Quantitative Imaging Biomarker Alliance

WHY QIBA:
PET-CT SPECIFICS

Corporation Visit

Autumn 2010

Andrew J. Buckler, MS

Program Director, QIBA

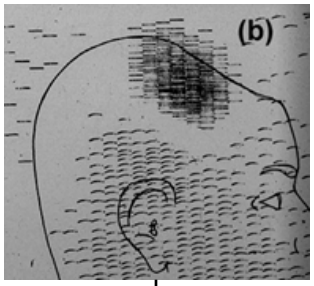
PRINCIPAL LOGISTICAL AND FINANCIAL SUPPORT PROVIDED BY RSNA

Our Team

See speaker notes for full list of individual names

Amgen
AstraZeneca
Beth Israel Deaconess Medical Center
BioClinica
Boston Medical Center
Brown University
Buckler Biomedical LLC
Cancer Imaging Program, NCI
CCS Associates, Inc.
Duke University
FDA
Fraunhofer MEVIS, Inst for Medical Image Computing
GE Healthcare
GlaxoSmithKline
Harvard Medical School
ICON Medical Imaging
Imagepace
Indiana University
Johns Hopkins University
King's College London
Medical Imaging & Technology Alliance
Merge Healthcare
MIMvista Corp.
NIST
Novartis
Perceptive Informatics, Inc.
Pfizer
Pharmtrace
Philips Healthcare
RadPharm
Segami Corporation
Siemens
SNM
State University of New York
TeraRecon, Inc.
University of California, Berkeley
University of California, Davis
University of California, San Francisco
University of Colorado, Denver
University of Iowa
University of Michigan
University of Utah
University of Washington
Vital Images, Inc.
VU Medical Center, Amsterdam, NL
Washington University in St. Louis
Weill Cornell Medical College
Wm. Beaumont Hospital

PET-CT: A Proud History of Innovation



1953 First coincidence positron imaging system

1975 PETT III

1989 whole-body imaging

1991 3D PET

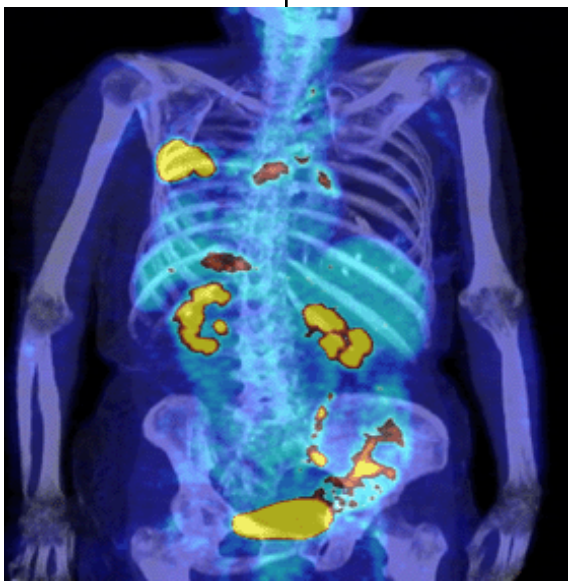
1998 PET/CT

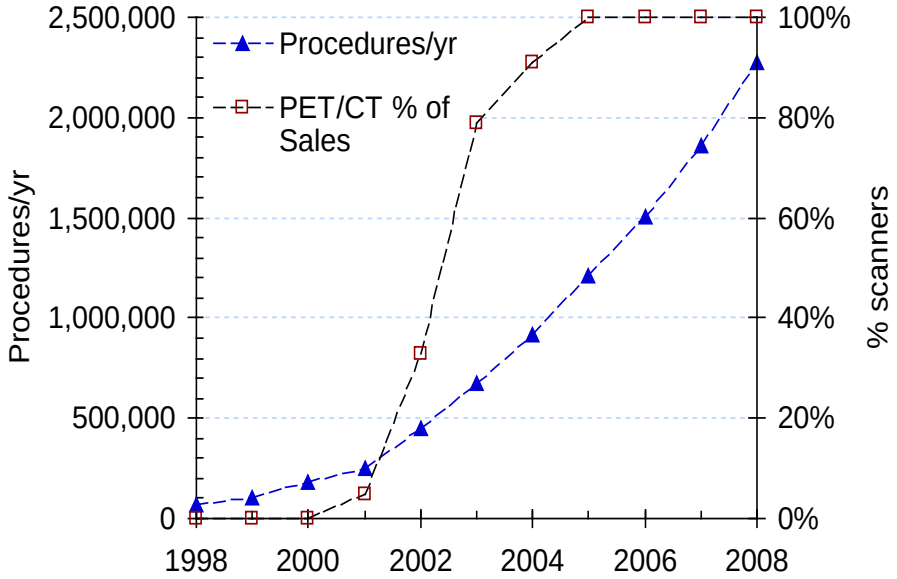
2005 respiratory gating

2006 time-of-flight

2008 PET/MR

?





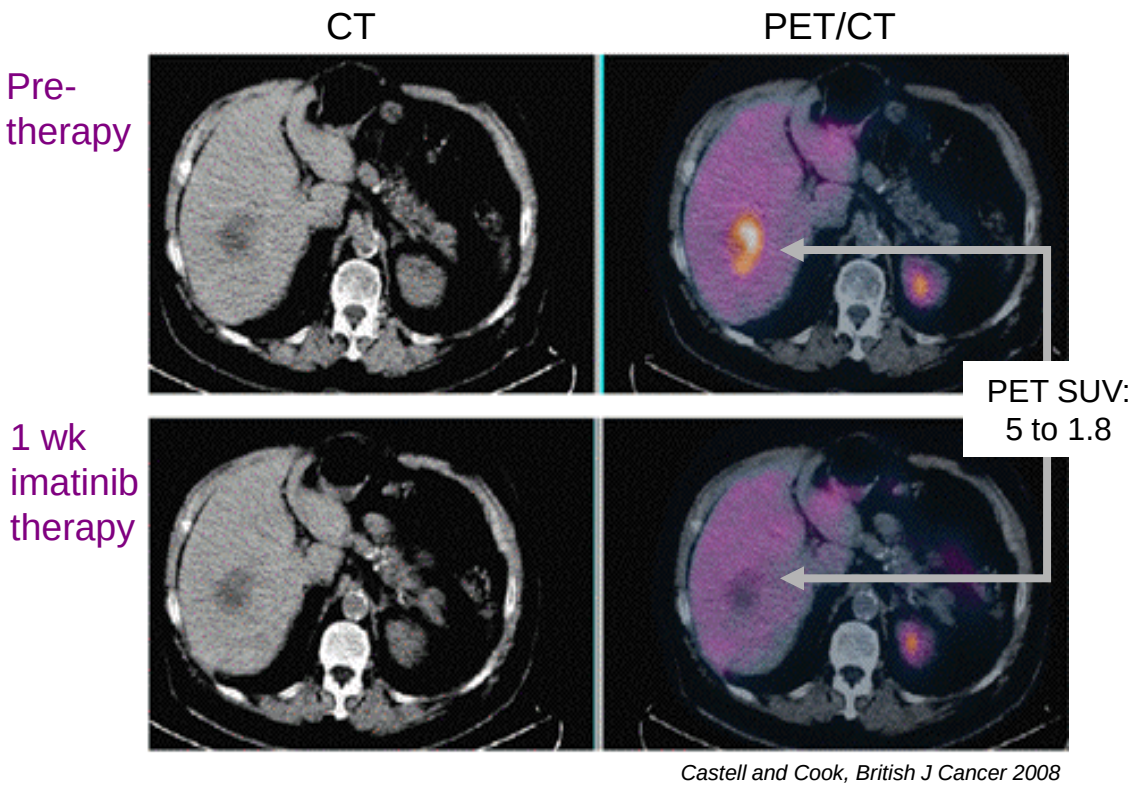
What's next? *Quantitative PET to* Characterize Disease Hallmarks

