Promoting QA in academic research environments

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US EPA's Quality Program Virtual Training Event-2022
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Disclosure:

Research Quality Coach, RQC, LLC

Establish and Implement research QA programs within basic/translational research environments: Schulze Diabetes Institute, University of Minnesota

Today's Remarks

The goal

The gap

Strategies

An example

How could we make this easier?

Published: 27 January 2016

How quality control could save your science

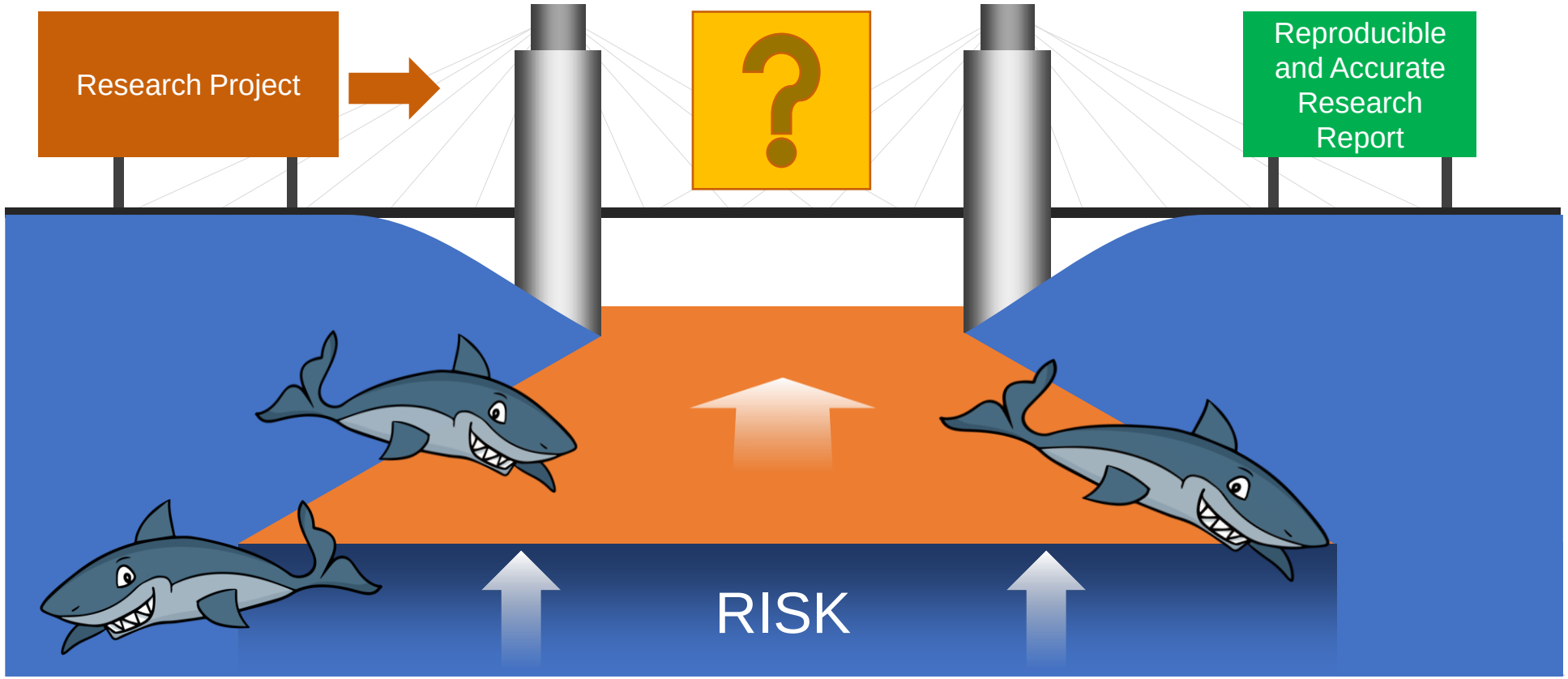
Monya Baker

Nature **529**, 456–458 (2016) | Cite this article

It may not be sexy, but quality assurance is becoming a crucial part of lab life.

There are at least six things in this picture that a quality-assurance manager would try to improve. Can you spot them?

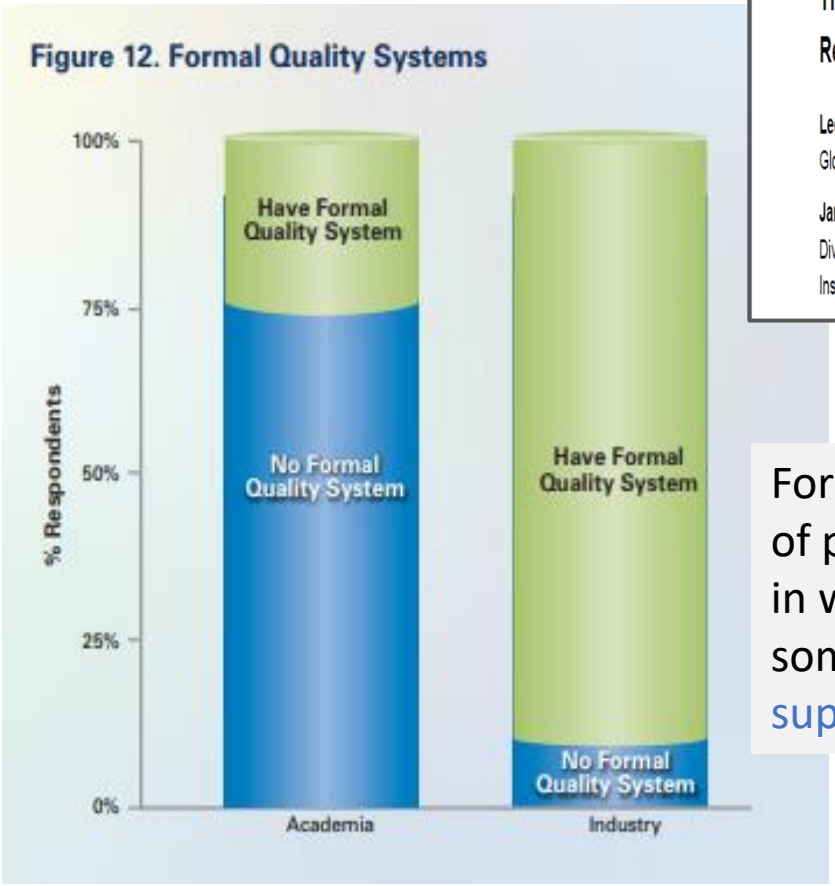
The goal: Conduct rigorous and reproducible research that generates data of discernible quality and integrity.



Uncertainty, Unintended variation, Error

The gap:

- ✓ Quality Systems support the generation of accurate, traceable, secure and verifiable data (data quality and integrity).
- ✓ Quality Systems are rare in non-regulated academic research settings
- ✓ Training in QA best practices is rare in academic research settings
- ✓ Scientists may not have experienced the value of QA.



