From IMI to IMI2
Status and timelines

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1. IMI delivers…

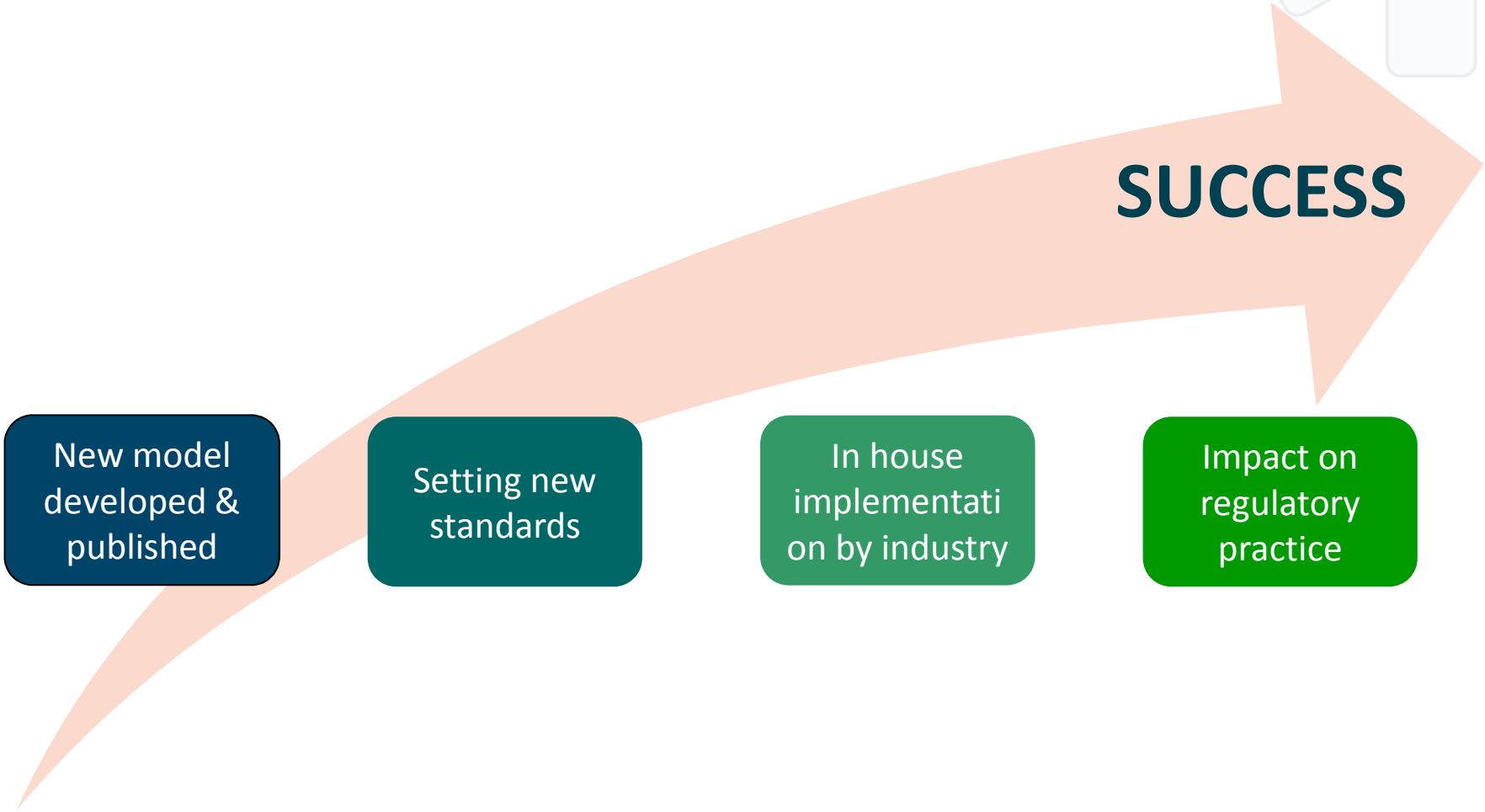
Results beyond the state of the art

- Established robust validated models for Alzheimer, diabetes, schizophrenia, asthma
- Developed clinically relevant biomarkers for Alzheimer, diabetes, schizophrenia, asthma
- Robust tools for drug safety prediction, prevention and monitoring
- Establishment and regulatory submission of key standards and tools for drug development in infectious diseases, COPD, diabetes
- Improved clinical trial design and process in schizophrenia, pain, autism
- Major programme on antimicrobial resistance (research & development)
- Projects launched and planned on use of real life data and alignment of regulators and payers data requirement

