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imi

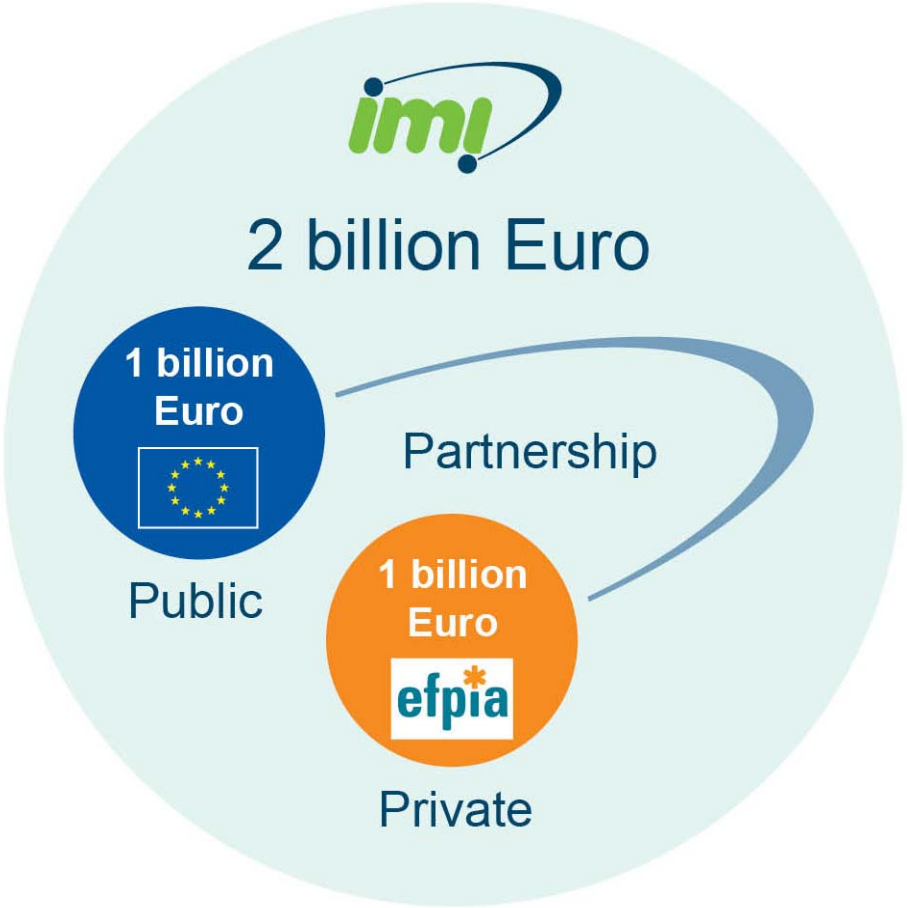
Innovative Medicines Initiative

Joint research for better medicines

Why IMI: an industry perspective

Ejner K. Moltzen, Director, Scientific Alliances, H. Lundbeck A/S
IMI Official Satellite Symposium of the AD/PD 2011 Conference
9 - 13 March 2011, Barcelona, Spain

Vision



The **European Union and the pharmaceutical industry**

have joined forces to make

drug R&D processes in Europe more

efficient and effective

and enhance Europe's

competitiveness in the sector.

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Mission

- The largest *Public-Private* funding initiative in pharmaceutical research (2008-2017).
- One of the EU's *Joint Technology Initiatives* to improve industry's competitiveness in Europe.
  - € 1 billion from the European Commission
  - € 1 billion in kind contribution by EFPIA
    - Funding for beneficiaries (Academics, SMEs, Regulatory Authorities, Patient Organisations)
- Accelerating R&D for safer and more effective drugs.
- Building partnerships between industry, academia, regulators(e.g. EMA), hospitals and patients' organisations in Europe.

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EFPIA Member Companies Participation

Participating companies:

