DIA Statistics SIAC
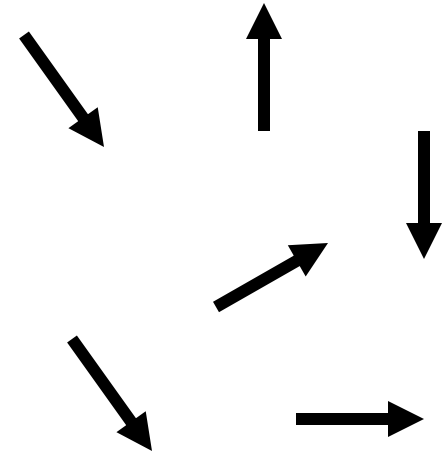## Collaboration Opportunities

Jerald S Schindler

Merck Research Laboratories

Chair, North American Statistics SIAC

Overview

- Collaboration process
- Collaboration opportunities
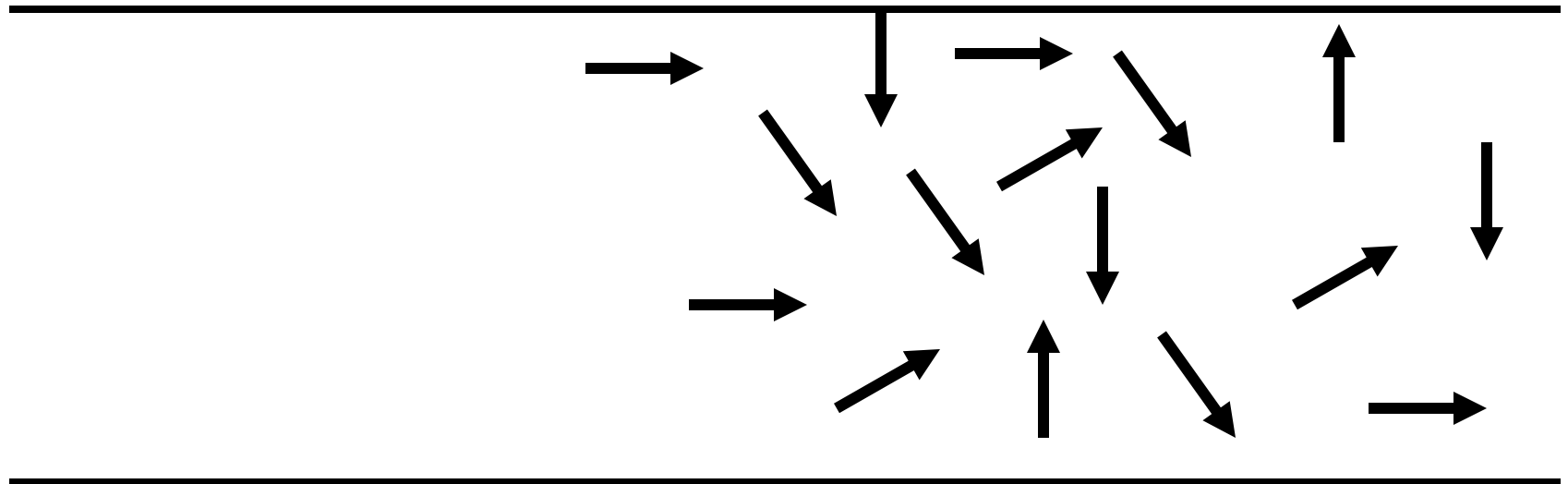- DIA SIACs
- DIA Statistics SIAC
- How to get involved

