Making the Case for Quality: Integrating Research Quality Assurance Support Within Academic Research Environments

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Symposium on Quality Management for Academic Research in Preclinical Biomedicine: Burden or Boom?
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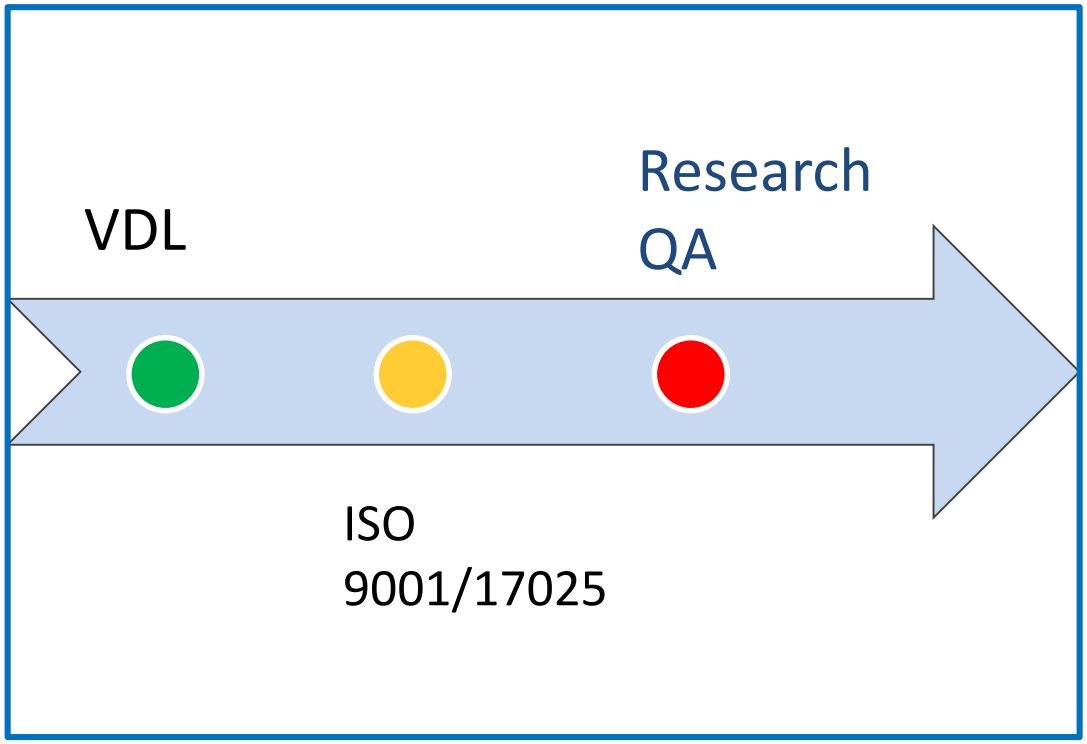
Personal Perspective: Scientist Driven Accountability



My interests:

- Adoption of r-QA best practices/commitments in academic research environment
- r-QA training and support programs
- r-QA infrastructure and sustainability: Science-Centered and Risk Based

