



EU dimension in innovation in oncology



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Policy and Scientific Officer in charge of cancer
Directorate E – Health Research
DG Research and Innovation
European Commission

Challenges for Cancer Policies for the next
decade: prevent, cure, care and pay (pc)²,
Sciensano, Brussels, 26 February 2019

HORIZON 2020



Health research H2020 – what we do

- **Fund collaborative health research and innovation with EU-added value**
- **Initiate and support EU research and innovation policies**

Horizon 2020 Health, demographic change and well-being challenge



OBJECTIVE



- Better health for all
- A more competitive European health industry and care sector
- Maximising the digital potential
- Addressing health as a global challenge
- Evidence for informed healthcare policies

- **Cancer: a global health priority**
- **A changing healthcare landscape**
- **Innovative drugs in the pipeline**
- **Leading personalised medicine**



EU cancer research – where in H2020?



Different programmes serving different communities & purposes





European
Commission

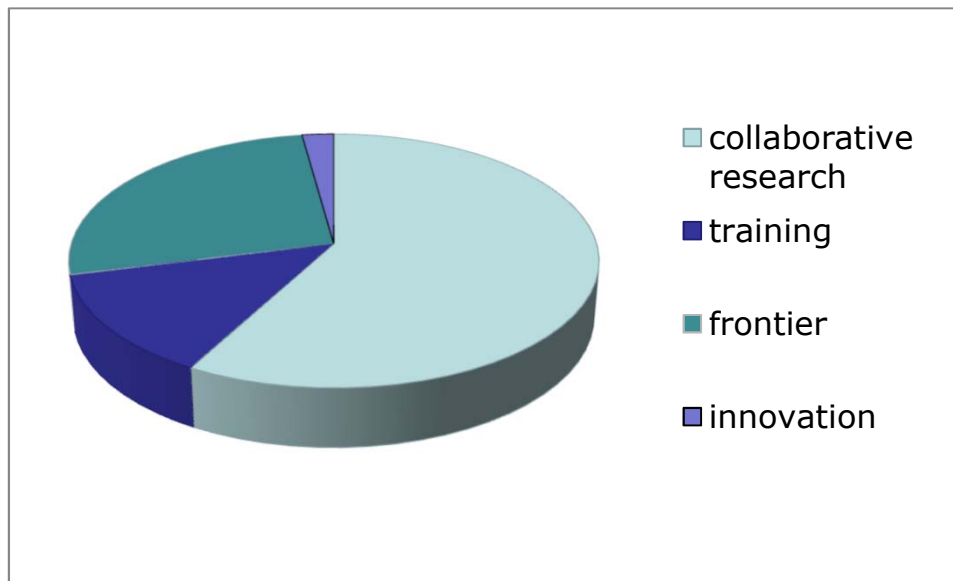
Horizon 2020: Three priorities



EU cancer research



what's being funded (FP7+HORIZON2020)



- *translational research*
 - **tumour-host environment**
 - **risk factors, biomarkers, imaging**
 - **models, technologies**
 - **large data, cloud computing**
 - **prevention, early detection**
 - **all possible treatment options**
 - **immunobiology and therapy**
- *investigator-driven trials*
- *palliative & end-of-life care*

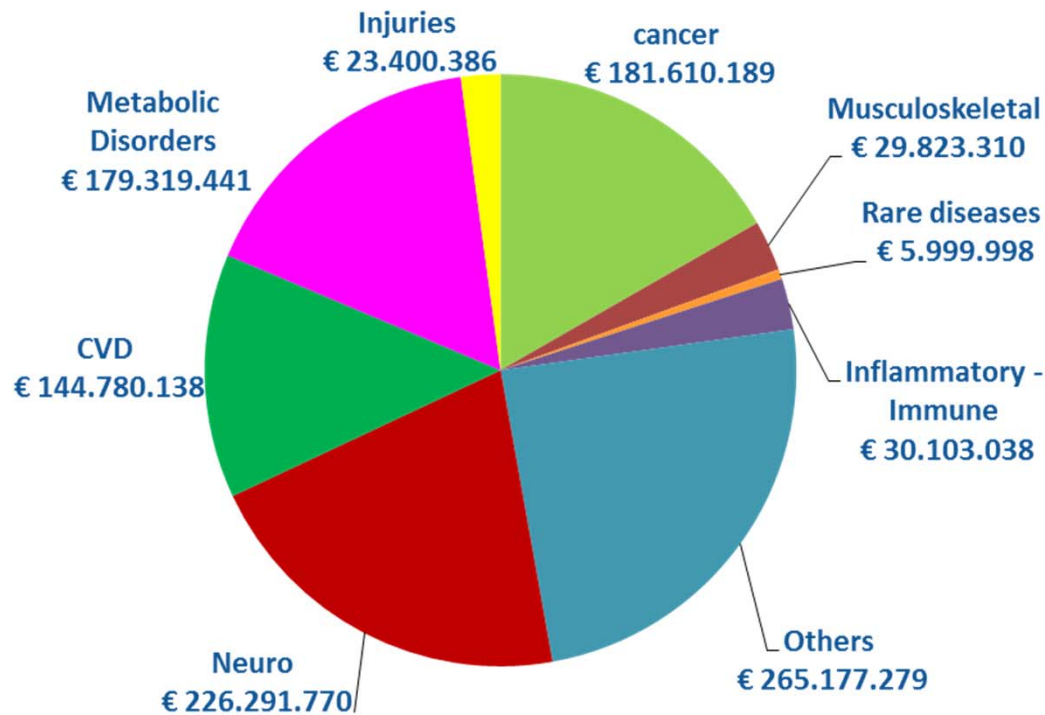
€ 2.8 billion (2007-2018)

- **focus on clinical solutions for patients, innovation, close-to-market**

Generating clinical evidence



> 340,000 patients recruited
165 Projects, 286 CTs , € 1.1 billion



Phase I : 16%
Phase I/II : 23 %
Phase II : 21%
Phase II/III : 5 %
Phase III : 6 %
Phase IV : 1 %
Interventional study: 17 %

