Quality Central

Sharpening the focus on sound science and quality practices

University of Minnesota
College of Veterinary Medicine

Show me the data: A strategy for supporting sound science using research QA best practices.

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National Data Integrity Conference
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Denver, Colorado
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Show me the data

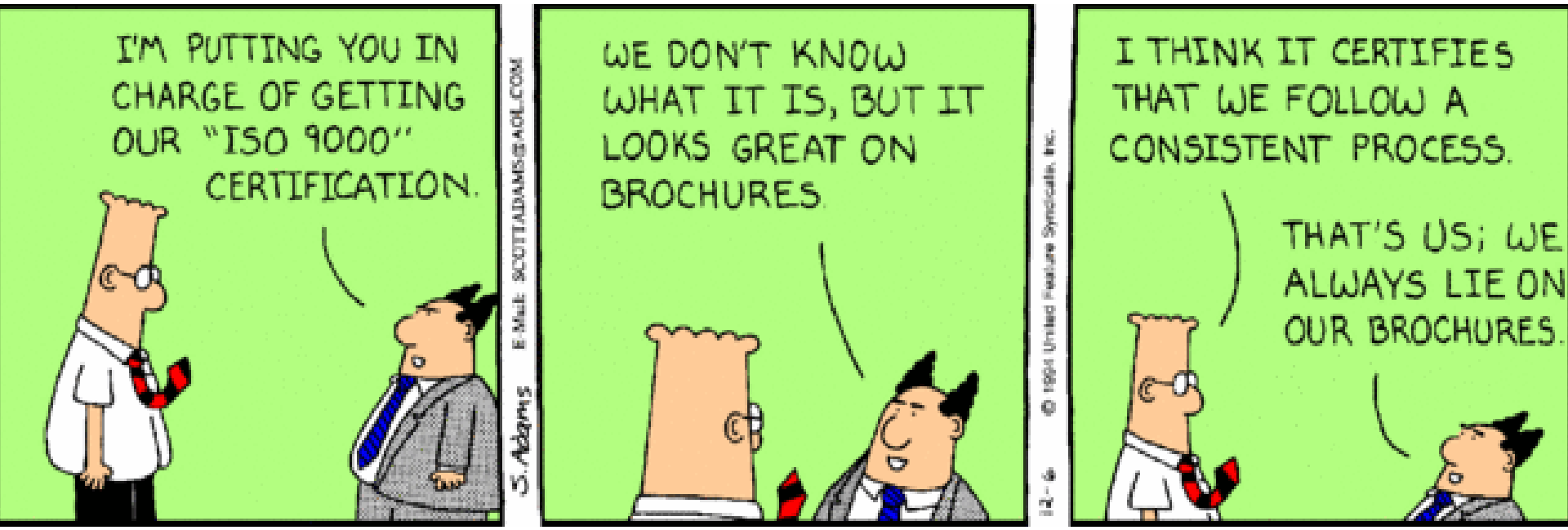
QA: A Primer

A Strategy
QA for Basic Research Data

A Better Strategy
Coordinated, Collaborative Approach to the Data Dilemma: It is going to ‘take a village’

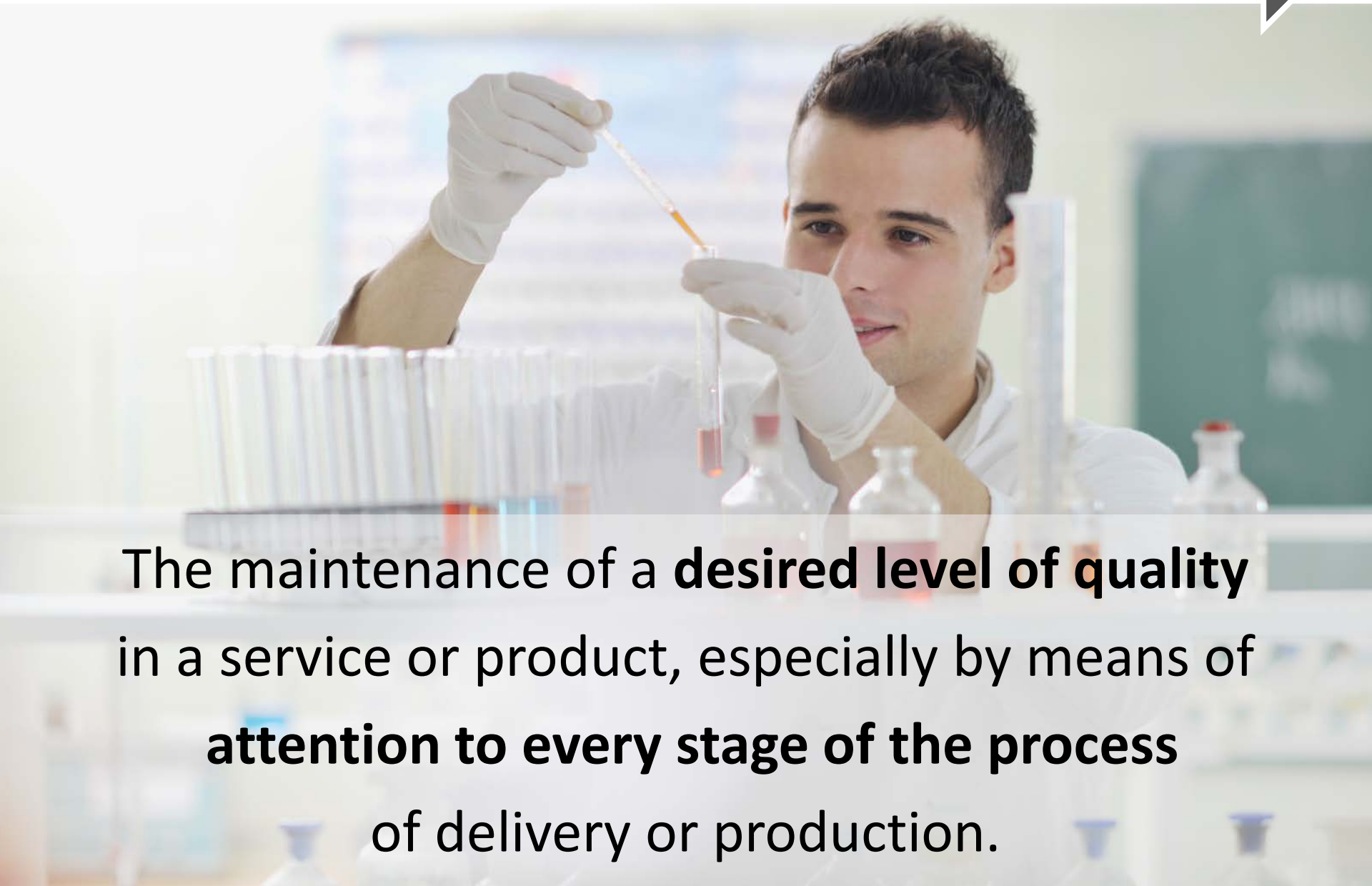
Conclusions

QA: A Primer



A process that ***provides evidence*** that the work performed is accurate (fits expected specifications), reliable, and ***can be reconstructed*** if necessary. Along the way, processes are improved.

Quality Assurance



The maintenance of a **desired level of quality** in a service or product, especially by means of **attention to every stage of the process** of delivery or production.

Quality Assurance Management Systems are designed to:

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

and establish routine performance

The products scientists produce are research data and inference

and the next generation of scientists

Quality Assurance support is rarely found in academic basic research settings

Scientific QA: The Translational Research Spectrum

DEVELOPMENTAL PIPELINE

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

← Not Regulated →

GLP GCP GMP

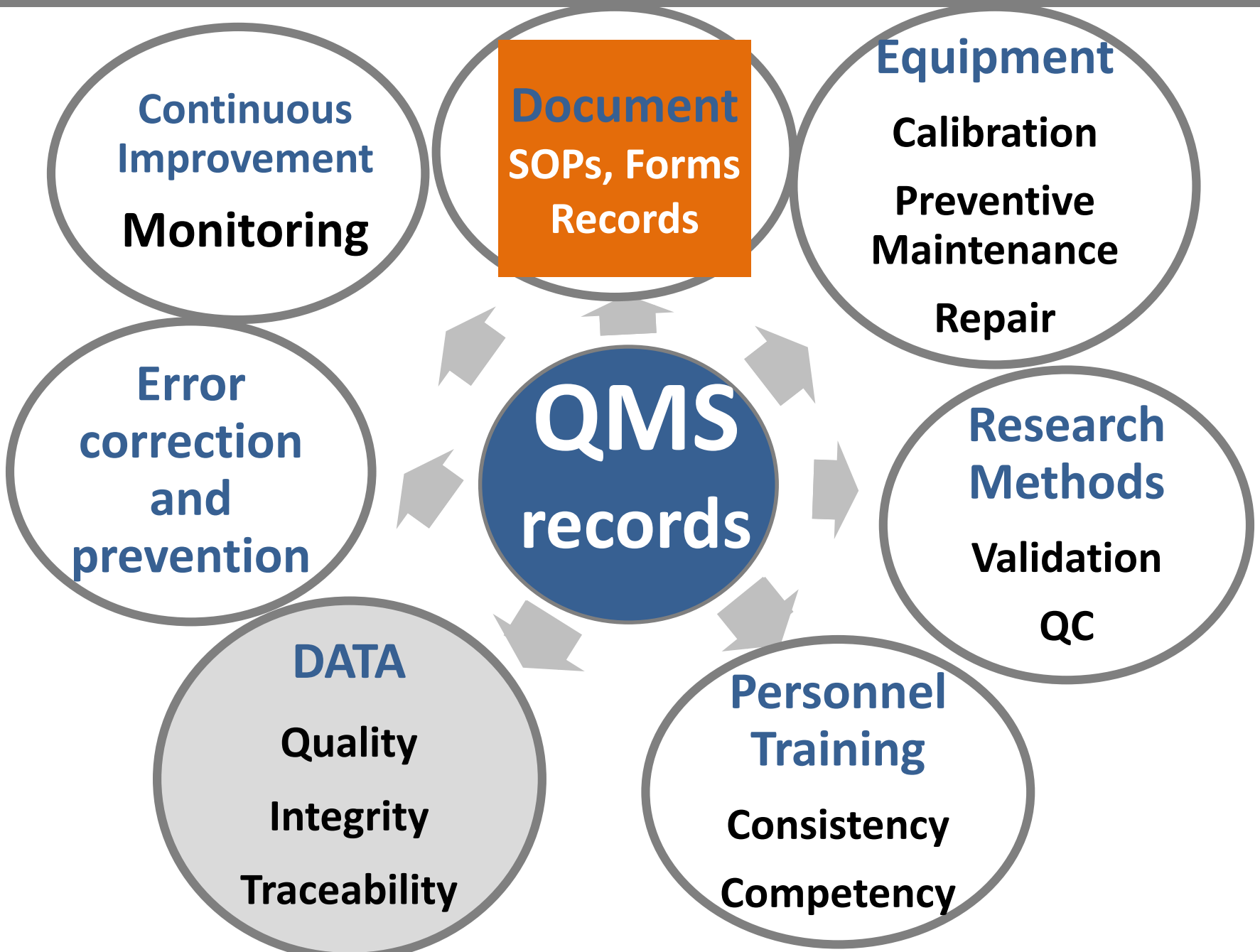
← 21 CFR Part 11 →

Voluntary QA here?