→ Many of the above pave the way for new regulatory pathways aligned with science and technology development and creating pull incentives

→ Uptake by Regulators has started (guidance, biomarkers)

The measures of success



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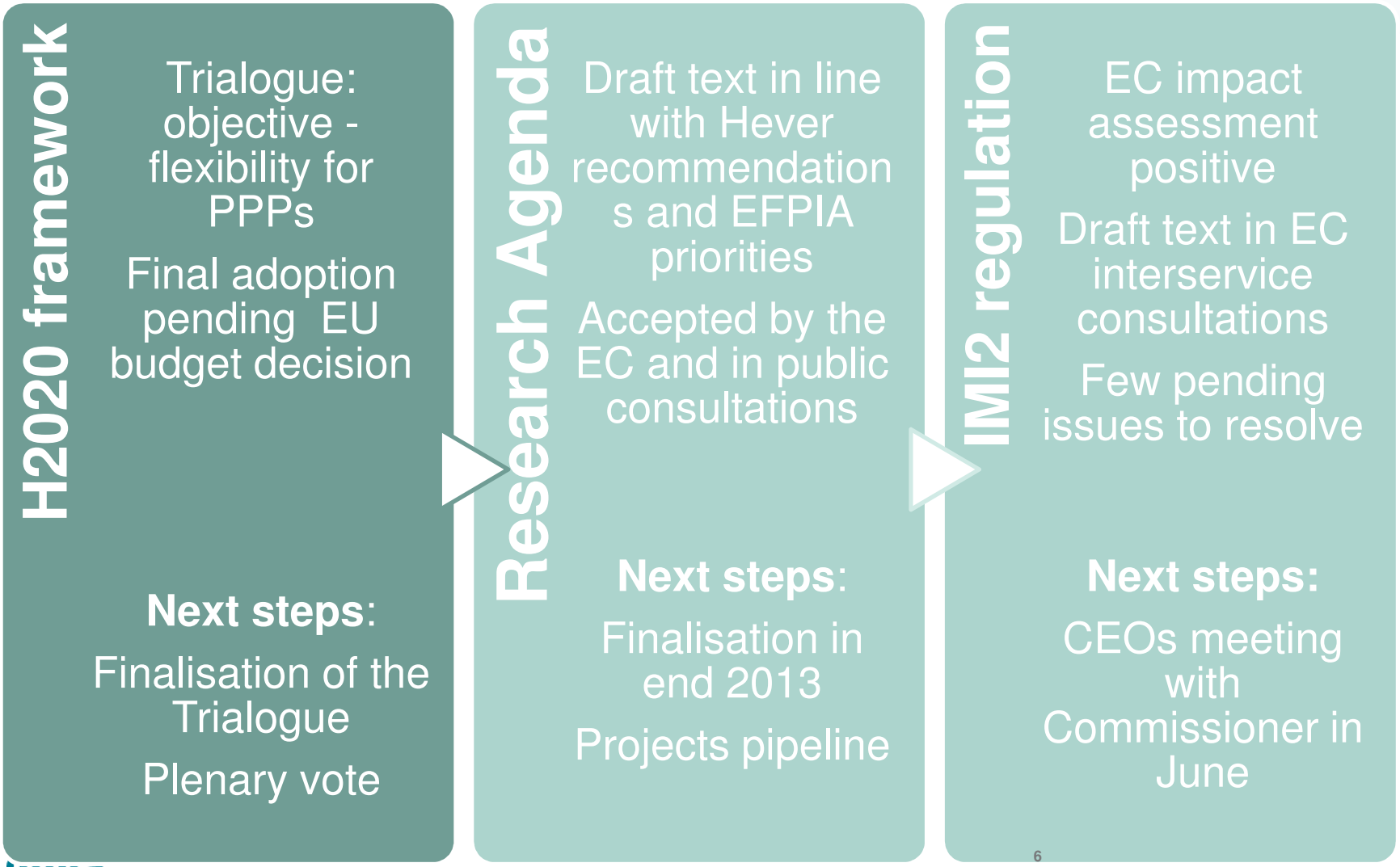
2. IMI2

