Scientist-Specific Solutions to Research Accountability Concerns

Rebecca Davies, PhD
Associate Professor
Director, Quality Central
University of Minnesota
College of Veterinary Medicine
St. Paul, Minnesota USA

Image: Mark Airs/Getty Images

University of Minnesota Clinical and Translational Science Institute

rdavies@umn.edu

Quality Central

Sharpening the focus on sound science and quality practices

Career Development Seminar Series:
Promoting and maintaining a culture of research accountability

February 13, 2018

Scientist-Specific Solutions to Research Accountability Concerns

Image: Mark Airs/Getty Images

1. Jan 26 2018: Scientific Sea-Change? Responding to the clarion calls for improved research rigor.

2. February 13, 2018: Scientist-Specific Solutions to Research Accountability Concerns.

3. April 13, 2018: Managing research data to improve research reproducibility.

Quality Central

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Seminar Series: Promoting and maintaining a culture of research accountability

Research accountability clarion call: a strongly expressed demand or request for action.

Objectives for today:

Discuss individual approaches to research accountability

Explain the use of research quality management systems as a strategic, science centered, systematic and risk-based approach to research and data management.

Propose some first steps that can be taken to improve research documentation practices.

Individual strategies for improving research accountability

Use available resources

Engage with your professional societies

Engage with your collaborators and core laboratories

Incorporate best practices and guidelines

Learn from clinical research

Individual strategies for improving research accountability

Use available resources

NIGMs Clearinghouse for training modules to enhance data reproducibility

NIH Web Portal on Rigor and Reproducibility

Journal Checklists

Center for Open Science

Stanford Meta-Research Innovation Center at Stanford

Molecular Biology of the Cell

Editorial

Expand

« Previous | Next Article »
Table of Contents

Setting the bar for cell biology best practices

Jean E. Schwarzbauer[a], W. Mark Leader[b], and David G. Drubin[c,*]

+ Affiliations

The reproducibility of scientific findings is of great importance to all researchers. If our work cannot be reproduced and built upon by our peers and successors, it is of little value to the scientific enterprise.

In a 2015 white paper, the American Society for Cell Biology Reproducibility Task Force noted that scientific journals have an important role in ensuring that the work reported in them is reproducible (American Society for Cell Biology, 2015). *Molecular Biology of the Cell* (*MBoC*) has always supported the sound

This Article

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Mol. Biol. Cell **September 15, 2016** vol. 27 no. 18 **2803**

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Editorial

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The checklist will have 4 sections: **Data Presentation, Methodology and Statistics, Reagents and Model Systems, and Data Accessibility**. Authors will answer 4 questions confirming that their article meets the applicable requirements for each section or, if it does not, to provide an explanation.'

MANAGING YOUR DATA

Got data? We're here to help you manage, share, and preserve your research data. In addition to our Data Repository for the U of M curation services, the Libraries will help you navigate available campus resources throughout the data lifecycle:

Before Your Research Begins

- Schedule a data management plan (DMP) consultation (Request Form) or use our Explore funding agency requirements for data and learn best practices for getting IRB approval for sharing data.
- See more tools for planning for data management

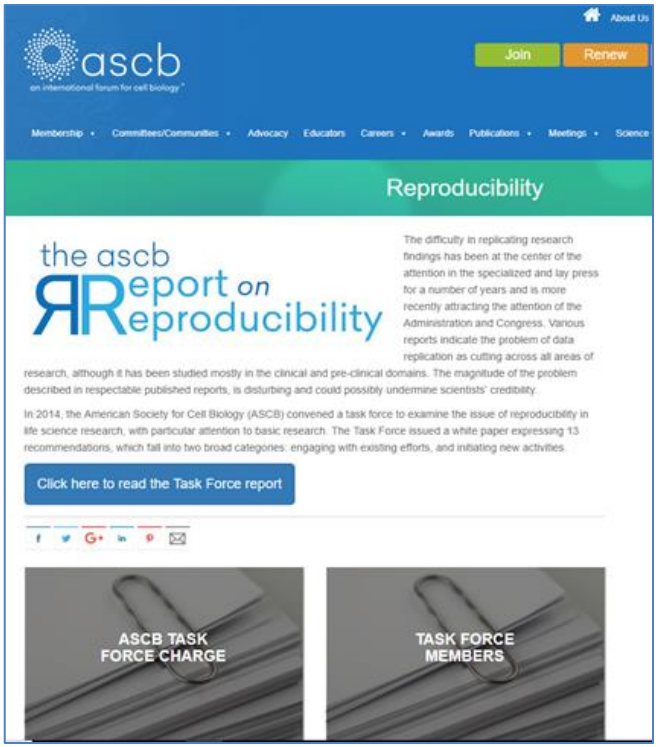
During Your Research

- Attend workshops and explore online training resources on best practices for data management
- Get help creating documentation and using metadata standards
- Discover appropriate U of M services for data, such as data storage
- See more tools for managing your data during your research

