Paper P018

Promotion Response Analysis in the Pharmaceutical Industry –Lessons to be Learned From Clinical Trials Methodologies

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Abstract

In 2002 the pharmaceutical industry spent close to $10 billion marketing their medicines to physicians. Pharmaceutical promotional events include dinner meetings, symposia, speaker training, teleconferences, web casting, conferences, detailing and samples. Depending on the evaluation methodology results on return on investment, ROI, will vary. Matching offers a method to build comparable groups of tests and controls for retrospective or prospective studies. However, within different matching techniques the accuracy and quality of matches will vary.

It is common to find groups within the same pharmaceutical company working in silos, using different approaches to similar research projects, and not communicating among them selves to compare ideas that will help build efficiencies and synergies. Analytical groups within same Pharmaceutical company will benefit greatly from sharing ideas concerning research and statistical methods. This paper will present an overview and results from different matching methods when analyzing pharmaceutical promotional programs with a special emphasis about the benefits of using the clinical trials research rigor and methods to improve promotion response process.

Results of a pharmaceutical promotional program impact analysis using; 1) Pre & Post Measurement, 2) Euclidean Distance Matching, 3) Mahalanobis Distance Matching, 4)Propensity Scores Matching, 6) Mahalanobis and Propensity Scores with Calliper Matching will be used to illustrate the advantages of in achieving greater bias reduction for measuring promotion response. In addition, benefits of sharing information about methods between business analytics and clinical trials groups are discussed.

2.1 Matching Methods Overview

Just as in a clinical trial patient selection is an important part of the study promotional pharmaceutical programs should build appropriate comparison groups when targeting physicians, patients or institutions for product promotional purposes and measuring ROI when appropriate[i]. Considering and integrating the appropriate evaluation methodology play a major role in determining the success of a promotional program.

Test & Control matching is used to measure the program effectiveness by comparing program participants, the tests, against a comparable (with similar characteristics) group of non-participants the control group. However, lack of emphasis on participant selection and tracking in the planning and execution stage of promotional programs poses tremendous challenges for promotion response analysis.

Matching offers a method to build comparable groups of participants and non-participants for retrospective or prospective studies. In the prospective analysis scenario, matching is a good method to create a well-balanced design experiment. In the retrospective analysis case, matching provides a method for finding a comparable group for the participants in the program and measure the program effect while reducing bias. Frequently many retrospective studies focus on reducing bias through matching and no estimation of the amount of bias reduced by a particular matching method is discussed. Cochran[ii] describes a method for estimating the percentage bias reduction in matching. Later in the article Cochran approach will be described in more detailed.

In the pharmaceutical marketing area the majority of retrospective studies are driven by the need to show results and organizations fall in two categories: Those that need to show results as a retroactive exercise in response of management request to know in a quantifiable fashion if the program worked and those that plan to show results prospectively because they believe in improvement and true accountability. The proactive group will contribute greatly to the success and improvement of the project.

Some of the most common evaluation methods used are:
1. Pre & Post Measurement
2. Frequency Matching
3. Standardized Euclidean distance Caliper Matching
4. Propensity Score Caliper Matching
5. Mahalanobis distance Caliper Matching

