

# QI-BENCH

A decorative wavy line in shades of blue and green, starting from the 'Q' and flowing towards the right, passing under the subtitle.

OPTIMIZING PERFORMANCE THROUGH  
CHARACTERIZATION

## *Lung Cancer Workshop:* Resources for Open Science

May 3, 2012

SPECIFY

FORMULATE

EXECUTE

ANALYZE

PACKAGE

WITH FUNDING  
SUPPORT  
PROVIDED BY  
NATIONAL  
INSTITUTE OF  
STANDARDS  
AND  
TECHNOLOGY

**Andrew J. Buckler, MS**  
**Principal Investigator,**  
**QI-Bench**

# Resources are needed to address widening gap in imaging capability as practiced vs. capability of modern medicine

## PERSONALIZED MEDICINE | How redesigning a clinical trial can speed drug development

1 cube = 10 patients

### Traditional clinical trial

Takes essentially all patients with a disease being studied and is typically intended to eliminate differences in patient characteristics that could bias measures of drug effectiveness.

### PHASE II

**Randomized or non-randomized trial:** In a randomized trial, about 60 patients are put in two groups: One receives the experimental drug and the other serves as a control group. In a non-randomized trial, about 40 patients receive the experimental drug.

### PHASE III

If a drug graduates to phase III, it typically takes **3,000 patients** and about three years to determine if it is safe and effective enough for approval.

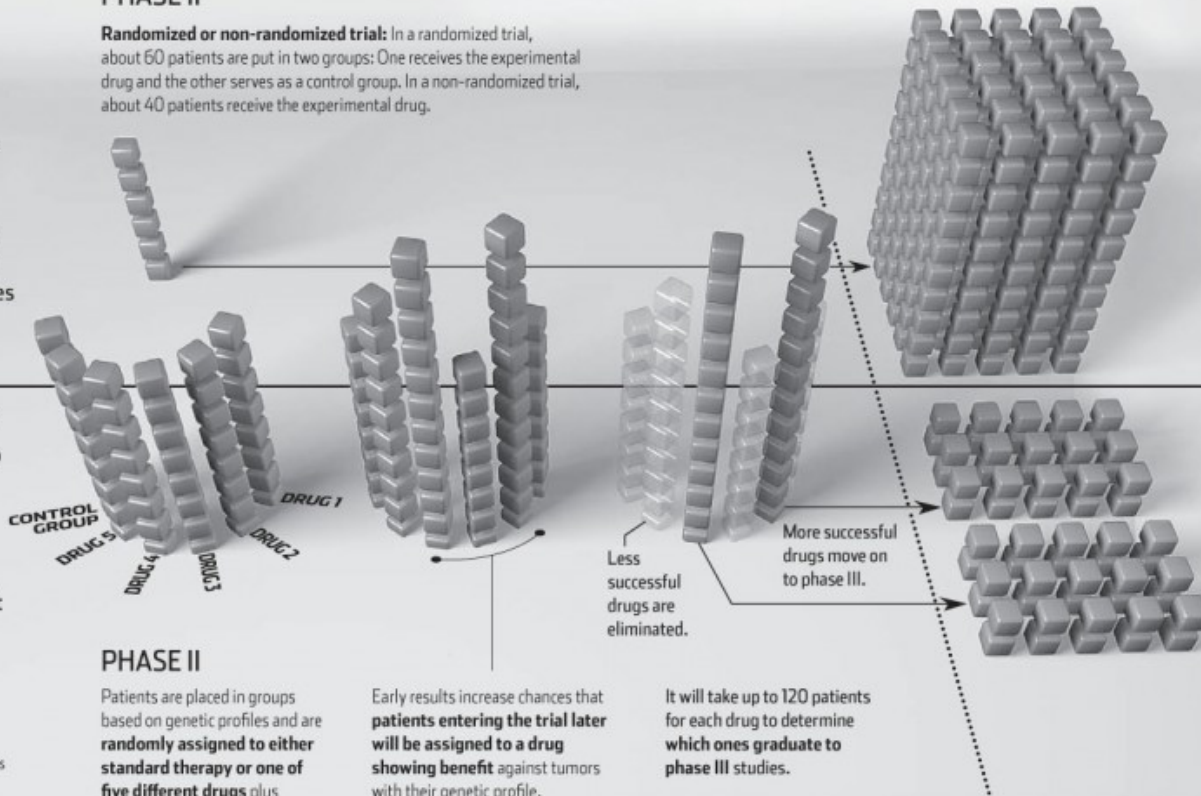


HISTORIC SUCCESS RATE

**30 TO 40%**

### New trial design

Uses genetic profiles to highlight 'biomarker' differences among patients and to match drugs to patients with biomarkers that predict a benefit.



### PHASE II

Patients are placed in groups based on genetic profiles and are randomly assigned to either standard therapy or one of five different drugs plus standard care.

Early results increase chances that patients entering the trial later will be assigned to a drug showing benefit against tumors with their genetic profile.

It will take up to 120 patients for each drug to determine which ones graduate to phase III studies.

### PHASE III

Researchers expect that drugs graduating from I-Spy 2 to phase III can be tested with **300 patients** selected according to genetic profiles found to respond to the drug in phase II. It is hoped that this will shorten the time to approval.



PROBABILITY OF SUCCESS

**85%**

Note: In all clinical trials, phase I consists of testing on human subjects to determine toxicity levels.