Drivers

- Clinical research, Clinical trials, and Drug discovery
- New molecular diagnostic agents
- Assessing individual response to therapy
- SUVs are now routinely reported, and are asked for, by referring physicians

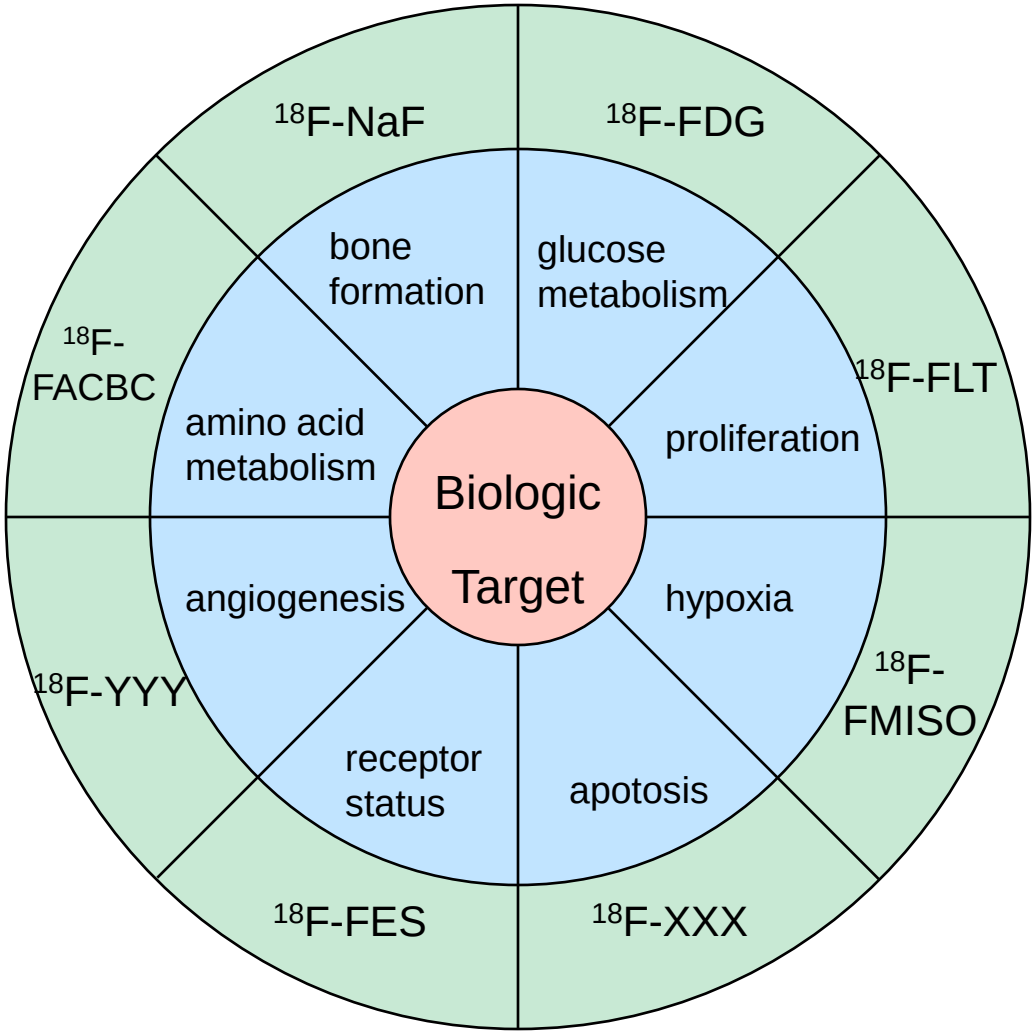
volume

Response to therapy of liver met GIST



Castell and Cook, British J Cancer 2008

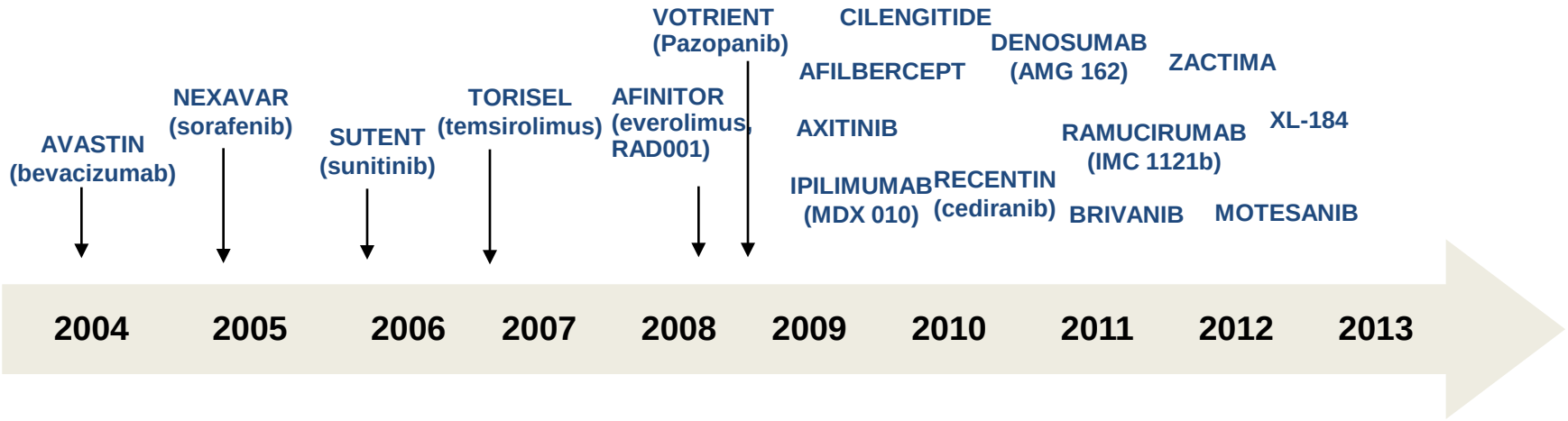
Biomarkers To Quantify Hallmarks of Cancer



