# REFLECTIONS ON STATISTICAL EDUCATION, PRACTICE, AND OPPORTUNITIES FOR LEADERSHIP

Lisa LaVange, PhD
ASA President
Professor and Associate Chair


ASA New Jersey Chapter/
Bayer Workshop
Bayer Campus
Whippany, NJ
November 2, 2018

# Outline

- Leadership opportunities in statistical practice
  - Industry
  - Academia
  - Government
- Training – statistics and data science
- ASA Leadership Institute

# LEADERSHIP OPPORTUNITIES

All Employment Sectors

# My Career

- Non-profit research (1976 – 1994)
- Large CRO (1996-2001)
- Small pharma (2001 – 2005)
- Academia (2005 – 2011)
- FDA (2011 – 2017)
- Academia (2018 to date)
- Retirement…?

# Leadership Opportunities in Industry

Examples

- Large research institutions (e.g., RTI, Quintiles) are often matrix organizations
  - Management positions with assigned leadership roles – e.g., director, vice-president
  - Additional leadership opportunities through multi-disciplinary project teams
- Pharma opportunity to lead a development team (esp. in small pharma)
  - Drug supply
  - Non-clinical studies
  - Clinical development
  - Strategic planning (e.g., market research)
  - External communication – scientific, regulatory, business

# Leadership Opportunities in Academic Research

- Collaborative research
  - R01 grants led by subject matter expert
  - Coordinating center grants for multi-site studies
- UNC Biostatistics has the oldest continuously funded NIH coordinating center (1971)
  - Clinical trials and trial networks
  - Epidemiology studies (longitudinal cohort studies)
  - Patient registries
- Coordinating Center PI is an important member of the study's steering committee
  - Usually the sole statistical voice among other disciplines
- Challenge is to build consensus for and ensure adoption of:
  - Most appropriate trial design and analysis plan
  - High quality study conduct, data collection, safety reporting, etc.
  - Efficient data sharing, publications, dissemination of results

# Leadership Opportunities in Academic Research

Examples

- PI for Coordinating Center of Hispanic Community Health Study/Study of Latinos
  - Epidemiology study of risk factors and health outcomes in cohort of 16,000 US Hispanics/Latinos
  - As voting member of Steering Committee, led initiative to apply household-based area probability sampling methods for recruitment of cohort – met with much resistance!
  - Impact of sampling design on recruitment, retention, and data analysis required continued leadership to carry to completion
- PrecISE – NHLBI funded trial network to study targeted therapies in severe asthma
  - Different designs optimal for different questions, e.g., select treatment(s) for further study *or* determine which treatment is better for a given subgroup *or* identify the subgroup most likely to benefit from treatment
  - Obtain consensus among statisticians while also obtaining buy-in from clinicians

# Opportunities to Lead at FDA

- Leading within the Office of Biostatistics
  - Growing the workforce
  - Training and mentoring statistical reviewers
  - Educating and influencing reviewers of other disciplines
- Owning statistical policy
  - Through guidance development and dissemination
  - Through internal discussions with other disciplines
- Leading innovation
  - Precision medicine
  - Smart use of non-standard trial designs and data sources
- Influencing decisions (when quantitative reasoning is critical)

"…Give priority to provisions that present the greatest opportunity for FDA to **foster innovation** and integrate advances in biological sciences, engineering, information technology, and, to most directly improve the Agency's product review tools and processes."

# 21st Century Cures Act

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

"… "Expert FDA staff with expertise in statistics, **data science,** meta-analysis, clinical outcomes research, and other areas will develop the framework and methodologies for evaluating the use of **real world evidence**

# Precision Medicine

- Personalized medicine is getting the right product to the right patient (and in case of a drug or biologic) at the right dose
- Key challenge is to identify targeted subgroups at the right stage
- FDA statisticians have long been involved:
  - Diagnostic device evaluation (CDRH)
  - Enrichment study designs (CBER and CDER)
  - Master protocols/platform trials (CBER, CDER, CDRH)
  - Biomarker validation and qualification (CDER)
- As medicines (or their targets) become more precise, traditional clinical trials become more difficult to conduct and/or less efficient
- Collaborative research paradigms, such as master protocols, are of increasing interest, as a result

# Master Protocols

- Multiple diseases, multiple patient subgroups (biomarker-defined), and/or multiple therapies studied under one, over-arching protocol
- FDA's advocacy has had an influence
  - Support of programs like I-SPY 2, Lung MAP, PREVAIL II, ADAPT, DIAN-TU
  - Path for patient advocacy groups to become involved, often driving collaborations
- NIH research a natural home for master protocols
  - Long history of supporting comparative effectiveness research
  - Goal of inference is to influence the practice of medicine
  - Treatment algorithms tailored to individual patients using machine learning methods
  - Real-world data presents challenges, e.g., mobile health data, EHRs, claims data

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D., and Janet Woodcock, M.D., *Editors*

# Master Protocols to Study Multiple Therapies, Multiple Diseases, or Both

Janet Woodcock, M.D., and Lisa M. LaVange, Ph.D.