The Case for Quality

Why QA?
Why Now?
Early Problems
First Steps
High Hopes

Research QA: Establish Expectations

At any commitment level

- Institutional
- Program
- Project
- Individual

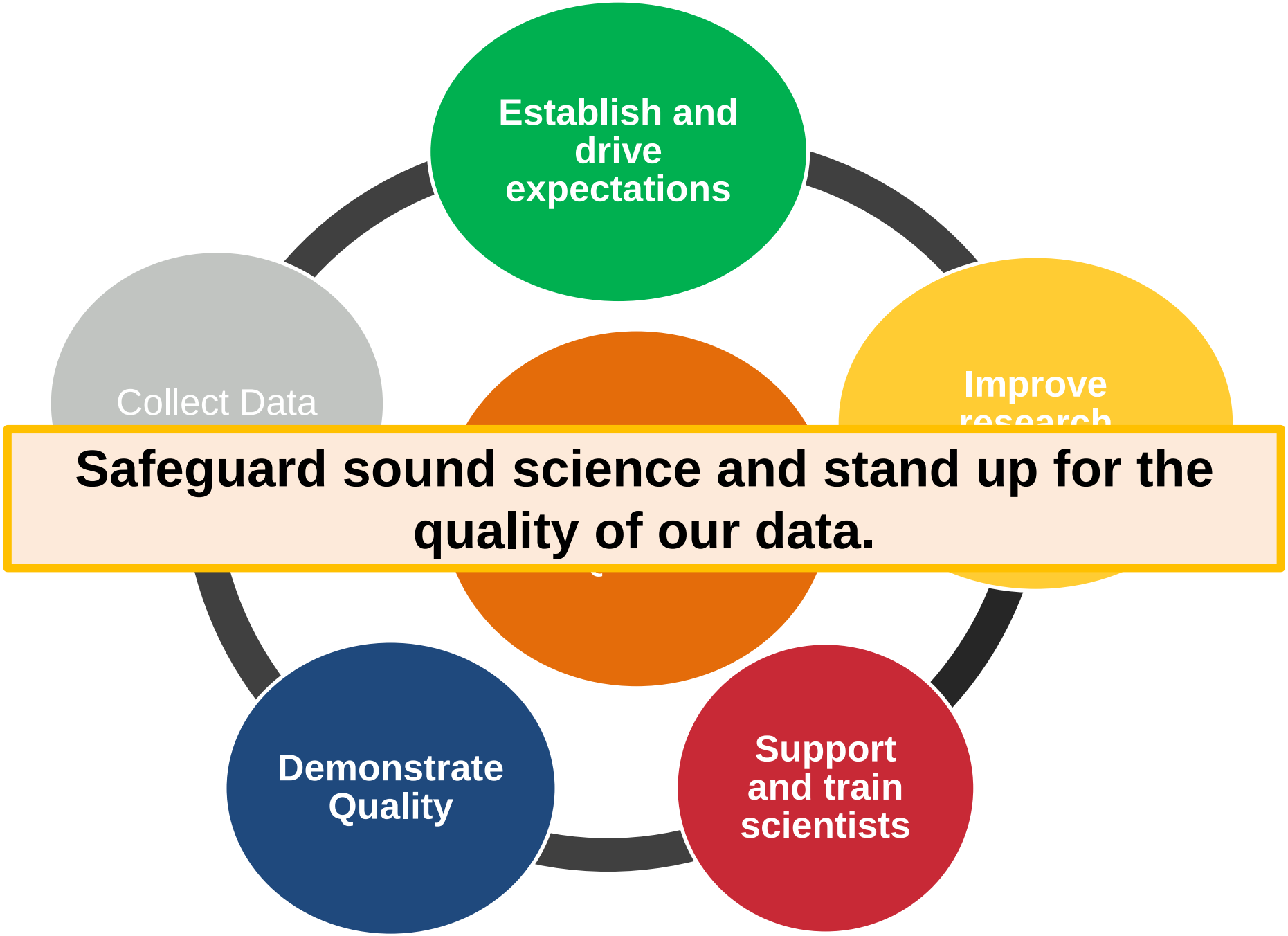
Burdens are not insignificant

Funding is a problem

Models are lacking

Find Champions

Add value


Establish and drive expectations
Improve
Collect Data
Safeguard sound science and stand up for the quality of our data.
Demonstrate Quality
Support and train scientists

Quality Assurance Management Systems are designed to:

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

and establish routine performance

The products we generate are research data, inference and publications


and the next generation of scientists

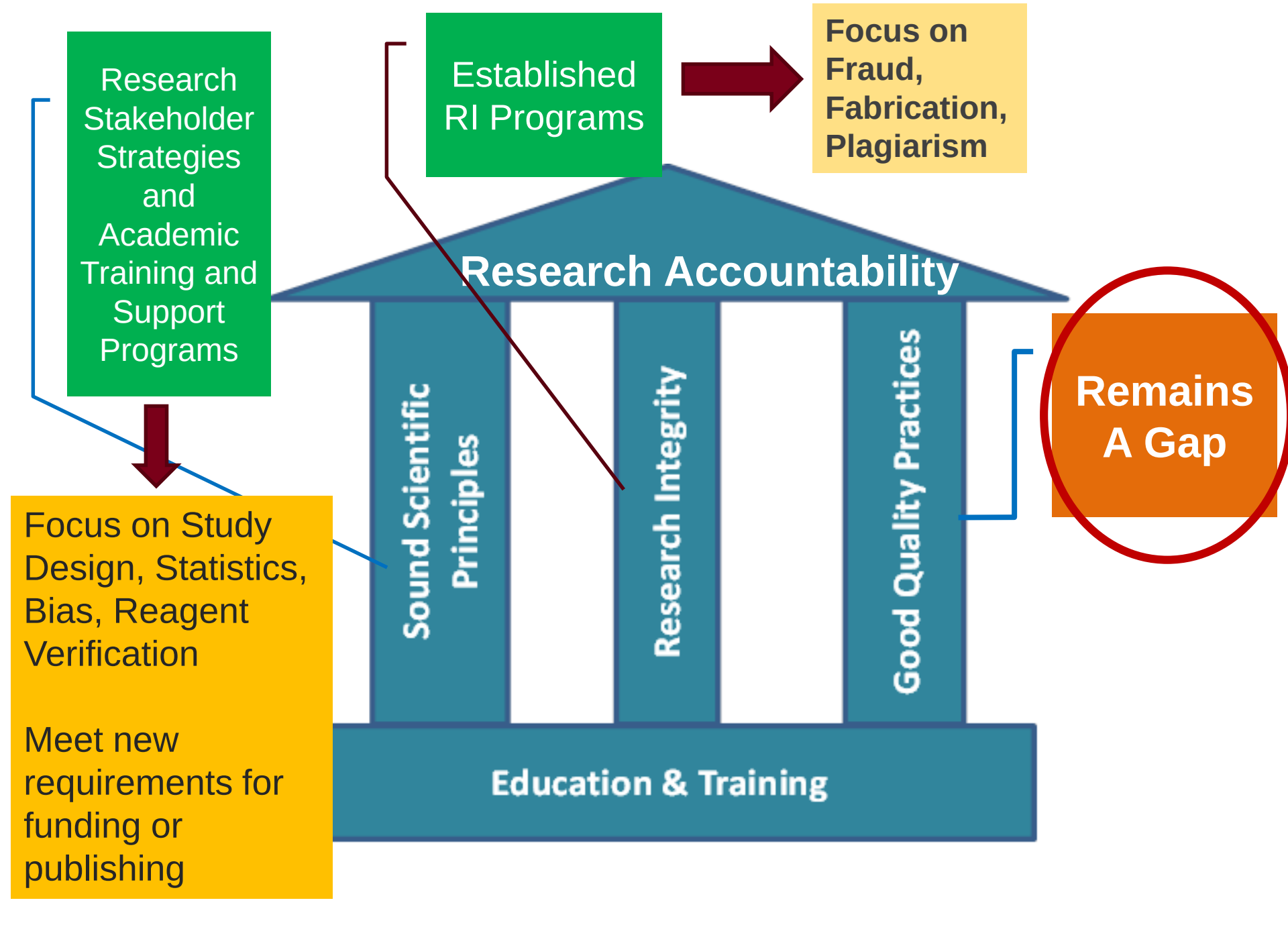
Systematic Approach: Credible Evidence

Evidence that the work is fit for its intended purpose

planning, management, execution of research activity throughout the research life cycle

Quality Assurance support is rarely found in academic basic research settings

What is happening at academic institutions?


Research Stakeholder Strategies and Academic Training and Support Programs
Established RI Programs
Focus on Fraud, Fabrication, Plagiarism
Research Accountability
Sound Scientific Principles
Research Integrity
Good Quality Practices
Education & Training
Remains A Gap
Focus on Study Design, Statistics, Bias, Reagent Verification
Meet new requirements for funding or publishing

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

(World Health Organization: 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

Sound Scientific Principles	Good Quality Practices
Premise, Hypothesis, Literature Review	Project Management Data Management
Study Design, Bias	Personnel
Statistics, Inference	Facilities
Variables (Example: Sex)	Equipment
Authentication of Critical Reagents	Materials and R
Quality Control	Method Validati
Method Selection	Procedures
Research Review	Research and W
	Research Qualit

Who, What, Where, When, How, Why

Research Records throughout the research and data life cycle.

