



# Leading by Example How to Build a Stronger Community

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# Disclosure

The presenters for today's session have no relevant financial relationships with respect to this educational activity.

Rachel Gartner is the Regulatory Affairs Specialist for Frestedt Inc.

Dr. Joy Frestedt is the Founder, President and CEO of Frestedt, Inc.

# Share Fair Learning Objectives

*Upon completion of this educational activity, you will be able to:*

- ▶ Describe aspects of clinical research practice that exemplify a broad range of contemporary concerns presented at The Share Fair
- ▶ Review differing approaches to the clinical research collaborative process, from the viewpoints of Sponsors and of clinical facilities
- ▶ Determine whether a technique applied by colleagues to a specific clinical research issue pertains to your research process

# Leading by Example

## Learning Objectives

Upon completion of this presentation participants should be able to:

- ▶ Describe the local Clinical Research community
- ▶ Identify your role in the community and how to connect with others in a meaningful way
- ▶ Strengthen your contributions in the local community by increasing your ACRP participation

# Biographies

**Joy L. Frestedt, PhD, CCTI, RAC, FRAPS** founded Frestedt Incorporated ([www.frestedt.com](http://www.frestedt.com)) in 2008 and Alimentix, the Minnesota Diet Research Center ([www.alimentix.com](http://www.alimentix.com)) in 2012. Dr. Frestedt has managed clinical, regulatory, and quality affairs for over 30 years in companies like Johnson and Johnson, Medtronic, Mayo Clinical Trial Services, AstraZeneca and Orphan Medical. Dr. Frestedt is among the “100 Most Inspiring People in the Life Sciences Industry” (PharmaVOICE, 2011) and the top 25 “Industry Leaders” (Minneapolis/St. Paul Business Journal, 2011). Dr. Frestedt initiated the concept and she reviewed, edited and submitted the article for publication. She can be reached at [jf@frestedt.com](mailto:jf@frestedt.com).



**Rachel Gartner, JD** received her Bachelor’s degree in Chemistry from the University of Minnesota –Morris and her Juris Doctor from the University of Minnesota Law School before coming to Frestedt, Inc. She now serves as a Regulatory Affairs Specialist at Frestedt, Inc. working on a variety of Clinical, Regulatory and Quality projects.

# Summary of Presentation

The Minnesota Clinical Research Community is composed of several types of entities including: pharmaceutical, medical device, consulting firms, research sites and independent contractors. Every clinical research professional should be able to identify ways to connect with others in the profession to share ideas, tips and opportunities to grow and develop. In addition, recognizing the differences in the types of companies, sites and contractors involved in clinical research in Minnesota will allow individuals to connect to the right people in order to work on right projects while building a stronger community.

# Clinical Research Community

Minneapolis/St. Paul has a variety of community members

## Larger Companies

- ▶ Medical Device
  - ▶ Medtronic, Boston Scientific, St. Jude, Covidien, Ecolab and dozens of others
- ▶ Pharmaceutical
  - ▶ Upsher Smith, Bayer, and a few others
- ▶ Consulting firms
  - ▶ RCRI, NAMSA, MedPace
- ▶ Research Sites
  - ▶ Univ of Minnesota, VAMC, many hospitals, Mayo Clinic

## Smaller Companies

- ▶ Medical Devices
  - ▶ HLT, Nonim, AtrCure and hundreds of others
- ▶ Pharmaceutical
  - ▶ Cima Labs, Paddock Labs, Biothera
- ▶ Consulting Firms
  - ▶ Frestedt Inc.
- ▶ Research Sites
  - ▶ Alimentix, PRISM, MARC
- ▶ Pre-Clinical
  - ▶ WuXi, APS
- ▶ Independent contractors

**What are some other companies?  
Talk to us about them.**

# Entity Roles

- ▶ Medical Device
  - ▶ Device research, development and production
- ▶ Pharmaceutical
  - ▶ Drug research, development and production
- ▶ Research Sites
  - ▶ Conduct trials and research for Pharmaceutical and Medical Device entities
- ▶ Consulting Firms
  - ▶ Project based work by an organization for other community entities
- ▶ Independent contractors
  - ▶ Project based work by an individual for other community entities

**Tell us about your role and what you and these other entities bring to our community.**



# Who works at those Entities?

- ▶ Medical Device
  - ▶ Engineers, researchers, regulatory, quality, production
- ▶ Pharmaceutical
  - ▶ Chemists, researchers, regulatory, quality, production,
- ▶ Research Sites
  - ▶ Investigators, coordinators, medical professionals, researchers
- ▶ Consulting Firms
  - ▶ Researchers, regulatory

What other roles have you encountered?

# Connection Activities

- ▶ Present a webinar
- ▶ Present at a conference
- ▶ Write for publications
  - ▶ Clinical Researcher
- ▶ Host events
  - ▶ Talks, mixers, lunches
- ▶ Get involved in professional organizations
- ▶ Mentoring

What is the best way to connect with your colleagues?

# Clinical Research Connections

- ▶ Association of Clinical Research Professional (ACRP)
  - ▶ ShareFair Host and professional certification organization for clinical researchers
- ▶ Life Science Alley
  - ▶ Minnesota based organization made of members of the life science business community
- ▶ American Medical Women's Association (AMWA)
  - ▶ Membership organization of health care professionals dedicated to the advancement of women in medicine and improving women's health.
- ▶ The Society of Clinical Research Associates (SOCRA)
  - ▶ Non-profit membership organization for all persons involved in clinical research activities, in industry, government and academia.
- ▶ Drug Information Association (DIA)
  - ▶ Professional global organization for those working in pharmaceutical and medical product development fields.
- ▶ Regulatory Affairs Professional Society (RAPS)
  - ▶ Non-profit professional organization involved in regulation of healthcare, medical devices, pharmaceuticals, biologics and nutritional products
- ▶ Graduate Women in Science, Sigma Delta Epsilon (GWIS)
  - ▶ Interdisciplinary society of scientists to support women in the field.
- ▶ Minnesota Clinical Research Alliance (MCRA)
  - ▶ Organization to support clinical research and clinical research education of industry, academia, media and government in Minnesota

**What group do you find most useful?**

**Does project work outside of your employment help to build connections?**



# Thank You for Connecting!

## **Contact Information**

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