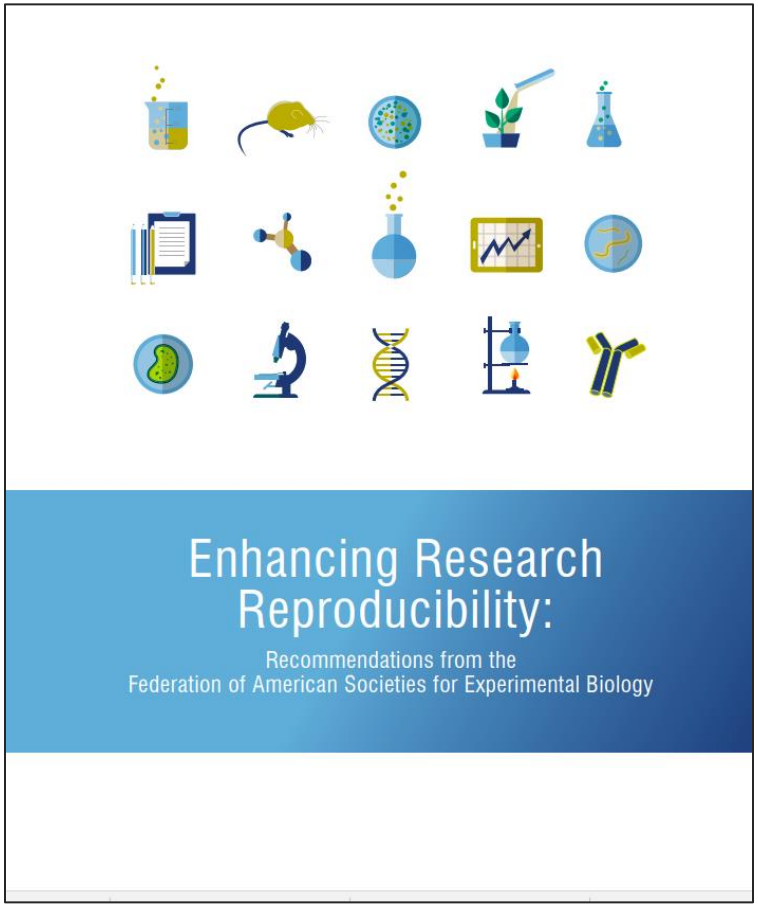
After Your Research Ends

Individual strategies for improving research accountability

Engage with your professional societies



Faseb: Enhancing Research Reproducibility



Overarching Recommendations

Recommendations Specific to Research Using Mouse and Other Animal Models

Recommendations Specific to Research Using Antibodies

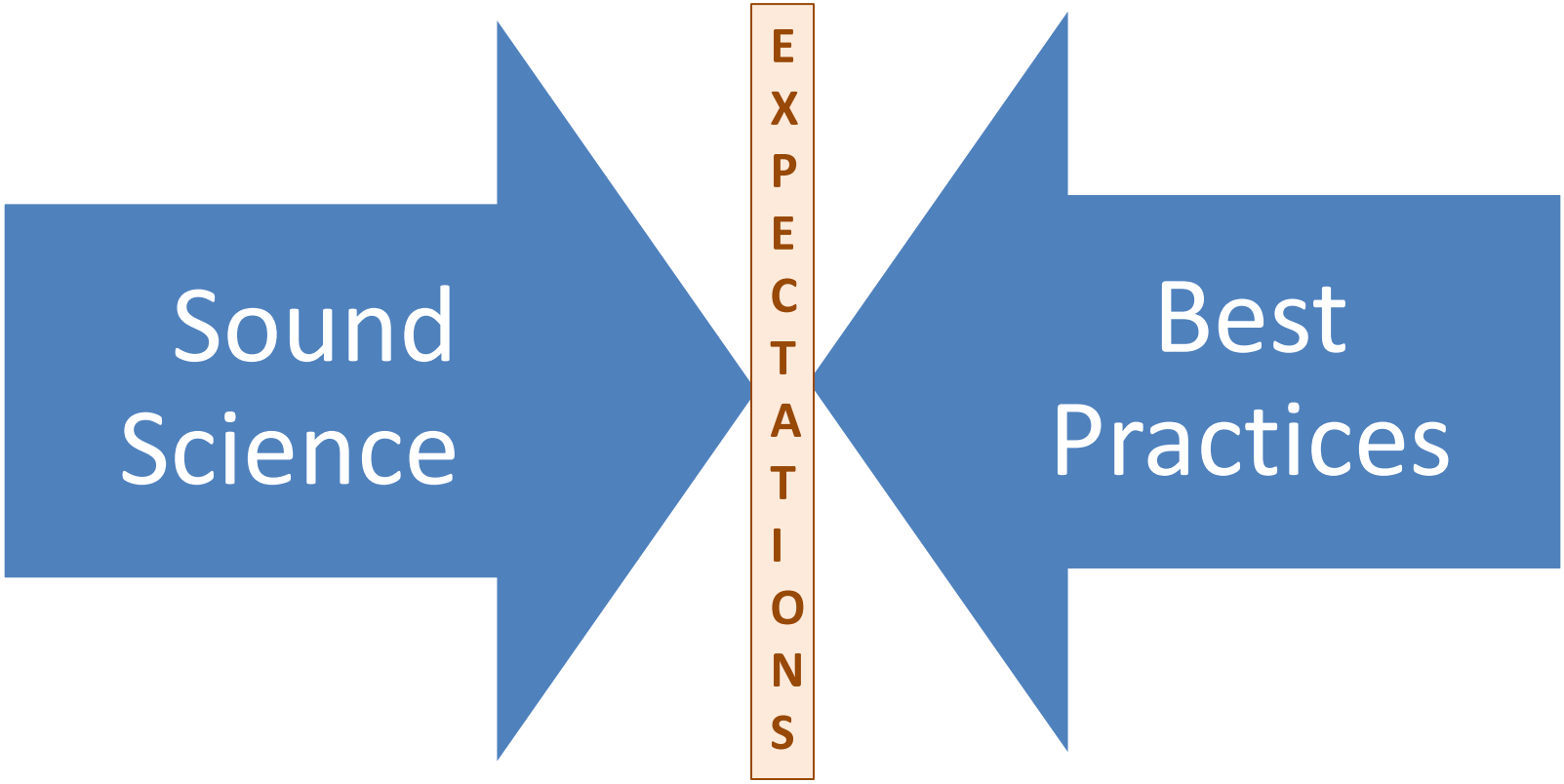
https://www.faseb.org/Portals/2/PDFs/opa/2016/FASEB_Enhancing%20Research%20Reproducibility.pdf

Individual strategies for improving research accountability

Engage with your professional societies

Individual strategies for improving research accountability

Engage with your collaborators and core laboratories



Consistent Procedures, Quality Checkpoints, Research Review

Individual strategies for improving research accountability

Use available resources

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Incorporate best practices and guidelines

Learn from clinical research

Incorporate best practices and guidelines

NIH Rigor and Transparency Guidelines

Principles and Guidelines for Reporting Preclinical Research

ARRIVE: Animal Research: Reporting of In Vivo Experiments

Biome

Molecu oducibility

Minimum Information About a Microarray Experiment (MIAME)

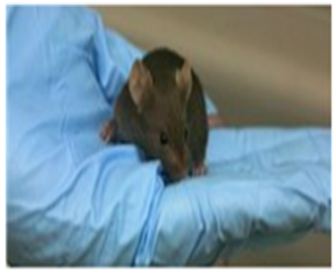
STAR Methods (Structured, Transparent, Accessible, Reporting (Cell Press))

Quality Practices for Biomedical Research/Good Research Practices/Research Quality Assurance

How are we doing?

Incorporate best practices and guidelines

Randomization, blinding, sample size estimation , and considering sex as a biological variable are considered crucial study design elements to maximize the predictive value of preclinical experiments.



Preclinical Studies Don't Regularly Adhere to Best Practices

By Kerry Grens

Animal experiments published in a handful of cardiovascular journals mostly ignore NIH guidelines.

