"Formative Evaluation in the ADDIE Model," Journal of GXP Compliance, Volume 12, Number 4, Summer 2008, pp. 66-73.

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This article is the sixth in a series on training and the ADDIE Model. The first article, "Strategy and Tactics of Task Analysis," appeared in the *Journal of GXP Compliance*, Volume 11, Number 3, April 2007; the second appeared as "The 'Design' Phase of the ADDIE Model," Volume 11, Number 4, July 2007; the third, "Developing Assessments of Trainee Proficiency," appeared in Volume 12, Number 1, October 2007; the fourth appeared as "Strategy and Tactics for Pilot Implementation in the ADDIE Model," in Volume 12, Number 2, January 2008; the fifth, "Strategy and Tactics of Training Recordkeeping," appeared in Volume 12, Number 3, Spring 2008.

GENERAL INTRODUCTION

The ADDIE model provides high-level guidance for the development and revision of programs of all sorts, including GXP training programs. The phases of the ADDIE model are analyze, design, develop, implement, and evaluate. These phases are sequential; each depends upon the successful completion of the preceding phase.

The analysis phase of the ADDIE model identifies a performance gap that can be addressed by a training program (i.e., a set of training and assessment materials, a qualified trainer, and a training audience). A performance gap is a discrepancy between a standard stipulated in a standard operating procedure (SOP) and some employee performance (1).

This is followed by the design phase, where a carefully planned approach, documented in a training outline, is prepared to address the performance gap. Also, behavioral objectives are specified in the design phase (2).

If management approves the design, the development phase comes next, where the training program—the training materials and the assessment materials—is developed to address the performance gap. There are four components of the development phase: identifying the objectives of the training module, based on the relevant operational SOP and the training outline; preparing the training materials, with special attention to structured on the job training (SOJT) materials and e-learning materials; preparing the assessment materials; and assembling these materials into the training program (3).

The implementation phase of the ADDIE model follows, where the training materials and assessment materials are rolled out, either provisionally in a pilot implementation (e.g., a proof of concept study) or in a final implementation. The notion that this phase may be a "pilot" of the training module, rather than just a finalized rollout, highlights the iterative feature of the model (4).

The evaluation phase follows implementation. In the case of a pilot implementation, the results of the program evaluation can be fed back, closing the loop, facilitating further refinement of the training program. This is called a "formative evaluation." As Robert Gagné and Leslie Briggs have stated (5), "Formative evaluations provide data on the basis of which to revise and improve the materials, the lesson plans, the performance tests, and indeed the operation of the entire instructional system." If the evaluation shows that the training module has shortcomings, those shortcomings are fed back to be analyzed again. Further design and development efforts follow, until the module meets organizational needs. Thereupon there is a final implementation, and an evaluation that documents the extent to which the training program meets the

organization's needs. This is called a "summative evaluation." "Summative evaluation is usually undertaken when development of an instructional entity is in some sense completed, rather than on-going. Its purpose is to permit conclusions to be drawn about how well the instruction has worked," state Gagne and Briggs (6).

The ADDIE model can be conceptualized as having two paths out of the development phase. One path leads to pilot implementation, followed by formative evaluation, from which a feedback loop allows further analysis, design, and development. At some point, determined by management, the training program is judged to be ready for the other path. As Gagne and Briggs (7) have pointed out, "There is no standard number of formative evaluations that small components or segments or the entire system undergo. The number depends on the budgets and time available, the degree of excellence set as the system design objective, and the total circum- stances surrounding the project." The program then moves to final implementation, followed by summative evaluation (see Figure 1).

There are several ways to conceptualize the ADDIE model at this point. One is to include pilot implementation and formative evaluation within the development phase. When the pilot and the formative evaluation are completed, the program moves into the (final) implementation phase, followed by the (summative) evaluation phase. Another conceptualization is to include two types of implementation, pilot and final, within the implementation phase, and two types of evaluation, formative and summative, within the evaluation phase. These different conceptualizations bear on the logic of the ADDIE model, but not on the process of program development.