FP7 Health Programme



Towards personalised medicine



Stratification and high risk groups

Molecular understanding of disease

Molecular classification of cancer subtypes

Molecular taxonomy

Biomarker identification for:

- Diagnosis
- Prognosis
- Prediction
- Monitoring

Medical Imaging to optimize treatment options

Wide range of animal models

In silico models

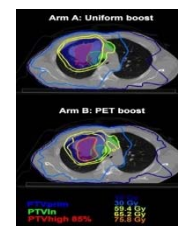
In vitro & ex-vivo models (xeno patients)

Targeted drug development via biology driven hypothesis

Bio-informatics for treatment decision making

Novel CT design

Identification of sub-groups for better quality of life



Prevention: lung cancer



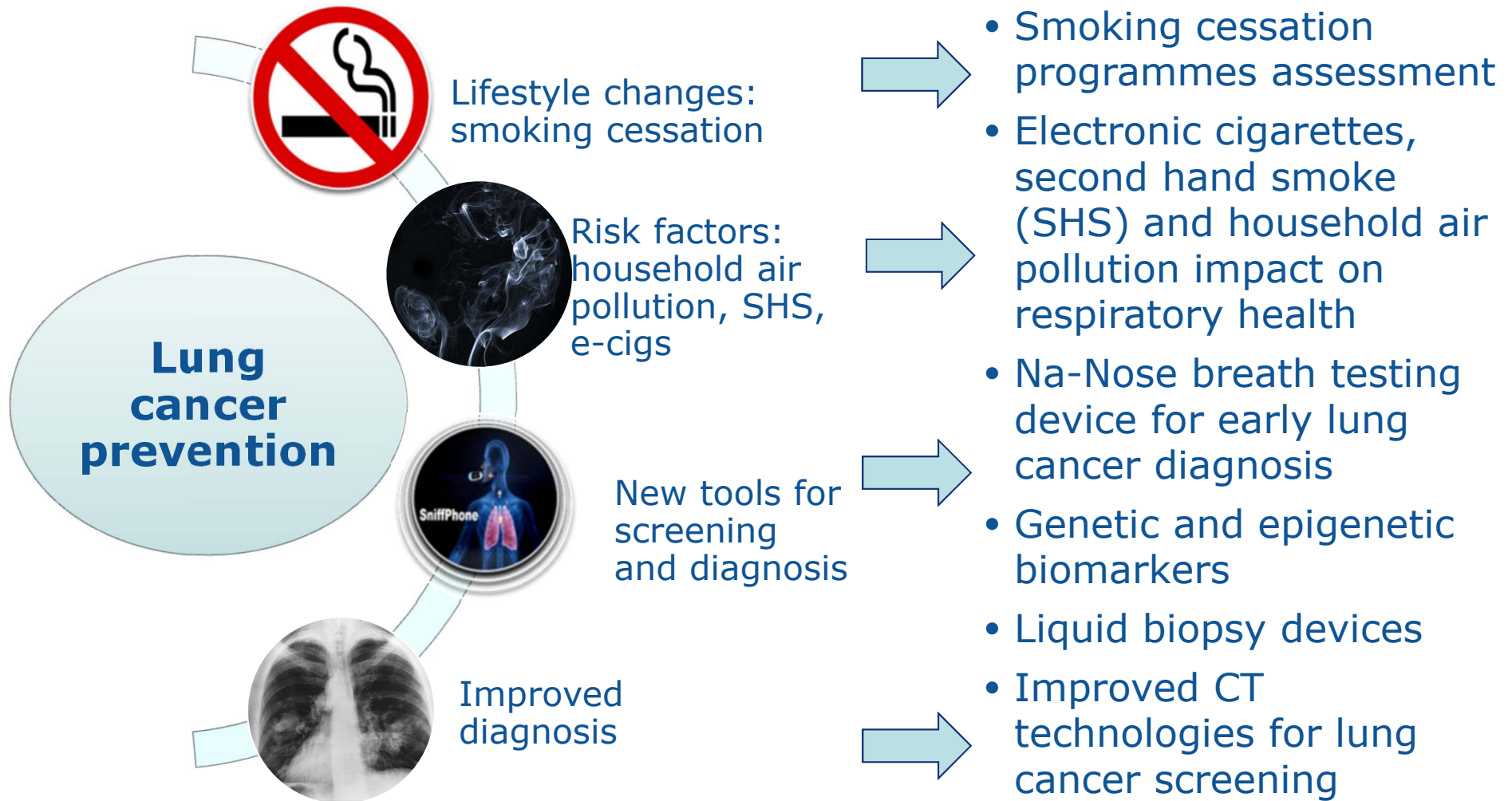
TackSHS

SNIFFPHONE

Smart Phone for Disease Detection from Exhaled Breath



iBILD



Changing breast cancer clinical practice



European Commission

FP6, 2002-2006

Horizon 2020, 2014-2020

€ 7 million

Validation of the 70-gene signature

€ 4 million

2015: MammaPrint final clinical utility



2002: 70-gene signature published

2007: FDA approves MammaPrint

2007 → 2011

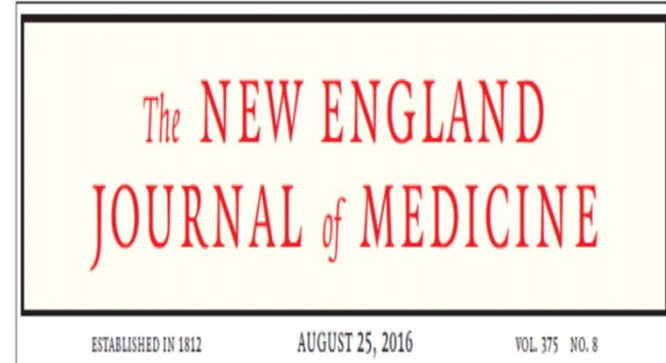
MINDACT trial : Microarray In Node negative Disease may Avoid ChemoTherapy

