

## An Advocate's Notes on ASCO 2007

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I attended ASCO for the first time this year as part of the "Focus on Research" program. This program is funded by PhRMA and administered by the Research Advocacy Network (RAN) to prepare and bring group of advocates to ASCO. Prior to the meetings we read material and participated in webinars about Genomics and Clinical Trial Design. Indeed, I developed the Tutorial on Clinical Trials Design (<http://www.gemini-grp.com/AdvocacyFiles/CTTutorial.pdf> ) and delivered two webinars on the topic. Clinical trial design and especially innovative approaches to trials (e.g., Bayesian and Adaptive Designs) are a natural interest for me. This is because in a previous life I was an experimental psychologist and taught statistics and experimental design.

Rather than focus on an organ-site track, many of the ASCO sessions I attended dealt with methodology. A better understanding of the methodological issues discussed in these sessions, I believe, could help increase the impact of research on patient outcomes. As is, a considerable amount of data are collected without adequately understanding what they will be capable of explaining, let alone how they might impact clinical practice. Further, methodological advances have great leverage since they can be applied to trials across all organ-sites.

Many of the speakers in these sessions seem to share my biases, often presented insightful points about existing problems, and sometimes remedies to them. All of these abstracts are available on the ASCO website (<http://www.asco.org/portal/site/ASCO> ) and most should be available as archived webcasts shortly. The following table captures some of the key topics from the methodological sessions I attended.

Session	Speaker	Key Topics
Tumor Marker Development: The Problems and Pitfalls of Translating Laboratory Observations To Clinical Utility: It Isn't Easy!	<ul style="list-style-type: none"> <li>• Hayes</li> <li>• Dorset</li> <li>• McCone</li> <li>• Ransohoff</li> </ul>	<ul style="list-style-type: none"> <li>• Levels of evidence for marker research</li> <li>• Examples of reliability and validity issues</li> <li>• Statistical Considerations</li> <li>• Bias and how to guard against it</li> </ul>
Multigame Signatures: Are they Ready for Prime Time in Breast Cancer?	<ul style="list-style-type: none"> <li>• Piccard</li> <li>• Ransohoff</li> <li>• Spartan</li> <li>• Rutgers</li> </ul>	<ul style="list-style-type: none"> <li>• Overview about moving from treating based on risk of recurrence to probability of benefit</li> <li>• Lessons learned (good and bad) from multigame signatures in breast cancer</li> <li>• OncotypeDX and the TailorX trial</li> <li>• Amsterdam signature and the MINDACT trial</li> </ul>

Session	Speaker	Key Topics
What Can the Decision Sciences Teach Us? Patients Policy, and Practice	<ul style="list-style-type: none"> <li>• Hillner</li> <li>• Ubel</li> <li>• Siminoff</li> <li>• Rawling</li> </ul>	<ul style="list-style-type: none"> <li>• Decision Aids</li> <li>• How patients approach decisions (innumeracy) and what can be done about it</li> <li>• What patients want—shared decision making</li> </ul>
Cost and Care from Treatment to Survivorship	<ul style="list-style-type: none"> <li>• Weeks</li> <li>• Rowland (Excellent discussants &amp; summaries of abstracts)</li> </ul>	<ul style="list-style-type: none"> <li>• Methods to measure non-financial costs of treatment are generally not adequate to conduct cost-benefit analysis</li> <li>• Some costs (e.g., time from work) are affected by culture</li> <li>• Many survivors and their health care providers do not know or follow appropriate long-term follow-up</li> </ul>
Evidence of Therapeutic Effectiveness: How Much is Enough to Change Clinical Practice?	<ul style="list-style-type: none"> <li>• Ellensberg</li> <li>• Green</li> <li>• Begg</li> </ul>	<ul style="list-style-type: none"> <li>• Few clinical trials are practice changing</li> <li>• Even meta-analyses rarely provide unambiguous conclusions</li> <li>• Many cultural factors influence the integration of evidence into clinical practice</li> </ul>
Has Pharmacogenomics Proven Its Place in Clinical Trials?	<ul style="list-style-type: none"> <li>• McLeod</li> <li>• Stearns</li> <li>• Ratain</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmacogenetics is beginning to provide insights into one of the reasons treatments only work for some patients</li> <li>• Still, it has yet to significantly change clinical practice</li> <li>• Examples from women's health study</li> </ul>
Promise and Pitfalls of Surrogate Endpoints in Cancer Prevention	<ul style="list-style-type: none"> <li>• Bernard Levin</li> <li>• Jennifer Miller (for Barry Kramer)</li> <li>• Keith Baggerly</li> <li>• David Ransohoff</li> </ul>	<ul style="list-style-type: none"> <li>• Biostatistical challenges in the use of surrogate endpoints</li> <li>• Focused on prevention, but also shed light on use of surrogates (and inherent problems) in treatment trials</li> </ul>