BIH QUEST CENTER FOR TRANSFORMING BIOMEDICAL RESEARCH

Quality | Ethics | Open Science | Translation

Paving the way to robust and reproducible research
Dr. med. Miriam Kip, MPH

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QUEST Mission

... to increase the value of biomedical research at the Berlin Institute of Health (i.e. Charité and Max Delbrück Center) and beyond.
Power failure: why small sample size undermines the reliability of neuro studies

Muddled meanings hamper efforts to fix reproducibility

Repetitive flaws

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

For decades, model important reduction in the mechanistic basis of research, the prime behind it mental designs examples, by lack and describe how at cell lines and a. These ensure the ad continuing the ad Over the past year statements and g Collectivity & self with unrelated from the federal for example, cell practice. The Se of these flaws
Our meta-analysis suggests an apparent lack of evidence of efficacy in animals in data collected before the start of the recent phase 2b trial in South African children that enrolled children between 15 July 2009 and 4 May 2011,” the authors wrote.

“SR of 8 studies showed no efficacy of the vaccine...”
QUEST Approaches

- Open Science
- Education
- Quality Assurance
- Incentives
- Stakeholder Engagement
- Meta Research
QUEST Structure

QUEST-Center
Founding Director: Prof. Ulrich Dirnagl

Research
- Transforming biomedical research
- Meta-research

Office
- Bioethics of translation
- Visiting fellows

Infrastructures & Services
- Projects
Services & Initiatives

- Electronic lab notebook
- Awards: Open Science, NULL, Preregistration
- Protected writing time
- Courses (scientific programming, Open Data)
- MERIT QUEST Criteria
Incentives and indicators - Research assessment

Indicators:
- JIF, RCR
- 3rd party funding
- number of publications
- number of patents
- author position

"Confluence of interests"

Verwertung
Auswahl der Fragestellung
Berichten und publizieren
Auswertung

Design und Durchführung
rewards hiring funding

Translation
Science-based, iterative policy implementation project that aims

• to incentivize robust research mechanism by introducing

1. Responsible indicators (QUEST criteria)
2. Robust evaluations

into the institutional research assessment for funding, hiring and promotion at BIH/Charité

-> to increase patient-oriented translation
MERIT – areas of implementation

1. Intramural funding schemes
2. Hiring of professors
3. Performance-based funding (LOM)
4. Doctoral programs
Two basic assumptions

• Robustness and reproducibility precede patient-oriented translation

• Robustness and reproducibility are multifactorial
Responsible indicators – robust evaluations

QUEST criteria

- different sets i.e. for animal studies, clinical studies
- relating to the mechanisms of robust research in 4 dimensions:
  a) Priority setting /Scientific Premise
  b) Strategies for establishing scientific rigor
  c) Transparency and dissemination of results
  d) Stakeholder engagement

Good evaluation practice guidelines

- **WHAT** research, researcher, environment?
- **WHY** to detect robust and reproducible research
- **HOW**
  - transparent, multidimensional criteria
  - anonymous evaluation
    1) independent reviewers
    2) consensus
  - transparent feedback

CURRENT STATE: feasibility phase/development phase
• **Priority setting /Scientific Premise**
  Systematic review of the evidence/literature
  SYRCLE
  Database search: registries
  Replacement

• **Strategies for establishing scientific rigor**
  e.g. Strategies to reduce risk of bias
  sex /gender consideration
  Reduction

• **Transparency and dissemination of results**
  (Pre)registration
  Reporting guidelines (ARRIVE)
  Timeline reporting of all results
  Layperson comprehensible version

• **Stakeholder engagement**

**CURRENT STATE:** feasibility phase/development phase
1. MERIT - Intramural funding schemes (BIH)

• Proof of concept QUEST criteria (2/2018-01/2019):
  • introduction to all major funding schemes
  • over 120 applications, 9 board meetings
  • approval of the BIH board

• Analysis, adaption
  
  -> status quo of current practices related to QUEST criteria
  
  → relevant for selection for funding
  
  → relevant for concept for educational measures
  
  -> different sets of QUEST criteria (resp. study design, research question)