Study Based → Process Based

Slide adapted from one created by Melissa Eitzen, UTMB

Quality Management Systems Generate Evidence



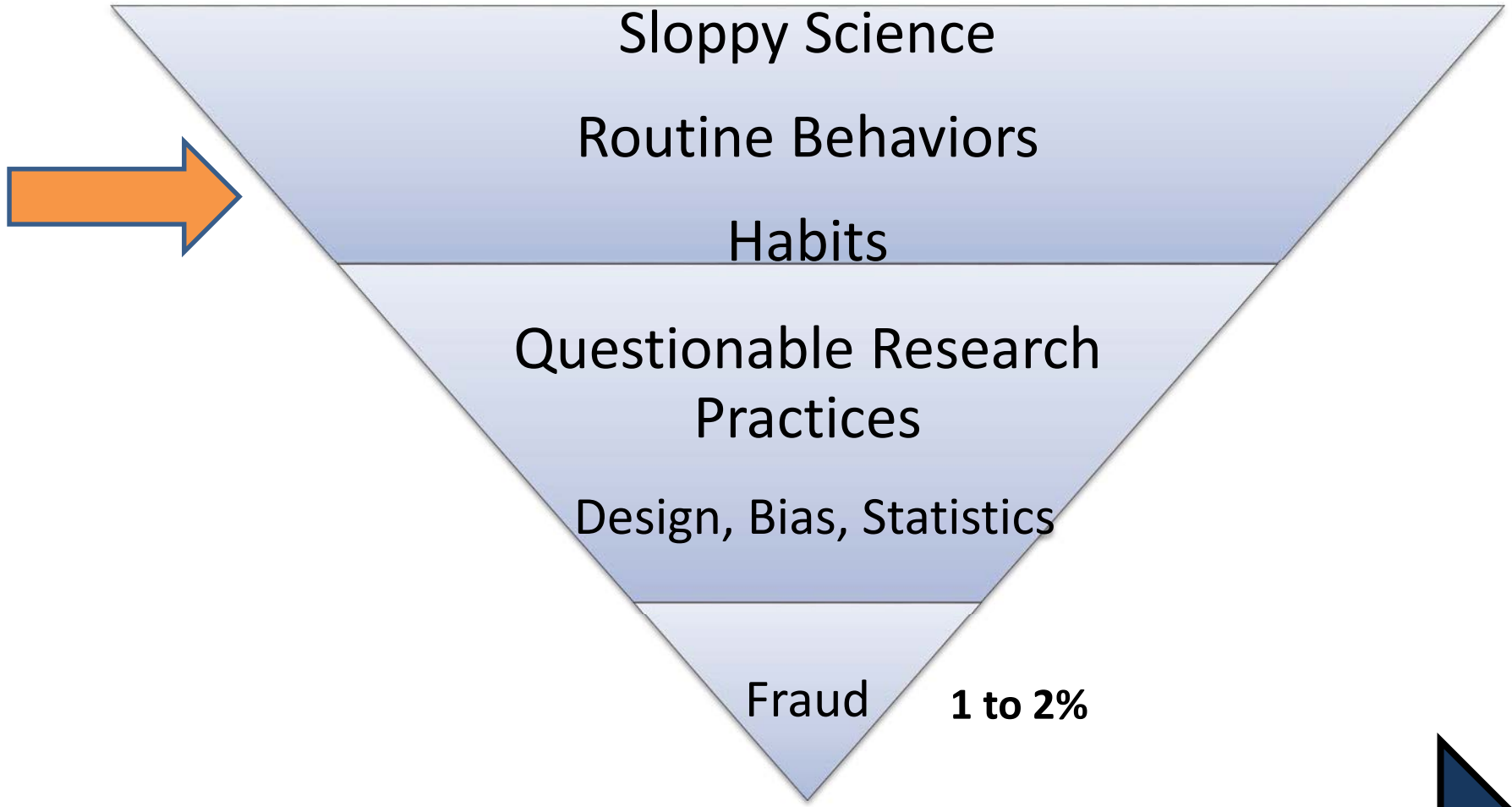
Quality Assurance Elements Influence Research Reliability

and mitigate the RISK associated with incomplete records

We may not understand QA, but the public does.

- ✓ Demonstrate Credible **Evidence** of Reliability and Value
- ✓ **Data** Inspire **Trust and Confidence** in the product

Threats to sound science



Quality Assurance Principles

Commentary

Nature 435 (9 June 2005)

Scientists behaving badly

Brian C. Martinson, Melissa S. Anderson, & Raymond de Vries

To protect the integrity of science, we must look beyond falsification, fabrication and plagiarism, to a *wider range of questionable research practices*, argue Martinson, Anderson and de Vries.

“our evidence suggests that mundane, ‘regular’ misbehaviors present greater threats to the scientific enterprise than those caused by high-profile misconduct cases such as fraud”

Self Reporting

Percentage of scientist who say that they have engaged in the behavior within the previous three 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 * ***low hanging fruit ?**	**27.5**

On the reproducibility of science: unique identification of research resources in the biomedical literature

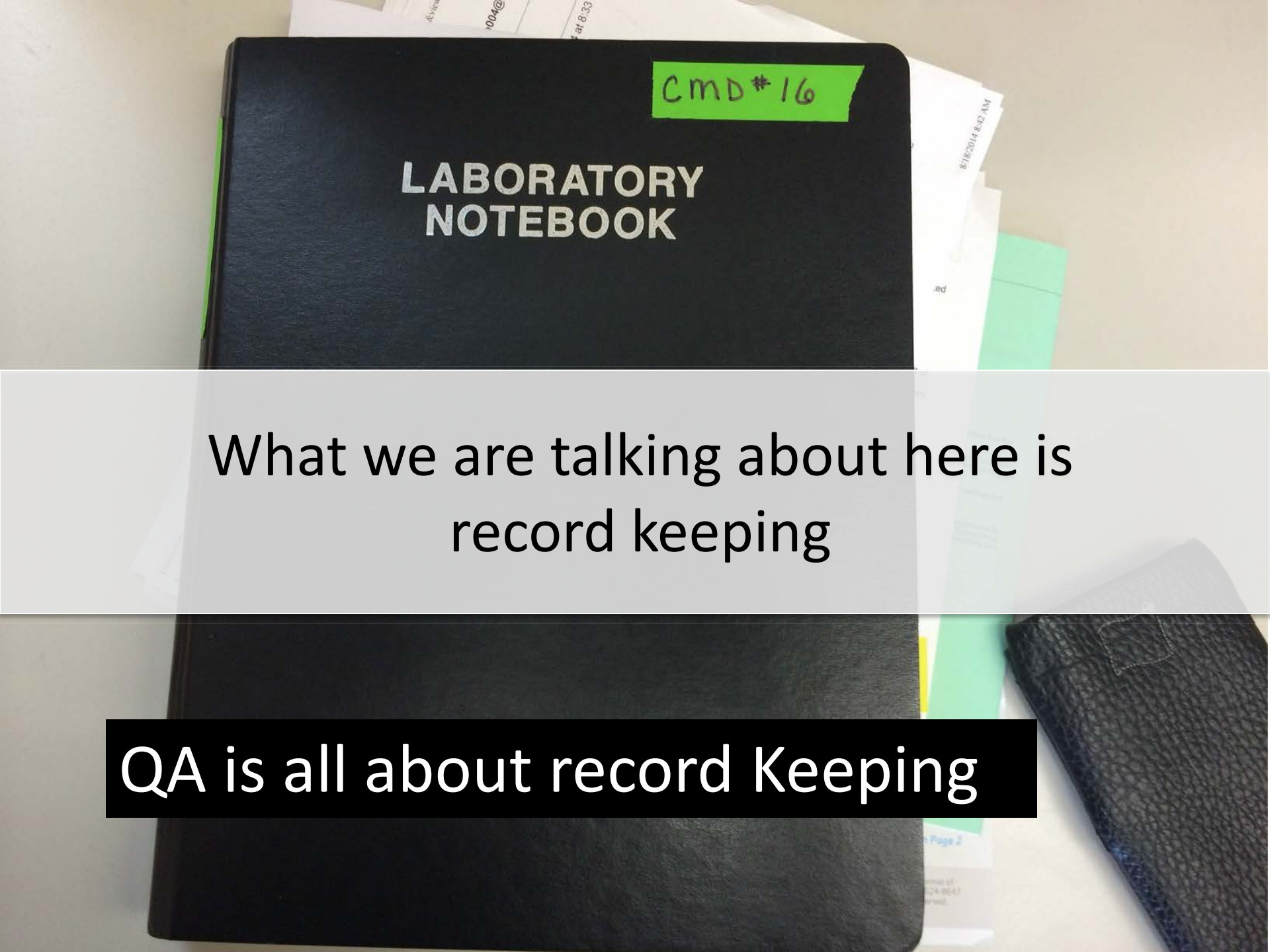
Vasilevsky et. 2013; PeerJ1:el 48;DOI10.7717

