

# Circle 5: Innovations in Dermatology and Clinical Trials

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PRESENTED BY:

MURAD ALAM, MD & PEARL E. GRIMES, MD



# New drugs, devices, cosmeceuticals

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- **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

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- 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

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- 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

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- 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

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- 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

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- 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



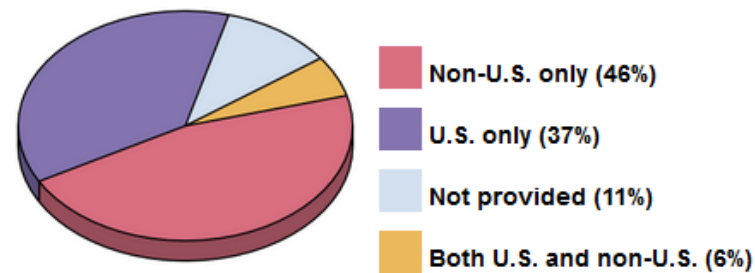
# Registered Studies

## 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 = 216,468 studies



Location	Number of Registered Studies and Percentage of Total (as of May 30, 2016)
Non-U.S. only	99,686 (46%)
U.S. only	80,934 (37%)
Not provided	23,422 (11%)
Both U.S. and non-U.S.	12,426 (6%)
Total	216,468