MINDACT

Leveraged funds: € 43 million

MammaPrint may reduce chemotherapy prescription post-surgery by 46% in high-risk group

Phase III CT 6693 women enrolled



70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer

F. Cardoso, L.J. van't Veer, J. Bogaerts, L. Slaets, G. Viale, S. Delaloge, J.-Y. Pierga, E. Brain, S. Causeret, M. DeLorenzi, A.M. Glas, V. Goulinopoulos, T. Goulioti, S. Knox, E. Matos, B. Meulemans, P.A. Neijenhuis, U. Nitz, R. Passalacqua, P. Ravdin, I.T. Rubio, M. Saghatelyan, T.J. Smilde, C. Sotiriou, L. Stork, C. Strahle, G. Thomas, A.M. Thompson, J.M. van der Hoven, P. Vuylsteke, R. Bernards, K. Tryfonidis, E. Rutgers, and M. Piccart, for the MINDACT Investigators[†]

THE MINDACT TRIAL

Rare cancers: EU-wide impact



European Commission



Conticanet

- Epidemiology, clinical registries
- World's largest sarcoma biobank
- phase I/II-III IDCTs: treatment and care, predictive and prognostic markers
- Prognostic CINSARC sarcoma signature



- virtual sarcoma biobank
- translational research (pathology, gene expression, immunology, signalling)
- translational biomarkers
- Early phase IDCTs
- ESMO clinical practice guidelines

INTEGRATION AND long-term COLLABORATION



- A first line treatment phase III IDCT to define standards of care for adjuvant chemotherapy (EuroEwing 2012)
- A second line treatment phase II/III IDCT which establishes a standard and will serve as a platform for testing new agents (rEECur)
- Companion studies - response, toxicity, biomarkers



- 8 innovative IDCT (phases I to III)
- methods for histological and molecular diagnosis of sarcoma
- translational research
- Patient involvement

clinical practice guidelines

Annals of Oncology 21 (Supplement 5): v199-v203, 2010
doi:10.1093/annonc/mdq209

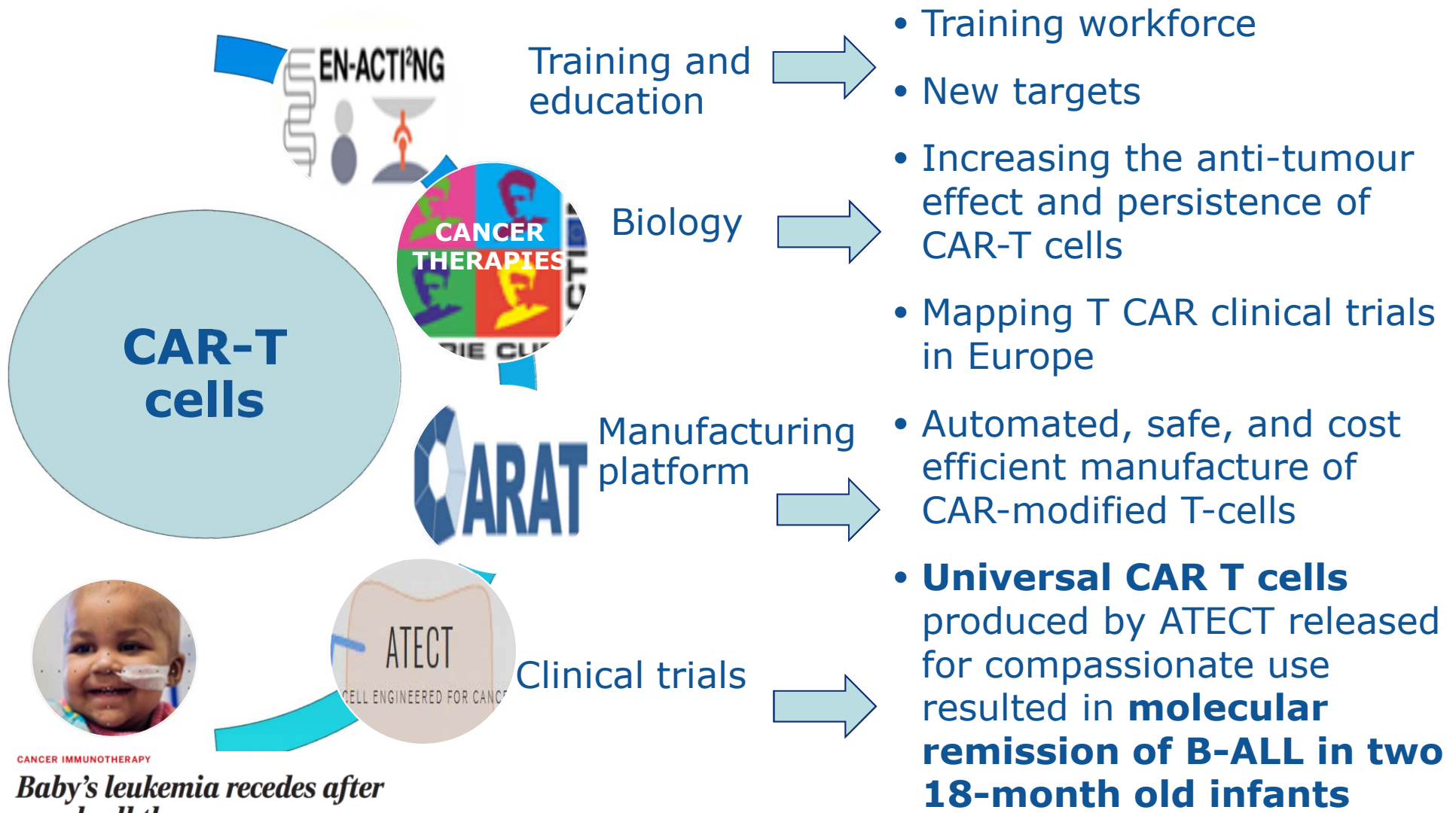
Soft tissue sarcomas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up