HIGH-QUALITY EVIDENCE IS WHAT WE USE TO GUIDE MEDICAL PRACTICE. The standard approach to generating this evidence — a series of clinical trials, each investigating one or two interventions in a single disease — has become ever more expensive and challenging to execute. As a result, important clinical questions go unanswered. The conduct of "precision medicine" trials to evaluate targeted therapies creates challenges in recruiting patients with rare genetic subtypes of a disease. There is also increasing interest in performing mechanism-based trials in which eligibility is based on criteria other than traditional disease definitions. The common denominator is a need to answer more questions more efficiently and in less time.

A methodologic innovation responsive to this need involves coordinated efforts to evaluate more than one or two treatments in more than one patient type or disease within the same overall trial structure.[1-4] Such efforts are referred to as master protocols, defined as one overarching protocol designed to answer multiple questions. Master protocols may involve one or more interventions in multiple diseases or a single disease, as defined by current disease classification, with multiple interventions,

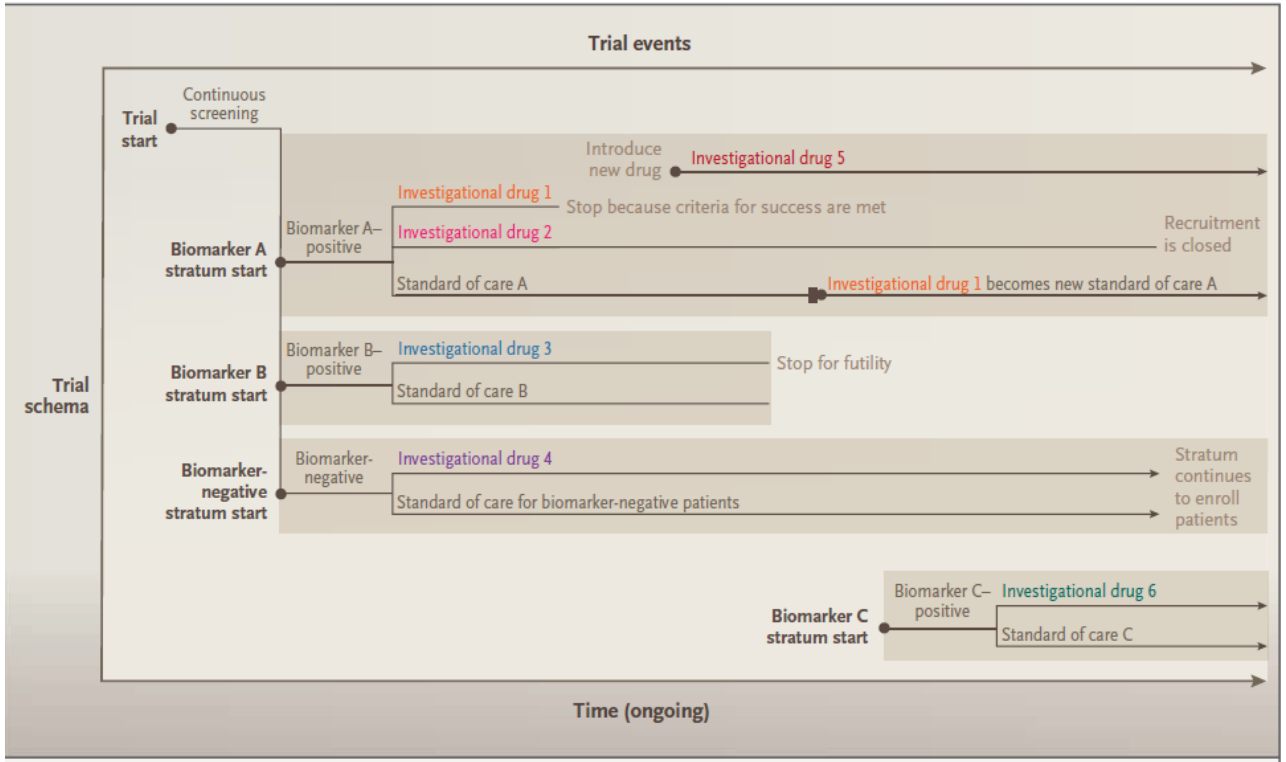


**Figure 2. Potential Design of a Platform Trial Involving a Single Disease.**

# 2 FDA Guidance Documents Issued Sep. 29, 2018

## Adaptive Designs for Clinical Trials of Drugs and Biologics

### Guidance for Industry

***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Scott N. Goldie at 301-796-2055, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**

