

# How to be a Drug Developer with statistical expertise

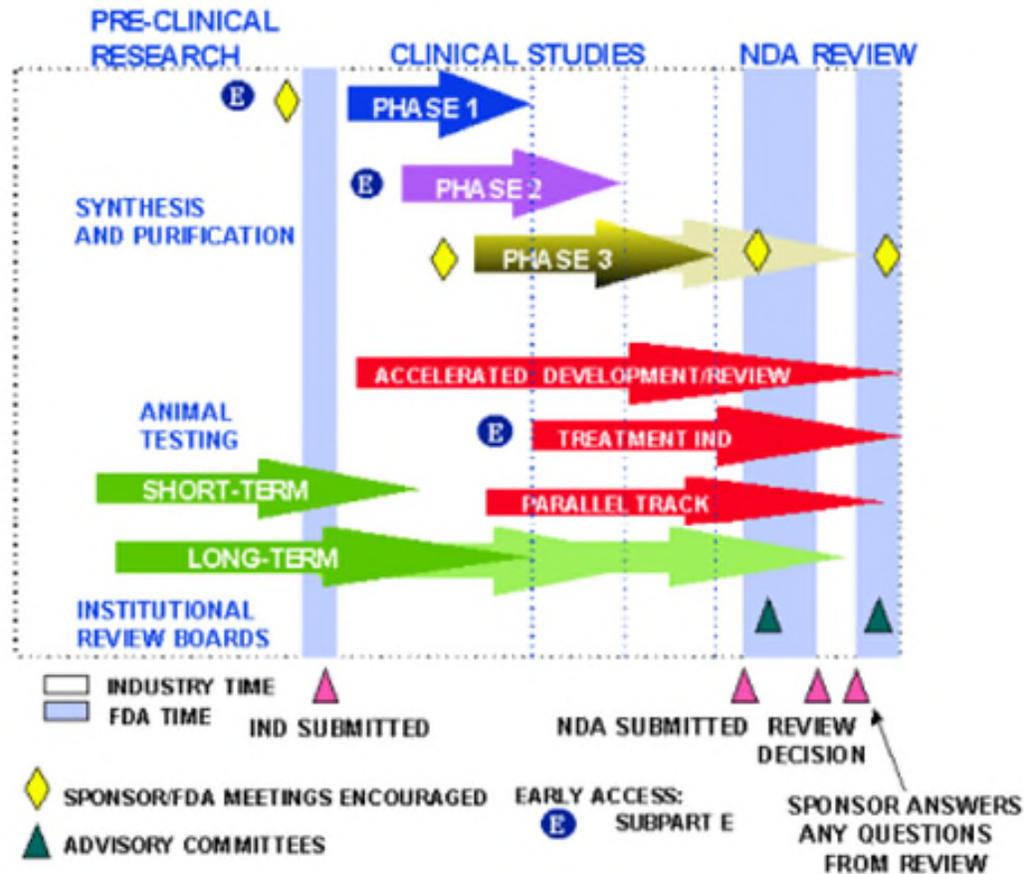
Joint NIC-ASA / ICSA Conference Oct. 6, 2022

Jamie Myles Ph.D.

# Disclaimer

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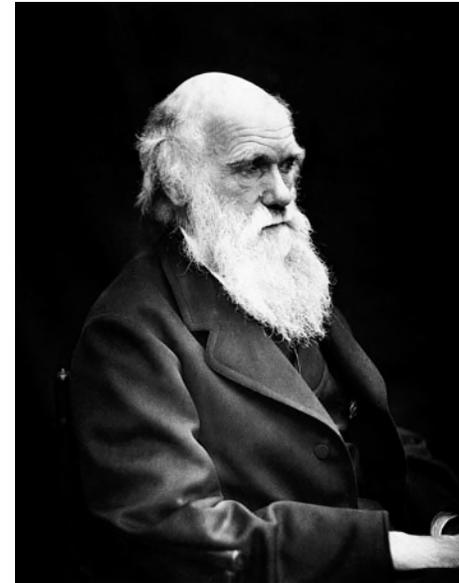
# What is Drug Development?



