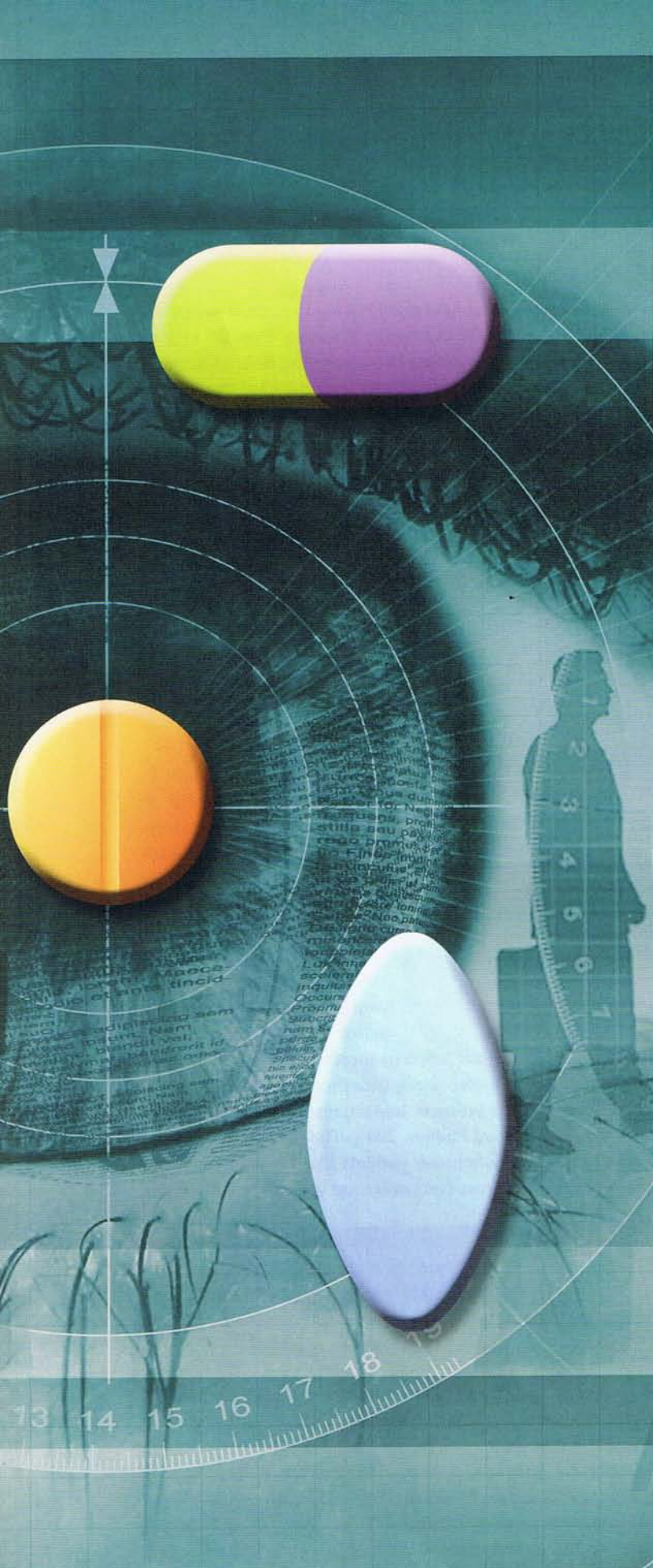


WHAT DRUG DEVELOPMENT CAN TEACH US ABOUT MEASURING LEARNING

by Roy V.H. Pollock, DVM, PhD

Photo-collage by Frederick Knutty



How best to measure the results of training is a hot topic these days, especially as the economic downturn puts even greater pressure than usual on training and development budgets. As learning professionals in pharmaceutical and biotechnology firms, what can we learn from the drug approval process that can help us with the challenge of proving training's efficacy?

There are many similarities between the challenges of proving clinical efficacy of a drug and proving business efficacy of a training program. I have chosen to highlight five:

1. You cannot make a claim if you don't have the data.
2. Someone else decides what counts as success.
3. Both are "high-stakes" evaluations.
4. Both take place in messy real-world situations.
5. Your results have to be better than doing nothing.