8 May 2017

The Scientist » News & Opinion » Daily News

Circulation Research
Journal of the American Heart Association

American Heart Association®

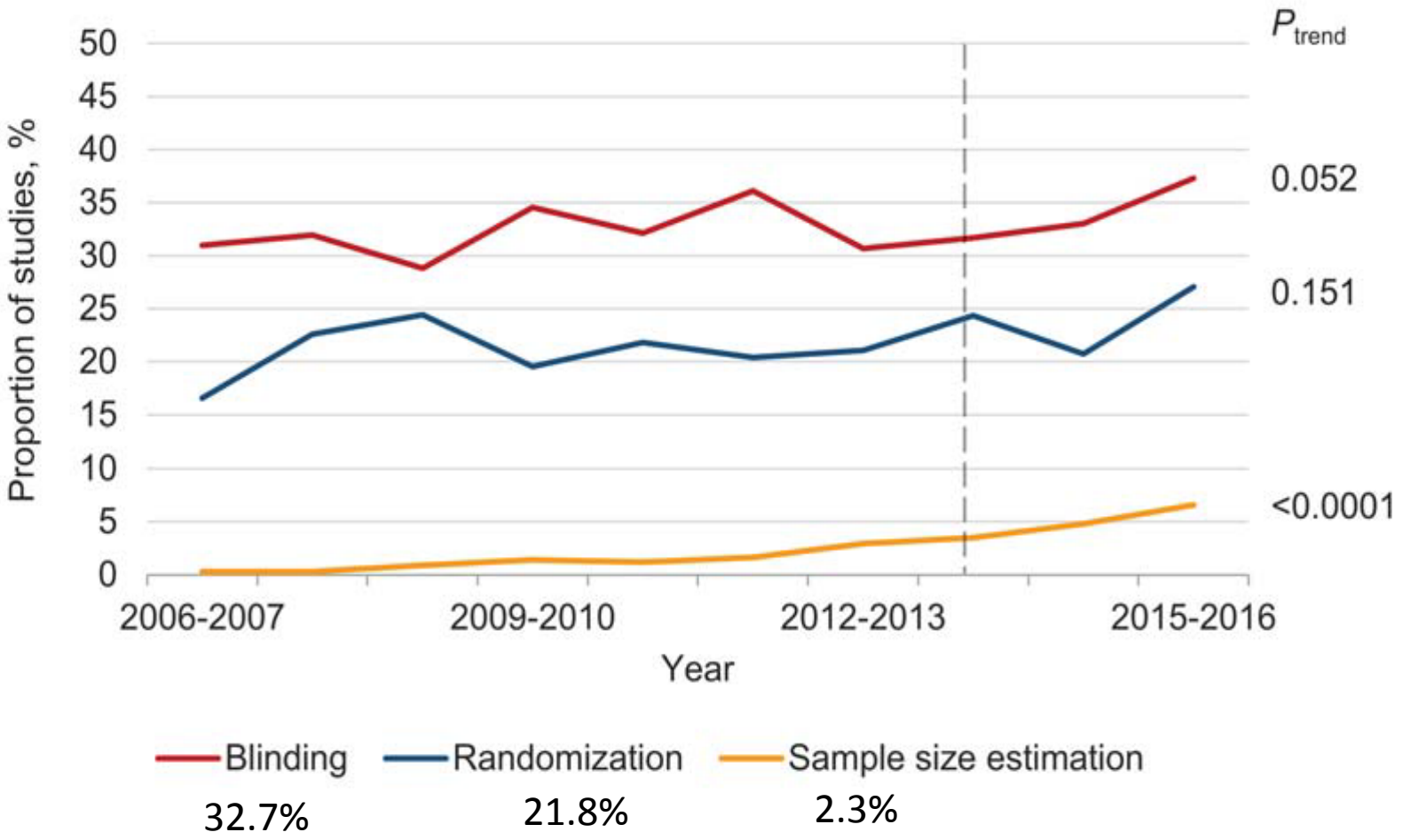
Conclusions:

‘Methodological shortcomings are prevalent in preclinical cardiovascular research, have not substantially improved over the past 10 years, and may be overlooked when basing subsequent studies.

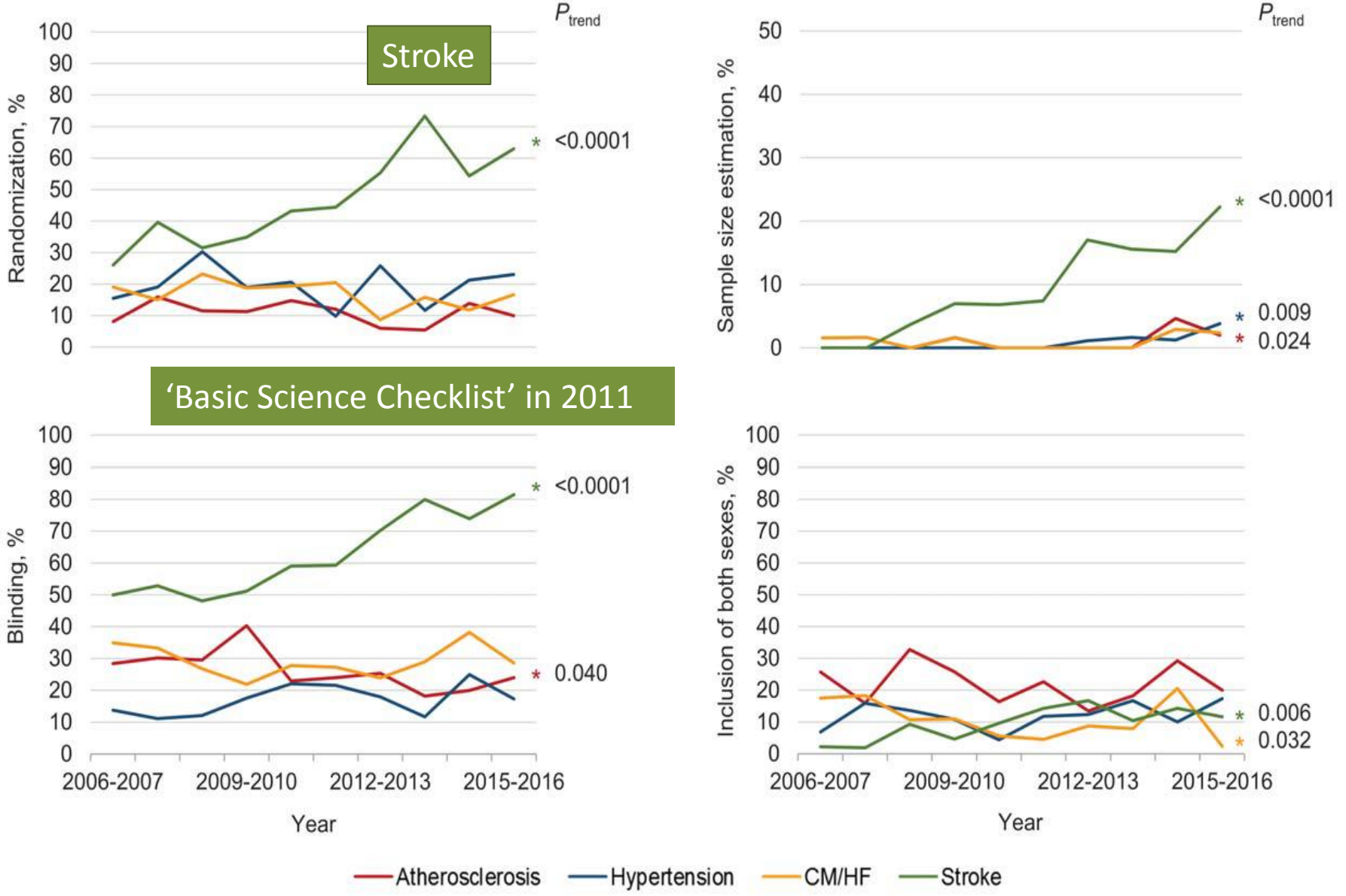
Stroke research quality has uniquely improved in recent years, warranting a closer examination for interventions to model in other cardiovascular fields.’

