



Collaborating for healthier lives - the patients are waiting:

The pharmaceutical industry's role in fostering research integrity & creating better systems

4th World Conference on Research Integrity, Rio Di Janeiro, Brazil

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June 2nd, 2015 | Janssen Research & Development a division of Janssen Pharmaceutica NV



Agenda

Disclaimer:

‘The views expressed in this presentation are solely those of the individual authors, and do not necessarily reflect the views of their employers’.

1. Janssen – who are we?
2. Pharmaceutical industry and data integrity
3. Janssen’s DDI initiative (Discovery Data Integrity)
 - Approach
 - Key success factors
 - Broadening our scope

Janssen – Who are we?

We're part of one of the broadest and most diversified family of healthcare companies

Johnson & Johnson

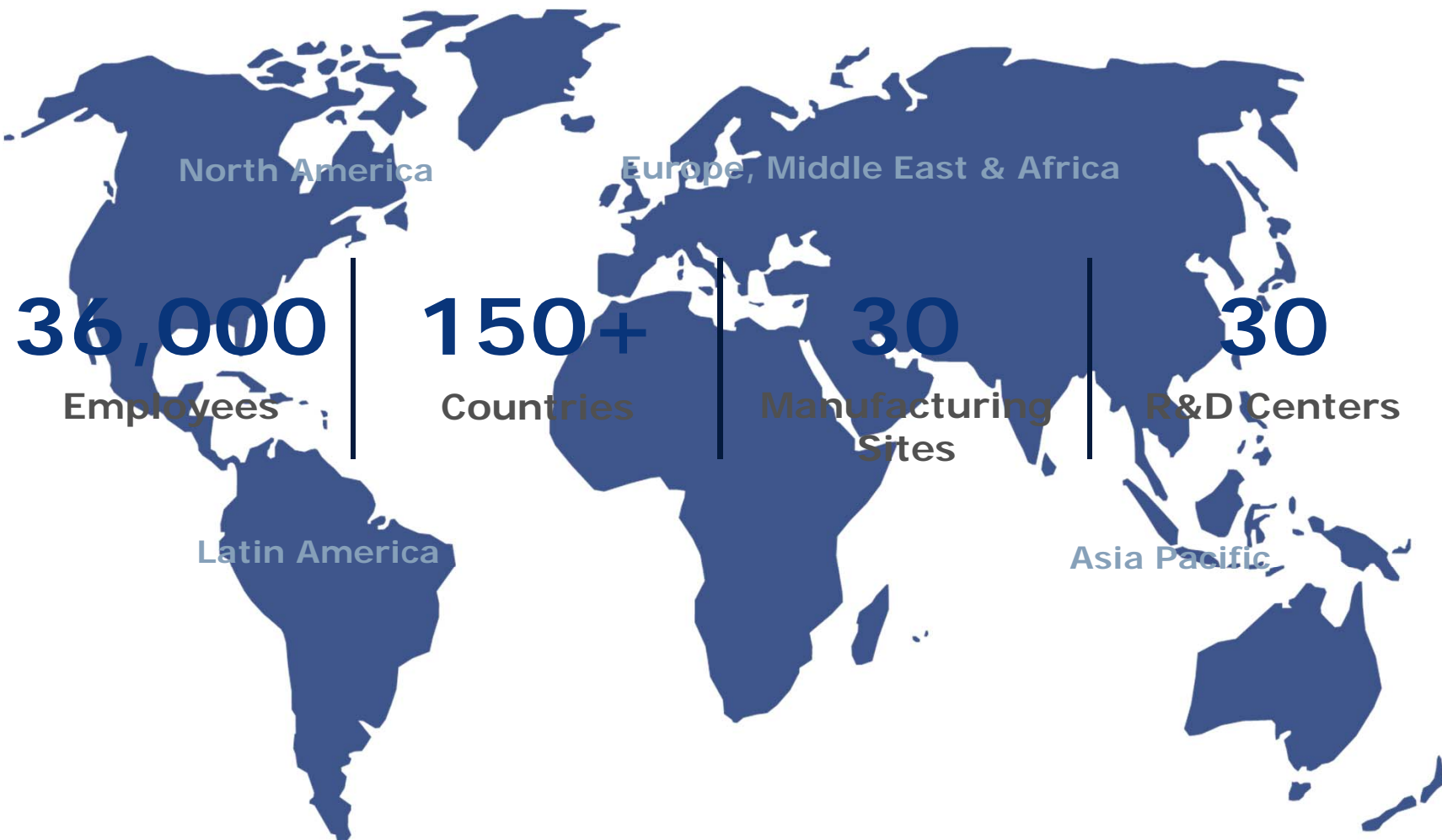
More than
125
years



janssen 

PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Our organization is global, yet our focus is the local community



Our Credo

We believe our **first responsibility is to the doctors, nurses and patients, to mothers and fathers** and all others who use our products and services. In meeting their needs **everything we do must be of high quality**. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are **responsible to our employees**, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