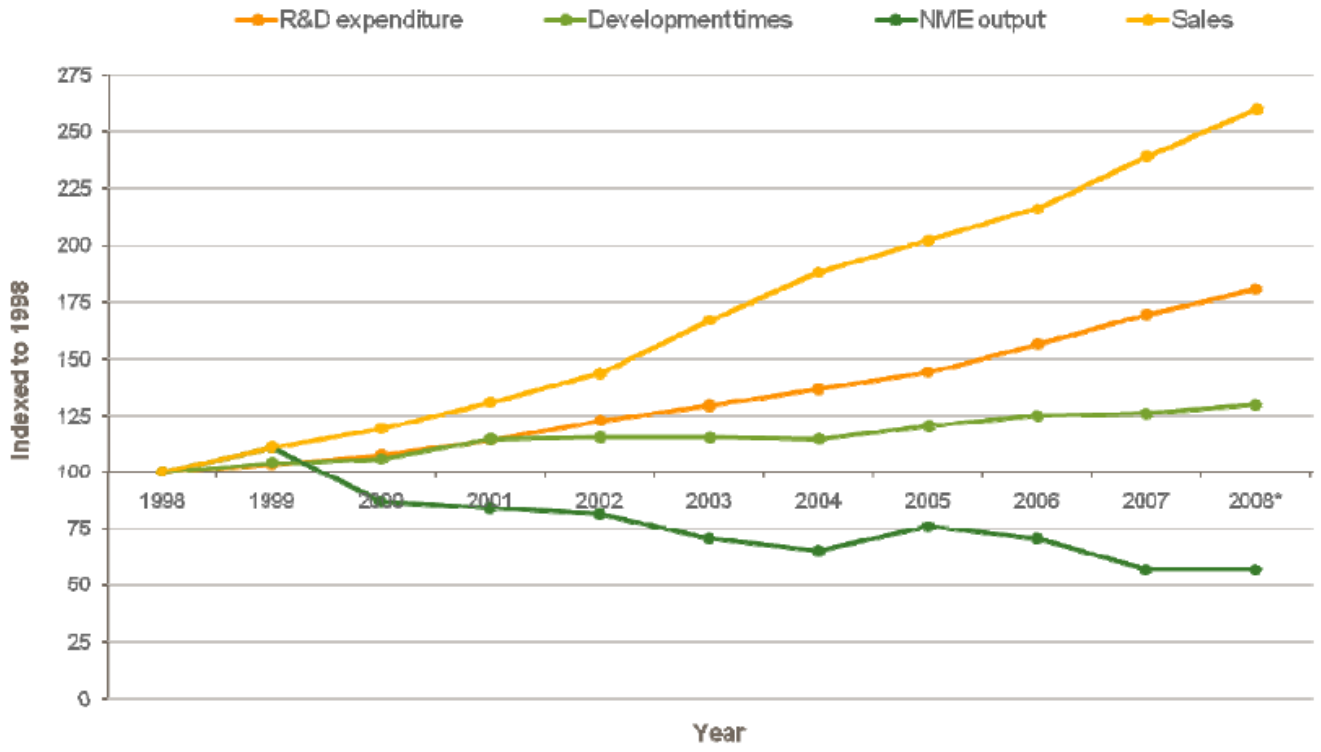
Changing the pharma industry: What's the urgency?

Change is not necessary -

survival is not mandatory

Declining productivity

GLOBAL R&D EXPENDITURE, DEVELOPMENT TIMES, GLOBAL PHARMACEUTICAL SALES AND NEW MOLECULAR ENTITY OUTPUT 1998-2008



*The development time data point for 2008 includes data from 2007 and 2008 only
Source: CMR International & IMS Health

THOMSON REUTERS

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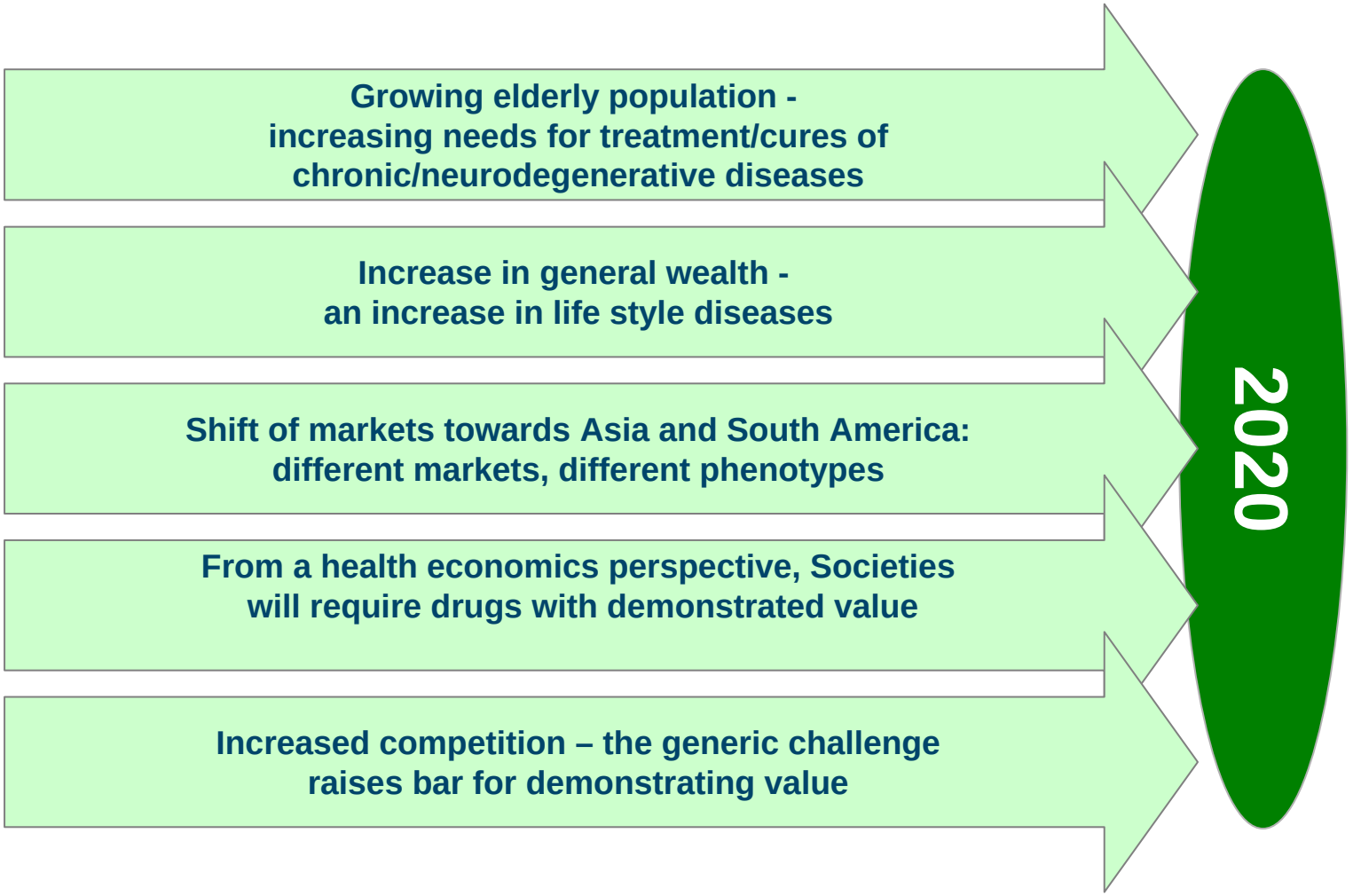
The old model is under pressure!