NO CLAIMS WITHOUT DATA

The FDA's regulation of pharmaceuticals and biologics was created in response to the unproved and often extravagant claims made for snake oil and "patent medicines" in the 19th century. The majority of these remedies were worthless and some were downright dangerous.

The fundamental premise is that a medicine ought to be safe, pure and efficacious and do what it claims it will do. If you want to make the claim that your drug is effective for such and such a condition, then you have to provide scientifically-sound, unbiased, and statistically-robust data to support that claim. You can't talk about benefits for which you do not have evidence acceptable to the FDA.

What's the parallel for training and development? In essence, we make the claim that "give us your people's time and your money, and we will improve their performance." In an evidence-intensive industry like ours, we ought to have data to back that claim. It need not be anywhere near as exhaustive or as exacting as drug development data, but if we want to command continued investment and respect in research-based companies, we need to show that our treatments really do work.

SOMEONE ELSE DEFINES SUCCESS

In drug development, it does not matter how great your research scientists think a new molecule is. It does not matter how excited sales and marketing are about it—or even what the clinical trial patients and physicians think. The FDA (and only the FDA) gets to decide whether you have adequately supported your claim.

What's the lesson for training and development? It does not matter how great you think your training is. It doesn't even

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really matter how much the participants liked the program or how much they learned. Success is defined by the sponsors (the persons who control the budget), and only by the sponsors. They decide whether or not the program delivered on its promise, met participant needs, and therefore whether or not it merits continued funding.

That means you have to start with the end in mind, not with a particular method. In drug development, the design of the

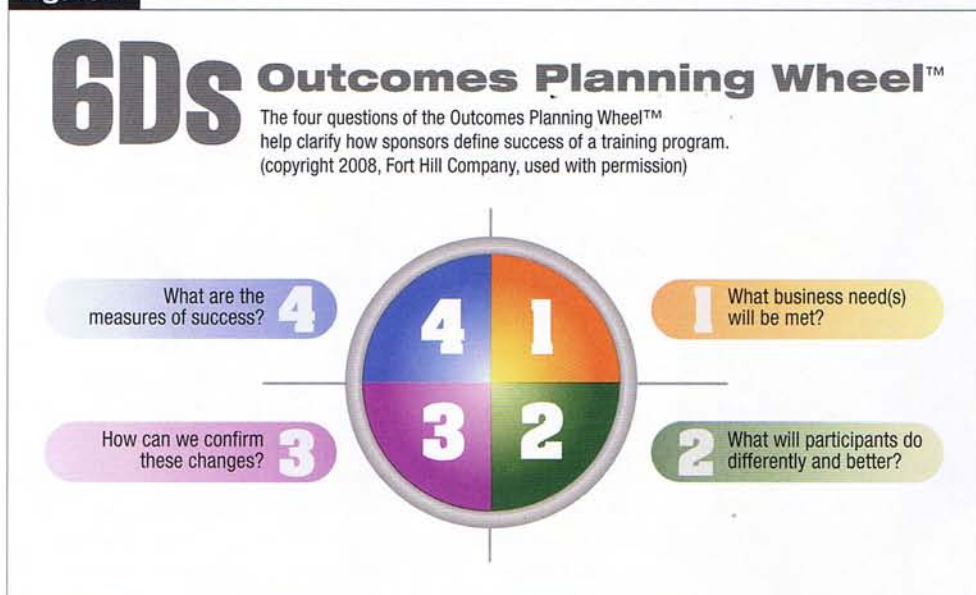
related: behaviors or results that help the organization achieve its objectives. The 6Ds Outcomes Planning Wheel™ (Figure 1) has helped many organizations clarify the desired business outcomes (Wick, Pollock, Jefferson and Flanagan, 2006).

THE STAKES ARE HIGH

A promising new pharmaceutical treatment can be made or destroyed by the way in which the clinical evaluations are designed and conducted. If the resulting data are judged insufficient or inconclusive by the FDA, that can set a product back months or years and cost millions of dollars. Getting it wrong could kill the product or even a company—especially a small start up.

