

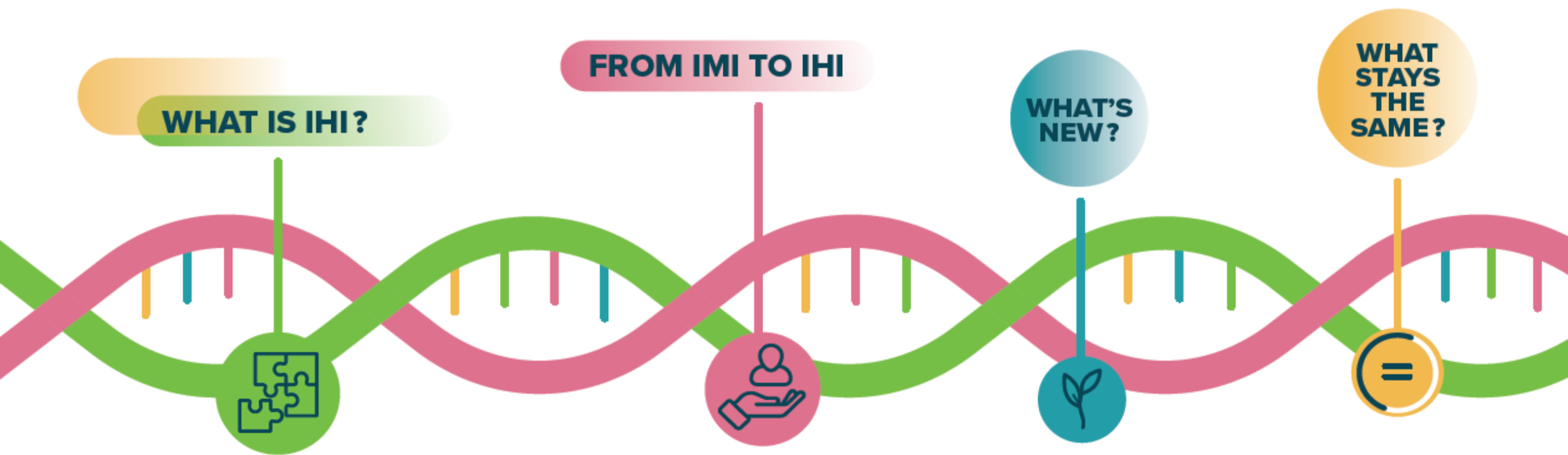


The Innovative Health Initiative

the European public-private partnership for health research and innovation

19 March 2025 – Lygature LIVE - Hugh Lavery





WHAT IS IHI?

IHI IS EUROPE'S NEW PARTNERSHIP FOR HEALTH

IHI is a **collaboration** between the EU and the biopharmaceutical, biotechnology, digital health and medical technology sectors, as well as academics, patients, regulators and other healthcare professionals.

FROM IMI TO IHI

IHI builds on the extensive experience of **IMI's 14 years and almost 200 projects** to create an interdisciplinary, sustainable, patient-centric health research partnership to help transform patients' lives.

WHAT'S NEW?

- The way we're governed.
- The scope of the partnership is broader than IMI as it covers the **entire continuum of care**.
- There are new, specific objectives that align with the EU's latest health policy strategies.

WHAT STAYS THE SAME?

- **Funding comes equally** from the public and industry partners.
- Calls for proposals are **open and competitive**.
- Projects started under IMI are managed by IHI.

IHI budget: **1.2 billion EUR EU + 1.2 billion EUR IND**

Purpose of IHI

- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need;
- Turn health research and innovation into **real benefits for patients and society**;
- Make Europe's health industries globally **competitive**.

Strategic Research & Innovation Agenda

Focus

- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

Goal

- Lay foundations for development **of safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

The need to demonstrate impact

- Why do we need to demonstrate the impact of the research we fund?
 - We use public funding
 - We use private funding
 - These are resources that could be used elsewhere
-
- We need to demonstrate the value of investing in research and innovation efforts to society and Europe



How to demonstrate impact?