As a final introductory point, it is clear that management has one very significant role in a formative evaluation; that is specifying the overall goal, and level of effort, for the evaluation. What might be management's response to evaluative findings gathered during the formative evaluation of a program? The response of the program designers and developers to evaluative findings is clear; they will consider making program improvements based on the evaluative findings. What about the response of management?

FEEDBACK VERSUS RESEARCH DESIGN

The question often arises in the formative evaluation of a training program or other program: what is the effect of the dissemination of evaluative findings during the life of the program? It is often assumed that the "experimental design" dictates that intervention (e.g., training materials, training "script," etc.) must remain invariant during the program cycle. Friedman, Furberg, and DeMets (8) state that a clinical trial study protocol "should be developed before the beginning of subject enrollment and should remain essentially unchanged except perhaps for minor updates. Careful thought and justification should go into any changes. Major revisions which alter the direction of the trial should be rare." If preliminary findings were fed back, this would allow a modification of the training materials and other aspects of the program, thus invalidating design and the evaluative research findings.

This position has until recently been held regarding clinical trials in the pharmaceutical industry. As Derek Lowe (9) has expressed it, in a clinical trial, you "establish your 'null hypothesis' (typically that your drug is no better than a placebo or the current standard of care) and you start collecting data, in the hopes that you'll fail to prove it. Everything stays carefully blinded. The investigators have no idea what they're administering and the patients have no idea what they're taking until a predetermined endpoint—to do otherwise would destroy the statistics." Notice the significance of "blinding" in

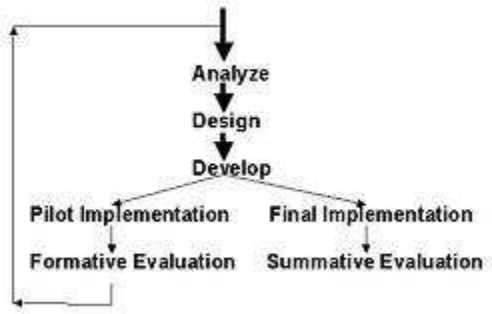

Figure 1: The two paths of the ADDIE model

clinical trials, particularly "double blinding," where both subjects and investigators are unaware of the assigned intervention—whereby findings for program improvement cannot straightforwardly be fed back (10). In contrast to the logic of blinding, the actual conduct of blinding in randomized clinical trials (RCTs) has been assessed in several recent studies, including Boutron et al. (11) and Fergusson et al. (12).

This position has been held by researchers outside the field of clinical trials as well: Michael Brooks (13) states that continuous feedback of evaluative findings ". . . has the unfortunate effect of tossing a monkey-wrench into the research design constructed at the program's outset." Daniel Stufflebeam, a leading figure in the evaluation community, describes (14) the development of his own position, "I had to reject basically everything I had thought necessary for evaluating educational projects, including behavioral objectives, experimental designs, and standardized tests. Instead, I advised educators to key evaluations to provide information for decision making."

The argument against the "experimental method" is a methodological, not a practical argument (15). The critics of experimental design are speaking of characteristics inherent to evaluation theory that account for a sharply limited utility. The critics are not suggesting that formative evaluation would be more successful if the experimental designs were more precisely constructed, if randomization of subjects were more diligently pursued, or if experimental methods were more carefully practiced. According to the critics, experimental method in program evaluation, especially RCT, is defective.

The importance of this matter can hardly be overstressed. As indicated above, feedback of evaluative findings is of vital importance for improving the process in training and development. If there is an incompatibility between feedback and the "experimental method," one obviously must be abandoned. But to abandon the former, evaluators forego their mandate to provide timely and relevant information for program adaptation. To abandon the latter, they seriously limit the research techniques they have available for evaluating the program; instead of Donald Campbell and Julian Stanley's famous "Experimental and Quasi-experimental Designs," the formative evaluator is restricted to just the quasi-experimental designs and even more inferior approaches, such as "pre-experimental designs" (16). As Green states, "RCTs are the gold standard of treatment trial methodology, and to deprive complex (often psychosocial) interventions of their imprimatur is potentially to undervalue these areas in an evidence-based climate (17)." Moreover, this limitation sacrifices what rigor the evaluators' discipline has. We find, however, that the critics of "experimental design" have misplaced their criticism.

