Monitoring Good Research Practices in discovery labs

A model to foster quality of scientific data in a pharmaceutical setting

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Disclaimer

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

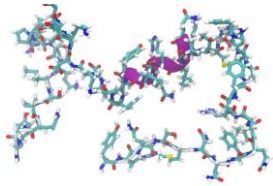
Janssen

Setting the scene

- Basic Research
- Pharmaceutical industry

- **Scientific community**
  - →Invention of new drugs
  - →Non-Regulated experiments

- **Quality Assurance**
  - →Independent team within Janssen
  - →Monitoring, fostering, promoting Good Research Practice



New Molecular Entity

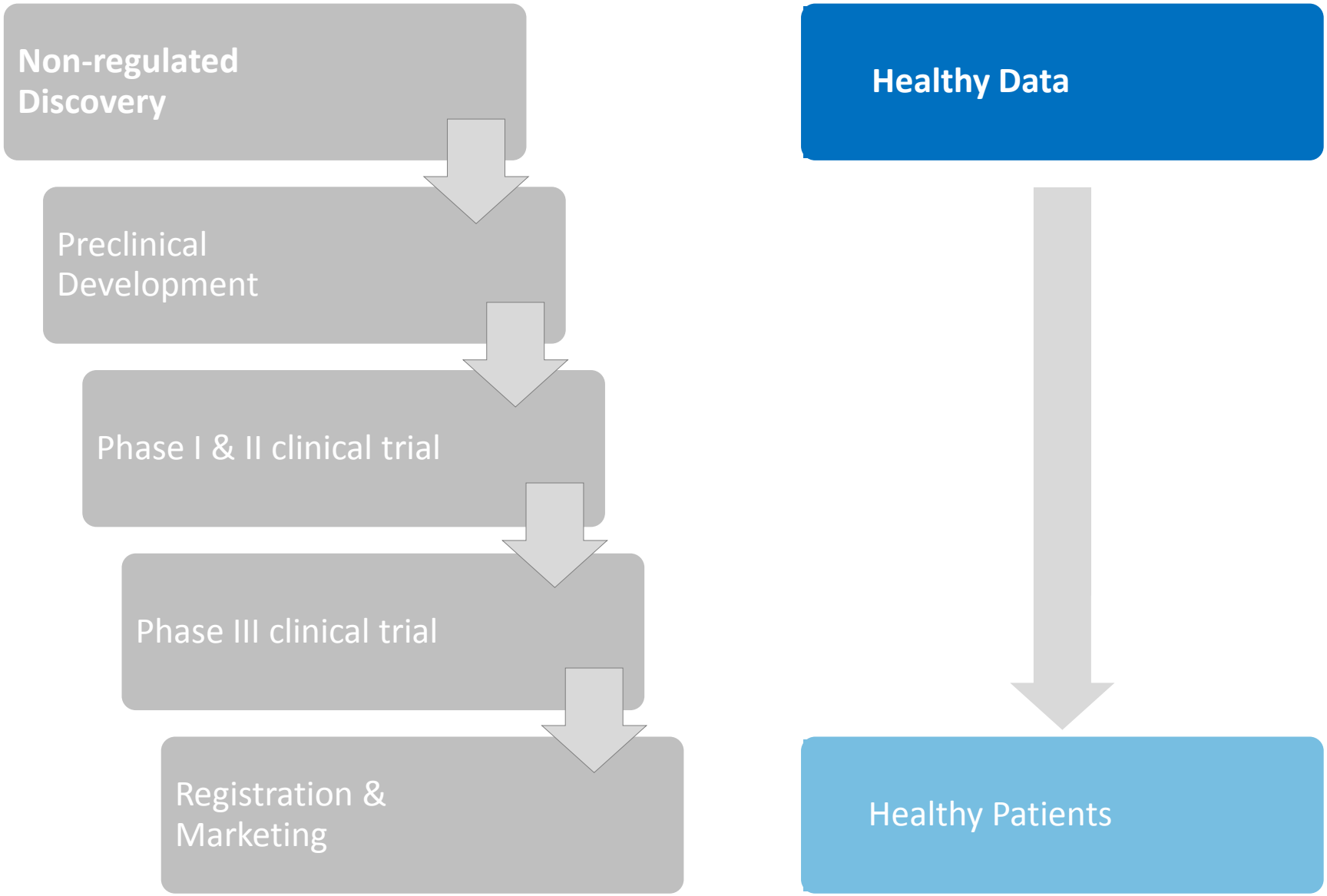
Non-regulated Discovery

Preclinical Development

Phase I & II clinical trial

Phase III clinical trial

Registration & Marketing


Non-regulated
Discovery
Preclinical
Development
Phase I & II clinical trial
Phase III clinical trial
Registration &
Marketing
Healthy Data
Healthy Patients

DDI Discovery Data Integrity

Safeguard
data traceability
&
data integrity

Regulate & Monitor
and
Preventive actions

Speeding tickets, …

Speed bumps, sensibilisation, …

Guidelines & Spot Check program

Training, awareness, quality culture

What is our focus ?

Reproducibility

Full Disclosure
&
transparancy

Data integrity
&
No bias

Data storage
&
IT Tools

Patent
&
confidentiality

Outsourced
Science

Partnership with scientists

- Guidelines on data handling expectations
- Training Program
- Quality Culture
- Network with experts (IT, statistics, legal, …)

Spot Check program

- Internal & External Science
- Observations & follow up
- Classification & trending

Take home messages

- Healthy data leads to healthy patients
- Our Data handling guidelines create clarity on RCR
- Prevention and monitoring go hand in hand
- Be cautious not to inhibit innovative science

Thank you !

Tom Lavrijssen

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Abstract

- Monitoring Good Research Practices (GRPs) in a discovery research environment is critical in delivering needed and innovative therapeutics to patients.
- A pharmaceutical company's reputation, intellectual property protection and decision making all depend on high quality data. The growing number of publications on poor reproducibility and cases of scientific misconduct in preclinical research brings awareness to the potential elevated risks associated with discovery data generated both in house and with our external contractors.
- Compliance to Good Research Practices is therefore seen as important but can only be done after a careful consideration on what the minimal quality expectations are versus the risk on inhibiting innovative science. We have implemented a monitoring program on data traceability and data integrity as a way to identify any meaningful data quality risks and to improve on data quality in future experiments.

- By all means, in the absence of clear regulations, the endeavor to find and keep the right focus for this spot check program is a key to success, but at the same time we see this approach as a huge opportunity to enhance good research practices