Lessons from 60 years of pharmaceutical innovation

Bernard Munos

Abstract | Despite unprecedented investment in pharmaceutical research and development (R&D), the number of new drugs approved by the US Food and Drug Administration (FDA) remains low. To help understand this conundrum, this article investigates the record of pharmaceutical innovation by analysing data on the companies that introduced the ~1,200 new drugs that have been approved by the FDA since 1950. This analysis shows that the new-drug output from pharmaceutical companies in this period has essentially been constant, and remains so despite the attempts to increase it. This suggests that, contrary to common perception, the new-drug output is not depressed, but may simply reflect the limitations of the current R&D model. The implications of these findings and options to achieve sustainability for the pharmaceutical industry are discussed.

2020+: The environment is changing



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Payers & Regulatory pressure

PAYERS

Medical importance of disease	• Clinical impact • Economic impact • Merits public funding
Therapeutic value of product	• Benefits clinically meaningful? • Place in therapy?
Benefits over existing treatments	• Benefits in practice? • Benefit to patient?
Value for money	• Costs vs existing treatment? • Increase in cost justified by the benefits?
Affordability	• How many patients? For how long? • Impact on (drug) budget?

REGULATORS

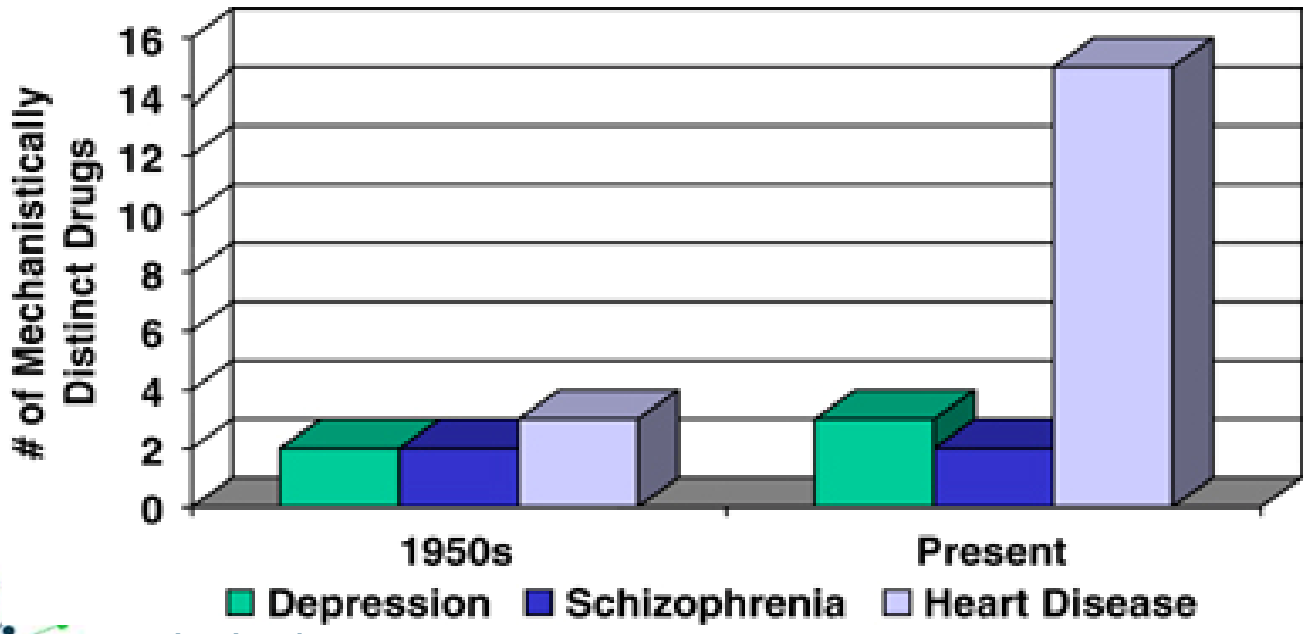
Enhanced focus on benefit/risk assessment for approval

