**Quantitative FDG-PET/CT:**

**Accelerating development of new therapies and improving assessment of response**

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**PET-CT: A Proud History of Innovation**

- 1913: First coincidence position imaging system
- 1975: PET II - whole body imaging
- 1989: 3D PET (PET/CT)
- 1990: Respiratory gating
- 1995: Time of flight (TOF)

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**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 routinemly reported, and are asked for, by referring physicians

**Response to therapy of liver metast GIST**

- PET/CT
- SUV 5 to 1.6

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**Biomarkers To Quantify Hallmarks of Cancer**

- New molecular diagnostic agents
- New uses for existing agents

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**Assist with increasing number of oncology targeted pharmaceuticals**

**Quantitation Improves Characterization of Disease Hallmarks**

- **Type:**
  - **Improve individual patient care**
  - **Current:** Proven detection and longitudinal quantitation for follow-up
  - **Future:** Moves imaging from diagnostics and staging to therapy assessment

- **Make clinical trials of new therapies more effective**
  - All tied to quantitative accuracy

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**QIBA FDG-PET/CT TC Projects**

<table>
<thead>
<tr>
<th>Title</th>
<th>PI</th>
<th>Status</th>
</tr>
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<tbody>
<tr>
<td>Meta-analysis to analyze the robustness of FDG SUV changes as a response marker, and during systemic and multimodality therapy, for various types of solid extracranial tumors.</td>
<td>H. Ouwelaars, U of the Netherlands</td>
<td>Completed</td>
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<tr>
<td>QIBA FDG-PET/CT Digital Reference Object Project</td>
<td>P. Krasnow, U of Washington</td>
<td>Completed</td>
</tr>
<tr>
<td>Analysis of SARC H11 Trial PET Data by PERIST with Linkage to Clinical Outcomes</td>
<td>R. Wail, Johns Hopkins</td>
<td>Close to completion</td>
</tr>
<tr>
<td>Personnel Support for PET-DG Profile Completion</td>
<td>E. Pearlman, FACG &amp; P. Krasnow, U of Washington</td>
<td>Completed</td>
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<tr>
<td>Evaluation of the Variability in Determination of Quantitative PET Parameters of Treatment Response Across Performance Sites and Readers</td>
<td>W. Wang, Johns Hopkins</td>
<td>Needs readers</td>
</tr>
<tr>
<td>Evaluation of FDG-PET SUV Correlates, Metrics and Response Criteria</td>
<td>J. Yap, Dana Farber</td>
<td>In Progress</td>
</tr>
<tr>
<td>Support of Retrospective Reviews of 2-3 Groupings of Clinical Trial Datasets (This includes the current Ouwelaars proposal)</td>
<td>H. Ouwelaars, Netherlands</td>
<td>In Progress</td>
</tr>
</tbody>
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**QIBA is an Active Sponsor in Regulatory Pathways that Leverage Collaboration**

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

**QIBA Groundwork for analyzing/creating data to inform profiles**

- Reports and Data Sets
  - Analyzing technical characteristics and sources of errors
  - Clinical performance in terms of intra- and inter-reader variability
  - Practicality and standardization across scanners

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**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
- 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
  - Profile testing and approval
  - Implementation of Profiles by QIBA and vendors
  - Clinical use of Profiling

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More information at [www.rsna.org/research/qiba/](http://www.rsna.org/research/qiba/)