Adoption of New Methods

Innovators begin to publish and present new ideas

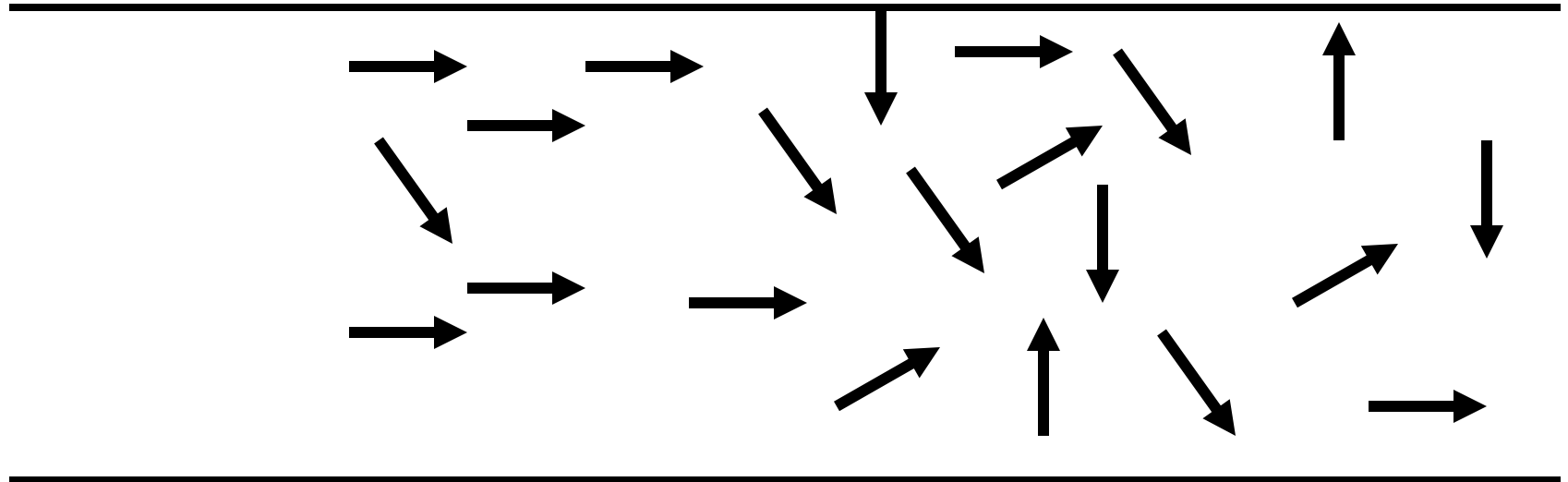**Lack of harmonization of ideas**

Adoption of New Methods

Early adopters begin to explore the use of these new methods

Most groups work independently

Lack of collaboration and harmonization of ideas
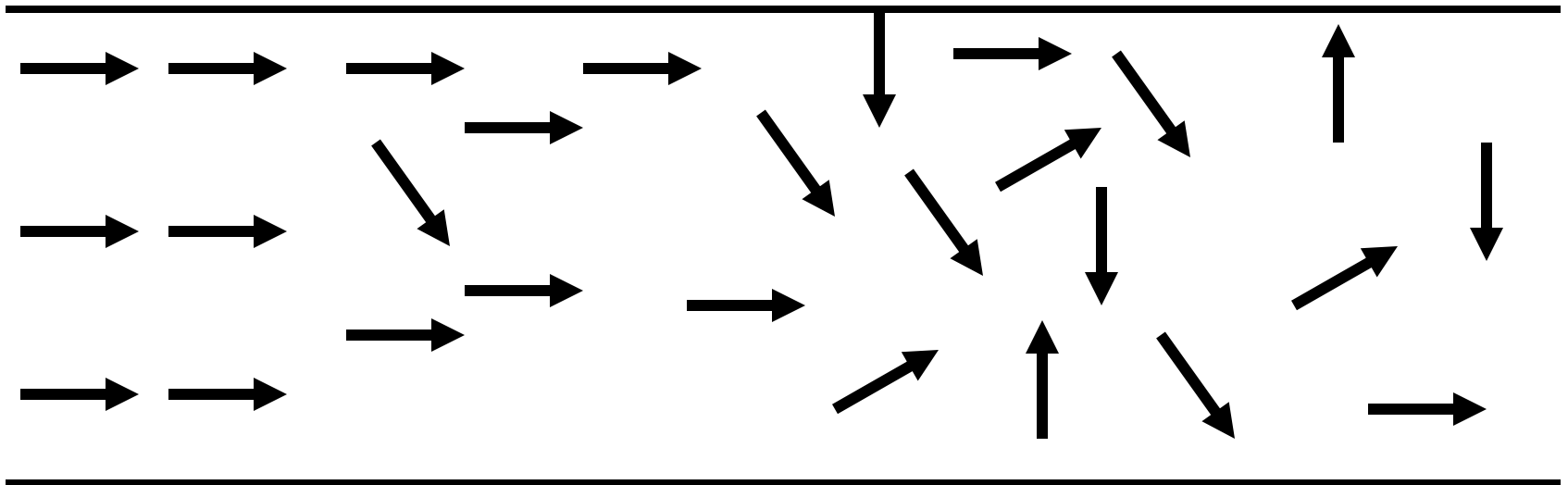
Adoption of New Methods

