# Imaging in Cancer Clinical Trials: A One Day Course

## Course Agenda*

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<th>Time</th>
<th>Session</th>
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<td>7:30 am to 8:00 am</td>
<td>Continental Breakfast</td>
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<td>8:00 am to 8:15 am</td>
<td><strong>Opening Remarks</strong>&lt;br&gt;<strong>Rick Patt</strong>, MD, Course Co-Director&lt;br&gt;RadMD/BRITI</td>
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<td>8:15 am to 9:15 am</td>
<td><strong>Presentation:</strong> The Role of Imaging in Cancer Clinical Trials&lt;br&gt;<strong>Wendy Hayes</strong>, DO&lt;br&gt;Bristol-Myers Squibb&lt;br&gt;Dr. Hayes is the Group Director of Imaging at Bristol-Myers Squibb; formerly Novartis Institutes for BioMedical Research Division of Imaging. She has been an active member of the PHaRMA/FDA initiative for standardization of imaging in clinical trials, and is a regular speaker at conferences globally and acknowledged an expert on implementing imaging in oncology trials.&lt;br&gt;<strong>Description:</strong>&lt;br&gt;• Historical perspective of imaging in clinical trials&lt;br&gt;• Description of various imaging modalities used in cancer clinical trials&lt;br&gt;• Selecting imaging modalities for a trial (micro or macro anatomic delineation, physiological process, function, drug class etc.)&lt;br&gt;• Role of imaging in early and late clinical development</td>
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<td>9:15 am to 10:15 am</td>
<td><strong>Presentation:</strong> Cooperative Efforts Towards Standardizing Imaging: Industry, Academia, and FDA Initiatives&lt;br&gt;<strong>Jim Conklin</strong>, MD&lt;br&gt;Extended Pharma Imaging Group&lt;br&gt;Dr. Conklin is the Chairman of the Extended Pharma Imaging Group and Senior Vice President for Medical &amp; Scientific Affairs at ICON Medical Imaging. He is a serial entrepreneur, who pioneered commercial imaging core laboratories as the founder, CEO and Chairman of Bio-Imaging Technologies (BITI), Inc. Dr. Conklin was also the Vice President of Product Development at Cytogen Corporation, held a senior position at Centocor, Inc. and was the Director of the Armed Forces Radiobiology Research Institute.&lt;br&gt;<strong>Description:</strong>&lt;br&gt;• Factors impacting image quality&lt;br&gt;• Challenges of imaging in multicenter/multinational trials&lt;br&gt;• Why standardization is necessary and the impact on quality&lt;br&gt;• Role of the radiologist and technologist in image standardization&lt;br&gt;• Recommendations for standardization (such as the use of phantom scans, use of standardized criteria, etc.)</td>
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<td>10:15 am to 10:30 am</td>
<td>Coffee Break</td>
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| 10:30 am to 11:30 am | **Presentation:** Independent Image Review: The Blinded Read Process  
Sanjay Saini, MD, MBA  
*Massachusetts General Hospital*  
Dr. Saini is a Professor of Radiology at Harvard Medical School and the Vice Chairman for Finance in the Department of Radiology at the Massachusetts General Hospital, where he practices abdominal radiology with an academic focus on liver imaging with CT and MR. From 2004 to 2006, he served as the Timmie Professor and Chairman of Radiology at Emory University. He is an author or coauthor of more than 300 peer-reviewed publications and three books and has lectured extensively around the world.  
**Course Description:**  
- The pharmaceutical practice vs. clinical practice of radiology  
- Why blinded reads?  
- Description of the blinded read process  
- Blinded read paradigms (number of readers, adjudication process, selective unblinding, consensus read)  
- Types of reads: efficacy reads, safety reads, inclusion reads, confirmation of progression reads, exploratory reads  
- Site reading and blinded reading |
| 11:30 am to 12:30 pm | **Presentation:** Drug and Disease-based Modifications to Imaging Efficacy Criteria  
