The Innovative Medicines Initiative

Achievements and future challenges

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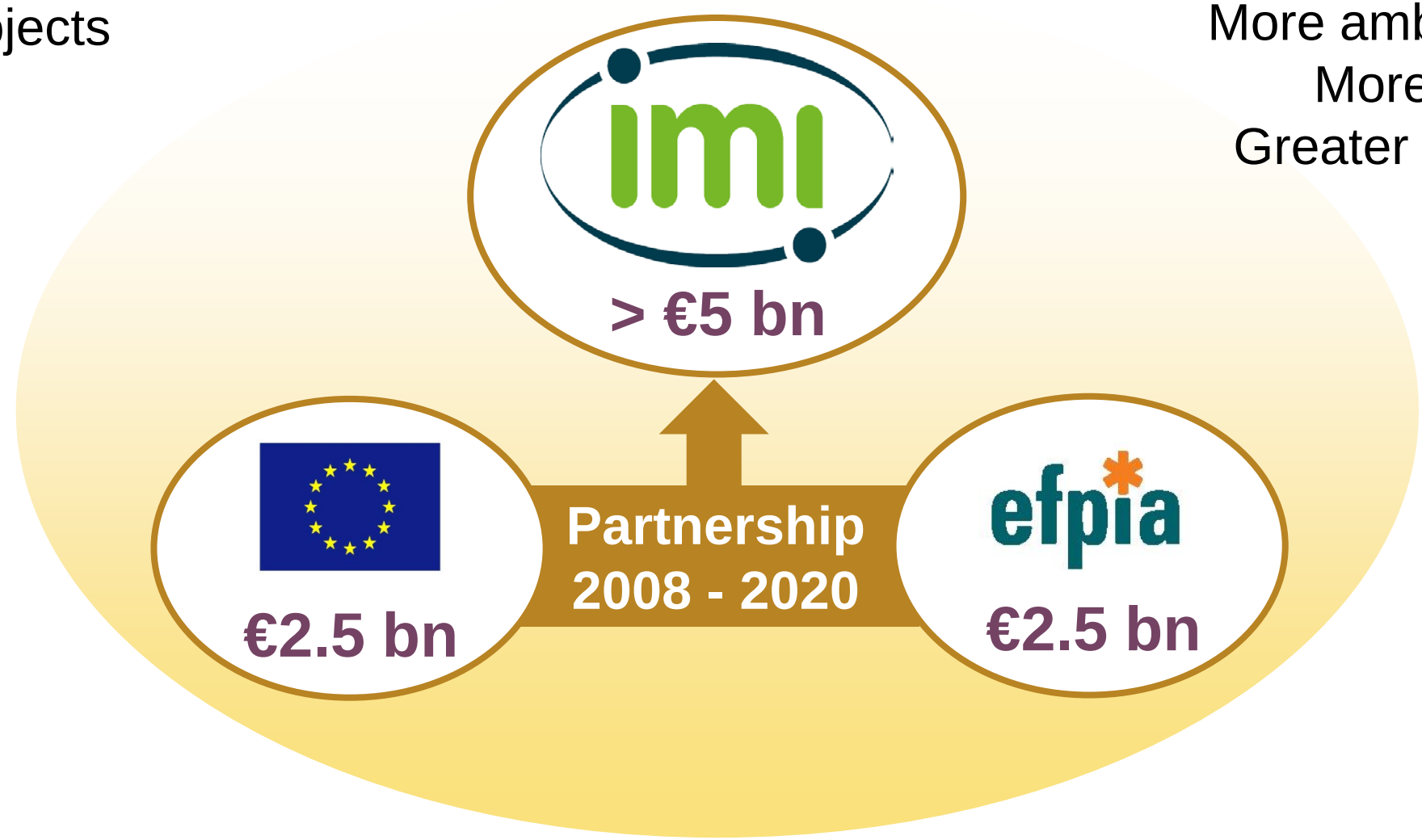
IMI – Europe's partnership for health