# Natural Selection for becoming a Biostatistician

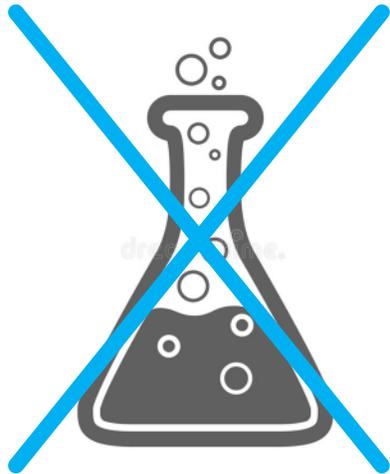
What made you become a biostatistician?

1. Math Nerd
2. Analytical
3. Computer Skills
4. Ability to see patterns in data
5. Curiosity about more than just mathematics
6. Comfortable with uncertainty
7. Desire to be able to apply your skills and knowledge to medical problems
8. Want to make a difference
9. Wanted to get a good job?



# What do you need to be able to succeed?

Think of yourself as a drug developer who brings statistical / analytical skills to the table!



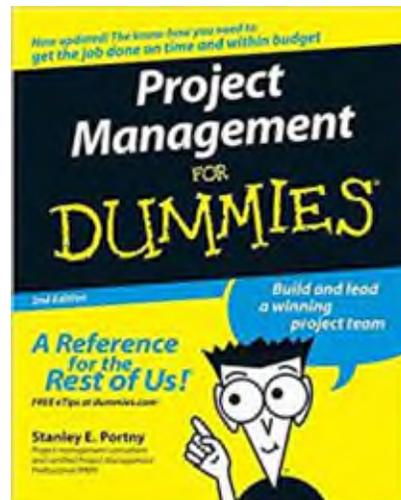
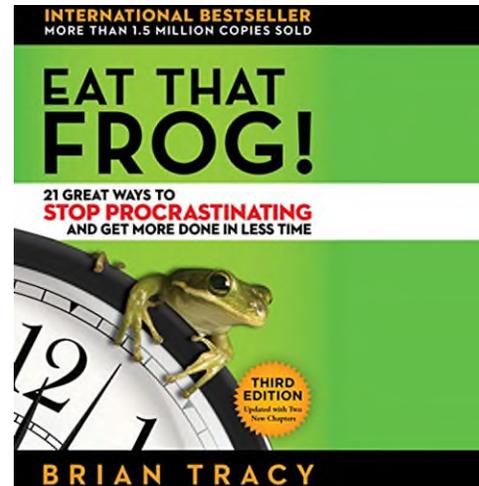
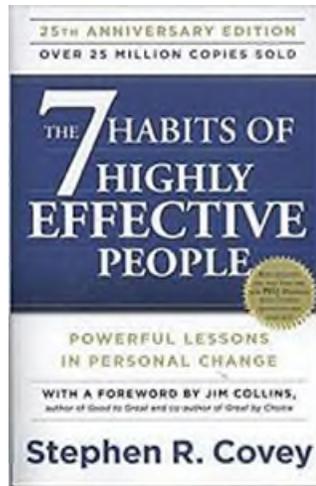
# What do you need?

In addition to the skills you need to be a statistician, you need a combination of people skills and general knowledge

1. Time / project Management
2. Self awareness / Confidence
3. Maintain your technical skills
4. Industry knowledge
5. Teamwork & Collaboration
6. Think on your feet
7. Communication
  1. Written
  2. Oral
  3. Presentation Skills
  4. Able to communicate statistical concepts to non-statisticians
8. Ethics
9. Curiosity \*
10. Influence \*

\* - Dealt with in our other sessions

# Time / Project Management



CAREERS

### Project Management Isn't Just For Project Managers: 4 Skills You Need To Know

Dana Brownlee, Senior Contributor @  
*I help professionals navigate workplace challenges*

