QUALITY MANAGEMENT FOR ACADEMIC RESEARCH IN PRECLINICAL BIOMEDICINE: BURDEN OR BOON?
THE QUEST FOR QM IN ACADEMIC PRECLINICAL BIOMEDICINE

Ulrich Dirnagl
Let’s think about cognitive bias
The human brain’s habit of finding what it wants to see is a key problem for research. Establishing

Reproducibility: Seek out stronger science

• Monya Baker

Mona Baker

Nature 533, 703–704

An open mind on open data
The move to make scientific findings transparent can be a major boon to research, but it can be tricky to embrace the change.

Pow

size undermines the reliability of neuroscience

Replicative flaws
Strikes a good balance of research aims and the reliability of neuroscience

THIS WEEK

Science quality is hard to define, and numbers are easy to look at. Science — even Leaders at two how the

Fewer numbers, better science

The evidence clinical biostatistics from mentation on a fertile group

Acknowledging and Overcoming Nonreproducibility in Basic and Preclinical Research

Low statistical power in biomedical science: a review of three human research domains

Thirds are study, subjective, and researchers. Following the advice of their scientific advisors, will reveal. Over the past year, a series of measures have been undertaken and guidelines to boost the reproducibility of research. Encourage the exchange of ideas and other work, and share results. Smaller, more open research teams are likely to contribute to the advancement of science.

Muddled meanings hamper efforts to fix reproducibility crisis
Researchers tease out different definitions of a crucial scientific term.

Confidence in preclinical research
For decades, model systems have contributed to the mechanistic basis


"85% of health research is wasted.”

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

THE LANCET

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DUE DILIGENCE, OVERDUCE
Results of rigorous animal tests by the Amyotrophic Lateral Sclerosis Therapy Development Institute (ALS TDI) are less promising than those published. All these compounds have disappointed in human testing.

Scientific method: Statistical errors

Due diligence,

Overdue


"85% of health research is wasted.”

C. Glenn Begley and Lee M. Ellis: propose how methods, publications and incentives must change if patients are to benefit.
Factors antagonizing research quality in preclinical biomed

In academic medicine:
- Patients, research, teaching: „Research after hours“
- Supervisors also have clinical duties
- Many students (often without formal training)
- Little supervision - lack of professionalism

In general:
- Very complex biology, very complex methodology
- Structural underfunding (project funding often ok)
- Hypercompetition, publish or perish
Quality management to the rescue?
QM vocabulary (‘jargon’) is aversive to scientists

Audit - Audit Criteria - Audit Evidence - Audit Findings - Audit Program
Characteristic - Competence - Complaint - Concession - Conformity - Context
Continual Improvement - Contract - Correction - Corrective Action - Customer
Customer Satisfaction - Data - Defect - Design and Development - Determination
Documented Information - Effectiveness - Feedback - Function - Improvement
Information - Information System - Infrastructure - Innovation - Interested Party
Involvement - Knowledge - Management - Management System - Measurement
Measuring Equipment - Monitoring - Nonconformity - Object - Objective
Objective Audit Evidence - Objective Evidence - Organization - Output
Outsource - Performance - Performance Indicator - PDCA - Policy - Process
Process Approach - Process-based QMS - Product - Provider - Quality
Quality Management - Quality Management System - Quality Objective
Quality Policy - Regulatory Requirement - Release - Requirement - Review
Risk - Risk-based Thinking - Service - Statutory Requirement - Strategy
Supplier - System - Top Management - Traceability - Validation – Verification....
(Mis?)perceptions regarding QM in academia

- (Unnecessary) regulatory burden
- Drains (non-existent) resources
- Stifles creativity through standardization, SOPs, regulations...
- Leads to surveillance culture (Monitoring/auditing)
- etc.
ISO 9001 at the Department of Experimental Neurology

Dedicated team

Handbook

Management review

Regular meetings

and:

Q-Policy
Q-Aims
Risk assessment
Dokument control
and.. and.. and...

Structure

Surveys

Indicators

Audits

(Re)Certification

Continuous improvement cycles

Handbook review

Regular meetings

and:

Q-Policy
Q-Aims
Risk assessment
Dokument control
and.. and.. and...
A bespoke set of quality assuring measures for academic preclinical biomedicine

- modular
- scalable
- lean / frugal
- financeable
- acceptable to all professionals in the academic research system
- adaptable to the needs both of small work groups and to those of an entire institute
- does not stifle creativity and originality of researchers
- minimal bureaucracy, research oriented terminology
- supportive of daily scientific laboratory practice
- peer – auditable
- open source
- complementary e-learning / e-training
European Quality In Preclinical Data (EQIPD)

The European Quality In Preclinical Data (EQIPD) project proposes to pool resources from both academia and industry to develop a quality management system, facilitated by analysis of historical datasets.

Thomas Steckler
Malcolm Macleod
PREMIER Quality Management System for academic Biomedicine

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QUEST Mission Statement

.... to increase the value of biomedical research at BIH and beyond.
• **Quality assurance**: promote compliance of preclinical and clinical research with standards and guidelines on design, conduct, analysis and reporting.

• **Education**: develop and implement training and teaching resources on experimental and study design, methods to reduce bias, new modes of publishing, open science, etc.

• **Open Science**: improve the accessibility and transparency of BIH research and its results through Open access and Open data.

• **Meta-Research**: identify opportunities for improving research practice and obtain evidence for the impact of its activities through ‘research on research’.
QUEST Approaches

• **Rewards and incentives:** develop, implement, and assess the impact of novel indicators incentives and metrics to complement the current system for rewarding researchers, appropriating funding and awarding academic degrees.

• **Research for and with the public:** foster public outreach and public involvement in BIH research (Citizen science / Participatory health research).

• **Bioethics of translation:** implement innovative, scientifically informed policies and training modules for research quality and human protections.

• **Think tank:** act as advisors to stakeholders in biomedicine from funders to politics.
It’s all about behaviour change...

Figure 1 The COM-B system - a framework for understanding behaviour.

Michie et al. Implementation Science 2011, 6:42
Open issues

• How could a QMS for academic preclinical biomedicine look like?
• Will such a system be accepted in the academic environment?
• Where do the resources needed for it come from?
• Would the QM be effective?
• Or does it rather stifle creativity?
• Are other measures much more important? Are we treating a consequence, but not the cause of other problems?
• How can we measure how effective preclinical research QM really is?