Enhanced focus on risk management & public health protection

- **Broad-targeted blockbusters with mediocre effect becoming impossible**
- **Assessment favors**
  - **Higher effect sizes**
  - **Targeting of higher unmet needs**
  - **Lower-prevalence indications / segments**

Understanding Disease Biology

- Depression & Schizophrenia
- Lack of Innovation in CNS Drug Development

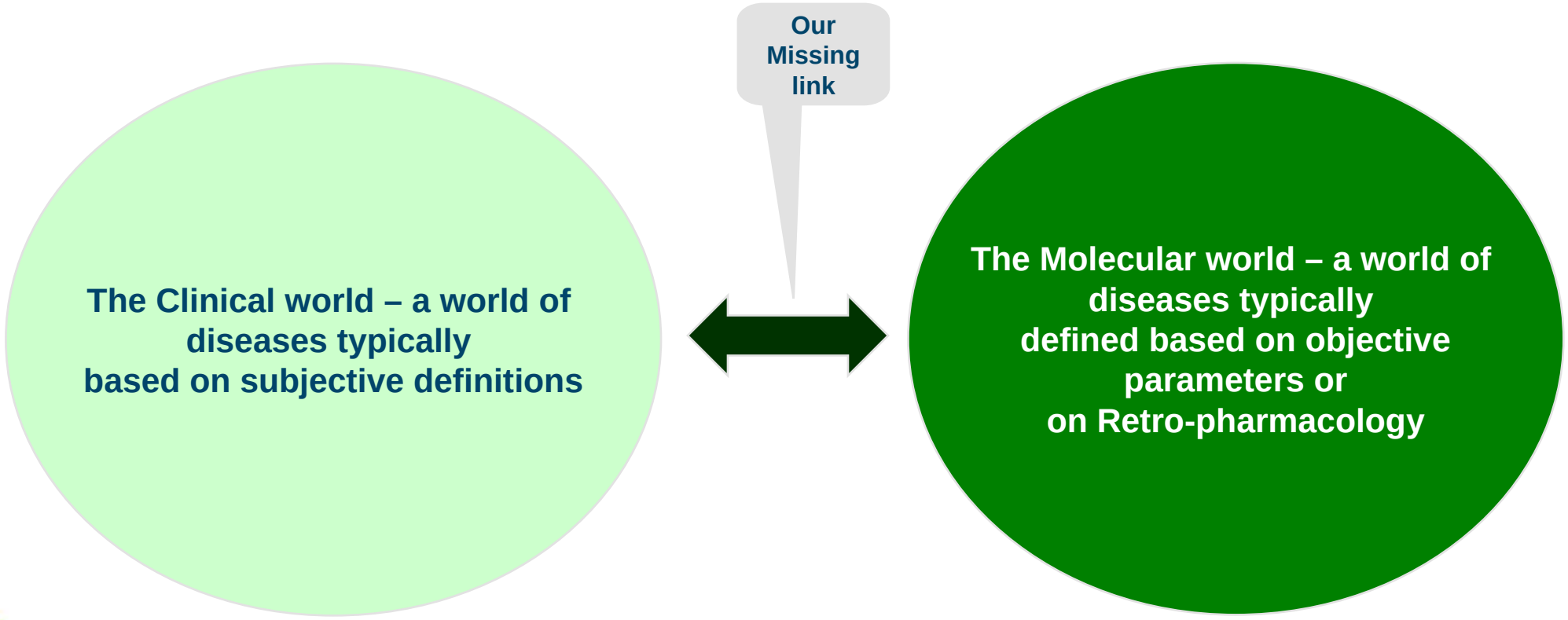


Insel, Mol Psychiatry 2006

Lack of novel drug targets reflects lack of disease biology understanding

Translational medicine and biomarkers to help identifying subgroup-specific objective endpoints and novel treatment targets

The Patient and Drug Discovery – two different worlds



Translational Medicine
From bench to bedside and back

Forward and Backward Translation

Setting up new processes that lead to improved clinical success

Target validation

Human tissue

Research Scientist
At Bench

Molecular diagnosis
- Based on disease biology knowledge

Mechanism of Action
- Confirm target mechanism
- Confirm that mechanism is related to pathophysiology