Jul 14, 2019, 04:00pm EDT

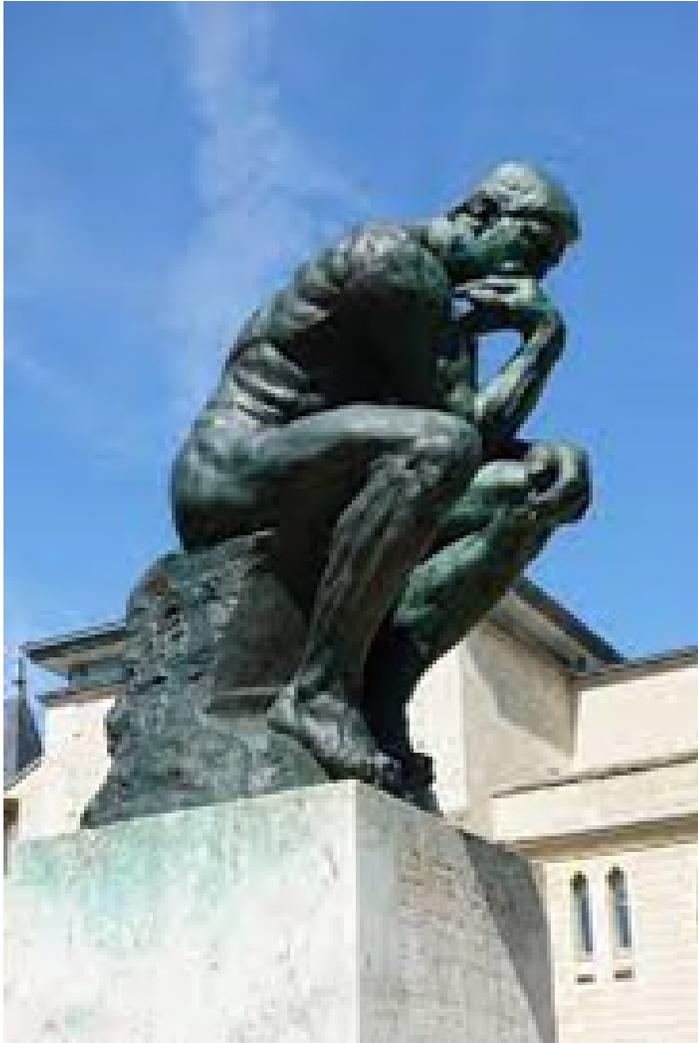
Listen to article 9 minutes

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Project management training. [u271](#)

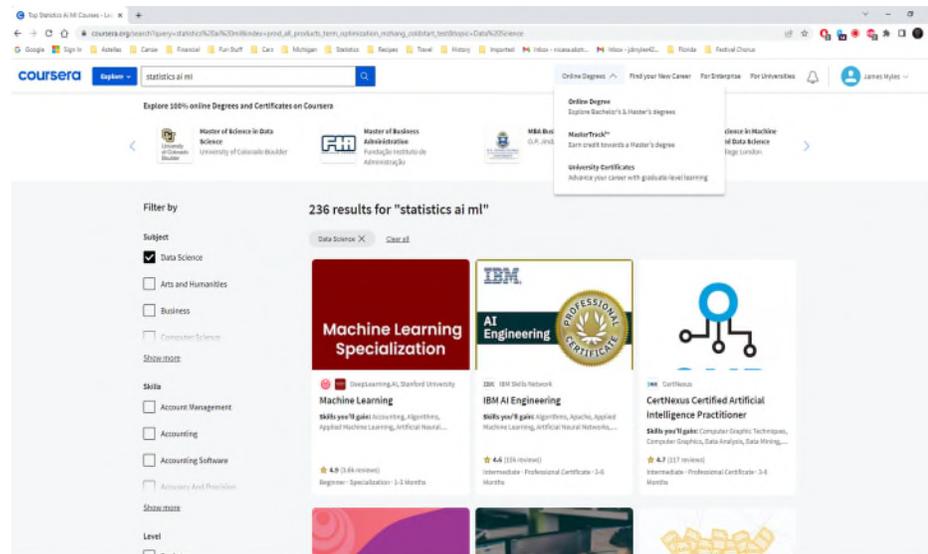
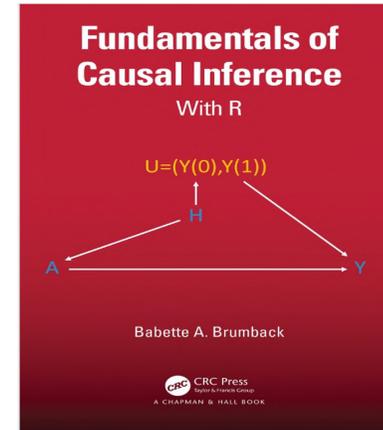
Believe it or not, over the years I've gotten more requests to provide Project Management training to non project managers than project managers. That may seem counter intuitive but not really. Organizations realize the benefits of those project management skills and abilities and...