…'the inability to *uniquely identify* research resources, such as antibodies and model organisms, makes it *difficult or impossible to reproduce experiments even where the science is otherwise sound'*

… 'we designed an experiment to ascertain the "identifiability" of research resources in the biomedical literature'

54% of resources are not uniquely identifiable in publications

‘…identifiability is a serious problem for reproducibility’



What we are talking about here is record keeping

QA is all about record Keeping

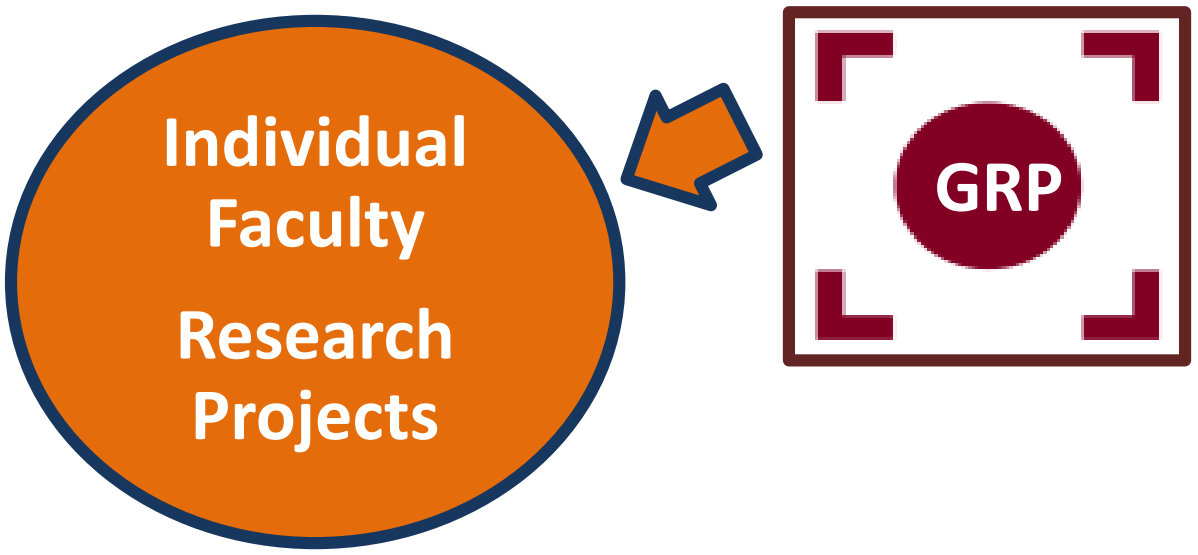
Credible Evidence for Research Quality

Do we fully support our scientists and their ability to reconstruct their data?

This is not a new idea

A call for the development of " Good Research Practices" (GRP) Guidelines	Glick JL et al. Accountability in Research. Vol 2, p 231-235. 1993.
Good Research Practices: A commonsense approach to ensuring quality in research facilities.	Herman DR et al. Quality Assurance Good Practice, Regulation and Law. 3:4, 355-359, 1994
Proposal for a National Quality Standard for Biomedical Research	Calabrese R; Quality Digest.com/print/4410.
The Role of Quality in today's Research University	**Bens, C. Quality Assurance Good Practice, Regulation and Law. 3:3, 248-253, 1994**
Quality: an old solution to new discovery dilemmas	Volsen SG et al. Drug Discovery Today, 9:21. 2004