Clinical Scientist
At Bed side

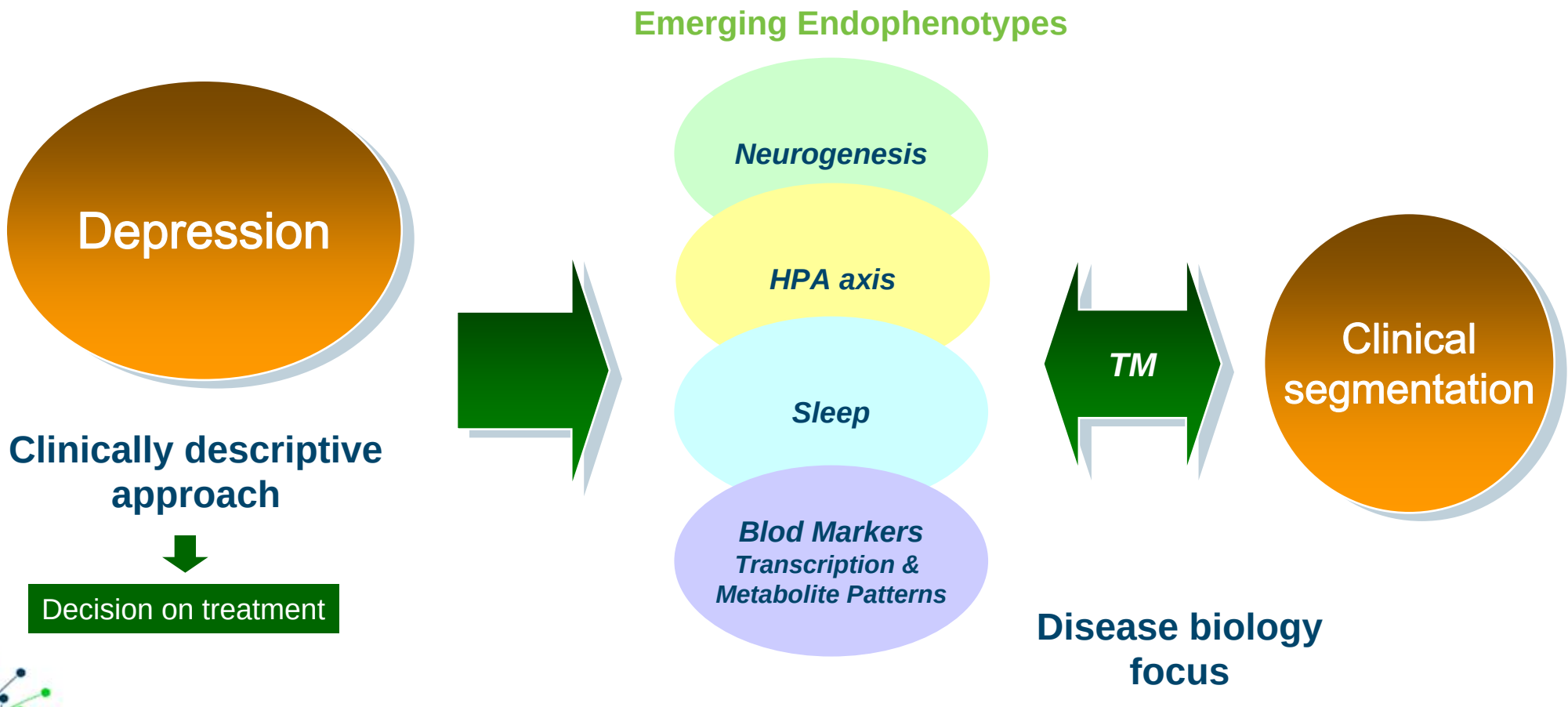
Drug candidate
+
Biomarkers

Proof of Concept
Confirm that compound can be used to treat disease

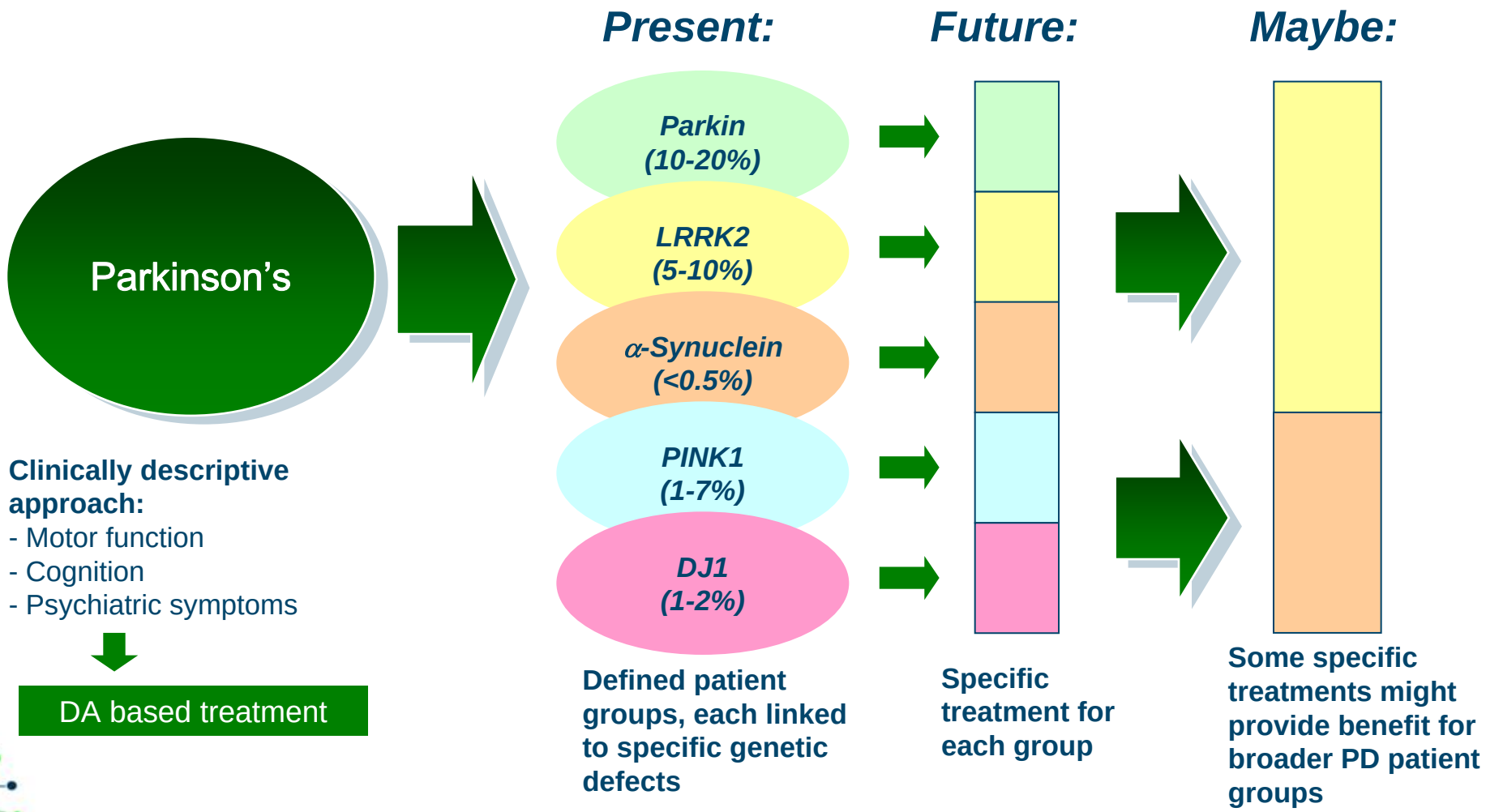
Discovery validation

Potential drugs