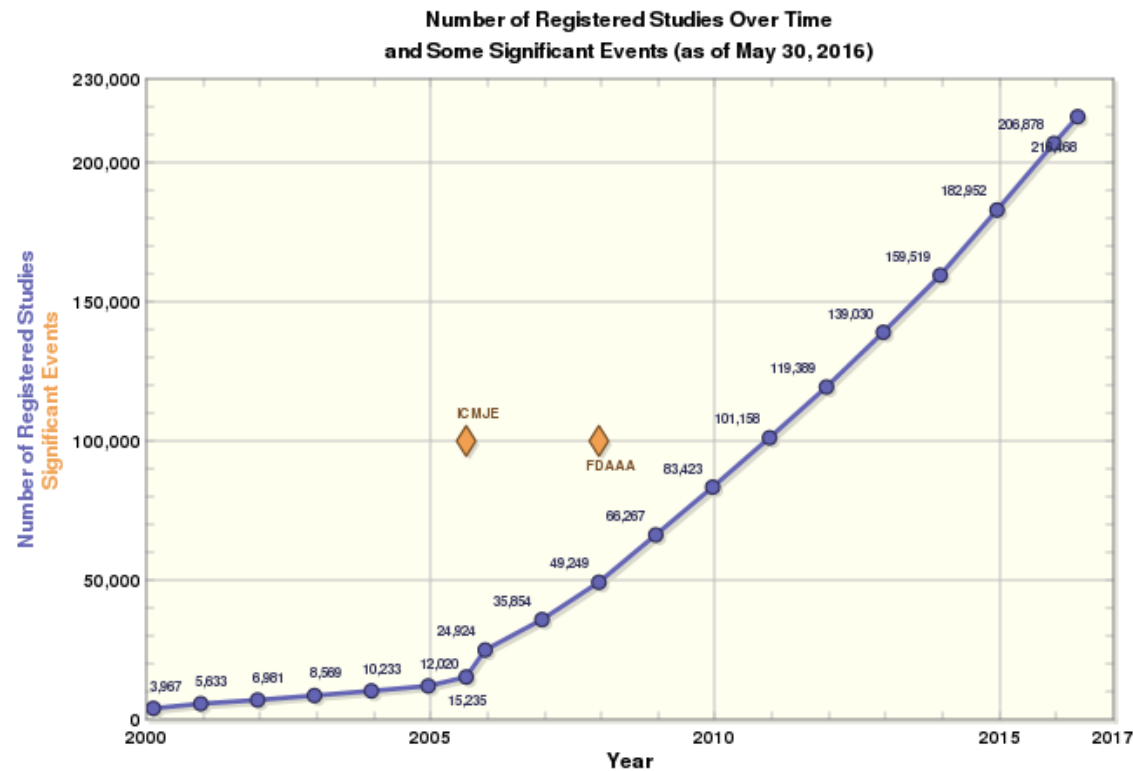




# Registered Studies

## 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

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1970 – 2010

## Trends in Subject Matter

Skin Cancer: 36.5%

Psoriasis: 23.7%

Skin Infections: 18.2%

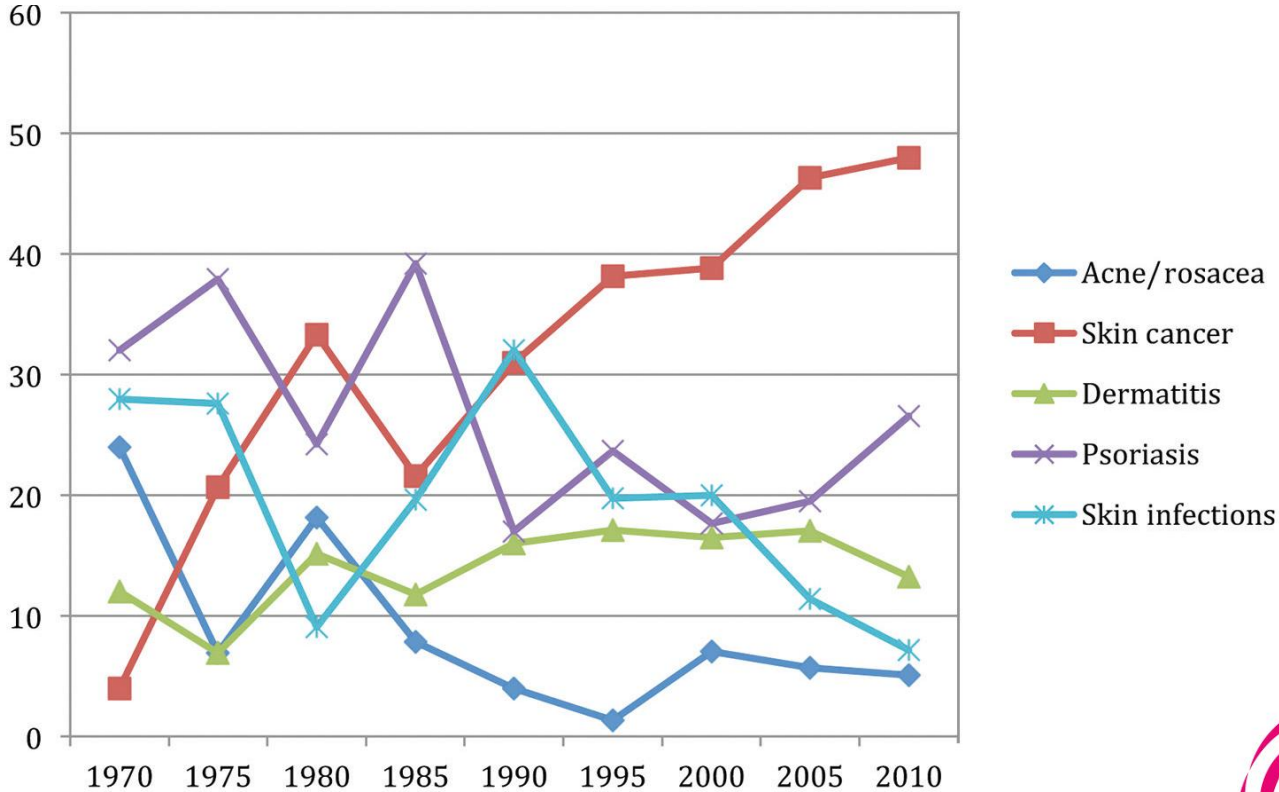
Dermatitis: 15%

Acne Rosacea: 6.6%

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



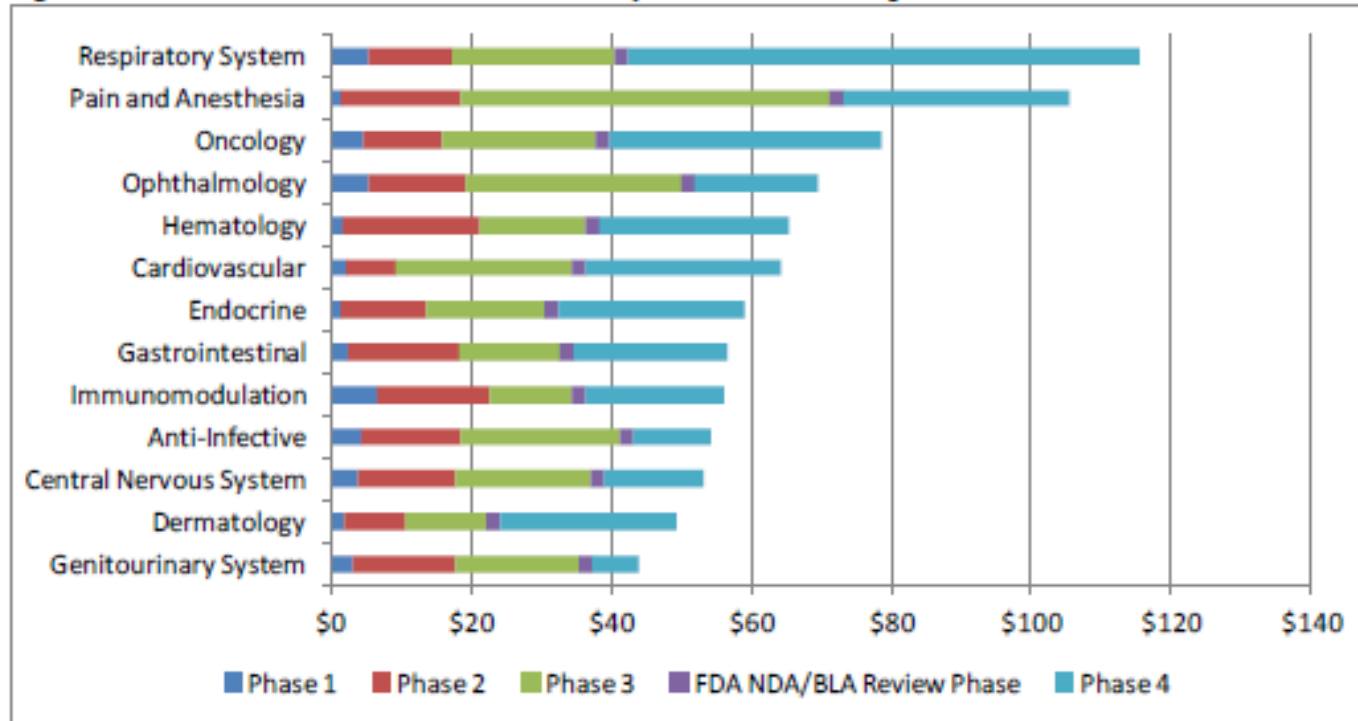
# Frequency of Research



Frequency of research into common dermatologic topics in the *Journal of the American Academy of Dermatology* and *Archives of Dermatology* over time.

# Trial Costs

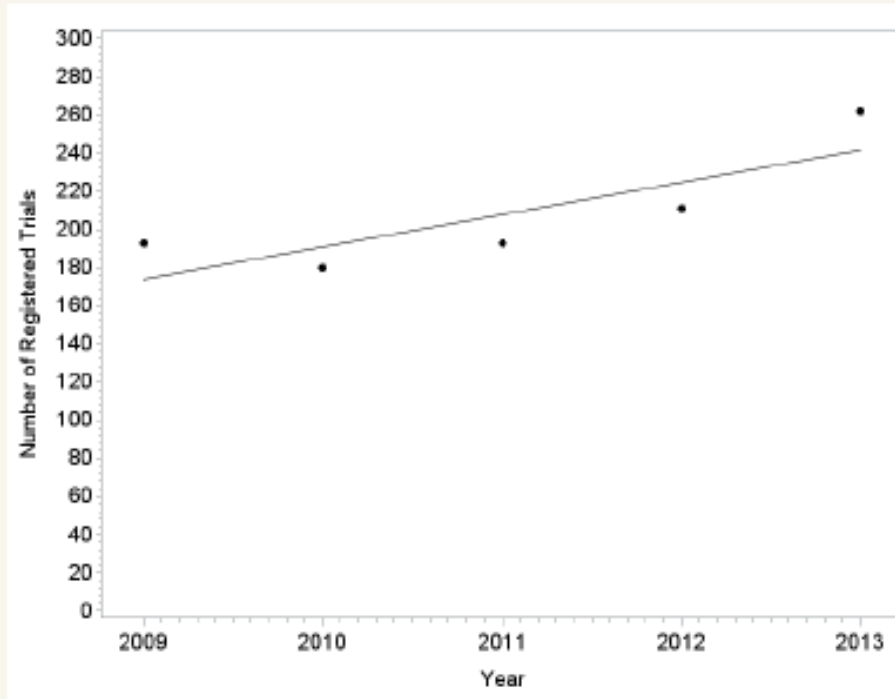
Figure 3: Clinical Trial Costs (in \$ Millions) by Phase and Therapeutic Area



Sertkaya A, Birkenbach A, Berlind A. Examination of Clinical Trial Costs and Barriers for Drug Development. Easter Research Group Inc., July. 2014 Jul 25;25.

# Registered Trials

**FIGURE 1.** Number of dermatologic clinical trials registered annually on ClinicalTrials.gov (2009-2013).



Patel SS, Huang KE, Fleischer AB, Feldman SR. Five-Year Trend in the Number of Dermatologic Clinical Drug Trials Registered on ClinicalTrials.gov. *Journal of drugs in dermatology: JDD.* 2015 May;14(5):497-500.

# Clinical Trials: The Advantages

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- New Revenue Stream
- Scientific Endeavor
- Changing the Therapeutic Landscape



# Clinical Trials: The Challenges

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- Time Commitment
- Space Commitment
- Staff Commitment
  - CRC
- “Feast or Famine”
  - Recruitment
- Adequate Budgets



# Barriers to Clinical Trials

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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

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Beyond Academic Centers



Private Practices

Research Centers

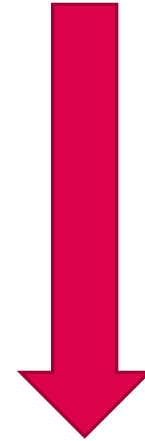


# Dermatologic Clinical Trials

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**Aesthetic**



**Medical**



# Clinical Trials and The WDS

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Women's Issues

Advisory Council for Protocol Design

WDS Clinical Trials Network

Mentoring Program

Social Media

Recruitment