Temporal patterns in randomization, blinding and sample size estimation in preclinical cardiovascular studies.

NIH Guidelines



Patterns in preclinical research for the most commonly studied CV diseases.



Stroke

JOURNAL OF THE AMERICAN HEART ASSOCIATION

Sub Group Analysis: practices before and after the publication of NIH guidelines and policies for reporting preclinical research and the implementation of a ‘Basic Science Checklist’ by the Stroke journal.

Stroke

JOURNAL OF THE AMERICAN HEART ASSOCIATION

‘No difference in the prevalence of the study design elements before and after the NIH principles and guidelines for reporting preclinical research were published in 2014’.

Sub group analyses: (CVD and animal model-adjusted comparisons of study design elements before and after presentation of checklist)

‘significant improvements in all measures of methodological quality (range of adjusted odds ratios 2.4-8.2, $p < 0.0001$ for all study design elements).

‘identified stroke as the CVD studied as an independent positive predictor of one or more study design element in every journal.’

Stroke
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Stroke, Vahidy et al. 2016; 47:2435-2438, Sep 13, 2016.

Editorials

Reporting Standards for Preclinical Studies of Stroke Therapy

Farhaan Vahidy, MD, PhD; Wolf-Rüdiger Schäbitz, MD; Marc Fisher, MD; Jaroslaw Aronowski, MD, PhD

The unmet need for development of new stroke therapies is enormous. Evidence generated from positive, null, or negative preclinical studies for various therapeutic agents is crucial to enhancing scientific progress. The scientific community shares a societal responsibility to practice and promote meticulous conduct and reporting of all experimental studies. A systematic survey conducted by the UK government–sponsored National Center for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs) reported that only 59% of biomedical animal studies stated the hypotheses and objectives, and <87% did not use randomization.[1] This, in part, led to the

emphasize, and communicate the crux of methodological and reporting issues.[10,11]

To improve quality of preclinical studies, a relatively simple checklist requesting reporting of randomization procedures, blinding, a priori definition of inclusion and exclusion, and so on was implemented in 2011. This basic science checklist is currently part of the submission process, and the document is evaluated by editors and reviewers but has not been published so far. A recent analysis revealed that the checklist implementation has led to improvements in reporting of key characteristics of the overall scientific quality.[12] However, relevant components

Individual strategies for improving research accountability

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Learn from clinical research

Quality Practices for Biomedical Research/Good Research Practices/Research Quality Assurance

Lessons to learn from clinical research

L Pedro-Roig, Emmerich CH. Medical Writing; Dec 2017; 26:4

The reproducibility crisis in preclinical research – lessons to learn from clinical research

Laia Pedro-Roig[1] and
Christoph H. Emmerich[2]

1 Trilog
Frankf
2 PAAS

Corre

crisis.[1] The published literature is a common

promotion, or tenure). Journal edit
and grant reviewers look for the p
simple, clear, and complete.[3] The
tempt investigators to cherry pick

fo
or
sig
Co

NATURE | NEWS FEATURE; 27 JAN 16

MONYA BAKER

QUALITY TIME

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

42

GBSI Global Biological Standards Institute

The Case for Standards in Life Science Research

Seizing Opportunities at a Time of Critical Need

Published in final edited form as:
Cancer Res. 2014 August 1; 74(15): 4024–4029. doi:10.1158/0008-5472.CAN-14-0925.

