

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.

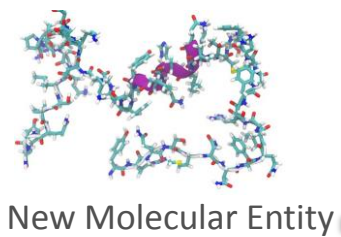


Setting the scene

- 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



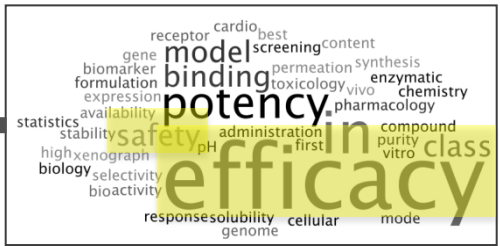
Non-regulated
Discovery

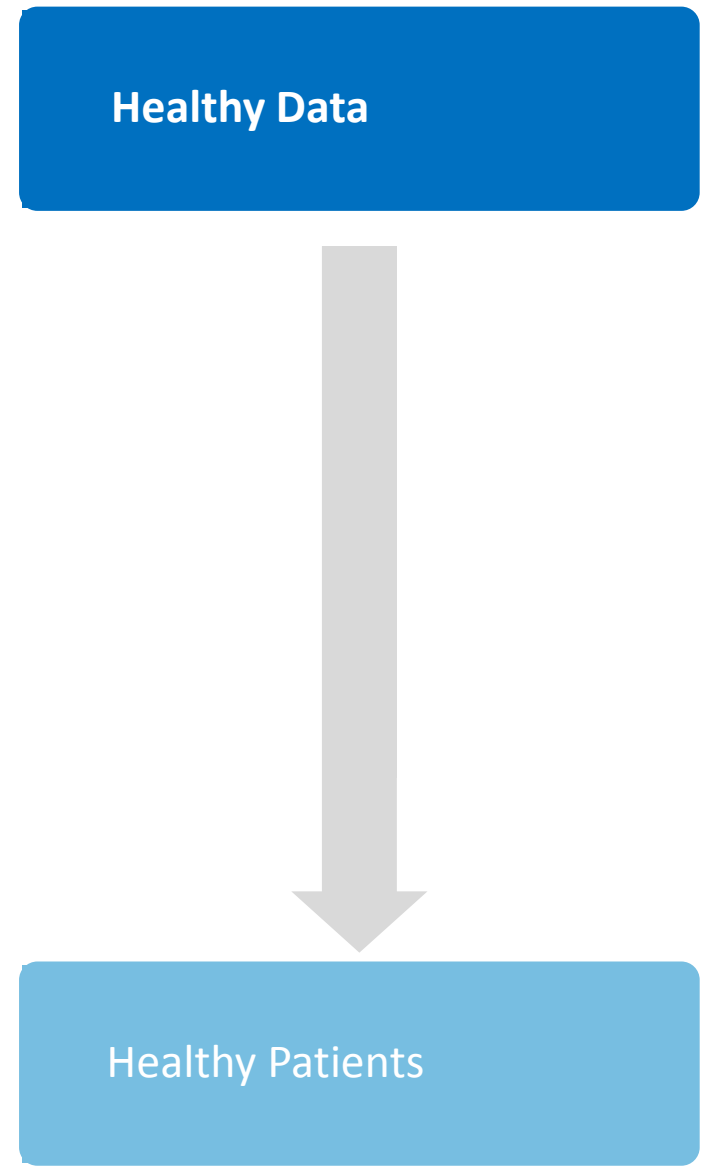
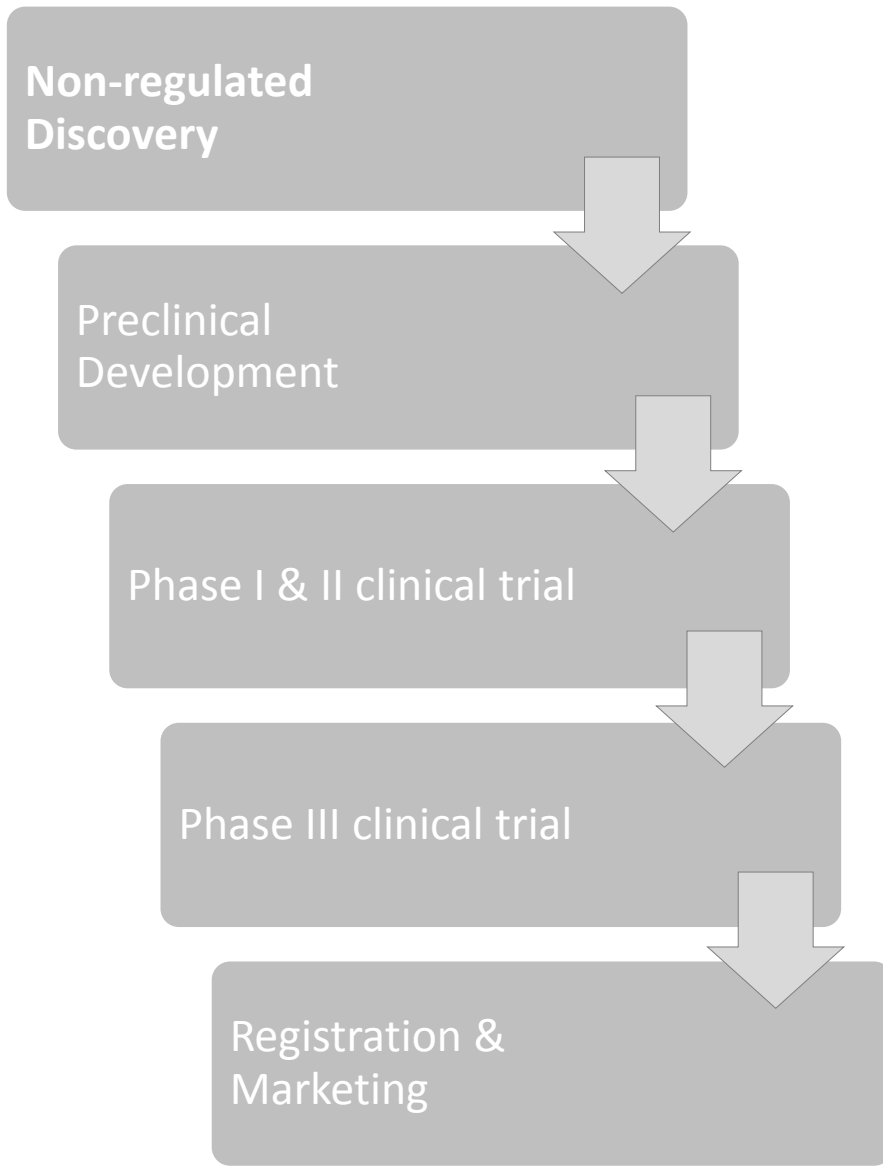
Preclinical
Development