Graphic by Maryanne Murray/WSJ

Source: Donald Berry, M.D. Anderson Cancer Center

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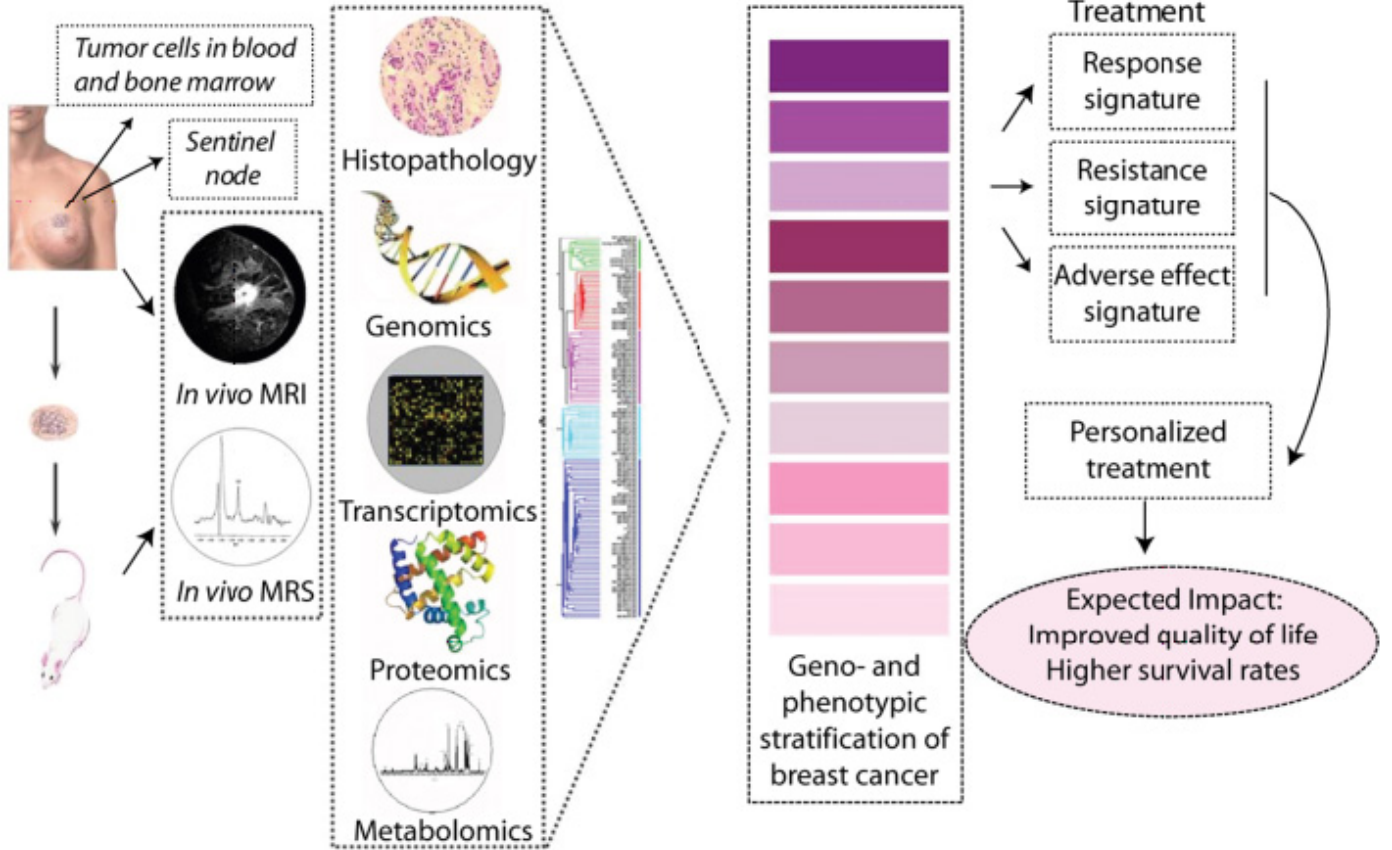
### PHASE II

