

Making Our Statisticians Bold and Entrepreneurial

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EFSPI – 10th Statistics Leaders Meeting
04 July 2019

Time for Reflections

A milestone anniversary is a good time to reflect on where we have been and what we need to do before the next milestone anniversary.



Outline

- Evolving role of statisticians in the pharma industry
- Statistical science has come a long way supporting product development
- 21st century is a scientifically exciting time
- Winning traits and skills for statisticians to be successful in the new environment
- Making our statisticians bold and entrepreneurial
- How leaders can help and lead in this journey

Evolving Role of Statisticians

Little use of Statistics ==>

“Required” use of Clin Statistics ==>

Tactical use of Statistics ==>

Strategic use of Statistics & “Statistical
Thinking”

1955

Now

Industry Perspective: “Then”

- Statisticians were hired to get things through the regulatory agencies.
- Statisticians were “number crunchers” to get analyses done.
- Statisticians blessed clinical trial designs with limited intellectual participation except for sample size.
- Statisticians focused on trials and manufacturing.
- There was very little statistical input outside of “the necessary”, low involvement in non-clinical areas.
- Statisticians played a secondary role.

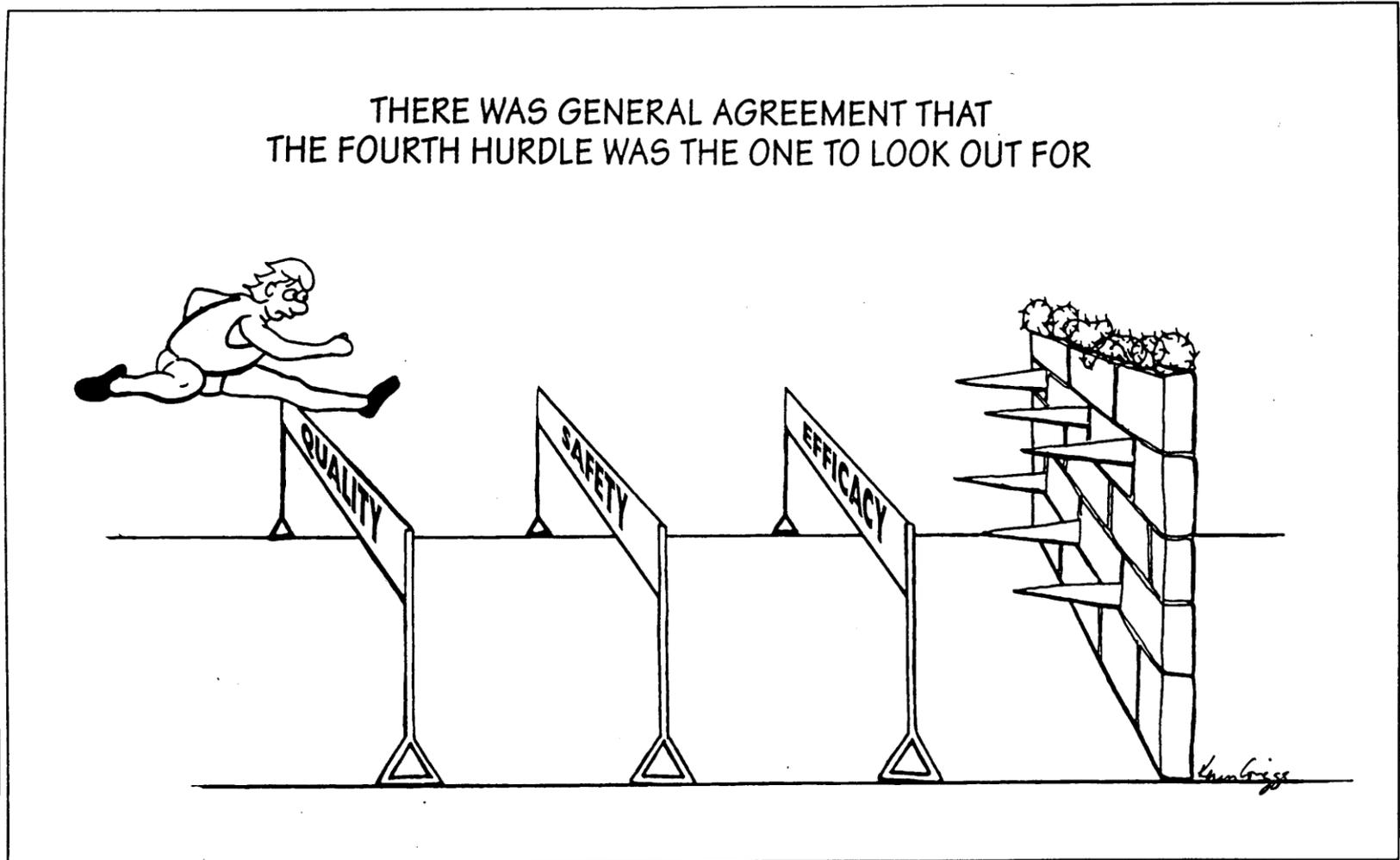
At the Turn of the 21st Century

- Statisticians were full and equal partners with basic, clinical & regulatory scientists.
- Statisticians focused on experimental design and development strategy, applying statistical thinking throughout the life cycle of a pharmaceutical product.
- Parallel development in other disciplines such as epidemiology, genomics, biomarker development, portfolio evaluation, and risk management has expanded statistician's contributions.
- Statisticians and the pharma industry had a fantastic run during the last 2 decades of the 20th century.