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

Formal QS: presence of policies outlined in writing that are in some way ~~enforced~~ supported

Quality Management Systems are protective and supportive

Establishes the standards (**requirements**) that you will work to and how you are going to meet them

Defines what people, actions and documents are going to be employed in order to carry out the work in a consistent manner, **leaving evidence of what happened**

May include manuals, handbooks, procedures, policies, records and templates

'Ensure that data are fit for purpose and to give assurance that the processes under which the data have been generated are completely accountable and transparent'

Guidelines for Quality in Non-Regulated Scientific Research, RQA 2014.

Quality Systems Workbook. Handy, L. et al., 2013 Research Quality Association

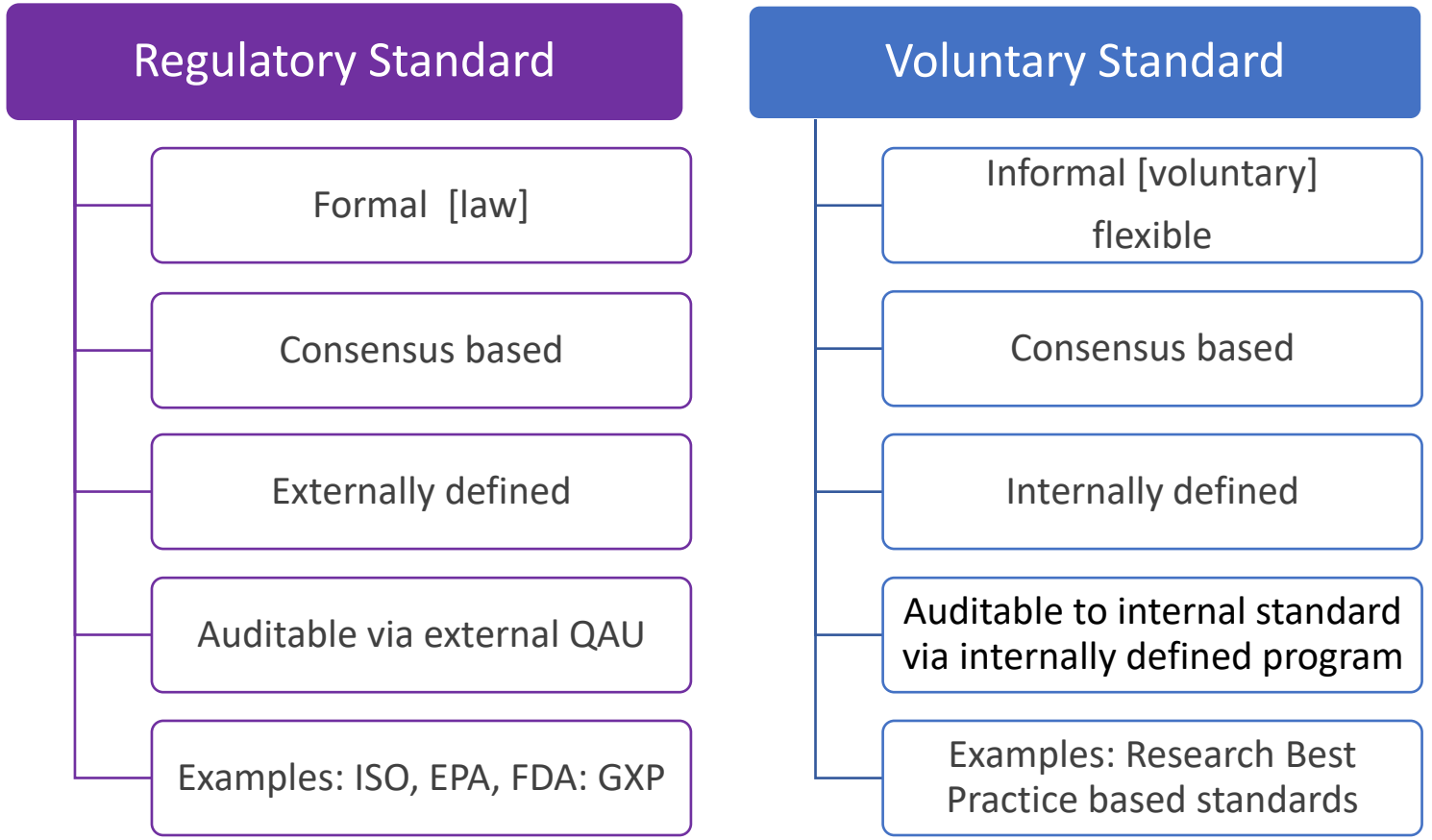
Strategies

-Voluntary Program

- Scientist Defined
- Institutionally Defined

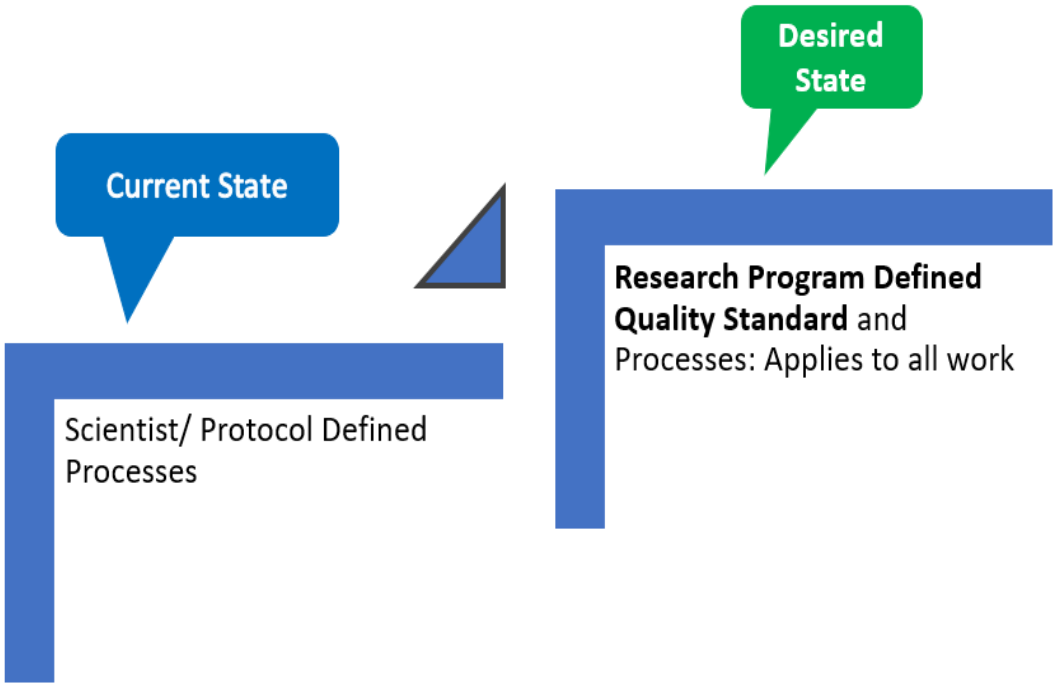
-National/Regulatory Program

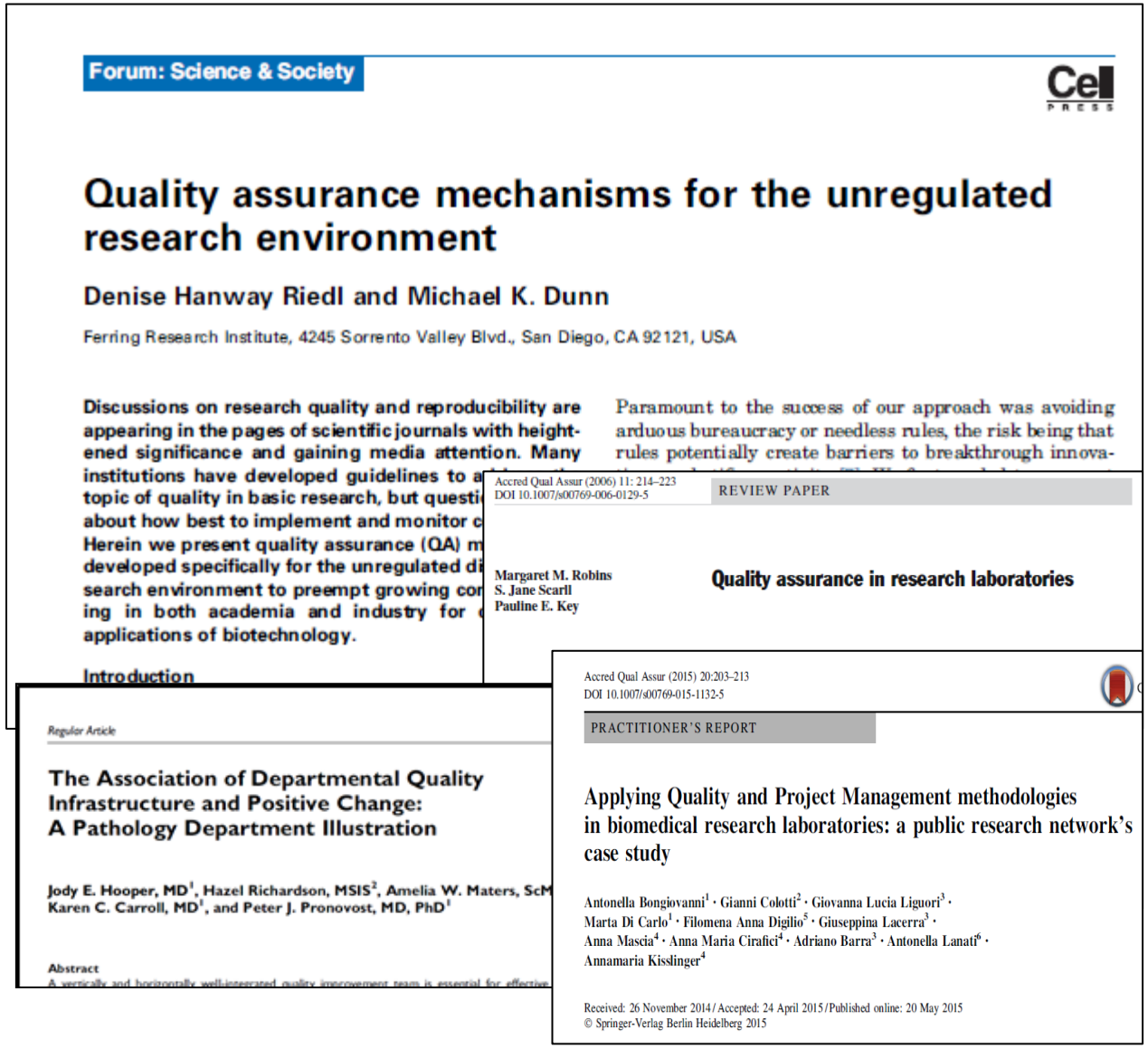
- Multi-agency development of a research standard



Scientist-Defined Program

Stepping up to a system approach





Forum: Science & Society

Cell PRESS

Quality assurance mechanisms for the unregulated research environment

Denise Hanway Riedl and Michael K. Dunn

Ferring Research Institute, 4245 Sorrento Valley Blvd., San Diego, CA 92121, USA