- New molecular diagnostic agents
- New uses for existing agents

Assist with increasing number of oncology targeted pharmaceuticals

Treatment Population	2007	2008	2009	2010	2011	2012	2013	2014	2015
Cancer patients treated with Anti-angiogenesis treatment	2.8%	3.4%	4.4%	5.3%	6.7%	8.1%	9.5%	10.3%	11.6%



Courtesy Richard Frank, GE Healthcare

Quantitation Improves Characterization of Disease Hallmarks

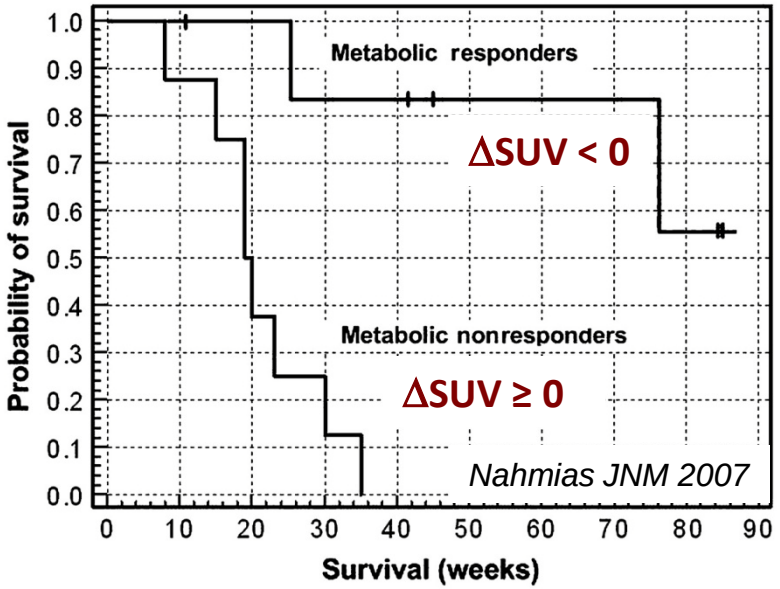
Improve individual patient care

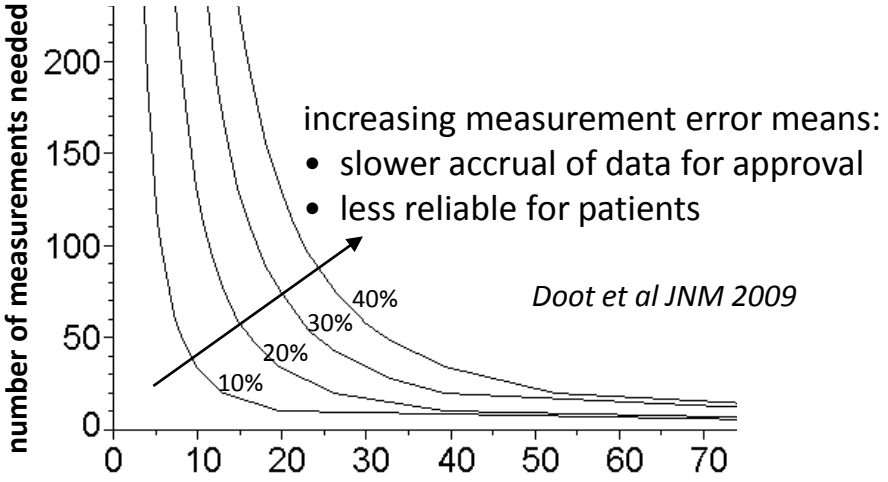
- Clinically proven detection and longitudinal quantitation for follow-up
- Moves imaging from diagnostics and staging to therapy assessment

Accelerate adoption of new molecular diagnostics

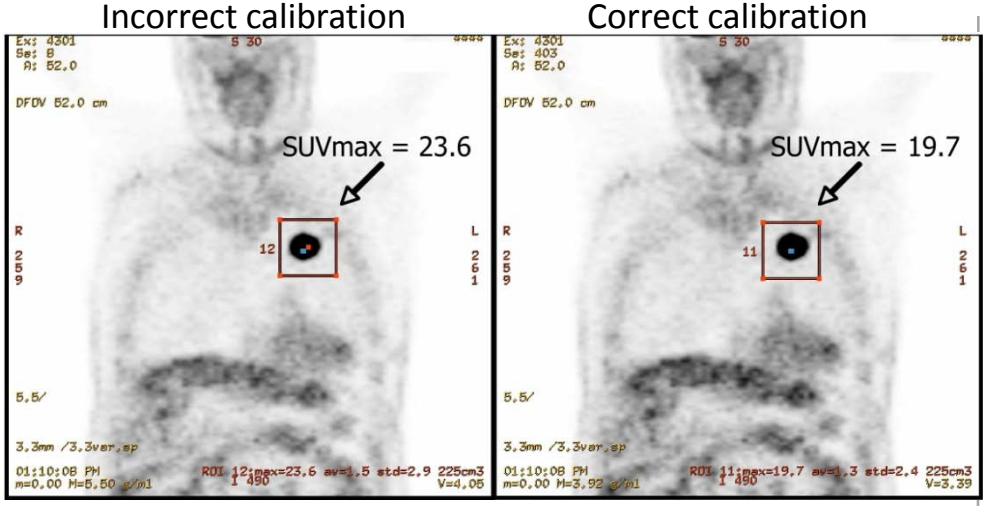
Make clinical trials of new therapies more effective