ICH E6 and E9 Affirmed Statistician's Role

- ICH E9(R1) Statistical Principles for Clinical Trial - Section 1.2: “ ..., *it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6.*” .
- ICH E6(R2) Good Clinical Practice – Section 5.4.1: “*The sponsor should utilize qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process*” .

21st Century: The Fourth Hurdle



Source: Chrissie Fletcher

More External Stakeholders

- Health care providers
- Patient care givers
- Regulators
- Journal editors
- Shareholders
- Health care payers
- And most importantly - **THE PATIENTS**



The Operating Model

- Acquisitions and mergers will continue.
- More alliances among industry partners to share risk and returns
- More academic-industry partnerships
- Increasing public-private partnership like the Innovative Medicines Initiative in Europe
- Advocacy groups have input into drug development and approval process
- More consortiums in the pre-competitive space to share science and technology advancements

Scientific Opportunities for Statisticians

- Methods to support all aspects of personalized medicine including biomarkers and subgroup strategy
- Strategy for global product development
- Adaptive trials and program-level strategies
- Strategies to better retain patients
- Statistical support for biosimilar development
- Standards for accessing and analyzing electronic health records for effectiveness and safety
- Risk/benefit and cost-effectiveness assessment
- etc

Statisticians Have Realized

- Being technically smart is not enough:
 - ◆ Understand the broad clinical, regulatory and public-health context
 - ◆ Build alliances with members from other disciplines
- Proactive, not passive:
 - ◆ Design: Options available, decision analysis
 - ◆ Execution: Quality control and risk mitigation
 - ◆ Analysis: Planned and unplanned, strengths/weaknesses
 - ◆ Interpretation: Pre-planned or data-driven
 - ◆ Presentations/Publications: Keeping audience in mind
 - ◆ Innovations: Develop new technical solutions

Still, We Often Found Ourselves

- Fight to be a member of the Core Team;
- Fight to have our voice heard;
- Fight to have our contributions recognized among quantitative scientists;
- Fight to remain a member of the decision-making body;
- Fight for our place at the table.

We Feel Pressured by

■ New players

- ◆ Pharmacometricians
- ◆ Outcome Research Scientists
- ◆ Pharmacoeconomists
- ◆ Analysts of Real World Data
- ◆ etc

**How could this be
when we have so
much to contribute?**



Are We Too Sheltered?

- Many industries have replaced the word "statistician" by "data analyst", using terms such as data analytics, machine learning and artificial intelligence instead of statistical analysis.
- Do statisticians become too complacent because our role in the pharma industry is protected by ICH and regulatory documents?

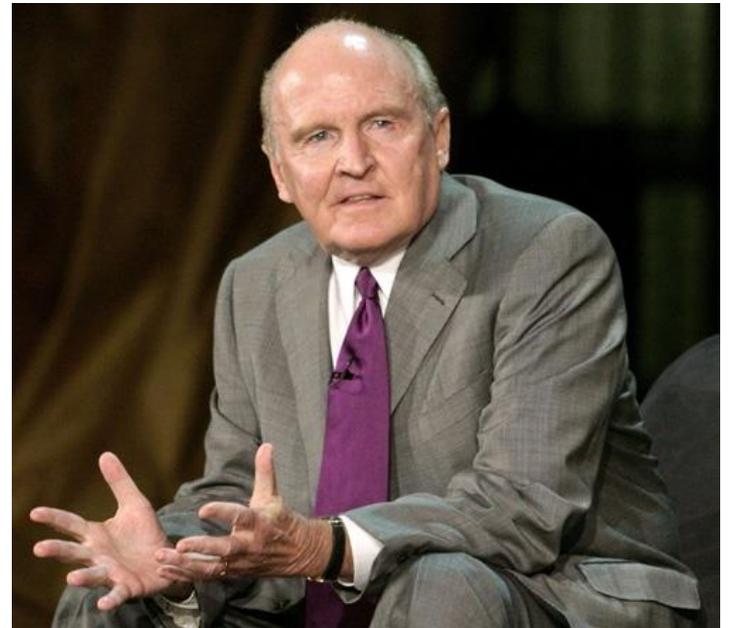
Are We Doing What We Should Be Doing?