# Self awareness / Confidence



Know who you are  
and where you  
are going

# Maintain your technical skills



# Industry knowledge



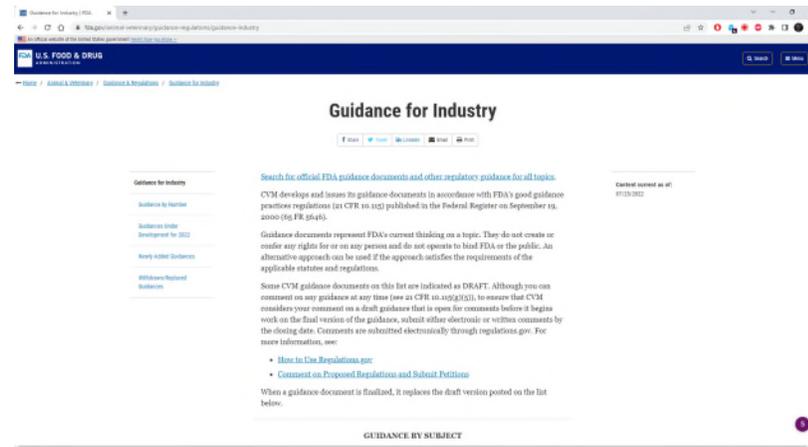
INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

## ICH HARMONISED TRIPARTITE GUIDELINE

### STATISTICAL PRINCIPLES FOR CLINICAL TRIALS E9

Current *Step 4* version  
dated 5 February 1998

*This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.*



# Teamwork & Collaboration

"Teamwork is the ability to work together toward a common vision. The ability to direct individual accomplishments toward organizational objectives. It is the fuel that allows common people to attain uncommon results." – Andrew Carnegie

"It is the long history of humankind (and animal kind, too) that those who learned to collaborate and improvise most effectively have prevailed." – Charles Darwin

# Think on your feet

The screenshot shows the homepage of the 'Think on Your Feet' website. The header is red with the company logo and tagline 'CLARITY | BREVITY | IMPACT®'. A navigation menu includes 'About', 'Services', 'Global Network', 'Success Stories', 'Media Room', 'Contact Us', and 'Other Products'. A phone number '1-800-862-2429' is displayed in the top right. The main content area features a 'THINK ON YOUR FEET® VIRTUAL-LIVE' banner with a 'Learn More' button. Below this, a text block states: 'Think On Your Feet® is the only workshop that trains you to analyze, organize and present your ideas... FAST!'. At the bottom, three boxes represent 'TRAINING FOR INDIVIDUALS', 'TRAINING FOR GROUPS', and 'TRAINING FOR COMPANIES'. A 'GLOBAL PUBLIC WORKSHOPS' section on the right lists events with dates and locations, including 'Virtual, (BST Zoom)', 'Milan, Italy', 'Penang, Malaysia', 'London', 'Manchester, UK', and 'Virtual, ET'.