P. G. Casali¹ & J.-Y. Blay²

On behalf of the ESMO/CONTICANET/EUROBONET Consensus Panel of experts*

*Department of Cancer Medicine, Istituto Nazionale dei Tumori, Milan, Italy; ¹INCEM USIG, Claude Bernard University and Department of Oncology, Edouard Belin Hospital, Lyon, France

CAR-T cells – a road to cure



- Training workforce
- New targets
- Increasing the anti-tumour effect and persistence of CAR-T cells
- Mapping T CAR clinical trials in Europe
- Automated, safe, and cost efficient manufacture of CAR-modified T-cells
- **Universal CAR T cells** produced by ATECT released for compassionate use resulted in **molecular remission of B-ALL in two 18-month old infants**

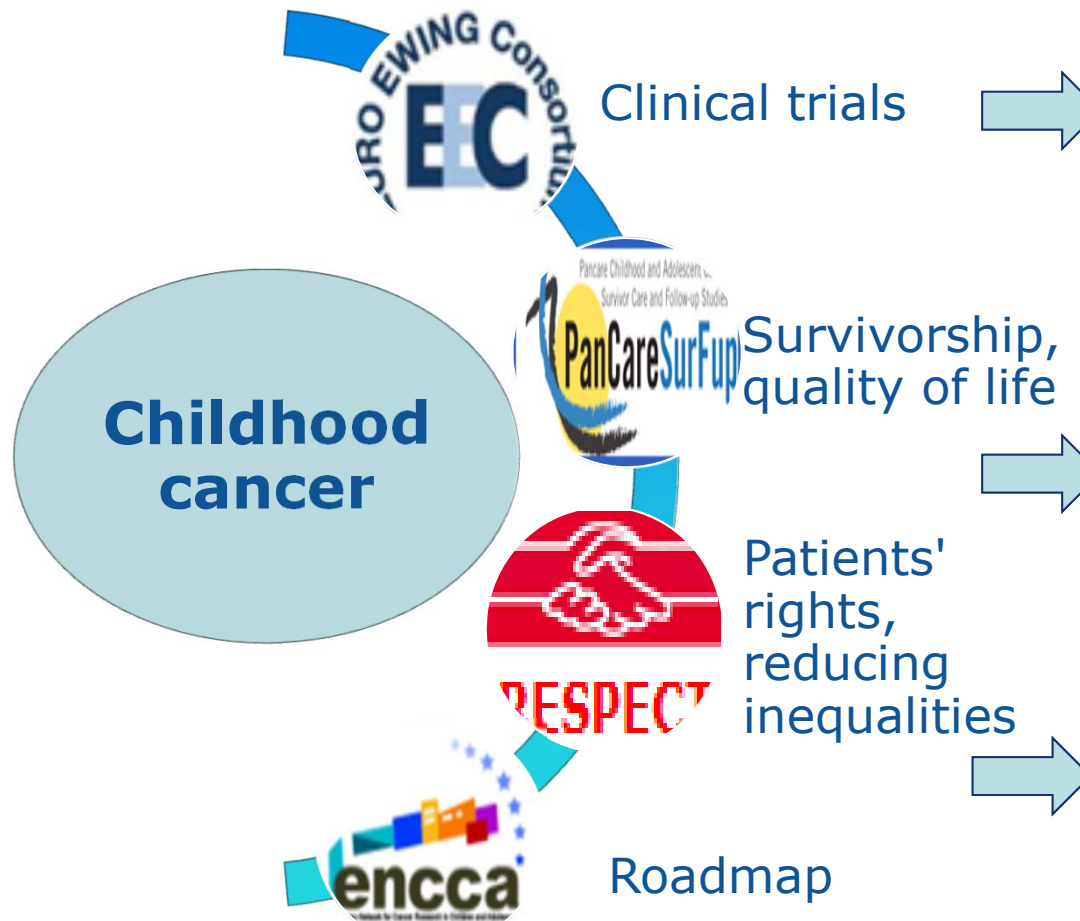
CANCER IMMUNOTHERAPY

Baby's leukemia recedes after novel cell therapy

Gene editing used to create "off-the-shelf" T cells



Childhood cancer – a long-term priority



- Specific paediatric formulations of oncology drugs

• **Clinical trials**

- Acute lymphoblastic leukaemia (IntREALL)
- Liver cancer (CHILTERN)
- Sarcomas (EuroSARC, EEC)

• **Survivorship studies**

- Large registries
- Risk estimates and follow-up guidelines
- **Survivorship PASSPORT** cloud-based IT Tool

- Novel trial methodologies, empowering patients, creating expert networks

• **European Cancer Plan for Children and Adolescents**



Patient-centred quality-of-life



REQUIRE

Validating predictive models of radiotherapy toxicity to improve quality-of-life and reduce side-effects in cancer survivors

ACTION

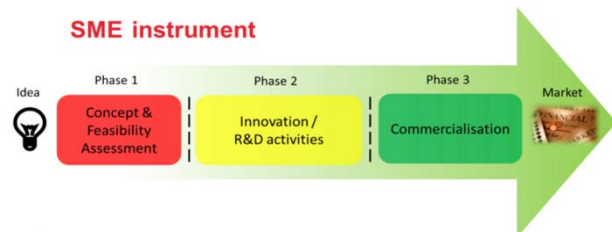
Advance Care Planning; an Innovative Palliative Care Intervention to Improve Quality of Life in Cancer Patients - a Multi-Centre Cluster Randomized Clinical Trial

eSMART

Randomised controlled trial to evaluate electronic Symptom Management using the Advanced Symptom Management System (ASyMS) Remote Technology for patients with cancers