Random  
about 60  
drug and  
about 40



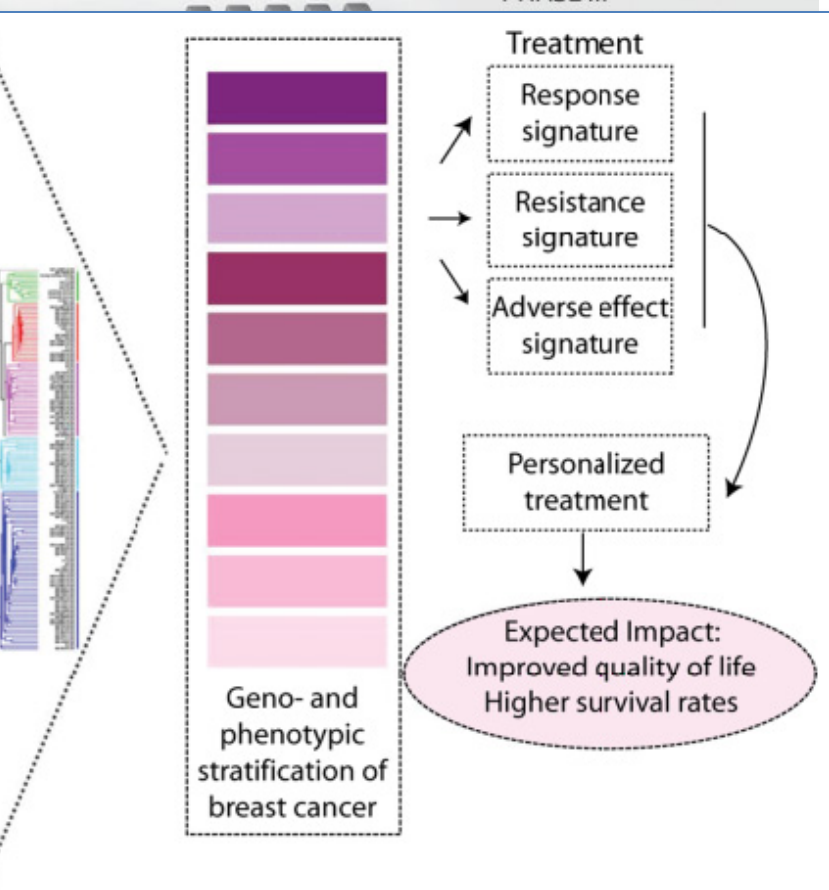
### PHASE III

Patients  
based on  
random  
standard  
five diffe  
standard

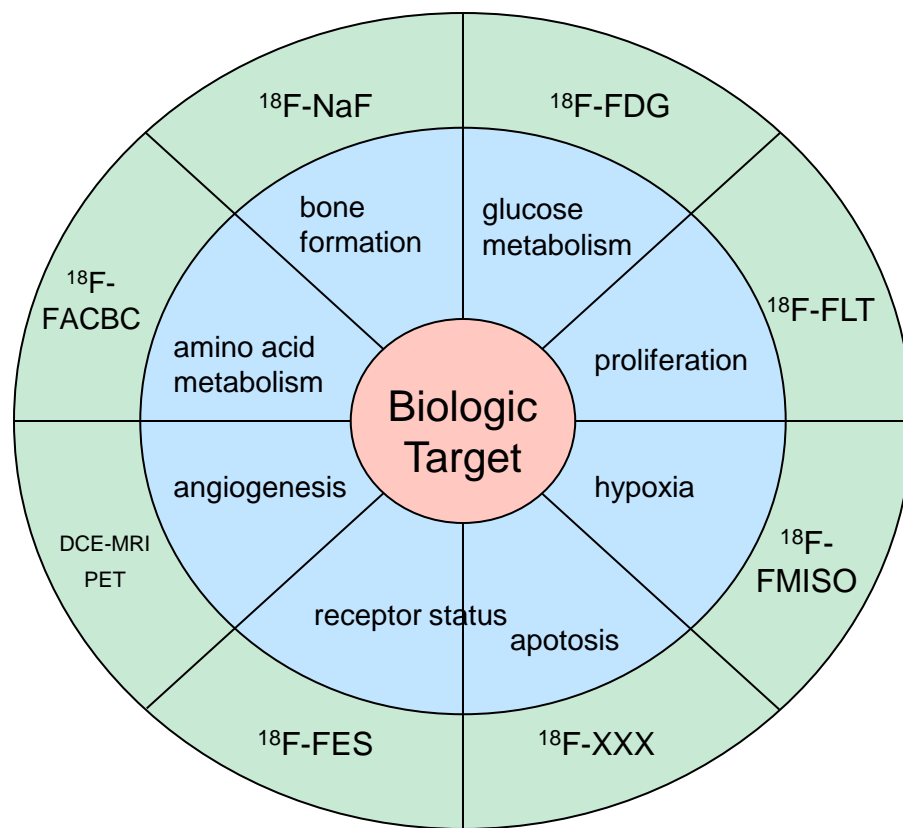


al trial can speed drug development

PHASE III

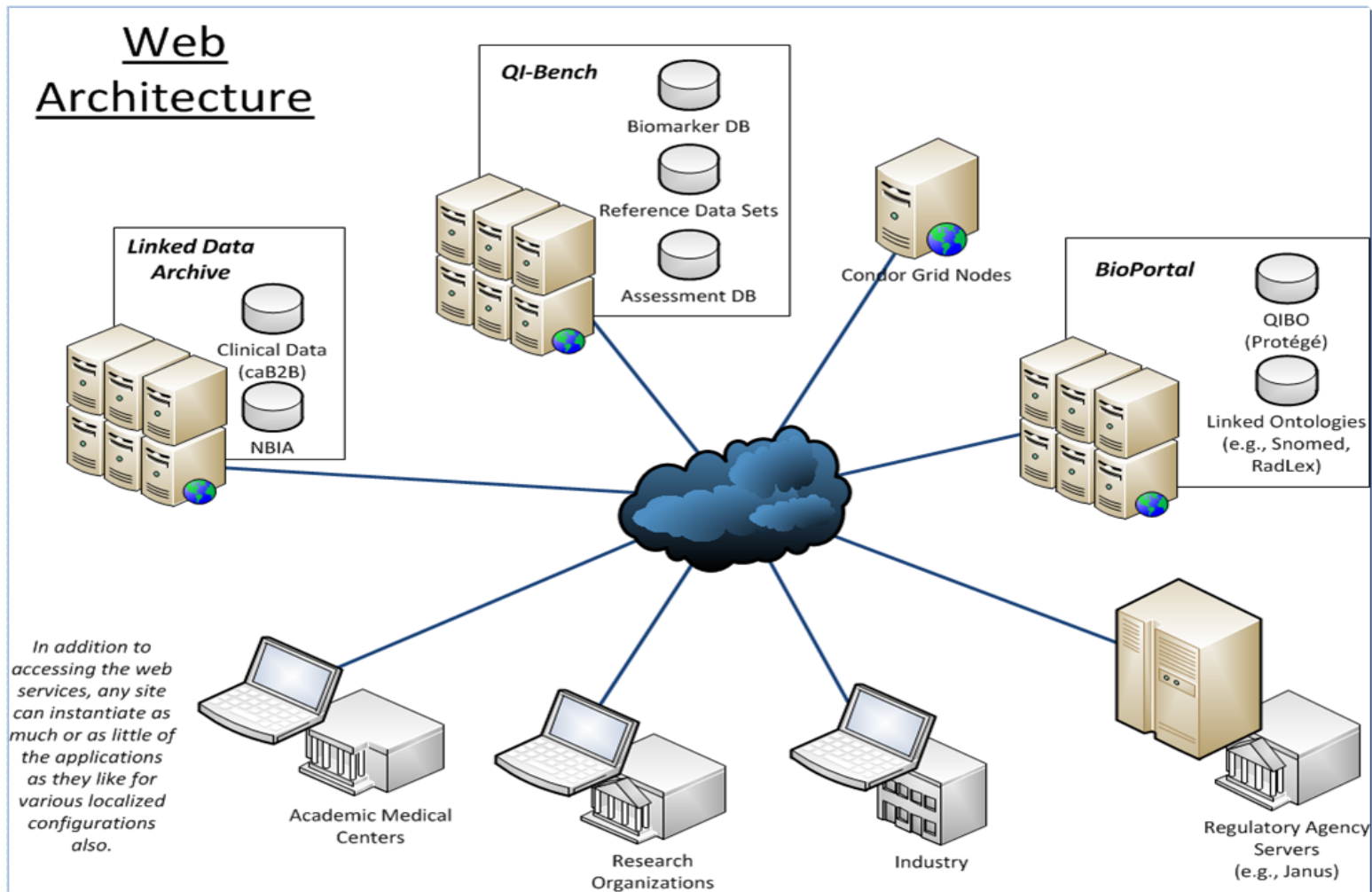


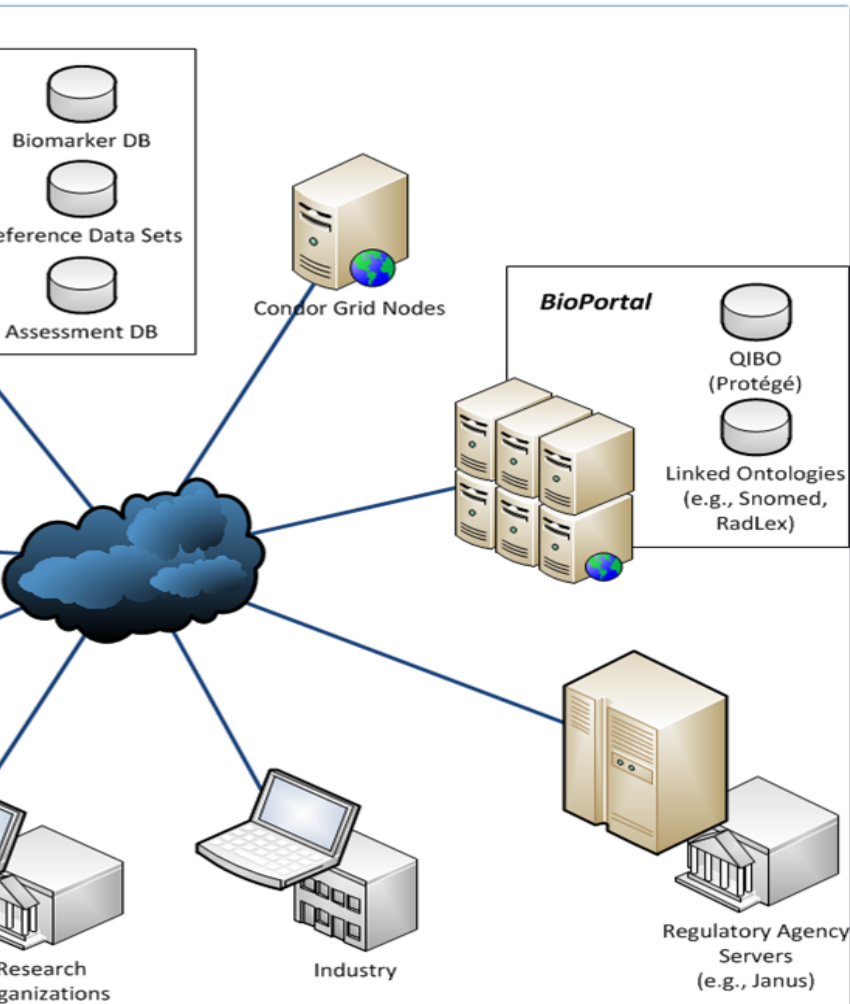
## Example: Beyond Anatomy to Palette of Functional Measures