Later adopters begin to learn from the experiences of others

Eventually papers and presentations are given describing these experiences
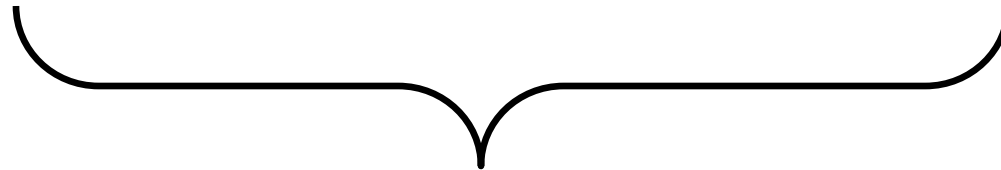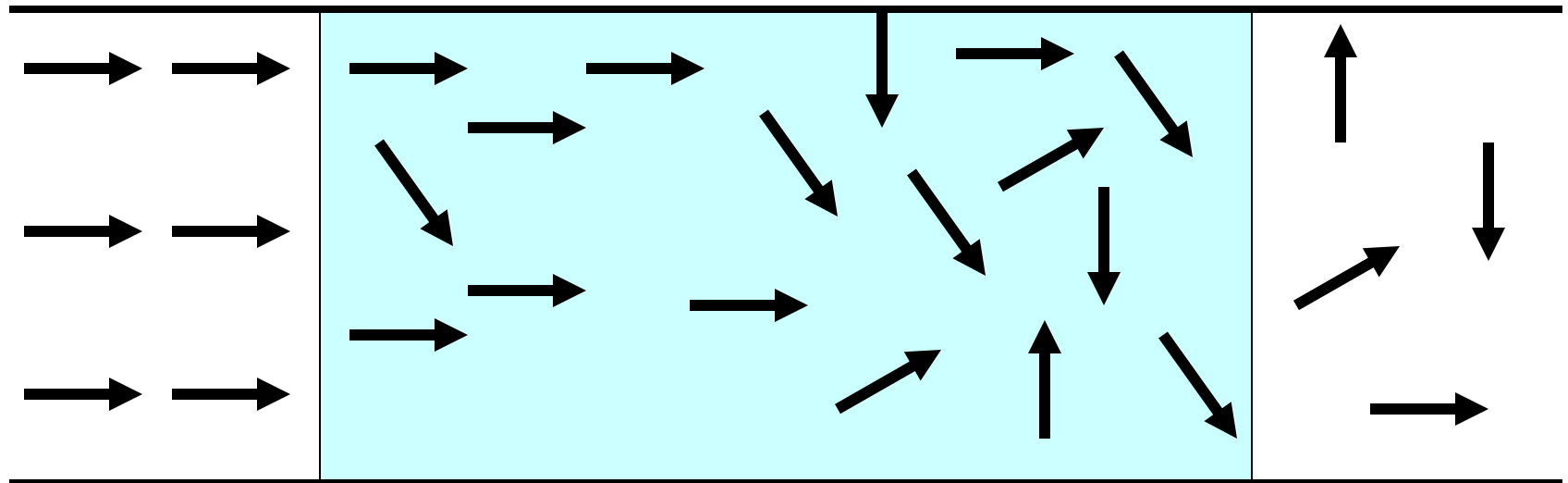
Regulatory Guidance becomes available

Adoption of New Methods

Eventually practice becomes harmonized

Adoption of New Methods

**Opportunity for proactive collaboration
Industry, Academia, regulatory agencies can work
together to establish best practices**

Collaboration

- Proactive collaboration on issues in drug development

- Work together to establish the scientific solutions for these issues

- Not related to any individual regulatory submission

- The best time to provide feedback on regulatory guidance documents is before they are written.