The screenshot shows a TED talk video player for Susan Cain's talk 'The power of introverts'. The video player shows a woman speaking on stage. Below the video, the title 'The power of introverts' is displayed, along with the speaker's name 'Susan Cain' and the TED2012 conference information. The video has 31,749,020 views and 952K likes. A 'Read transcript' button is visible. To the right of the video player, there is a 'Become a TED Member' section and a 'Watch next' section with several video thumbnails, including 'The hidden power of sad songs and rainy days', 'The power of vulnerability', 'Embracing otherness, embracing myself', and 'Who are you, really? The puzzle of personality'.

# Communication

- ▶ Written
  - ▶ Email
  - ▶ Reports
  - ▶ Response to Health Authorities
- ▶ Oral
- ▶ Presentation Skills
- ▶ Able to communicate statistical concepts to non-statisticians

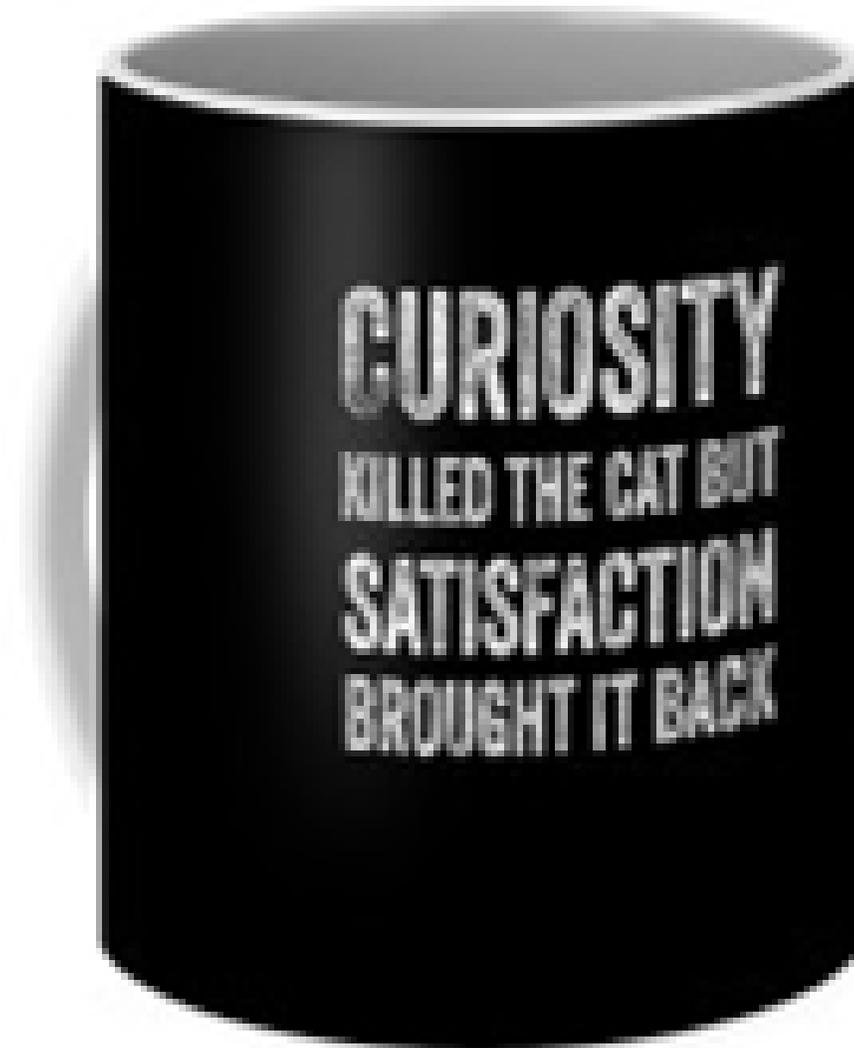
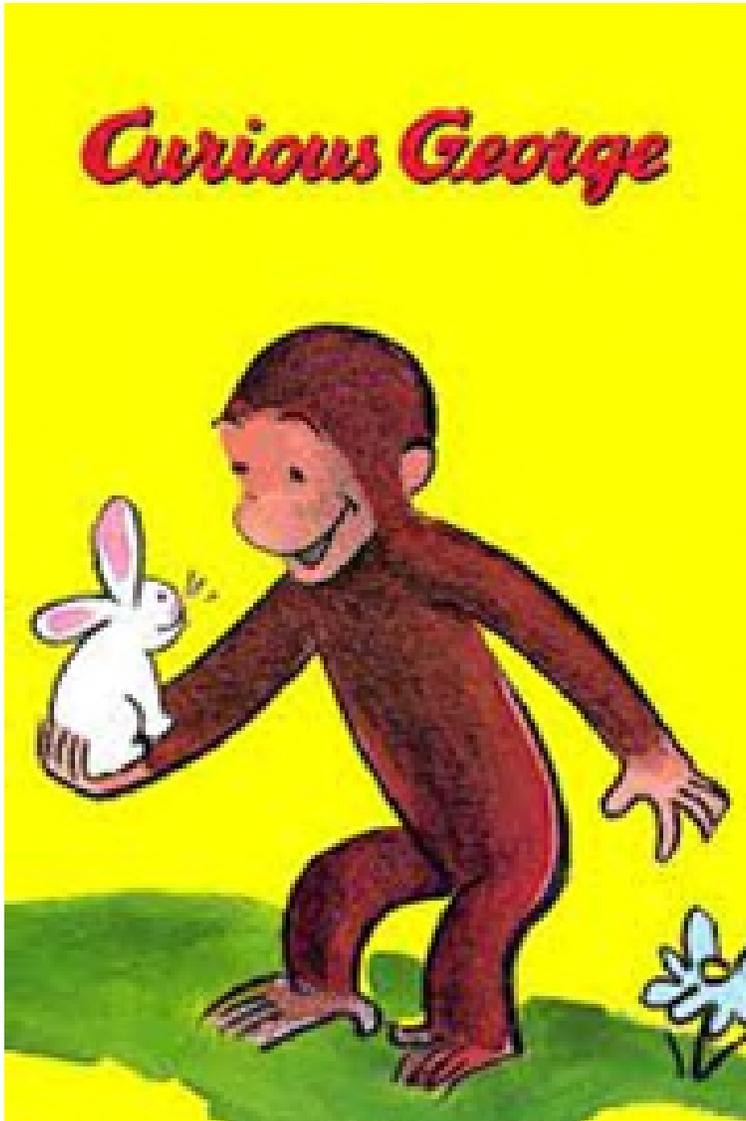
# Ethics