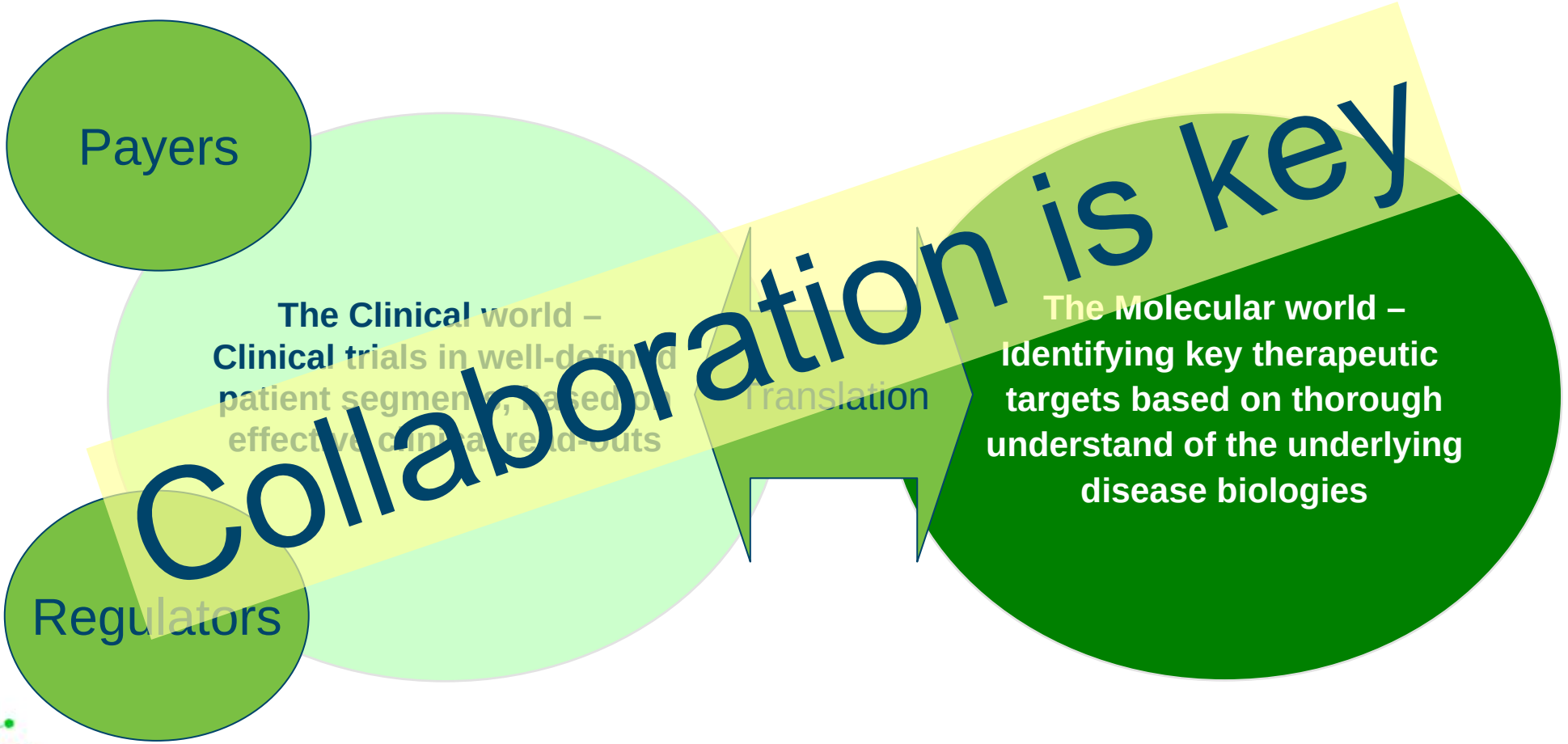
Translational Medicine
Example: Depression



Translational Medicine
Example: Parkinson's disease



A way to better drugs:



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Why is industry enthusiastic to collaborate through IMI?