# QI-Bench is a resource that may be used by single sponsors, defined-entity consortia, or true open science programs



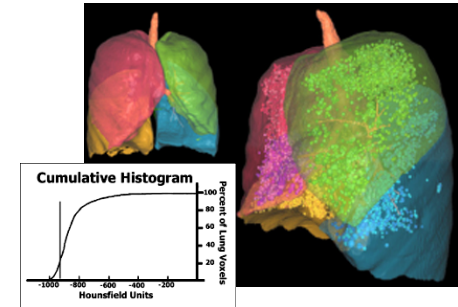


## Example: COPD

Either:

- To assist individual suppliers in optimizing their offerings
- To assist groups like COPDgene consortia
- To enable open development such as by QIBA

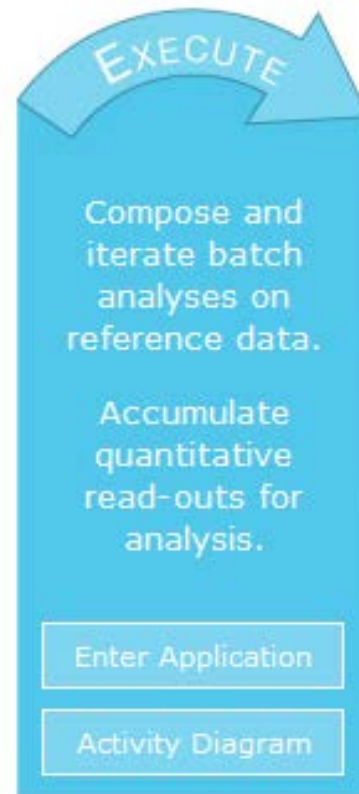
or flexible mix of these.



# QI-Bench is composed of building blocks: central feature is capable data warehouse

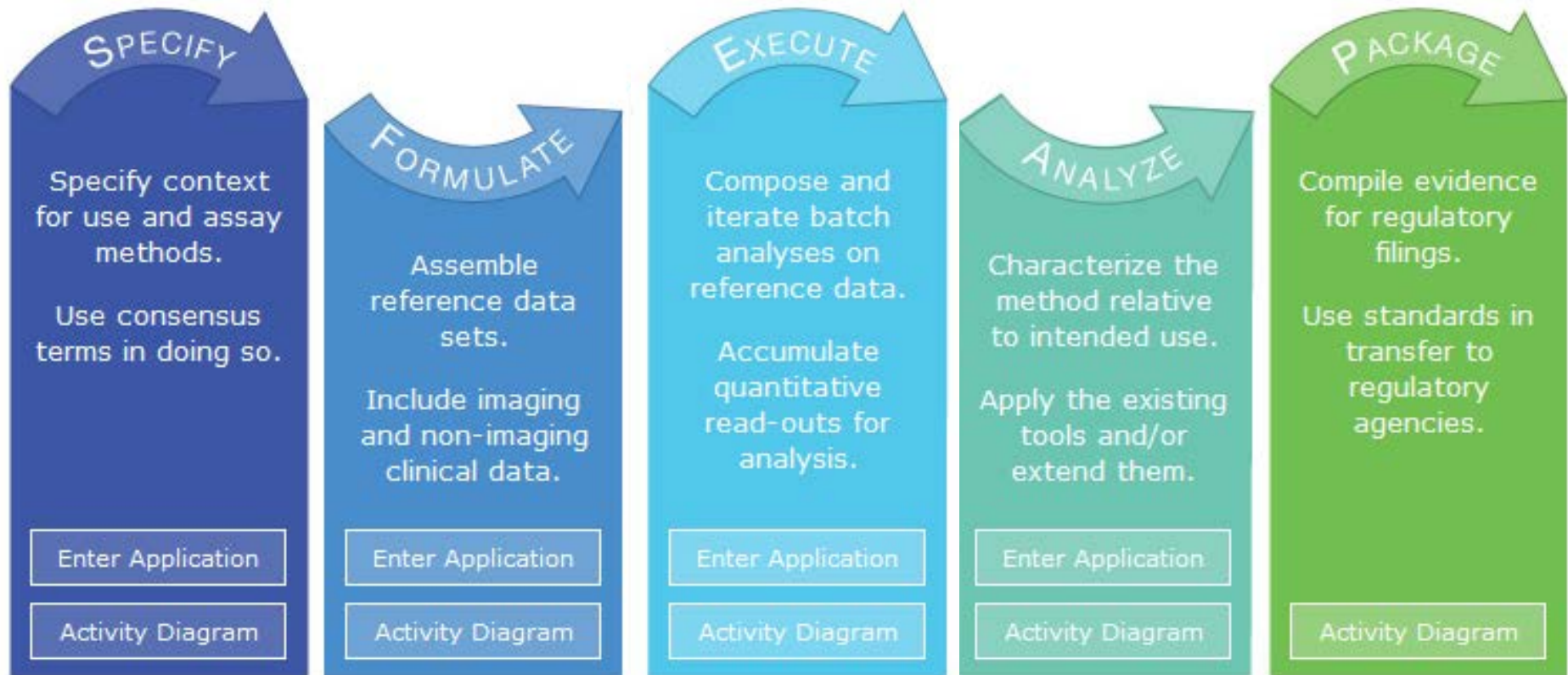


Add to that ability to conduct experiments with grid computing for automated algorithms and interactive RIS worklist generator for reader studies