The stakes are high in training or development as well. Generating outcome measures that the sponsor considers irrelevant or insufficient could kill the program or cost you your job, especially in times like these when budgets are tight. And business leaders are not satisfied with the typical

Figure 1



clinical trial follows from the claim that is being pursued. The principles of experimental design apply to all trials, but the specific approach, the data collected, and the analysis follow from the goal of the study.

The same should be true for learning and development. The goals of the evaluation (the outcomes the sponsor wants to see documented) should drive the method employed rather than vice-versa. It is easy for training measurement discussions to get bogged down debating so-called levels or which eponymous method to use and lose sight of the measures that truly matter to the business.

So, forget smile sheets, Kirkpatrick's levels, completion rates, and other learning-centric measures. What really matters is how the decision-makers define success. You have to find out the business outcomes they are trying to achieve through training and what they consider relevant, credible, and compelling evidence that you have supported your claim.

It's not always ROI, by the way, at least not as commonly measured by training organizations (Charlton and Osterweill, 2005), but the real outcome measures of interest are business

measures in place today. A recent survey of Fortune 500 CEOs found that the most important data they want from learning and development is business impact; reaction data was rated dead last (Phillips and Phillips, 2009). The FDA is not going to approve a drug just because patients like the taste; it has to actually work. Likewise, companies are increasingly unwilling

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to invest in learning just because people enjoyed it; they want to see evidence of performance improvement and business-relevant outcomes.

Given the high-stakes nature of drug development, it is in both the company's and the FDA's best interest to have a meeting at the end of Phase 2, before clinical trials begin, to agree on the claims desired, the design of the trials, the data

to be collected, the means of analysis, and the definition of success.

Likewise, because the stakes are high for training and development, learning leaders should sit down with the business sponsors, before training begins, to agree on the data to be collected, the means of analysis, and the definition of success. Nothing is more tragic that to expend the time and effort on an evaluation only to have the sponsor say “that is not what I was looking for.”

Getting drug development trials right is critical, and therefore pharmaceutical and biotech companies have measurement experts on staff, and they never hesitate to consult outside experts about the design and analysis when necessary. Learning organizations should follow suit. Your companies have on staff PhDs, research scientists, Six Sigma Black Belts, market researchers or others with advanced training in study design and analysis; tap their expertise when you need it.

NOTHING IS SIMPLE

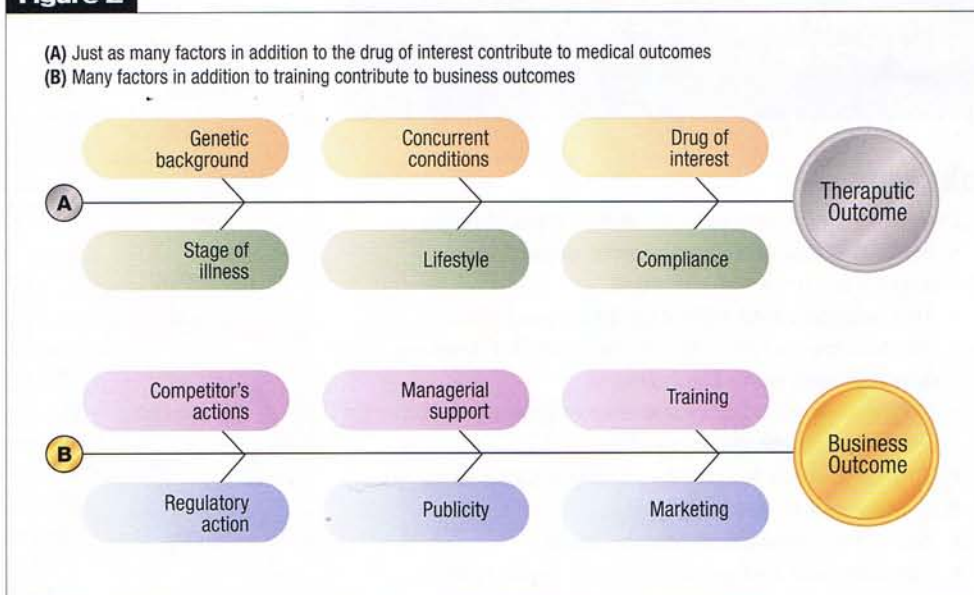
Clinical trials, by definition, have to be conducted in real patients with real diseases in real world situations. But real patients often have other medical problems; they may or may not take their medications as prescribed, or even tell the truth about their symptoms. It doesn't matter to the FDA. If you want your drug approved, you have to show that it does what you claim it does in messy real-world situations. Trials and analyses have to be designed and conducted in a way that convincingly demonstrates the effect of the drug in spite of concurrent conditions and effects.