The Increasing Urgency for Standards in Basic Biological Research

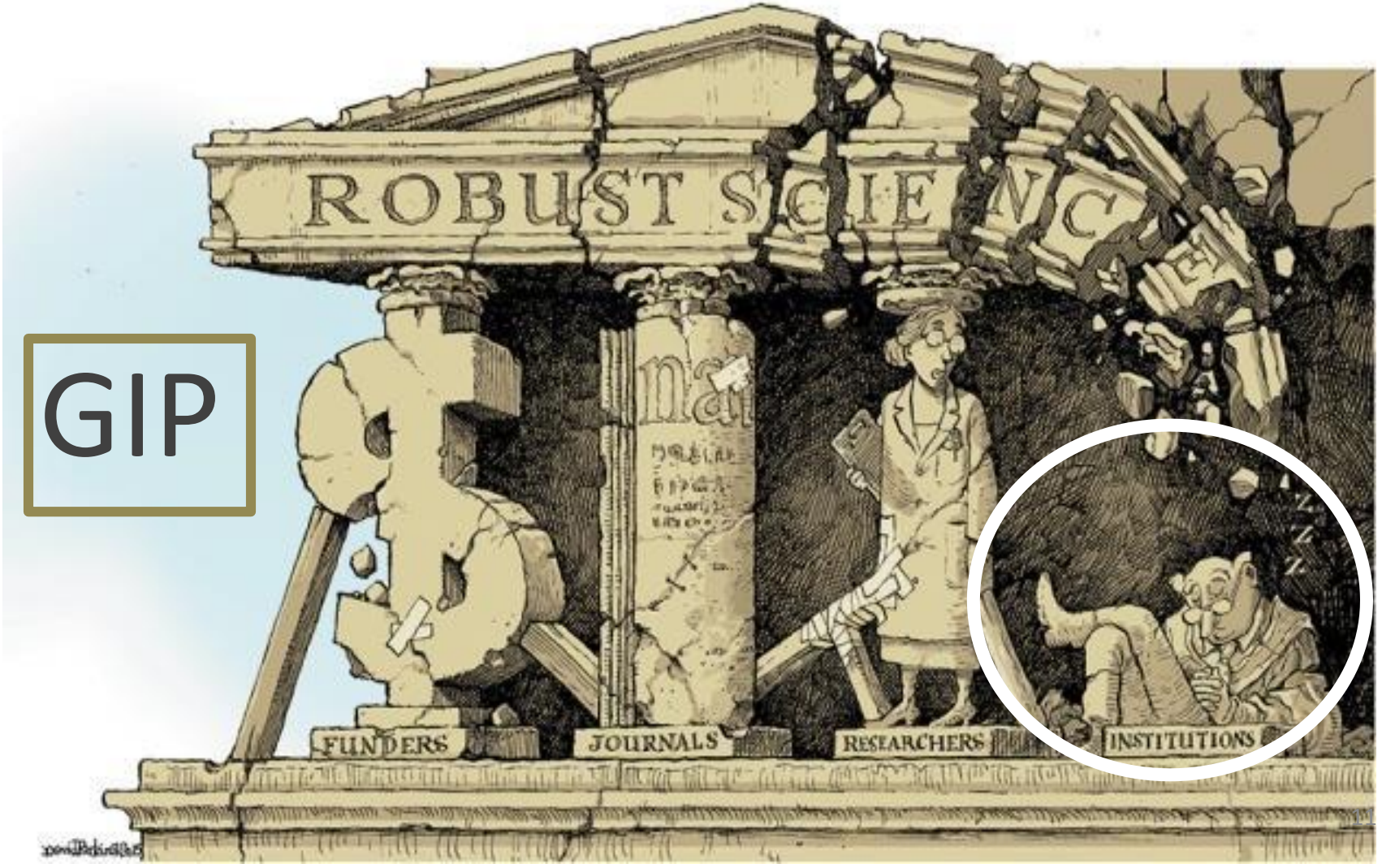
Leonard P. Freedman and
Global Biological Standards Institute, Washington, DC, USA

James Inglese
Division of Pre-clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health, Bethesda, MD, USA

Robust research: Institutions must do their part for reproducibility

C. Glenn Begley, Alastair M. Buchan & Ulrich Dirnagl

Nature|Comment 01 Sep 2015



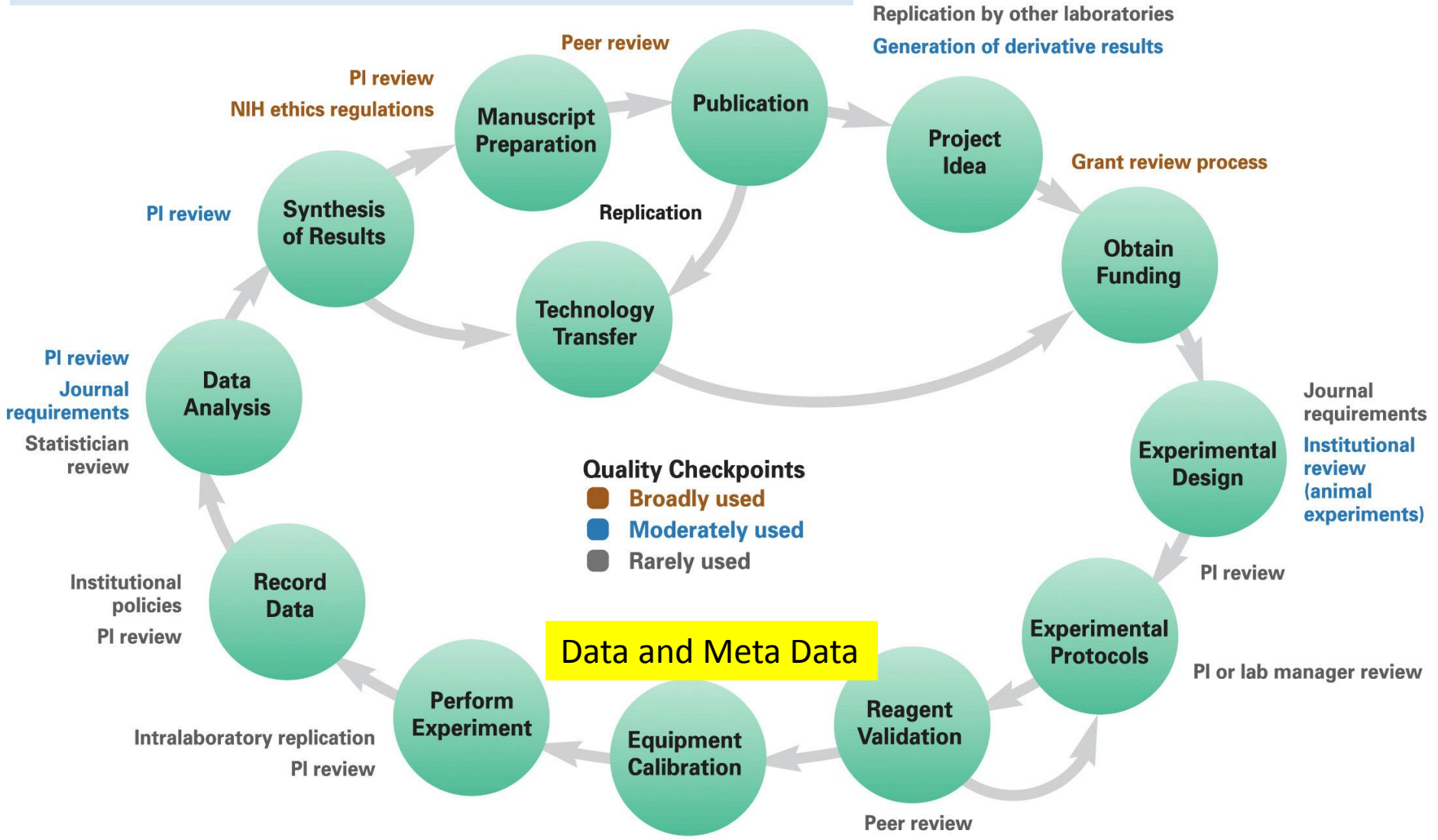
GIP

Good Institutional Practices

- Use of established standards
- Routine discussion and critique of research methods
- Incident, error, occurrence flagging, reviewing
- Training and standards
- Records and Quality Management
- Appropriate incentive and evaluation systems
- Enforcement
- Monitoring
- Audit

"We propose that research institutions that receive public funding should apply the same kind of oversight and support to ensure research integrity as is routinely applied for animal husbandry, biosafety and clinical work."