Biomarkers/tests serving healthcare



Cancer indication	Project	Beneficiary	EU funding	What it will deliver
Multiple	NO-META	Cytofind	€ 50,000	Liquid biopsy using a new method to count and isolate CTCs based on single cell determination of the anomalous metabolic properties of tumour cells (Warburg effect)
Multiple	MAINTRAC-Auto	SIMFO GmbH	€ 50,000	Automatization and validation of a liquid biopsy assay "Maintrac-AUTO CTC-analyser"
Colorectal cancer	CYTOPRO	CYTOTRACK APS	€ 50,000	A device to identify and isolate metastatic cancer cells from a blood sample based on CTC KRAS analysis
Multiple	ONCOCHECK	LIFE LENGTH	€ 50,000	Prognosis and monitoring test based on the determination of telomere length in peripheral blood
Leukaemia	SENSITIVITYMARKERS	NTRC	€ 50,000	Clinical validation of prognostic biomarkers of chemotherapy response in liquid biopsies
Lung cancer	CELLETEST	STEM SEL	€ 50,000	medical device for non-invasive diagnosis and prognosis of metastatic lung cancer



IMI supports cancer research



CancerID
Circulating tumour
cell based
biomarkers



MARCAR
Cancer risk biomarkers



Quic Concept
Imaging
biomarkers



ONCOTRACK
Omics,
xenoponents

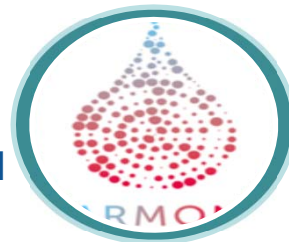


**From biomarkers
to models to big data**



PREDECT
In vitro models

HARMONY
Big data in
haematological
malignancies



ITCC-P4
Paediatric
cancers PoC
platform

**Over
EUR 130
million**

Future calls:

- **Patient-reported outcomes and quality of life endpoints**
- **Advanced therapy medicinal products (several)**
- **CAR-T**



Loans: eg InnovFin - support to cancer vaccines



EIB supports Bavarian Nordic's development of Ebola and cancer vaccines

Display in: [da](#) [de](#) [en](#) [fr](#)
Release date: 12 May 2015
Reference: 2015-102-EN



The European Investment Bank (EIB), the world's largest multilateral bank, today reaffirmed its firm commitment to respond to the Ebola pandemic. The Bank has provided a EUR 50 million loan to Bavarian Nordic, an international biopharmaceutical company, for accelerated development of an Ebola vaccine with long-term efficacy. The financing is also backing research into vaccines for treating other infectious diseases

and multiple cancer indications.

InnovFin
Large Projects

France: EIB lends EUR 20m to Transgene

Release date: 28 January 2016
Reference: 2016-022-EN



Today, 28 January 2016, the European Investment Bank (EIB) and Transgene announced that they have entered into a EUR 20m financing agreement. The event organised to mark the granting of this loan will take place at Transgene's headquarters in Illkirch-Graffenstaden, in the presence of Ambroise Fayolle, EIB Vice-President responsible for innovation, Alain Mérieux, Chairman of Institut Mérieux, Transgene's leading shareholder, and

Philippe Archinard, Transgene's Chairman and CEO.

InnovFin
Infectious Diseases



Health - research and innovation policy



Coordination of national research policies - Stronger together



- Linking national/regional cancer registries and bio-banks to improve quality of data collection, optimise cancer control in Europe and evaluate therapy effectiveness

➤ **Basis for creation of European Cancer Information System (ECIS)**



- Linking national/regional and charity funding organisations in MS on translational cancer research.

➤ **1st joint call on 'Tumour heterogeneity'**

➤ **2nd joint call on 'Immunotherapy'**

➤ **3rd joint call on ' Early detection and/or progression'**

➤ **4th joint call on 'Translational Research on Rare Cancers'**

RESEARCH FUNDING

**Toward Variable Funding
for International Science**

European ERA-NETs offer lessons for flexible international funding to better meet the needs of science and society.



ICPerMed - International Consortium for Personalised Medicine



WHAT

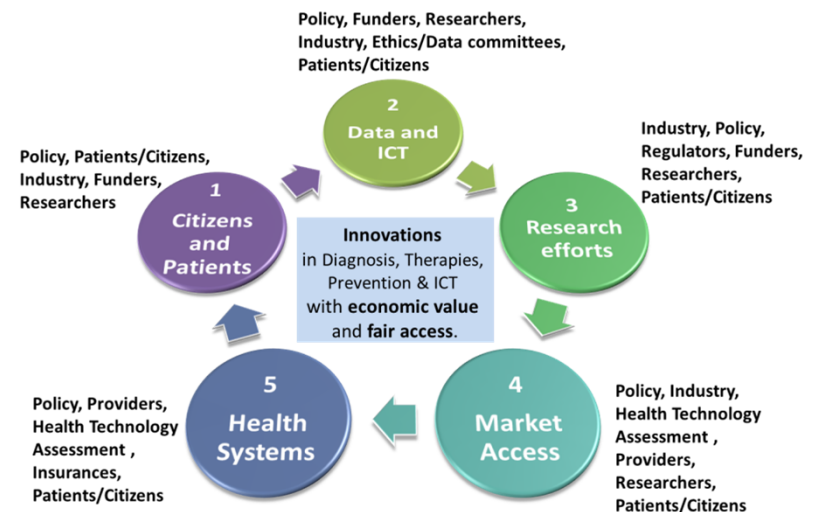
Collaboration of 30 research funders and policy makers across the EU and beyond

