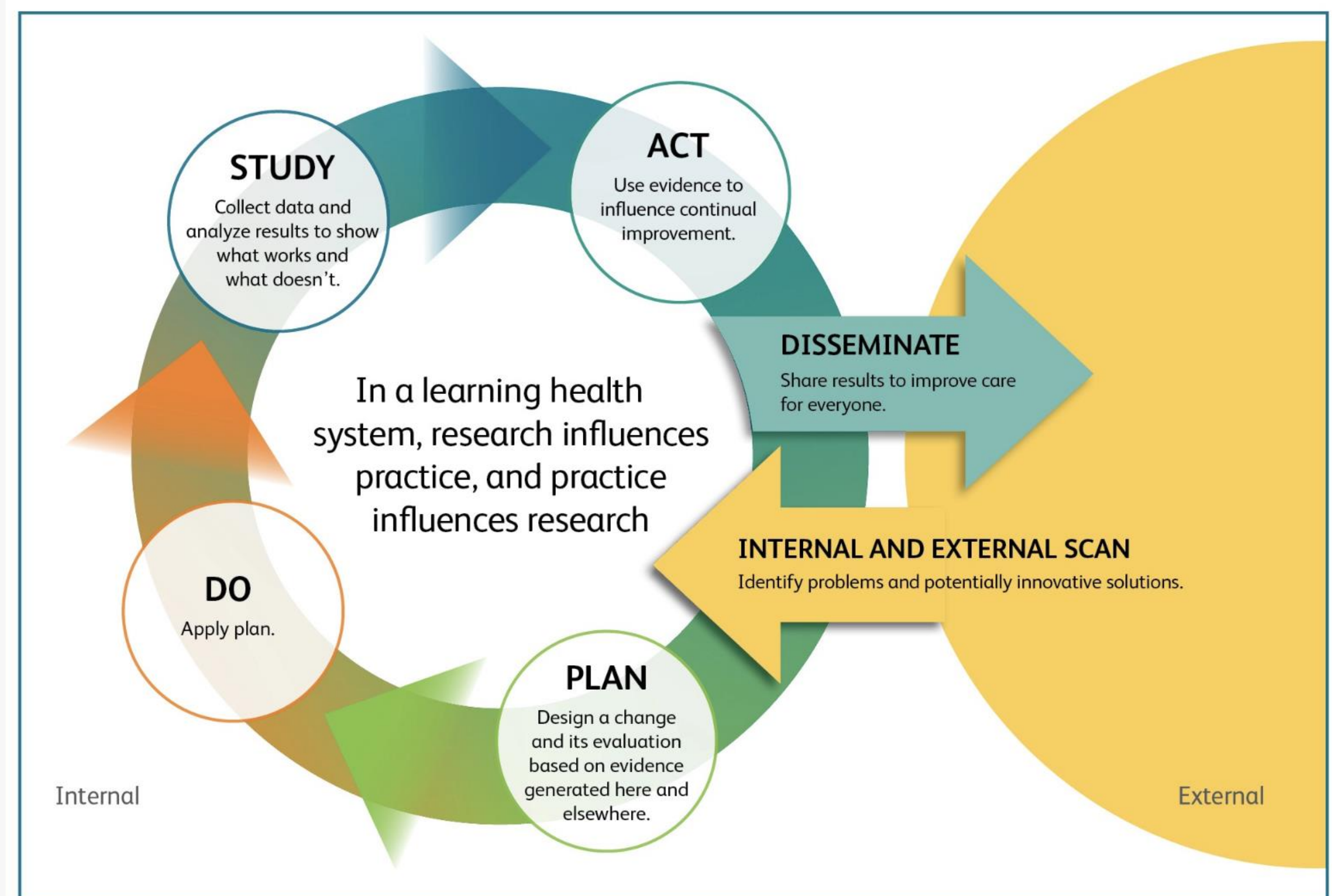
Position Paper

Published by Centre for Innovation in Medicine in the context of
Romanian Presidency of Council of European Union

EU Cancer Plan: Data, Technology and Human Touch



Digital Twins



Learning and literate health systems

Implementation of the vision



Horizon Europe

- European Innovation Council
- Mission on Cancer

European Commission has proposed to establish the European Innovation Council (EIC) as one of the key novelties of the new EU programme for Research and Innovation, Horizon Europe (2021-2027). The EIC will be a one-stop shop to bring the most promising ideas from lab to real world application and support the most innovative start-ups and companies in scaling up their ideas.

Cancer is one of the 5 Missions proposed by the European Commission for Horizon Europe.

Voluntary cooperation of Member States

At Member States level, political will is also very important for the implementation of the vision. Voluntary cooperation of Member States driven by European Commission should be reinforced on the following initiatives, as a background for a common action on cancer at EU level:

- E-health Network
- European Network of Cancer Registries
- Million European Genome Analysis Project
- Declaration of cooperation on Artificial Intelligence
- European Network for Health Technology Assessment
- International Consortium for Personalised Medicine

Croatia to follow us next year