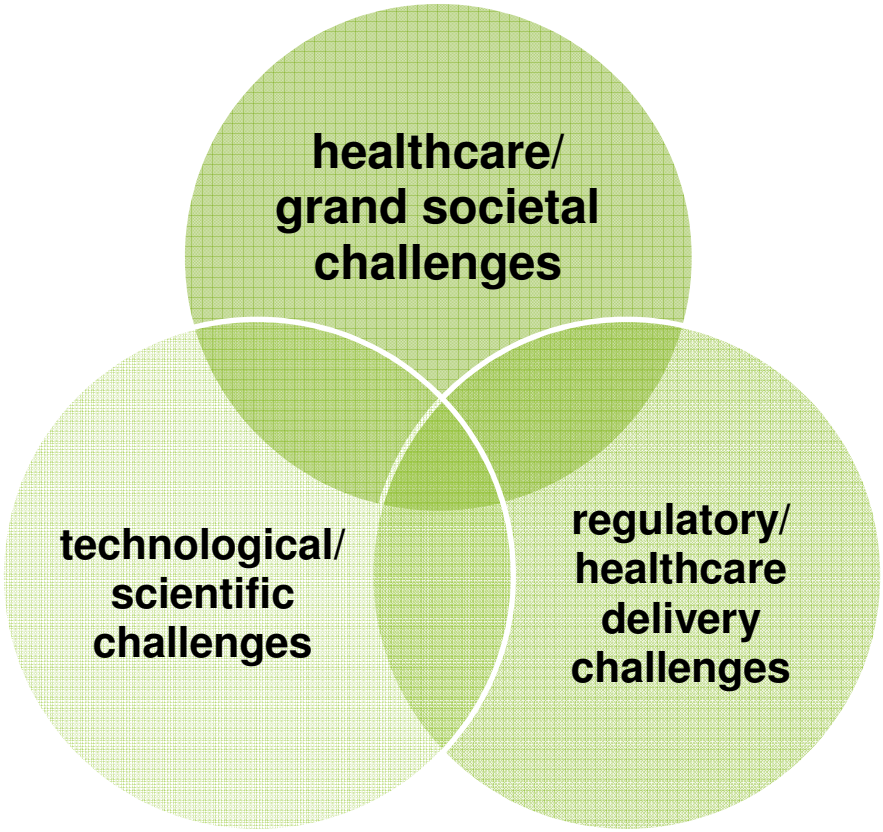
IMI2 – objective: Start in January 2014



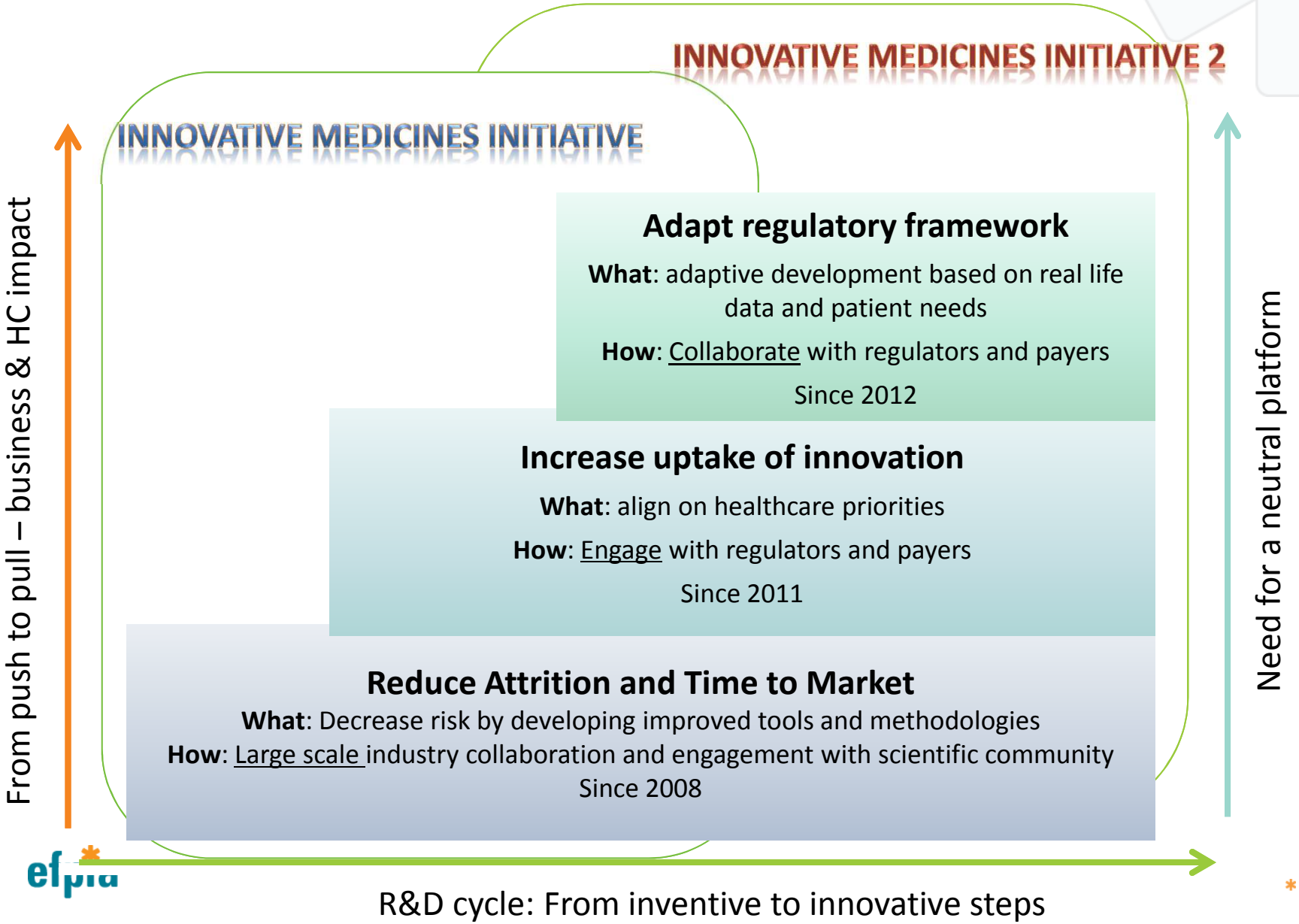
3. The Strategic Research Agenda of IMI2