The next section will give an existence proof that formative evaluation can be conducted within the framework of experimental design, and evaluative findings can at the same time be provided for improvement of the training program. This means that the full range of evaluative approaches is available to the formative evaluator, including experimental designs (i.e., RCT) as well as quasi-experimental designs.

THE GOOD NEWS, PART 1

It is not the case that training intervention must remain invariant. Program enhancement, in light of feedback from a formative evaluation, can take place concurrently with an evaluation in the framework of the RCT experimental design. Of course, desirable modification practice does not (or should not) mean a hodgepodge array of "random" interventions resulting from poor program definition; this should have been preempted in the design phase of the ADDIE model. Nor should "random" interventions result from the capacity of those who implement training programs to understand adequate definitions; that should have been addressed in the implementation phase (18). It makes no difference, for the experimental method, whether an evaluative judgment of program ineffectiveness is available for program adaptation or not. It makes no difference, for the experimental method, whether changes in training intervention are implemented or not. Evaluators can fill their mandate for dissemination of timely data and concomitant programmatic change.

The evaluator can realize, based on an on-going program evaluation, that "training intervention G will not produce the desired results." The intervention can be revised in the "middle of the stream," so to speak, and evaluators can still complete their formative evaluation.

The dissemination of evaluative findings through an appropriate study monitoring committee, and a managerial reaction to such findings, enhancing the likelihood of program success, will not invalidate the evaluation effort, even though an initial judgment predicted program failure. Only a misunderstanding of the nature of evaluative research could foster the view that the training intervention is fixed.

Assume that an evaluation of a training program is underway. The program, in essence, takes a set of inputs and given conditions, Z, and by means of some process G, transforms the inputs into an output described by the dependent variable x. We assume x to be a behavior. The dependent variable may be a business measure, such as number of reworked batches, or an index, such as OSHA recordables. The evaluator is randomly assigning employees to control or treatment groups, manipulating variables, recording and communicating results, etc.

Thus behavior x is a function G of a complex state of affairs z, given by

$$x = G(z). \text{ [Equation 1]}$$

This says G and an index z of the set of independent variables Z are sufficient for the prediction of the dependent variable x, in the absence of dissemination of G or z. This can be represented by a two dimensional diagram (see Figure 2).

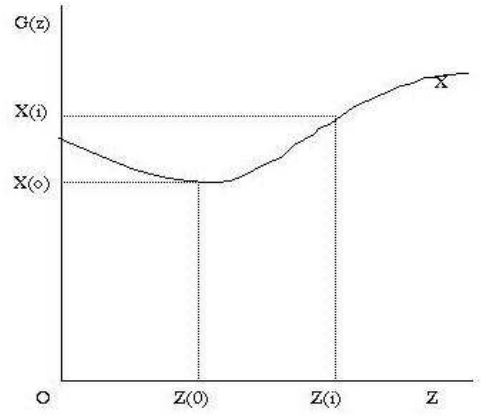

Figure 2: Performance levels of hypothetical program.

We note that for a given interval [z(o), z(i)], x will have a range of [x(o), x(i)]. Thus z might be an index of prior training history, on-the-job experience, etc. and x, a measure of productivity such as unit output, impounded batches, or quantity reworked. The set Z would include such items as appear in the employee's training history, etc. We assume throughout that the interval of x is continuous and closed.

THE COEXISTENCE OF RCT AND DISSEMINATION OF RESULTS

Consider the following scenario. G is the training and qualifying process, exemplified in a particular training program and including training materials, training "script," etc. Through an appropriate channel such as the study monitoring committee, the program manager has discovered a credible RCT evaluation report indicating that some aspect of G was tending to increase the quantity of rework. Say this aspect was the hour in the shift (i.e., whether the training event occurs early in the shift or late). Say further that the manager would be held accountable for the increase of rework. Then the manager might react to the report and implement a change from G to G*. An example of such a change would be mandating all training programs be offered early in a shift. Then the output, rather than being x would be x* (19).