Phase I & II clinical trial

Phase III clinical trial

Registration &
Marketing





EDITORIALS

POSTSCRIPTS More pay but fewer jobs on the way p.430

WORLD VIEW Treat antibiotic resistance as an ecological crisis p.430



OPINION Tiny flying robots with power to stick around p.441

Reality check on reproducibility

A survey of Nature readers revealed a high level of concern about the problem of irreproducible results. Researchers, funders and journals need to work together to make research more reliable.

Tackling reproducibility in academic preclinical drug discovery

Stephen V. Frye¹, Michelle R. Arkin², Cheryl H. Arrowsmith³, P. Jeffrey Conn⁴, Marcie A. Glucksman⁵, Emily A. Hull-Ryde¹ and Barbara S. Slusher⁶

The reproducibility of biomedical research on novel drug targets has become suspect.

How Do You Know It Is True? Integrity in Research and Publications

AOA Critical

Joseph A. Buckwalter, M.S., M.D., Vernon T. To

SWISS MED WKLY 2010;140(12-14):102-108 www.smmw.ch 18

Scientific integrity, misconduct in science

Emilie Bissel

President of the Scientific Integrity Committee of the Swiss Academies of Sciences, Berne, Switzerland

A call for transparent reporting to optimize the predictive value of preclinical research

Stacy C. Leachis¹, Susan G. Amsam², Khaguru Asadullah³, Chris P. Austin⁴, Robert B. Darnell⁵, Robert J. Ferrante⁶, Howard Fellin⁷, Robert Finkelstein⁸

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

Florian Prinz, Thomas Schlange and Khusrav Asadullah

A recent report by Arrowsmith noted that the to Yasuda/marketable, and the financial costs

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
&
transparency



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

Acknowledgments:

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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