IMI1: 2008-2013

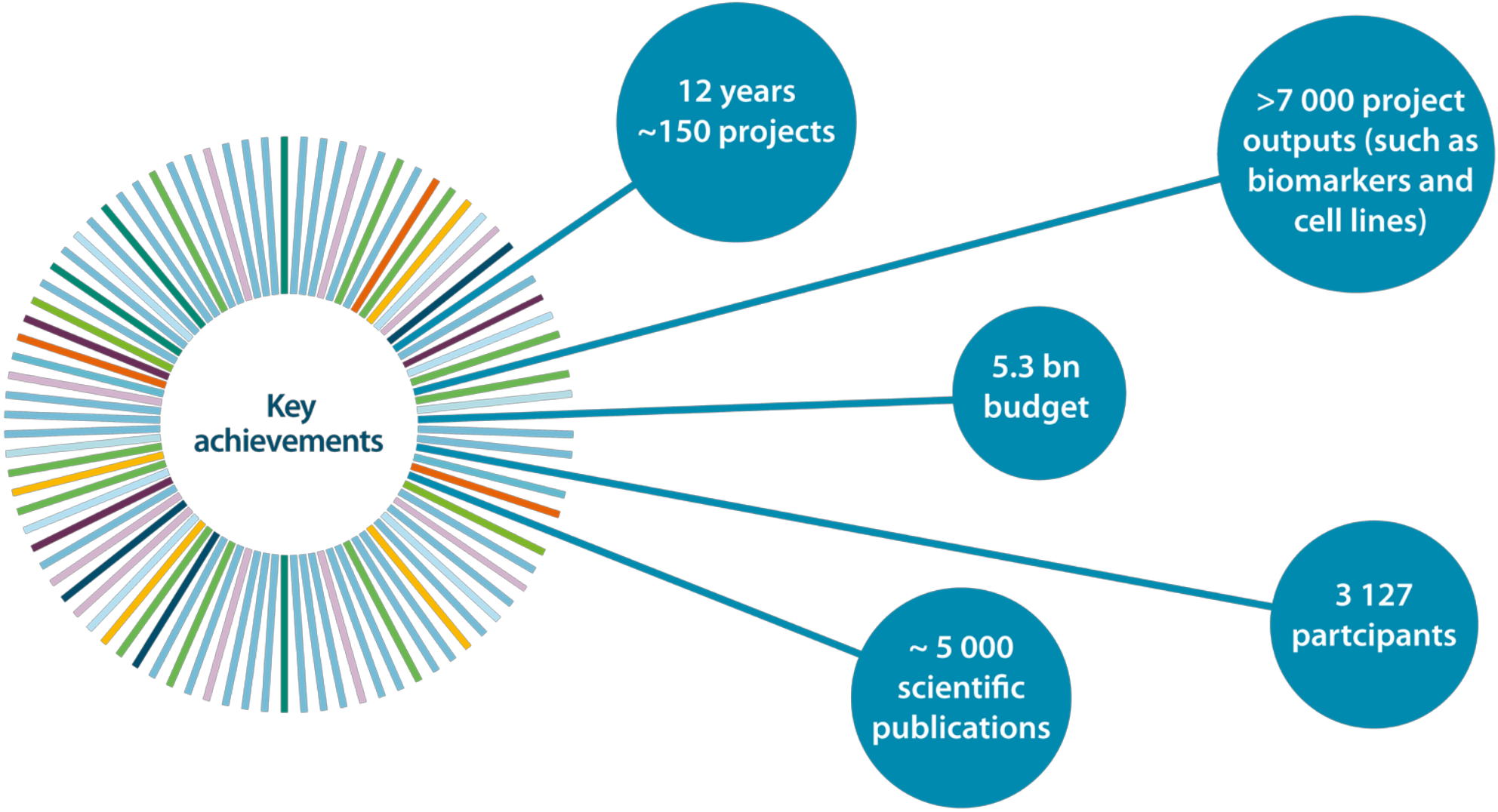
€2 bn budget
59 projects

IMI2: 2014-2020

€3.3 bn budget
More ambitious
More open
Greater scope



IMI in a nutshell



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Updated January 2020

10 YEARS OF BREAKTHROUGHS
A HEALTHIER FUTURE

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IMI2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines

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IMI – Ecosystem for innovative collaborations

"Radical collaboration" a term coined by Carlos Moedas

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges in areas of unmet medical needs**.