Data Integrity

Reproducibility2020: Progress and Priorities

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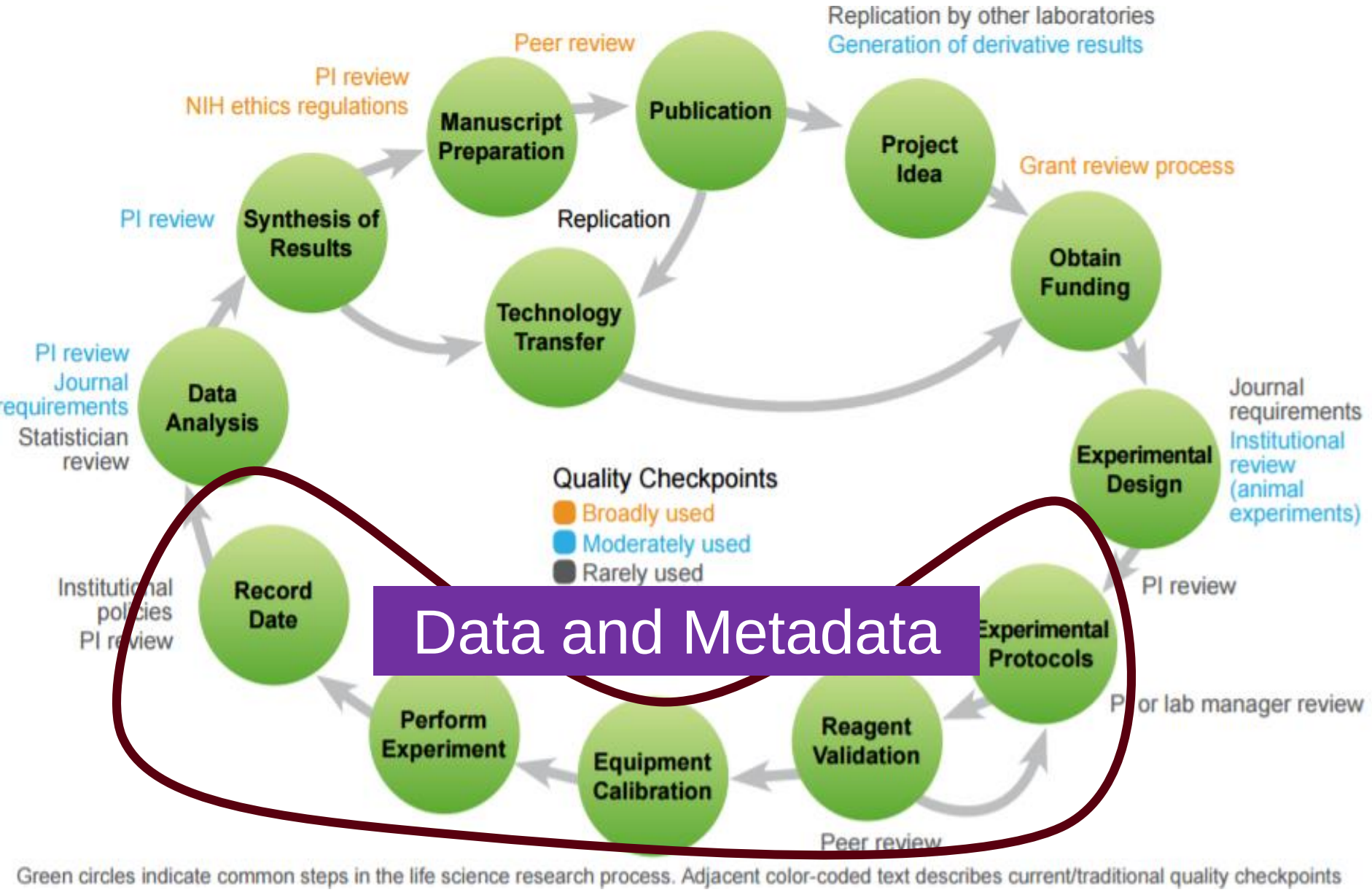
Have we got this covered?