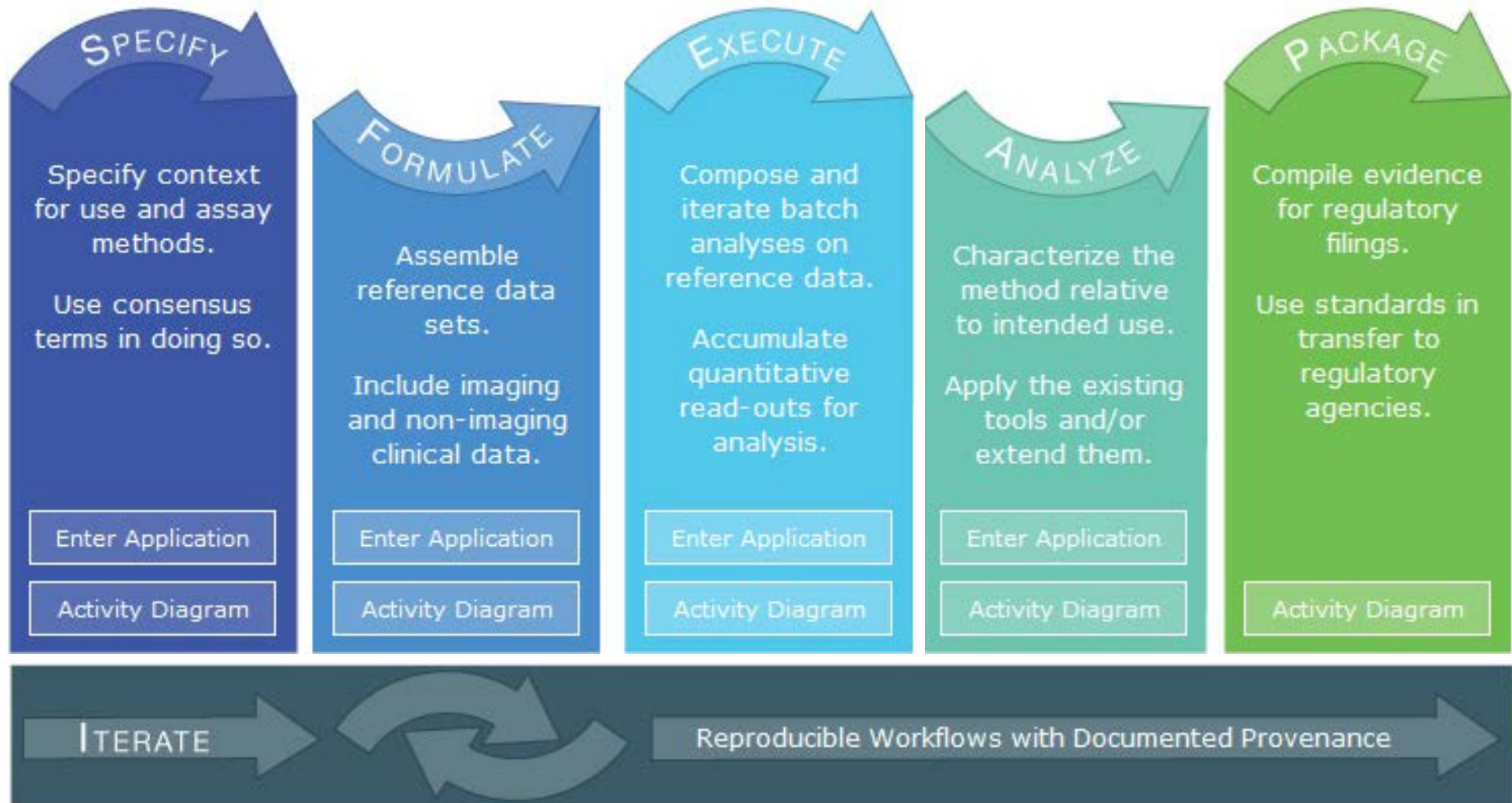




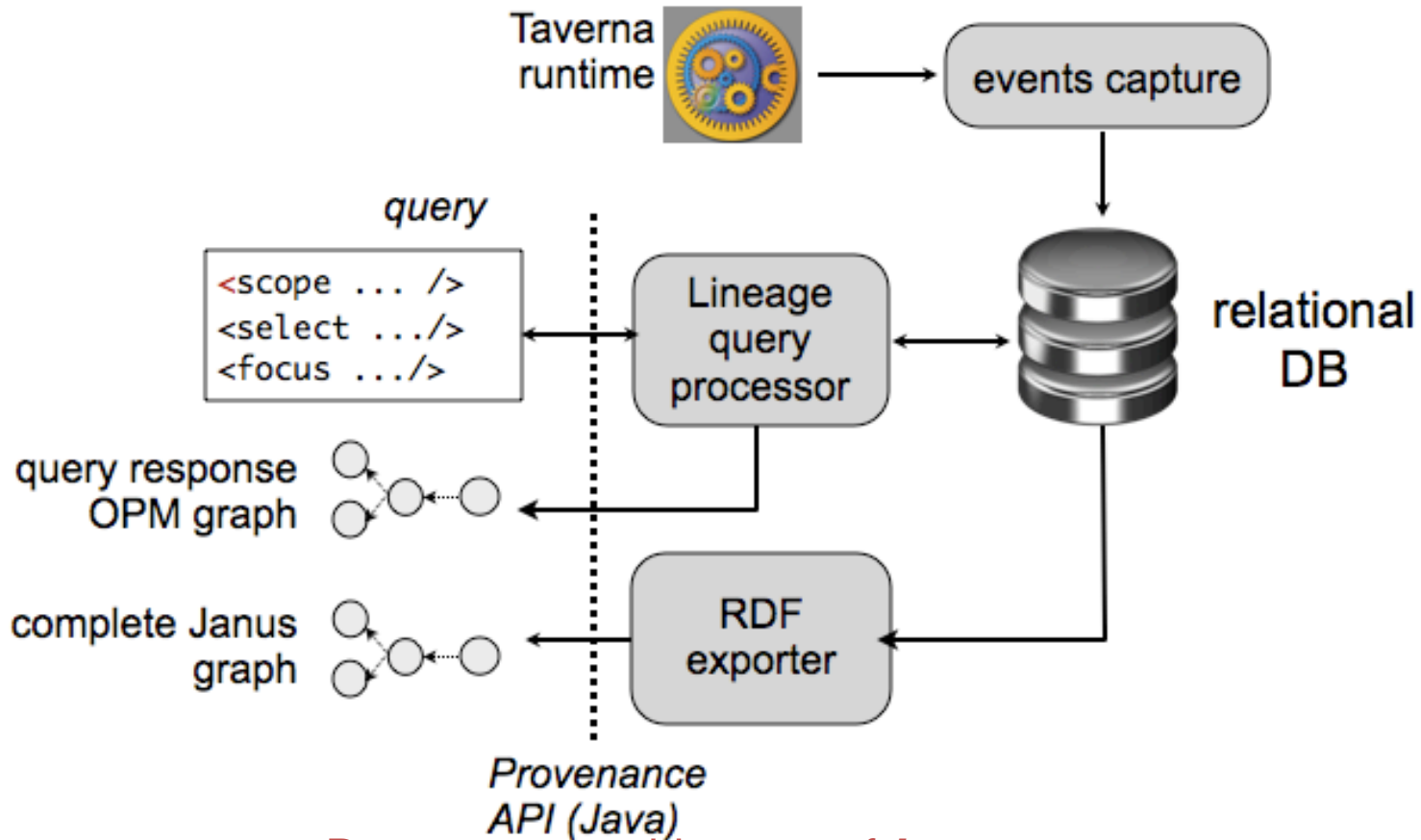
# Next, layer context at front, and statistical analysis and results interpretation at back



