Recruiting Patients for Cancer Trials: Focus on the Physicians!

Presentation by
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SCOPE Annual Meeting
Wednesday, February 8, 2012
In 2010, 31% of all compounds in clinical testing were oncology drugs or immunomodulators.
Oncology trials currently utilize traditional recruitment techniques

Accrual enhancement tactics:

- Informed consent aids
- Inclusion/Exclusion cards
- Pocket protocols
- Posters
- Brochures/Flyers
- Trial websites
- Internet-based recruitment
- Newsletters
- Journal advertisements
- TV advertisements

Despite all the efforts, cancer clinical trial recruitment remains abysmal

Why do these tactics work in other areas, but not for oncology?
Cancer is different

Cancer patients

- Cancer is a life-threatening illness
- Cancer diagnoses often result in fear, uncertainty, and has emotional impact
- Oncologists are important sources of psychological support for patients
- Unique relationship between oncologist and patient
- Shared decision-making
- Patients’ unmet need is information

Other therapeutic areas

- May not be life-threatening
- Less emotional impact on patients
- Specialty physicians may not be involved
- Patients may make decisions without consulting with their physician
- Individual decision-making
- Information easily accessible for patients in various media outlets

Cancer research is changing

- Targeted therapies are evolving
  - Biomarkers are being identified
  - Screening for molecular targets is required before enrollment
  - Need for bio specimen donation by patients
- Targeted therapeutics are gaining FDA approval
Complexity is increasing

Changes in Clinical Trials: Resources, Length and Participation

Unique Procedures: 38%
Total Procedures: 49%
Execution Burden: 54%
Total Eligibility Criteria: 58%
Volunteer Enrollment Rates: -21%
Volunteer Retention Rates: -30%

New specialties are involved in patient identification

- **Pathologists**
  - Early determination of subjects eligibility for clinical trials
  - Untapped potential for subject identification and referrals

- **Surgeons**
  - Highly involved in trials with a surgical component

- **Radiologists**
  - Interventional radiology Involved in obtaining tissue for biomarkers

- **Referral Medical Oncologist**
  - Increased awareness results in more referrals
A new approach: Focus on the Physicians!

• **Physician education is key to accrual**
  • Continued medical oncologist education and engagement through peer to peer interactions proven to increase enrollment

• **Frequent interactions with physicians to:**
  • Discuss patient eligibility issues in cooperation with the medical monitor
  • Quickly resolve eligibility queries
  • Identify and discuss opportunities to accelerate accrual at the site
  • Share best practices
  • Keep sites informed about accrual status
  • Discuss other trial issues at the site
  • Review data presented in public forums and in public sources of new and emerging trials and drug data of interest which could affect trial accrual
A new approach: Focus on the Physicians!

- **Pathologist, surgeon & referral physician interactions**
  - Expand outreach, education & engagement of key stakeholders
  - Pathologist, surgeon & referral physician are becoming key players in patient identification

- **Accrual Visits**
  - Face to face meetings with physicians to deliver protocol key messages

- **Accrual Workshops**
  - Small, interactive meetings to educate investigators through case-based learning activities
# Case-based learning

## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>12:00 p.m. – 12:30 p.m.</td>
<td>Lunch/Networking time</td>
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<tr>
<td>12:30 p.m. – 1:00 p.m.</td>
<td><strong>Introductions:</strong> Welcome, Goals and Objectives, Site introductions and overview</td>
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<tr>
<td>1:00 p.m. – 1:20 p.m.</td>
<td><strong>Overview of Her-2 Positive MBC:</strong> Choice of chemotherapy, Ummet clinical needs</td>
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<tr>
<td>1:20 p.m. – 2:20 p.m.</td>
<td><strong>Advancing HER-2 blockade in MBC:</strong> Protocol rationale, Clinical trial issues (eligibility, imaging, etc.), Adverse event management</td>
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<tr>
<td>2:20 p.m. – 2:35 p.m.</td>
<td>Break, With refreshments</td>
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<tr>
<td>2:35 p.m. – 3:45 p.m.</td>
<td><strong>Case Presentations and Discussions:</strong> Discussion of cases related to appropriate patient selection, enrollment challenges, adverse event management and any other issues</td>
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<tr>
<td>4:00 p.m. – 5:00 p.m.</td>
<td><strong>Strategies to Accelerate Accrual:</strong> Communicating with potential referring physicians, New ideas, learning, sharing of best practices and take away points</td>
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## Case Study
**Case #3: 70W with ER-/HER-2+ MBC progressing after trastuzumab**