The screenshot shows a web browser displaying an article on the Fierce Pharma website. The article title is "Novartis appears to have a systemic ethics problem. What can it do to make amends?". The author is Angus Liu, dated Oct 14, 2019 11:22am. The article features a large image of a compass with the word "ETHICS" written in green on the dial. Below the image is a "OUR NEWSLETTER" section with a "GET THE NEWSLETTER" button and a form for email and country. A small text box at the bottom of the image reads: "Even with commitment from execs and the right compliance program, the ethics transformation at Novartis could take years to work through, experts say. (Cover: Le Monde/ Shutterstock)"

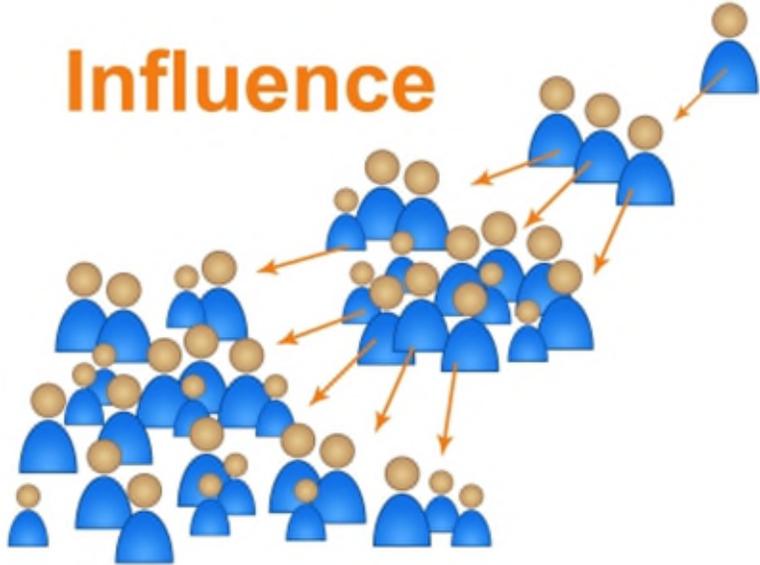
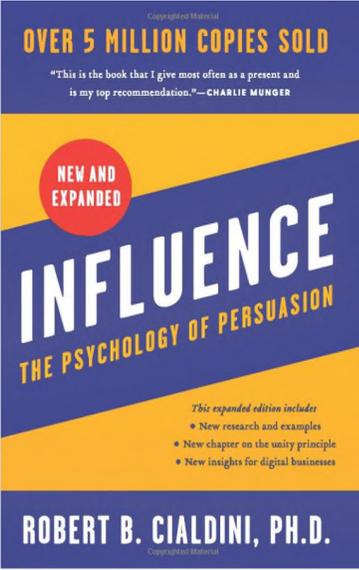
The screenshot shows a web browser displaying a press release on the FibroGen website. The title is "FibroGen Provides Additional Information on Roxadustat". The sub-headline is "Company Continues to be Confident in the Benefit / Risk Profile of Roxadustat". The main text includes: "Company to Host Investor Call Today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time)". The date is "SAN FRANCISCO, April 06, 2021 (GLOBE NEWSWIRE) - FibroGen, Inc. (Nasdaq: FGEN) (the 'Company') today provided clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses from the roxadustat Phase 3 program for the treatment of anemia of chronic kidney disease ('CKD')." A quote from Enrique Costales, Chief Executive Officer, states: "While all of the analyses set forth below, including the differences in the stratification factors, were included in the NDA, we promptly decided to clarify this issue with the FDA and communicate with the scientific and investment communities."

The screenshot shows a web browser displaying the "Ethical Guidelines for Statistical Practice" document from the American Statistical Association. The document is prepared by the Committee on Professional Ethics of the American Statistical Association and approved by the ASA Board of Directors on February 1, 2022. It includes a "PDF Download" button and a section titled "Purpose of the Guidelines". The text states: "The American Statistical Association's Ethical Guidelines for Statistical Practice are intended to help statistical practitioners make decisions ethically. In these guidelines, 'statistical practice' includes activities such as designing the collection of, summarizing, processing, analyzing, interpreting, or presenting data and model or algorithm development and deployment. Throughout these guidelines, the term 'statistical practitioners' includes all those who engage in statistical practice, regardless of job title, profession, level, or field of degree. The guidelines are intended for individuals, but these principles are also relevant to organizations that engage in statistical practice." It further states: "The ethical guidelines aim to promote accountability by informing those who rely on any aspects of statistical practice of the standards they should expect. Having benefits from informed judgments supported by ethical statistical practice. All statistical practitioners are expected to follow these guidelines and encourage others to do the same." It concludes: "In some situations, guideline principles may require balancing competing interests. If an unexpected ethical challenge arises, the ethical practitioner seeks guidance, not exceptions, in the guidelines. To justify unethical behaviors, or to report gaps in the guidelines, is unprofessional and inconsistent with these guidelines."

# Curiosity



# Influence



# Some useful websites to investigate

- ▶ <https://stattrak.amstat.org/2012/06/01/successfulstatistician/>
- ▶ <https://theeffectivestatistician.com/>
- ▶ <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process>
- ▶ <https://phrma.org/>
- ▶ <https://www.ich.org/>
- ▶ <https://www.amstat.org/your-career/ethical-guidelines-for-statistical-practice>
- ▶ <https://onlinedegrees.mtu.edu/news/top-skills-needed-statisticians>

Thanks for your attention