Discussions on research quality and reproducibility are appearing in the pages of scientific journals with height-ened significance and gaining media attention. Many institutions have developed guidelines to a topic of quality in basic research, but questi about how best to implement and monitor c Herein we present quality assurance (QA) m developed specifically for the unregulated di search environment to preempt growing cor ing in both academia and industry for applications of biotechnology.

Introduction

Paramount to the success of our approach was avoiding arduous bureaucracy or needless rules, the risk being that rules potentially create barriers to breakthrough innova-

Accred Qual Assur (2006) 11: 214–223
DOI 10.1007/s00769-006-0129-5

REVIEW PAPER

Margaret M. Robins
S. Jane Scarll
Pauline E. Key

Quality assurance in research laboratories

Regular Article

The Association of Departmental Quality Infrastructure and Positive Change: A Pathology Department Illustration

Jody E. Hooper, MD[1], Hazel Richardson, MSIS[2], Amelia W. Maters, ScM
Karen C. Carroll, MD[1], and Peter J. Pronovost, MD, PhD[1]

Abstract

Accred Qual Assur (2015) 20:203–213
DOI 10.1007/s00769-015-1132-5

PRACTITIONER'S REPORT

Applying Quality and Project Management methodologies in biomedical research laboratories: a public research network's case study

Antonella Bongiovanni[1] · Gianni Colotti[2] · Giovanna Lucia Liguori[3] · Marta Di Carlo[1] · Filomena Anna Digilio[5] · Giuseppina Lacerra[3] · Anna Mascia[4] · Anna Maria Cirafici[4] · Adriano Barra[3] · Antonella Lanati[6] · Annamaria Kisslinger[4]