Research Life Cycle: Quality Check Points



Green circles indicate common steps in the life science research process. Adjacent color-coded text describes current/traditional quality checkpoints.

Good Quality Practices: A critical gap?

Data and Metadata
Who, what, where, when, how, why
Equipment
Personnel training
Supplies
Documentation
Methods
Facility and environment
Research records

Research accountability clarion call:
a strongly expressed
demand or request for action.

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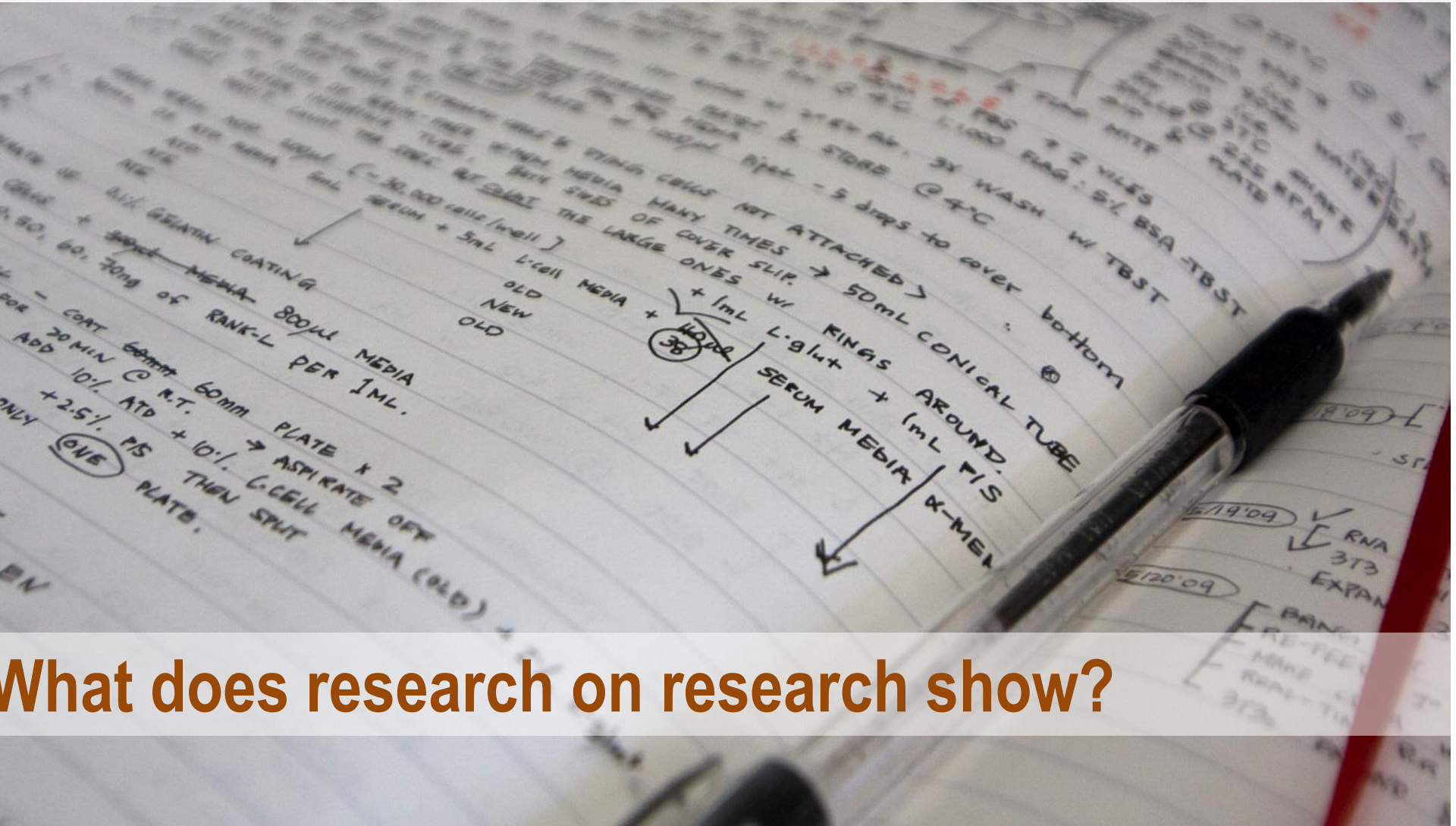
Explain the use of research quality management systems as a strategic, science centered, systematic and risk-based approach to research and data management.

Propose some first steps that can be taken to improve research documentation practices.

Recognizing that data and metadata reconstruction are critical to research reproducibility



What does research on research show?

Survey of NIH funded, early career scientists who say they have engaged in the behavior within the previous 3 years, n= 3247

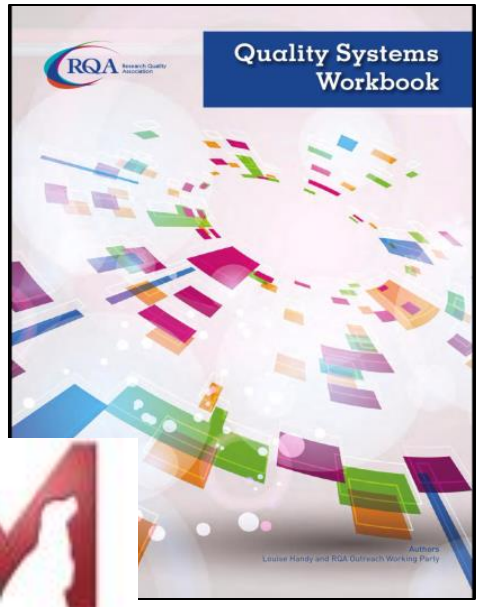
Behaviors	All early/ mid career
Changing design, methodology or results of a study in response to pressure from a funding group.	**12.5**
Using inadequate or inappropriate research design	**13.5**
Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	**15.3**
Inadequate record keeping related to research projects *	**27.5**