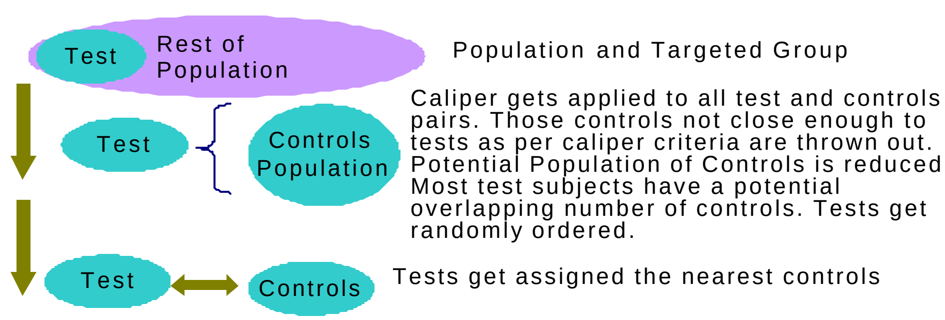
In the Pre & Post Measurement method, the treatment group is its own control introducing threats to the internal validity of the design. This is the least desirable of the methods. Frequency Matching finds a control group wit the same frequency distribution as the test group in the chosen matching covariate. This can be as a one to many matches or one to one match, A one to one frequency matched will be equivalent to a categorical match. The Standardized Euclidean distance Caliper Matching, Propensity Score Caliper Matching, and Mahalanobis distance Caliper Matching are methods that find one to one, test and control matching pairs by selecting the control with the distance, within a margin or caliper matching, to the test. The distance between tests and controls being defined as the Euclidian, propensity score or Mahalanobis distance based on the matching covariates.

1.1 Caliper Matching

Caliper Matching is a pair matching technique that attempts to achieve comparability of the treatment and control groups by defining two subjects to be match if they differ on the value of the numerical confounding variable by no more than small tolerance, E. That is $|x_{test} - x_{control}| \le E$.
The caliper E is used to create a pool of controls from the entire control population. Each test subject has a subset of controls that are within the caliber limits. Different tests may have some of the same possible controls in their controls set. Test and control pairs are chosen in the following way:

1. Randomly ordered test subjects.
2. For the first subject in the test group find all the available controls that are within the caliper limit. Match the test subject with the control subject with the nearest value of the matching variable.
3. Remove the test and control pair found in 2 and repeat step 2 until no more test subjects are available.

In general the procedure is



1.2 **Cochran Bias Reduction Analysis**

In an article published in 1973 in The Indian Journal of Statistics, Sankjya, titled “Controlling Bias in Observational Studies: A Review” Cochran and Rubin discussed the effect of the variance of the matching variable, x, with respect to the percent bias reduction.

They define the amount of intitial bias in x as :

$$B = \frac{(\eta_1 - \eta_2)}{\left(\frac{\sigma_1^2 + \sigma_2^2}{2}\right)^{\frac{1}{2}}}$$

Where :

$\eta_1 \Rightarrow$ Mean of test group

$\eta_2 \Rightarrow$ Mean of control pool

$\sigma_1^2 \Rightarrow$ Variance of matching variable in the test group

$\sigma_2^2 \Rightarrow$ Variance of matching variable in the control pool

They defined the caliper, e, as : $e = a\sqrt{\left(\frac{s_1^2 + s_2^2}{2}\right)}$

Percent Reduction in Bias of x for Caliper Matching to Within + or - **E** with normal x

a	$\sigma_1^2 / \sigma_2^2 = \frac{1}{2}$	$\sigma_1^2 / \sigma_2^2 = 1$	$\sigma_1^2 / \sigma_2^2 = 2$
0.2	0.99	0.99	0.98
0.4	0.96	0.95	0.93
0.6	0.91	0.89	0.86
0.8	0.86	0.82	0.77
1	0.79	0.74	0.69

A tight matching (a=0.2) removes practically all the bias, while a lose matching (a=1.0) removes around 75%

The results hold for B<0.5 but for B between 0.5 and 1, the percent reductions are only 1 to 1.5% lower than the figures shown above

Their analysis indicates that the more homogeneous the test group is compared to the control the easier to find a suitable control group and greater bias reduction. In other words in the test group is all over with regards to the matching variables or has higher variance than the control pool it will be very hard to come up with good controls. Estimating the initial bias, variances and using the table above can be used as a guidance as to estimate the amount of bias reduction given by given method. The above analysis assumes variance derive from variable normally distribute it and complete matching.

