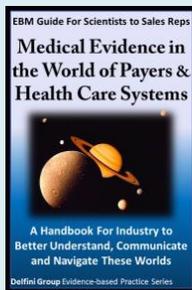




Delfini Co-Founders

Michael E Stuart MD, President & Medical Director
Sheri Ann Strite, Managing Director & Principal



Available on Amazon.

Delfini is a public service entrepreneurship founded to help people improve health care decision-making through **"applied" evidence-based clinical quality improvement and communications** with a focus on value and patient-centered care.

We are **evidologists, medical information scientists & evidence-based clinical improvement (EBCQI) experts**, and we—

- Specialize in training others in **critical appraisal** of the medical literature
- Come from **managed care** environments
- Have extensive experience working with a variety of **medical decision-makers**—managed markets, health systems, health plans, government, pharmacy & therapeutics and individual clinicians, among others
- Are authors of a six-part evidence-based practice series including a **book for manufacturers**:

EBM Guide for Scientists to Sales Reps—
Medical Evidence in the World of Payers & Health Care Systems: A Handbook for Industry to Better Understand, Communicate and Navigate These Worlds.

Delfini principals have a long history of working successfully with manufacturers. Activities include—

1. Training company staff + customers in **evidence-based methods** and **clinical improvement** including **clinical guideline development, implementation** and **communication aids**.
2. Training in working with payers and health systems.
 - How industry can improve payer acceptance of clinical evidence through **research design** and **evidence reporting**.
 - How to open doors through **more effective communication** about evidence with payers.
3. **Evidence reviews** including **special analyses**.
4. **Advisements** about payer perspectives.
5. Clinical **guideline** development & **decision support** tool creation.
6. Quality improvement project **facilitation** and **implementation**.
7. Evidence- and value-based **training** and **tools** for customers.

We can craft projects and training programs from any of these elements for staff or customers.

THE VALUE OF PARTNERING WITH DELFINI

Not only have we worked with many different customers and customer types all around the country, we are well-respected, our work is well-received, and we receive very high marks ranging from our trainings to our products. We both worked at Group Health Cooperative for more than two decades. We understand managed care, not-for-profits and individual care providers. We both have academic experience. We've worked with and trained medical content providers. We are considered to be some of the best evidologists, evidence reviewers and trainers in this clinical quality improvement, including critical appraisal.

We will provide you with information **that we believe no other potential partner possesses** and **unique, high quality products** based on the following—

- We are consistent—although a little more rigorous in places—with Cochrane Collaboration. However, we do not just serve up the traditional evidence-based medicine (EBM)-cannon. We cut out anything we find that is wrong. We work to simplify complex topics to make them as easy-to-understand as we can make them. We take an applied approach based on what is logical and practical to apply.
 - Example: One prominent biostatistician leader said of our work on attrition analysis that our unique and logical approach was a great complement to their work as it made the information accessible for a non-statistician payer audience who could not otherwise understand the complexities of what they could communicate.
 - Example: An evidence review for one company was used to modify communication aids, such as slide decks, and resulted in a poster paper that was accepted by a prominent national group.
- Combined, we have more than thirty years of deep expertise working with and directly participating in P&T and medical technology assessment groups. We have seen the dynamics and how individuals can change decisions made by committees. We can provide many insights based on this experience.
- Our lack of bias against industry. Yes, industry has made some mistakes—we do note when a study is industry conducted or funded—but our position is that everyone involved in research should be assumed to be biased. Plus we are aware of the very fine and important work done by industry. So the focus should be on evaluation of the science—not the participation in it.
- Our evidence reviews have been embraced by customers—even knowing of our industry funding—because of our rigor, transparency and quality of our work.
 - Example: We performed a comparative safety review, funded by industry. This review was received favorably by all payers we shared it with because of the high quality of the work and its reporting both in terms of transparency and clarity. Quote: One group said, "I believe we will never *not* be able to have this agent on formulary again." Another group embraced the report and even chose to participate in improving its messaging for clarity.

Example Program ●●●●●●

"FROM SCIENTISTS TO SALES REPS" EVIDENCE-BASED TRAINING CONFERENCE

This 5-day conference, with optional 2-day follow-up, is designed to examine—

- I. What are key drivers in the **universe of the medical decision-maker**?
- II. What constitutes **reliability and clinical usefulness** in medical evidence?
- III. How does **my company's evidence** hold up to scrutiny and how does it compare to my **competitors'**?
- IV. How can I optimize my **communications with my customers**, using an evidence-based approach?

Training Conference Objectives

Attendees will—

1. Better understand the landscape and variation in **medical decision-makers**
2. Increase understanding of the **evidence-based approach** to evaluating published studies
3. Develop greater insight into the wide spectrum of **how published studies and other industry data** are perceived, evaluated and applied by medical decision-makers (including frequent **misunderstandings or misapplications**)
4. **Evaluate** selected studies for reliability, clinical usefulness and potential reporting gaps
5. Gain skills in **preparing for and communicating with** customers and colleagues using evidence knowledge
6. Increase skills in **addressing concerns or issues** raised by medical decision-makers in communications about evidence and study results

Training Conference Highlights

The primary focus for this conference, and the majority of time spent, will be on **critical appraisal of the medical literature**. The secondary focus will be pulling back the curtain on the universe of **medical decision-makers and medical decision-making** and **discussing optimizing communications using evidence-based information and a structured approach**.