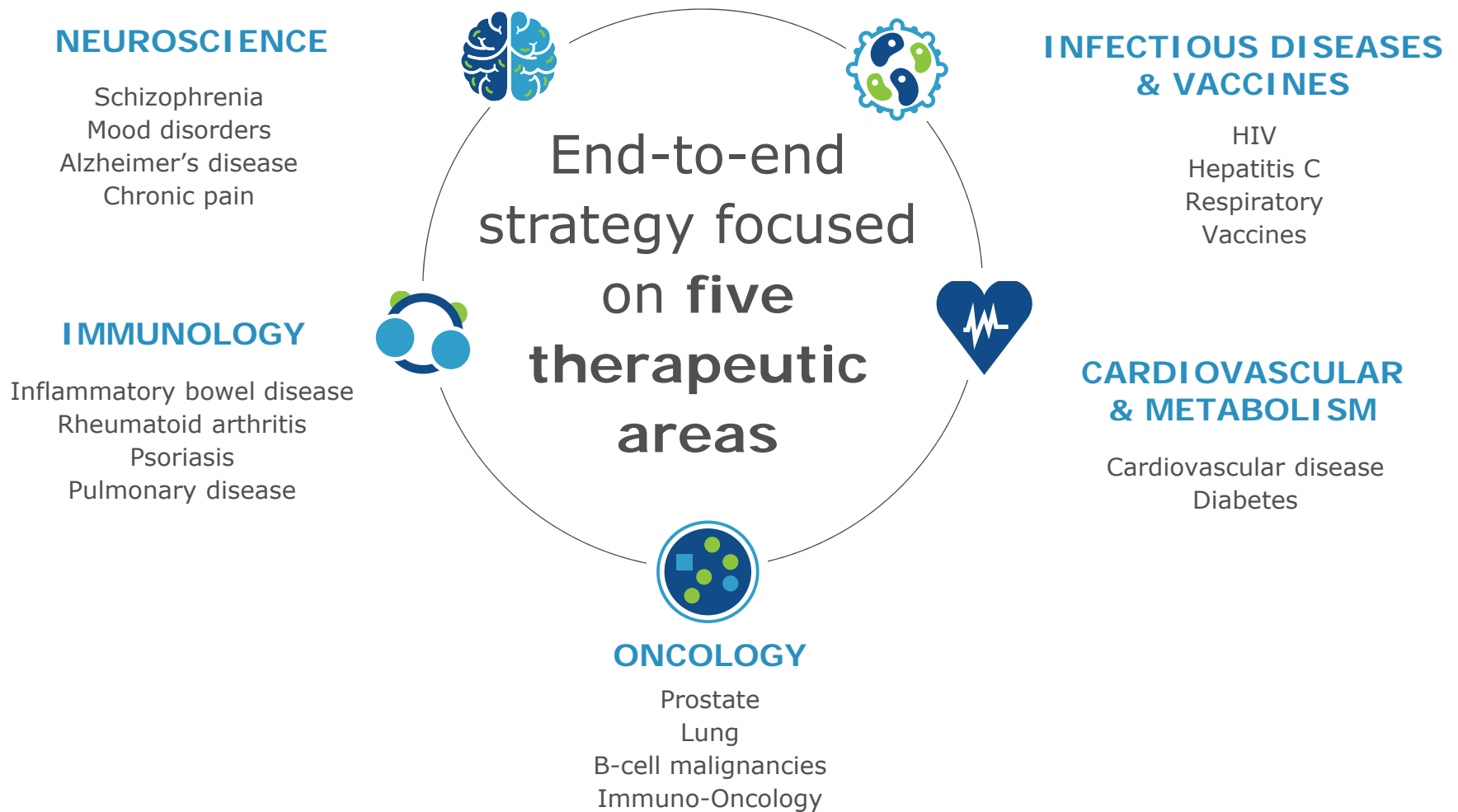
We are **responsible to the communities** in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our **final responsibility is to our stockholders**. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Johnson & Johnson



Focusing on solutions that will make a difference for our patients



Pharmaceutical industry and data integrity

Non-Regulated

Discovery

Clinical candidate

Regulated

Preclinical Development

IB

Phase I & II clinical trial

Phase III clinical trial

Registration & Marketing



Quality Discovery data
 =
 Quality decision making
 =
 Quality compounds
 moving forward

\$2.000.000.000 over 20 years

Translation issues affecting Pharmaceutical Industry

Nature Reviews Drug Discovery 10, 328-329 (May 2011) |

BIOBUSINESS BRIEFS

Trial watch: Phase II failures: 2008–2010

See also: [Correspondence by Prinz, Schlange & Asadullah](#)

Joh

“Only healthy data
lead to healthy patients”

Believe it or not: how much can we
rely on published data on potential
drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah
Nature Reviews Drug Discovery 10, 328-329 (May 2011)

Raise standards for
preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and
incentives must change if patients are to benefit.