- Are we effective in marketing ourselves?
- Are we participating in innovations beyond the core statistical responsibilities?
- Are we active in building bridges?
- Are we engaged in expanding our sphere of influence?
- Are we aware of the rate of change outside the statistical world?

Rate of Change

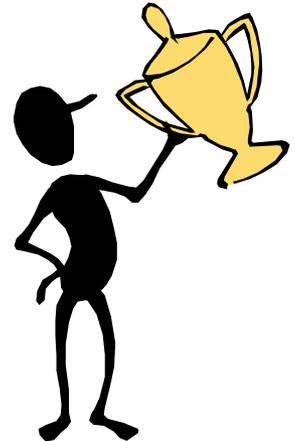
“When the rate of change internally is less than the rate of change externally, you are living on borrowed time.”

- Jack Welch



Winning Traits (Traditionally)

- **Passion** about what we do
- **Courage** to face our fears
- **Tenacity** to reach our goals
- **Curiosity** to stimulate innovations
- **Adaptivity** to embrace change



Winning Skills (Traditionally)

- Effective communication skills
- Leadership (influential) skills
- Business/organizational acumen
- Following through on promises



Business/Organizational Acumen

- Knowing what our business does
 - ◆ Who are our clients/customers?
 - ◆ How do we fit it?
- Understanding how decisions are made
- Figuring out our business' process flow
- Knowing what defines success at our organization

Adding to the Winning Traits and Skills

- **Bold and Entrepreneurial**, proactively seeking new opportunities.
 - ◆ Simply reacting to external challenges is no longer enough.
 - ◆ Statisticians need to be willing to initiate change with reasonably thought-out plans.
 - ◆ Statisticians need to be a driver of change.

Why Bold?

- ***Bold* implies “a willingness to take risks”**

If you are taking a risk, what you are really saying is, “I believe in tomorrow and I will be part of it”.

- Linda Ellerbee

A ship in a harbor is safe, but that is not what ships are built for.

- John A. Shedd

Taking Risk

- Taking risk can be hard for statisticians
 - ◆ We have been trained not to judge until we have enough evidence.
 - ◆ We are worried about “exceptions”.
 - ◆ We are good at articulating and quantifying risks, and not as good at articulating and quantifying potential gains.
 - ◆ Many feel that our job is to present data (and risks associated with different actions) and let others draw the conclusions.

Examples of Risk-Averse Behaviors

- Hedging our answers when asked for our opinions in meetings.
- Slow to speak up in meetings unless we have something to criticize.
- Reluctant to try new things unless we are pretty sure of their chance of success.
- Good at debates, but less so at taking actions.

Nothing would be done at all if we waited until we could do it so well that no one could find fault with it.

- *John Henry Newman*

Result of Risk-Averse Behaviors

- Decision makers at meetings are confused by our answers when they are looking for a binary recommendation.
- We are perceived as indecisive.
- We yield to other scientists who are vocal and practice the trial-and-error approach.
- We become less visible and less called upon unless regulators specifically ask for us (the statisticians).

Entrepreneurial Behaviors

- **Definition of an entrepreneur:**

A person who organizes, operates, and assumes the risk for a business venture.

- ***Entrepreneurial* implies “a willingness to embrace change and to take risks”; a willingness to journey on roads less traveled.**

Bold and Entrepreneurial

- Helps moderate our "risk-averse" behaviors.
- Propels us to explore new possibilities and seek new lands in the presence of risks (both known and unknown).
- Helps us become leaders and champions of change.
- Results in our having more control of our own destiny.



Freedom lies in
being bold.