# Last but not least, add workflow engine to allow composition and reproducible workflows with provenance documentation

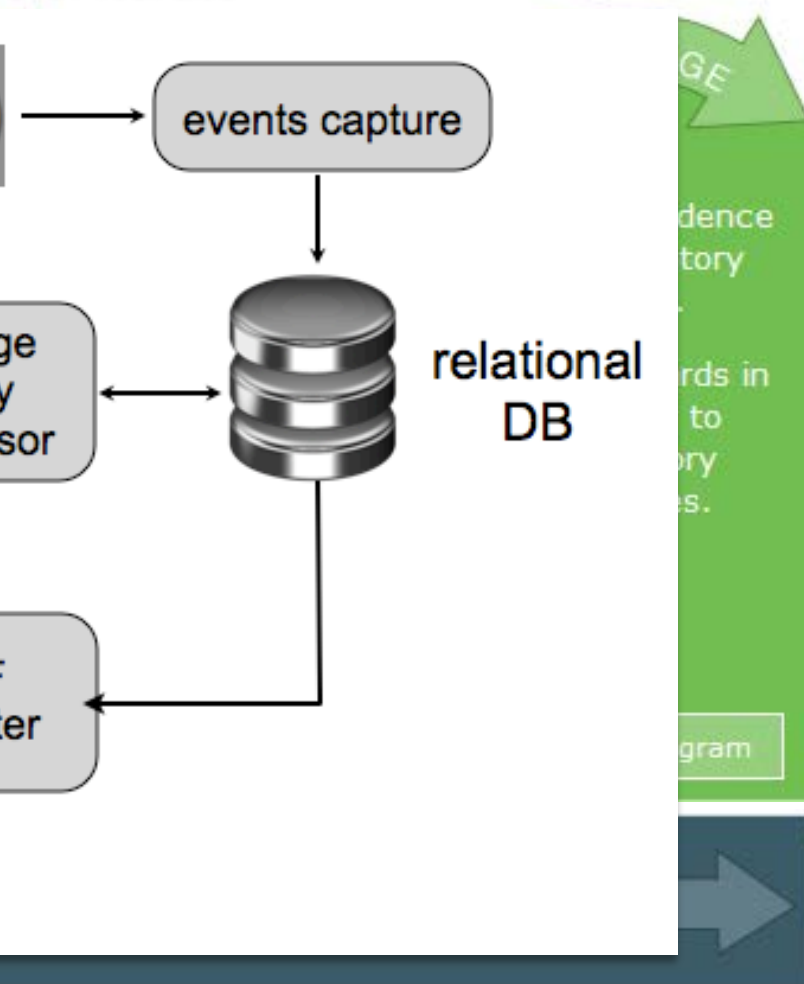


# The workflow engine utilizes a best-in-class capability from sister fields of 'omics assay development and optimization



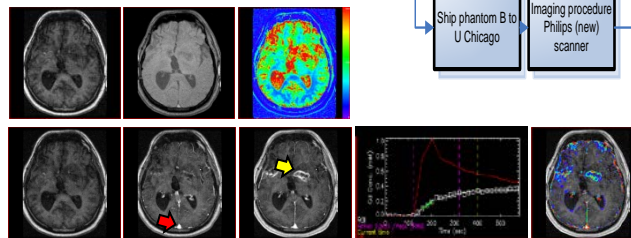
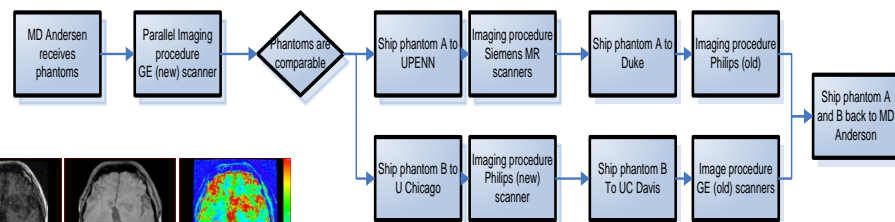
Provenance architecture of *Iterate*

of *Iterate*



## Example: DCE-MRI using Patient, Synthetic, and Phantom Data

- Curate, maintain and serve reference data sets
- Execute batch runs over multi-parameter synthetic data
- Characterize performance

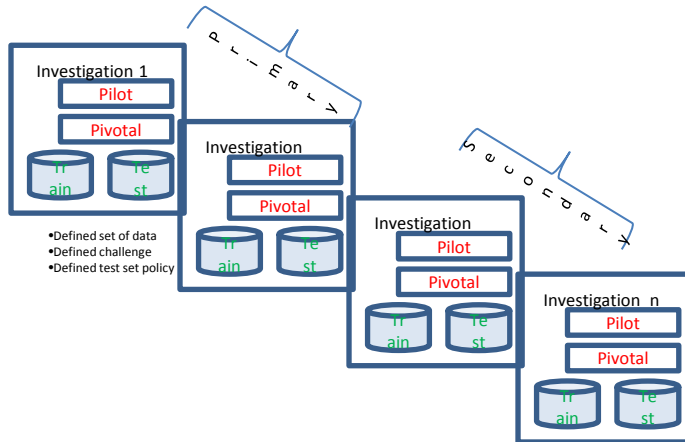




# Test bed: CT volumetry method challenge ("3A")

## Some of the Participants

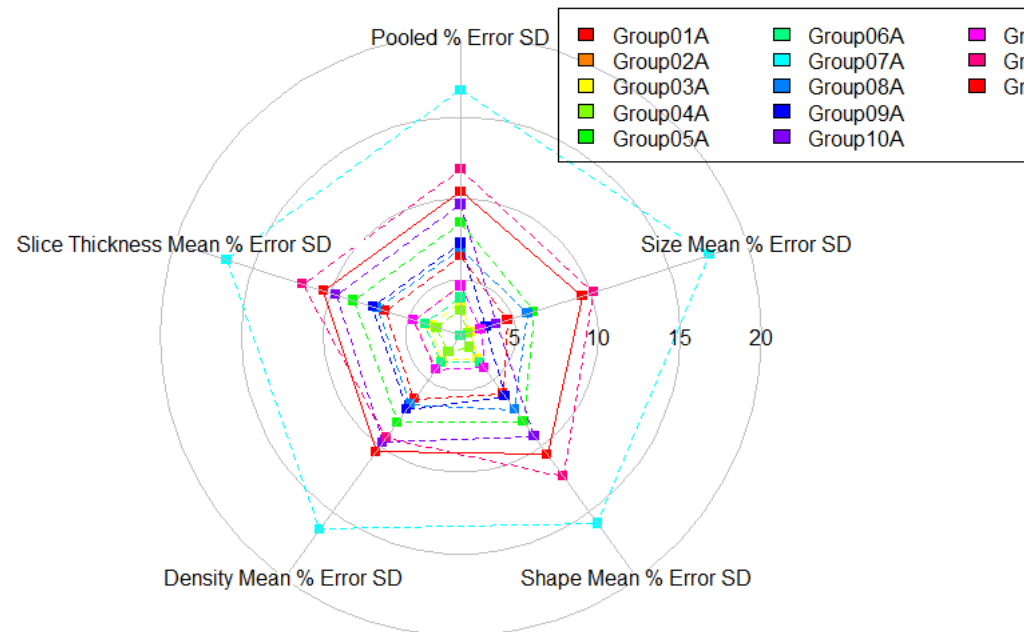
1. Median Technologies
2. Vital Images, Inc.
3. Fraunhofer Mevis
4. Siemens
5. Moffitt Cancer Center
6. Toshiba
7. GE Healthcare
8. Icon Medical Imaging
9. Columbia University
10. INTIO, Inc.
11. Vital Images, Inc.