29 MARCH 2012 | VOL 483 | NATURE | 531

DDI Discovery
Data Integrity

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of Johnson & Johnson | 10

J&J Global Pharma group rebranding

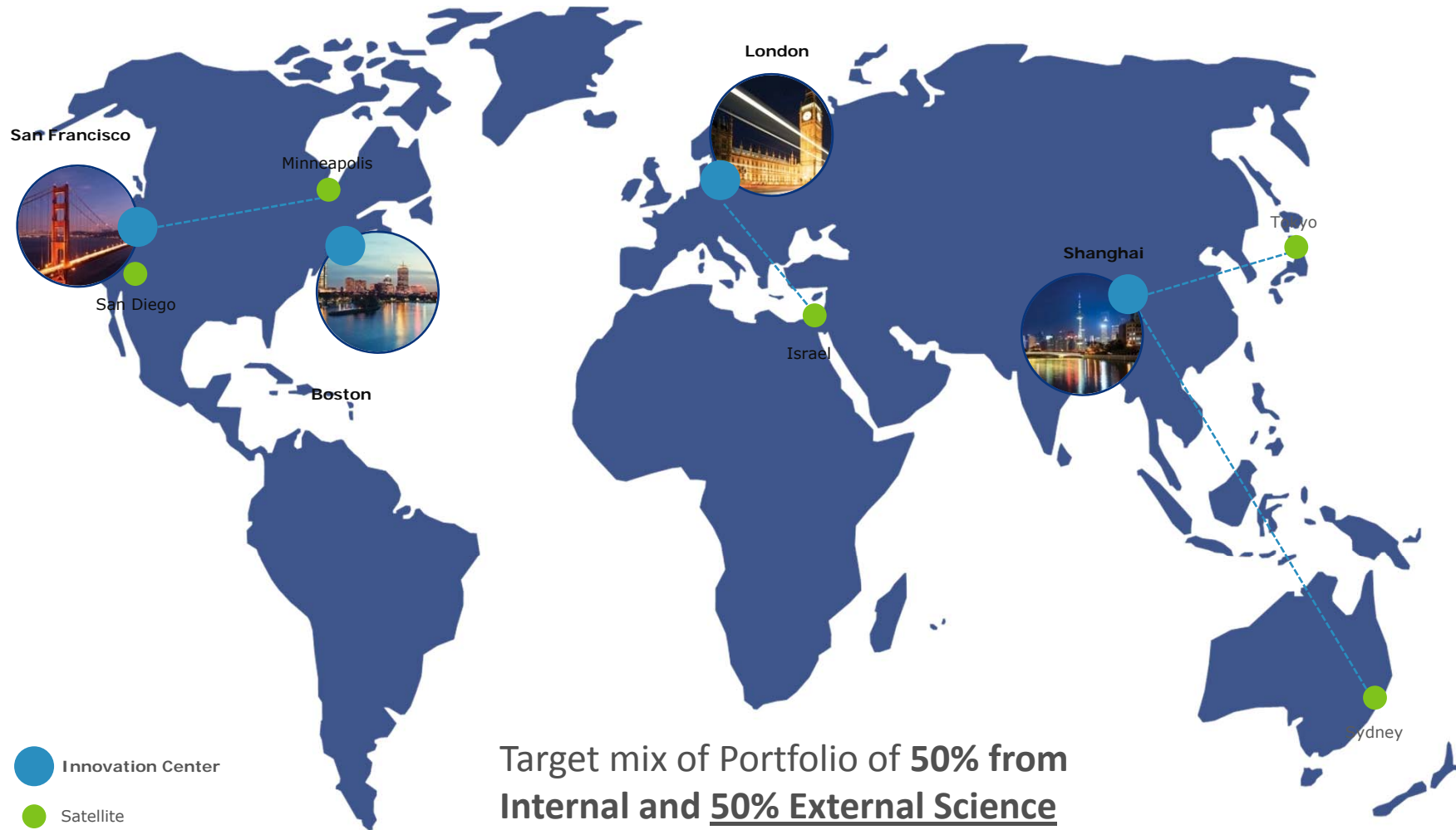
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PHARMACEUTICAL COMPANIES

OF *Johnson & Johnson*

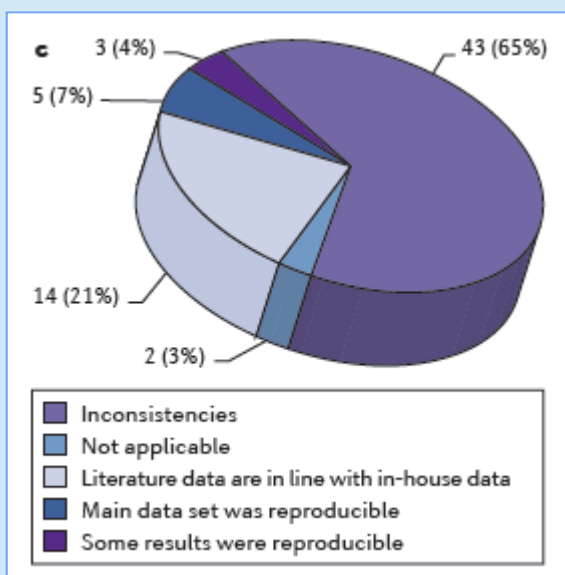


J&J's Shifting Strategy: Innovation Centers (2012)



Increasing Awareness & Challenges...

Issues with data integrity in research environment



Only **25 %** Studies in in-house projects reproduced at Bayer

(Oncology, Women's Health, Cardiovascular)

Prinz, F., Schlange, T. and Asadullah, K. 2011. *Nature Rev. Drug Discov.* 10, 712.

Many landmark findings in preclinical oncology research are not reproducible, in part because of inadequate cell lines and animal models.

Raise standards for preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

Of 53 Oncology landmark studies, in only 6 cases the scientific finding were confirmed (**11 %**)

(In these 6 studies, the authors had paid close attention to controls, reagents, investigator bias and description of the complete data set)

Begley, C.G. and Ellis, L.M. 2012. *Nature* 483, 531-533.