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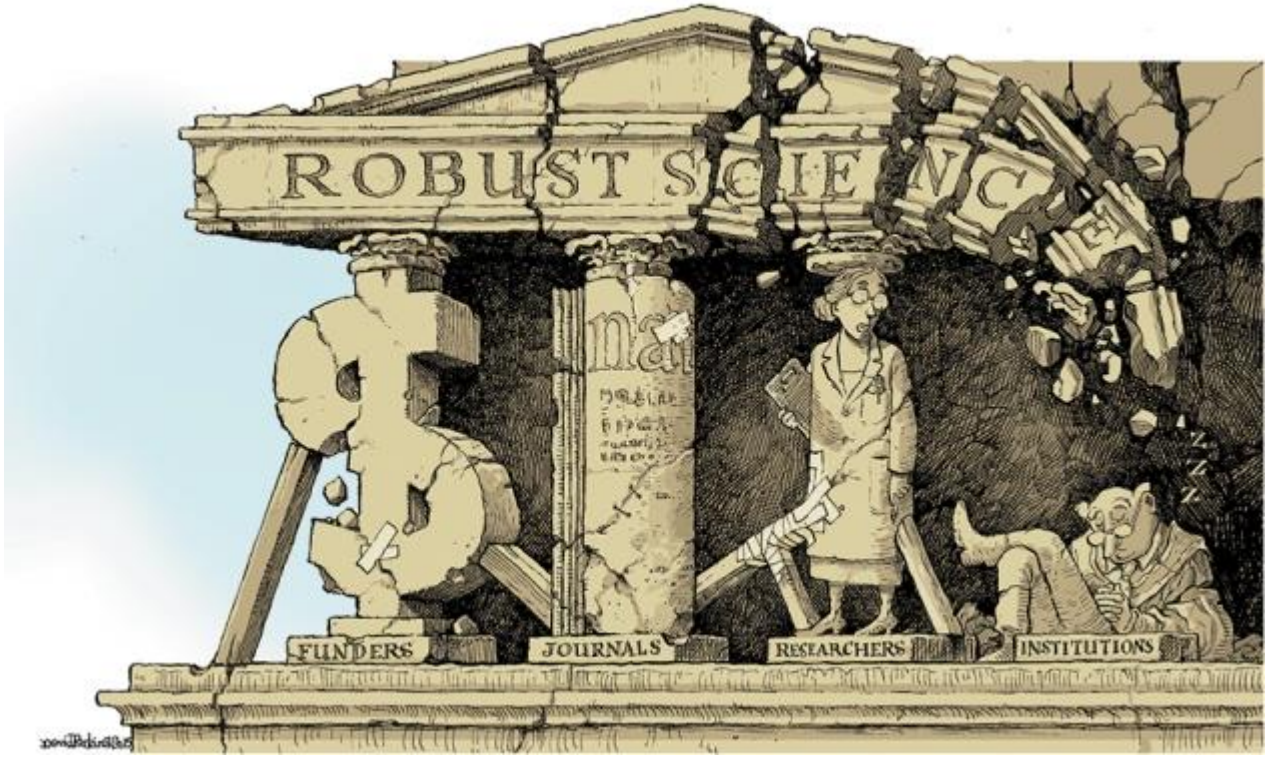
Institution-Defined Program

Good Institutional Practices:

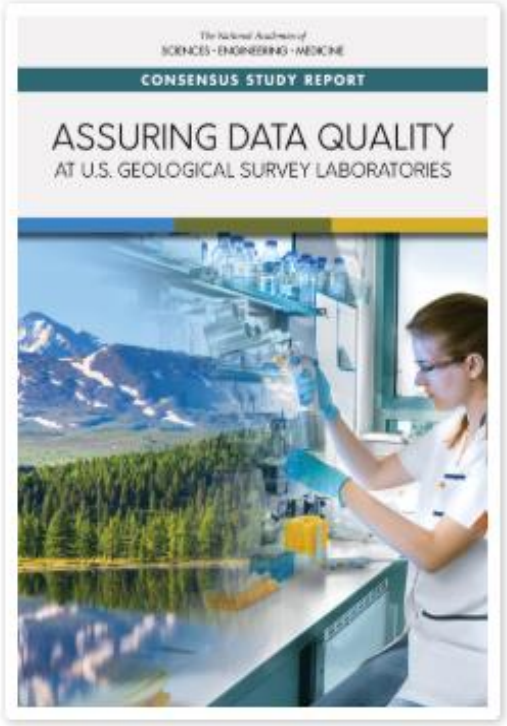
“We propose that research institutions that receive public funding should apply the same kind of oversight and support to ensure research integrity as is routinely applied for animal husbandry, biosafety and clinical work”

Robust Research: Institutions must do their part for reproducibility.

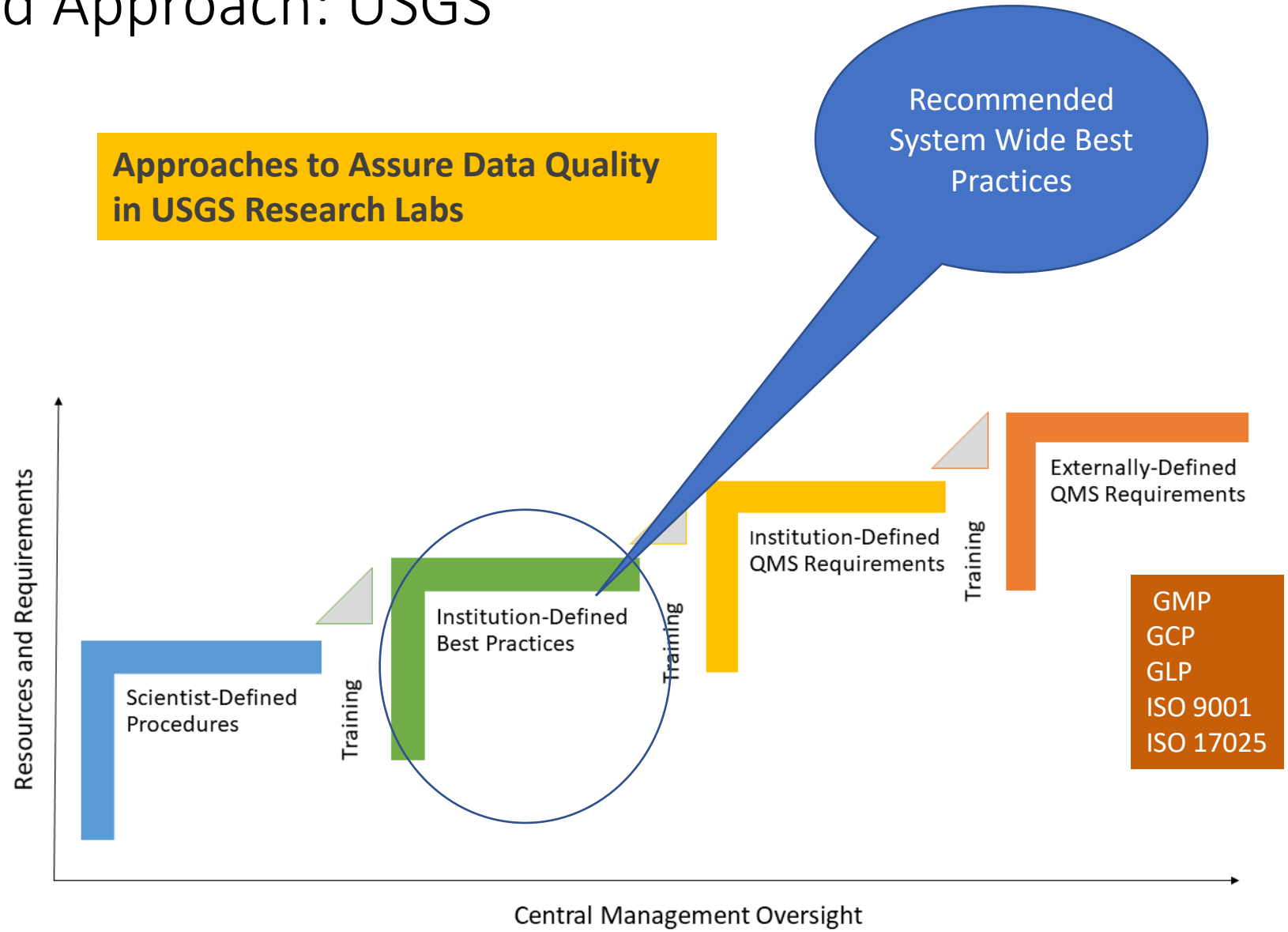
Nature Comment; 01 Sep 2015
Begley CG et al.