If univariate analysis shows the data not being normally distributed. A transformation must be considered. G.E.P. Box and D.R. Cox[iii] in their 1964 paper suggested the following transformation to for non normal positive data:

$$x(l) = \frac{(x^l - 1)}{l},\ l \neq 0$$

$$x(l) = \ln(x),\ l = 0$$

l will be the value at which the log likelihood, LL, function gets maximized. The LL function is given by:

$$f(x,l) = -\frac{n}{2}\ln\left[\sum_{i=1}^{n}\frac{\left(x_i(l)-\bar{x}(l)\right)^2}{n}\right] + (l-1)\sum_{i=1}^{n}\ln(x_i) \quad \text{where} \quad \bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i(l)$$

1.3 Mahalanobis Distance

The Mahanobis distance is a distance measure that computes the square distance between two points in an abstract multidimensional space. It is based on correlations between the variables and by which different patterns could be identified and analyzed with respect to base or reference point[iv] .

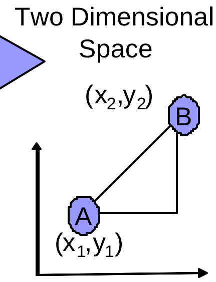
Euclidian Distance

$$d = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2} \text{ in 2 dimensional space}$$

$$d = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2 + \ldots + (y_p - y_p)^2} \text{ in p dimensional space}$$

Mahalanobis Distance

$$\mathrm{d} = \sqrt{(\mathrm{x}-\mathrm{y})^t S^{-1} (x-y)} \text{ in p dimensional space}$$



1.4 Propensity Score

Rosenbaum and Rubin defined the propensity score as the conditional probability of assignment to a particular treatment given a vector of observed covariates[v]

Propensity Score Caliper Matching is similar to caliper matching in that test and controls pairs are select based on their propensity score closeness within a caliper.

$$\left| p_{test} - p_{control} \right| \leq e$$

$$p(\text{Attend} \mid x_1, x_2, \ldots x_n) =$$

Probability that would attend given "n" number of covariates, characteristics,

Where $x_1, x_2, \ldots . x_n$ are covariates that can be used to predict the likelyhood or probability that some one would attend or particpate in an event

For example :

$x_1 \Rightarrow$ Baseline NRx

$x_2 \Rightarrow$ Baseline TRx

$x_3 \Rightarrow$# of Details

$x_4 \Rightarrow$# of Samples

$x_5 \Rightarrow$# of Events Attended

One functional form commonly used for the propensity score is the logistic probability function that has the following exponential form:

$$p\left(\text{Attend}\middle|x_1, x_2,...x_n\right) = \frac{e^{\left(\beta_0+\beta_1 x_1+\beta_2 x_2+....+\beta_n x_n\right)}}{1+e^{\left(\beta_0+\beta_1 x_1+\beta_2 x_2+....+\beta_n x_n\right)}}$$

After taking the natural log, it acquires a linear form and becomes:

$$\ln\left(\frac{p}{1-p}\right) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + ... + \beta_n x_n$$

Where $\beta_0, \beta_1, \beta_2, ...\beta_n$ are regression coeficients

The advantage of using the propensity score is that it combines information from all the other covariates into a single variable.

Why must we estimate the probability that a subject receives a certain treatment since we know for certain which treatment was given? An answer to this question is that if we use the probability that a subject would have been treated (that is the propensity score) to adjust our estimate of the treatment effect, we can create a 'quasi randomized' experiment[vi].

Build the propensity score model, calculate propensity scores from the final model and apply caliper. See Marcelo Coca-Perraillon[vii] for more information and references about propensity scores in observational studies.

If matching variables are normally distributed and independent. The Euclidian distance may be a good matching metric candidate. For independent matching variables, the Euclidian distance represents the spherical case (standardized if units are different).

If matching variable are correlated, the Mahalanobis distance is recommended. This is a Elliptical distance measure due to the covariance factor in the distance formulation.

If matching variable are not normally distributed, correlated and with outliers EM dispersion methods can be used (see Stephanie P. Olsen 1997 dissertation titled "Multivariate Matching With Non Normal covariates in Observational Studies, UMI Microforom 9814896)

Use of Propensity scores in conjunction with the above metrics are the recommended method in the literature (see "Matched Sampling for Causal Effects" by Donald B. Rubbin, Cambridge University Press 2006)

2.1 The actual numbers

This study consisted in analyzing the impact of a pharmaceutical disease management program which goal was to increase adherence to treatment and increase total prescriptions, TRx.