Increasing Awareness of...

Issues with data integrity in Research environment

GlaxoSmithKline Fires China R&D Boss for 'Misrepresented' Data

Dan Mangan | @_DanMangan
Tuesday, 11 Jun 2013 | 6:35 PM ET



Francois Lo Presti | AFP | Getty Images

Anonymous email tip prompted an investigation that determined data used in a 2010 research paper were "misrepresented,"

Increasing Awareness & Challenges of...

Issues with data integrity in Research environment



Science 4 April 2014:
Vol. 344 no. 6179 p. 23
DOI: 10.1126/science.344.6179.23

NEWS & ANALYSIS

STEM CELL RESEARCH

RIKEN Panel Finds Misconduct in Controversial Paper

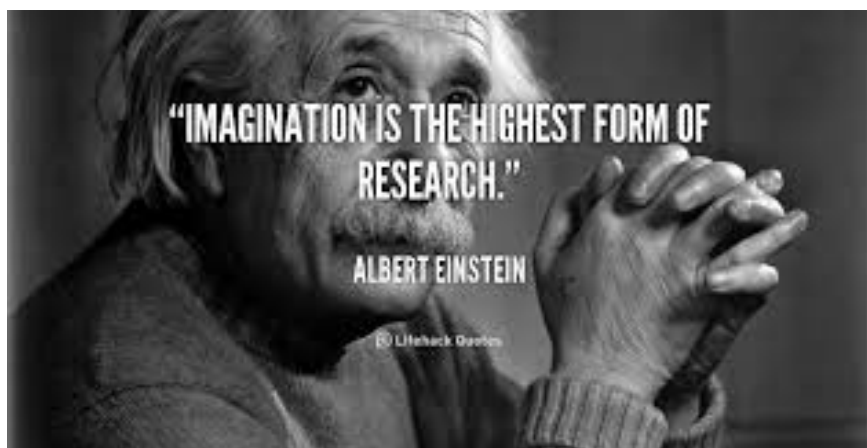
- Jan 2014: RIKEN (Japan's biggest research institute) reports (Nature) easy way creating stem cells
- Bloggers immediately indicated possibly manipulated images
- Replication was not possible & fraud was found + lack of management oversight and push for breakthrough results
- RIKEN's Center for Developmental Biology was stripped of half its staff, renamed and placed under new management.

<http://news.sciencemag.org/asiapacific/2014/04/riken-panel-finds-misconduct-reprogrammed-stem-cell-papers>

Janssen's DDI initiative: Approach

Finding the Balance...

Innovation & Quality



DDI Discovery
Data Integrity

$$\Sigma [i(A) + T(H) * R(D)]^2$$

I-INTEGRITY
A-ACCURACY T-TRACEABILITY
H-HONESTY R-RECONSTRUCTABILITY
D-DOCUMENTATION

The Janssen unique formula
for scientific excellence.

*Innovation
Research
Exploration*



*Integrity
Accuracy
Reconstructability*

<http://74211.com/Great-Man-Wallpaper-Albert-Einstein-Imagination-is-More-Important-than-Knowledge-1280X1024-free-wallpaper-download/>

Janssen's Discovery Data Integrity (DDI)

- Started in 2011: Baseline analysis of practices/systems across legacy J&J Pharmaceutical family of companies
- Motivation: Only "healthy data lead to healthy patients"
- Key words:
 - Accuracy
 - Traceability
 - Reconstruction
 - An unbiased approach
 - Open scientific collaboration

Janssen's DDI Initiative – Cross-Company Baseline Practices/Systems Analysis

Outcome:

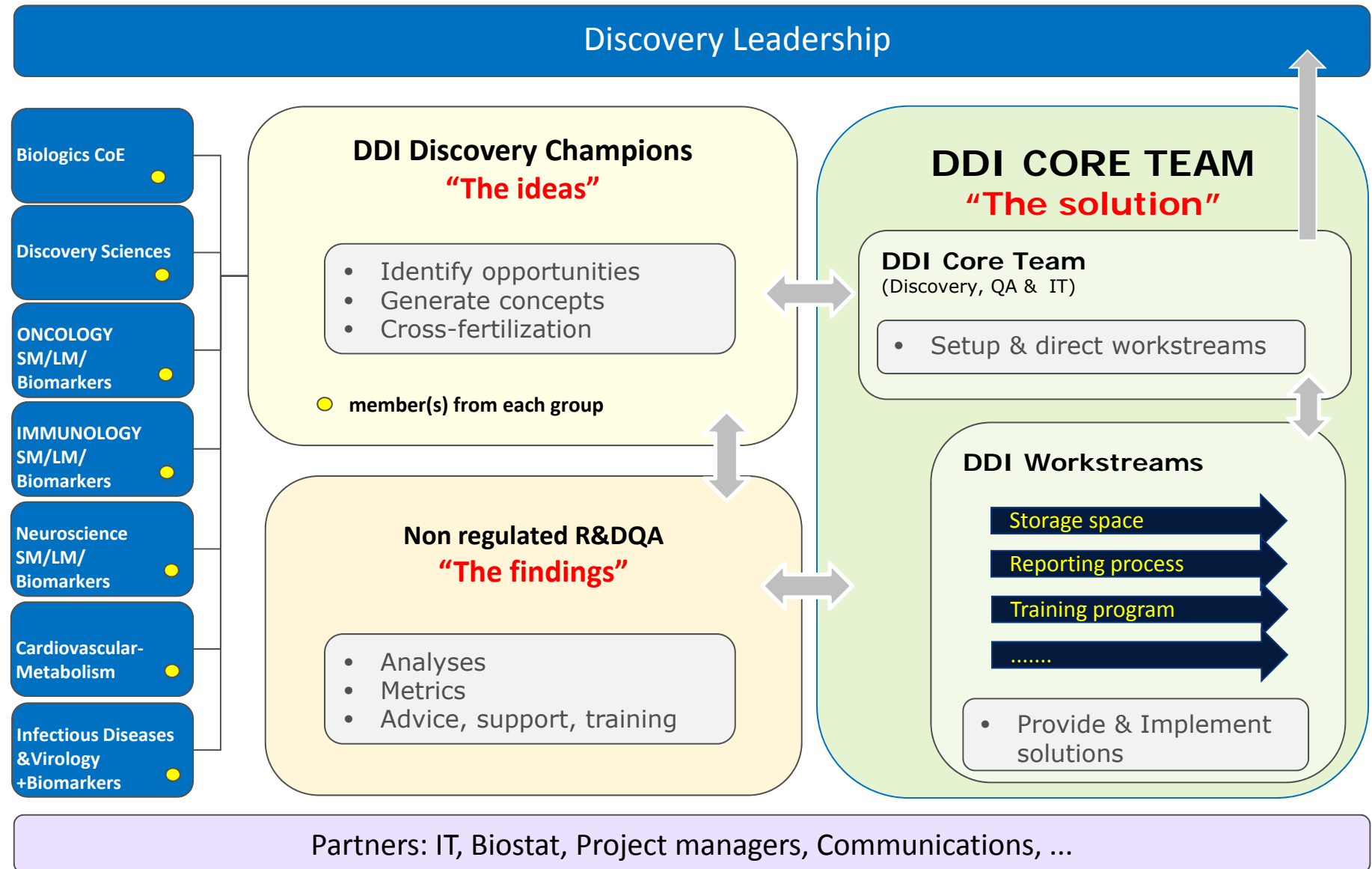
- Highly motivated scientists eager to share best practices
- Cross-functional collaboration to improve systems
- Momentum for change

Gaps identified across various locations/business groups

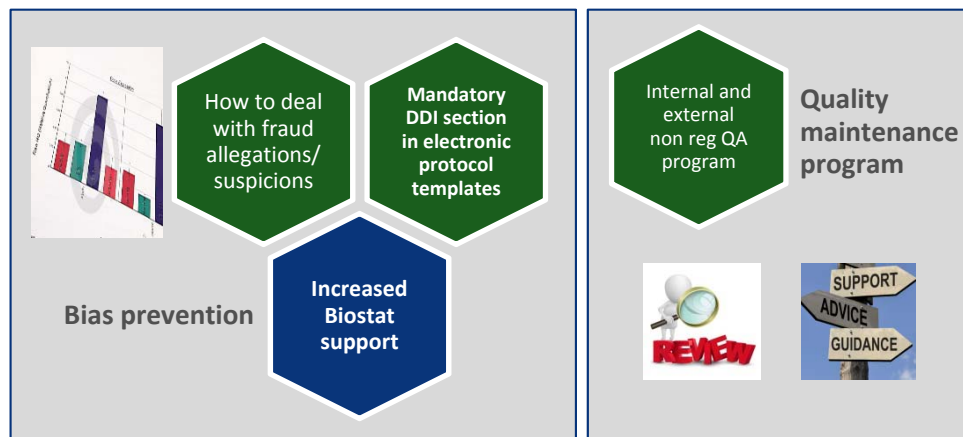
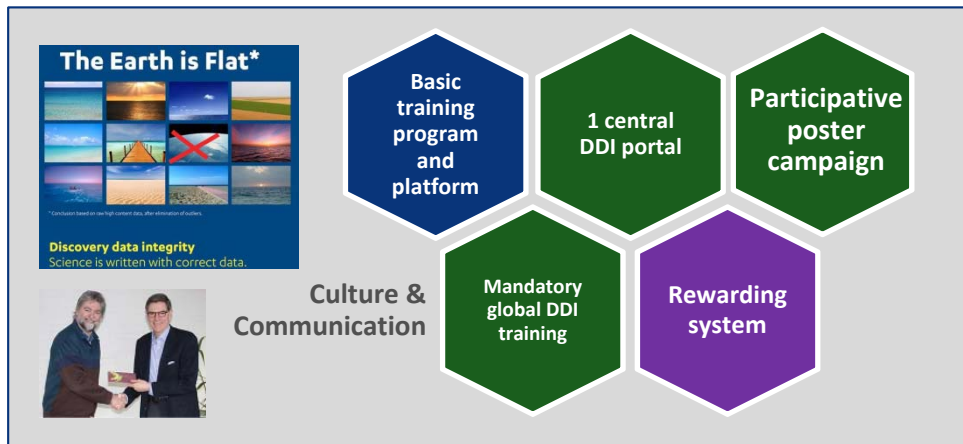
- Variety of **data management systems** and processes, some more adequate than others
- Storage space issues (want to keep everything, without archiving)
- Limited support from biostatisticians
- Opportunity to improve cross referencing/linking data for easy retrieval