Let a reaction function R be introduced, indicating the dependence of the actual outcome x* on the program manager's knowledge of the disseminated judgment (or prediction) of x. This is given by

$$x^* = R(x) \text{ [Equation 2]}$$

Given the relevant range [x(o), x(i)], we can represent the reaction function by a two-dimensional diagram (see Figure 3).

With the variance of x through the range x(o), to x(i) will be associated a variance of x* between x(o)* and x(i)*. If R(x) is continuous over [x(o), x(i)], and if R(x) is bounded (i.e., $0 < R(x) < F$) then by the generalized Brouwer Fixed-point Theorem there exists at least one x and one x* such that, $x = x^*$. Also, for $x = x^*$, the system described by equations 1 and 2 is in equilibrium (20) (i.e., the manager will cease to react to x). Thus, for $x = x^*$, that value of x is the correct public

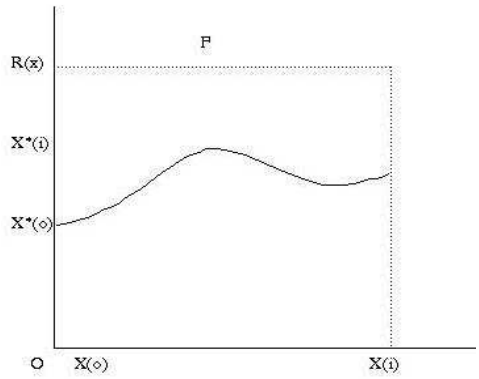

Figure 3: Reaction function for hypothetical program.

prediction, as well as the correct formative evaluative judgment.

In this section, we have shown that formative evaluation can be conducted within the framework of experimental design, and evaluative findings can at the same time be provided to the manager of the training program that is being evaluated, via the study monitoring committee or another appropriate channel. This means that the full range of evaluative approaches is available to the formative evaluator, including not only quasi-experimental designs but experimental designs (i.e., RCT) as well.

THE GOOD NEWS, PART 2

The preceding material incorporated an existence proof, showing that under specified conditions, training program modification could take place in response to evaluative findings developed within an experimental design. The following questions can still be raised: What are the implications of this for evaluation practice? Does anyone care? The answer to these questions is yes.

Let us look at a methodologically analogous situation, that of clinical trials of investigational new drugs. There is a long history of interest in adaptive designs in clinical trials, dating from Abraham Wald's pioneering researches in the 1940s (21). The US Food and Drug Administration has expressed interest in adaptive clinical trials and the associated research designs. The dilemma of clinical trials has been described well by Lowe: *"In too many cases, the chief result of a trial is to show that the trial itself was set up wrong, in ways that only became clear after the data were unblinded. Did the numbers show that your dosage was suboptimal partway into a two-year trial? Too bad—you probably weren't allowed to know that. Were several arms of your study obviously pointless from the start? Even if you knew, what could you do about it without harming the validity of the whole effort?" (22)*

The problem is to conduct clinical trials so that both the rigor of the experimental design (RCT) will be maintained throughout, and program revision can occur, based on the timeliest data. And, methodologically speaking, that is precisely the problem cited by Lowe, with reference to the evaluation of training programs.

As Scott Gottlieb, FDA Deputy Commissioner for Medical and Scientific Affairs, has expressed it, FDA is interested in "adaptive sampling designs, including response-adaptive designs for statistical experiments, where the accruing data from experiments—the observations—are used to adjust the experiment as it is being run (23)." He goes on to say "the advantages of these approaches, rigorously designed, are becoming more evident, including among the ranks of our experts at FDA. It's essential that we at the FDA do all we can to facilitate their appropriate use in modern drug development." Gottlieb discusses several adaptive approaches to the design of experiments including the following:

• In an adaptive clinical trial, patient outcomes can be used as they become available to adjust the allocation of future patients or some other aspect of the study design

• A second type of adaptive trial design involves on-going assessment of the sample size, to avoid under- or over-allotment of patients (24)

• [Another includes] seamless designs that allow learning to be more iterative and less method-limited. That allow continuous discovery that isn't defined by phases but rather by what we learn as we go (25).

