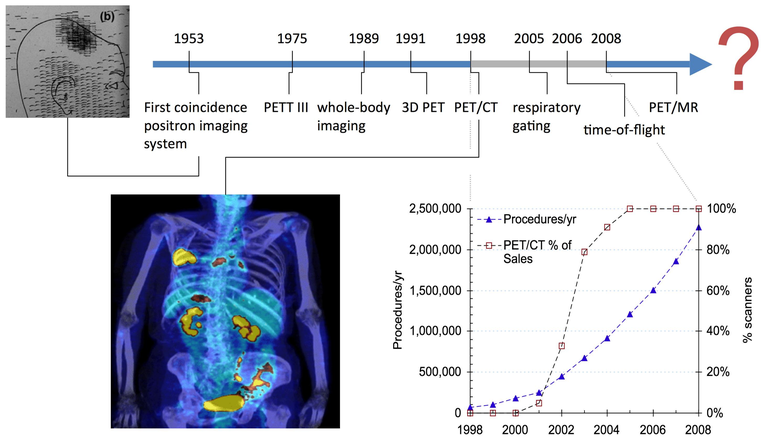
Quantitative FDG-PET/CT: Accelerating development of new therapies and improving assessment of response

Quantitative Imaging Biomarkers Alliance — RSNA

PET-CT: A Proud History of Innovation



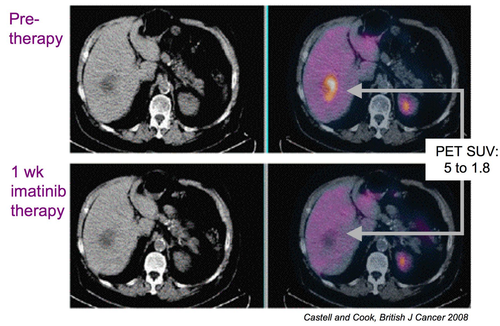
What's next? *Quantitative PET to* Characterize Disease Hallmarks

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

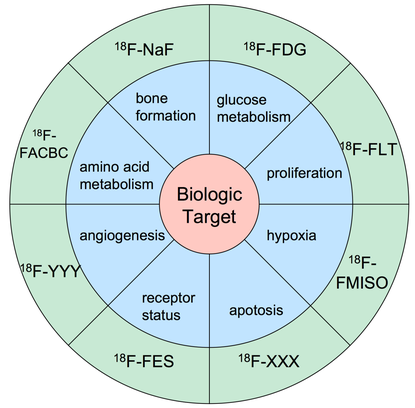
volume

Response to therapy of liver met GIST



Castell and Cook, British J Cancer 2008

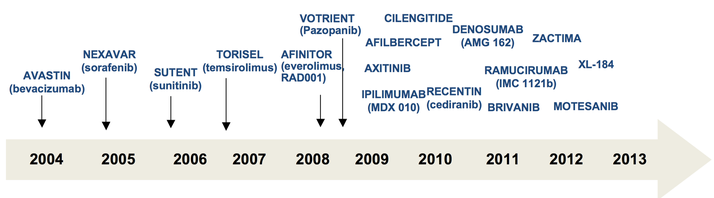
Biomarkers To Quantify Hallmarks of Cancer



- 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%



Quantitation Improves Characterization of Disease Hallmarks

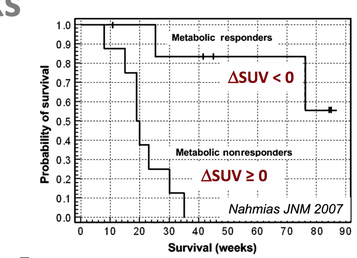
Improve individual patient care

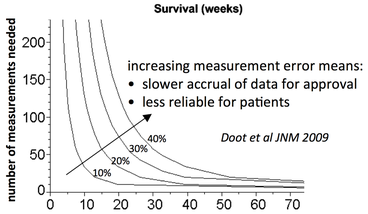
- Clinically proven detection and longitudinal quantitation for follow-up
- Moves imaging from diagnostics and staging to therapy assessment