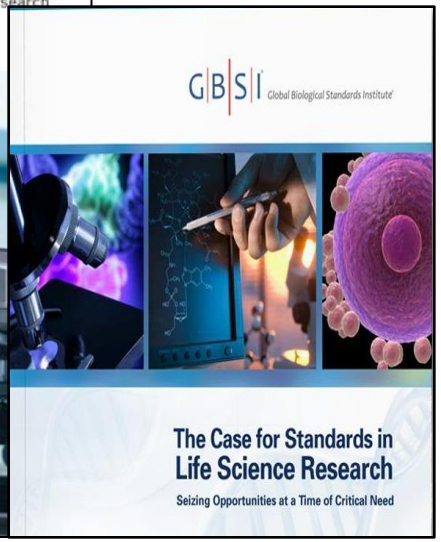
Scientists behaving badly

Nature 435, June 2005

BC Martinson, MS Anderson et al

Learning from clinical research: the case for standards in life science research





Scientific QA: The Research Continuum

DEVELOPMENTAL PIPELINE

Basic Research → Disease Discovery → Drug Discovery → Preclinical Development → Clinical Trials I, II, III → Manufacturing

← Not Regulated →

GLP GCP GMP

← 21 CFR Part 11 →

* RQA Integration

Study Based → Process Based

Slide adapted from one created by Melissa Eitzen, UTMB

Quality Assurance Management Systems are designed to:

Improve and maintain the precision and accuracy of a **product**

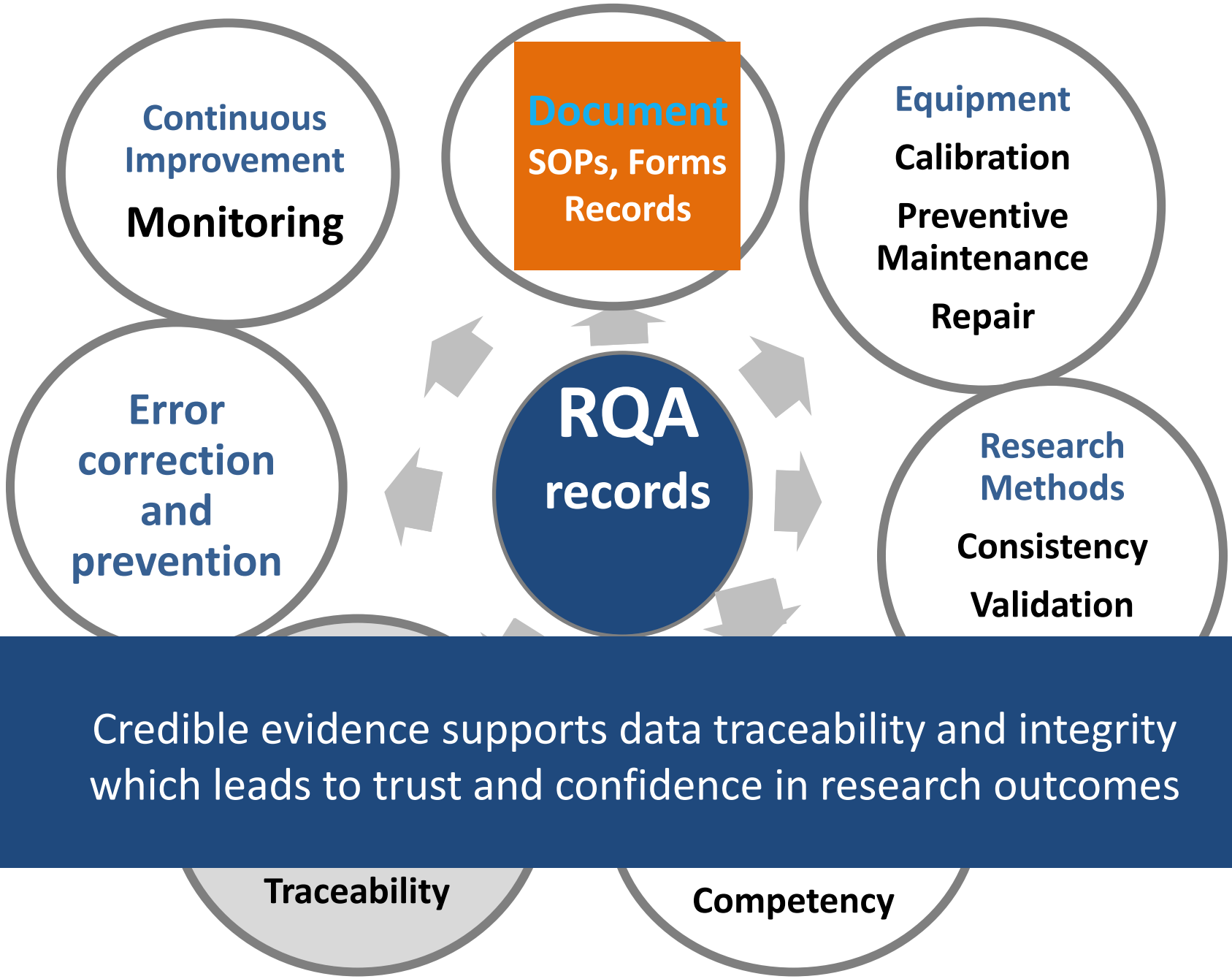
and establish routine performance

The products we produce are research data, inference and publications

And the next generation of biomedical scientists

Quality Assurance support is rarely found in academic basic research settings

Quality Management Systems Generate Evidence



Credible evidence supports data traceability and integrity which leads to trust and confidence in research outcomes