All tied to quantitative accuracy

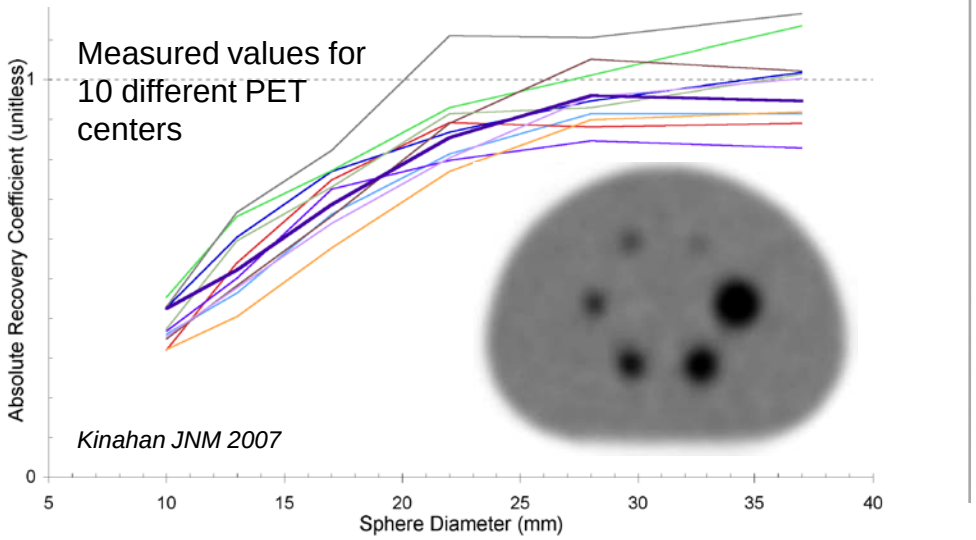




Technical as well as Business Obstacles Impede Realization of the Opportunity



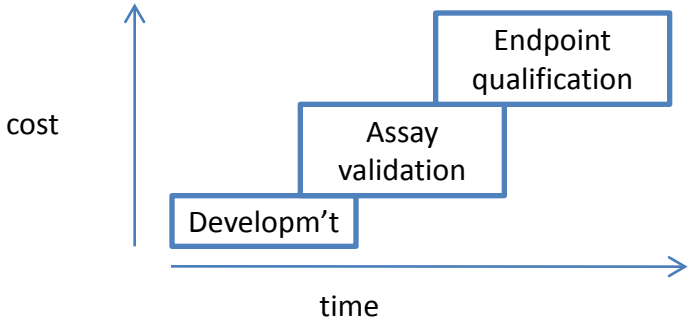
Lockhart JNM 2009



Efforts by individual manufacturers to qualify quantitative imaging applications:

- *Are more costly, and*
- *Run over longer time periods…*

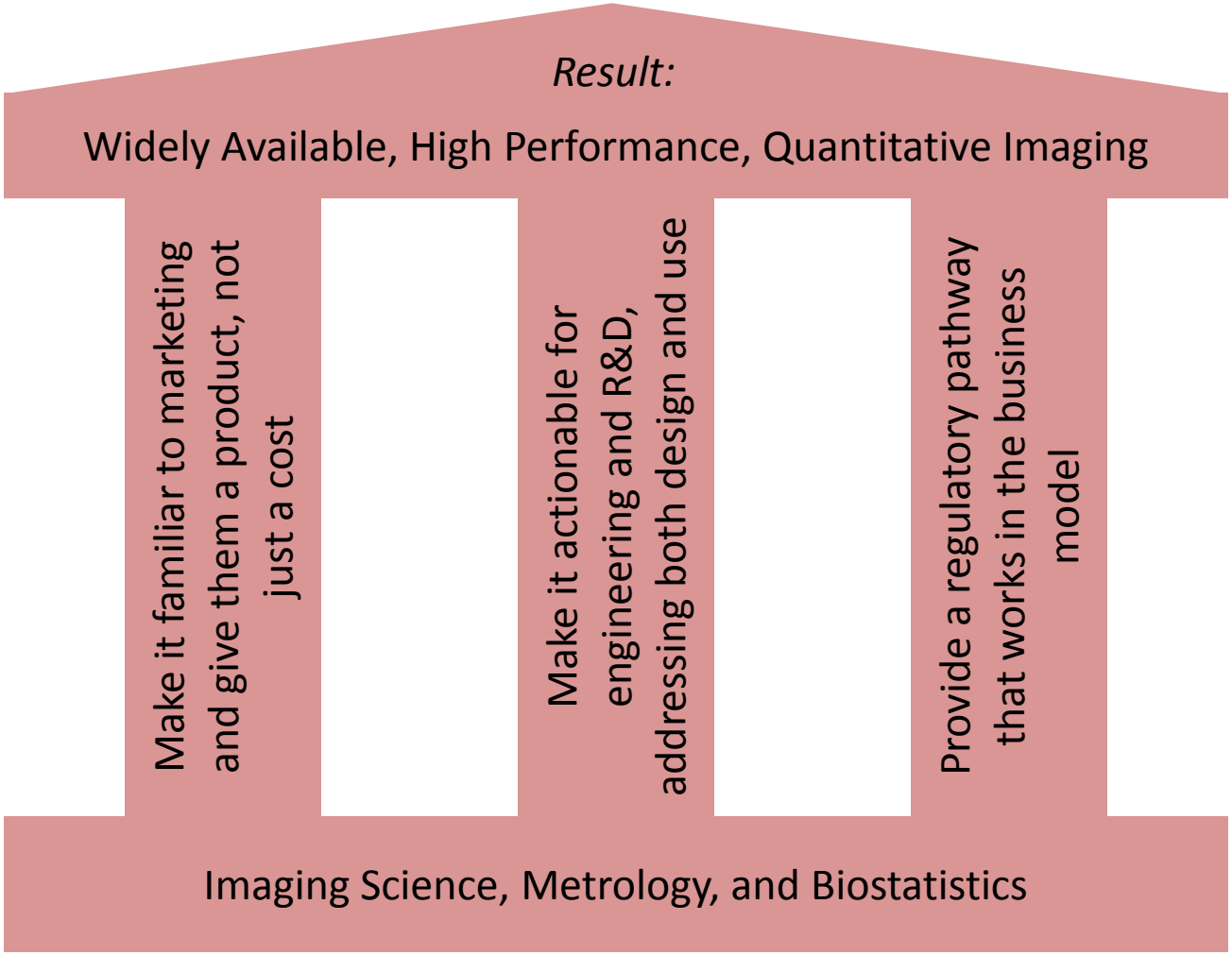
…than the business model of device and software manufacturers generally support.



These issues are exacerbated by lack of clarity in regulatory and reimbursement policy which increase the risk while decreasing the incentive

Even when individual companies do these steps, community need for standards required to address multi-vendor reproducibility are not accounted for.

QIBA Addresses the Obstacles, Enabling Profitable New Products



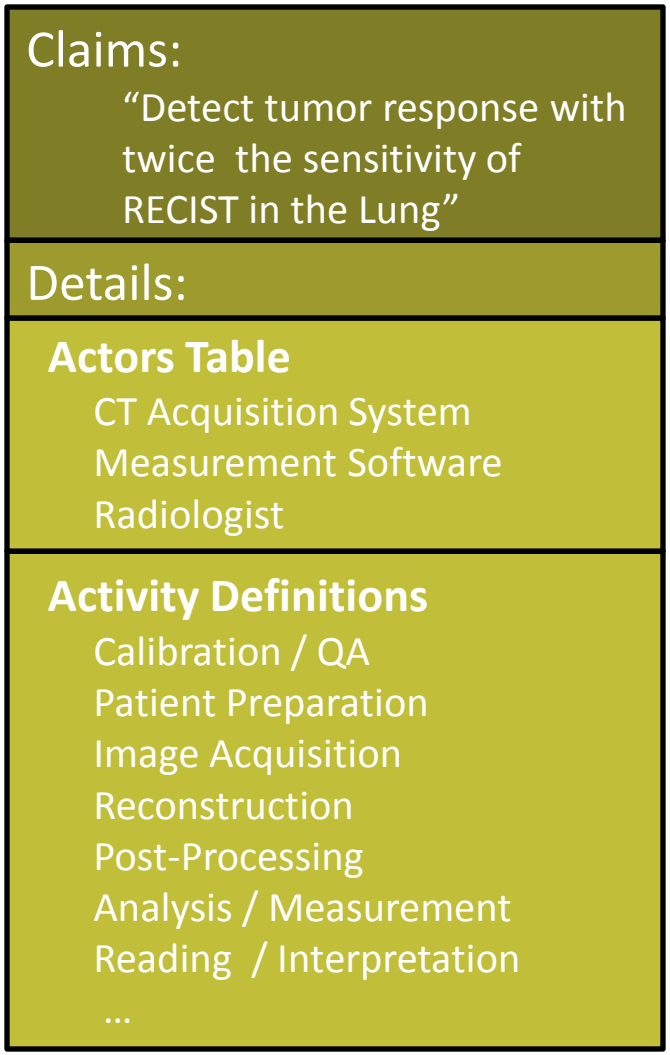
QIBA Profile Content

User Perspective

Will it do what I need?