### History
- 70 yr women initially presented with a positive mammogram
- Biopsy demonstrated ER-/HER-2 Positive IDC
- MRM on 6/17/06 demonstrated a 3.5 cm mass with 3/12 + LN
- Treated with TCH x 6 then 1 year of trastuzumab ending 7/07

### Recurrence
- On 10/08 she developed pain in the back. Bone scan demonstrated widely metastatic disease with biopsy confirming HER-2 + MBC.
- Treated with 10 cycles of paclitaxel and trastuzumab then developed increase RUQ pain and CT demonstrated new liver metastasis.

**Questions:**
- Would you continue trastuzumab and change the chemotherapy?
- For this patient, when would you discuss the study trial?
Accrual Workshop impact

85% Cumulative Accrual Increase

6 AWs in multi-center phase III trial
- Dallas, TX – 15 sites
- Boston, MA – 15 sites
- Philadelphia, PA – 11 sites
- Los Angeles, CA – 21 sites
- Chicago, IL – 6 sites
- New York, NY – 13 sites

Average of 20 pts accrued after each workshop vs. 12 pts before workshop

120 day accrual pre-AW vs. post-AW
## Overall interaction summary

### Site Interactions

<table>
<thead>
<tr>
<th>Interaction Type</th>
<th>Total # of Interactions</th>
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</thead>
<tbody>
<tr>
<td>TOTAL # OF INTERACTIONS</td>
<td>970</td>
</tr>
<tr>
<td>Site Engagement</td>
<td></td>
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<tr>
<td>MD Interactions</td>
<td>226</td>
</tr>
<tr>
<td>CTS Interactions</td>
<td>642</td>
</tr>
<tr>
<td>Site Visits</td>
<td>3</td>
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</table>

### Accrual Enhancement

<table>
<thead>
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<th>Interaction Type</th>
<th>Total # of Interactions</th>
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</thead>
<tbody>
<tr>
<td>MD Interactions</td>
<td>34</td>
</tr>
<tr>
<td>CTS Interactions</td>
<td>51</td>
</tr>
<tr>
<td>Accrual Visits</td>
<td>3</td>
</tr>
<tr>
<td>Accrual Workshop Attendees</td>
<td>11</td>
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### 2 Investigator Meetings
- San Diego, CA
- Miami, FL

### ASH Orlando Accrual Workshop
- 9 MDs, 2 research staff

### 462 MD and CTS Phone Interactions

### 6 Accrual Visits

### DAVA Site Visits

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**THE AMERICAN SOCIETY OF HEMATOLOGY**
**52ND ANNUAL MEETING**
**DECEMBER 2010**
Overall impact of physician education & engagement

Source: DAVA Oncology. Impact of direct physician-to-physician contact on accelerating oncology clinical trial accrual in multiple tumor types. Poster presentation at ASCO 2011
Trial specific impact of physician education & engagement

**DAVA Supported Sites**

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<tr>
<th></th>
<th>Period 1</th>
<th>Period 2</th>
<th>Change</th>
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<tbody>
<tr>
<td>Enrollment (Pt/S/Mo)</td>
<td>0.118</td>
<td>0.203</td>
<td>+72%</td>
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**Other Sites**

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<th></th>
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<th>Period 2</th>
<th>Change</th>
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</thead>
<tbody>
<tr>
<td>Enrollment (Pt/S/Mo)</td>
<td>0.296</td>
<td>0.204</td>
<td>-31%</td>
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Thank you for your participation!

If you have any questions, please contact me!

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