Robert Frost

quote fancy

Bold and Entrepreneurial on Innovation

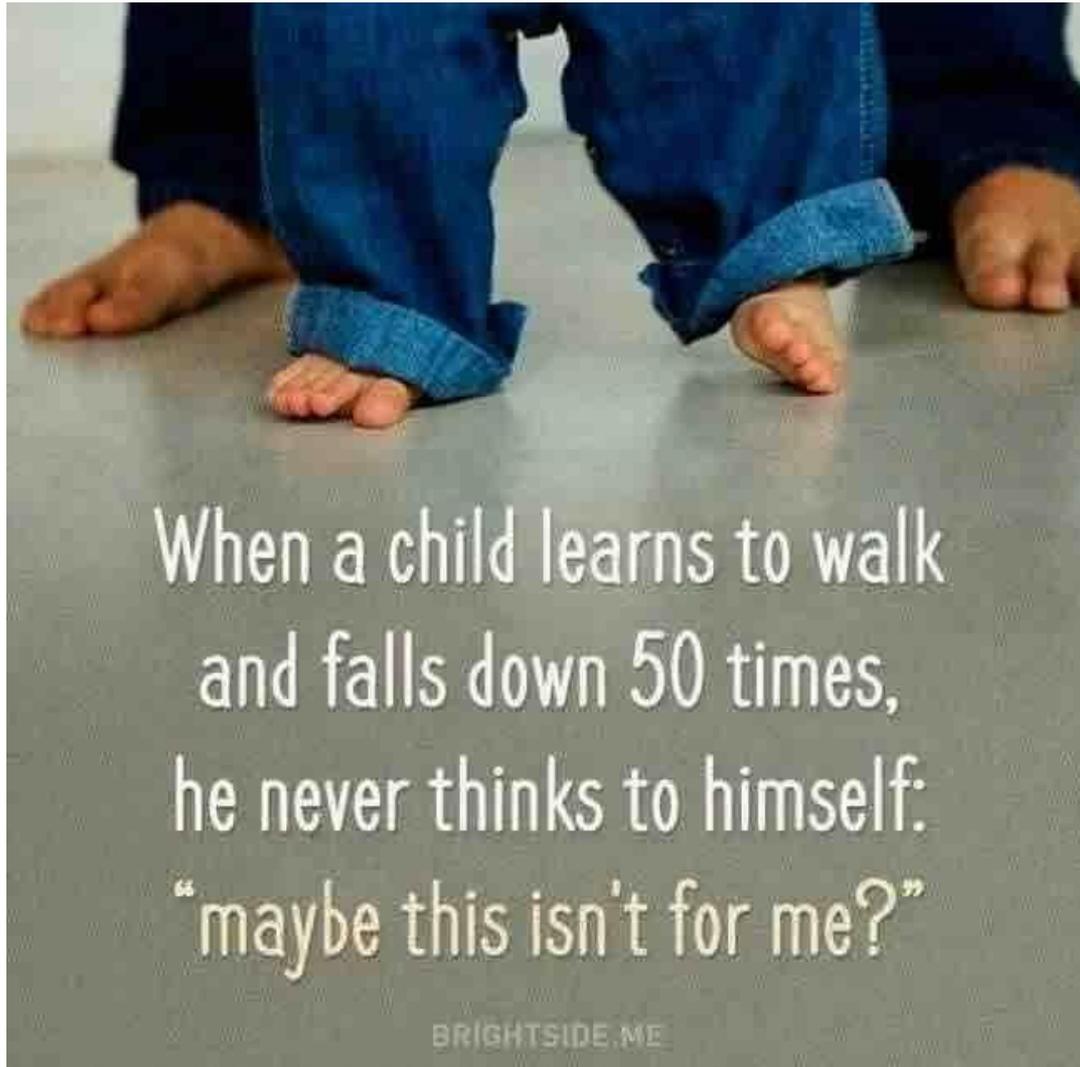
- Helps us “think outside the box” and fosters innovation.
- Motivates us to try new things without being paralyzed by fear of failure.
- Helps us accept that not all innovations will lead to success.
- Makes us become more aware of other innovations and how the latter could help with our work.

Some Examples of Bold Innovation

- Bayesian approach to trial design/analysis and go/no go decisions.
- Usage of and response to our products in the real world setting.
- Graphic solutions to data presentation.
- Analytic portals for various applications.
- Randomized trials using existing healthcare data-capture systems.
- Use of apps to help increase adherence.

As Leaders, How Can You Help?

- Be a champion and lead by examples.
- Prioritize statisticians' activities.
- Allow some mistakes.
- Sponsor an “idea farm”.
- Introduce your innovators to senior leaders.
- Publicize innovation stories and reward the efforts.



When a child learns to walk
and falls down 50 times,
he never thinks to himself:
“maybe this isn't for me?”

BRIGHTSIDE.ME

**Everybody likes a
compliment.**



**YOU
ROCK**

**“THE KEY TO SUCCESSFUL
LEADERSHIP TODAY IS
INFLUENCE, NOT AUTHORITY”**

- Kenneth Blanchard

Gentle Persuasion



**The fabled
story about the
sun and the
wind.**



Being Inspirational

- Should you shield the canyons from the windstorms, you would never see the beauty of their carvings.
- Elisabeth Kubler-Ross
- If you want to be a diamond, you need to be willing to be cut.



The Story of the Two Wolves



**“Fortune
favors
the bold.”**

—NICCOLÓ
MACHIAVELLI,
PHILOSOPHER

Acknowledgements

- My collaborators, Ray Bain, Cassie Burton, Cyrus Hoseyni, Frank Rockhold, Steve Ruberg and Ji Zhang, on a joint publication titled “Statisticians in the Pharmaceutical Industry: The 21st Century” published in *Statistics in Biopharmaceutical Research* 2010, 2(2):145-152.
- Authors (known or unknown) whose work and pictures appeared in my presentation.