What/who do I need to get started?

What do I have to do (procedures, training, performance targets) to achieve the Claims?



Vendor View

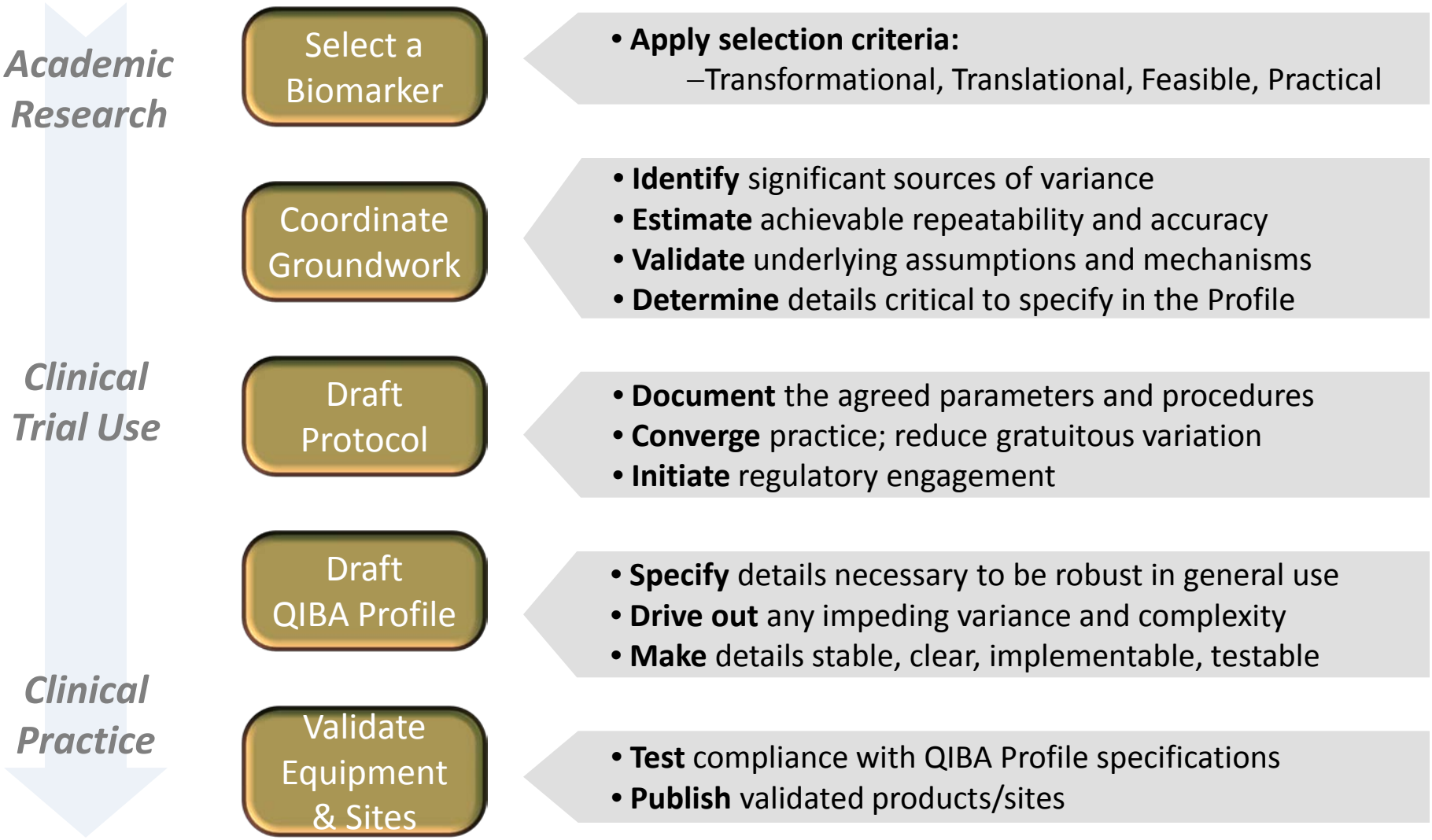
Why do you want me to do this?

Which of my products are affected?