In this conference, attendees will **learn critical appraisal principles** and **apply them directly to company-selected studies**. They will also discuss **key talking points** which emerge from their findings. Lastly, studies will be examined for **reporting issues**.

Training Conference Themes

These themes will be addressed—

Value Proposition vs "P-values"

- Who is the **medical decision-maker** and what is their universe?
- How does the medical decision-maker **use (and potentially misuse) clinical evidence & other factors** to make decisions?

Evidence Evaluation for Value: Reliability and Clinical Usefulness

- Why knowing the **reliability and clinical usefulness** of health care information is bedrock.

Optimizing Communications with Colleagues and Customers

- **Health Care Decision-Making Dimensions** = Information + Communication + Engagement + Medical Decision-maker Requirements
- **RRAPP**™ = Research, Reporting, Appraising, Preparing to Communicate and Preparing to Connect
- **Know your** evidence, competitor's evidence, colleagues, customers and customers' cultures and environments.

Training Conference Details

I. Introduction

1. Goals for this training & why
2. The worlds of medical decision-makers
3. Customer reactions to industry-funded studies (and ways to deal with this)
4. Critical appraisal: what it is, why it matters, why interest and application are increasing

II. Know your evidence/know your competitors' evidence

5. Critical appraisal essentials (**many topics**)
6. Case studies
7. Common misunderstandings & pitfalls
8. Using critical appraisal concepts for "just-in-time teaching" communications
9. Other evidentiary issues: connect and disconnect
 - External validity
 - Comparative effectiveness
 - Real world and big (and little) data
 - Economic analysis
 - Evidence sources
10. Critical appraisal exercises
11. Critical appraisal intensive to company-selected studies

III. Know your customer

12. Customer's environment
 - Mission and other drivers
 - Leadership
 - Culture (includes individual, social contexts/connections, etc.)
 - Work elements
13. Medical evidence and the customer

- The evidence-sophistication continuum
- 14. Medical decision-making and the customer
 - Differences in professional worlds: physicians and pharmacists
 - The P&T Committee
 - Leadership/staffers
 - Members
 - Triangulations in making decisions (e.g., evidence, costs, patient-centered care, accreditors, performance measurement, risk management, medical community, public relations, etc.)
- 15. Meeting with the customer: what to do/what not to do/dealing with pitfalls
 - Top evidentiary problem areas cited by payers
 - Some evidence discussions that can resonate
 - Burden of illness
 - Some areas of misconception
 - Gap analysis (e.g., "if cost were not an issue, what are your other issues...?")
 - Closing gaps

IV. Know various communication methods and tools

- 16. Life in the sweet spot versus life in the "gray zone"
 - Keys to successful clinical evidence communications
 - Dealing with variances in evidence sophistication
 - Dealing with strengths and limitations of evidence
 - Published and unpublished information
 - Toggling between strengths, weaknesses, reinterpretations, teaching, listening, perspectives
- 17. Dealing with company slide decks and conducting presentations
- 18. Reporting and reports
- 19. Communication aids: information aids, action aids and decision support

V. Summary

- 20. RRAPP: Research, Reporting, Appraising, Preparing to Communicate and Preparing to Connect

For this program, critical appraisal findings of company-selected published studies will occur in the context of the conference. Optionally, Delfini can do a full evidence review with or without company advisements—Delfini-evidence reviews are priced separately depending upon the project.

Optimally, a 2-day session follows several months later to reinforce information, answer questions, discuss outcomes, etc.

A 3-day option instead of 5-days would involve limited review of company-selected studies, and less time would be spent on considerations other than critical appraisal. A 2-day option is available for critical appraisal only.

Why This Kind of Training Matters

Your customers make decisions based on a variety of factors. The application of medical evidence—its use and misuse—is increasingly a key piece of the decision-making puzzle. And even when it is not, companies that understand the worlds of their customers, their decision-making and potential evidence issues are better equipped to communicate with their customers.

Further, many companies are unaware that, when a rigorous critical appraisal of the medical literature approach is adopted by payers, many studies will not pass—even if published in the best medical journals. Often times this is due to staff not understanding elements that should be addressed in the publication. Sometimes, even a couple of omissions in reporting are sufficient to fail a study.

You may have only one chance to connect. This training can help increase your chances of making your best case and keeping the lines of communication open.

Example: Bias in study design, methodology, execution, performance and reporting can meaningfully distort study results. Many researchers on bias have discovered that, while not always the case, bias usually tends to favor the intervention of interest. Attendees of our critical appraisal conferences learn what these biases are and about this likely effect.