POC: Individual Faculty Research Model: GRP



Research Grant Budget
QA Justification
Focus on Data Rigor

Project Based, 2 projects funded
2 more projects pending

SOPS and RECORDS:
Equipment management

Reagent management

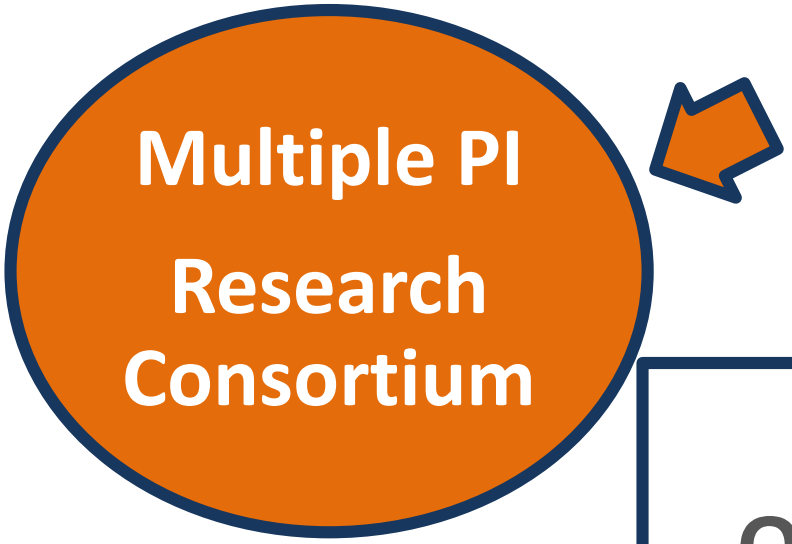
Notebook review

Method validation

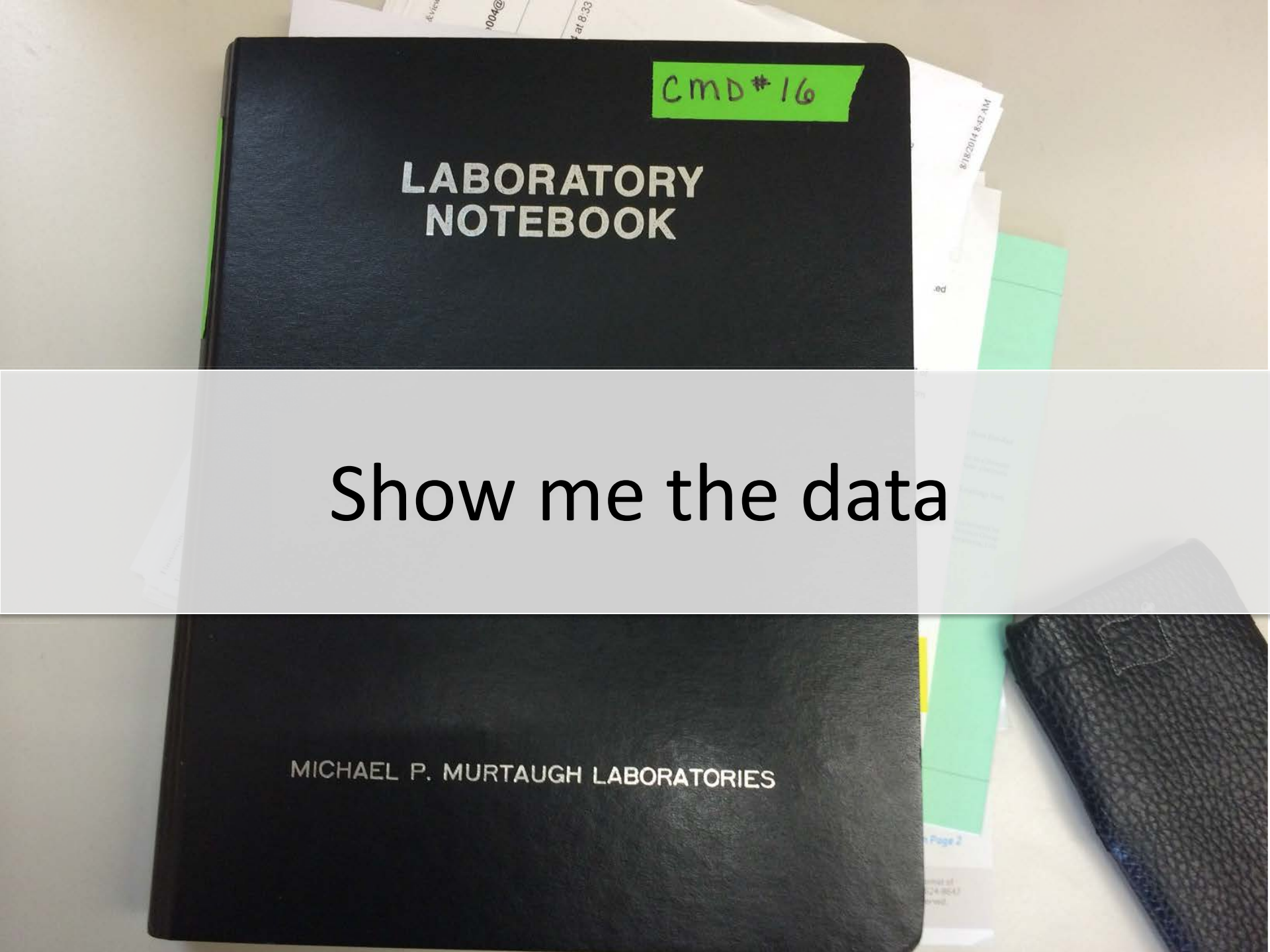
Training

Audit

Research Consortium Model

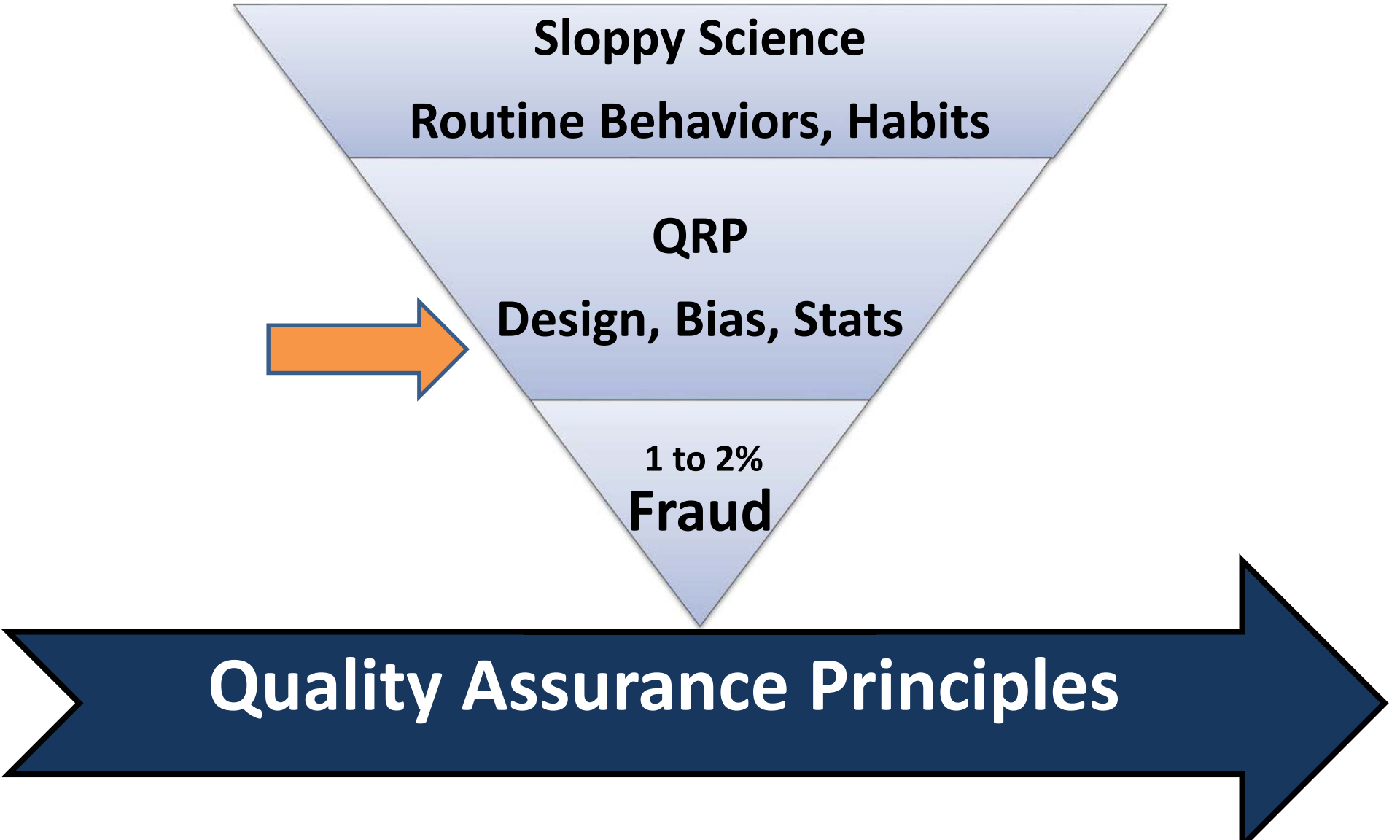


QA funding pool
QA cost included in grant
Focus on data reliability and reconstruction



Show me the data

Threats to sound science



Research Credibility/Research Wastage

Nature 2012 doi:10.1038/483531a

Many landmark findings in preclinical oncology research are not reproducible, in part because of inadequate cell lines and animal models.

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.

fforts over the past decade to | trials in oncology have the highest failure | investigators must reassess their approach to

cess has been remarkably low'. Sadly, clinical | cess rate is not sustainable or acceptable, and | mouse models' make it difficult for even

29 MARCH 2012 | VOL 483 | NATURE | 531