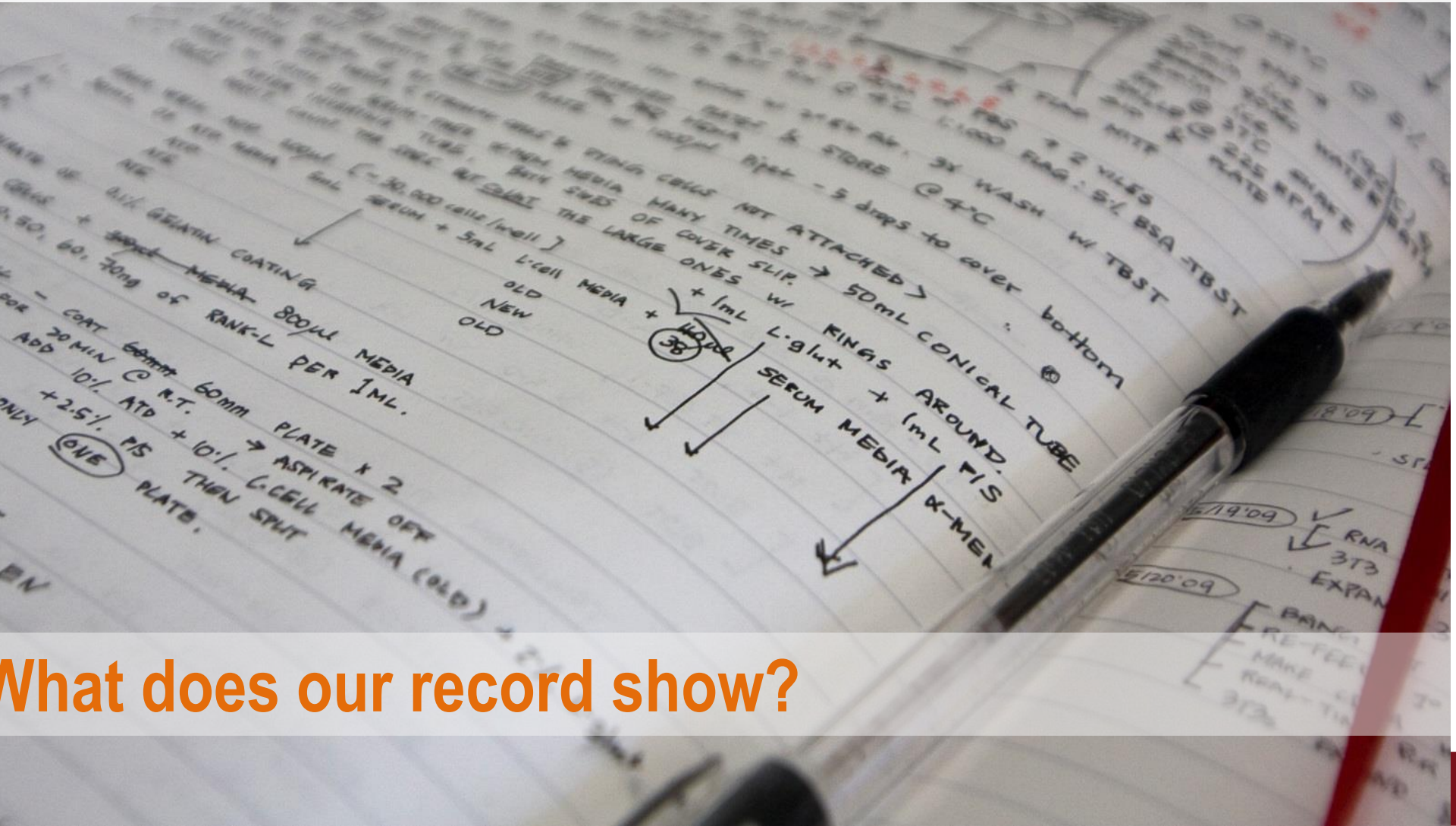
bioRxiv preprint first posted online Feb. 16, 2017; doi:http://dx.doi.org/10.1101/109017

Reproducibility 2020: Progress and priorities: http://www.gbsi.org/wp-content/uploads/2017/11/F1000-Case-for-Standards.pdf



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

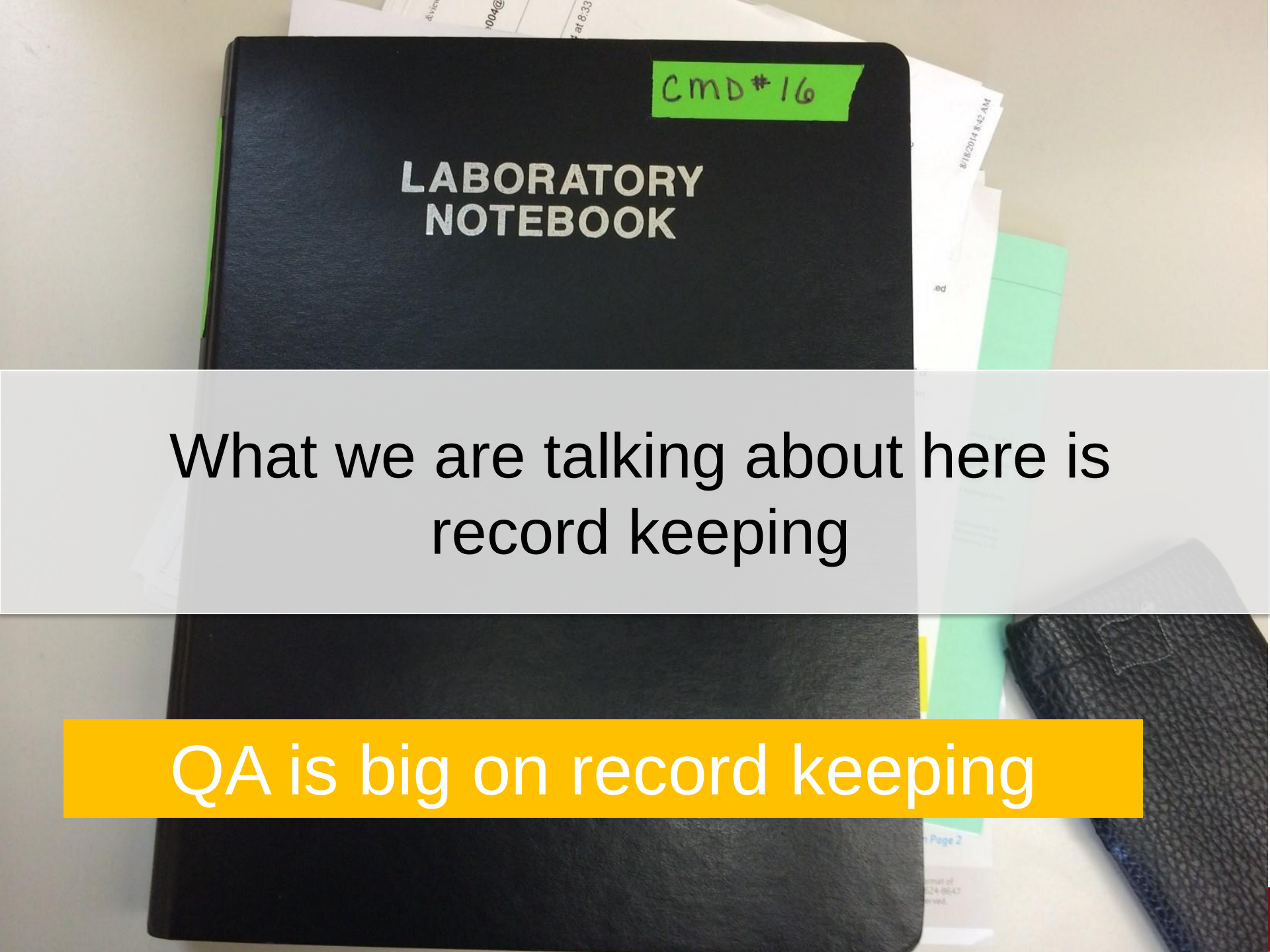
Recognizing that data and metadata reconstruction are critical to research reproducibility



What does our record show?