StudyDescription\_Pilot3A\_1.0a - Microsoft Excel

	A	B	C	D	E	F	G
	Reader	SeriesNumber.002000	LesionUID	ReplicateNumber	Bio marker	AnalysisSWModel	ReadOutValue
1348	Group12A_Reader	9553	8	1	V	Group12A_PILOT	5290
1349	Group12A_Reader	9553	29	1	V	Group12A_PILOT	37140
1350	Group12A_Reader	9553	38	1	V	Group12A_PILOT	4310
1351	Group12A_Reader	9553	36	1	V	Group12A_PILOT	36670
1352	Group12A_Reader	9553	62	1	V	Group12A_PILOT	400
1353	Group12A_Reader	9559	6	1	V	Group12A_PILOT	740
1354	Group12A_Reader	9559	8	1	V	Group12A_PILOT	4860
1355	Group12A_Reader	9559	9	1	V	Group12A_PILOT	5080
1356	Group12A_Reader	9559	29	1	V	Group12A_PILOT	37190
1357	Group12A_Reader	9559	33	1	V	Group12A_PILOT	4230
1358	Group12A_Reader	9559	36	1	V	Group12A_PILOT	35190
1359	Group12A_Reader	9559	62	1	V	Group12A_PILOT	340
1360	BatchReader	39	4	1	V	LSTK Reference	465.686
1361	BatchReader	39	10	1	V	LSTK Reference	4209.93
1362	BatchReader	39	41	1	V	LSTK Reference	530.012
1363	BatchReader	39	43	1	V	LSTK Reference	4160.5
1364	BatchReader	51	4	1	V	LSTK Reference	457.704

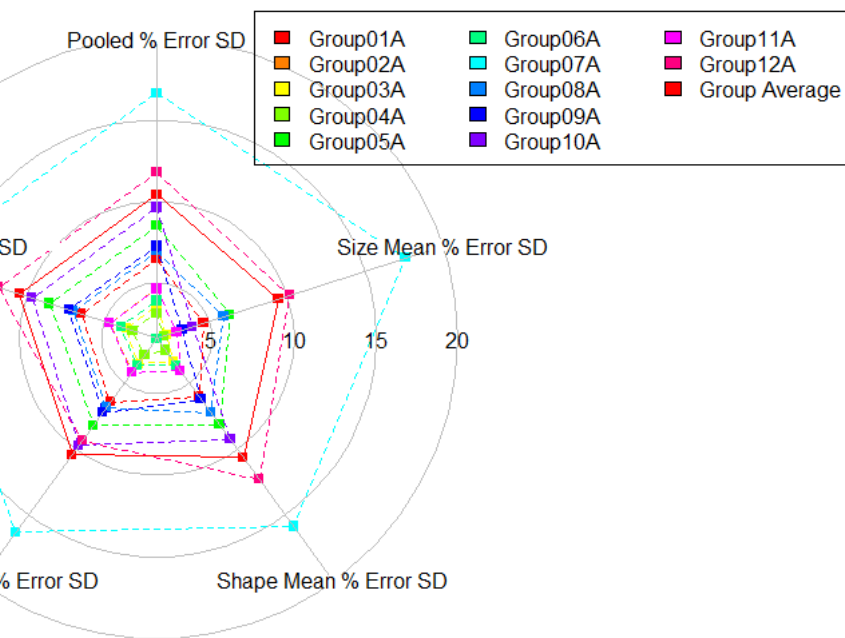
Percent Error SDs for Each Factor, Group Average Shown in Solid Line



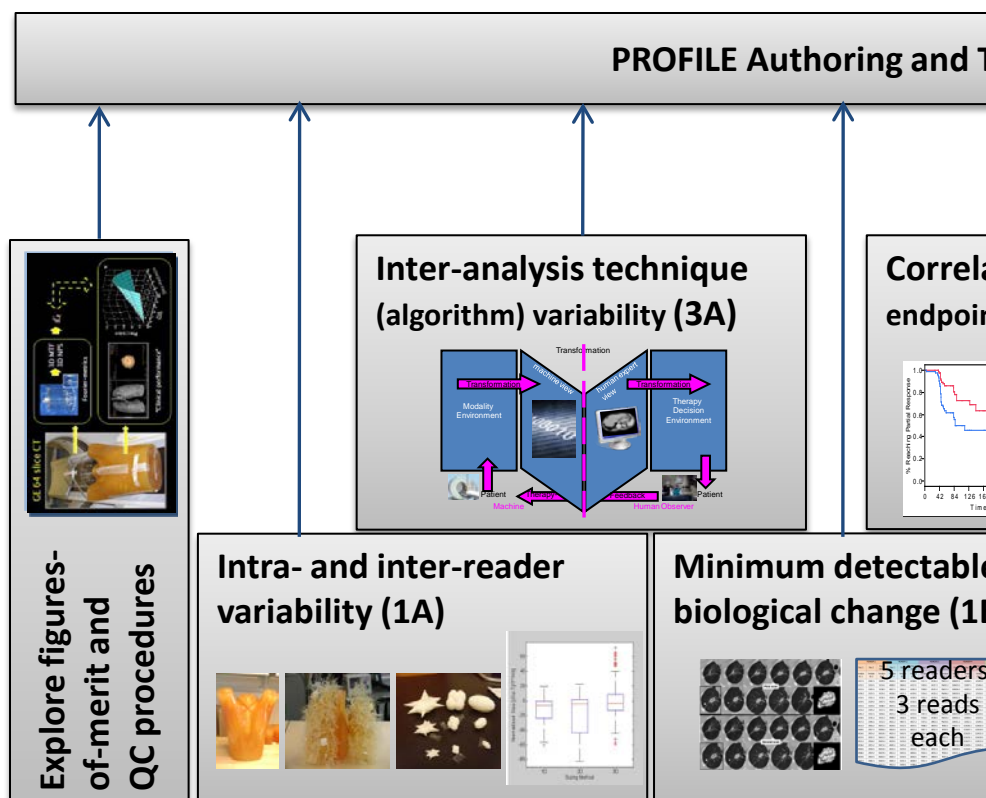
# f the Participants

- |               |     |                      |
|---------------|-----|----------------------|
| Technologies  | 7.  | GE Healthcare        |
| es, Inc.      | 8.  | Icon Medical Imaging |
| ofer Mevis    | 9.  | Columbia University  |
| s             | 10. | INTIO, Inc.          |
| Cancer Center | 11. | Vital Images, Inc.   |

Each Factor, Group Average Shown in Solid Line



## Broader capability: Systematic qualification of CT volumetry





# Up and running now for you to use

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[Why QI-Bench](#)

## Resources

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[For Developers](#)

[Issue Tracking](#)

[Lab Protocol](#)