Quantitative

- KPIs (53 KPI measures under IHI)
- Dissemination activities including bibliometric analysis
- Outputs/Open science approaches
- Number of Patents?
- Products on the market?
- Programme evaluations (interim/final)

Qualitative

- Explaining the challenges
- Demonstrating how a project has 'moved the needle' in a particular domain
- Newsletters
- Publications
- Meetings/conferences/congress
- Close-out meetings/in conversation with...
- Project consortia are key partners in these tasks

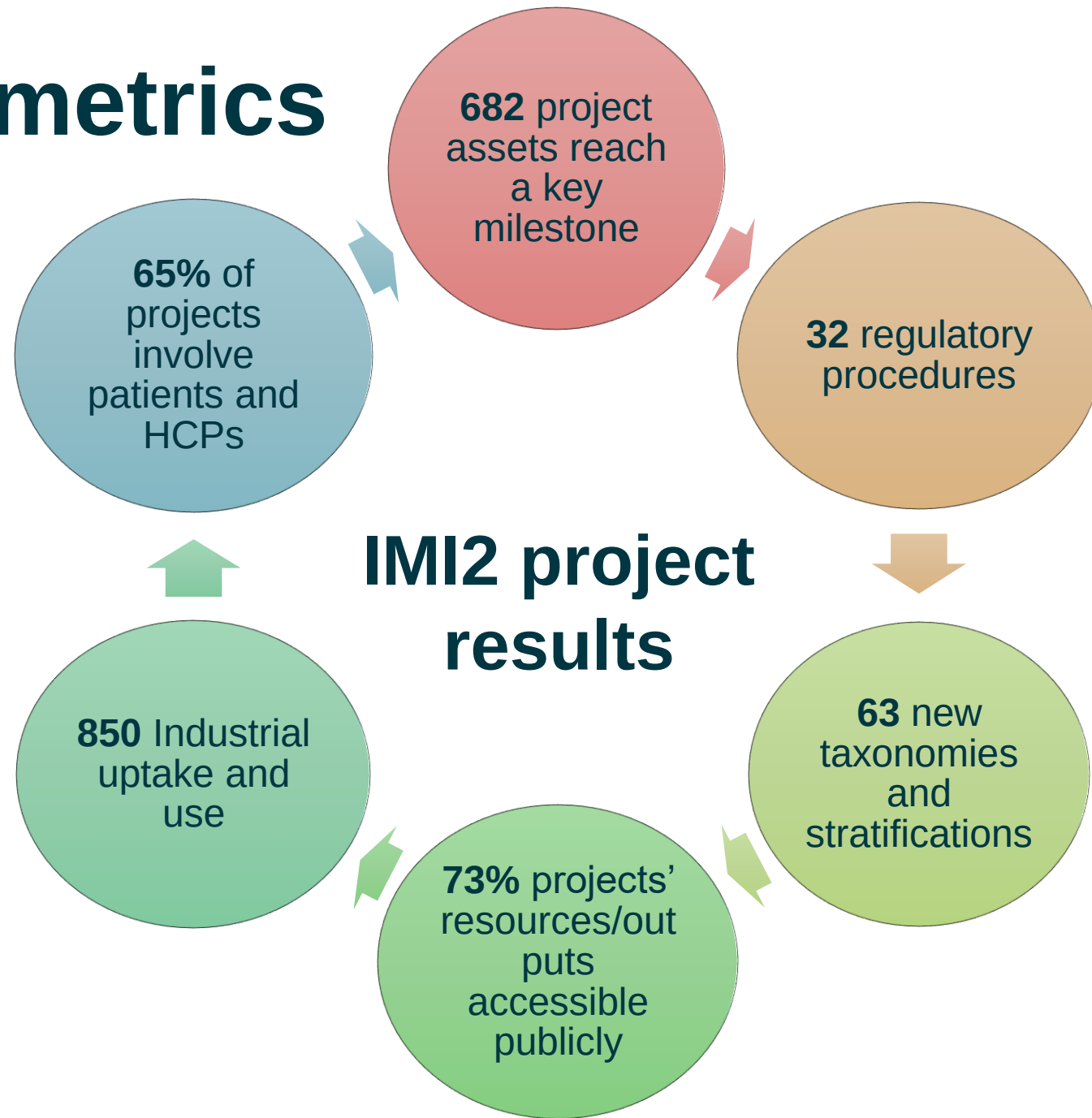
10 IMI2 Key Performance Indicators

https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf

IHI KPI framework

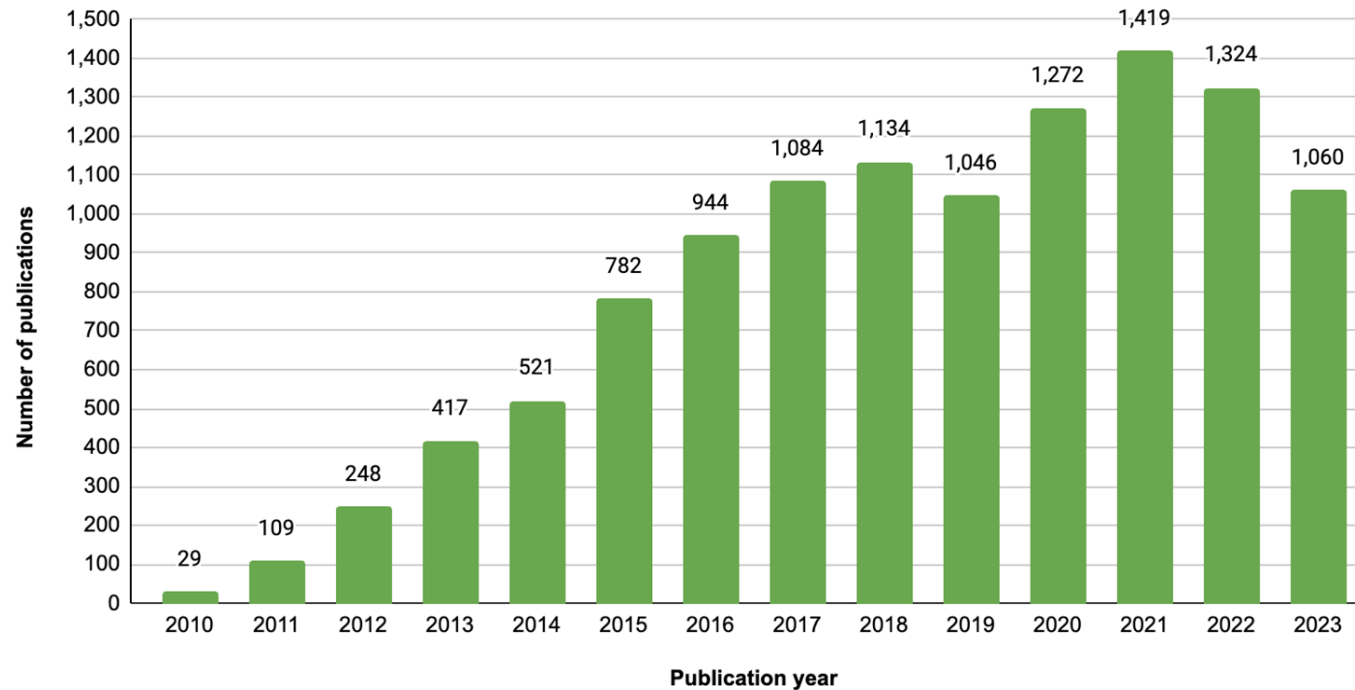
<https://www.ihl.europa.eu/about-ihl/impact>