**September 2018**
**Clinical/Medical**

## Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics

### Guidance for Industry

***DRAFT GUIDANCE***

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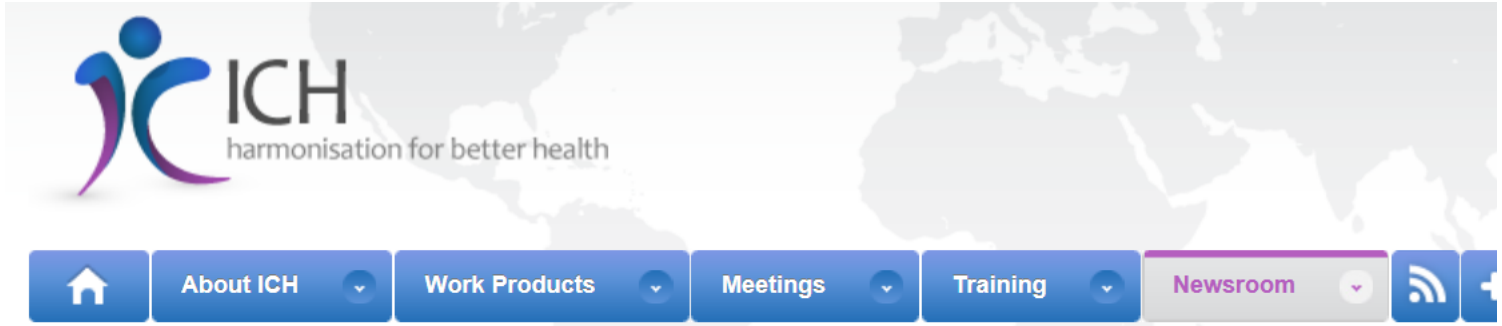
**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**
**Oncology Center of Excellence (OCE)**

**September 2018**
**Procedural**

# Master Protocols – NIH application

- PrecISE – Precision Medicine in Severe, Exacerbation Prone Asthma network
- Adaptive platform trial conducted under a master protocol
- 6 novel interventions identified for study
  - Early futility testing to drop interventions
  - Add other interventions, as they become available
- Randomization probabilities based on biomarker-defined subgroups of patients targeted by each intervention
- Precision medicine interim analysis to refine definition of target subgroup
  - Refine cut-point delineating biomarker + and – patients
  - Refine the biomarkers themselves
- Final precision medicine analysis to identify best course of treatment among overlapping subgroups using machine learning methods

- FDA Reflection paper on E6, E8
- Proposal to
  - Revise E8 (R1)
  - Renovate E6
- Office of Biostatistics:
  - Co-authored reflection paper
  - Leading E8 revision




# ICH Reflection on "GCP Renovation": Modernization of ICH E8 and Subsequent Renovation of ICH E6



*12 January 2017*

ICH is inviting public review and comment on a reflection paper on Good Clinical Practice (GCP) "Renovation", which contains the ICH proposal for further modernization of the ICH Guidelines related to clinical trial design, planning, management, and conduct. The scope of the proposed renovation includes the current E8 General Considerations for Clinical Trials and further revision to the E6 Guideline for Good Clinical Practice, which is already undergoing modernization with the recent production of ICH E6(R2).

The reflection paper is available for download via the following link:

- Reflection paper on GCP Renovation

The goal of the potential renovation is to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of study types and data sources that are being employed to support regulatory and other health policy decisions, as appropriate. The underlying principles of human subject protection and data quality would remain. ICH's decision to invite stakeholder comment on the proposed renovations at this early stage, ahead of guideline development efforts, recognises the considerable stake and relevant expertise in the research community beyond ICH.

The seeking of stakeholder comment on the current reflection paper is seen as a first step in an enhancement of the ICH process with respect to public consultation for the revision of ICH E8 and E6. The GCP Renovation reflection paper outlines additional steps that are also being considered to enhance stakeholder engagement.

# ICH E8 General Considerations for Clinical Trials

- 1999 guideline describes:
  - Phases of drug development
  - Features of trial design
  - Importance of protecting safety of participants
- Expert working group formed for revision; two meetings held to date
  - Target date of 1st quarter 2019 for draft guideline available for public comment
  - Statistician is rapporteur; EWG includes variety of disciplines
- Revised document:
  - Introduces quality by design approach; critical to quality factors managed proportionate to risk
  - Expands types of trial designs beyond RCTs
  - Expands data sources to include real-world data*