- The best time to provide feedback on standard industry practices is before they are established.

- How can we accomplish this?

DIA Statistics SIAC
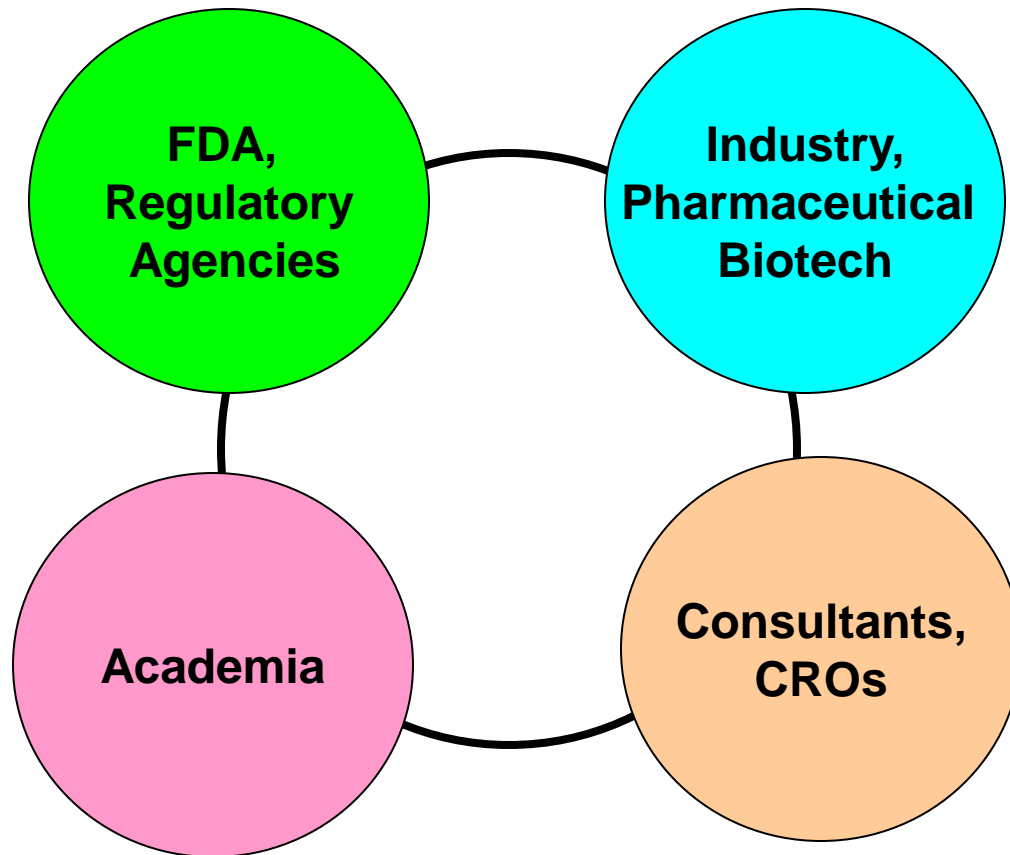## Collaboration Opportunities