Pharmaceutical company provided disease management treatment tools to physic ians to help their patients understand treatment and cope with side effects. A retrospective analysis of physicians prescribing patterns was used to determine the effectiveness of the program.104 physicians were enrolled for the program however the analysis focused on 91 physicians that had active prescribing activity before or after the program.

Table 1.1 indicates that the program may have not increased or maintained TRx and TRx share. However without the program TRx volume and share may have decreased at a higher rate.

Table 1.1

	Measure	Mean
Pre	Mkt Trx	223
	Product Trx	79
	Share	35.3%
Post	Mkt Trx	216
	Product Trx	67
	Share	31.2%

To measure the impact of the program retrospectively a control groups of physicians that did not participate in the program was chosen using a one to one matching method. Product TRx, Market Trx were six months prior and market TRx during the program were used as matching variables. Nearest Neighborhood matching was analyzed using the following matching metrics :

1) Euclidian distance
2) Mahalanobis distance
3) Mahalanobis distance including the propensity score.
4) Propensity Scores

The variables used in the calculations of the the measures below are : Pre and Post market and pre product Trx and Nrx. For assessing the quality of the matched only Trx were considered. Table 1.2 shows the differences between test and control

Table 1.2 shows the matching results of 1 trhough 2:

Method	Difference	Low CL	Mean	Upper CL	Standar Error
Euclidian	Post Mkt Trx	-170.6	-78.6	13.5	46.7
	Pre Mkt Trx	-118.5	-39.7	39.1	39.9
	Pre Product Trx	-53.7	-14.6	24.4	19.8
Mahalanobis	Post Mkt Trx	-231.8	-160.7	-89.5	36.1
	Pre Mkt Trx	-211.4	-156.5	-101.6	27.8
	Pre Product Trx	-85.0	-57.5	-30.0	13.9

On first look, the Euclidian method produces the best test and control matches. Donald B. Rubbins, "Matched Sampling for Causal Effects", Cambridge , June 2006 explains different methods to build control groups. Propensity scores, and Mahalanobis distance including the propensity scores are discussed in details and appear to be the prefer methods.

To come up with the propensity scores different models were tried. Trx data was broken down by volume to come up with the best model. 56 models were tried and analyzed. To select the best model the following criteria were used:

1) R^2
2) Model Significance
3) Significance in the model parameters
4) Not statistical differences between test & control groups on selected matching variables
5) Model variables , degrees of freedom

Table 1.3 shows the definition of the variables in the best models that were selected. Variables were recoded using the test group data as reference to ensure adequate cell frequencies. All the other models failed in significance levels of the model parameters or overall model. Not effort was made to fit any model that would produce the best matching control but that will violate fundamental statistical assumptions.

Table 1.3

Recoded Variables	Description
btrxc	Pre Product Trx Category
amtrxc	Post Mkt Trx Category
qpre_mnrx	Distributional Quartile(0-25, 25-50, '50-75, 75+) based on Test Group Pre Mkt Nrx
qpost_mnrx	Distributional Quartile(0-25, 25-50, '50-75, 75+) based on Test Group Post Mkt Nrx
qpre_mtrx	Distributional Quartile(0-25, 25-50, '50-75, 75+) based on Test Group Pre Mkt Trx
qpost_mtrx	Distributional Quartile(0-25, 25-50, '50-75, 75+) based on Test Group Post Mkt Trx
shr	Pre Trx Share
qpre_pnrx	Distributional Quartile(0-25, 25-50, '50-75, 75+) based on Test Group Pre Product Nrx

Pre Product Trx category and "amtrxc" is Post Mkt Trx category. These variables were defined as follows in table 1.4:

Table 1.4

	Recode	Post Mkt Trx	
Post Mkt Trx	0	0	1240
	1	1240	2480

	Recode	Pre Product Trx	
Pre Product Trx	0	0	670
	1	670	1340

Table 1.5 shows the results for the best four models.