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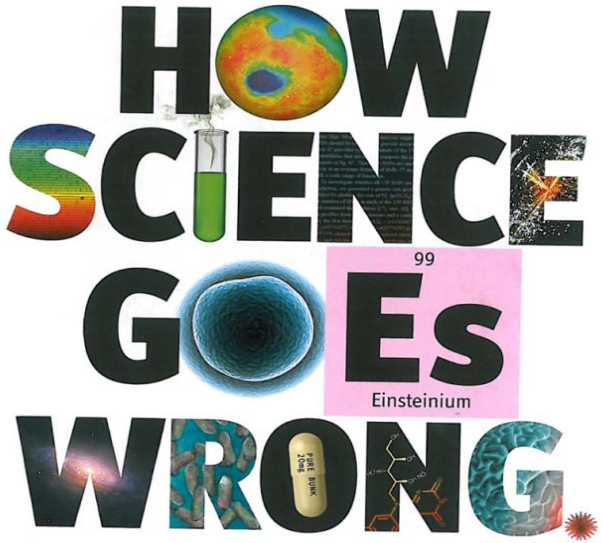
11% Reproducibility

Essay

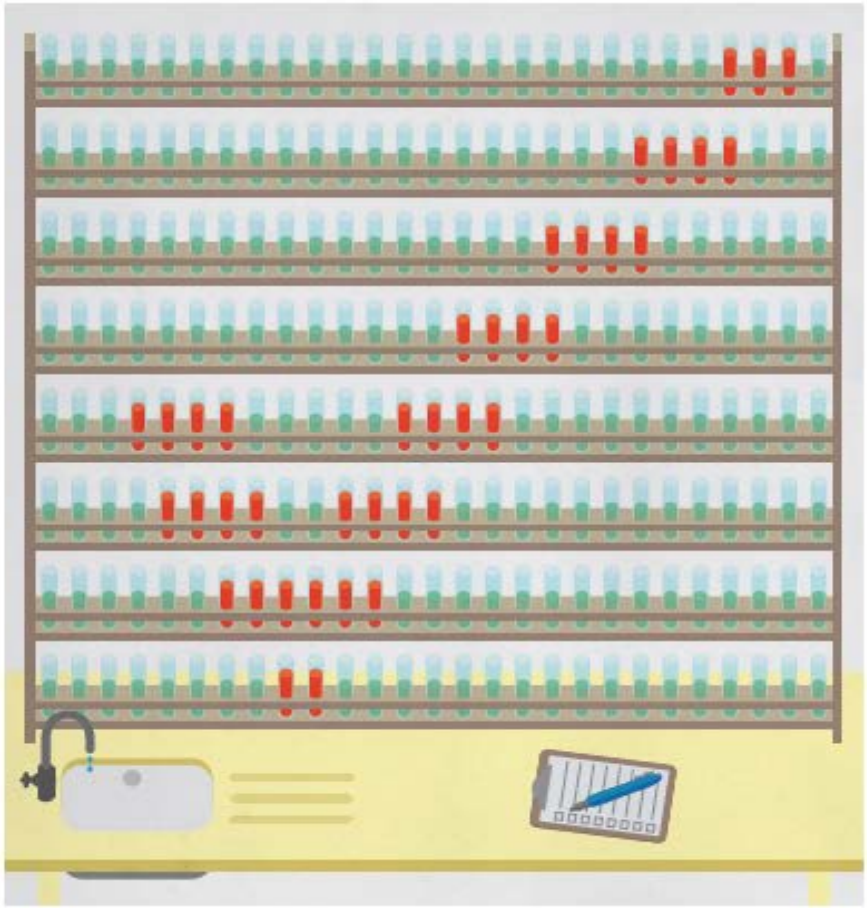
Why Most Published Research Findings Are False

John P.A. Ioannidis

PloS Medicine 2005
doi:10.1371/journal.pmed.0020124



October 2013



NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

Nature | Comment

Policy: NIH plans to enhance reproducibility

Francis S. Collins & Lawrence A. Tabak

27 January 2014

Discuss initiatives that the US National Institutes of Health is exploring to ***restore the self-correcting nature of preclinical research***.

"Efforts by the NIH alone will not be sufficient to effect real change in this unhealthy environment."

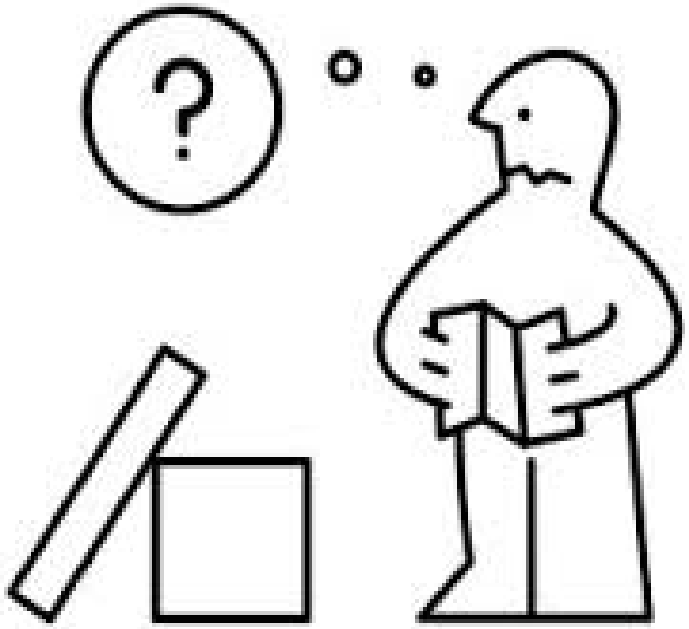
National Institutes of Health

Turning Discovery Into Health

Updated Application Instructions to Enhance Rigor and Reproducibility

- ✓ Scientific Premise of Proposed Research
- ✓ Rigorous Experimental Design
- ✓ Consideration of Sex and Other Relevant Biological Variables
- ✓ Authentication of Key Biological and/or Chemical Resources.