*Jarow, LaVange, and Woodcock, *JAMA*, 2017

# Other Initiatives

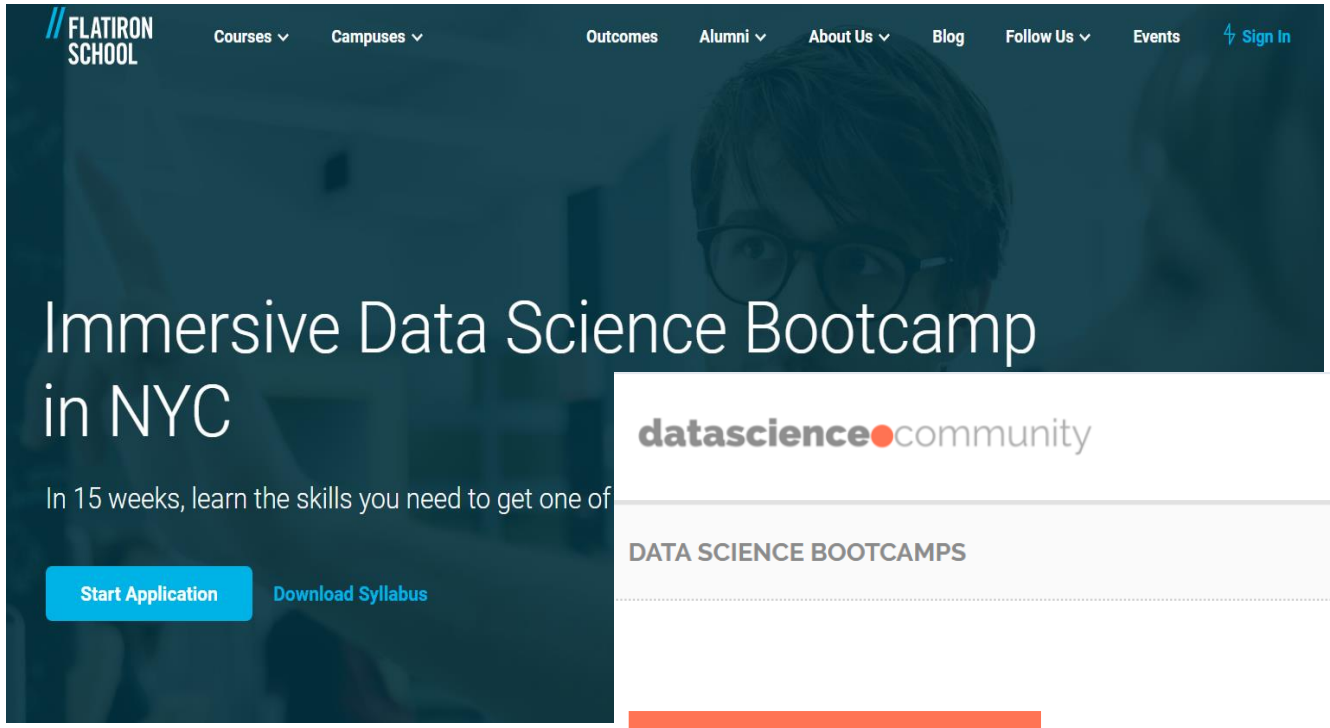
- PDUFA VI
  - Complex Innovative Designs – pilot program
  - Analysis data standards
  - Patient-focused drug development
  - Real-world evidence
- Pediatric trials – new approaches
- Catching up with academia– dynamic treatment regimes and machine learning

# TRAINING

Statistics and Data Science

# Training Statisticians

- Probability and statistical inference
  - Theory and application
- Specialty areas, e.g., clinical trials, statistical genetics, Bayesian statistics, sample surveys, etc.
- **Data Science and Machine Learning**
- **Leadership**

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This list is based upon the **Awesome Data Science Bootcamps** list on Github. **Would you like your bootcamp to be listed?**

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| **Data Science Dojo** (Data Science and Data Engineering Bootcamp) | US and others | | F | 2999 | 5-day immersive data science bootcamp, no pre-requisites |
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| **Bit Bootcamp** (Data Science) | US | NY | F | 0 | 6 week data science program and 4 week big data program |
| **DS12** (Data Science+Engineering) | US | CA | F | 0 | 12 candidates for 12 weeks. Scala/Spark focused with expert instructors. Embedded in DataScience Inc - stipend provided |

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## Top-ranked, most comprehensive curriculum

NYC Data Science Academy's 12-week Immersive Bootcamp prepares you with everything you need to land a job as data scientist. Our Bootcamp students receive over **420 hours** of education and hands-on practice. You'll learn data science with **R, Python, Machine Learning, Hadoop & Spark, Github, and SQL** as well as the most popular and useful R and Python packages like XgBoost, dplyr, ggplot2, Pandas, Scikit-learn, and more.

Throughout the program, you'll build at least **4 projects** using techniques from visual and statistical analyses to supervised and unsupervised machine learning algorithms and big data technologies. Nothing proves your skills better than having solid projects presented in your portofolio.