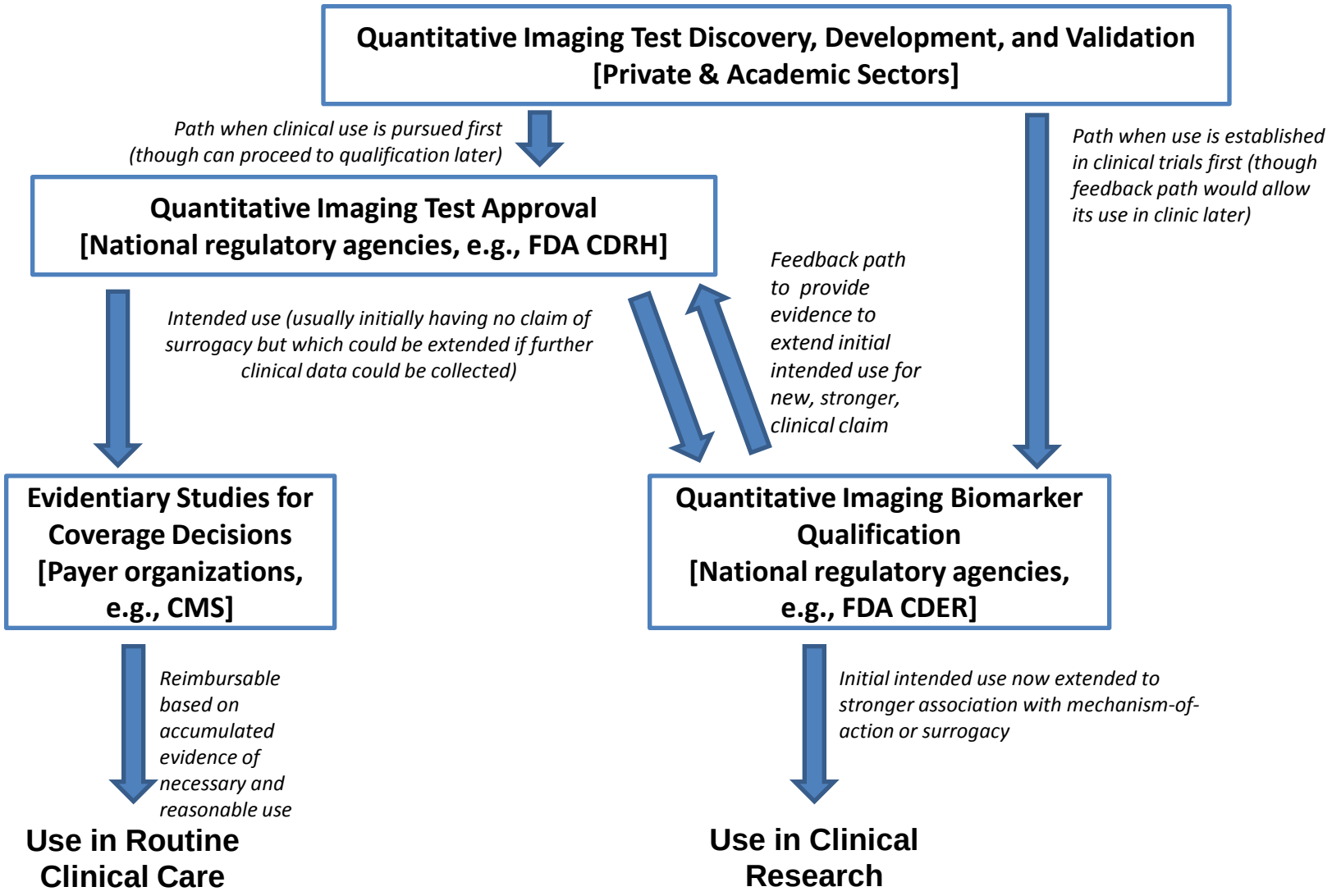
What do I have to implement; (features, capabilities, performance targets)

How will I be tested?

