Best Practices for Boosting Enrollment in Oncology Trials
Introduction

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The Sobering Facts

Cancer is **#2** leading cause of death

- **1.6M** new cancer cases diagnosed in 2012 (NCI)
- **577,000** cancer-related deaths in 2012 (NCI)
- NIH in 2008 estimated overall cost of cancer to be **$200B**
- **850** cancer drugs and vaccines in development (Tufts)

Although **20%** are eligible, only **3%** of adult cancer patients in the U.S. participate in clinical trials

But...

Only **2%** of primary care providers routinely discuss oncology trials with patients

**SOURCES:**
2. Crosson J Cancer Educ, 2001
Consequences of Poor Enrollment

1. INCREASED COSTS
2. DELAY IN PATIENT TREATMENT
3. SHIFTING TREATMENT LANDSCAPE
   - New therapies can change standard of care
   - Aspects of ongoing trial could become obsolete
4. WANING INTEREST ON PART OF INVESTIGATORS AND STAFF
Barriers to Enrollment (Patient)

✅ Insurance
  - US:
    • Standard of care treatment costs usually covered by health insurance
    • State laws and individual provider policies dictate coverage
    • Research costs often not covered
  - PPACA – March 2010

*Uninsured patients represented only 5.4% of all clinical trial participants (NCI)*

✅ Logistical challenges
  - Additional visits to clinic
  - Travel between buildings at some sites
  - Ability to receive same treatment outside of trial
Barriers to Enrollment (Patient)

✓ Negative perceptions
  – 71% Americans say participating in clinical research is of “great value” (2007, Research America)
  – Only 57% respondents said it was “likely” they would participate in a study

✓ Patients say they fear clinical trials because:
  – Being a “guinea pig” furthers career of scientists without benefiting patient or current condition
  – Trials are a last chance for someone who has no hope
  – A trial is what you do when your current treatment is not working
  – A trial means your physician thinks your death from cancer is imminent

✓ Low literacy/language differences
  – Forms and patient tools in English only
  – Complexity
Barriers to Enrollment (Sites)

- Complex, burdensome protocols
  - Decrease patient enrollment, patient retention and trial quality
  - Increase cost

AVG. CLINICAL TRIAL PROTOCOL

- 13 Endpoints
- 167 Procedures
- 35 Inclusion & Exclusion Criteria
- 11 Visits for 175 Study Patients

SOURCE: GETZ, 2012
Barriers to Enrollment (Sites)

✓ # of tailored cancer therapies under investigation has increased > shrinks pool of eligible participants

✓ Physician lack of awareness about available trials
  – In the community
  – Referrals
So what can WE do?
Polling Question #1
Best Practices for Boosting Enrollment

✓ PRACTICE #1: USE AN ADAPTIVE TRIAL DESIGN

- Changes planned in advance rather than on an ad hoc basis
- FLEXIBILITY > FEWER PATIENTS, EASIER ENROLLMENT
- FEWER PATIENTS TREATED AT INEFFECTIVE DOSES

- 3+3 design still most often utilized in early phase oncology trials
- Adaptive uses accumulating data to determine modification aspects of study
- Doesn’t undermine validity or integrity of trial
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✓ PRACTICE #2: SIMPLIFY YOUR TRIAL DESIGN
  - Input from study coordinators and others with practical study experience
  - Focus endpoints on safety and patient benefit
  - Choose what data is essential – decrease the number of CRF pages
  - Start the study with a FINAL protocol
  - Avoid protocol amendments – employ multifunctional protocol governance
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✓ PRACTICE #3: INCORPORATE MOLECULAR PROFILING
  - Most cancer cases classified as a rare disease
  - The age of “blockbusters” is over - individualized medical is the future of clinical research
  - Allows for matching patients with experimental treatments that offer greatest likelihood of benefit
  - Tailored therapies > greater incentive to patient participation
  - Companion diagnostics
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✓ PRACTICE #4: UTILIZE PATIENT-CENTRIC ENROLLMENT

<table>
<thead>
<tr>
<th>TRADITIONAL ENROLLMENT MODEL</th>
<th>PATIENT-CENTRIC MODEL</th>
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<tr>
<td>- Identify, research sites in advance of enrolling patients</td>
<td>- Patients identified across a large # of potential study centers</td>
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<td>Start-up = time-consuming, costly, some sites may never enroll a patient</td>
<td>- Sites not activated until eligible patient identified</td>
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<td>- Rare clinical events or diseases detected over a larger sample</td>
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<td>Sites activated accrue faster and within days of initiation</td>
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✓ PRACTICE #5: CONSIDER ALTERNATIVE TRIAL SITES

- Not typical “go-to” sites
  - Evaluate productivity of site in past trials
  - Complete feasibility for each trial

- International
  - Country / site selection
  - Disease prevalence
  - Competitive trials
  - Prior therapy(ies) and comparator agents
  - FDA will accept foreign data
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✓ PRACTICE #6: INCREASE INSURANCE COVERAGE
  – Expand population of oncology patients who can feasibly enroll in studies
  – Advocacy needed in government and industry
  – Conduct outcomes research related to coverage vs. non-coverage
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✓ PRACTICE #7: ENCOURAGE COMMUNICATION AND COLLABORATION

- Between healthcare team members and within study centers
- Keeping trials in front of practitioners throughout healthcare system key to identifying patients who may be good fit for studies
- Provide tools and recruitment materials
- What is the role of technology?
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✓ PRACTICE #8: MAKE PATIENT & FAMILY EDUCATION PART OF YOUR STUDY

- Increase willingness of members of target population to enroll
- Perceive benefits in potential to improve their health or advance medicine
- EVERY patient receives a letter prior to their first clinic visit
  - Explain that offering a clinical trial is the norm at your institution
  - Patient should expect to be asked about a clinical trial
  - The option of standard treatment is also available
  - Result: Enrollment in clinical trials increased 18%
- Other tactics:
  - Stories in publications with broad reach
  - Work with advocacy groups
Polling Question #2
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✓ PRACTICE #9: USE TECHNOLOGY

– Smartphone apps
  • ClinicalTrialSeek and VaxTrak
  • SMS texts
  • iPads for patient education and informed consent
  • Gather patient data using patient devices

– Social media
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✓ In Summary

– Increasing enrollment rate from 3% to 8% could shorten the development timeline of drugs by over a year and get promising therapies to patients more quickly

– 69% of non-participation in clinical trials is due to lack of awareness of trials taking place – we have to communicate amongst ourselves
  • Between investigators and referral centers
  • Directly to the patient by educating about clinical trials and that they are the norm, not a last ditch effort
  • Become active in patient advocacy groups

– Simplify protocols to increase patient enrollment and retention

– Use an adaptive trial design when appropriate and tailor therapies to individual patients

– Consider alternative trial sites

– Use technology
Questions?