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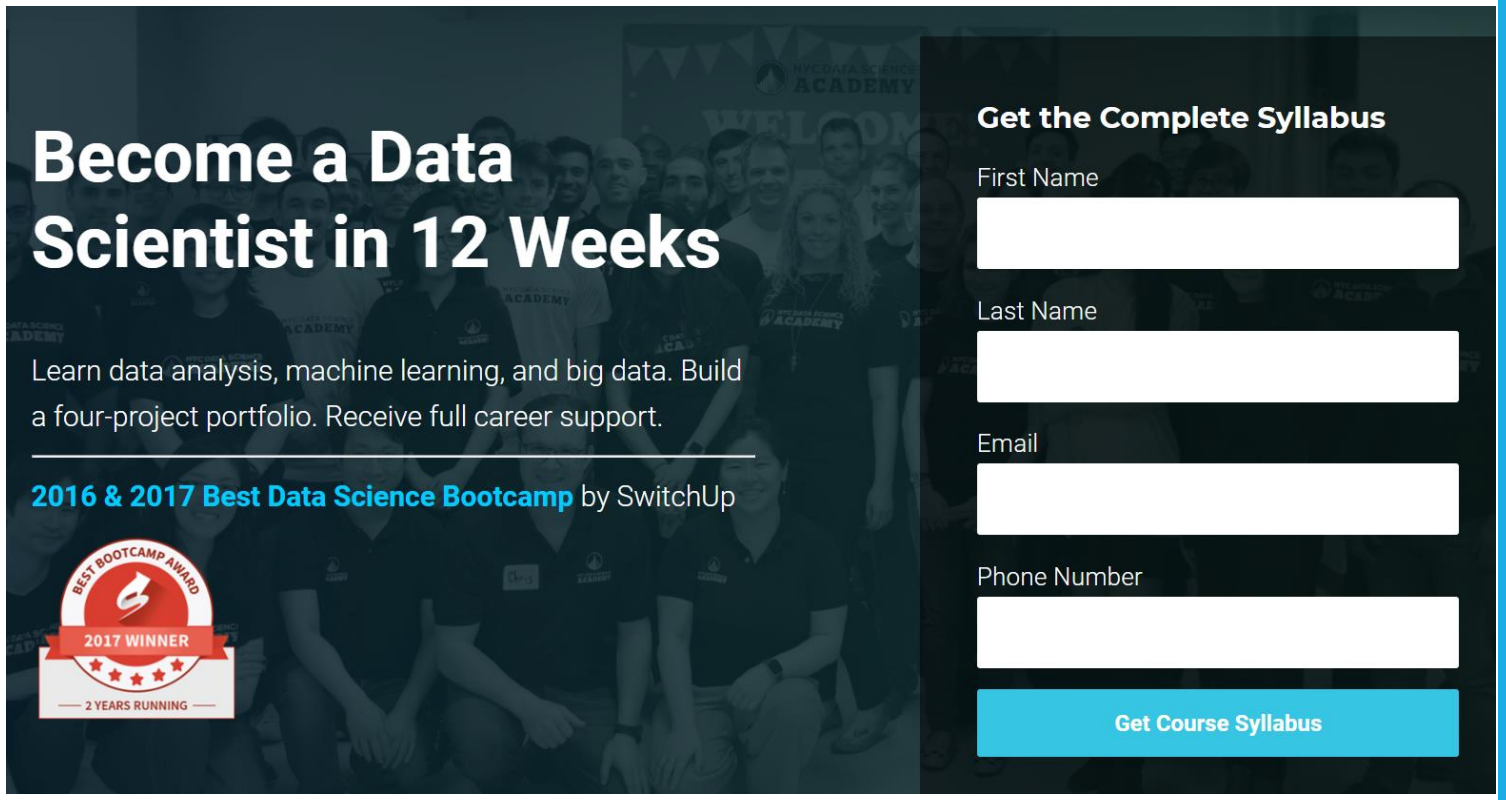

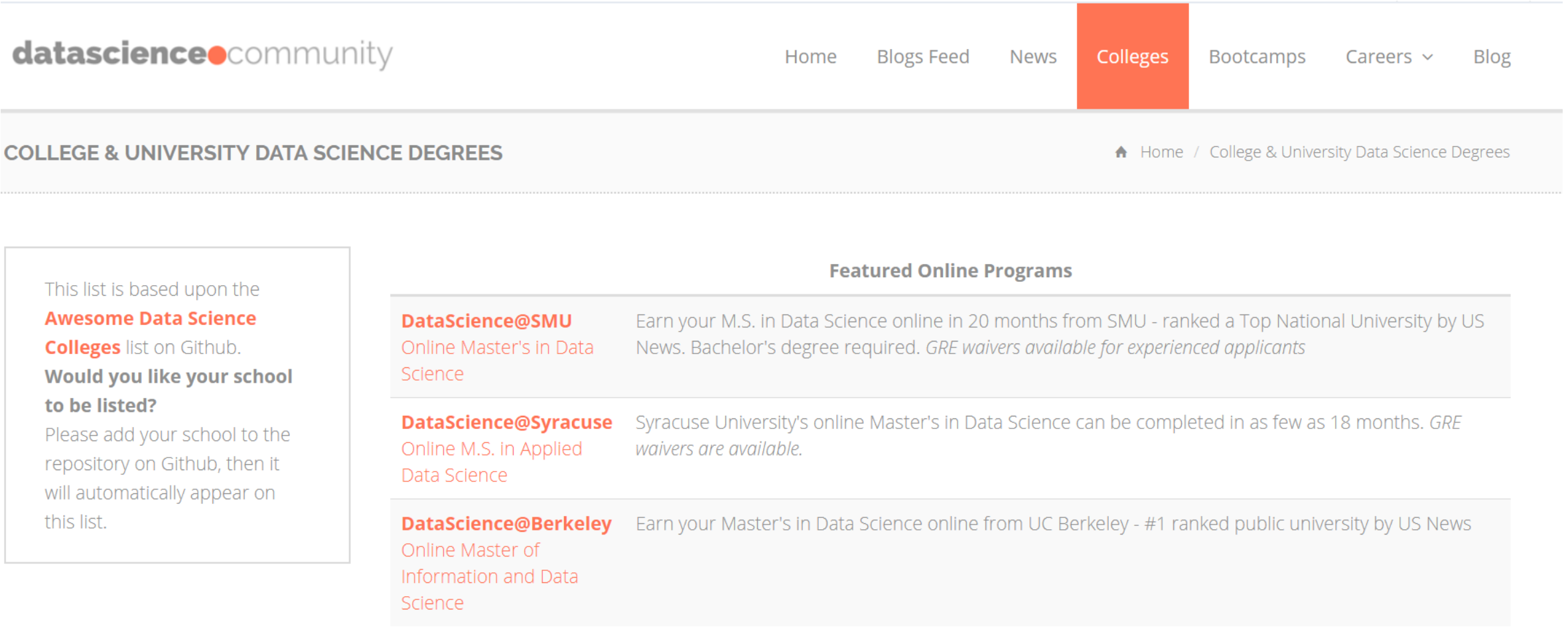


582 entries in college/university degree programs

http://datascience.community/colleges

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# Top 23 Schools with Data Science Master's Programs

Looking to freshen your résumé and improve your earning potential? You're in exactly the right place at exactly the right time. According to Glassdoor, there are over 15,000 jobs in the analytics and data science fields as of January 2018. In response, universities have been looking to improve their existing degree data and analytical programs and to create entirely new degrees offerings, both online and on-campus. We've listed 23 of these programs below.