WHY

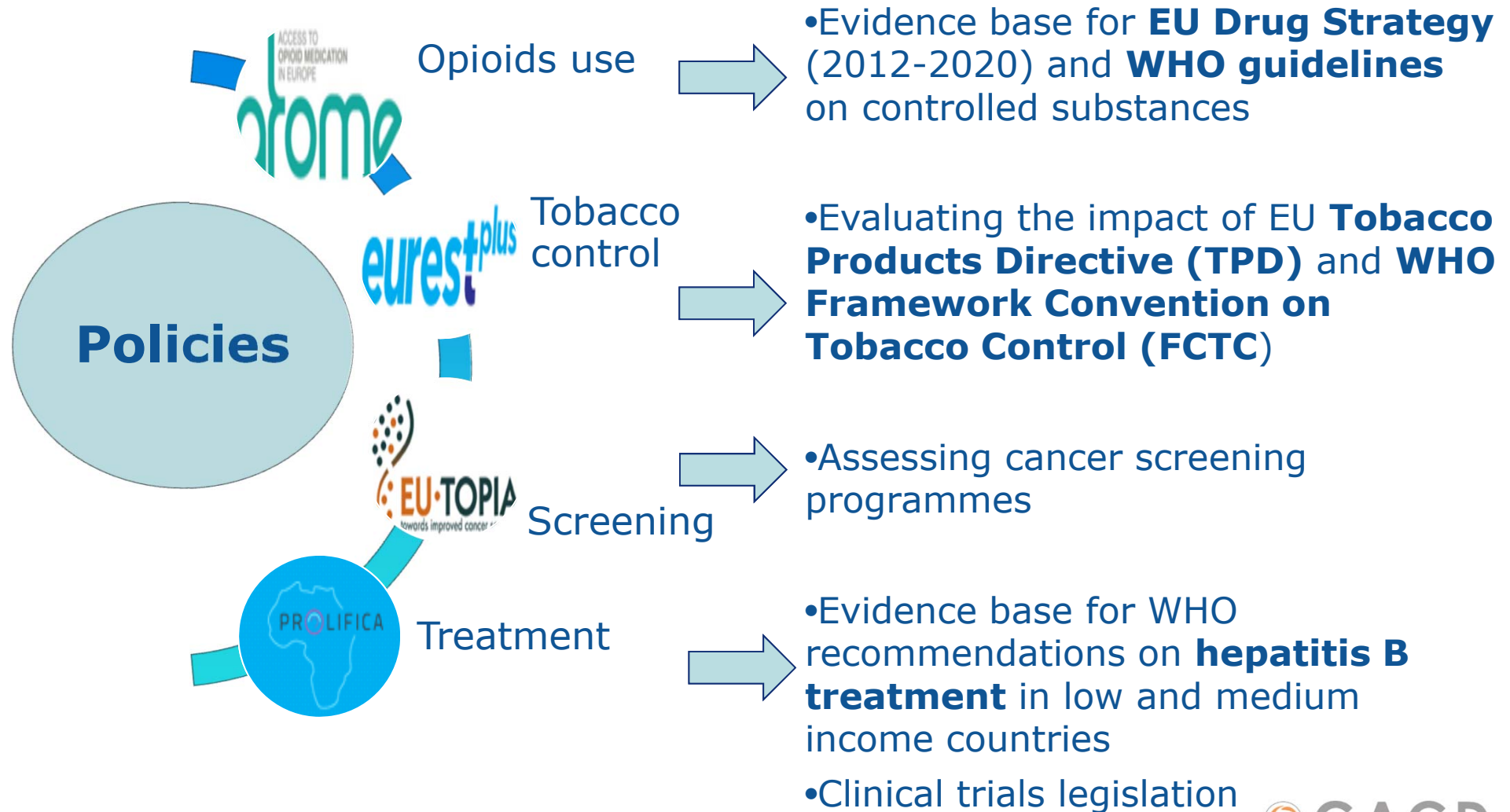
- Establish Europe as a global leader in PM research
- Support PM science-base via a coordinated research approach
- Support research to demonstrate benefits of PM to citizens and healthcare systems
- Prepare for PM approaches for citizens

HOW

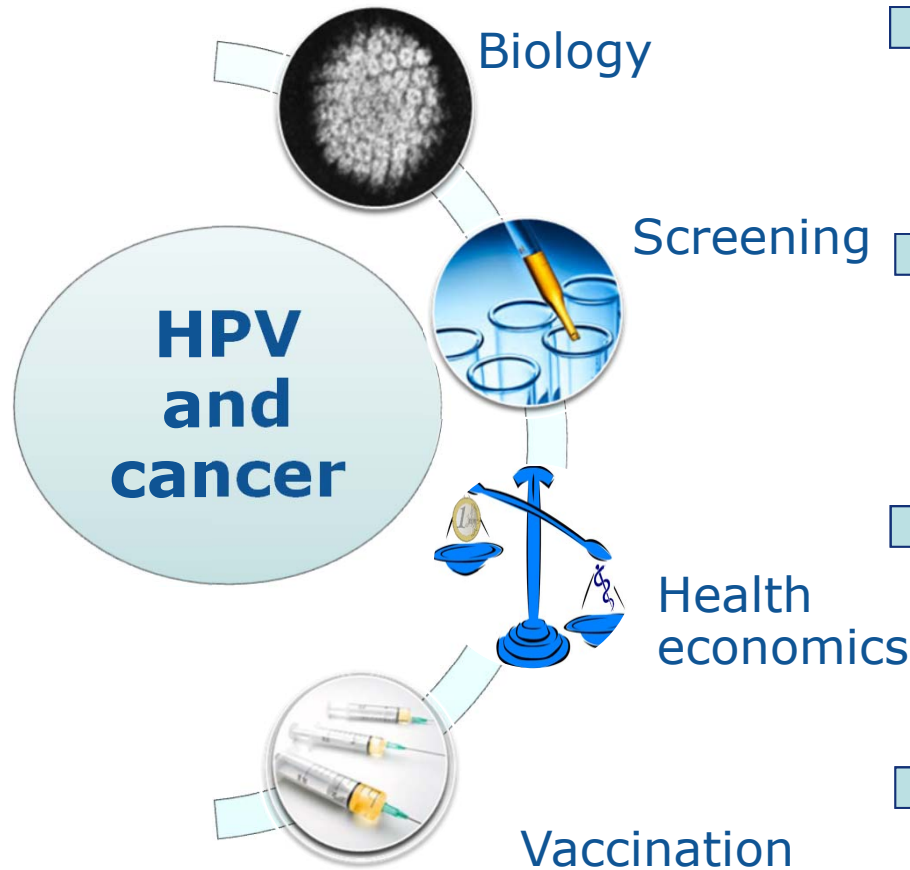
- ✓ Implementation based on PerMed Strategic Research Agenda
- ✓ **ICPerMed Action Plan: 22 research, 8 support actions.**