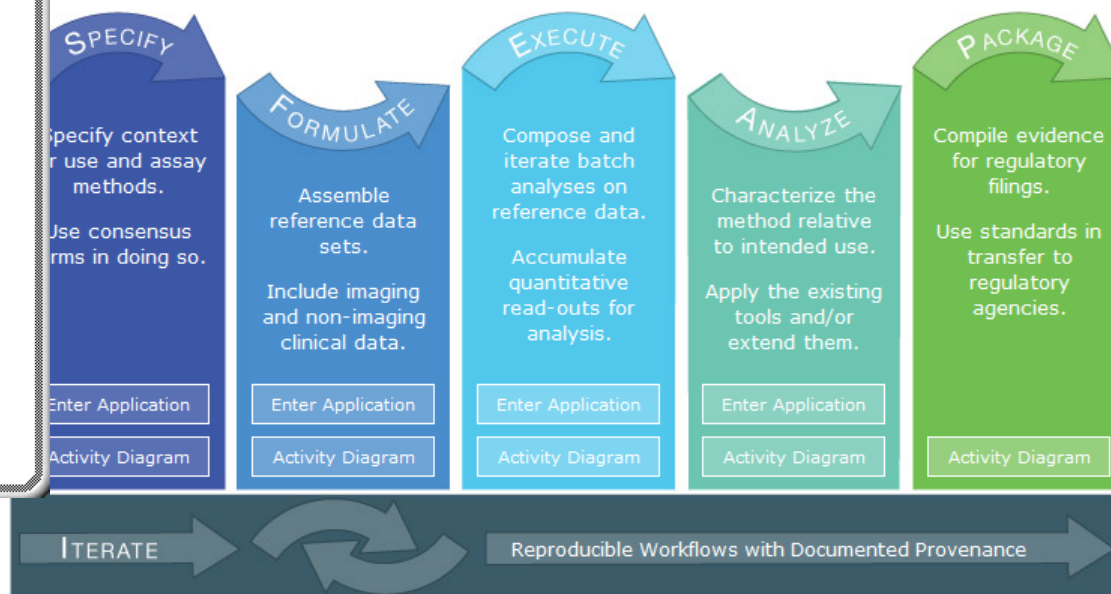
[References](#)

[Licensing](#)

Quantitative imaging applications such as imaging biomarkers advance the utility of medical imaging. They may detect and characterize disease, before, during or after a course of therapy. They may also predict the course of disease, with or without therapy.

A precondition for use is the demonstration of performance according to recognized descriptive statistics:

- In a defined patient population,
- For a specific biological phenomenon associated with a known disease state,
- With evidence in large patient populations, externally validated.



Open-source informatics tooling used to characterize the performance of quantitative medical imaging as needed to advance the field. These tools may be deployed internal to an organization or used for collaborative work across organizations. The data on which they work may be accessible only to identified individuals, or more broadly in an open archive, to suit the specific project purpose.

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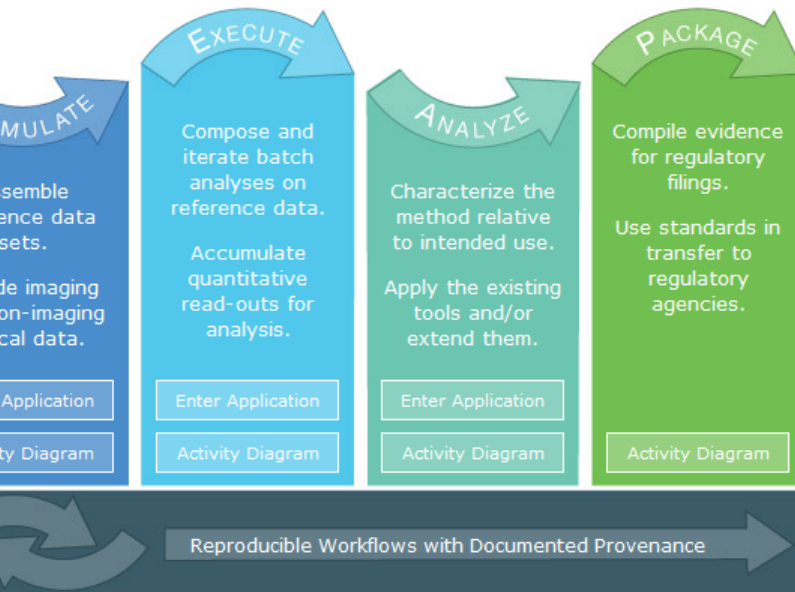
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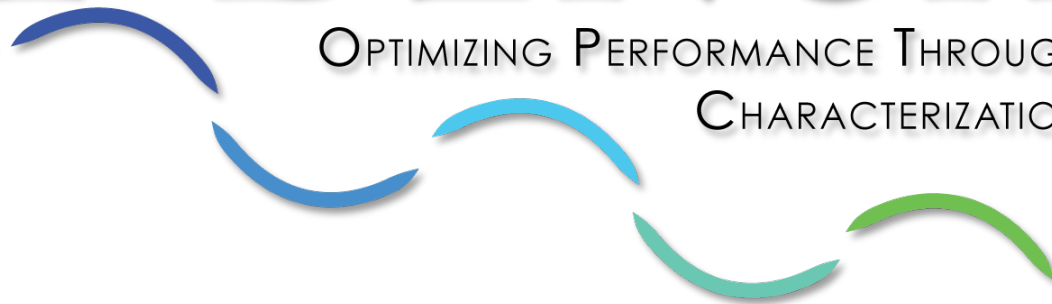
## Fill in your example here

- *Lung cancer screening?*

(join us at [www.qi-bench.org](http://www.qi-bench.org))  
(and/or our monthly meetings)

# QI-BENCH

OPTIMIZING PERFORMANCE THROUGH  
CHARACTERIZATION



# Value proposition of QI-Bench

- Efficiently collect and exploit evidence establishing standards for optimized quantitative imaging:
  - Users want confidence in the read-outs
  - Pharma wants to use them as endpoints
  - Device/SW companies want to market products that produce them without huge costs
  - Public wants to trust the decisions that they contribute to
- By providing a verification framework to develop precompetitive specifications and support test harnesses to curate and utilize reference data
- Doing so as an accessible and open resource facilitates collaboration among diverse stakeholders

# Summary: QI-Bench Contributions

- We make it practical to increase the magnitude of data for increased statistical significance.
- We provide practical means to grapple with massive data sets.
- We address the problem of efficient use of resources to assess limits of generalizability.
- We make formal specification accessible to diverse groups of experts that are not skilled or interested in knowledge engineering.
- We map both medical as well as technical domain expertise into representations well suited to emerging capabilities of the semantic web.
- We enable a mechanism to assess compliance with standards or requirements within specific contexts for use.
- We take a “toolbox” approach to statistical analysis.
- We provide the capability in a manner which is accessible to varying levels of collaborative models, from individual companies or institutions to larger consortia or public-private partnerships to fully open public access.

# QI-Bench

## Structure / Acknowledgements

- Prime: BBMSC (Andrew Buckler, Gary Wernsing, Mike Sperling, Matt Ouellette)
- Co-Investigators
  - Kitware (Rick Avila, Patrick Reynolds, Julien Jomier, Mike Grauer)
  - Stanford (David Paik)
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- Collaborators / Colleagues / Idea Contributors
  - Georgetown (Baris Suzek)
  - FDA (Nick Petrick, Marios Gavrielides)
  - UMD (Eliot Siegel, Joe Chen, Ganesh Saiprasad, Yelena Yesha)
  - Northwestern (Pat Mongkolwat)
  - UCLA (Grace Kim)
  - VUmc (Otto Hoekstra)
- Industry
  - Pharma: Novartis (Stefan Baumann), Merck (Richard Baumgartner)
  - Device/Software: Definiens, Median, Intio, GE, Siemens, Mevis, Claron Technologies, ...
- Coordinating Programs
  - RSNA QIBA (e.g., Dan Sullivan, Binsheng Zhao)
  - Under consideration: CTMM TraIT (Andre Dekker, Jeroen Belien)