## Choose the Best Masters in Data Science Program For You

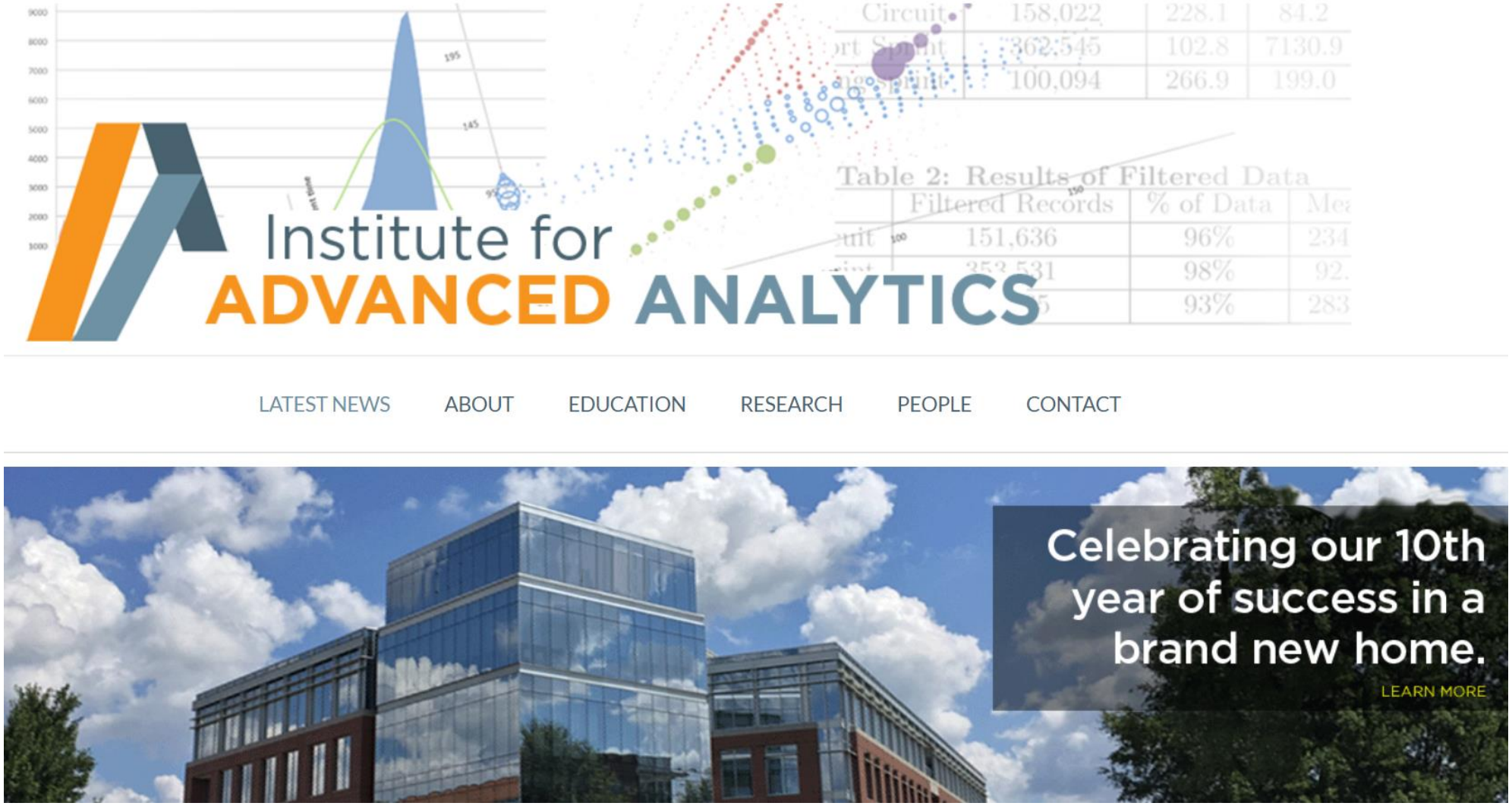
CAREER PROFILES

Business Analyst
Data Analyst
Data Architect
Data Engineer
Data Scientist
Marketing Analyst
Quantitative Analyst
Statistician

SCHOOLS BY STATE

Alabama
Arizona

https://www.mastersindatascience.org/schools/23-great-schools-with-masters-programs-in-data-science/




https://analytics.ncsu.edu/

1st Master's program in Advanced Analytics

# UNC MPH Program Launches in 2019

UNC | GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

DEGREES STUDENTS DEPARTMENTS DISCOVER GILLINGS GIVE FULL MENU

Accessibility

**CONTACT US**

Student Services Manager: Veronica Stallings, MS

Concentration Leader

Primary Contact: Lisa LaVange, PhD

- Master of Public Health
- Gillings MPH Core
- Applied Epidemiology Concentration
- Environmental Health Solutions Concentration
- Global Health Concentration
- Health Behavior Concentration
- Health Equity, Social Justice and Human Rights Concentration
- Health Policy Concentration

## Public Health Data Science Concentration

Scientific discoveries made by the Gillings School's Dr. Michael Kosorok, left, were put into practice by pediatric pulmonologist Dr. George Retsch-Bogart. The result was better hospital care and better health for children with cystic fibrosis.