Institution Defined Approach: USGS



Approaches to Assure Data Quality in USGS Research Labs



National Academies of Sciences, Engineering, and Medicine. 2019. *Assuring Data Quality at U.S. Geological Survey Laboratories*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25524.

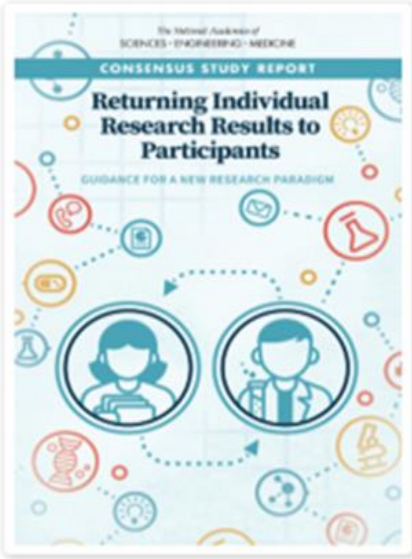
Nationally Defined Program

National Academies of Sciences, Engineering, and Medicine. 2018.

Returning individual research results to participants Guidance for a new research paradigm

The National Academies of | SCIENCES ENGINEERING MEDICINE

About Ordering Information New Releases



National Academies of Sciences, Engineering, and Medicine. 2018. *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25094.

National Academies of Sciences, Engineering, and Medicine. 2018. *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25094.

"…support is growing among investigators, sponsors, and regulators in the United States for the development of a standardized QMS for biomedical research laboratories.

However, given the myriad of interested and invested parties, a coordinated effort will be needed with all stakeholders at the table to provide input on the quality system elements and key implementation processes.

Many government agencies, private institutions, pharmaceutical companies, and patient organizations are sponsoring and participating in research that would benefit from the development and use of a QMS for biomedical research laboratories. A joint effort by these stakeholders would increase efficiency and avoid waste, redundancy, and confusion on the part of investigators from different quality standards across sponsors and funding agencies."

Returning individual research results to participants Guidance for a new research paradigm

National Academies of Sciences, Engineering, and Medicine. 2018. *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25094.

"With proper representation, an externally accountable QM that details best practices for laboratories across the biomedical research spectrum has the potential to improve the conduct of research, address current gaps in training and practice, and benefit the whole of the research enterprise."

Recommendation 2: NIH should lead an interagency effort including nongovernmental stakeholders to develop an externally accountable QMS for non-CLIA certified research laboratories testing human biospecimens.

Recommendation 4: Ensure adequate resources and infrastructure to generate high-quality research result.

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Scientist/Program Defined QMS

Schulze Diabetes Institute

University Of Minnesota

Dr. Bernhard Hering: Executive Director

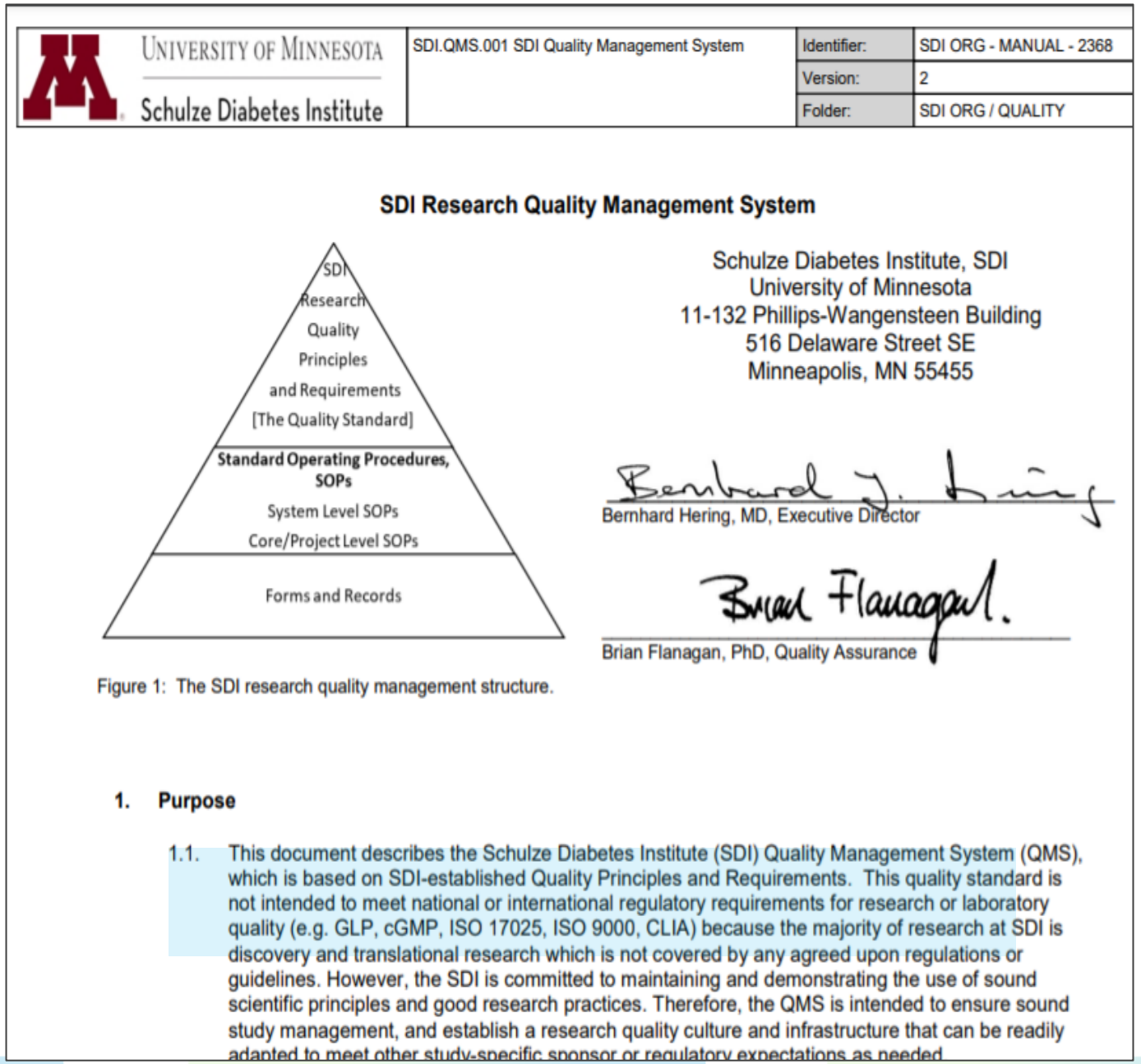
Mission: Pioneering superior transplant therapeutics for people burdened with diabetes.