Table 1.5

			- 2 Log L		AIC		SC	
Model	R^2	Max-Rescale R Square	Intercept Only Model	Model With Intercept & Covariates	Intercept Only Model	Model With Intercept & Covariates	Intercept Only Model	Model With Intercept & Covariates
btrxc amtrxc	**0.272%**	**3.6%**	**1099.1**	**1060.8**	**1101.134**	**1066.8**	**1108.7**	**1089.5**
qpre_mnrx qpost_mnrx	0.158%	2.1%	1099.1	1076.9	1101.134	1082.9	1108.7	1105.5
qpre_mtrx qpost_mtrx	0.173%	2.3%	1099.1	1074.8	1101.134	1080.8	1108.7	1103.5
shr qpre_pnrx	0.105%	1.4%	1099.1	1084.3	1101.134	1090.3	1108.7	1113.0

The first model was selected because it had the highest R^2, and lowest -2 Log L, AIC and SC values. The second and third models may show some correlation between the variables. In that market volume is constant. The last model may have some challenges since Share is a continuous variable and was not categories. Values with share missing due to market volume equals to zero may influence model results.

Table 1.6 shows the results of the test and control differences using these four models:

Table 1.6

Model	Difference	Low CL	Mean	Upper CL	Standar Error
btrxc amtrxc	Post Mkt Trx	-131.9	-46.6	38.7	43.2
	Pre Mkt Trx	-134.9	-68.2	-1.6	33.8
	Pre Product Trx	-56.4	-23.9	8.5	16.4
qpre_mnrx qpost_mnrx	Post Mkt Trx	-107.1	-17.3	72.6	45.6
	Pre Mkt Trx	-90.2	-14.6	61.0	38.3
	Pre Product Trx	-42.9	-0.1	42.7	21.7
qpre_mtrx qpost_mtrx	Post Mkt Trx	-118.7	-34.7	49.2	42.5
	Pre Mkt Trx	-97.5	-26.8	43.9	35.8
	Pre Product Trx	-52.2	-18.8	14.6	16.9
shr qpre_pnrx	Post Mkt Trx	-149.8	-66.8	16.1	42.0
	Pre Mkt Trx	-109.7	-37.7	34.4	36.5
	Pre Product Trx	-42.9	-5.1	32.6	19.1

Additional analysis was made on the first three models in the table above to determined if better controls could be obtained A caliper based on the propensity score and defined using Cochrans method discussed earlier was applied. The Euclidian and Mahalanobis metrics were calculated using different variables and analysis was repeated for the entire pool of controls and for the pool of controls defined by the propensity score caliper. The variable used in the different metrics definitions were:

1) The full variables set. Using pre and post market TRx & NRx and Pre product TRx & NRx in the Euclidian and Mahalanobis metrics.

2) The partial Trx variablesset. Using pre and post market TRx and Pre product TRx in the Euclidian and mahalnobis metrics.

The table 1.7 summarizes the overall analysis for each model.
Table 1.7

	With Propensity Score Caliper	Without Propensity Score Caliper
Full variables set to build Mahalanobis and Euclidian distance	1) btrxc amtrxc 2) qpre_mnrx qpost_mnrx 3) qpre_mtrx qpost_mtrx	1) btrxc amtrxc 2) qpre_mnrx qpost_mnrx 3) qpre_mtrx qpost_mtrx
Partial TRx variables set to build Mahalanobis and Euclidian distance	1) btrxc amtrxc 2) qpre_mnrx qpost_mnrx 3) qpre_mtrx qpost_mtrx	1) btrxc amtrxc 2) qpre_mnrx qpost_mnrx 3) qpre_mtrx qpost_mtrx

The models that produced the closest distance used the full variables set and are listed in table 1.8:
Table 1.8