Problems reported with research records

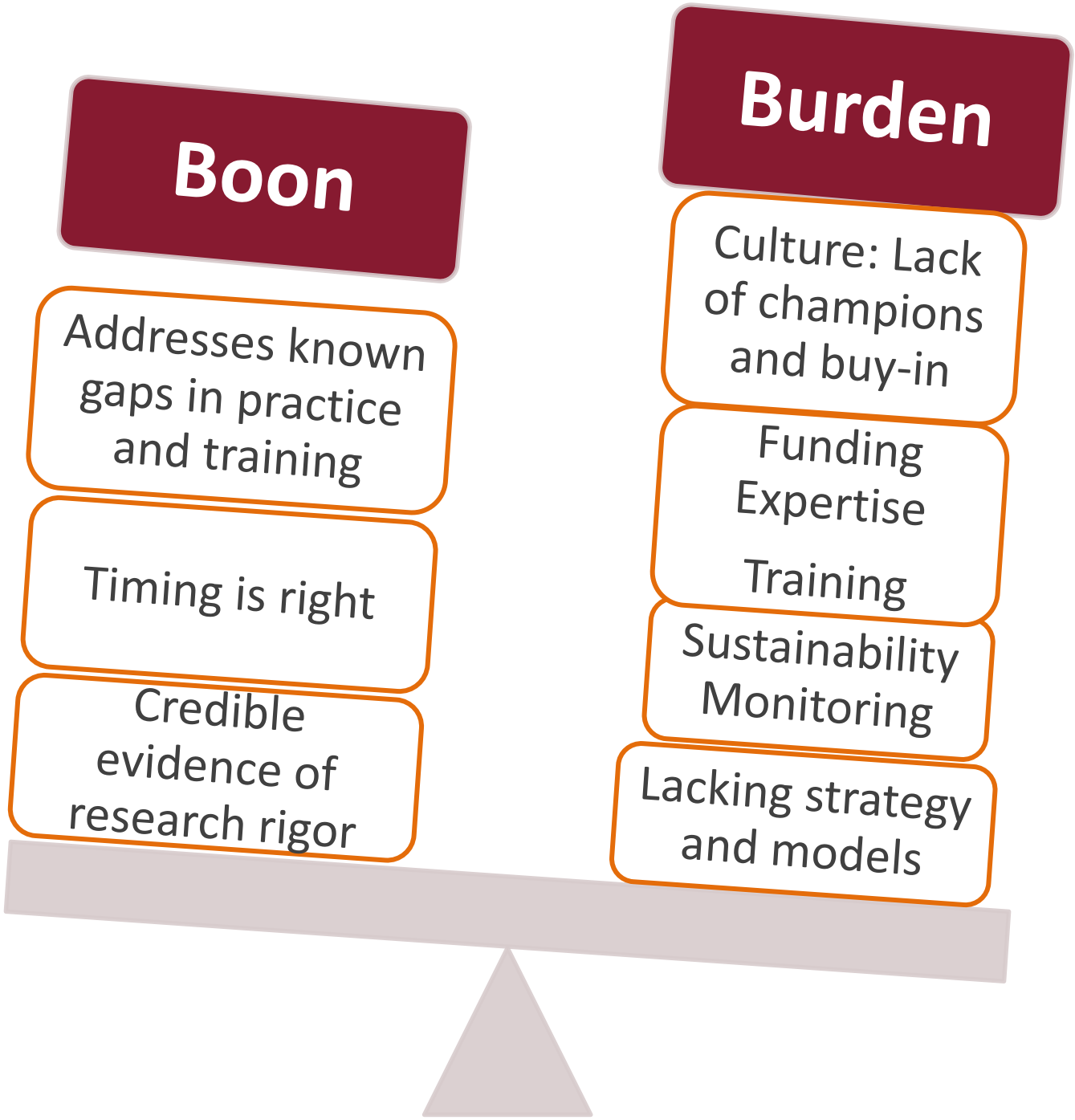
Publication	Results
On the reproducibility of science: unique identification of research resources in the biomedical literature . Vasilevsky et al, PeerJ1:el 48, 2013;	**54% of resources are not uniquely identifiable in publications**
Who's sample is it anyway? Widespread misannotation of samples in transcriptomics studies; L Toker et al, F1000Research, 2016	**Apparent mislabeled samples in 46% of the datasets studied**
Gene names are widespread in the scientific literature; Ziemann et al, Genome Biology 2016	**About one fifth of papers with supplementary Excel gene lists contain erroneous gene name conversion**
Scientists behaving badly Martinson et al, Nature 435, June 2005	**27.5% of scientists self report inadequate record keeping**