4 Research cores

16 -18 scientists (faculty, supervisory scientists, technicians, students)

1 Quality Manager Role

QA is everyone's job and duties are shared across the program



UNIVERSITY OF MINNESOTA Schulze Diabetes Institute	SDI.QMS.001 SDI Quality Management System	Identifier:	SDI ORG - MANUAL - 2368
		Version:	2
		Folder:	SDI ORG / QUALITY

SDI Research Quality Management System

Figure 1: The SDI research quality management structure.

Schulze Diabetes Institute, SDI
University of Minnesota
11-132 Phillips-Wangensteen Building
516 Delaware Street SE
Minneapolis, MN 55455

Bernhard Hering, MD, Executive Director

Brian Flanagan, PhD, Quality Assurance

1. Purpose

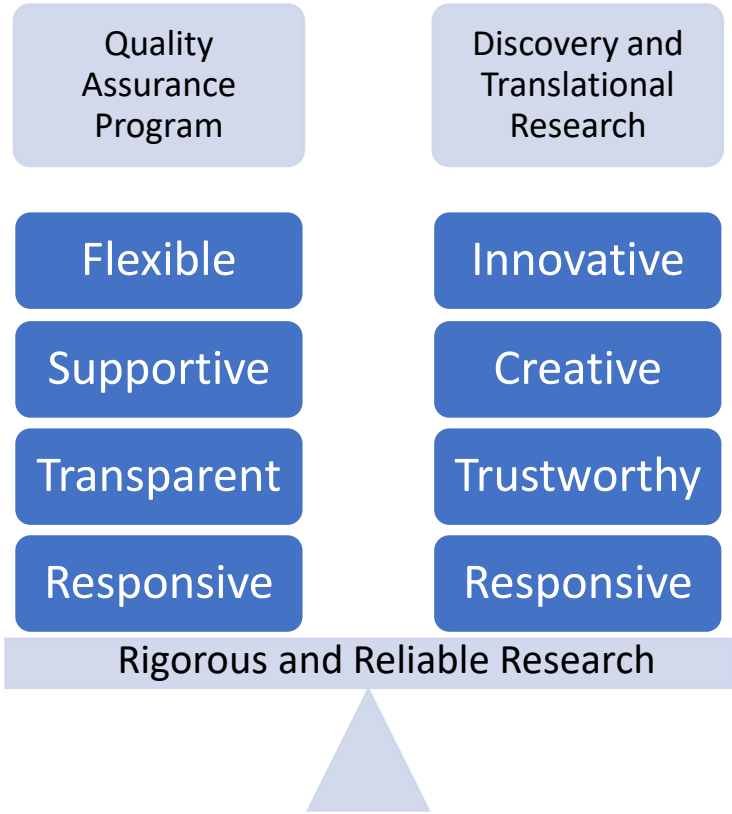
1.1. This document describes the Schulze Diabetes Institute (SDI) Quality Management System (QMS), which is based on SDI-established Quality Principles and Requirements. This quality standard is not intended to meet national or international regulatory requirements for research or laboratory quality (e.g. GLP, cGMP, ISO 17025, ISO 9000, CLIA) because the majority of research at SDI is discovery and translational research which is not covered by any agreed upon regulations or guidelines. However, the SDI is committed to maintaining and demonstrating the use of sound scientific principles and good research practices. Therefore, the QMS is intended to ensure sound study management, and establish a research quality culture and infrastructure that can be readily adapted to meet other study-specific sponsor or regulatory expectations as needed.

Mission: Pioneering superior transplant therapeutics for people burdened with diabetes

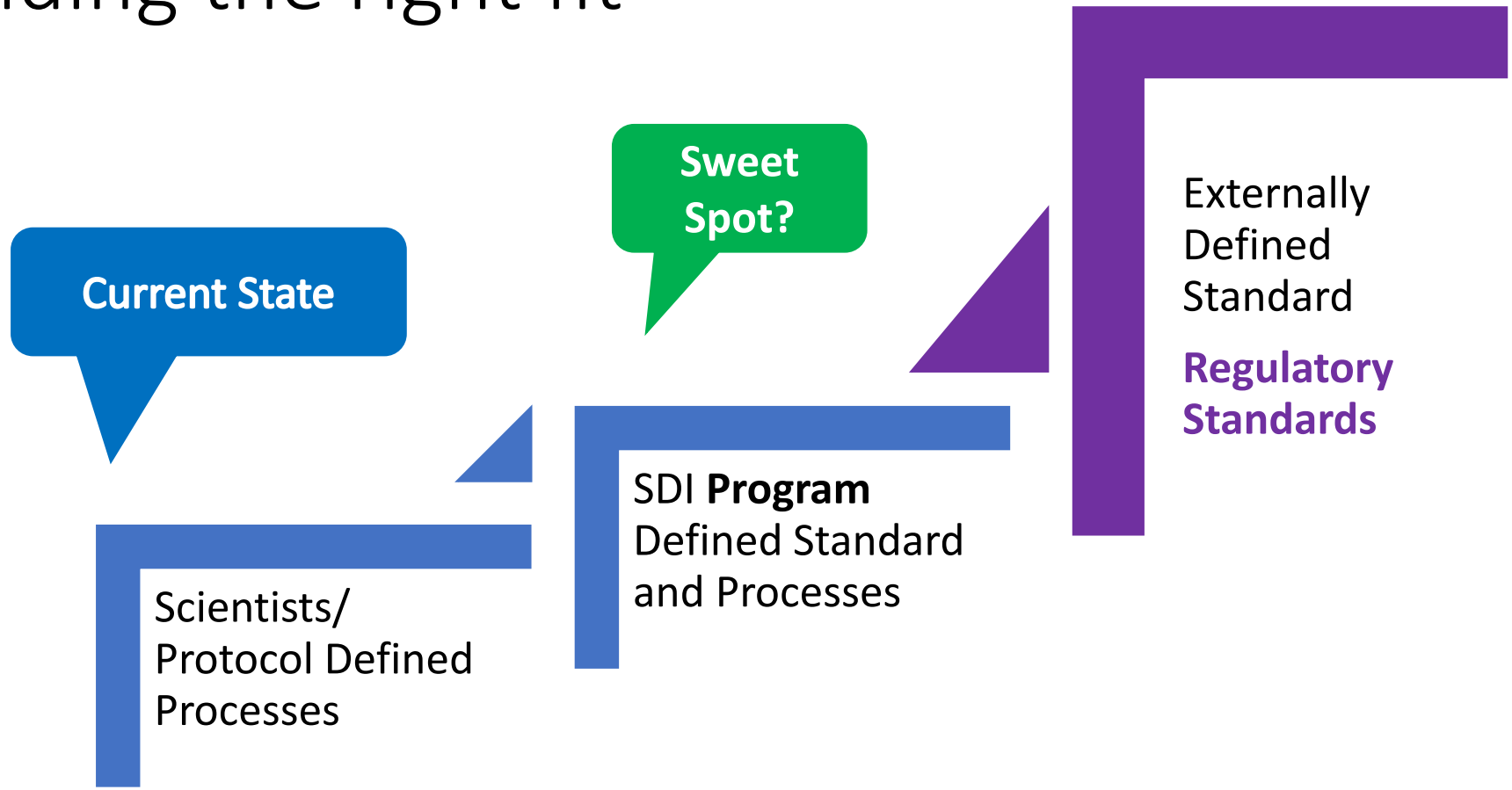
SDI wants their data to meet FDA expectations right from the start