Method	Model	Difference	Low CL	Mean	Upper CL	Standard Error
Propensity Score Within Propensity Score Caliper	qpre_mtrx qpost_mtrx	Post Mkt Trx	-99.4	2.4	104.3	51.6
		Pre Mkt Trx	-66.4	32.2	130.8	50.0
		Pre Product Trx	-49.5	-13.1	23.4	18.5
	qpre_mnrx qpost_mnrx	Post Mkt Trx	-109.9	-21.6	66.6	44.7
		Pre Mkt Trx	-89.1	-5.3	78.6	42.5
		Pre Product Trx	-52.5	-16.0	20.5	18.5
Propensity Score Without Propensity Score Caliper	qpre_mnrx qpost_mnrx	Post Mkt Trx	-107.1	-17.3	72.6	45.6
		Pre Mkt Trx	-90.2	-14.6	61.0	38.3
		Pre Product Trx	-42.9	-0.1	42.7	21.7

The control groups in table 1.8 were ran through an analysis of covariance.

The first model, (propensity score(qpre_mtrx qpost_mtrx) within caliper), had post Mkt Trx and Pre Product Trx passing the variance homogenous test at significance level of 5%. However, covariance analysis shows this variable having a significant interaction with the group variable (test/control) indicating that these covariates may have different slopes and violating one of the essential assumptions of analysis of covariance.

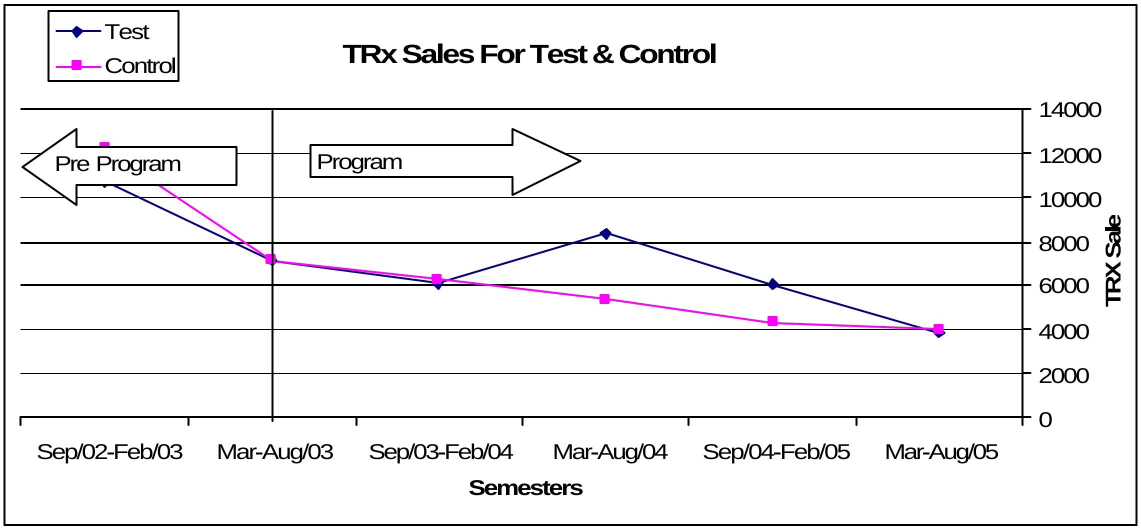
The second model, (propensity score(qpre_mnrx qpost_mnrx) within caliper), had similar results with respect to pret Mkt Trx and Pre Product Trx variables. Interaction of these covariates with the group variable was found indicating different slopes.

The third model, (propensity score(qpre_mnrx qpost_mnrx) without caliper), had similar results with respect to pret Mkt Trx and Pre Product Trx variables. However, there were no interactions between these covariates and the group variable.

The pre Mkt Trx variable was not significant and not interactions with the group variable.

There was not significant effect on the group variable for the first six months after the program however, a significant effect was observed after the first 12 months. Indicating a possible lag effect while the program got on its way and gained traction (see graph 1.1).