The analogy to learning and development is that training is only one of many factors that influence business outcomes (Figure 2). Sales training would like to claim, for example, that it contributed to an observed increase in revenue. But so would sales management, marketing, the advertising agency, and anybody else remotely connected with a success. (The opposite is not true, however; if sales go down, everyone will claim they had nothing to do with it).

So, to convincingly demonstrate training's value to the organization, we need to borrow some of the techniques

used in clinical trials to make sure that the right people are admitted to the trial, bias is controlled as much as possible, outcomes are clear, measurements are reliable and so forth. Only then will we be able to convincingly demonstrate the training played a key part in a beneficial outcome. Use the checklist in Table 1 to help you make sure you have included all the key elements of an effective evaluation.

Figure 2



YOUR RESULTS MUST BE BETTER THAN DOING NOTHING

To get a drug claim approved, you have to show that patients treated with the active compound do better than untreated patients (patients treated with the placebo). This can be especially challenging in psychiatric disorders, in which the

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placebo effect can be very strong: many patients on the placebo report significant improvement in their symptoms.

For training to earn continued investment during tough economic times, we have to demonstrate that training is better

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than doing nothing and that it produces “clinically relevant” improvement. In business, that means showing that training contributed in a meaningful way to better performance through more effective or efficient behaviors, greater customer satisfaction, enhanced credibility and willingness to prescribe, and so forth.

We have to provide convincing evidence that it is actually more expensive to do nothing.

SUMMARY

1. Drugs live or die on the outcome of clinical trials.
 - So do training and development departments.
2. It doesn't matter what you think.
 - You have to prove your case to the authorities.
 - For pharmaceuticals, that's the FDA; for training and development, that's the business.
 - They decide whether or not your evidence is sufficiently relevant, credible and compelling.
 - You'd better know how they define success in advance.
3. It is important to get it right.
 - Badly done evaluations can be costly.
 - Plan carefully and get expert help if you need it.
4. Doing nothing is always cheaper.
 - We have to provide convincing evidence that it is actually more expensive to do nothing.
 - That providing training yields greater value for the business.

The challenges of evaluating the beneficial effects of training are, in many respects, similar to the challenges of proving clinical efficacy of a new drug. As learning professionals in the pharmaceutical and biotechnology industry, we should borrow ideas, approaches, expertise, and “lessons learned” from our colleagues in clinical development. Our long term credibility and value will be enhanced by the practice of “evidence-based training and development.”

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Table 1 A check list of the elements of an effective evaluation

Advance Agreement	The way in which the program will be evaluated has been discussed and agreed to with the program's sponsor prior to the evaluation.
Key Indicators	A small number of the key indicators that the program is having a positive business impact have been identified and agreed to.
Early Indicators	The earliest indicators that the program is working have been identified. A plan is in place to use these as in-process checks to drive improvement during the roll-out.
Data Sources	The sources of the data that will be used in the evaluation have been identified.
Data Collection	A plan is in place to gather additional data if they are not already collected routinely.
Comparators	The control or “placebo” - what the post-training results will be compared to, to demonstrate efficacy - has been decided.
Confounders	The factors most likely to confound (obscure or invalidate) the effects of training have been considered. There is a plan to control for them.
Review	The evaluation plan has been reviewed by someone “skilled in the art” for validity and reliability.
Presentation Plan	How the data will be reported and presented has been considered.

From: Wick et al (2008), *The Six Disciplines Workshop Workbook*, used with permission.

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