DIA SIACS

Special Interest Area Communities (SIACs)-

Each SIAC provides a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field.
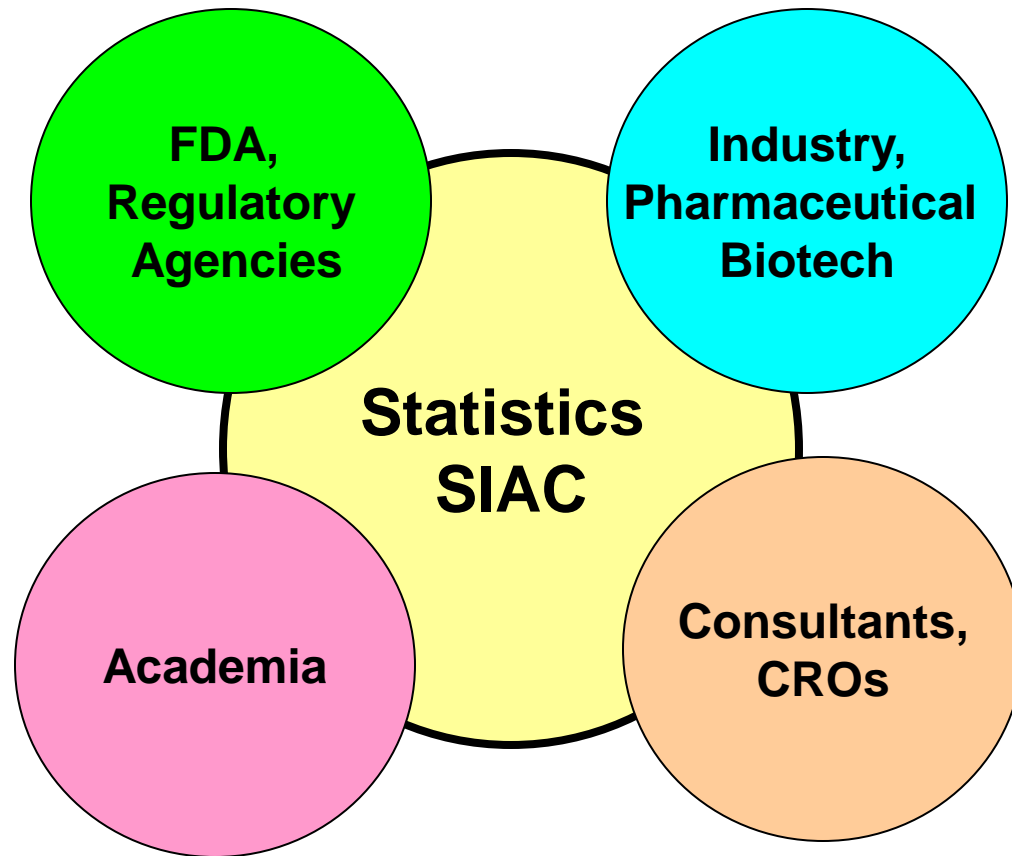
SIAC Role in DIA

SIACs provide a forum for volunteers to network and exchange information. SIACs also assist DIA in identifying professional development needs in particular interest areas and in providing information to members in career and professional development, to meet those needs.

Statistics SIAC Membership

Statistics SIAC Membership

DIA Statistics SIAC

- **Mission:** Establish an interactive collaborative community of DIA members who are interested in statistical issues in the pharmaceutical industry

- **Activities:** Determined by the Statistics SIAC members

- **Cost: Free** for DIA members

- **To join:** SIAC@diahome.org

Statistics SIAC Opportunities

- Best Practices Committees (planned)
  - Groups of statisticians meet to discuss special statistical topics
    - Possible topics:
      - Missing data
      - Multiplicity
      - Meta Analyses
      - Graphics
      - Bayesian methods
      - Open source software