Strategic Research Agenda: Preliminary thinking – 3D dimensional approach

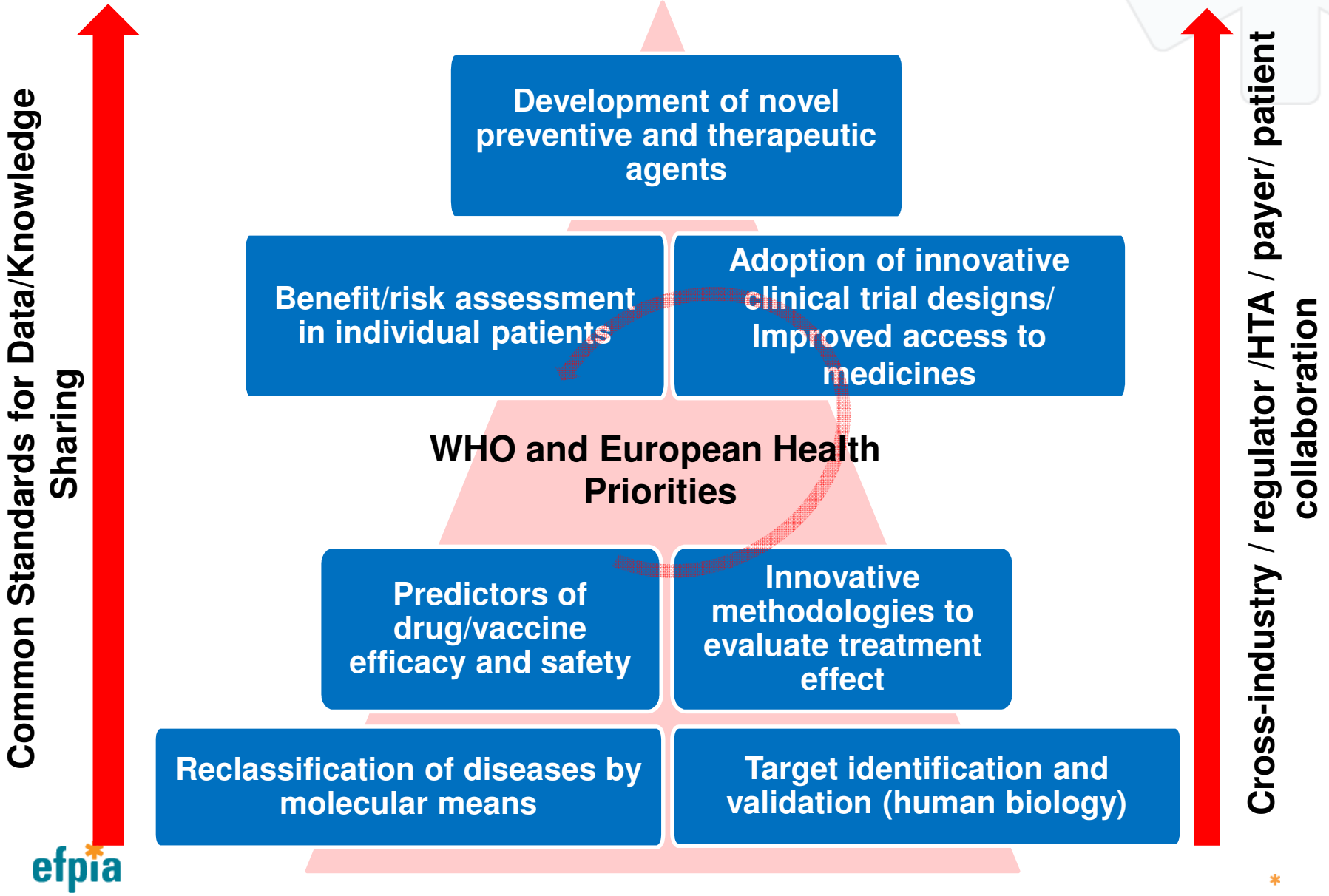
7 key areas of focus have been identified which combine