Data issues are bigger than QA



Effective Data Reconstruction/Reproducibility requires more than QA

http://3bugmedia.com

Show us the data

The DATA DILEMMA

"… witnessing a dramatic shift in our relationship with data:

where researchers once managed discrete, controllable building blocks of knowledge, they must now contend with a tsunami of information that paradoxically *feeds the growing scientific output while simultaneously crushing researchers with its weight"*

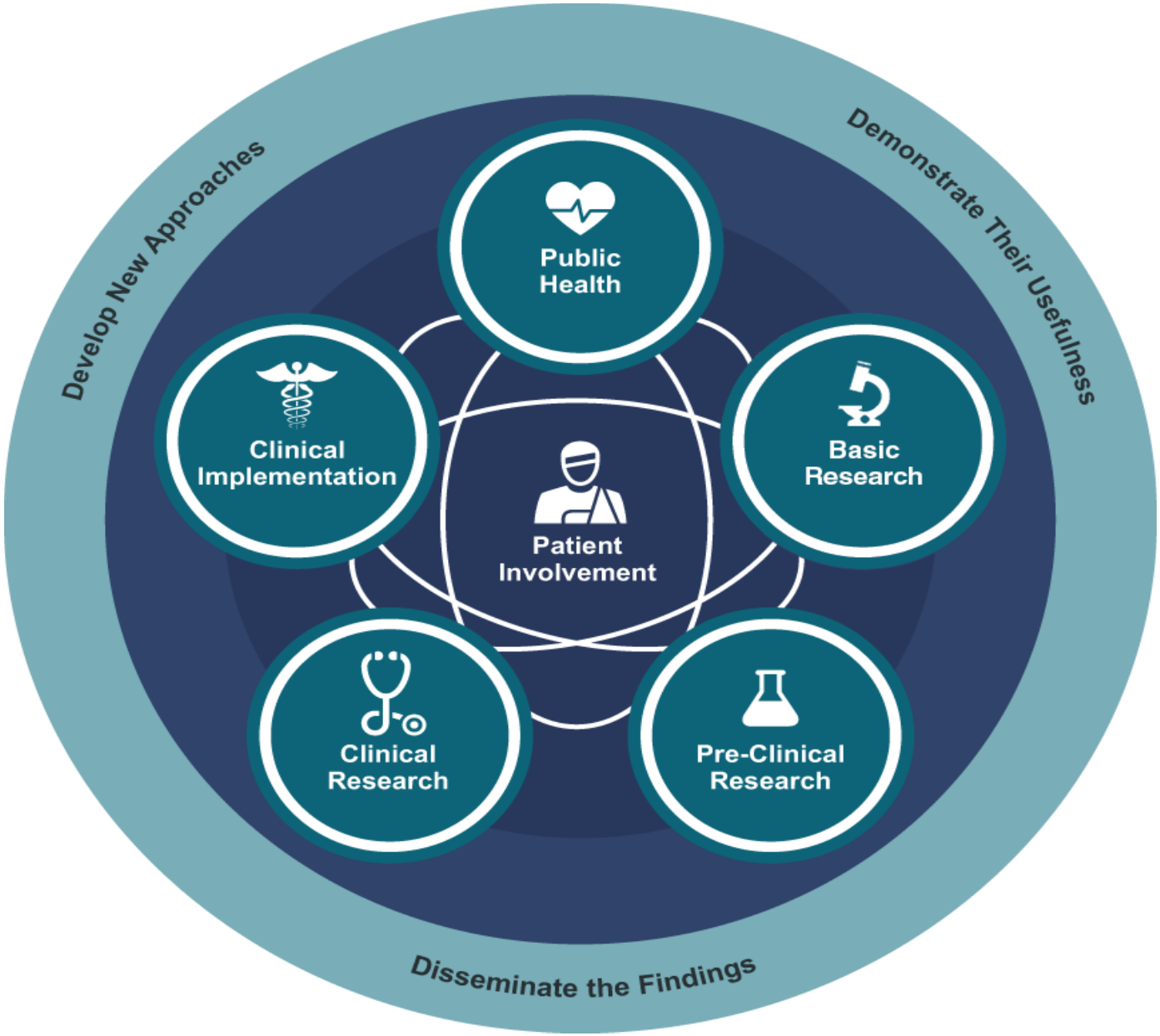
Haendel MA et al. 2012; Dealing with Data: A Case Study on Information and Data Management Literacy. PLoS Biol 10(5).e:1001339

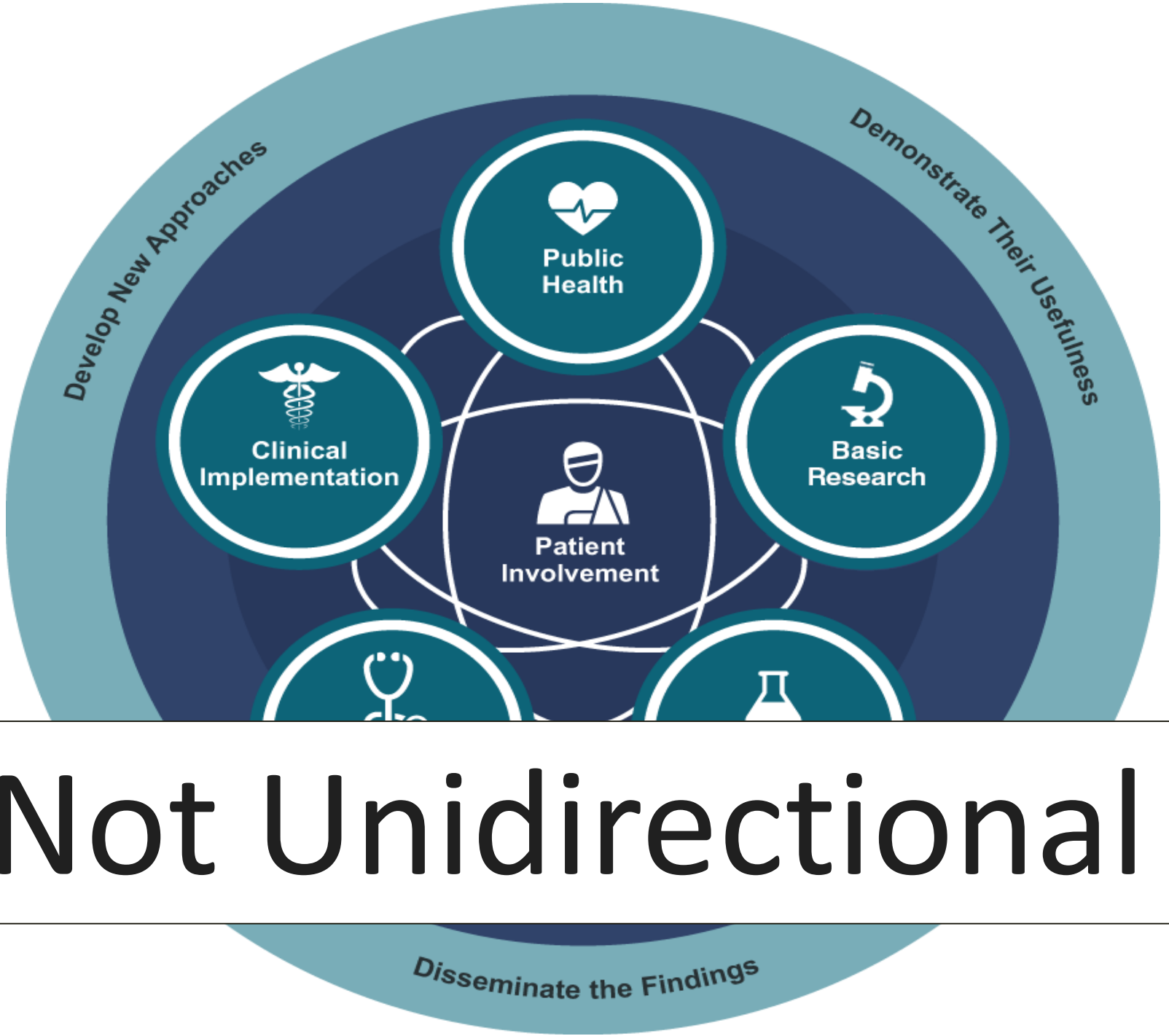
BIG Data

‘every scientist needs to understand how to manage, navigate, and curate huge amounts of data’.

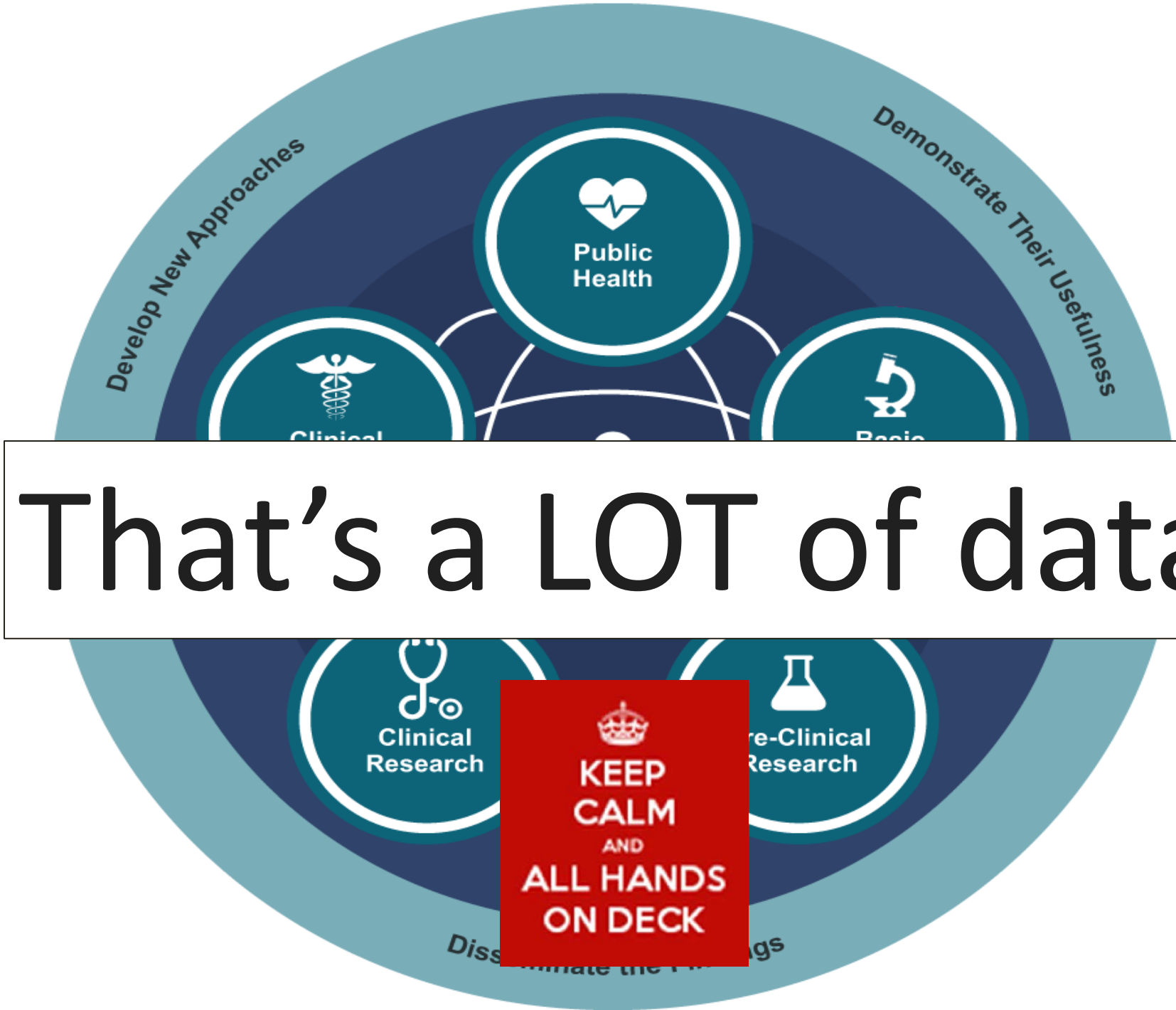
Haendel MA et al. 2012; PLoS Biol 10(5).e:1001339

