

# Innovative Trials & Collaborative Initiatives- Role of Patient Advocacy, Foundations & Institutes

Moderator: Jeremy Goldberg, President, JPG Healthcare LLC

Panelists:

- Lou DeGennaro, PhD, President and Chief Executive Officer, The Leukemia & Lymphoma Society
- Lorraine Egan, President and Chief Executive Officer, Damon Runyon
- Ramy Ibrahim, MD, Vice President, Clinical Research & Development, Parker Institute
- T.J. Sharpe, Patient Writer, Speaker, & Patient Experience Advisor, Starfish Harbor, LLC



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# Challenge of Recruiting Patients to Cancer Clinical trials

- Only (3% in 2013) of adult cancer patients enroll in cancer clinical trials<sup>1</sup>
- Too few patients for too many trials
  - 28,000 oncology trials<sup>2</sup>
  - 1,500 combination trials for I/O
- Issues include
  - Cost
  - Availability
  - Proximity to cancer center
  - Inclusion/ Exclusion Criteria
- Role of Patient Advocates / Foundations to help recruit patients ?

Source: 1. NCI Report: Operational Efficiency Working Group of the Clinical Trials and Translational Research Advisory Committee. Compressing the Timeline for Cancer Clinical Trial Activation

2. Clinicaltrials.gov (searched active, enrolling, recruiting, not yet recruiting, unknown status for cancer)

# Need for new Regulatory framework to approve oncology drugs

- FDA has been responsive with new faster pathways to approval
  - Of 174 new drug approvals, 60% were in at least 1 expedited program<sup>1</sup>.
    - Drugs in at least 1 expedited review program spend on average **1 fewer year** in clinical development while breakthrough designation drugs spend on average **3 fewer years** in clinical development (**32% shorter** than fast-track drugs)
  - J&J approval on Erleada based on new endpoint, metastasis free survival
  - Adaptive trials
  - Breakthrough / Fast Track / other FDA approaches to speed review & approval
- What can Foundations / Patient Advocates do going forward to continue to improve on Oncology regulatory review ?

# Critical role of Foundations / Non Profits to continue funding Cancer Research

- Risk of Maintaining Cancer research funding by Government
  - Current administration budget request for 20% decrease in NIH funding (- \$5.8 Billion)
  - Sequestration - 722 fewer grants FY 2013 vs FY 2012
- Foundations increasingly important
  - CF Foundation monetizes Kalydeco royalties for \$3.3B
  - Parker Institute commits \$250 MM for Cancer Immunotherapy
  - 12 Damon Runyon scientists have received Nobel Prize