The Evolution



7 axis of activity



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Working together we can succeed

Right prevention and treatment,
for the right patient, at the right time

SOCIETY

Rational use of HC budgets
Decreased societal cost burden
Continued investments in R&D
More productive economies/job creation

PATIENTS

New, more effective and safer medicines faster
Personalised treatment approaches
Faster detection and intervention in cases of adverse effects

ACADEMIA

Involvement in shaping research & innovation agendas
Business development opportunities
Access to data and industrial networks

INDUSTRY

Efficient clinical trial design
Reduced attrition
Better informed go/no go decision
Reshaping regulatory framework

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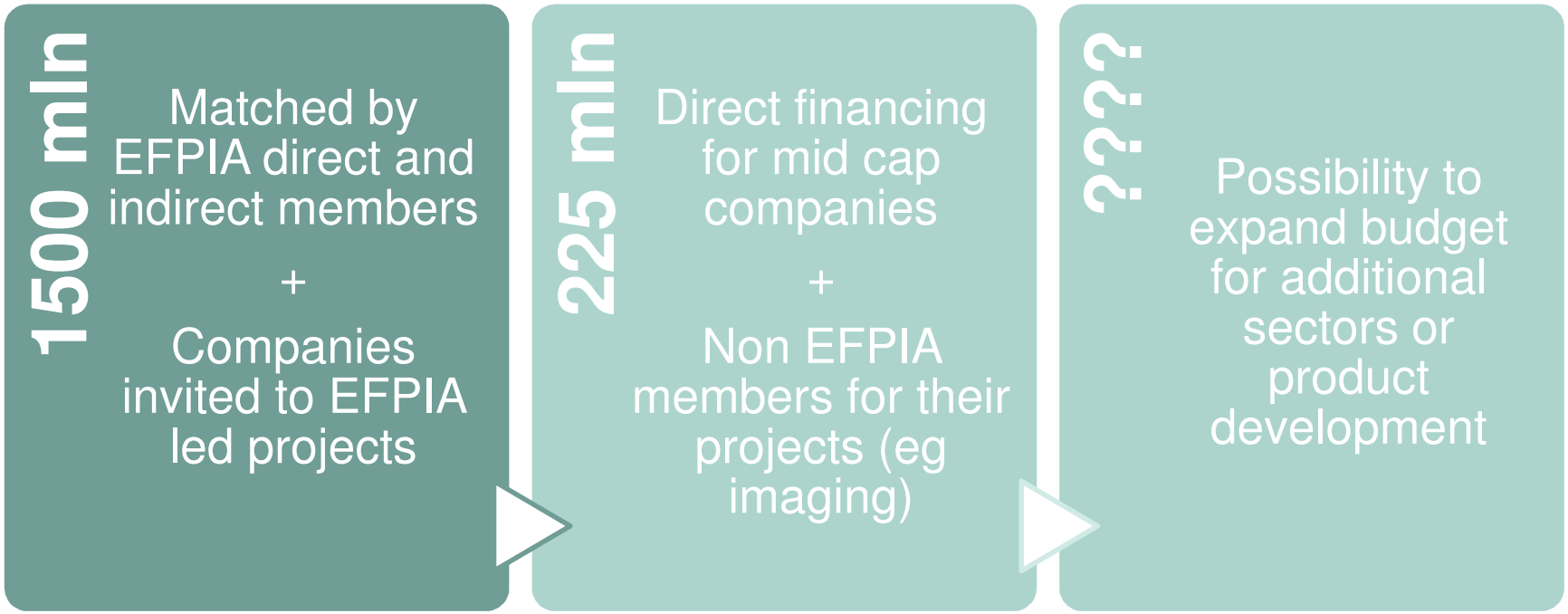
4. IMI2 budget