- Because IMI is addressing these key critical issues !

The IMI Strategic Research Agenda (SRA)

- Identified pre-competitive bottlenecks in R&D process
- Proposed recommendations to address these bottlenecks
- Proposed a new model of Public-Private collaboration to implement recommendations

IMI - A unique opportunity

- The ‘research’ pillars of IMI:
  - Predicting **Safety & Efficacy,** Improving **knowledge Management,** Addressing gaps in **Education & Training**
- Unique access to world-class research consortia spanning the breadth of Europe
- Unique access to new technologies, tools, and knowledge
- New standards in sharing pre-competitive data / intellectual property
- Unique societal and socio-economic benefits to European citizens

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IMI aims at:

Building on ***Strengths*** and tackling ***Weaknesses*** in the EU

- Major pharma companies based in Europe
- High-quality research and medical centres
- Critical mass assembled through EU programmes
- Biomedical clusters based on PPP*

- Insufficient global investment in R&D
- Fragmented legal framework for IP rights
- Insufficient incentives for bioentrepreneurs
- Education programmes not adapted to industry needs

*PPP Public Private Partnership

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What does industry bring to IMI

- EFPIA membership has committed to match the EC's €1bn funding through both cash and in-kind contributions
  (over lifetime of IMI 2008-2017)

- Beyond that, industry is bringing to the consortia:
  - Provision of high-calibre industrial R&D expertise and insight
  - Access to industry labs and technologies
  - Multi-disciplinary skills (science, training, project management)
  - International reach and critical mass
  - Knowledge of best practice outside Europe

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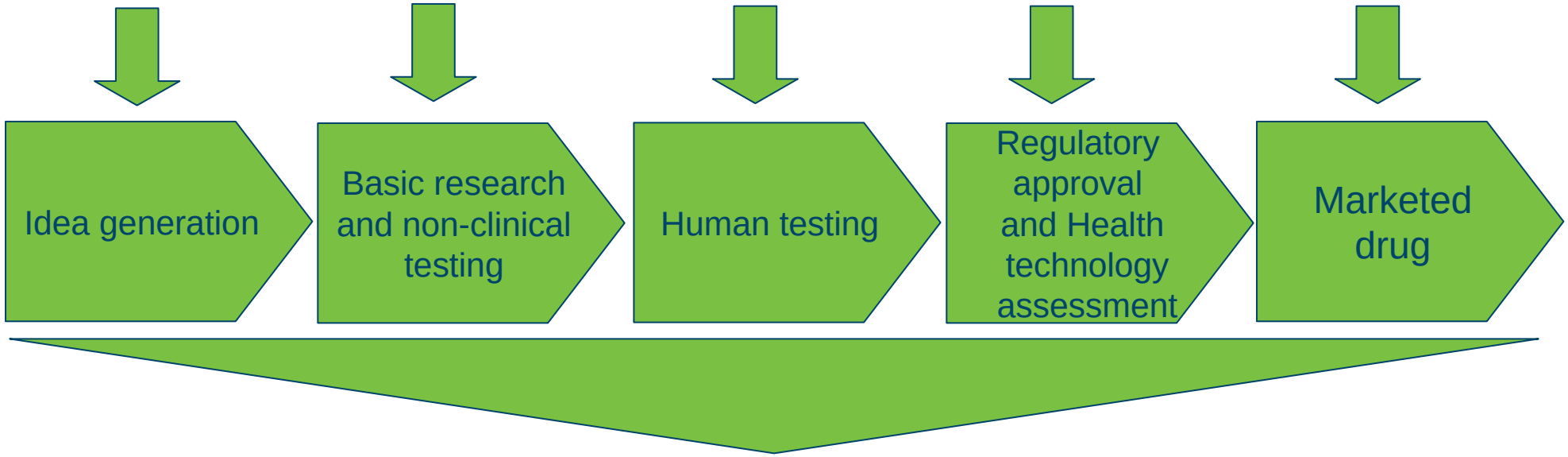
IMI will help industry to:

make **drug R&D processes in Europe more efficient and effective** and enhance Europe's **competitiveness in the sector.**



- **To the benefit of EU**: Improved healthcare status of individuals and society and positive economical impact
- **To the benefit of Pharma Industry**: facilitate development of next generation drugs