This knowledge can be very useful to industry. Imagine a situation in which one company has some very biased research compared to one that had high quality research supporting its product. It is very possible that the competitor's poor research would make its product appear to be better than it actually is. Depending upon the results, this could result in a payer—who does not understand these effect—thinking the competitor's product is superior. Staff trained in understanding these issues could potentially turn the tide by pointing out the effects of bias and, thereby, keep the door open for discussion.

TESTIMONIALS FROM INDUSTRY ATTENDEES OF DELFINI CRITICAL APPRAISAL TRAINING

- The expert education I have received from Delfini has greatly assisted me and my company in meeting the rigorous clinical detail needed by decision-makers in evaluating new therapies. Delfini's expertise assisted my company in presenting data to decision making experts on new therapies. AN
- The science behind pharmaceutical research and development has been evolving over the last several decades. The science behind reviewing new medications for their societal value has also been evolving at a very rapid pace. The folks at Delfini Group are experts in both worlds and provide an exceptional training program that allows clinical pharmacists and medical management personnel from the payers, as well as medical affairs and account management personnel from the manufacturers, to learn together how this shift in the drug review process, when approached collaboratively, can yield the highest level of product coverage to support the Triple Aim of healthcare reform.

I have attended several of the training seminars conducted by Mike and Sheri. At each event I continue to learn more about how to critically assess the trials of my own products and work with my customer base to understand how they interpret the same information. This interactive style of training allows both parties a chance to better understand the needs of both sides to provide information that would help them make a stronger decision regarding product coverage. BH

- The Delfini seminars have increased my understanding and comprehension of applying the principles of critical appraisal to my work. Their approach to breaking down complex data into practical concepts is exceptional. Sheri and Mike integrate the fundamentals for critical appraisal with timely and relevant evidence-based challenges we face today in the dynamic healthcare landscape. I would highly recommend the Delfini seminars. MB
- It's my opinion that part of the reason that industry has a bad reputation is because most sales people can only speak to the information splashed across glossy marketing pieces AND certainly have no clue how to critically appraise studies. I've found that critical appraisal helps me to best frame the clinical data for my products when I'm talking to physicians. If we have certain clinical data that is particularly good, I know that I can emphasize the validity of the data with confidence. For this reason, I'm very thankful for you and Mike. GW

THE VALUE OF SUPPORTING TRAINING PROGRAMS FOR CUSTOMERS

Doors have opened for industry staff as a result of supporting us training their customers in critical appraisal and evidence-based clinical quality improvement methods. We've experienced at least two instances of major customers—who otherwise refused to see industry staff—change their relationship as a result of hiring us to provide this invaluable training. Industry testimonials follow:

Industry Manager

Name & Company Name Confidential I

National Account Manager

Major Pharmaceutical Firm

I'd like to offer an unequivocal endorsement of the nature and value of the training and programs Delfini produces and delivers. I have known Mike and Sheri for over three years. They have completed six programs directly for customers of mine. These training sessions have contained components of evidence-based medicine, critical assessment of medical literature and communications with providers. The comments from my customers (Clinical PharmD's, and MD's) have been consistently excellent.

In my experience, it has been a pleasure working with Mike and Sheri on both a professional and personal level. They both work extremely hard and have excellent experience and a high level of expertise. They are highly effective trainers and enable people not to just improve their clinical skills, but also to help them feel motivated, confident and inspired.

The training materials that Mike Stuart and Sheri Strite produce are incredibly practical and useful. They have taken time to tailor programs specifically to the requests of my accounts clinical/business needs.

They have gone above and beyond to meet my company's and particularly my clients' expectations. In several cases this has occurred without additional funding for customization, but solely because Mike and Sheri truly believe in their mission of improving the quality of health care. It is clear that they spend many hours updating and refining their materials and presentations.

Mike and Sheri have proven to be a trusted, reliable resource for my company and for my customers. They follow up on requests in a timely manner. Most importantly, they deliver results, as measured by improved clinical performance on the part of my clients and an enhanced reputation for my company for delivering such high level programs.

I highly recommend Mike Stuart, MD, Sheri Strite, Delfini and the programs they develop and present! CV

Industry Manager

Name & Company Name Confidential II

Government Account Manager

Major Pharmaceutical Firm

Sheri Strite and Dr. Mike Stuart have conducted numerous programs for this organization and our strategic customers over the past several years throughout the various segments of our business, and without exception, they have been extremely well received and have consistently garnered the highest praise possible in post program evaluations.

We have had nothing but complete satisfaction with the value they have brought to our organization. They are highly effective trainers not just in enabling people to do the work of critical review of literature and practice and implement evidenced based medicine, but also to feel motivated, confident and inspired.

The materials that Sheri and Mike produce are practical and useful as is the wealth of information on their website which is accessible to participants in the programs.

They have always been willing to customize their work to meet the individual needs of attendees even if that is a deviation from the original concept we jointly established. From my personal attendance at several of the programs, their cutting edge experience and expertise is continually evident, and I would recommend them to your organization. MT

For more information on services for industry—

Short: www.delfini.org/Delfini_Industry_Work.pdf

Web Page: www.delfini.org/delfiniIndustry.htm

For more information on Delfini, go to—

www.delfini.org