Translational Science





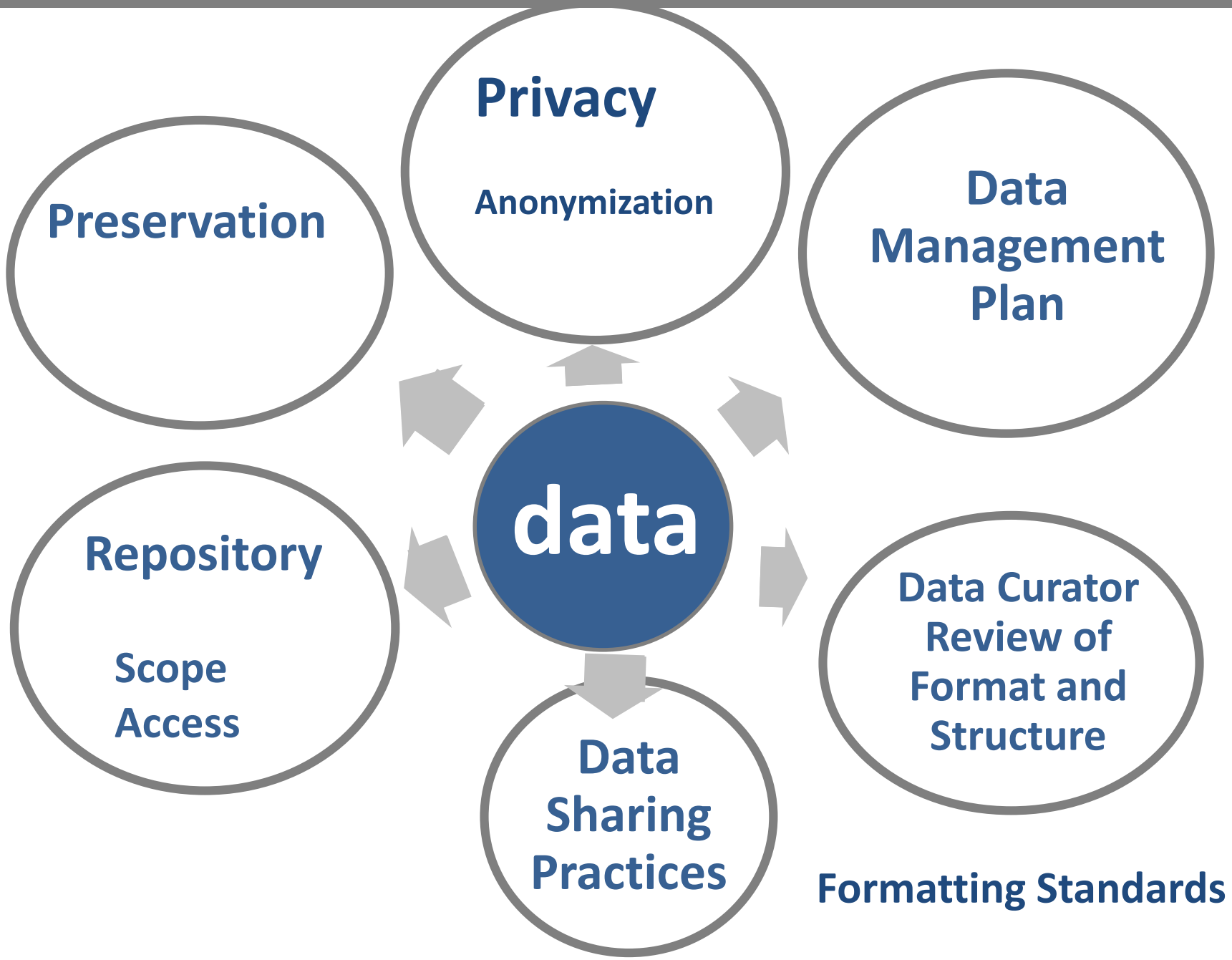
Not Unidirectional

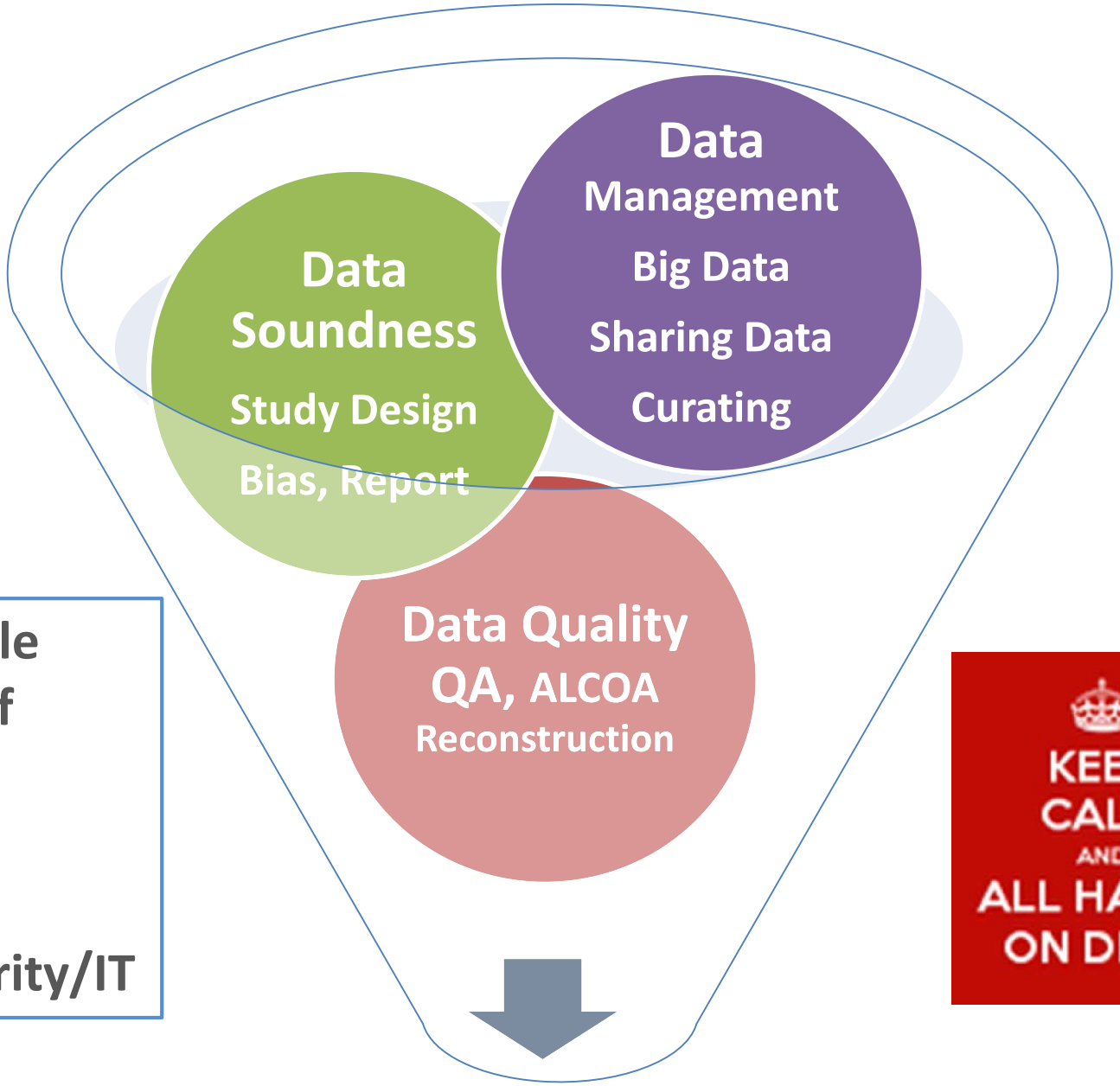


That's a LOT of data

Strategies are needed to fill the data literacy gaps

Critical Data Management Resources



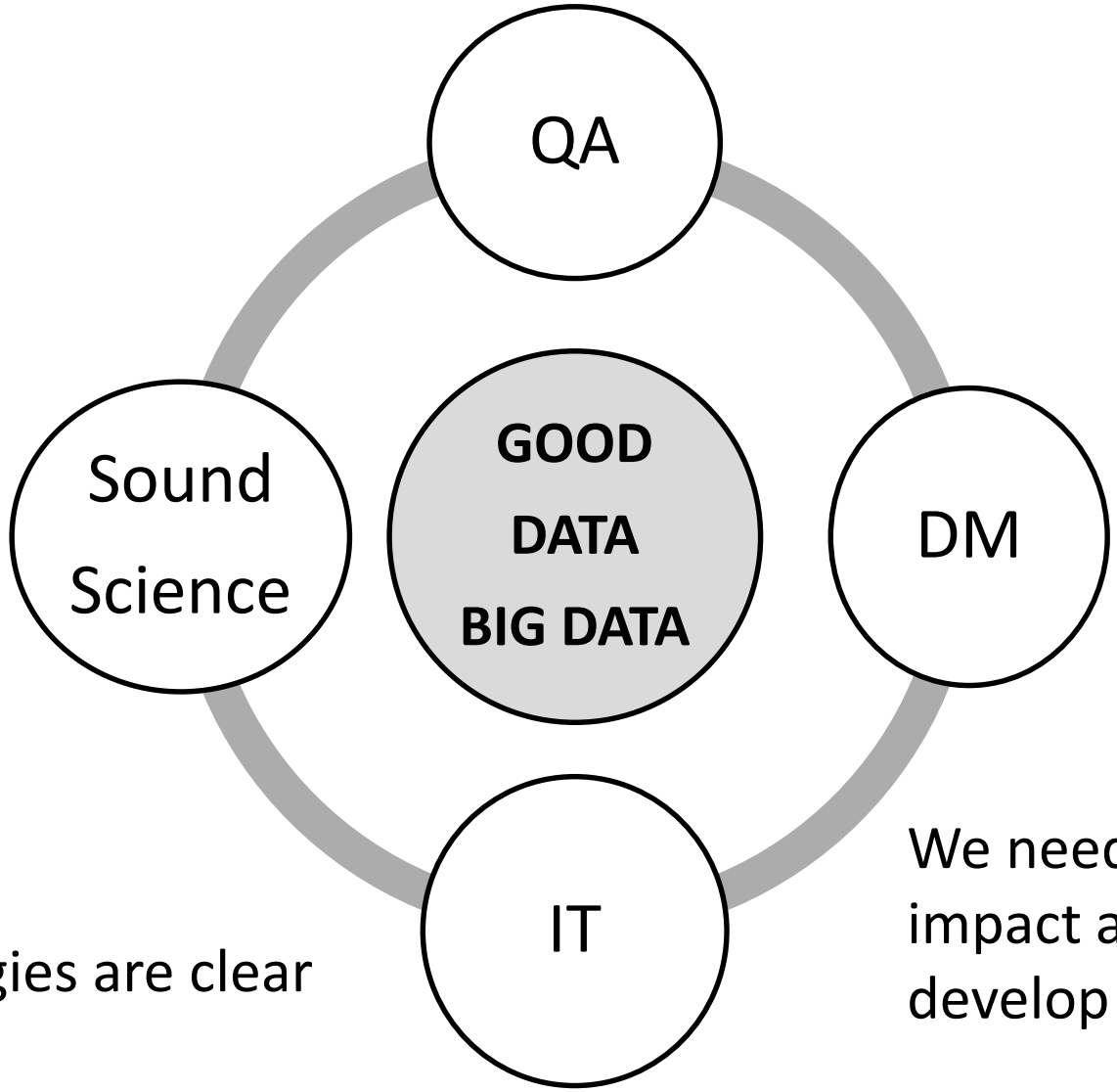


Responsible Conduct of Research [Ethics]

Data Security/IT

Reproducible Research Inference/Outcome

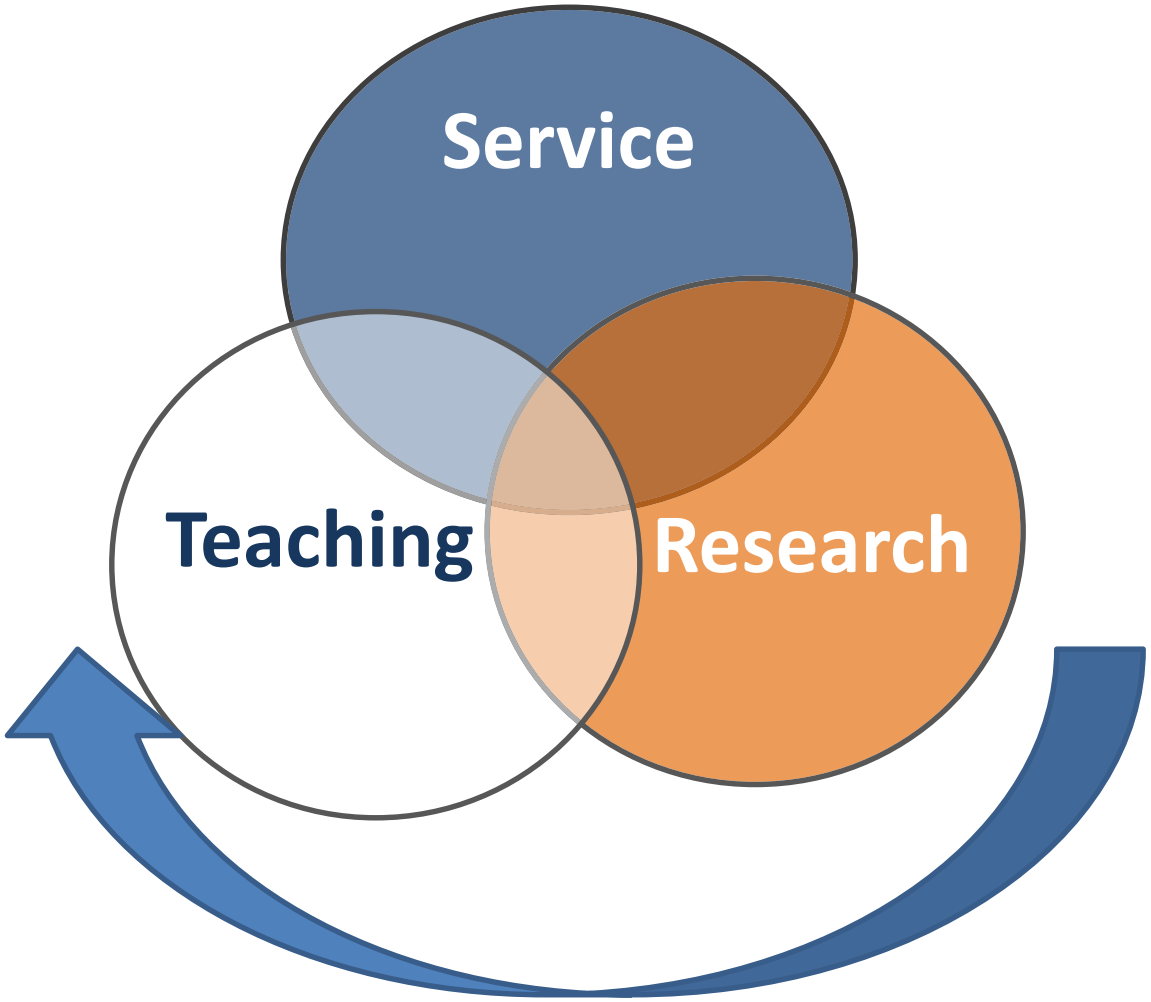
It is going to ‘take a village’



The synergies are clear

We need to evaluate impact as we develop

A mission -based approach to data quality, management and literacy



Integrate Data Support within all missions.