Key IMI2 metrics



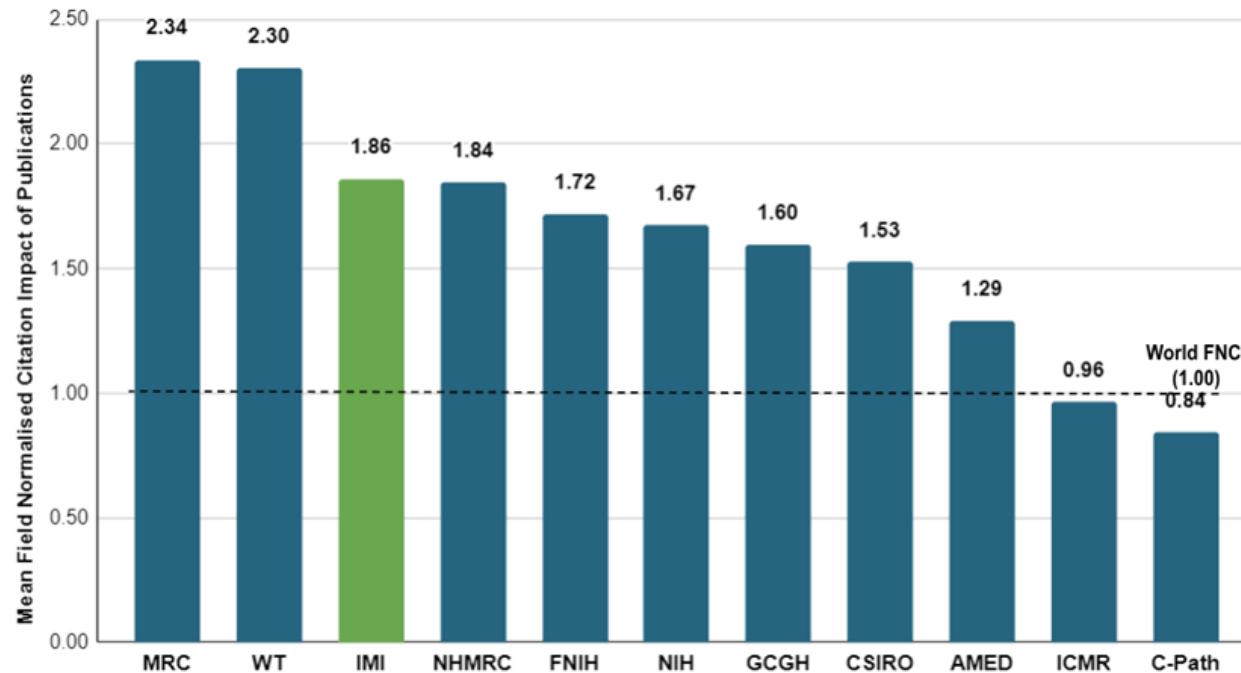
There are now over 11,000 IMI publications

11,389
IMI publications
(2010-2023)



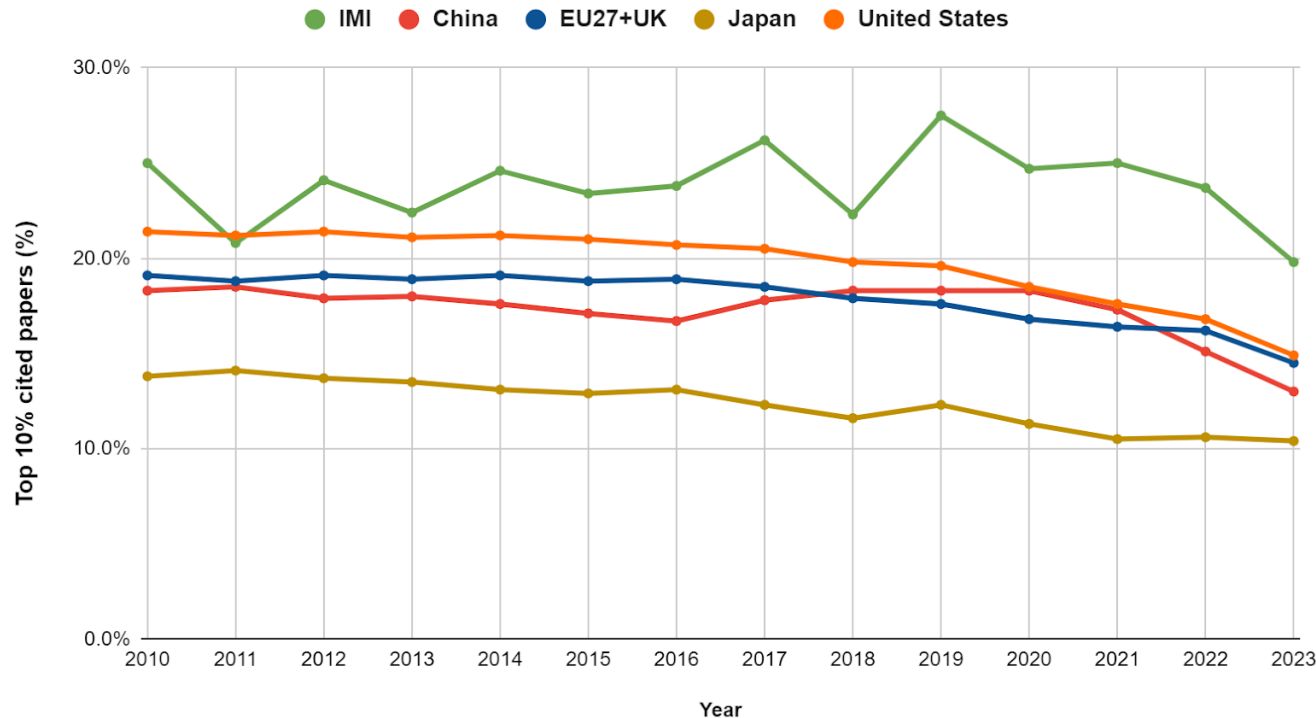
- In 2023 alone, IMI funded research generated 1,060 publications.
- Over the past 5 years, an average of more than 1,220 publications have been generated from IMI funding each year.