All partners needed to find transformative solutions to **reduce late stage attrition, speed patient access** and **improve health outcomes** and find solutions for a sustainable healthcare system

Academia

Charities

Regulators

SMEs

HTA bodies

Pharma companies

Payers

Diagnostic companies

Healthcare practitioners

Other sectors (e.g imaging, nutrition…)

Public health bodies

Patients

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

Associated Partners e.g. charities, non-EFPIA companies

IMI 2 total budget €3.276 billion

EFPIA Partners in Research

IMI2 Associated Partners (as of February 2020 – excluding Call 19)

Accelerate Diagnostics	JDRF
Autism Speaks	Klinikum der Universität München
Autistica	KTH Royal Institute of Technology
BD Switzerland Sarl	McGill University
Bill and Melinda Gates Foundation (BMGF)	Medicines for Europe
Bio-rad Laboratories	Medicines for Malaria Venture (MMV)
Cepheid Europe	Obesity Action Coalition
CHDI Foundation	Ontario Institute for Cancer Research
Children's Tumor Foundation	Parkinson's UK
Coalition for Epidemic Preparedness (CEPI)	Simon Foundation Autism Research (SFARI)
Datapharm	Software AG
Diamond Light Source	Springworks Therapeutics
Deutsches Zentrum für Infektionsforschung (DZIF)	T1D Exchange
European Hematology Association (EHA)	TB Alliance
Helmsley Charitable Trust (HCT)	Trial Nation
International Diabetes Foundation (IDF)	University of Dundee
Invicro	Varian Medical Systems Particle Therapy
Ion Beam Applications (IBA)	Wellcome Trust

Total Number of Associated Partners: 36

Total Commitment: EUR 201,612,560

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What have we focused on in IMI?

- Tackling big societal challenges at a scale
- Some examples:
    - Pooling of assets from disparate sources (across the public/private divide) in order to tackle big issues in new medicines development
        - Big data
        - Drug safety
    - Catalysing new infrastructures representing significant gaps in the system
        - Clinical research platforms
        - Health research data networks
    - Tackling really big societal challenges that seem to be “stuck”
        - Market failures like Anti-microbial resistance
        - Scientifically challenging topics like dementia
        - Pandemic preparedness and response (R&D)
    - Problems where different stakeholder groups are required to be at the same table from day1 (Regulators, Patients, HTA bodies)
    - Opportunities for technology convergence to be operationalised in high risk areas
        - New actors- new industrial sectors- important role for European SMEs
    - Areas that challenge the traditional thinking around the precompetitive space

IMI response to the COVID-19 pandemic

1. Leveraging past investments
2. Running a new programme dedicated to COVID-19

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Using the existing IMI's projects to progress research against COVID-19

Valuable contributions to the global effort to tackle COVID-19 from:

- **ZAPI** – knowledge and tools for a rapid response to a coronavirus outbreak
- **EHDEN** – harmonising clinical data to facilitate reuse and advance research
- **EHDEN, ConcePTION and ADVANCE** - helping the EMA gather real-world data on COVID-19 treatments and vaccines
- **COMBACTE** – access to a clinical trial network specialised in infectious disease studies e.g involved in site selection in 20 European countries in REMAP-CAP Pandemic Strata study
- **ELF/ESCulab** – fast track assessment for COVID proposals
- **HARMONY** – COVID-19 data initiative
- **AETIONOMY & PHAGO** – tools for a new COVID-19 knowledge space
- **c4c** – resources on COVID-19 for children and families
- **eTRIKS** – standards starter pack
- **DO>IT** – informed consent forms for clinical research
- **EUPATI** – reliable resources for patients

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ZAPI: Recent Results on Betacoronavirus

Wang C *et al.* **A human monoclonal antibody blocking SARS-CoV-2 infection.** Nat Commun 2020 May 4;11(1):2251.
doi: 10.1038/s41467-020-16256-y. PMID: 32366817

- Report a human monoclonal antibody that neutralizes SARS-CoV-2 (and SARS-CoV) in cell culture, which targets a communal epitope on these viruses and may offer potential for prevention and treatment of COVID-19.
- ZAPI's platform and recent results feeding in into 2 COVID-19 proposals that have been recently selected for funding:

  1- MANCO (n. 101003651 H2020 Call SC1-PHE-CORONAVIRUS-2020 call). GMP manufacturing of the broadly cross-reacting ZAPI's antibody in high-yield CHO cell-lines for prophylactic and/or therapeutic use and testing into a Phase I clinical trial.