Promote scientific excellence

Improve data reproducibility

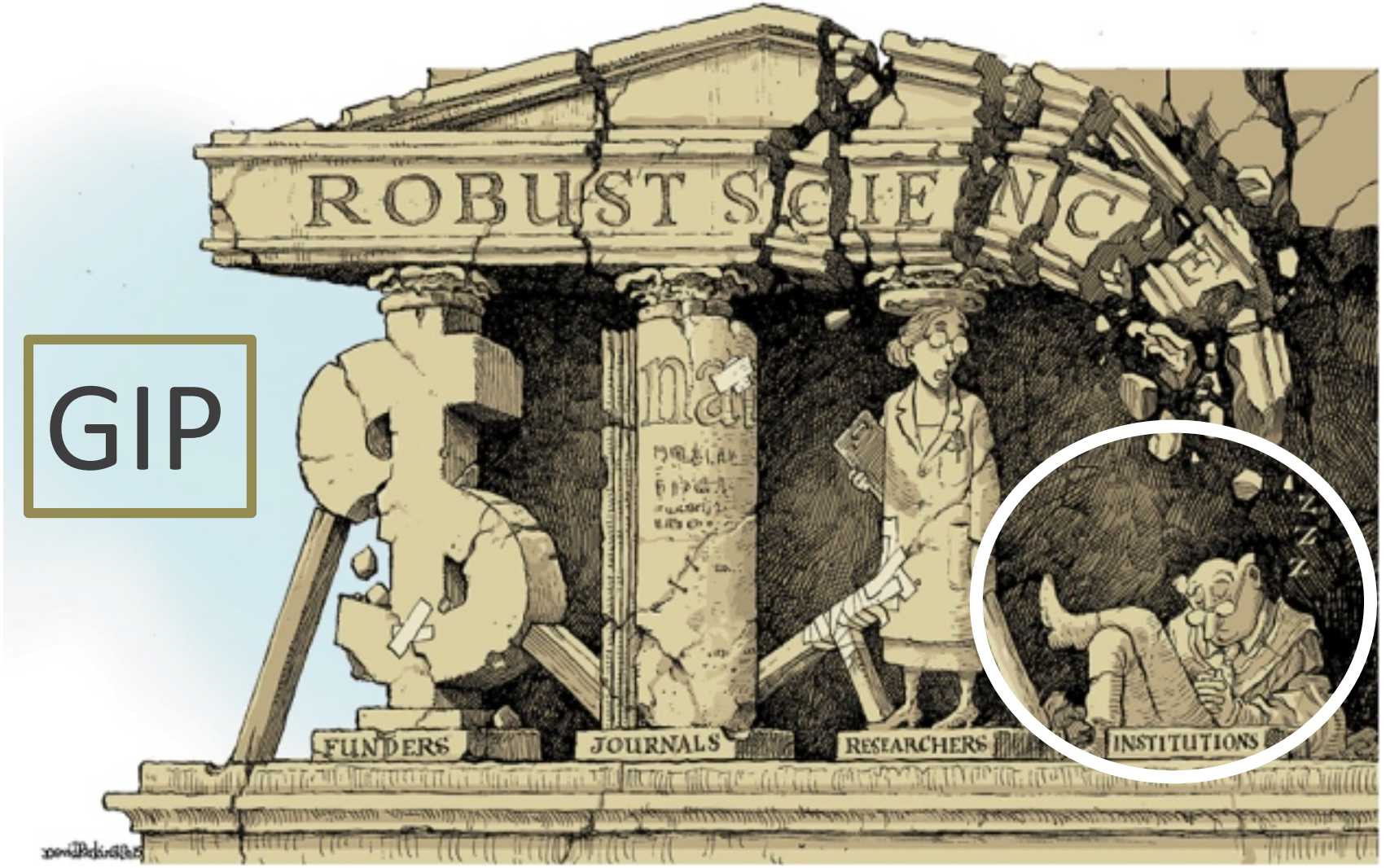
Support our scientists

Train research scientists

Robust research: Institutions must do their part for reproducibility

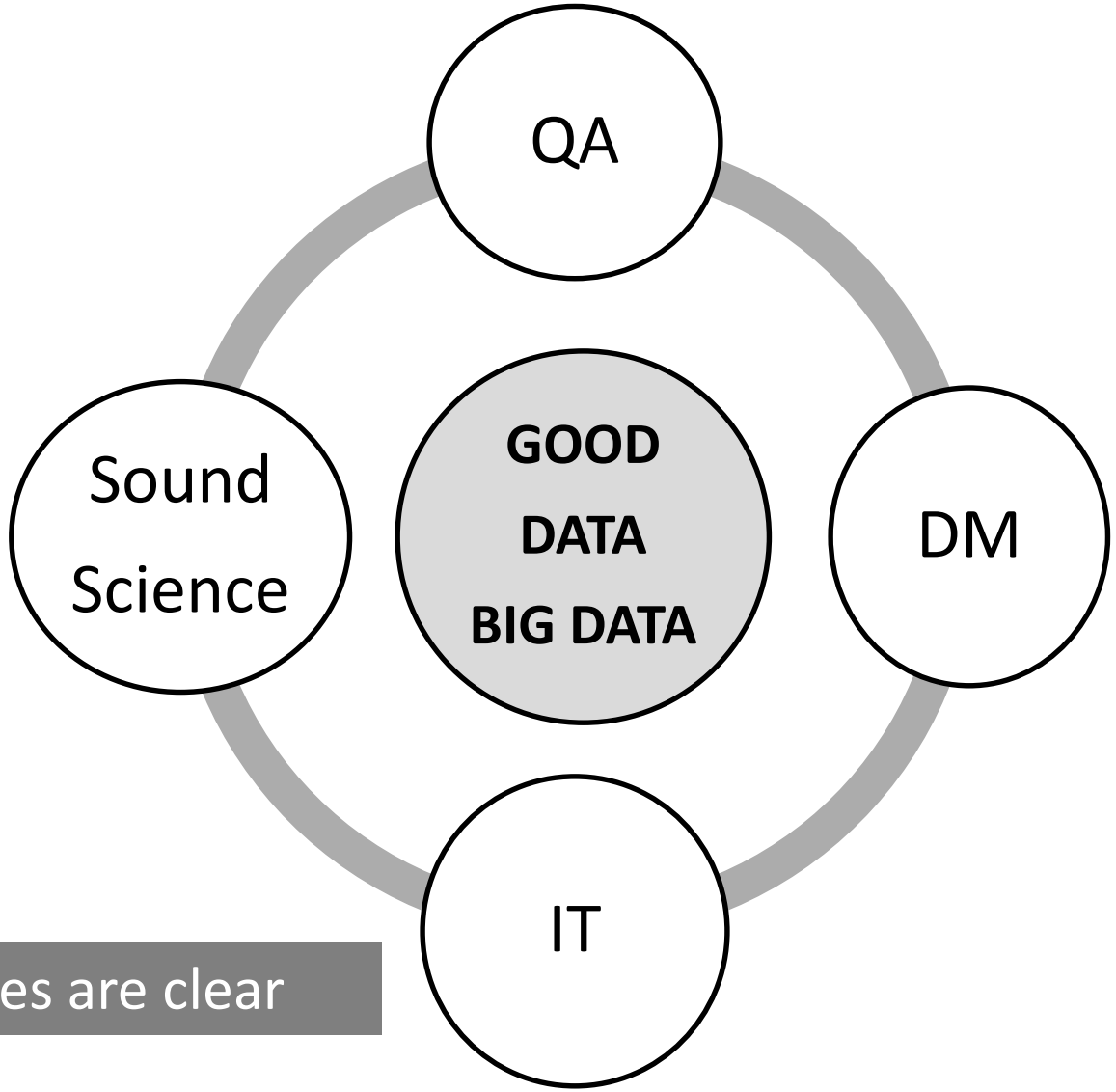
C. Glenn Begley, **Alastair M. Buchan** & **Ulrich Dirnagl**

Nature | Comment 01 Sep 2015



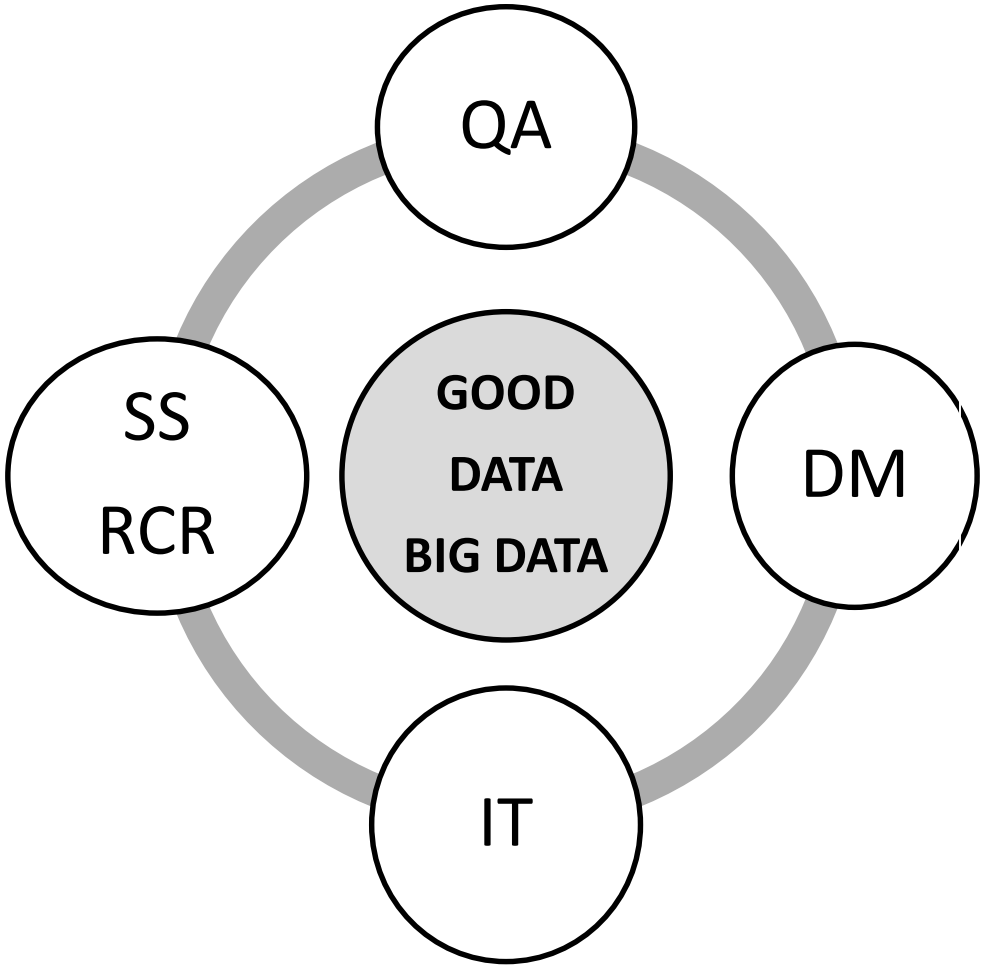
GIP

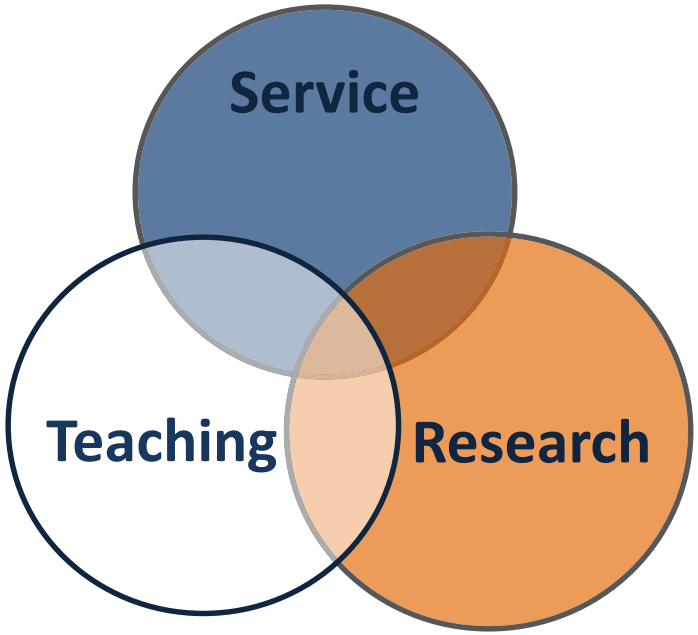
What might coordination look like?



The synergies are clear

Strategic, Sustainable, Coordinated





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Conclusions

Strategic initiatives are underway: funding agencies, scientific publishers and research institutions are engaging:

We need **scientists** to lead this narrative **[with institutional support]** and provide voluntary and effective solutions to closing the data quality and literacy gap.

Scientists must stand up for
the quality of their data

Acknowledgements

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Margret Tuisalo'o, Carrie Wees, Katrina Laube

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