Gottlieb acknowledges that "adaptive approaches are not a panacea to all of our challenges, and enabling them is not a sure thing. Adaptive procedures are more complicated to design and to analyze, and in some settings

are more difficult to implement." Moreover, he is well aware of "trepidation about the use of adaptive features and reluctance to consider a variety of enrichment and adaptive designs. In many cases, researchers are still unaware of the option to use adaptive designs because standard statistical courses and packages do not include them." (op. cit.)

There are political and ethical issues here as well. "Purists will argue that changing a trial midway through a study somehow benefits pharmaceutical companies by potentially allowing them to manipulate results. Some worry that bias is more likely when results are known during the trial, compared with keeping trials blind," notes Steve Zisson (26). Concrete proposals are under consideration to mitigate such worries (27).

Since FDA is interested in adaptive designs for the study of investigational new drugs, it is unlikely they would object to the use of adaptive designs in the formative evaluation of training programs. What works for clinical trials can just as well work for the evaluation of training initiatives.

Several uses of such adaptive designs include the following:
• The formative evaluator can communicate interim training outcomes through a channel such as the study monitoring committee to the program manager, allowing timely revision of the training intervention, including revision based on comparison of programmatic alternatives
• The evaluator can use interim training outcomes to allow more effective assignment of trainees to particular training sessions, for example by sequential sampling.

"The manner of conducting formative evaluations varies widely," state Gagné and Briggs (28). We are suggesting that one approach to formative evaluation of training programs is utilizing an adaptive RCT design. "Quantitative data are definitely necessary for formative evaluation," state Gagne and Briggs (29).

The steps in conducting a formative evaluation can be summarized as follows:
• The first step is to develop a formative evaluation plan for the training module, including an evaluation design, and any evaluative instruments
• The second step is to collect evaluative data as you begin to pilot the training module, including data from both the pilot trainees and from your training and development peers
• The third step is to review all the evaluative data you have gathered, in light of the statistical portion of the formative evaluation plan
• Then, prepare an evaluation report summarizing the evaluations; propose revisions to the training module
• Get the study monitoring committee as well as management approval of these revisions
• The sixth step is to utilize the feedback for program improvement
• Then, continue the pilot (with further adaptations as required), until management is satisfied that the training module meets the organization's needs.

The essence of this process is the negotiation between the evaluator and program manager. This negotiation works towards a settlement that takes into account both methodological rigor on the one hand, and program goals and values on the other.

MANAGEMENT'S PREROGATIVE

Management has an overarching role in a formative evaluation. That role is to specify the overall goal, and level of effort, for the evaluation. What does management want from this evaluation? There is a range of possibilities here. Does management want the most credible evaluative report possible? Or does management want the most blatant problems in the pilot project to be corrected? The evaluator must negotiate with management to determine the actual goal.

Once management's goal is set, the evaluator can recommend approaches to aspects of the formative evaluative design, such as the following:
• Parallel group or cross-over design
• Recruitment of trainees
• Random assignment
• Blinding
• Sample sizes
• Statistical analyses.

With recommendations of costs and benefits of each approach, management can decide between

the approaches. A memorandum of understanding between management and evaluator can then be prepared, including a statement of the level of effort that will be required to attain the goal that management has set.

At that point the evaluator can begin to plan the logistics of the formative evaluation. The primary audience for this evaluation will be the instructional designer who will make program revisions as warranted.

CONCLUSION

This article has reviewed the possibilities for formative evaluation of training programs as well as any other kind of program, within the framework of the ADDIE model. It can be concluded that the formative evaluation of training programs can utilize the full range of experimental and quasi-experimental designs, as well as any other approaches. In this paper, the possibilities of employing adaptive designs have been considered. Thereby, the data gathered in that evaluative effort can at the same time be made available to management, during the course of the training process, to allow decisions to be made about program improvement. FDA has recently expressed interest in the use of adaptive designs in clinical trials.

