

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





THE QUEST FOR QM IN ACADEMIC PRECLINICAL BIOMEDICINE

Ulrich Dirnagl

THIS WEEK

EDITORIALS

DRUGS New agreement to tackle pharmaceutical pollution p.164

WORLD VIEW Vaccination the best way to measure health care p.165

WIND OVER Rolling beetles fooled by look-alike seeds p.167

Let's think about cognitive bias

The human brain's habit of finding what it wants to find is a key problem for research. Establishing robust methods to avoid such bias will make results more reproducible.

Reproducibility: Seek out stronger science

• **Monya Baker**

Nature 537, 703–704

nature

DATA SHARING

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

Repetitive flaws

Strict guidelines to improve the reproducibility of experiments are a welcome move.

From next week, scientists who submit grant applications to the National Institutes of Health (NIH) will be asked to take more care. As part of an increasing drive to boost the quality of research, the NIH will require applicants to explain the premise behind their proposals and defend the quality of the mental designs. They must also account for biological variability, by including both male and female mice in planned experiments and describe how they will authenticate experimental materials as cell lines and antibodies.

These demands are timely, sensible and, if researchers follow the advice of their scientific societies, will sound. Over the past year, a string of organizations have published statements and guidelines to boost the reproducibility of research.

Collectively, the message is show your work, and don't rely on unreliable reagents or shoehorned data. Updated guidelines from the Federation of American Societies for Experimental Biology, for example, call for standard ways to cite antibodies and animal-care practices. The Society for Neuroscience has asked for random sampling of cell lines and antibodies.

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.

Fewer numbers, better science

Scientific quality is hard to define, and numbers are easy to look at — but they can be misleading. Leaders at two institutions are trying to change the way they do science.



QUALITY TIME

IT MAY NOT BE SEXY, BUT QUALITY ASSURANCE IS BECOMING A CRUCIAL PART OF LAB LIFE.

WORKPLACE CLIMATE

Metrics for ethics

Focus on perceived working conditions could help graduate schools to train responsible researchers.

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Research



Confidence in preclinical research

For decades, model organisms have been used to study the mechanistic basis of disease. But the results of these studies are often inconsistent, leading to a loss of confidence in preclinical research.

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

Acknowledging and Overcoming Nonreproducibility in Basic and Preclinical Research

The evidence from clinical biomedicine suggests that a fertile ground for research is being lost.

REPRODUCIBILITY Twenty teams, one data set, one question, many answers.



nature

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NATURE | NEWS

Missing mice: gaps in data plague animal research

Reports of hundreds of biomedical experiments lack essential information.

Hide results to seek the truth

More fields should, like particle physics, adopt blind analysis to thwart bias, urge Robert MacCoun and Saul Perlmutter.

ICE

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

EDITORIAL

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Archive | Volume 506 | Issue 7487 | News Feature | Article

NATURE | NEWS FEATURE

Scientific method: Statistical errors

les in their efficiency and complexity of the research.

DUE DILIGENCE, OVERDUE

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

Perrin S (2014) Nature 407:423–425

Riluzole*

Creatine

Published†
ALSTDI

THE LANCET

"85% of health research is wasted."

NATURE | VOL 533 | 26 MAY 2016

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.

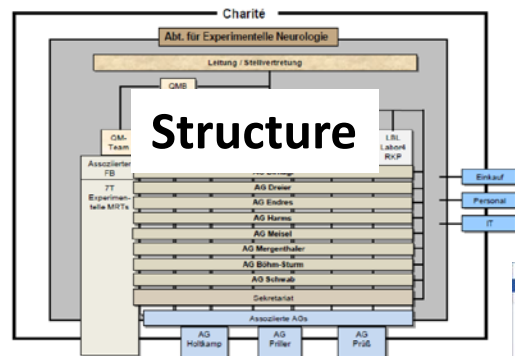




ISO 9001 at the Department of Experimental Neurology



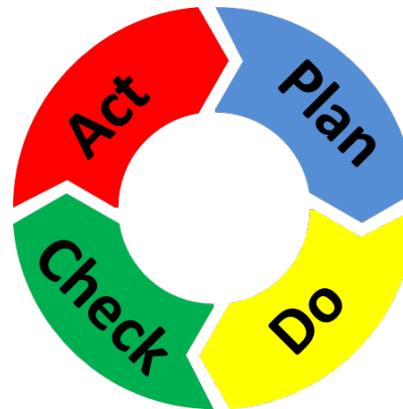
Dedicated team



Structure

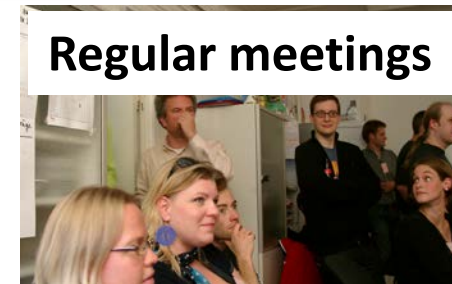
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Experimentelle Neurologie	
QM-Handbuch - Allgemeiner Teil	
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Handbook



Abteilung für Experimentelle Neurologie des Charité - Berlin (ENB)	
Management Review 2016	
Qualitätsbericht	
Berichtszeitraum: 01.01.2015 - 31.12.2015	
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Management review