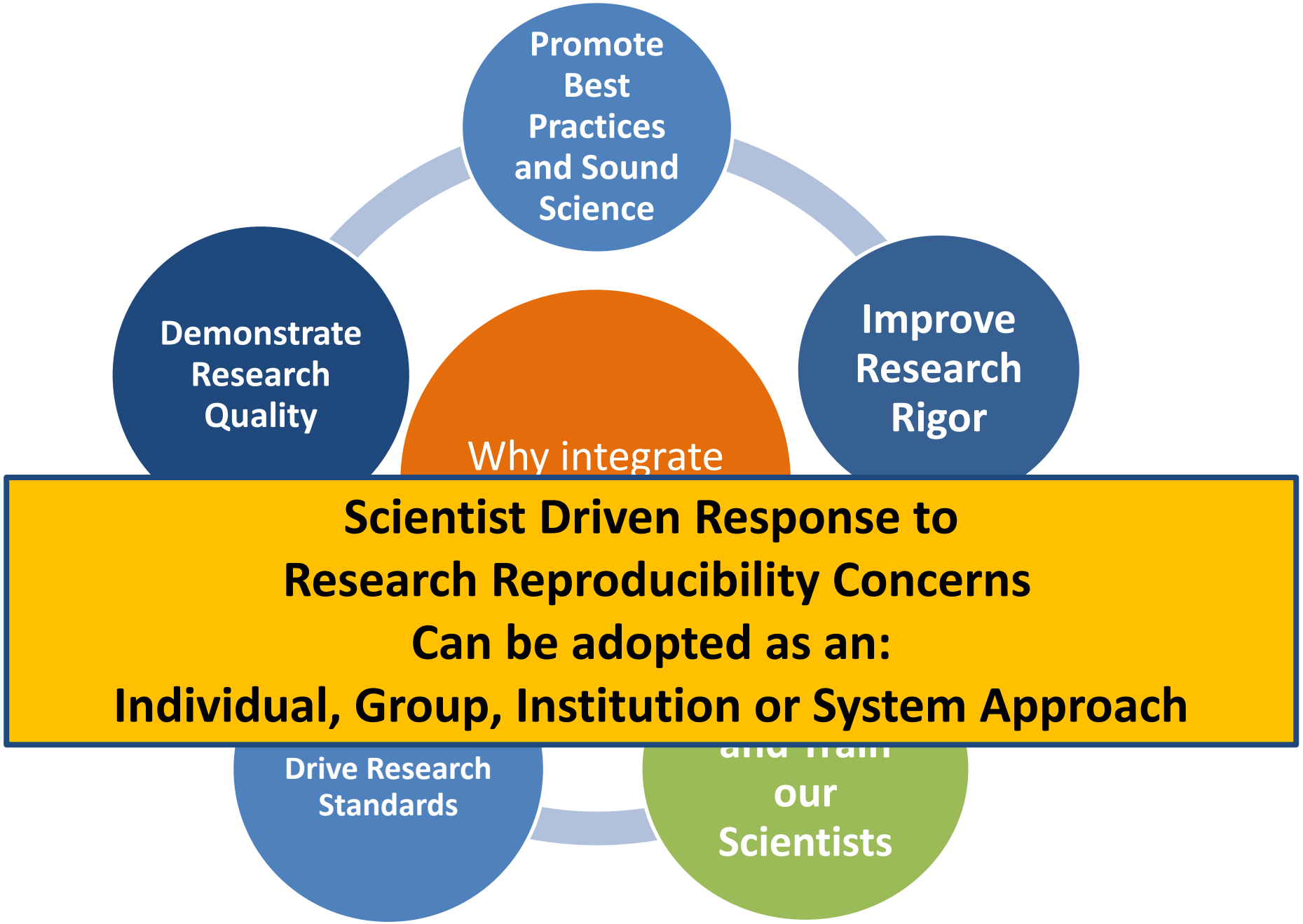
Research Quality Assurance is all about research records and documentation practices

How sound scientific principles and good quality practices contribute to the credibility of results

(WHO: Quality Practices in Biomedical Research Handbook, 2006)

	Sound Scientific Principles	Good Quality Practices	Credibility of Results
Study 1	No	No	No
Study 2	No	Yes	No
Study 3	Yes	No	No
Study 4	Yes	Yes	**Yes**

Both are critical for reproducible research


Promote Best Practices and Sound Science
Improve Research Rigor
Demonstrate Research Quality
Why integrate
Scientist Driven Response to
Research Reproducibility Concerns
Can be adopted as an:
Individual, Group, Institution or System Approach
Drive Research Standards
our Scientists

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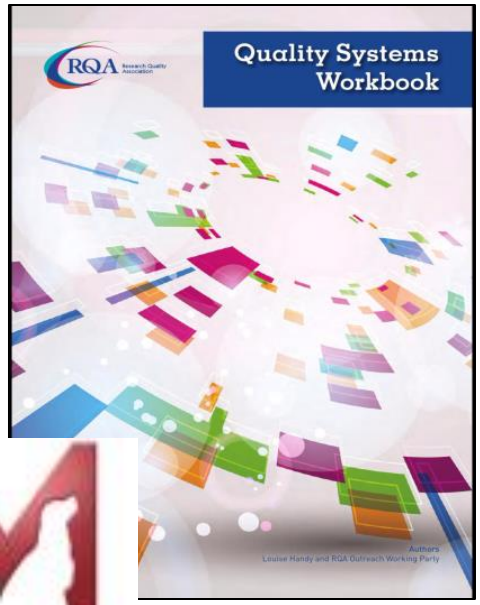
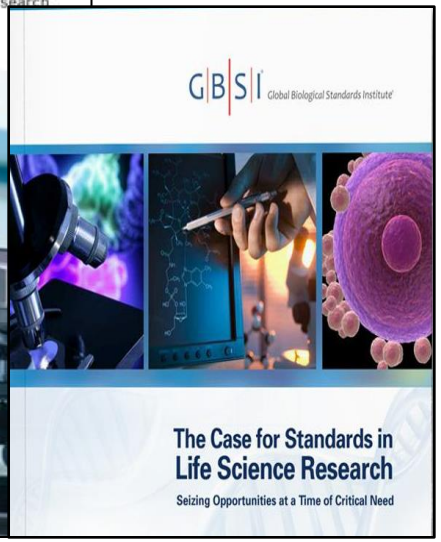
Basic QA Rule 1: If it wasn't documented, it wasn't done





Where to start?

‘ALCOA’ + C

Good Documentation Principles [FDA]

- **A**ttributable
- **L**egible
- **C**ontemporaneous
- **O**riginal
- **A**ccurate
- **C**omplete

A good question

The data curating process is time-consuming.

I have been involved in preparing the data for curation which typically occurs AFTER funding for the project has ended.

Where are the resources for the additional effort required for research accountability tasks when grant funding barely covers the cost of data analysis?

Scientist-Specific Solutions to Research Accountability Concerns

Image: Mark Airs/Getty Images

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RESEARCH ETHICS

Register at: z.umn.edu/ResearchIntegrityReg

Research Integrity and Trustworthy Science: Challenges & Solutions

Thursday, March 8, 2018
8:30am-1pm
Coffman Theater
University of Minnesota

Presented by the Office of the Vice President for Research; Consortium on Law and Values in Health, Environment & the Life Sciences; and Masonic Cancer Center

Part of Research Ethics Week, March 5-9, 2018

Prof. John P.A. Ioannidis, MD, DSc Stanford University

Prof. C.K. Gunsalus, JD

National Center for Professional and Research Ethics (NCPRE); University of Illinois

Prof. Barbara Spellman, JD, PhD

University of Virginia

*This conference is part of **Research Ethics Week** (March 5-9, 2018), during which the University of Minnesota will focus on professional development and best practices to ensure safety and integrity in research.*

April 19, 2018

College of Veterinary Medicine

Ivan Oransky from Retraction Watch

Quality Central

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