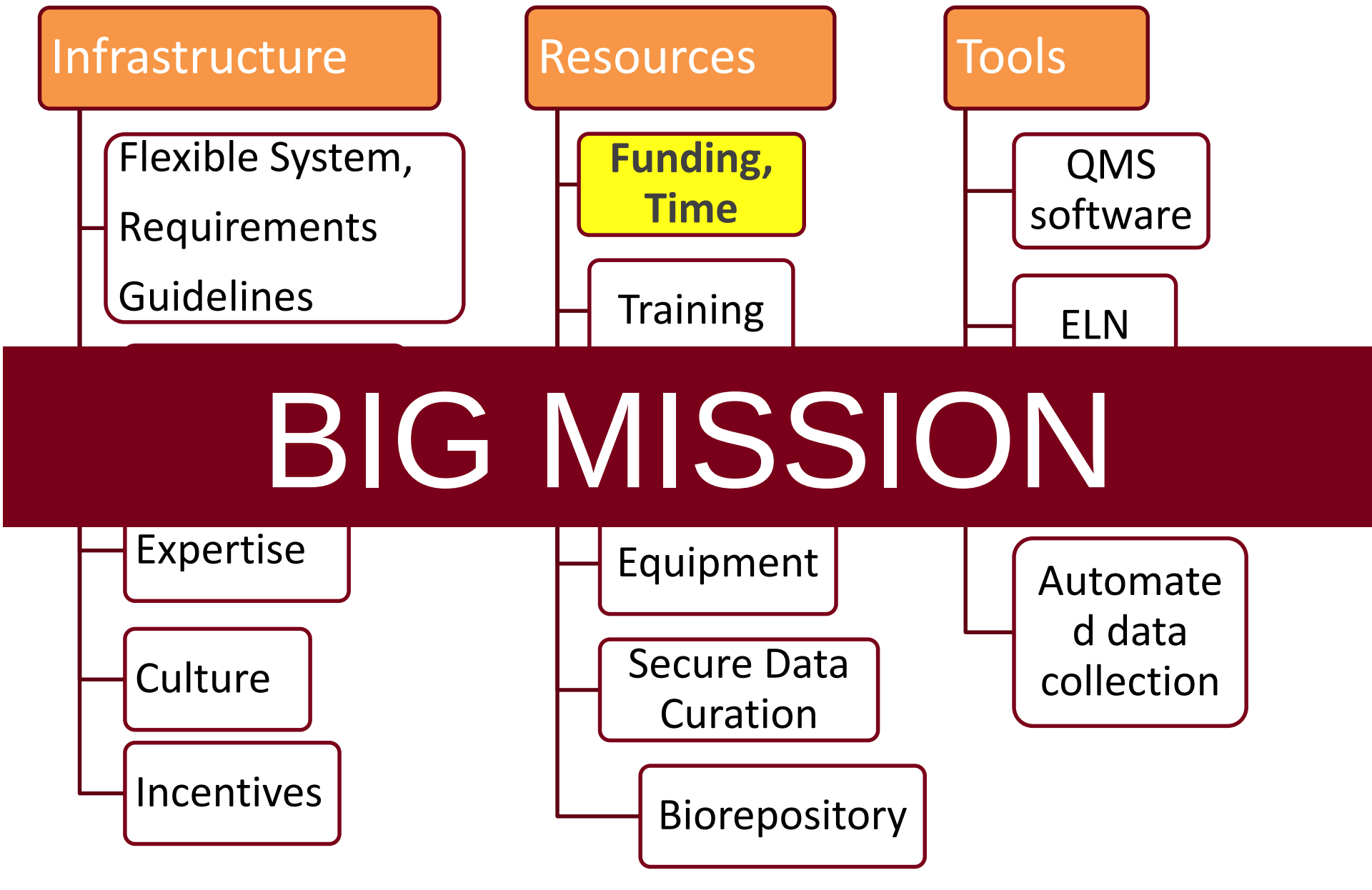
What we are talking about here is record keeping

QA is big on record keeping

Strategies are need to fill the gaps

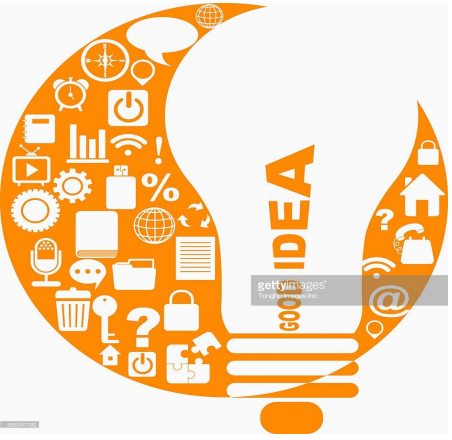

Boon
Addresses known gaps in practice and training
Timing is right
Credible evidence of research rigor
Burden
Culture: Lack of champions and buy-in
Funding
Expertise
Training
Sustainability
Monitoring
Lacking strategy and models

Infrastructure and Resource Needs



Scientist needs

- Requirements and checkpoints that add value
  - Science Centered
  - Risk Based