Accelerate adoption of new molecular diagnostics

Make clinical trials of new therapies more effective

All tied to quantitative accuracy

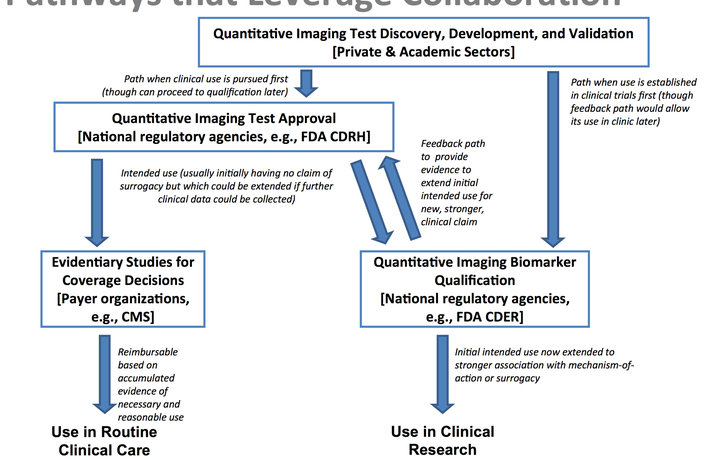




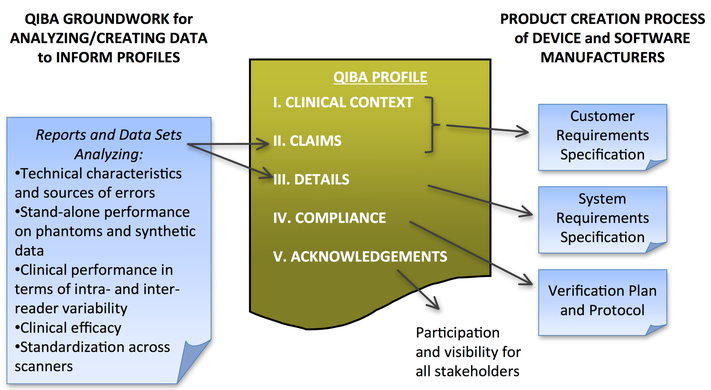
QIBA FDG-PET/CT TC Projects

Title	PI	Status
Meta-analysis to analyze the robustness of FDG SUV changes as a response marker, post and during systemic and multimodality therapy, for various types of solid extracerebral tumors.	O. Hoekstra, U of the Netherlands	**Completed**
QIBA FDG-PET/CT Digital Reference Object Project	P. Kinahan, U of Washington	**Completed**
Analysis of SARC 11 Trial PET Data by PERCIST with Linkage to Clinical Outcomes	R. Wahl, Johns Hopkins	Close to completion
Personnel Support for FDG-PET Profile Completion	E. Perlman, PAG & P. Kinahan, U of Washington	**Completed**
Evaluation of the Variability in Determination of Quantitative PET Parameters of Treatment Response Across Performance Sites and Readers	R. Wahl, Hopkins	Needs readers
Evaluation of FDG-PET SUV Covariates, Metrics and Response Criteria	J. Yap, Dana Farber	In Progress
Integration of Retrospective Reviews of 2-3 Groupings of Clinical Trial Datasets (This includes the current Hoekstra proposal) Will utilize the PERCIST analysis	O. Hoekstra, Netherlands	In Progress
Supported by NIBIB contract HHSN268201000050C		

QIBA is an Active Sponsor in Regulatory Pathways that Leverage Collaboration



The QIBA Profile Provides Guidance for all aspects of quantitative FDG-PET/CT



What we've done and how you can participate

- ✓ Collection of recommendations for quantitative FDG-PET
- ✓ Presentation (joint with FNIH) to FDA
- ✓ NIBIB grant application
- ✓ Year 1 research targets

Completed

- Collaboration with UPICT on Protocols
- Bi-weekly telephone conferences
- Annual QIBA meetings and updates at RSNA and SNM
- Working visits with vendors
- Profile development
- Year 2 research targets

In progress

- o Profile testing and approval
- o Implementation of Profiles by QIBA and vendors)
- o Clinical use of Profiles

TBD

More information at www.rsna.org/research/qiba/