After the third semester, the effect dies off.
Graph 1.1



2.1 What is there to learn from business driven retrospective studies?

As a general methodology, different matching methods must be tried. According to the literature propensity, scores combined with propensity scores caliper and Mahalanobis distance since to work the best for most situations. However, coming up with an acceptable propensity scores model and calipers is a very time consuming and challenging exercise and there is not guaranteed that it will be found.

Given that there is not way to control at front in business driven retrospective studies variance on matchin g variables of test groups may be significantly higher than the variance of the control pool posing a very challenging matching scenario. Also defining the test and control group population may become very challenging. For example what about if for some operational reason participants to the programs were not selected properly. In one hand, if they are under performers that should not be targeted then they will drive down results even if the program is excellent. On the other hand if over performers are targeted when they should not be poses a similar problem because they will drive up results without benefiting from the program.

With potential selection issues data analysis complications are introduced that will require extensive analysis time and resources to come up with a directional results at best or inconclusive at worst.

This is why marketing and sales organizations in the pharmaceutical industry will benefit significantly from exchanging ideas and planning their programs with more rigor.

The impact that a promotional program will have on sales depends on the program design, and execution. A program that has been planned, executed or evaluated poorly will bring minimum return on investment, ROI. Using the appropriate approach to the management and improvement of promotional events will maximize ROI. An appropriate approach should have the following characteristics:

- A primary objective that is well understood and easily communicated.
- Understand the background of the program. Why is it being done?
- Have Quantifiable program indicators.

- Develop adequate evaluation methodology.
- Work plan with timelines, deliverables, roles and responsibilities.
- Good communications among project team members.
- Adequate project documentation

An article titled "Time to make promotion productive: how good a promotional strategy is, and not a high ad budget, will determine product success" in Med Ad News, 2/03/03, lists the following ten ways to maximize return on promotion:

i. Align investment with the commercial potential of product
ii. Be aware of the investment patterns of market competitors.
iii. Decide on key performance criteria.
iv. Invest in the appropriate therapeutic and geographic markets.
v. Recognize that the relationship between promotion and sales is linear.
vi. Prioritize portfolio to determine which products are worth the investment
vii. Capitalize on Synergies within the target audience.
viii. Allocate more funds to promotional activities than other activities.
ix. Don't over invest because company can afford it.
x. Increasing the number of sales reps leads only to short-term competitive advantage.

Common problems in promotional programs are:

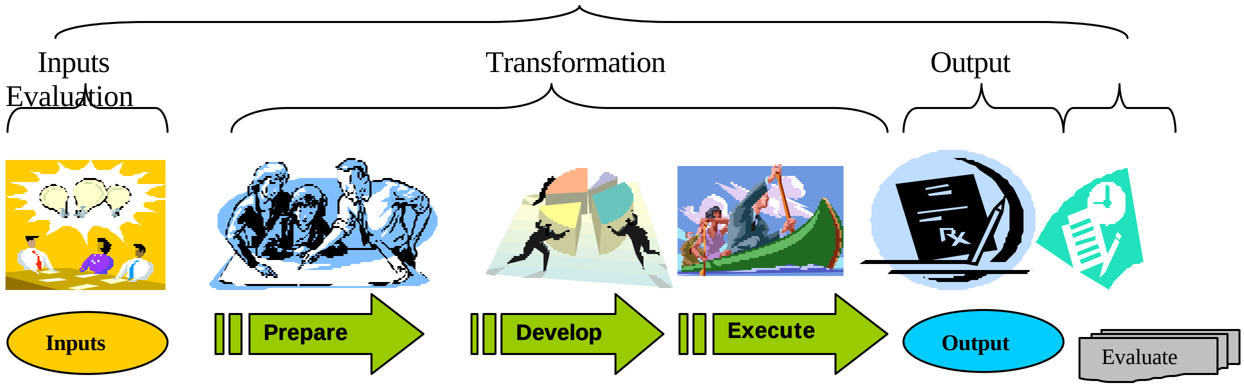
1. Method for selecting physicians invited to the program is poor. Detail profile of attendees is unknown. Project manager knows conceptually who is to be invited to the program but lack controls to ensure who gets invited in reality.
2. Project manager does not know exactly who was invited and attended the program. There is not master list of invitees with appropriate ME numbers or database identifiers.
3. There are not reporting requirements for agencies. Agency submits contact information of program attendees to project manager. Attendees contact information needs to be matched against databases to get ME number.
4. There is not evaluation of the program by the attendees.
5. For those attendees that are not physicians, there is not follow up to understand their relationship with the physicians the program is trying to impact.
6. Data is not produced in a timely fashion.
7. There is not standard ROI methodology making it hard to compare programs.
8. There is not database that tracks physician participation, programs characteristics and outcomes.