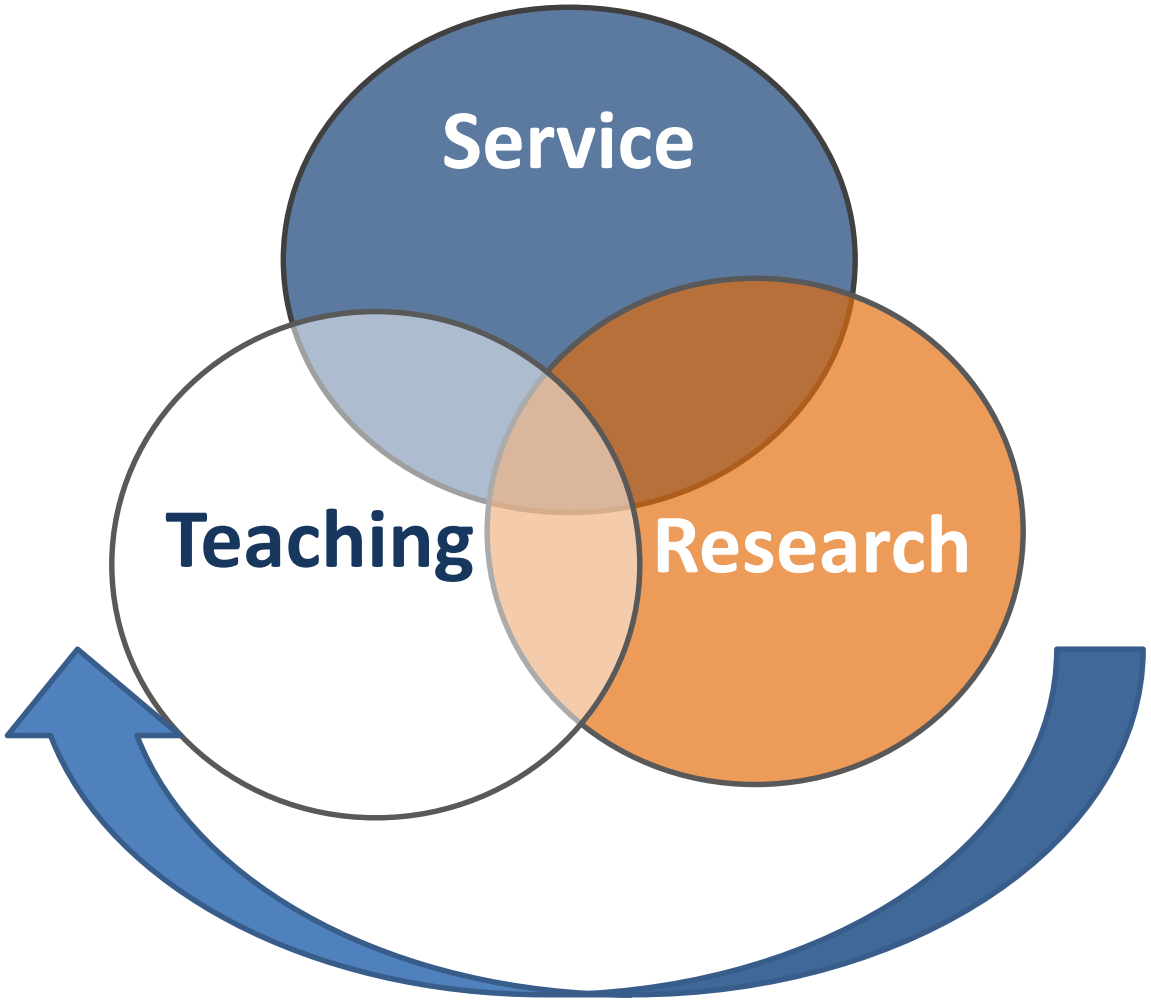
- Input
  - Flexibility
  - Creativity
  - Efficiency
  - Training

Quality Central

Sharpening the focus on sound science and quality practices

Systematic Approach : Credible Evidence

A mission (and system)-based approach to research and data accountability



Promote scientific excellence

Improve research accountability

Support scientists

Train scientists

Planting seeds: research practice

Scientist driven strategy for sustaining and demonstrating research accountability

Awareness building

Germination

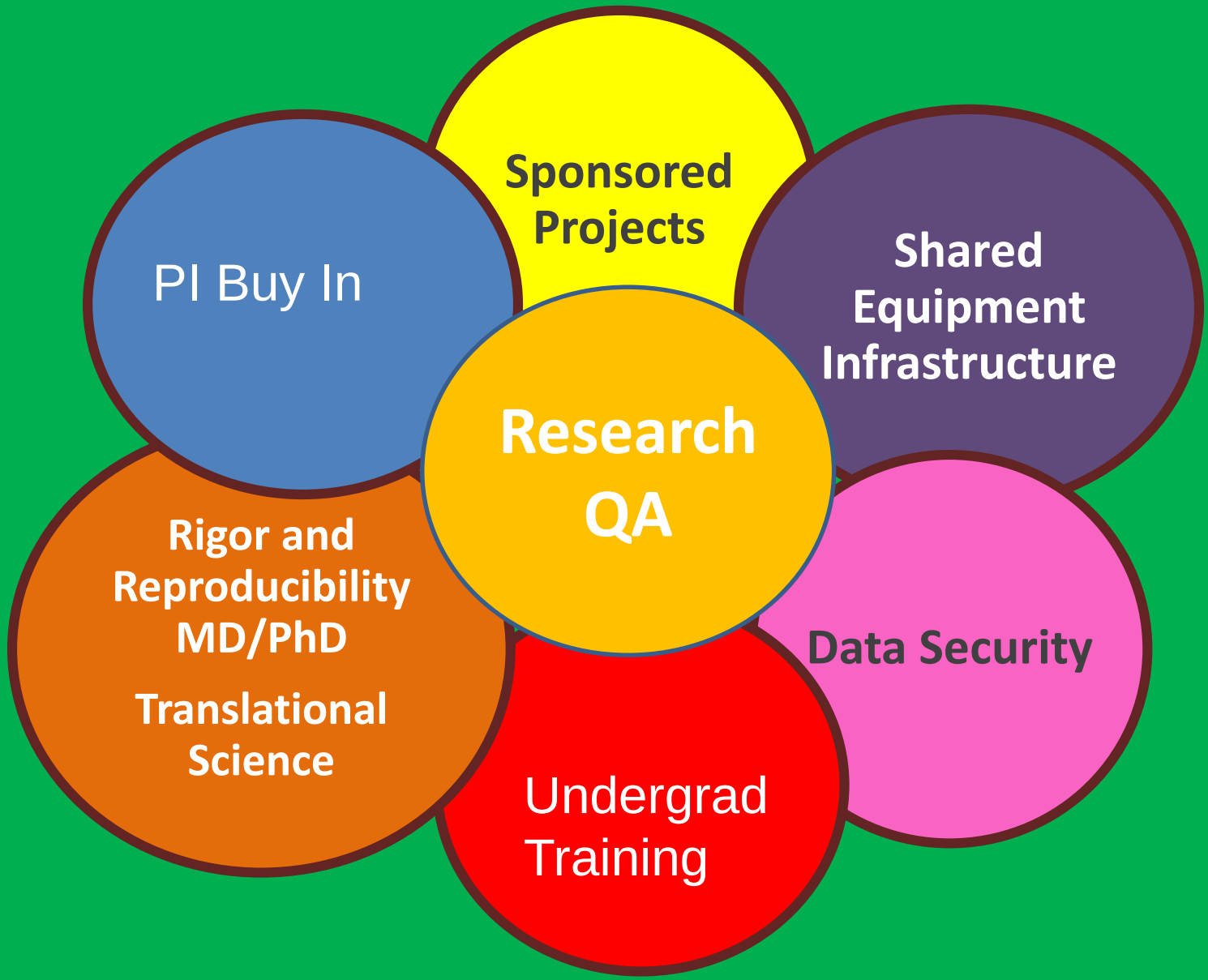
Central

Collegiate

Program

Project/Study

Individual Scientist


Sponsored Projects
PI Buy In
Shared Equipment Infrastructure
Research QA
Rigor and Reproducibility MD/PhD
Translational Science
Data Security
Undergrad Training

“I want our research data to reflect the biology of the pig - not the effect of equipment, reagents, method uncertainty or poor sample quality.