Underpinning healthcare policies



Addressing global health challenges

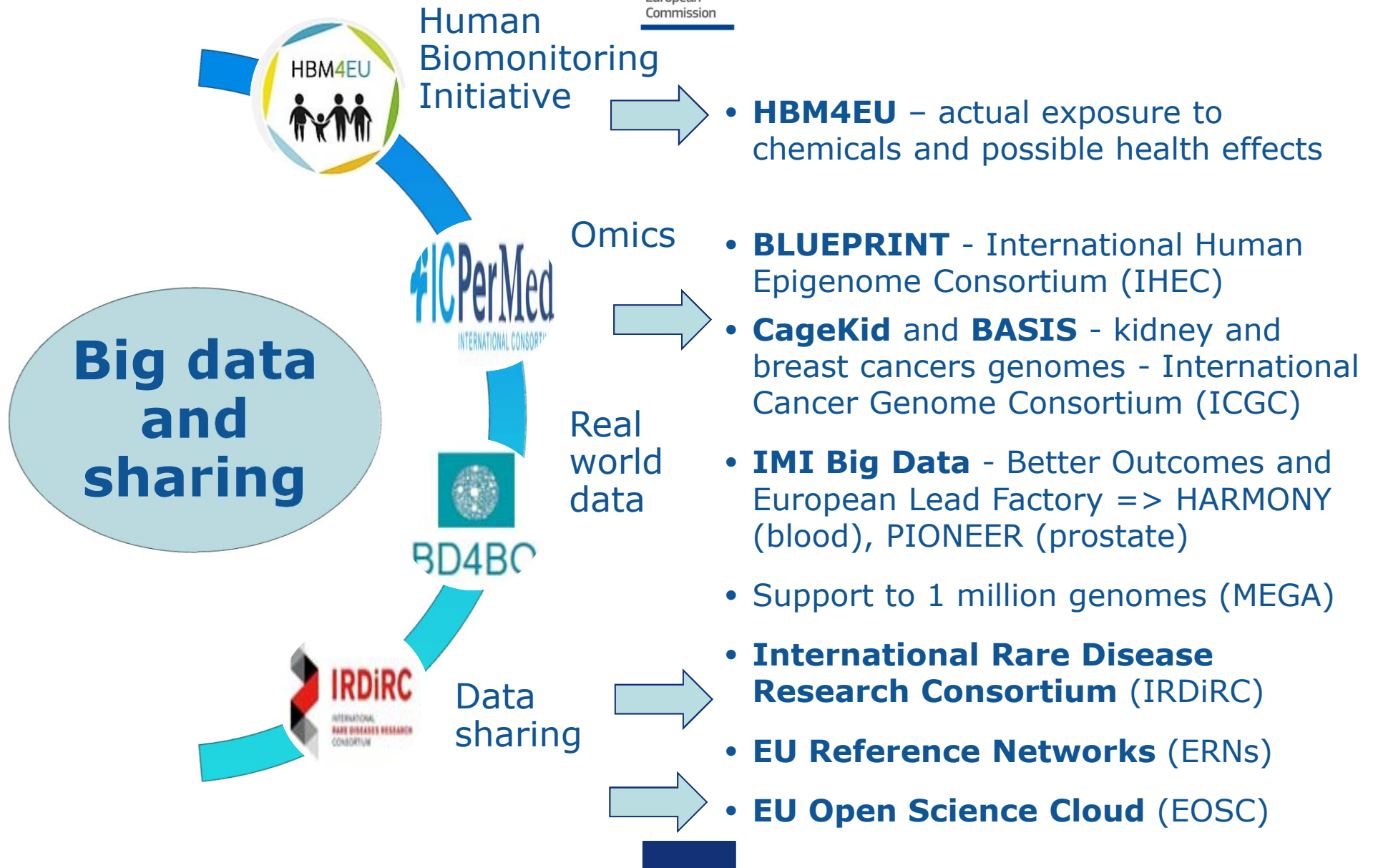


- High risk for **cervical cancer** in African women living with HIV
- **Head and neck cancer** prognosis depends on HPV status
- **Cervical cancer screening** recommendations for specific populations
- **Cost-effectiveness of HPV DNA screening in low-income countries**
- Basis for roll out of **HPV DNA based cervical cancer screening** programmes in Africa
- Supporting WHO recommendation for **two HPV vaccine doses**
- **Facilitating HPV vaccination GAVI initiative**
- **Women self screening**

Studies in Europe, CELAC, Africa and India



Big data for health



Horizon Europe

is the Commission proposal for a **€ 100 billion** research and innovation funding programme for seven years (2021-2027)