Objectives

- Establish a QMS based on research best practices to document policies and procedures for SDI research activities
- Provide standardized instructions for how routine work should be done to ensure data quality and integrity and to optimize traceability in data and reporting.
- Provide a mechanism for routine supervision, review and audit of research and data quality to confirm authenticity and accuracy of results
- Provide assurances that the processes under which data have been generated are accountable and transparent.
- Foster a rigorous research culture and opportunities for continuous improvement
- Support the generation of reliable and traceable data to supplement regulated study activities and advance translational research.



Finding the right fit



Risk Based Effort, Training and Resource Investment

The SDI Quality Standard

1.A **voluntary quality standard** that describes how work is to be managed, executed, documented and monitored across all SDI activities.

2.Based on **recommended best practices** for **non-regulated research**.

3. 11 quality principles and associated requirements that apply to managerial and technical activities (System Level Requirements).

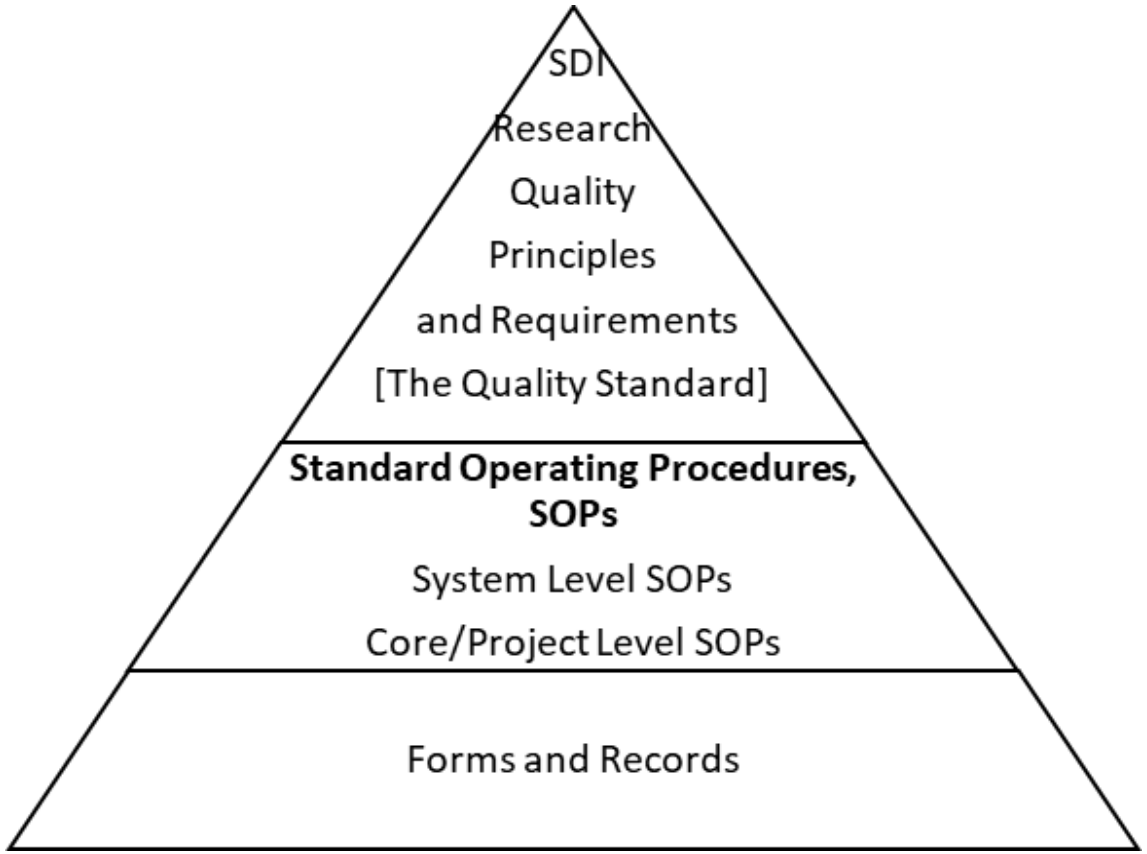
4.Not intended to ensure compliance with formal, external, regulatory quality standards like CGMP, GLP or ISO.

5.Is intended to make it easier to meet those standards if needed.

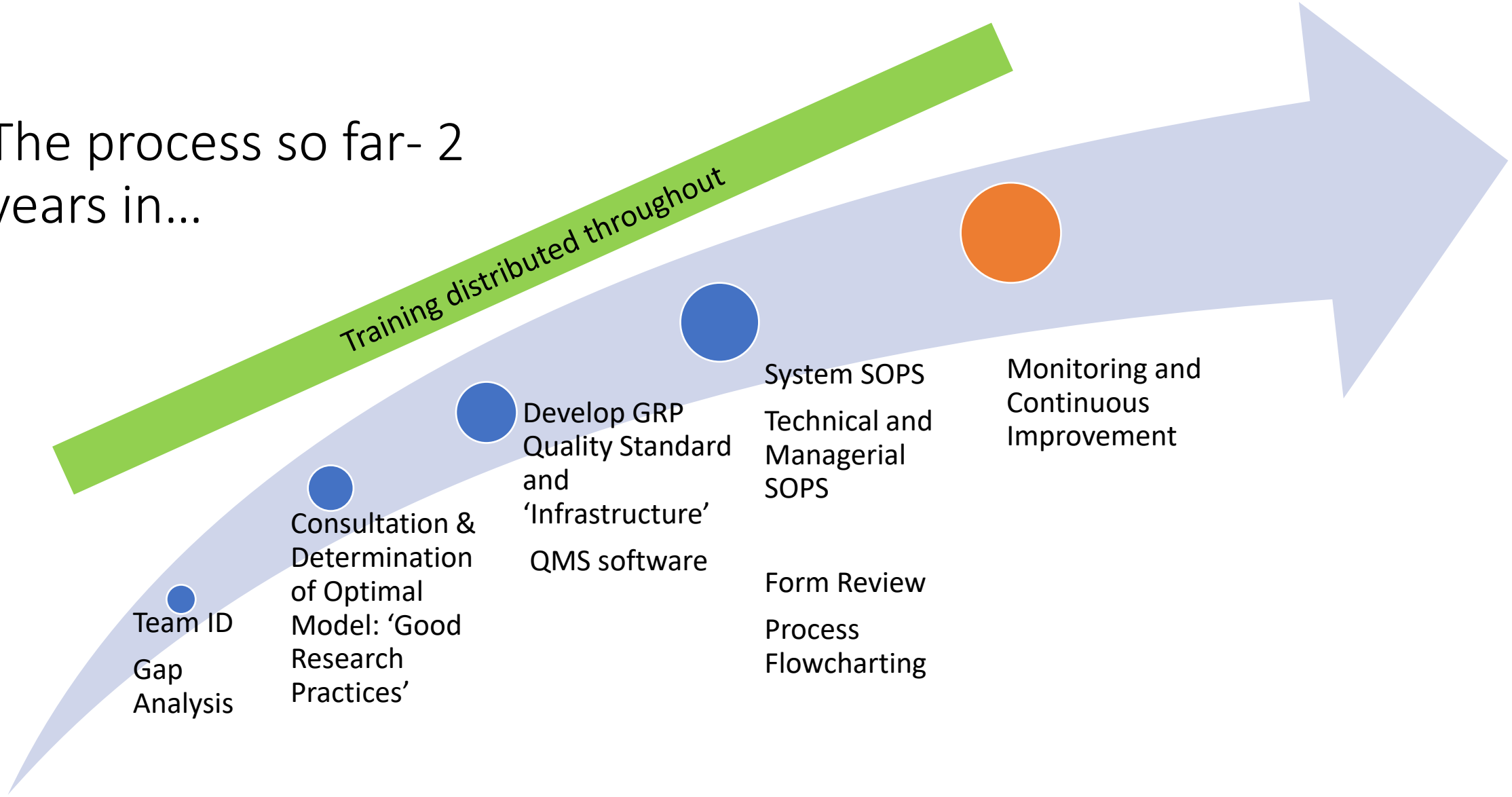
https://www.therqa.com/resources/publications/booklets/guidelines-for-quality-in-non-regulated-scientific-research-booklet/