This does not mean that the evaluator must use any particular design or approach. While the full range of methods and techniques is available, the decision about which of those techniques and methods will depend upon two factors. One is management's goal for the evaluation; the other is the needs of the main audience of the formative evaluation, namely the needs of the instructional designer who will revise the training program. The formative evaluation and re-piloting of the training module can continue until management has decided that the needs of the organization have been met. Once the formative evaluation has been completed and all necessary changes to the module have been made, it is time to move to final implementation of the training program.

ENDNOTES

1. Gordon Welty, "Strategy and Tactics of Task Analysis," *Journal of GXP Compliance*, Vol. 11, No. 3, April 2007, pp. 26-34.
2. G. Welty, "The 'Design' Phase of the ADDIE Model," *Journal of GXP Compliance*, Vol. 11, No. 4, July 2007, pp. 40-52. See also John W, Hansen, "Training Design," *Advances in Developing Human Resources*, Vol. 8, No. 4, November 2006, pp. 492-499.
3. G. Welty, "Developing Assessments of Trainee Proficiency," *Journal of GXP Compliance*, Vol. 12, No. 1, October 2007, pp. 64-73.
4. G. Welty, "Strategy and Tactics for Pilot Implementation in the ADDIE Model," *Journal of GXP Compliance*, Vol. 12, No. 2, January 2008, pp. 12-19.
5. Robert Gagné and Leslie Briggs, *Principles of Instructional Design* (2nd ed) NY: Holt, Rinehart and Winston (1979), p. 37; see also p. 290: "Evidence of an instructional program's worth is sought for use in making decisions about how to revise the program while it is being developed. In other words, the evidence collected and interpreted during the phase of development is used to form the instructional program itself."
6. Gagné and Briggs, op. cit., p. 293. See also Joseph S. Wholey, "Formative and Summative Evaluation: Related Issues in Performance Measurement," *Evaluation Practice*, Vol. 17, Issue 2, Spring 1996, pp. 145 ff. and Greg Wang and Diane Wilcox, "Training Evaluation," *Advances in Developing Human Resources*, Vol. 8, No. 4, November 2006, pp. 528-539, esp. pp. 529-530.
7. Gagné and Briggs, op. cit., p. 38.
8. Lawrence Friedman, et al., *Fundamentals of Clinical Trials*, Boston: John Wright, 1981, p. 6.
9. Derek Lowe, "Adaptive Trials," *Pharmaceutical Executive*, Vol. 26, Issue 7, July 2006, pp. 70-77, esp. p. 72.
10. See, for example, Kathryn Webert, "Treatment Allocation in Clinical Trials," *Transfusion*, Vol. 47, Dec. 2007, pp. 2187-2188, also Damian McEntegart, et al. "Blinded by Science with Adaptive Designs," *Applied Clinical Trials*, Vol. 16, Issue 3, March 2007, pp. 56-64. A classic statement is found in Friedman et al., op. cit., pp. 58-67.
11. Isabelle Boutron, et al., "Methods of Blinding in Reports of Randomized Controlled Trials Assessing Pharmacologic Treatments," *PLOS Medicine*, Vol. 3, Issue 10, October 2006, pp. 1931-1939.
12. Dean Fergusson, et al., "Turning a Blind Eye: The Success of Blinding Reported in a Random Sample of Randomized, Placebo Controlled Trials," *British Medical Journal*, Vol. 328, February 2004, p. 432.
13. Michael P. Brooks, "The Community Action Program as a Setting for Applied Research," *Journal of Social Issues*, Vol. 21, No. 1, 1965, p. 38; see also Susan Jacobson, Julie Morris, J. Scott Sanders, Eugene Wiley, Michael Brooks, et al., "Understanding Barriers to Implementation of an Adaptive Land Management Program," *Conservation Biology*, Vol. 20, No. 5, 2006, 1516–1527, esp. p. 1518: "Adherence to an experimental design […] may preclude