## About

Accurate interpretation and use of data is crucial to understanding health needs and devising and implementing comprehensive, evidence-based solutions.

The Public Health Data Science concentration—one of the first applied data science programs situated within a school of public health—will give you the skills and knowledge to employ cutting-edge data science tools and, in turn, respond to pressing public health issues and advance effective solutions.

# ASA AND DATA SCIENCE

# 2000 PROGRAM

## Joint Statistical Meetings

American Statistical Association
160th Annual Meeting

Institute of Mathematical Statistics

International Biometrics Society
Eastern North American Region
Western North American Region

Statistical Society of Canada

Celebrate Diversity in Statistics

JSM 2000
Indianapolis, Indiana
August 13-17

## SPECIAL INVITED LECTURES

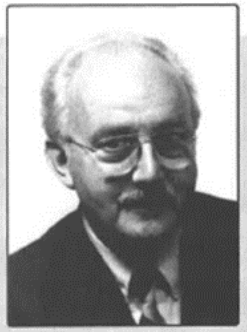
### ASA President's Invited Address
TUESDAY, 8:00 PM

INVITED ADDRESS

**DR. DENNIS GILLINGS**
Chairman and Chief Executive Officer
Quintiles Transnational Corporation

### Deming Lecture
TUESDAY, 4:00 P.M.

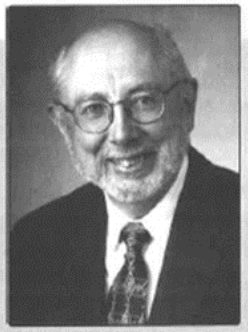
DEMING LECTURE



**DR. GEORGE E. P. BOX**
Professor Emeritus, University of Wisconsin and ASA Past President

### ASA Presidential Address
TUESDAY, 8:00 PM

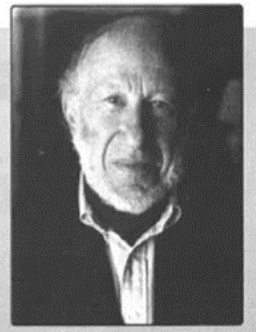
PRESIDENTIAL ADDRESS



**DR. W. MICHAEL O'FALLON**
Mayo Clinic
and ASA President

### Fisher Lecture
WEDNESDAY, 4:00 P.M.

FISHER LECTURE



**DR. INGRAM OLKIN**
Stanford University

# ASA and Data Science

- ASA statements and curriculum guidelines state three foundational components:
  - Mathematics
  - Statistics
  - Computer Science
- July 2017 Board Meeting
  - Met with NY Data Science Academy to discuss their program, curriculum, evaluation, and job placement
  - Discussed among Board members the possibility of accreditation in data science to ensure adequate statistical training
    - Similar to Pstat accreditation program
    - AMS having similar discussions
- April 2018 Board Meeting
  - Broad discussion on data science and ASA's role in the field
  - Consensus reached that statistical leaders will be working with, managing data scientists going forward

# ASA Statement on the Role of Statistics in Data Science

1 OCTOBER 2015 10,486 VIEWS 13 COMMENTS


**Statement Contributors**

David van Dyk, *Imperial College* (chair)

Montse Fuentes, *NCSU*

Michael I. Jordan, *UC Berkeley*

Michael Newton, *University of Wisconsin*

Bonnie K. Ray, *Pegged Software*

Duncan Temple Lang, *UC Davis*

Hadley Wickham, *RStudio*


The rise of data science, including Big Data and data analytics, has recently attracted enormous attention in the popular press for its spectacular contributions in a wide range of scholarly disciplines and commercial endeavors. These successes are largely the fruit of the innovative and entrepreneurial spirit that characterize this burgeoning field. Nonetheless, its interdisciplinary nature means that a substantial collaborative effort is needed for it to realize its full potential for productivity and innovation. While there is not yet a consensus on what precisely constitutes data science, three professional communities, all within computer science and/or statistics, are emerging as foundational to data science: (i) Database Management enables transformation, conglomeration, and organization of data resources, (ii) Statistics and Machine Learning convert data into knowledge, and (iii) Distributed and Parallel Systems provide the computational infrastructure to carry out data analysis.

Certainly, data science intersects with numerous other disciplines and areas of research. Indeed, it is difficult to think of an area of science, industry, commerce, or government that is not in some way involved in the data revolution. But it is databases, statistics, and distributed systems that provide the core pipeline. At its most fundamental level, we view data science as a mutually beneficial collaboration among these three professional communities, complemented with significant interactions with numerous related disciplines. For data science to fully realize its potential requires maximum and multifaceted collaboration among these groups.