IMI-funded research compares well with large international health research funders



- IMI is a small funder in international comparison.
- However, **IMI publications rank third** when comparing across a cohort of international health research funders.

IMI excellence in research strengthens European competitiveness



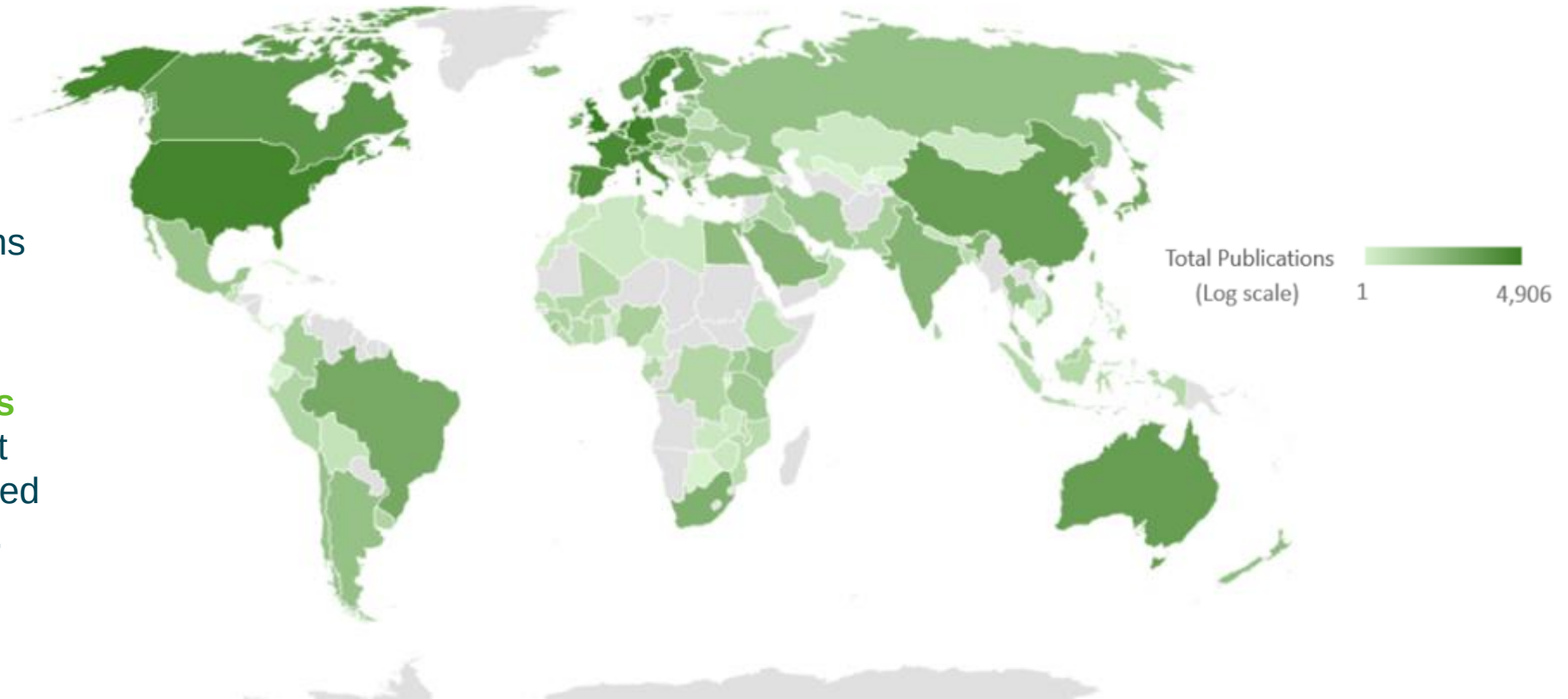
- The top10% highly cited papers is a key scientific metric to show **strong fundamental in science** (Draghi report, Part B, 188)
- The scientific excellence of the joint undertaking contributes to European competitiveness in health research

Trends in share of highly cited (top 10%) papers from total number of papers per year compared with selected comparators regions
Publications type: Article and Reviews
Data criteria: Considered only journals where IMI or IHI papers have published

IMI research is international and has a global reach

133 countries have at least one IMI-funded publication

- IMI funded research collaborations span **all** continents.
- **67 countries** have at least **ten** IMI-funded publications.



