



Greenpark Collaborative: A US Perspective  
Marc L. Berger, M.D.  
Executive VP & Senior Scientist, OptumInsight

### Signaling Life Science Companies: What is the Right Evidence?

- Regulatory – FDA
  - “Safe and Effective”
  - Consultation; End-of-Phase II meeting
  - Guidance Documents
  - Biomarkers as Outcome Measures:
    - Critical Path Initiative; Biomarker Consortium
  - IOM: Medical Devices and the Public Health: The FDA 510(k) Clearance Process at 35 years (July 2011)
- CMS
  - “Reasonable and Necessary”
  - Coverage with Evidence Development: Observational Studies
  - “Parallel Review” with FDA of Medical Devices
    - Voluntary Pilot Program

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- Commercial Payers
  - FDAMA 114, AMCP Dossier
    - Economic assessment of value
  - Payer Advisory Boards for Life Sciences
- NIH
  - Randomized Clinical Trials
- PCORI
  - Range of Evidence
    - Meta-analyses → PCTs → Observational Studies

September 20, 2011

Currently, there is not great alignment about evolving development needs from the FDA, public payers, and private payers.

Greenpark Collaborative offers an opportunity for dialogue and better alignment of messages to life sciences companies

- Focus on methodology is good as it minimizes potential for conflicts based on different legal, regulatory, and other requirements
- Focus on methodology is consistent with FDA critical path initiative to focus on “pre-competitive space”

September 20, 2011