Regular meetings

4. Disagree
5. Strongly disagree

Ability to use mobile devices (Tablets / Smartphones as input devices for the ELN)

1. Strongly agree
2. Agree
3. Neither agree nor disagree

4. Disagree
5. Strongly disagree

Ability to use templates for recurring types of entries (standard procedure)

1. Strongly agree
2. Agree
3. Neither agree nor disagree

Surveys

Wissenschaft		Kommunikation QM 2015		Anleitung		Wissenschaft	
Stellenangebot / Stellenausschreibung	Stellenangebot / Stellenausschreibung	Anzahl Bewerberinnen / Bewerberinnen	Anzahl Bewerberinnen / Bewerberinnen	Anzahl Bewerberinnen / Bewerberinnen	Anzahl Bewerberinnen / Bewerberinnen	Anzahl Bewerberinnen / Bewerberinnen	Anzahl Bewerberinnen / Bewerberinnen
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Indicators



**Audits
(Re)Certification**

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



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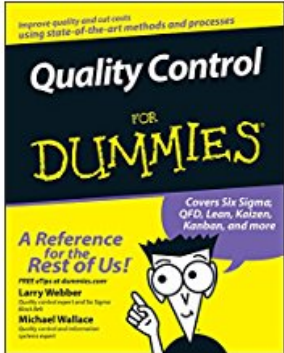
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QUEST Mission Statement



.... 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’.



- **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).

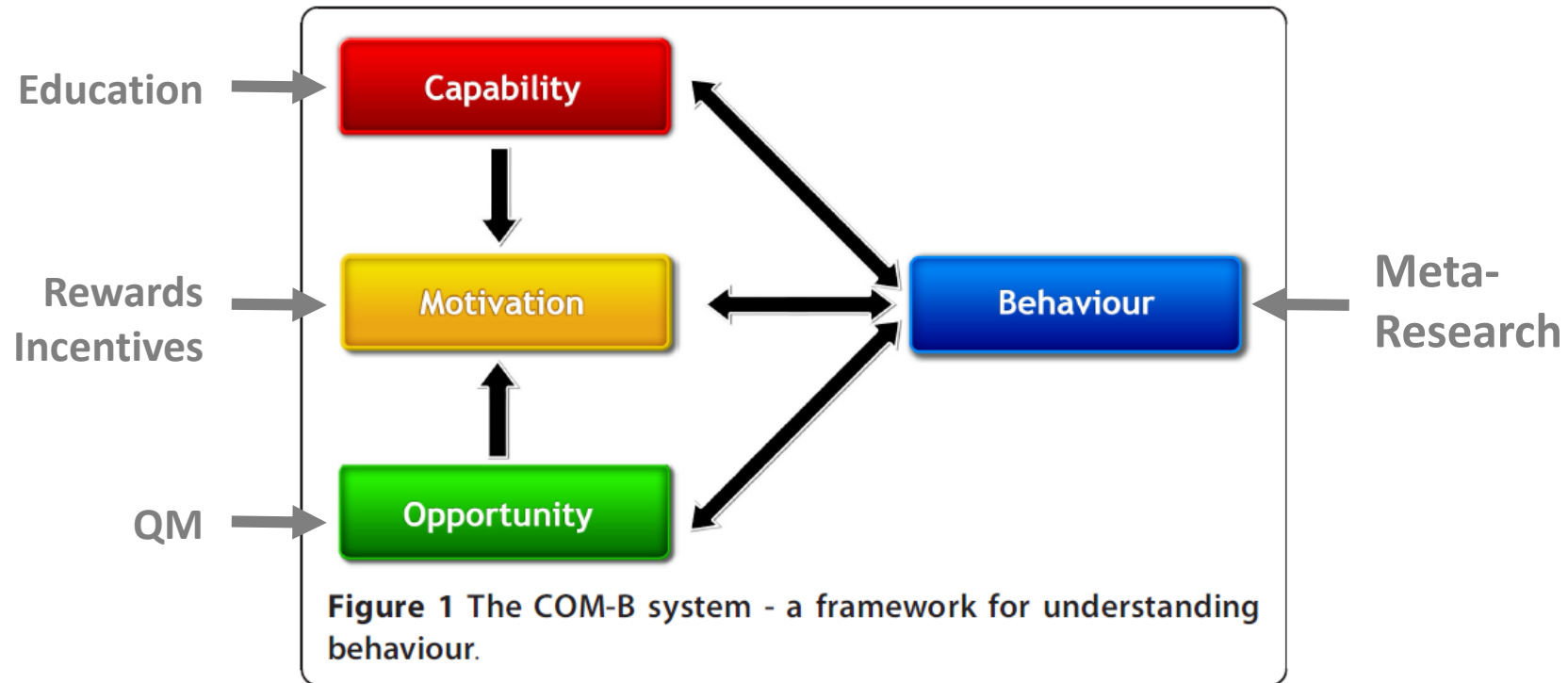


- **Bioethics of translation:** implement innovative, scientifically informed policies and training modules for research quality and human protections.



- **Think tank:** act as advisors to stakeholders in biomedicine from funders to politics.

It's all about behaviour change...



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?