• Development good evaluation practice guidelines
“The Charité attaches great importance to transparent, replicable research and supports the objectives of Open Science (Open Access, Open Data). This includes the registration of studies in registries (clinicaltrials.gov, DRKS, etc.), the preregistration of studies, and the publication of negative and zero results. How have you been pursuing these goals so far and what are your plans for the future?”
3. MERIT – performance-based funding
Open data LOM 2019

- Successful implementation of new indicator “open data” in LOM system Charité (and equivalent for MDC researchers)

- First medical faculty in Germany
  - Development of ODD Algorithm (Riedel, Bobrov, Kip)
  - Retrospective identification of publications with Open Data in institutional publications record (PURE and FACT Science)
  - ca. 3% of all journal articles (2015-2017) with open data (Charité)

- Next Step: Preregistration in LOM by 2021
Awards

The QUEST 1,000 € Preregistration Award

*Preregister your preclinical studies challenge – Increase the credibility of your results and get early credit for your ideas!*

The QUEST Center supports the preregistration of planned preclinical studies. Preregistration increases the credibility of results, the conclusions based on them, and secures the originality of ideas and hypotheses before experiments have been performed.

QUEST is offering **15 awards of 1,000 €** to first/last/corresponding BIH, MDC or Charité authors of preclinical research papers containing preregistered (basic or translational, not clinical) studies.

The QUEST 1,000 € NULL results and Replication study Award

*Publish your NULL results – Fight the negative publication bias!*

*Publish your Replication Study – Fight the replication crises!*

The QUEST Center supports the publication of results which do not support the initial hypothesis, so called NULL results, sometimes unfairly labelled as ‘negative studies’. We also want to promote the publication of studies with the explicit attempt to replicate own results or the results of others.

QUEST is offering **15 awards of 1,000 €** each to first/last/corresponding BIH, MDC or Charité authors of research papers in which the main result is a NULL or ‘negative’, or in which the replication of own results or the results of others is attempted. Basic, translational as well as clinical studies are eligible.

THE QUEST 1,000 € OPEN DATA REUSE AWARD

*Make use of Open Data!*

Open data sharing to increase robustness and value in biomedical research is becoming increasingly common. It is requested by many funders and journals, and both the Charité and the MDC have also signed the Berlin Declaration, which endorses the open sharing of research data. The rapidly growing amount of openly available data has also spurred the development of dataset search engines, which allow the location of relevant datasets. Corresponding to this...
QUEST Protected writing time

• in cooperation with GB Forschung
• identifies potential candidates for up to 3 months protected time to finalize a first DFG-application

• criteria (selection):
  • research output (minimum of three 1\textsuperscript{st} author publications in the past 5 years)
  • AND minimum of 2 QUEST criteria shown in at least one of the publications
  • women - men ratio 1:1
Institutional publication record (PURE)

- Set up of a comprehensive, continuously updated monitoring instrument of the institutional research output
- Reporting of status quo and trends regarding, e.g.
  - Open science (open data, open access)
  - Preregistration
  - Null results and replication
  - Gender
  - Internationality
Science base MERIT

- Theory validation
  Development QUEST criteria and Good evaluation practice guidelines
  - systematic review of the literature, relevant documents (incl. grey literature, policy documents, reviewer guidelines etc.), expert opinions
  - iterative testing and validation
- Implementation
  Introduction to the field
  Data collection and analyses (applications, publication records, field notes, interviews etc.)
- Capacity building
  Teaching measures, tools, services
- Program evaluation and analysis
  Infrastructure, process and outcome evaluation
Policy implementation plan MERIT

- Need and field assessment of the institutional incentive structures
  - identification of relevant areas
  - mapping of the areas (stakeholders,
    - legal or other requirements (approvals, data protection etc...)
    - attending relevant board meetings, committees, trust building

- Agenda and strategy setting
  - engagement of relevant stakeholders
  - development action plans
  - trust building

- Introduction to the field
  - to funding schemes, hiring commissions etc...
    - data collection, document analyses, field notes, interviews
    - development and introduction of teaching measures

- Adjustment
• Wissenschaftsrat 2018 QUEST`s Development of new criteria for the assessment of research “best practice”

• DORA: MERIT hiring commission project among top 10 most promising projects in 2018
THANK YOU!

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