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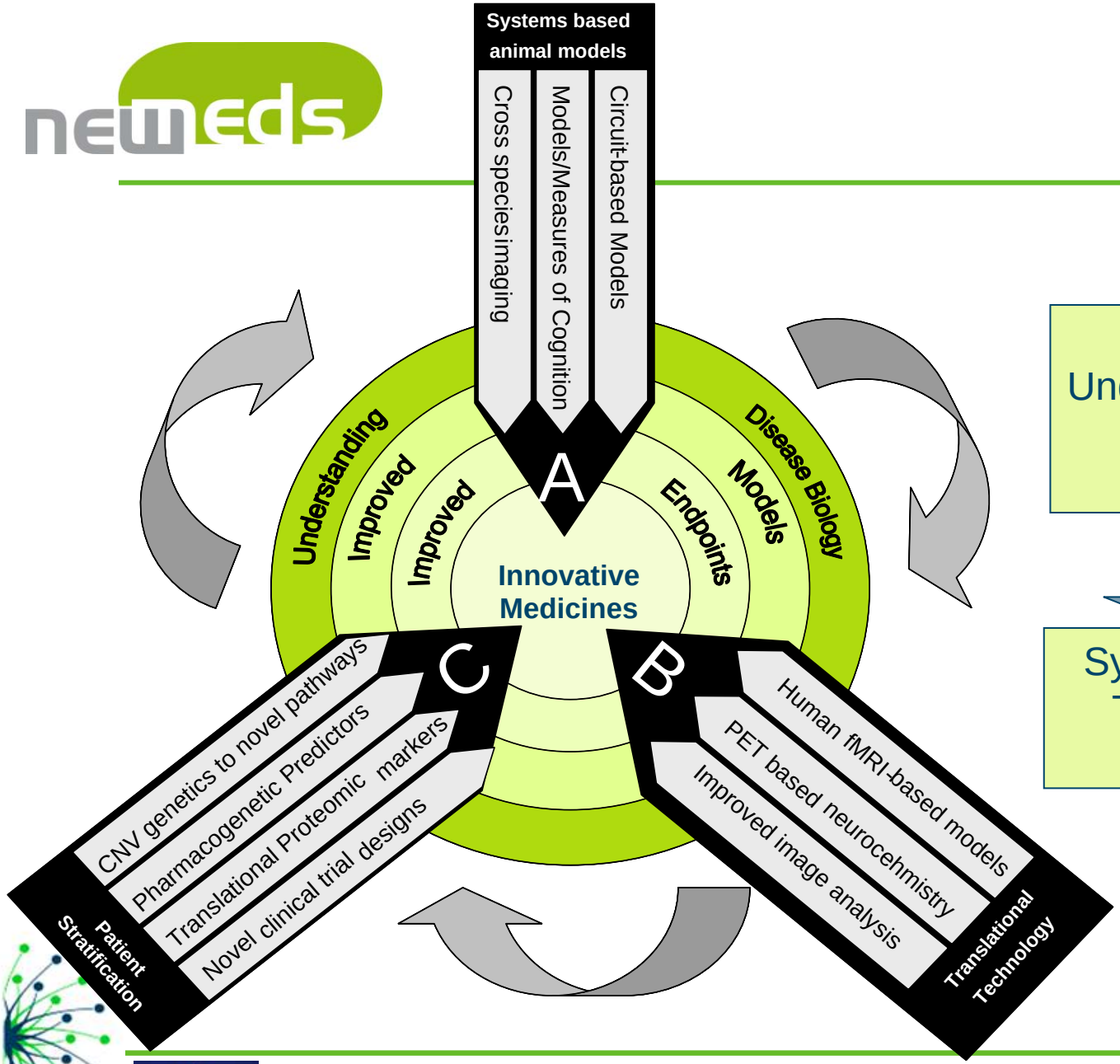
IMI projects show success!



Focus on psychiatry:
Understanding disease biology
Improve Models
Improve Endpoints

Systems based animal model
Translational technologies
Patient stratification

Participants

EFPIA companies

H. Lundbeck A/S, AstraZeneca AB, Eli Lilly and Company Ltd, Janssen Pharmaceutica, NV, Novartis Pharma AG, Orion Corporation, Pfizer Limited, F. Hoffmann-La Roche AG, Institut de Recherches Servier, (Abbott - including), (GSK - exit)

Universities

King's College London *(UK), Karolinska Institutet (Sweden), The University of* Cambridge *(UK), Central Institute of Mental Health (Germany), CSIC (Spain),* The University of Manchester *(UK), Bar Ilan University (Israel)*

SMEs

DeCode *(Island), Psynova (Cambridge), GABO:mi (Germany)*

Achievements so far

- Highly engaged and motivated (> 100 attendees at project meetings)
- 3 Published papers and 1 review submitted
- 2 Clinical trials initiated
- The largest database on schizophrenia trials enrolled in EFPIA studies (> 23,000 patients)
- The largest genome database on Depressed populations generated
- Phenotyping (Psychiatric and Antroprometric measures) of approx 1000 CNV carriers and structural MRI for > 300 pts
- 14 animal models of schizophrenia evaluated in a proteomic markers panel

Conclusions

will be a key driver for:

- The industry to develop new and better drugs
- For the research community in increasing the understanding of disease biology
- For the patient to get better treatments
- For society to improve on health economics and general welfare

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