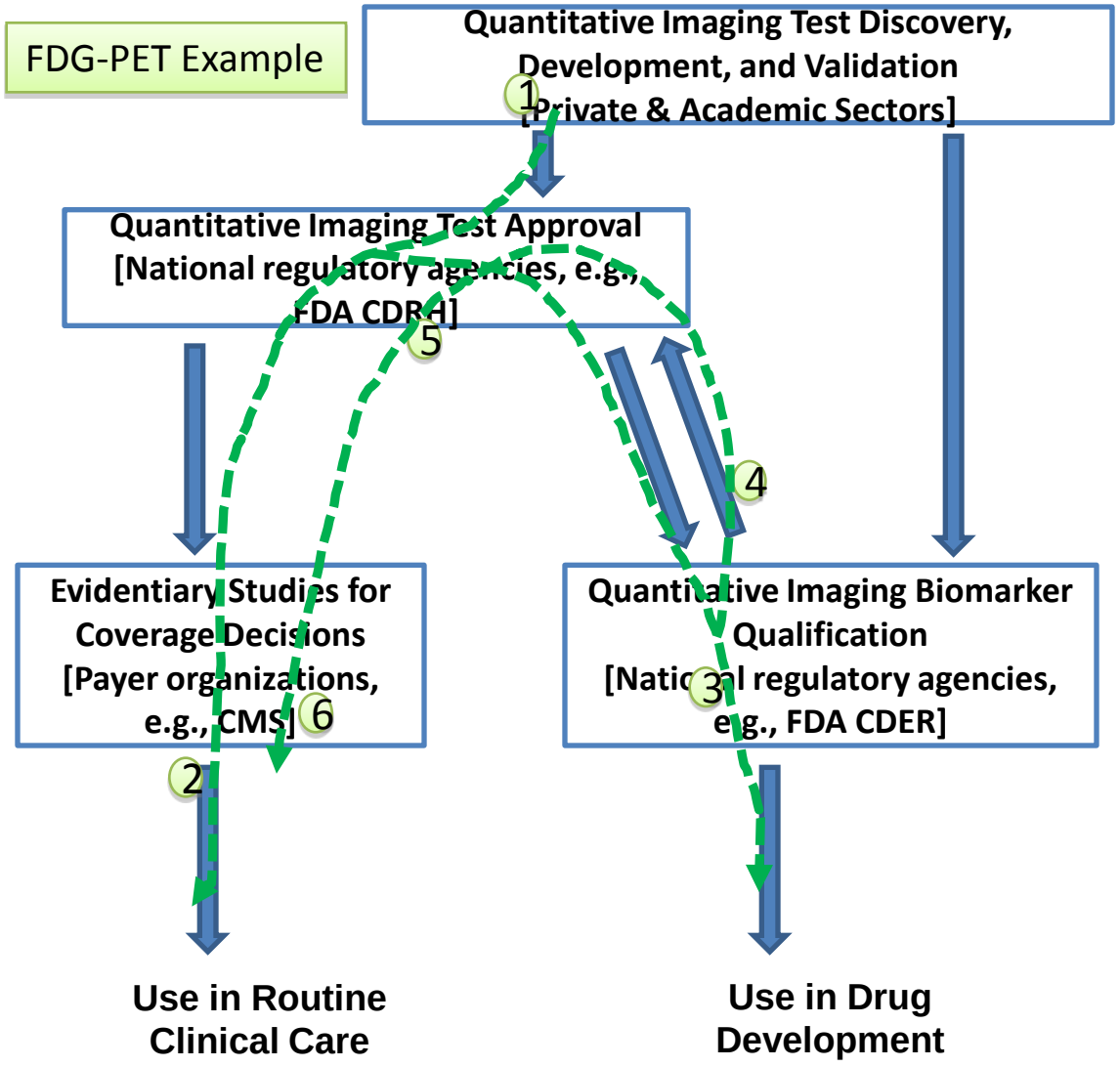
QIBA "Industrializes" QI



QIBA is an Active Sponsor in Regulatory Pathways that Leverage Collaboration

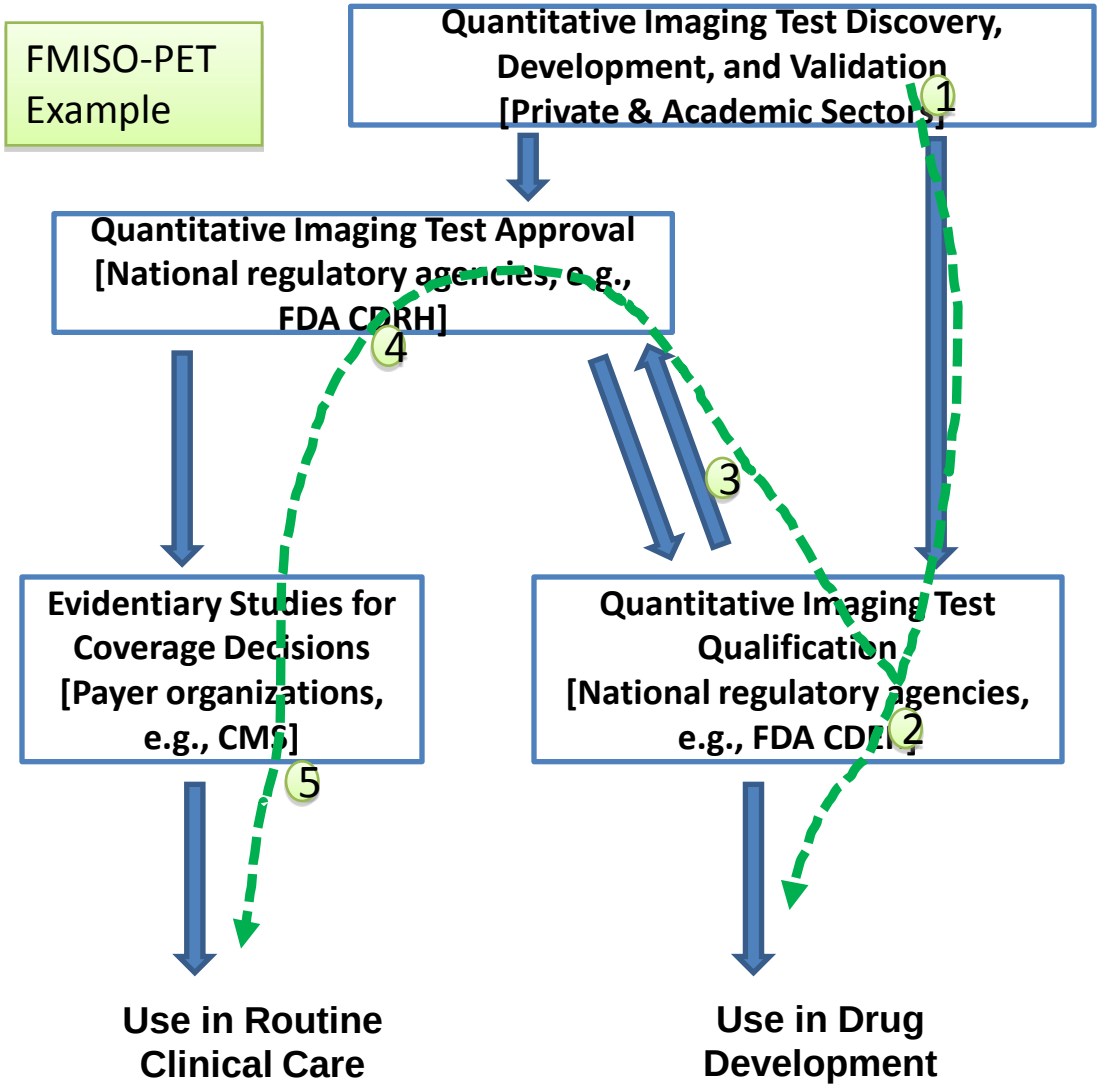


Example Drill Down: How Pathways may be Applied to Quantitative FDG-PET



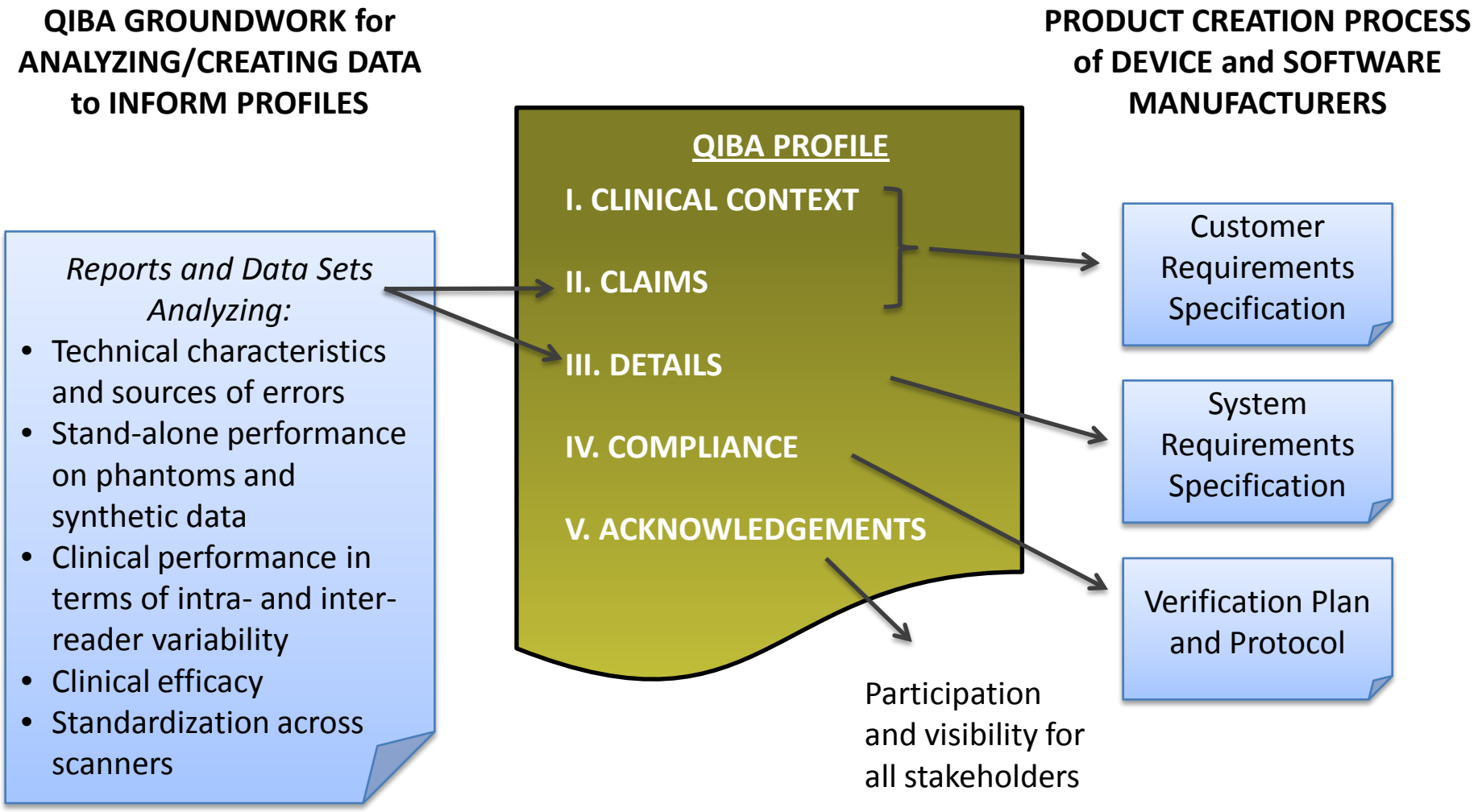
1. Vendors have developed and continue to refine FDG-related products (hardware, software, agent.
2. Products have been approved by CDRH using the approval pathway, and— based partly on data from the National Oncologic PET Registry (NOPR) -- they are reimbursed for clinical care, but only for disease stratification and diagnosis, not in quantitative applications for therapy monitoring.
3. A sponsoring collaborative would qualify the class of devices for clinical research applications by following the qualification pathway.
4. Data collected during the qualification activity, substantiating performance as a response measure, could be referenced by vendors to add therapy monitoring (and thereby expand their market) as a new indicated use (claim). This would be done by establishing compliance with the class by referencing data collected as part of the qualification pathway in the validation pathway.
5. These "qualification data" would be available to be contributory as evidence for individual device sponsors as they re-register their products (if they are already a compliant implementation) or re-engineer them (to become compliant).
6. Payers could extend coverage decisions to include therapy monitoring as an additional code for reimbursement.
7. Subsequently, the intended use claims may be extended to additional settings (e.g., tumor types or subtypes) and/or for different therapeutic approaches (e.g., cytotoxic vs. targeted, etc.).