QuARRC
Quality Assurance Research Reproducibility Collaborative

Who

- **Trainees**: 12 MD/PhD and PhD predoctoral trainees [Lab Med & Path, Biochemistry, Neuroscience, Genetics, Microbiology, Immunology, and Cancer Biology]
- **Instructors:** Scientists with expertise in Quality Assurance (Quality Central Program), Educational Paradigms (Center for Education Innovation) and Data Management (Library)

What

- **Pilot program** to facilitate the adoption of Research Quality Assurance (RQA) best practices within basic research settings to enhance research rigor and reproducibility.

How

- **Trainee project based – 'Research in context'**

Boon [add value]

On Wed, Feb 28, 2018 at 10:50 AM,

Hello Rebecca,

We're putting together the Summer Scholars schedule and Bruce and I are hoping you'll again discuss quality assurance and reproducibility with the group.

This is one of the items the T35 panel picked out as a strength.

Please advise if you can participate again. Thanks.
Mark

Boon [identify champions]

Rebecca -

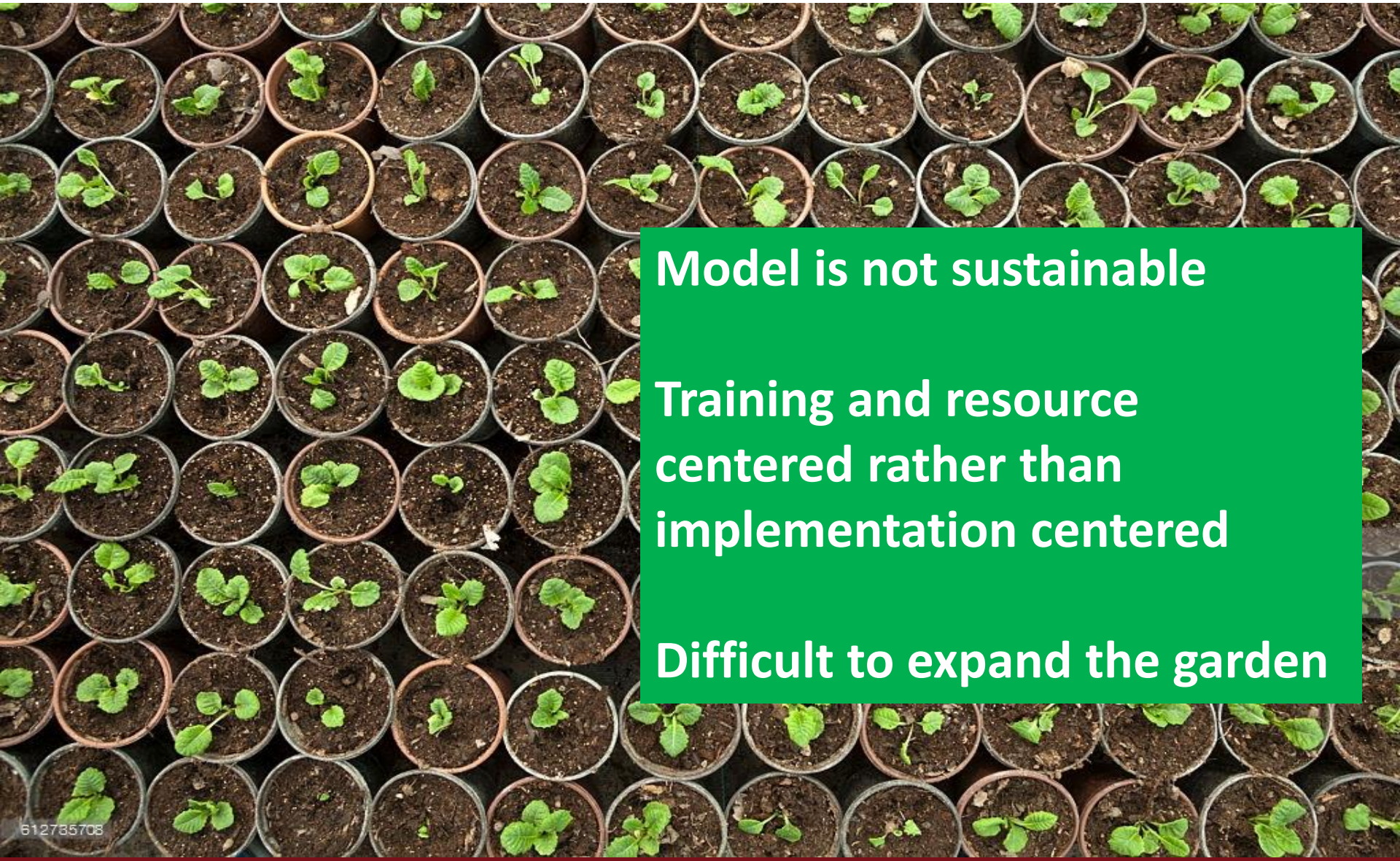
I wanted to let you know that the training grant got an amazing score. In it, we promised that we would continue to develop RQA training. …the reviews are extremely positive.

One of the things they particularly liked (and called out as a strong positive) was the RQA program. So I kind of want to continue to develop it.

I wanted to let you know the status on this, both because if this grant gets funded, you can note that **RQA played a role**, and because if funded, I **don't want to lose the RQA program.**

I want to develop it into something we can incorporate into something we do annually. David

Burden



Model is not sustainable

Training and resource centered rather than implementation centered

Difficult to expand the garden

The Time is Right for Research QA

Scientists must stand up for the quality of their work

Burden or Boon?

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Why Now?
Early Problems
First Steps

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Thank you!

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