Nature Research Intelligence reports remain neutral with regards to contested jurisdictional claims in published maps and network charts

Some IHI projects transforming their research area

- C4C - <https://conect4children.org/>
- ITCCP4 - <https://itccp4.com/>
- CONCEPTION - www.imi-conception.eu
- AIMS-2-TRIALS - <https://www.aims-2-trials.eu/>
- INFECTIOUS DISEASES - <https://www.ih.europa.eu/>
- iPIE/PREMIER - <https://imi-premier.eu/>
- EHDEN - <https://ehden.eu/>
- EUbOPEN - <https://www.eubopen.org/>
- RESOLUTION - <https://re-solute.eu/resolution>

IMI contribution to regulatory science & clinical trials

Large portfolio of IMI projects addressing various aspects to enable clinical trials and more broadly contribute to regulatory science through developing tools that can be used to inform regulatory decision-making, e.g.:

Clinical trial networks

- Single point of contact; speed up recruitment and better-quality clinical trials e.g. **c4c** (> 250 hospital sites in 21 countries); **COMBACTE/ECRAID** (> 1,200 hospital sites in 42 countries); **Innodia/Innodia Harvest** (46 accredited sites); **Aims-2-trials** (120 sites in 37 countries)

Innovative trial designs

- Platform trial/Master protocols e.g. **EU-PEARL**, **INNODIA**, **Necessity**, **UNITE4TB**
- Decentralised trials **Trials@Home**
- Pragmatic trials **GetREal**
- ¹³ ● Patients preference studies **PREFER**

IMI contribution to regulatory science & clinical trials

Novel endpoint measure

- Outcome measures e.g **Necessity, HARMONY/HARMONY PLUS**
- Patient-reported outcomes e.g **SISAQOL-IMI, PRO-Active**
- Clinical endpoints e.g **MACUSTAR**
- Biomarkers e.g **AmyPad, Beat-DKD, Aims-2-trial**
- Digital endpoints e.g **MOBILISE-D, IDEA-FAST**

Other tools that can improve clinical trials

- Digital tools for Remote assessment of diseases and relapse e.g **Radar-AD**
- Blockchain technology e.g for e-consent, e-enrollment **PharmaLedger**
- e-product information **Gravitate Health**
- Patient access to clinical trial data **FACILITATE**
- Adherence **BEAMER**
- Standards e.g **c4c** User Guide for paediatric clinical trials
- Real-world data e.g **EHDEN, ConcePTION**

IHI contribution to regulatory science & clinical trials

Clinical trials/studies

- **REALISE-D** in rare diseases
- **READI** enhancing representativeness in studies
- **Project- COMFORT** ability to test and monitor for illnesses using Patient Centric micro-Sampling (PCmS) as an alternative to venous blood-draw
- **HEU-EFS** early feasibility studies for medical devices

Other tools/methods

- **IDERHA** integration of heterogeneous data and evidence towards regulatory and HTA acceptance
- Biomarkers **Autopix, Brecise, Intercept, Viromarkers**
- **VICT3R** virtual control groups in toxicological research
- IHI Call 6 RWD/RWE (in GAP)
- IHI Call 8 regulatory sandbox
- IHI Call 10 e-labelling

Demonstrating impact

- KPIs
 - Bibliometric analysis
 - Publications – office and project
 - Project stories
 - Newsletter
 - Social media
 - Meetings and congresses
 - CAAR, Interim and final evaluations
-
- IMI/IHI is a recognized global leader in fostering public-private collaborations in health research

How will we know that IHI is a success?

New models
developed &
published

Setting new
standards

Use
by industry

Inform
regulatory
science

Change
Healthcare
delivery

Better evidence-based decision
making

Demonstrating impact in uncertain times

- In a changing world resources are coming under increasing pressure
- We must explain our work and the results we generate in a better way to political decision makers, civic society and citizens
- We have a wonderful story to tell, we have an important role in helping improve patients' lives and supporting the European economy
- We should remain positive, optimistic and relentless in explaining the value of research and the value it brings to society



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