# Curriculum Guidelines for Undergraduate Programs in Data Science*


Richard D. De Veaux,[1] Mahesh Agarwal,[2] Maia Averett,[3] Benjamin S. Baumer,[4] Andrew Bray,[5] Thomas C. Bressoud,[6] Lance Bryant,[7] Lei Z. Cheng,[8] Amanda Francis,[9] Robert Gould,[10] Albert Y. Kim,[11] Matt Kretchmar,[12] Qin Lu,[13] Ann Moskol,[14] Deborah Nolan,[15] Roberto Pelayo,[16] Sean Raleigh,[17] Ricky J. Sethi,[18] Mutiara Sondjaja,[19] Neelesh Tiruviluamala,[20] Paul X. Uhlig,[21] Talitha M. Washington,[22] Curtis L. Wesley,[23] David White,[24] and Ping Ye[25]



Annu. Rev. Stat. Appl. 2017. 4:2.1–2.16

The *Annual Review of Statistics and Its Application* is online at statistics.annualreviews.org

This article's doi: 10.1146/annurev-statistics-060116-053930





*Author affiliations can be found in the Acknowledgments section.



**Keywords**

curriculum, statistics education, computer science education



**Abstract**

The Park City Math Institute 2016 Summer Undergraduate Faculty Program met for the purpose of composing guidelines for undergraduate programs in data science. The group consisted of 25 undergraduate faculty from a variety of institutions in the United States, primarily from the disciplines of mathematics, statistics, and computer science. These guidelines are meant to provide some structure for institutions planning for or revising a major in data science.

# Success, Opportunities, and Challenges for Statistics and Biostatistics in the Data Science Era

A Report of the July 2016 NSF-Sponsored Workshop for Chairs of Departments of Biostatistics and Statistics

ASA

# ASA AND LEADERSHIP TRAINING

The ASA Leadership Institute

# Leadership Training

- Curriculum*
  - Vision and strategic thinking
  - Communication
  - Diversity
  - Ethics
  - Basic management skills and financial literacy
  - Transformational leadership, empowerment, and innovation
  - Personal leadership styles
  - Organizational leadership and culture
  - Conflict resolution
  - Decision making and decision analysis

**Curriculum from Biostatistics 844, University of North Carolina at Chapel Hill, Fall, 2018*

# ASA Leadership Institute

2018 Presidential Initiative

1. Support development of leaders of statistics groups/organizations – *assigned leadership*
2. Support development of leaders of multi-disciplinary groups -- *emerged leadership*
3. Offer elements of statistical leadership to leaders of other disciplines


# ASA LEADERSHIP INSTITUTE Steering Committee

- **Michael Rappa** – Goodnight Director and Distinguished University Professor, Institute for Advanced Analytics at North Carolina State University

- **Bob Rodriguez** – Senior Director in SAS Research and Development and former ASA President

- **Aarti Shah** – Senior Vice President and Chief Information Officer and former Vice President of Biometrics and Advanced Analytics at Eli Lilly and Company

- **Erica Groshen** – Visiting Senior Scholar at the Industrial and Labor Relations School at Cornell University and former Commissioner of Labor Statistics (2013–2017)

- **Debbie Hughes** – Vice President for Higher Education and Workforce Development at the Business and Higher Education Forum

# ASA Leadership Institute

- Steering Committee met Jan. 23 to brainstorm about initiatives
- Identified three points in a statistician's career for leadership training:
  - Pre-career
  - Early- to mid-career
  - Mid- to late-career
- Different objectives at each stage
- Different opportunities for engagement

# 2018 Launch – Three Initiatives

- Pre-career: Future Leaders Program
  - 5-student teams recruited through ASA student chapters
  - Coaching provided to solve a leadership challenge problem
  - Present solutions to ASA Board in April 2019
- Early- to mid-career:
  - Extend current JSM short course to offer more in-depth training
  - Open to JSM 2018 workshop registrants plus past cohorts
  - Learning opportunities planned in-person and via web
- Mid-late career:
  - Engage 'C-suite' leaders to understand organizational needs
  - Identify resources to provide for members seeking to take the next leadership step
  - Roundtable co-sponsored by BHEF to include executives from industry, academia, and government


5 Teams Selected; Met with coaches at JSM; Webinar Series planned for fall/winter

# Mid-Career Leadership Training

- Pilot-test as year-long follow-up to JSM 2018 Leadership Workshop
- 3 Modules offered between Fall 2018 and Spring/Summer 2019

1. Cultural Competency in Leadership
2. Decision making and decision analytics
3. Communicating with the C-Suite, or Executive Presence for Statisticians

# Mid-Career Workshops

- 20 Attendees
  - 8 from JSM 2018 Leadership Course
  - 12 alums from prior JSM courses
- Guest speakers from FDA and Industry
- Focus on diversity and leadership


**Leading with Cultural Competency**
**October 12 - 13, 2018**

# C-Suite Roundtable

Convene C-suite executives from industry and academia to provide insight into their organizational leadership models and training needs, and ultimately champion ASA activities.

# Summary

- Data science permeates all aspects of statistics, from education to employment
- Leadership opportunities abound, as a result
- Presidential initiative to develop an ASA Leadership Institute
  - Supports membership at all career stages
  - Provides a home for ASA professional development offerings
  - Is sustaining
  - Strives to become a recognized resource in leadership training, for statisticians and beyond
  - Choose to Lead!