DDI community model



15 DDI workstreams



- Planned
- Proposal in review by Janssen Discovery leadership
- Implementation phase
- Fully implemented

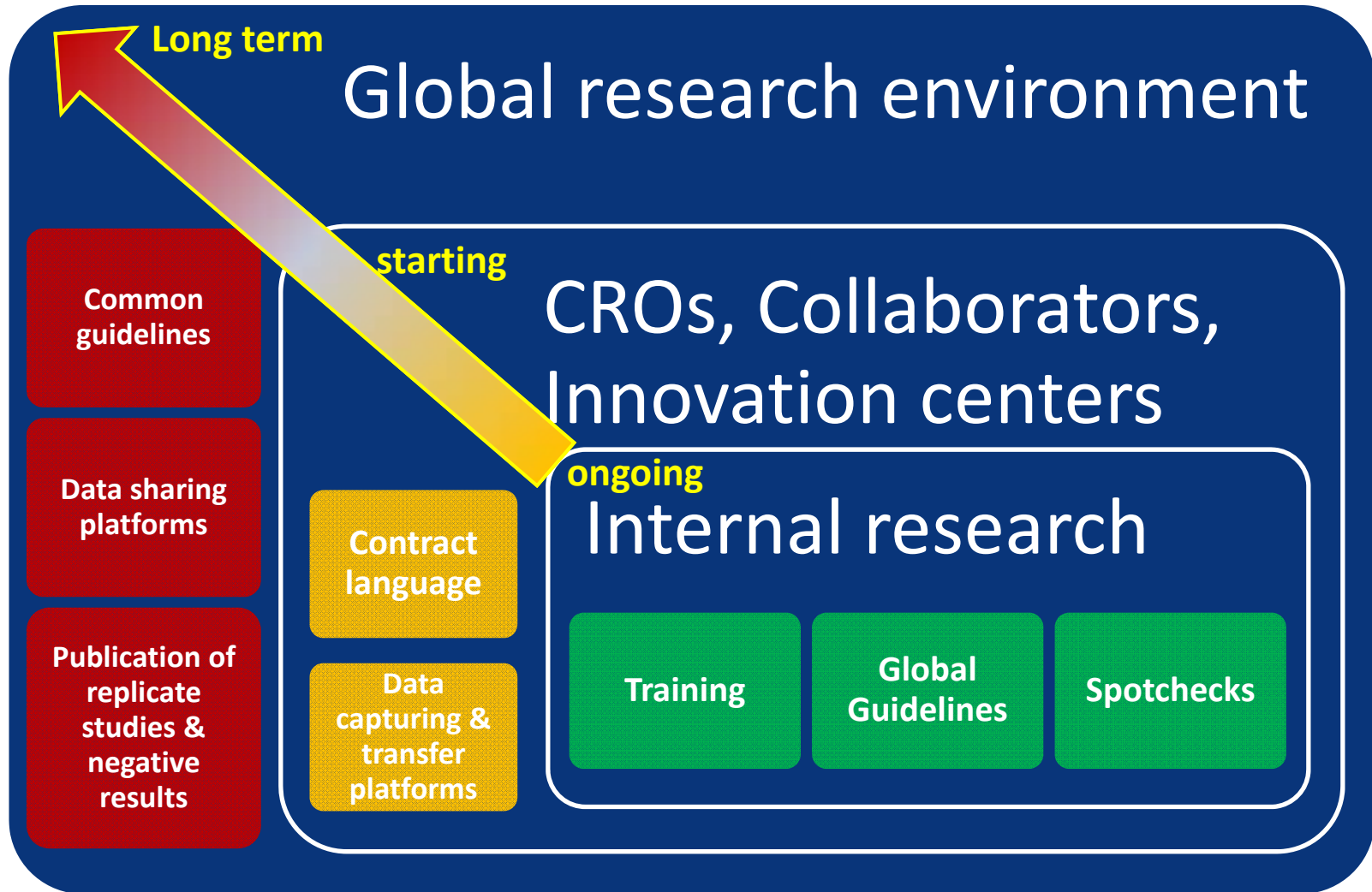
Janssen's DDI initiative: Key success factors

Key success factors

- Role Models: Senior leaders sponsorship & support
 - *“Talking the talk, walking the walk”*
- Mandatory education for all staff
- Community participative poster campaigns
- Partnerships: QA, IT, Biostatisticians, Communications, ...
- Simple, sustainable solutions and *“fit for purpose”* guidance
 - By scientists, for scientists
- Transparency: central data sharing
- Spot check program (= measure of success)
- Speak up culture (hotline)

Janssen's DDI initiative: Broadening our scope

Broadening our scope



Ongoing: Training & guidelines

- Training to scientists and QA personnel (external)
 - International societies
 - Janssen collaborators
- Participate & present in international conferences:
 - Scientific: ECNP, FWO, ...
 - QA: RQA, SQA
- Contribute to guidelines (RQA)