Example Drill Down: How Pathways may be Applied to Advance Newer Tracers

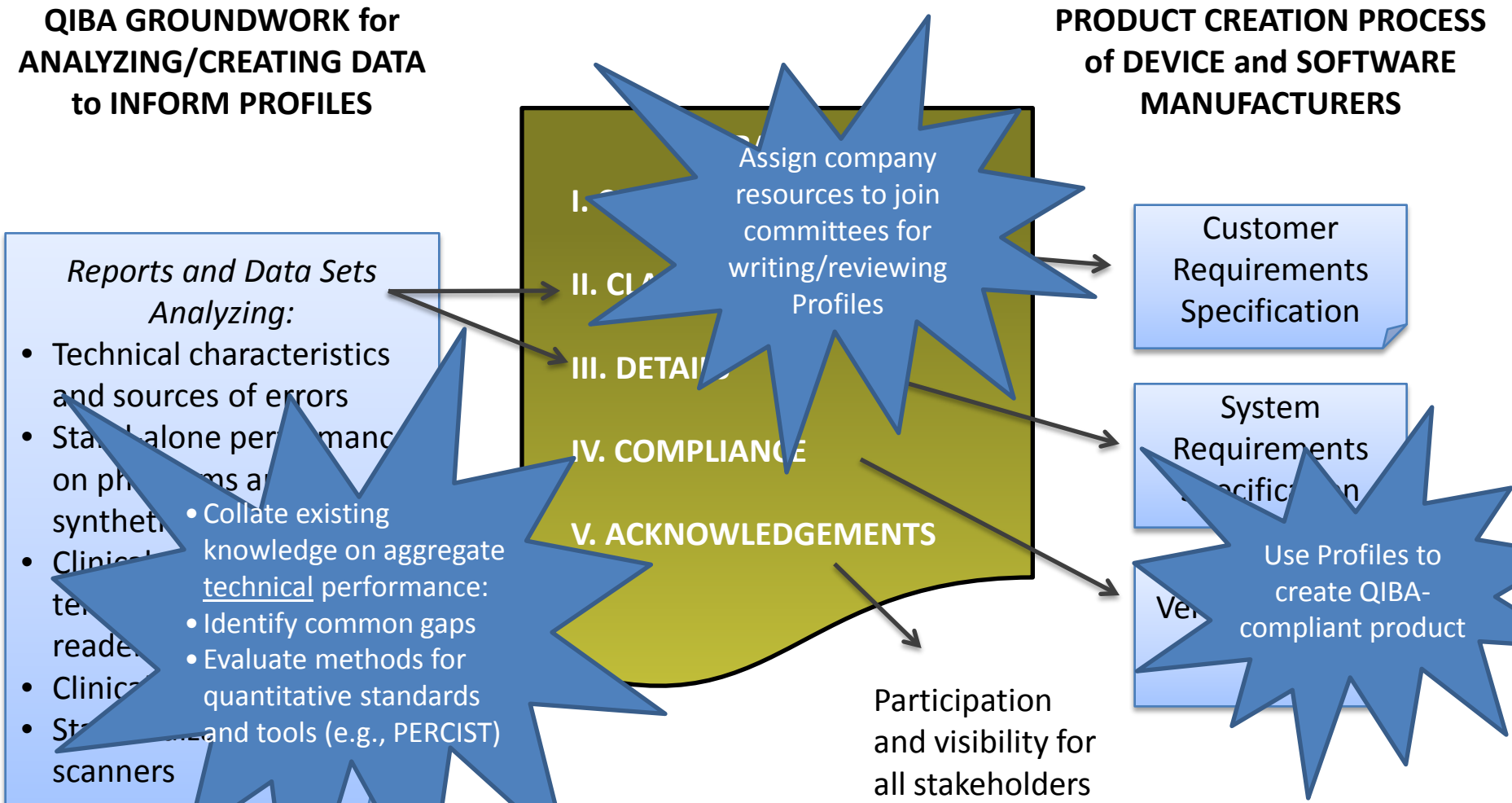


1. Vendors develop and refine FMISO imaging methods for hypoxia.
2. The first application might be in clinical trials and not clinical care, so qualification would precede approval to market.
3. The qualification data may be used by vendors if they also intend to sell a product for clinical care to efficiently seek approval from CDRH.
4. Ultimately, payers might make decisions based on already-collected qualification data, or with additional collection using a model similar to that used by the National Oncologic PET Registry.

QIBA Leverages Resources and Bridges Perspectives Across Communities



Our Offer – and our Request – is to Increase your Engagement with Us



To be specific, for FDG-PET now and newer tracers soon, we are requesting:

- Assist with collaborative groundwork activities:
  - Participate in experimental studies for characterizing performance.
  - Review requests and provide feedback on standardizing acquisition system characteristics.
- Apply engineering resources to help refine QIBA profiles:
  - Assist with the engineering analysis being performed to arrive at requirement levels and functional specifications.
  - Assist with the writing of QIBA profile claims.
- Prepare for future product development and marketing:
  - Review QIBA profiles and current product performance claims.
  - Perform QIBA studies and internally validate QIBA compliance.
  - Obtain approval to claim QIBA compliance.

We can't do it alone, you can't do it alone. We need to do it together.

- Utilization of imaging grows as it is used for monitoring response and adapting therapy.
- Technical as well as business obstacles impede commercialization.
- QIBA addresses these obstacles, accounting for individual stakeholder value propositions.
- The commercialization model is similar to IHE, including relationship to product creation process.
- Collaborative resources in precompetitive model address the science and provide critical mass as well as cost sharing for regulatory data collection.
- We invite you to join us in making the critical step of defining Profiles.
- New products compliant with the outputs of this process will fuel a virtuous cycle of innovation in this next generation of imaging, rewarding all participants.