Statistics SIAC Opportunities

- Worked Examples (planned)
  - Groups of statisticians meet to plan and compile a collection of interesting examples including:
    - The problem to be illustrated
    - Example data
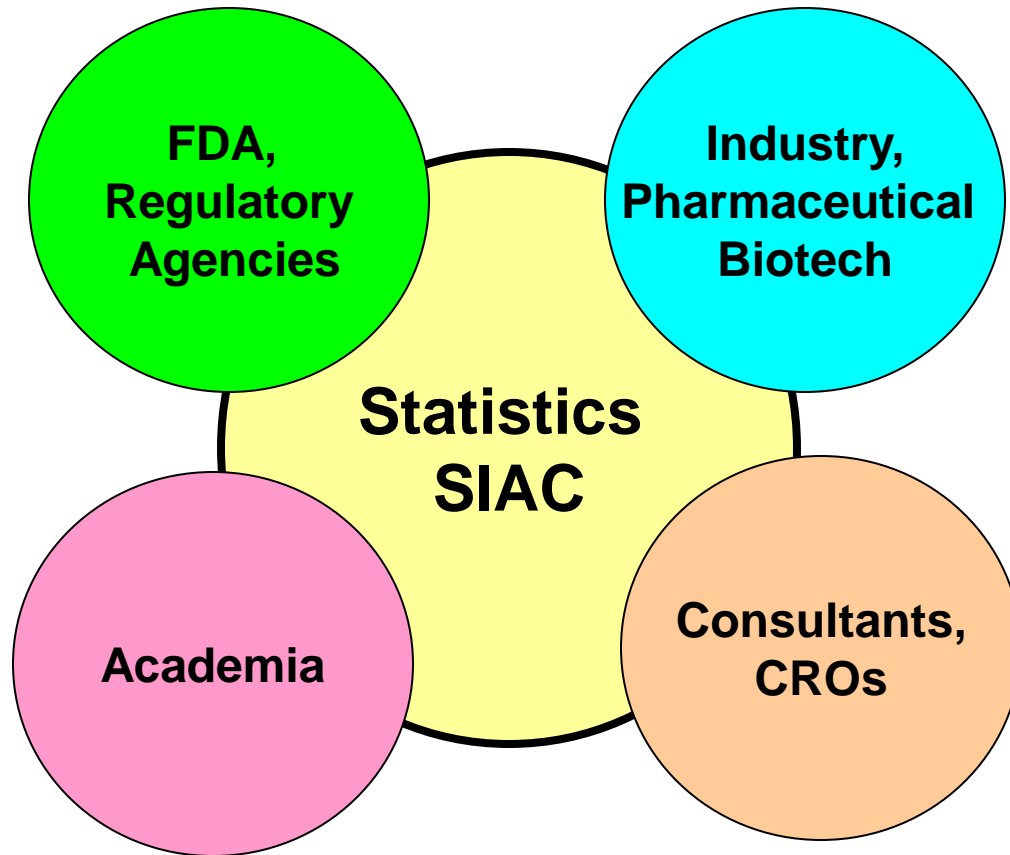   - The analysis
    - Display of results