11 Quality Principles that apply to managerial and technical activities

- Management
- Personnel
- Facilities
- Equipment
- Materials and Reagents
- Method Validation
- Procedures
- Research Records
- Computer Systems
- Research Review
- Quality Systems and Continuous Improvement



The process so far- 2 years in…



Faculty and Sponsor Perspectives

SDI Director

"A QMS provides SDI with the opportunity to maintain and demonstrate a rigorous research culture and capture opportunities for continuous improvement"

SDI Research Sponsor

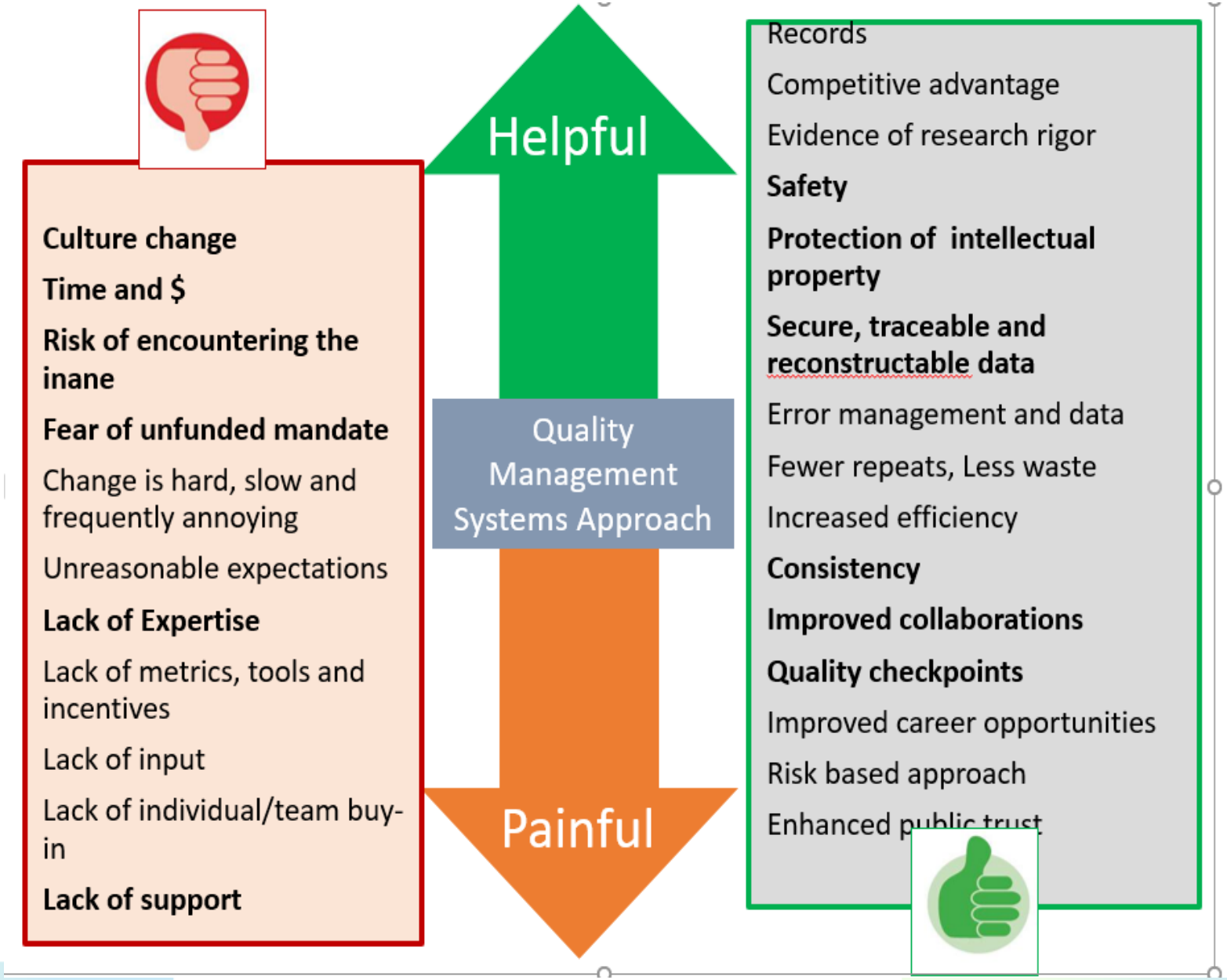
President and Chief Operating Officer of Diabetes Free Inc (DFI).

"Instituting a quality assurance program early in pre-clinical development in collaboration with UMN was an important consideration for our company as it will support data quality, integrity and research reproducibility and increase the likelihood of a smooth clinical progression."

Challenges and Finding Value

What makes this process hard?

What makes this process worthwhile?



How could we make this easier?

- Promote QA Best Practices within research lab environments
- Share the *value of* QMS for generating evidence of data quality
- Provide accessible training in QA principles and tools for QMS implementation
- Advocate for Institutional resources dedicated to QMS infrastructure and support
- Participate in (or promote) inter-agency advocacy for QMS support (resources) and perhaps…help design a workable approach
- Continue to champion quality through EPA mentoring, requirements and expectations