Circle 5: Innovations in Dermatology and Clinical Trials

PRESENTED BY:
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New drugs, devices, cosmeceuticals

- Help companies disseminate their findings
  - Access in residency and shortly thereafter
  - Booklets about products, online or paper

- Teach our members to work with companies in discovery and refinement
  - Developing cosmeceuticals
  - Working in translational research
  - Clinical trials

- Keep members aware of changing regulatory environment for products and drugs (HHS, FDA, USP)
  - Work with industry on advocacy issues of common interest
  - Minimize regulation of drugs, devices, access
New diagnostics

- Telemedicine/ teletriage

- Dermatoscopy

- Molecular tests for melanoma and other tumors

- WDS can be at forefront of co-development and dissemination
Change in delivery of care and outreach to large practice groups

- In future, most derms will be employed by academic centers or large groups, and without these steps, WDS membership may stall
  - Poses threats and opportunities for WDS and pharma in terms of access to/education of derms
  - **Cost saving mechanisms** in such practices may reduce WDS membership, result in more aggressive negotiations with pharma regarding purchases

- Outreach to large derm practices to encourage membership on and affiliation with WDS
  - Cooperative programs with industry partners
  - Local chapters at very large practices
  - Offer WDS benefits to these entities that are most aligned with their needs (training, mentorship, etc)
Clinical Trials: Find the Right Venue

- Industry is best served by clinical trials sites that are:
  - (1) Speedy in IRB approval
  - (2) Able to accrue rapidly
  - (3) Cost-effective
  - (4) Provide clean and complete data, with few dropouts

- The right place can be in academics or private practice
  - Industry should try to avoid preference for either type and judge sites on merits
  - WDS can provide brochure or listing of investigators, which reports their capacities in a standard way
  - WDS can help train new investigators-involvement for younger physicians and access fort pharma
Clinical Trials: Find the Right Venue

- The best new academic centers have evolved
  - (1) IRB approval in 1 month for funded trials
  - (2) Rapid accrual: special accrual department, very large population (>200,000 patients per year), affiliated regional practices
  - (3) Cost containment: local PI can adjust budget to fit pharma needs
  - (4) Outstanding data acquisition by all MD-level research assistants

- Private practice offers additional opportunities
Clinical Trials

- Only 1 in 5 drugs tested in clinical trials eventuate in drug approval
- The Goal: to demonstrate safety and efficacy of a drug, cosmeceutical or device
- Trials in dermatology, endocrinology, gastroenterology, lowest overall cost
Registered Studies

Locations of Registered Studies
The chart below shows the distribution of locations for all studies registered on ClinicalTrials.gov.

Percentage of Registered Studies by Location (as of May 30, 2016)
Total N = 216,466 studies

<table>
<thead>
<tr>
<th>Location</th>
<th>Number of Registered Studies and Percentage of Total (as of May 30, 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-U.S. only</td>
<td>99,686 (46%)</td>
</tr>
<tr>
<td>U.S. only</td>
<td>80,934 (37%)</td>
</tr>
<tr>
<td>Not provided</td>
<td>23,422 (11%)</td>
</tr>
<tr>
<td>Both U.S. and non-U.S.</td>
<td>12,426 (6%)</td>
</tr>
<tr>
<td>Total</td>
<td>216,466</td>
</tr>
</tbody>
</table>

Registered Studies

Number of Registered Studies Over Time

The graph and table below show the total number of studies registered on ClinicalTrials.gov since 2000, based on the First Received date. The first version of ClinicalTrials.gov was made available to the public on February 29, 2000.

Trends in Original Research in Acne Vulgaris, Rosacea, Dermatitis, Psoriasis, Skin Cancer and Skin Infections

1970 – 2010

Trends in Subject Matter

Skin Cancer: 36.5%
Psoriasis: 23.7%
Skin Infections: 18.2%
Dermatitis: 15%
Acne Rosacea: 6.6%

Choi, Y. WJJ: Perm J 2015 Winter 19(1) 44-47
Frequency of Research into common dermatologic topics in the *Journal of the American Academy of Dermatology* and *Archives of Dermatology* over time.

Choi, Y. WJJ: Perm J 2015 Winter 19(1) 44-47
Trial Costs

Registered Trials

Clinical Trials: The Advantages

- New Revenue Stream
- Scientific Endeavor
- Changing the Therapeutic Landscape
Clinical Trials: The Challenges

- Time Commitment
- Space Commitment
- Staff Commitment
  - CRC
- “Feast or Famine”
  - Recruitment
- Adequate Budgets
Barriers to Clinical Trials

High Financial Costs

Decrease in Clinical Trails Workforce

Recruitment and Retention of research participants

Regulatory and administrative barriers

Lengthy time lines (7.5 years)

Barriers at Academic Institutions:

Academic Centers- 110 ; Non-Academic- 60
Clinical Trials in Dermatology

Beyond Academic Centers

Private Practices

Research Centers
Dermatologic Clinical Trials

Aesthetic

Medical
Clinical Trials and The WDS

Women’s Issues
Advisory Council for Protocol Design
WDS Clinical Trials Network
Mentoring Program
Social Media
Recruitment