to strengthen the EU's scientific and technological bases



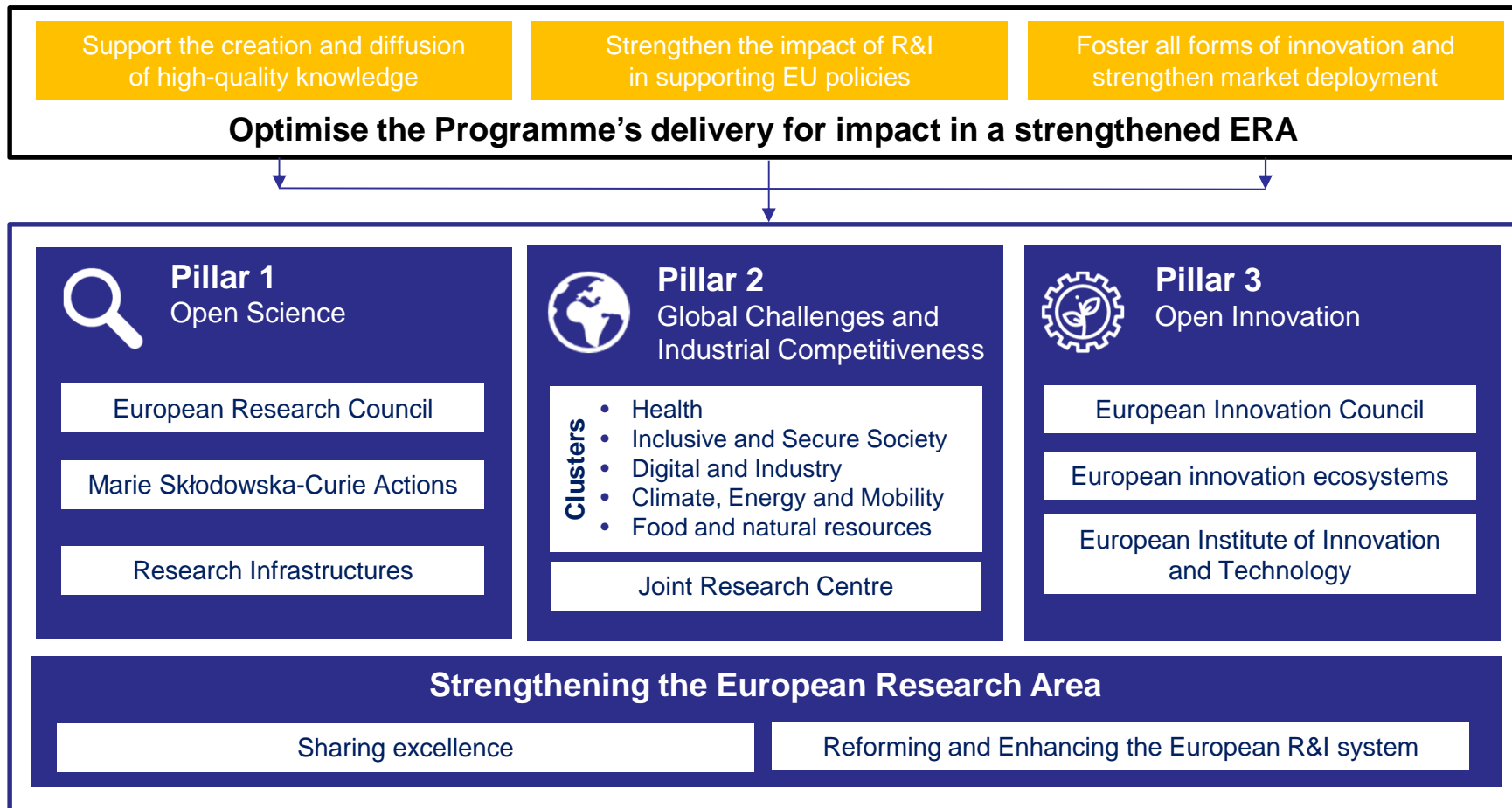
to boost Europe's innovation capacity, competitiveness and jobs



to deliver on citizens' priorities and sustain our socio-economic model and values

Horizon Europe: evolution not revolution

Specific objectives of the Programme



Six main areas of intervention



Health throughout the Life Course



Environmental and Social Health Determinants



Non-communicable and Rare Diseases



Infectious diseases



Tools, Technologies and Digital Solutions for Health and Care



Health Care Systems

Lessons Learned

from Horizon 2020 Interim Evaluation



Support breakthrough innovation



Create more impact through mission-orientation and citizens' involvement



Strengthen international cooperation



Reinforce openness



Rationalise the funding landscape



Key Novelties

in Horizon Europe

European Innovation Council

R&I Missions

Extended association possibilities

Open science policy

New approach to Partnerships

OPEN INNOVATION

€13.5 billion stimulating market-creating breakthroughs and ecosystems conducive to innovation

European Innovation Council

- Support to innovations with breakthrough and market creating potential

€10.5 billion

European innovation ecosystems

- Connecting with regional and national innovation actors

€XXX billion

European Institute of Innovation and Technology (EIT)

- Bringing key actors (research, education and business) together around a common goal for nurturing innovation

€3 billion



*"We need to define **missions** that breakdown silos.*

We have made progress in Horizon 2020 to focus resources in selected areas. But we still support too many different projects that disperse or fragment our funding.

We need to set our eyes on a specific target, and drive our scientific efforts towards reaching that target. And we need to be ambitious about it."

Carlos Moedas, Commissioner





R&I Missions

R&I Missions

Relating EU's research and innovation better to society and citizens' needs; with strong visibility and impact

A mission is a portfolio of actions intended to achieve **a bold and inspirational as well as measurable goal** within a set timeframe, with impact for science and technology, society and citizens that goes beyond individual actions

Horizon Europe proposal defines mission characteristics and elements of governance

Specific missions will be **co-designed with Member States, stakeholders and citizens** and programmed within the Global Challenges and Industrial Competitiveness pillar (drawing on inputs from other pillars)

Criteria for selecting R&I missions



- **Bold, inspirational, with wide societal relevance**
- **A clear direction:** Targeted, measurable and time-bound
- **Ambitious but realistic R&I actions**
- **Cross-disciplinary, cross-sectoral and cross-actor innovation**
- **Multiple bottom-up solutions**

Next steps for Horizon Europe





Thank you!

#HorizonEU

Horizon Europe dedicated website

<http://ec.europa.eu/horizon-europe>

European Innovation Council

<http://ec.europa.eu/research/eic>

EU budget for the future

http://ec.europa.eu/budget/mff/index_en.cfm