Rick Patt, MD  
*Principal, RadMD/BRITI*  
Dr. Patt is a co-founder and principal in RadMD. He has a broad prior experience in medical imaging, which includes research and development of contrast agents, therapeutic and medical device clinical development. He is co-founder of RadMD and BRITI.  
**Description:**  
- Development of image based criteria  
- RECIST and common modifications (disease and drug class)  
- Regulatory considerations  
- Case studies and pitfalls  
- Beyond RECIST |
| 12:30 pm to 1:15 pm | Lunch                                      |
| 1:15 pm to 2:15 pm | **Presentation:** Biostatistical Considerations and Reader Performance Evaluation  
David Raunig, PhD  
*Pfizer, Inc.*  
Former Associate Director, Oncology Pharma Therapeutics Research Statistics, currently the director of Neurosciences Research Statistics at Pfizer. Dr. Raunig has written and spoken extensively on biostatistical issues related to imaging in trials, and considered a thought leader in pharmaceutical imaging biostatistical issues. He participates in numerous cooperative groups including Metrics Champion Consortium and extended Pharma Imaging Group.  
**Description:**  
- Statistical considerations when using imaging in cancer clinical trials  
- Description of imaging-based efficacy end points (PFS, TTP, Response Rate, etc.)  
- Bias and variance  
- Reader performance: inter- and intra-reader variability, adjudication rates, etc.  
- Statistical “land mines” and solutions |
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| 2:15 pm to 3:15 pm | **Presentation:** **Quantitative Imaging Biomarkers**  
Andy Buckler, MS  
*Buckler Biomedical, LLC*  
Mr. Buckler is a Principal at Buckler Biomedical. With years of experience in the medical device industry and past roles as Project Manager, Director of Software and Systems Engineering, Section Manager, and R&D Director (Imaging Systems) at Phillips Medical Systems, Mr. Buckler is a leader in advanced product development and launch, with focus on commercialization of research, cross functional program management, and multi-disciplinary organizational design. He has also served as a subject matter expert for NCT's caBIG program and co-chair of the Quantitative Imaging Biomarkers Alliance (QIBA).  
**Description:**  
- Qualifying imaging biomarkers in drug trials  
- Cancer-specific biomarkers  
- PET and PET/CT in the trial setting  
- Volumetric vs. 2D CT in evaluating drug efficacy  
- QIBA initiative |
| 3:15 pm to 3:30 pm | Coffee Break |
| 3:30 pm to 4:30 pm | **Presentation:** **Managing Risk Associated With Imaging in Cancer Trials**  
Kohkan Shamsi, MD, PhD  
*RadMD/BRITI*  
Dr. Shamsi is co-founder and principal of RadMD and is a radiologist with extensive research experience in the pharmaceutical industry. He has authored several books and chapters in addition to publishing more than 80 full publications and abstracts in indexed journals. Dr. Shamsi has over 15 years of experience in worldwide clinical development. Before founding RadMD, he served as Head of Medical Development in the Diagnostic Imaging and Radiopharmaceuticals at Berlex Labs.  
**Description:**  
- Risk identification and assessment of risks that can impact outcomes: (risks in the planning phase, at sites, with recruitment, in imaging evaluations, in data analysis and acceptability of the data)  
- Risk mitigation strategies (trial design, selection of imaging modalities, site selection, site training, inclusion reads, reader training and reader performance monitoring) |
| 4:30 pm to 5:30 pm | Panel Discussion: **Current Controversies Related to Imaging in Oncology Trials**  
**Description:**  
Our presenters will discuss current issues such as:  
- Can site reads replace central reads?  
- Are adjudication rates in blinded reads a reflection of trial quality?  
- Is overall survival a better endpoint then PFS for all trials? |
| 5:30 pm to 5:45 pm | Closing Remarks |

*Agenda and topics are subject to change.*