Statistics SIAC Opportunities

- Training/tutorials (planned)
  - Groups of statisticians meet to plan and compile a collection of courses on special topics in statistics
    - Use the output of the Best Practices committees and the worked examples to create training courses and tutorials to expand knowledge
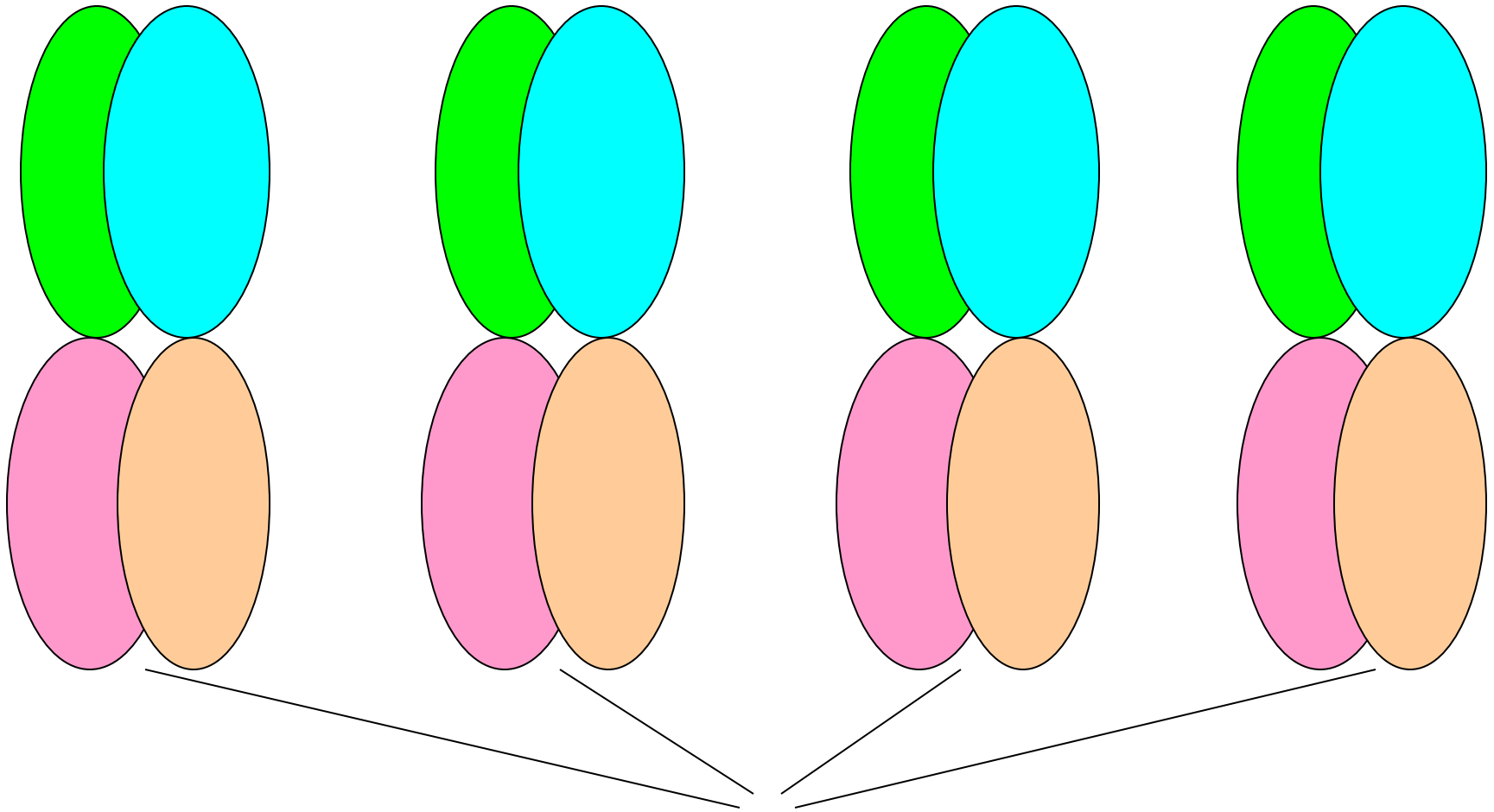
SIAC Committees

- Focus is on the science
- Committees have regular teleconferences
- Annual face to face meeting
- Share documents
- Create articles, white papers, software to be shared
- Provide ideas and topics for future DIA meetings

Collaboration within the Statistics SIAC

Collaboration among SIACs

Cross SIAC Collaboration

- Create similar committees combining members of multiple SIACs
    - Best Practices
    - Worked Examples
    - Training

- Opportunity for some of the PhRMA PISC committees to continue as new DIA committees
    - Adaptive Trials Working Group

Virtual Journal Club

- Presentations of selected journal articles by the authors

- By teleconference

- For Statistics SIAC members

- Free

The Statistics Special Interest Area Community (SIAC) of DIA welcomes DIA members to our 2nd in a series of "Virtual Journal Club" teleconferences for the year 2010.

Good Practices for Adaptive Clinical Trials in Pharmaceutical Product Development

By:
Brenda Gaydos, PhD (Eli Lilly)
and
Keaven Anderson, PhD (Merck)
Drug Information Journal 2009; 43:539-556.

Monday, May 24, 10:30-12:00 Eastern Time

The presentation will be followed by a discussion
by **Dr. Sue-Jane Wang (FDA)**

We need you

- All of these activities are driven by "volunteers"

- Time and energy of interested individuals

- Join the Statistics SIAC
    - SIAC@diahome.org

- If you are interested in working on any committee – chairing, participating, or being on the mailing list
    - Jerald_Schindler@merck.com