A promotional event process is like any other process. There are inputs, transformations, and outputs. The quality of the inputs and the transformation will determine the quality of the outputs. Inputs can be anything that needs to be transformed. Transformation is the mechanism used to transform the inputs into outputs. Outputs are the end result of the transformation. Inputs can be raw materials, transactions, communication, ideas etc… Transformations can be the production of goods, services, messages… etc.. Outputs can be goods, materials, ideas, reports, analysis, outcomes ….etc.

A promotional program must be as structured as possible as in the clinical studies to ensure its success. The idea that a promotional program must be developed and analyze without any rigor must be abandoned. In the same way that Clinical studies must be well designed to proof or supports the benefits of a treatment, promotional programs must be developed and conducted with the due diligence to be able to measure their effectiveness.

The diagram below shows the anatomy of an ideal typical process in the area of promotion:

The Promotional Event Process



1	2	3	4	5	6
• Ideas • Informati on • Data	• Understand the Problem • Set Goals • Estimate Opportunity • Build Consensus	• Develop Program • Get Support • Form Team • Set Work Plan and Milestones • Develop Evaluation Methodology	• Run Program • Review Interim Results • Make Program Adjustment s	• NRx Sales • Producti vity Gains	• Evalua te & Measur e

Planning Completing Evaluate

Project Cycle

The input phase is similar to the pre phase 1 clinical trials. In the prepare phase there is a concrete idea of what needs to be done. The development phase involves more rigor to understand how the project will be carry out, who is going to be targeted, what are the opportunities and how success will be measure. In this phase pharmaceutical companies business units will benefit tremendously from the methodological input form the clinical trials groups.

In the business world, the notion of randomization is forbidden. It is an alien concept that is perceived as hindering into current business processes. With frequency, business units prefer to do activities and bet on results to be validated later in an unspecified fashion. However, the benefits of a randomized design are enormous to evaluate the return on investment of a program. In many situations, a randomized design operationally is very difficult but not impossible. It involves thinking as a researcher and businessperson, considering changing sales process for an intern time at the same time.

Some of the advantages are:

a. Selection bias can be controlled.

b. Quantifiable indicators or measurements are predefined.

c. Impact of the program is hypothesized.
d. Important operational and program design factors are uncovered.
e. People are held accountable with objective quantifiable measures.
f. Can be part of continuous improvement efforts.

For example, a disease management program may be rolled out sequentially to physicians as follows:

1) Divide the program life span in cycles (lets say a 12 months program gets divided in four months cycles)
2) Build the program target population. Let say there are 3,000 physician as targets.
3) Based on the objective of the program come up with a research question or hypothesis
4) Based on a preliminary data analysis conduct sample size and power calculations need ito test the hypothesis.
5) Develop a study methodology
6) Identify what would be the control factors
7) Execute each phase with 1,000 physicians
8) For the first phase, build experimental pairs. For example if you study requires 50 physicians, select 50 randomly with their corresponding controls form the list of 3,000.
9) With 50 pairs, randomly assign one of the pairs to the program and the other put it in a waiting list.
10) Depending on the study design., move to second phase taking a random test and control pair of 50 or following the initial 50.

Pharmaceutical business units would benefit greatly exchanging methodological study design methods and information with the clinical trials units. Similarly, the clinical trials groups would benefit because they will be able to incorporate business knowledge into their studies and to contribute with new ideas to help improve business performance.

Trademarks

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