Distribution of funding



Industry: types of companies

Micro	• Up to 250 employees, up to 50 mln turnover (EU definition) • IMI beneficiaries: EU SME definition • EBE members • Promethera, NovImmune, Clovis Oncology …
Small	• Up to 1000 employees, up to 500 mln turnover • Too small to contibute, too big to benefit from EU funding • EBE members • Dompe, Aicuris, Myriad Genetics…
Medium	• 2 to 4 bn capitalisation (mid-cap Euronext) • Larger companies but relatively small in pharma context • Vaccines Europe & EFPIA members • Menarini, Lundbeck, Almirall, UCB …
Large	• Vaccines Europe and EFPIA members

Eligibility for EU funding for non competitive projects (including AMR-like programmes)

Large	Medium up to 4 bn capitalisation	Small up to 500 mln turnover	Micro up to 50 mln turnover
Not eligible	Case by case eligibility	Automatic eligibility	Automatic elibigility

5. IMI2 regulation

Questions resolved

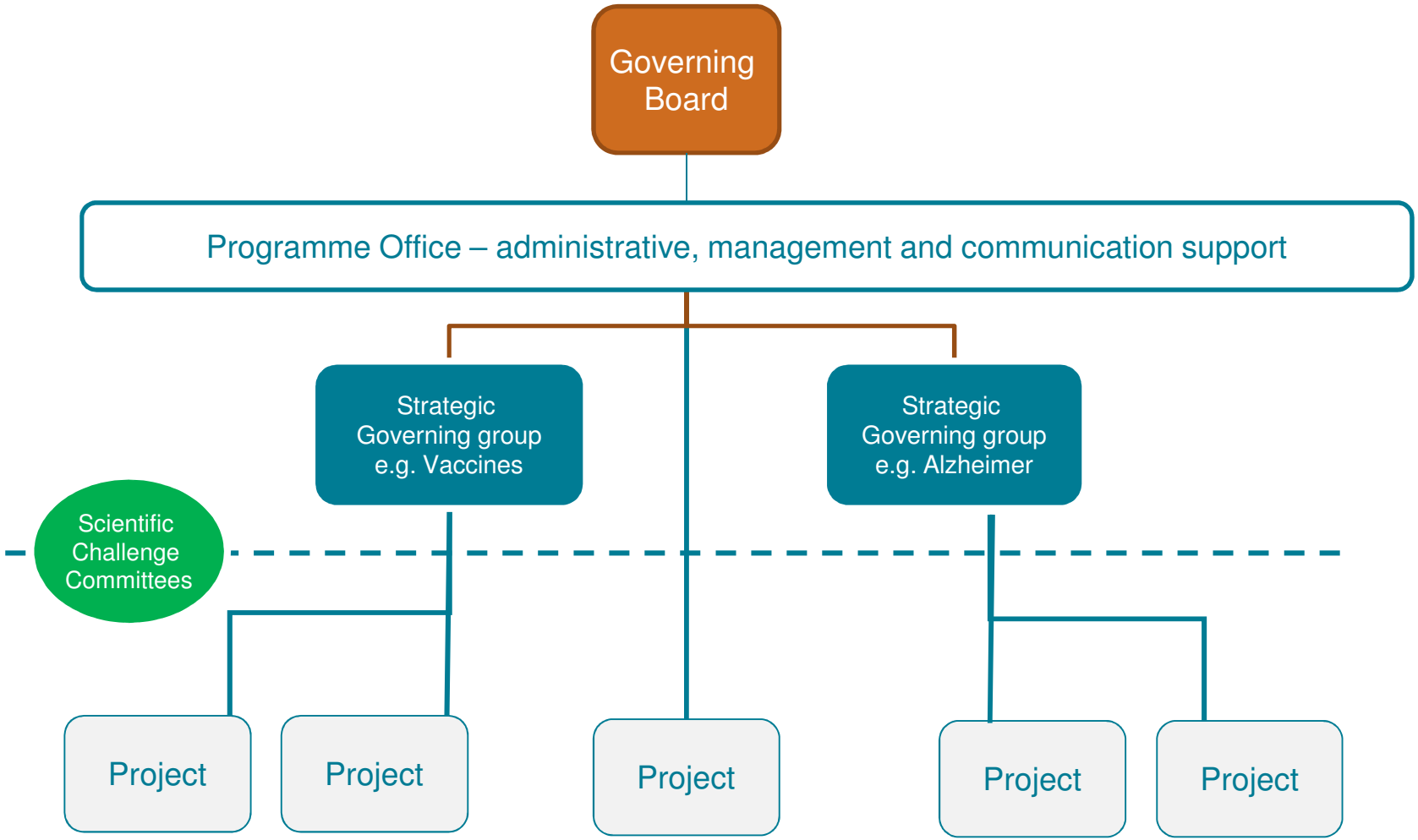
IMI is different from other JTIs:

- Derogations: eligibility for funding vs. IMI IP policy
- But financing rules for beneficiaries – identical to H2020
- Additional rules for contributors – in kind/cash contributions
- Flexible governance in Statutes

Pending questions

- Joint ownership
  - Direct/indirect discharge
  - Central services: IT, legal, audits
- In kind/cash contribution
  - including non EU
  - In kind for running costs
  - Definition of in kind (e.g. data/samples)
- Eligibility of small companies (beyond EU definition) for funding

Overall Governance structure



6. Product development

Why product development scheme?

- Attract R&D private investments in non competitive projects
- Fully implement H2020 objectives – from invention to innovation
- To move IMI/IMI2 results to next innovation step in the valuechain
- To restore balance and attractiveness vs other regions (direct public R&D funding to companies, e.g. NIH program)

IMI 2 funding mechanisms

Non Competitive collaborative projects

EU funding = **public partners**

Product Development Projects

EU funding = **Small & Mid Size companies (?)**

1) Direct funding; 2) guarantees for bank loans

Funding for SMEs

No funding for EFPIA members

vs. ADAPTED IP POLICY

Includes ND4BB-like projects

+ additional budget for other sectors involvement

INITIAL PROPOSAL

Any company

vs. PAY BACK IN CASE OF SUCCESS

Withdrawn on 22 March = general H2020 budget cut & lack of experience with such novel instruments

ALTERNATIVE PROPOSAL

- **Strict criteria**: unmet medical need + health priority + in line with SRA + market failure
- **Option**: For moving IMI results to next stage
- Horizontal measure in H2020 FP) **outside IMI2** as a first step (RSFF?)

Product development - Link to IMI2: Proposed project selection criteria

- **In all cases projects must address unmet medical need and high interest for society, and be in line with the Strategic Research Agenda,** and should fulfill one or more of the following criteria

- **Projects offering low return on investment but high interest to society, high risk** (e.g. for addressing serious but sporadic healthcare issues such as outbreaks of infectious disease, vaccination of rare diseases, pilots for vaccination in oncology and diabetes, specific orphan diseases, combination therapies, adaptive clinical design strategies) and/or personalised medicine (adaptive licensing/progressive patient access).

- **Projects requiring long-term or large-scale epidemiological and safety studies** (e.g. prevention, environment, life style factors, CV risk studies, new comparators); or efficacy outcome, mortality

- **Projects involving novel technologies / development approaches (new innovation)** where success with one medicine would pave the way and establish evidential and regulatory pathways for follow-on products and open up new opportunities for therapeutic development – e.g. Regenerative medicine, new drug formulations.

Wrap up

- IMI is a success but we want to bring it to the next level = IMI2:
  - Learn from experience – reduce red-tape
  - Continue « conventional » non-competitive projects
  - Implement output from IMI
  - Ensure that health care are developed with focus on unmet needs - (concepts and thinking)
  - Ensure unmet needs are addressed even in areas with commercial attractiveness