  2- CARE (n. 101005077 H2020-JTI-IMI2-2020-21-single-stage call). Generation of a diverse library of anti-SARS-CoV-2 neutralising antibodies (targeting different Spike epitopes and functions) with proven therapeutic potential and good manufacturability characteristics, via a broad spectrum of antibody generation methods.

COVID-19 Study-a-thon

- On 26-29 March, EHDEN and the OHDSI community organised a 3-day remote COVID-19 study-a-thon involving more than **330 researchers, with 37 healthcare databases from 30 different countries.**

- The aim was to design and execute studies to **inform healthcare decision-making** during the COVID-19 pandemic.

- Initial results include **two high-impact papers:**
  1. The largest ever assessment of the **safety of hydroxy-chloroquine** which has being considered for COVID-19 https://www.medrxiv.org/content/10.1101/2020.04.08.20054551v1
  2. International **characterisation of COVID-19 patients** https://www.medrxiv.org/content/10.1101/2020.04.22.20074336v1

Using the existing IMI's projects to progress research against COVID-19

- Through action from the European Commission, the IMI COMBACTE-NET project is coming together with PREPARE and ECRIN to synergize in creating a European –wide CT infrastructure for COVID-19

- The Janssen SARS-CoV-2 vaccine program is leveraging AdVac® technology, which was used to develop Janssen's European Commission-approved Ebola vaccine that was in part supported by IMI through the EBOVAC projects

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IMI projects on COVID-19 from Call 21 (Therapeutics)

- **CARE: Corona Accelerated R&D in Europe** (started 01/04/2020)

will identify existing drugs that could be effective as treatments for the COVID-19 pandemic, and develop new drugs specially designed to tackle the SARS-CoV-2 virus.

- **Impentri: Development of Impentri, an intravenous imatinib formulation for COVID-19 acute respiratory distress syndrome** (started 01/07/2020)

will test in a randomised, double-blind clinical trial the efficacy and safety of the imatinib as a treatment for COVID-19 patients with lung inflammation.

- **MAD-CoV 2: Modern approaches for developing antivirals against SARS-CoV 2 (**started 1 August 2020)

will dive into the molecular details of the SARS-CoV-2 virus and use this knowledge to develop new COVID-19 treatments by engineering human tissue to test new antiviral treatments in the laboratory.

IMI projects on COVID-19 from Call 21 (Diagnostics)

- **DECISION**

A miniaturized disposable molecular diagnostics platform for combatting coronavirus infections (started 01/07/2020)

- **RAPID-COVID**

Robust Automation and Point of Care IDentification of COVID (started 1 August 2020)

- **KRONO**

Evaluation of a production ready portable, point-of-need platform (instrument and reagents), direct from nasal swab test for the molecular diagnostic detection of COVID-19 infection.

- **DRAGON**

Rapid and secure AI imaging based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics

- **COVID-RED**

COVID-19 infections - remote early detection

Interactions with the EU research infrastructures (1)

- Infrastructures have come into IMI projects as public consortium partners at the competitive stage
- Considered valued partners from both public and private perspectives
- Have been critical in trans-European harmonisation – especially in data projects and those catalysing new transnational initiatives in challenging areas (especially in clinical research)
- Are critical also in prospects of sustainability of valuable assets built during IMI projects
- Have been key in training initiatives

Interactions with the EU research infrastructures (2)

(specific IMI projects)

ELIXIR:

EMTRAIN, ONCOTRACK, eTRANSAFE and FAIRPLUS

BBMRI

CONCEPTION

EMTRAIN

EATRIS

EU-PEARL

ECRIN

COMBACTE-NET; MACUSTAR ;C4C; NECESSITY; EU-PEARL; IDEA-FAST

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Future Plans for a new Public–Private Partnership under Horizon Europe

- New PPP (Joint Undertaking under Article 187) being proposed under Horizon Europe

- Takes advantage of the ongoing technology convergence across industry sectors involved in healthcare

- Also addresses many of the recommendations coming from previous independent evaluations of IMI

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Thank you

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