some of the flexibility managers have experienced previously."
14. Daniel S. Stufflebeam, "The CIPP Model for Evaluation: An Update," Presented at the 2003 Annual Conference of the Oregon Program Evaluators Network (OPEN), Portland, OR, October 3, 2003. See also his early "The Use and Abuse of Evaluation in Title III," *Theory into Practice*, Vol. VI: 3, 1967, p. 128: "the application of experimental design to evaluation problems conflicts with the principle that evaluation should facilitate the continual improvement of a program. Experimental design prevents rather than promotes changes in the treatment because treatments cannot be altered in process if the data about differences between treatments are to be unequivocal." Subsequently, in "MetaEvaluation," *Occasional Paper Series*, No. 3. Kalamazoo, MI: Evaluation Center, Western Michigan University, 1975, p. 54, he maintained that "experimental design often would not provide timely feedback for decision making." See also his "Evaluation Checklists," *American Journal of Evaluation*, Vol. 22, Issue 1, Winter 2001, p. 72: "almost everything I had learned about experimental design, measurement, and statistics was largely irrelevant to evaluating new, heavily funded, but ill-defined projects […] Gradually, I began to evolve an approach to evaluation that seemed to work […] The approach was directed to designing evaluations that would address stakeholders' evaluative questions and provide them a flow of timely, relevant information."
15. On the often misused term methodology, cf. Fritz Machlup, "Papers and Proceedings," *American Economic Review*, Vol. 53, 1963, p. 204.
16. Donald T. Campbell and Julian C. Stanley, *Experimental and Quasi-experimental Designs for Research*, Chicago: Rand McNally, 1963.
17. Jonathan Green, "The Evolving Randomized Controlled Trial in Mental Health," *Advances in Psychiatric Treatment*, Vol. 12, 2006, p. 270.
18. As Gallo et al. have put it regarding desirable modification practice, "changes are made 'by design,' and not on an ad hoc basis; therefore, adaptation is a design feature aimed to enhance the trial, not a remedy for inadequate planning;" see Paul Gallo, et al. "Adaptive Designs in Clinical Drug Development," *Journal of Biopharmaceutical Statistics*, Vol. 16, Issue 3, June 2006, pp. 275- 283, esp. pp. 276. On the project management requirements this raises for the roll-out and maintenance of a training program, see John N. Fabac, "Project Management for Systematic Training," *Advances in Developing Human Resources*, Vol. 8, No. 4, November 2006, pp. 540-547.
19. The general treatment of these cases is given in Emile Grunberg, "Some Methodological Observations on Macroeconomics," *Konjunkturpolitik*, Vol. 13, 1967, pp. 34-37. Cf. also E. Grunberg and Franco Modigliani, "The Predictability of Social Events," *Journal of Political Economy*, Vol. LXII , 1954, pp. 465-478.
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22. Derek Lowe, "Adaptive Trials," op. cit., p. 72
23. Scott Gottlieb, "Remarks," Speech before the 2006 Conference on Adaptive Trial Design, Washington, DC, July 10, 2006. See also Anna W. Mathews, "FDA Signals It's Open to Drug Trials That Shift Midcourse," *Wall Street Journal*, July 10, 2006.
24. See also Paul Gallo, op. cit., pp. 281-282.
25. See also Paul Gallo, op. cit., pp. 280-281.
26. Steve Zisson, "Adapting To A New Kind Of Trial," *Clinical Trials Today*, 17 July 2006.
27. See Paul Gallo, op. cit., pp. 278-279.
28. Gagné and Briggs, op. cit., p. 290.
29. Gagné and Briggs, op. cit., p. 291.

ARTICLE ACRONYM LISTING

ADDIE Analyze, Design, Develop, Implement, Evaluate
FDA US Food and Drug Administration
RCT(s) Randomized Clinical Trial(s)
SOJT Structured On the Job Training
SOP(s) Standard Operating Procedure(s)

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