Co-ordinate the development of
common European standards



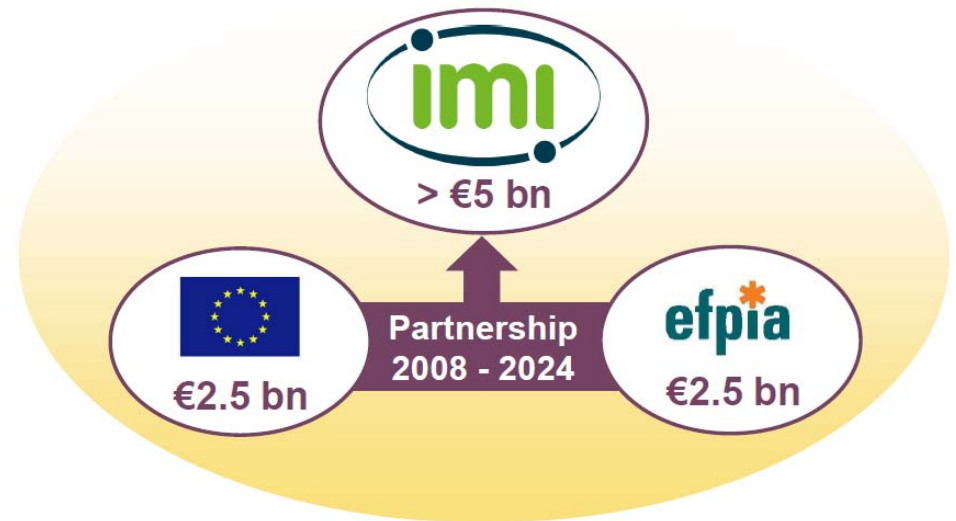
<http://www.therqa.com/>

Short term: IMI Project 'proposal'

What is the Innovative Medicines Initiative (IMI)?

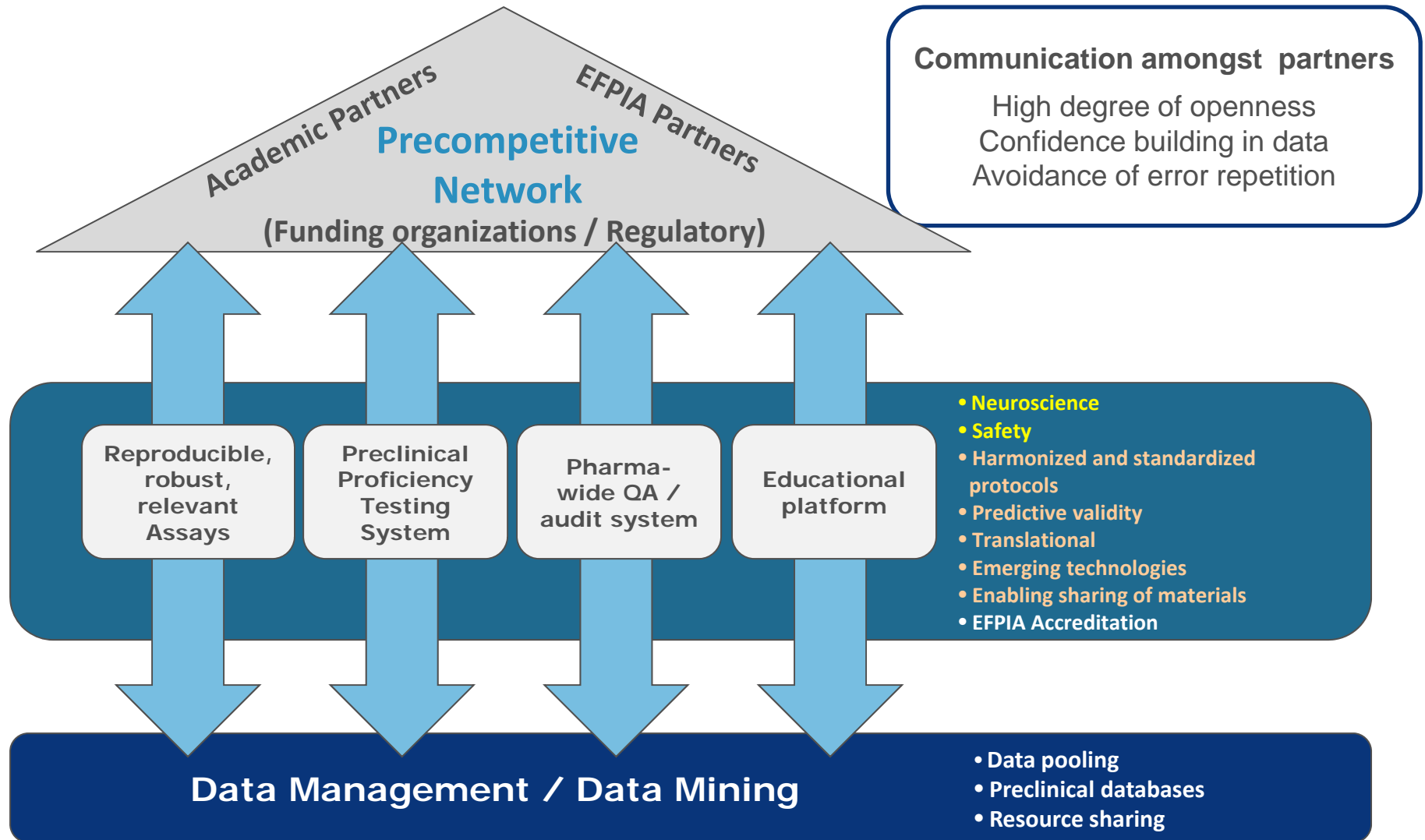
Key Concepts:

- 1) Focus on unmet needs
- 2) Non-competitive collaborative research
- 3) Competitive Calls for proposals
- 4) Open collaboration in public-private consortia
 - a) Data sharing, dissemination of results...
 - b) Material / model sharing
- 5) Industry contribution is in kind
- 6) IMI: Collaboration by design



<http://www.imi.europa.eu/>

Improving Data Quality as Key Deliverable in 'NeuroSafe' IMI Initiative 'Proposal'



Similar initiatives in clinical space to open sharing of data (Jan 2014)



Clinical Trial Data Sharing Agreement with Yale School of Medicine's Open Data Access (YODA) Project

A new approach to evaluation and transparency

Yale School of Medicine will serve as an independent body to review requests from investigators and physicians seeking access to Janssen clinical trials

<https://www.inj.com/news/all/johnson-and-johnson-announces-clinical-trial-data-sharing-agreement-with-yale-school-of-medicine>

TransCelerate BioPharma

Joint effort between Janssen & nine other companies

Non-profit organization focused on advancing innovation in R&D, identifying and solving common R&D challenges and further improving patient safety



<https://www.inj.com/news/all/janssen-research-development-announces-establishment-of-global-cross-pharmaceutical-clinical-trial-investigator-databank>

Long term

- Will soon all pharmaceutical companies be auditing their partners, collaborators ?
 - Need for common guidelines (WHO, RQA, Universities, Pharmaceutical companies, National research offices, ...) ?
 - Time to bring these together and develop 1 set of guidelines ?
- Can we help since our guidelines:
 - Were made in collaboration with scientists and QA
 - Are simple
 - Are proving to be successful
-



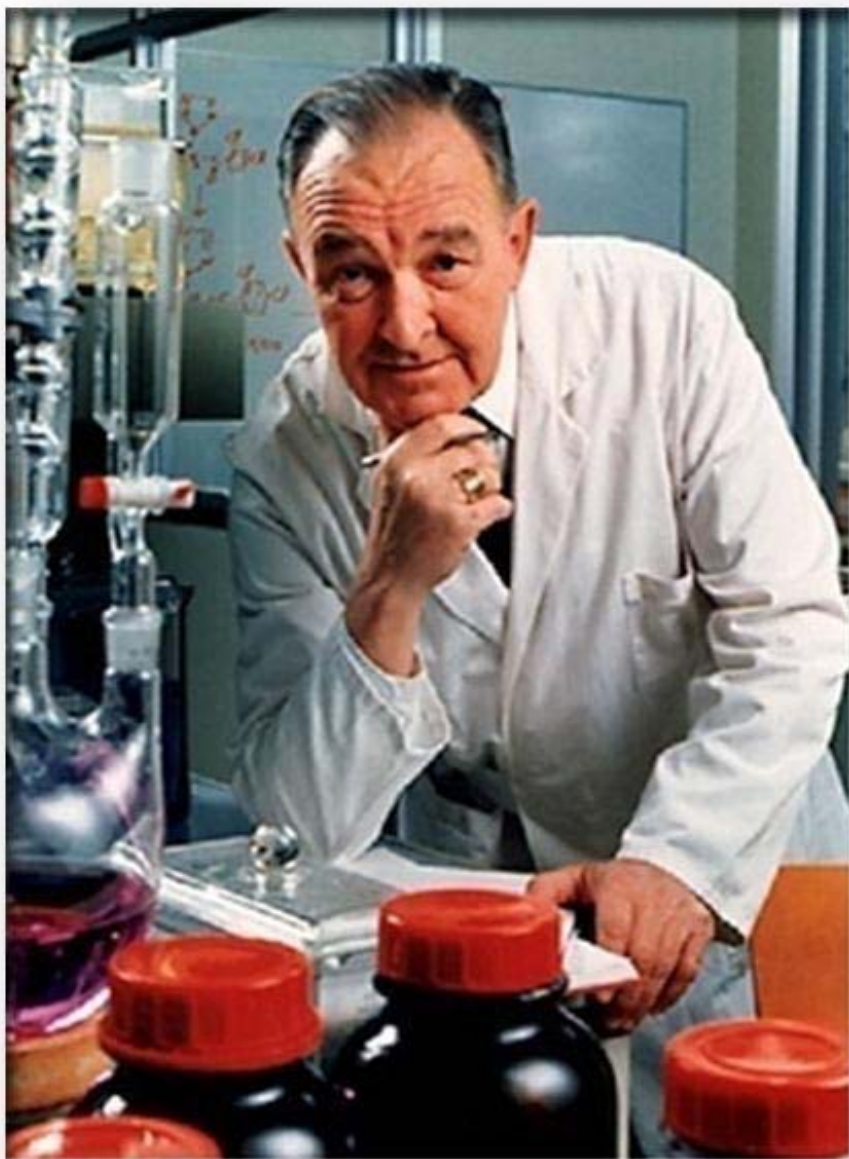
The world is our laboratory



Our ultimate goal is to make a difference for patients by identifying the most promising opportunities and collaborating with the best minds in the world to develop innovative new solutions to advance healthcare in society

We are all in this together.... !





“

**There's so much
more to be done.
Patients are waiting.**

–Dr. Paul Janssen

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**Obrigado !
Thank you !**