

# **Patient Enrollment Best Practice Model Significantly Improves Timeline Outcomes**

by Frank S. Kilpatrick  
Jeanne Floyd  
Hershel Goulson, MBA

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## Contact Information:

Frank S. Kilpatrick, President  
Healthcare Communications Group  
310-606-5700  
[fkilpatrick@hcg.com](mailto:fkilpatrick@hcg.com)  
[www.hcg.com](http://www.hcg.com)

With clinical trial development through-put in consistent decline in recent years, the problem of delayed Phase II, III and IV clinical trial completion has reached a critical level. The historically-viable expectation of study sites' responsibility for timely enrollment, now juxtaposed against the dismal statistic that 85% of current research trials are not completed on-time<sup>1</sup>, has mandated the quest for a new approach. Clinical trial enrollment can be problematic for a variety of reasons: Low subject (and referral source) eligibility awareness, overly-demanding protocol inclusion/exclusion criteria, and multiple competitive studies seeking the same population.

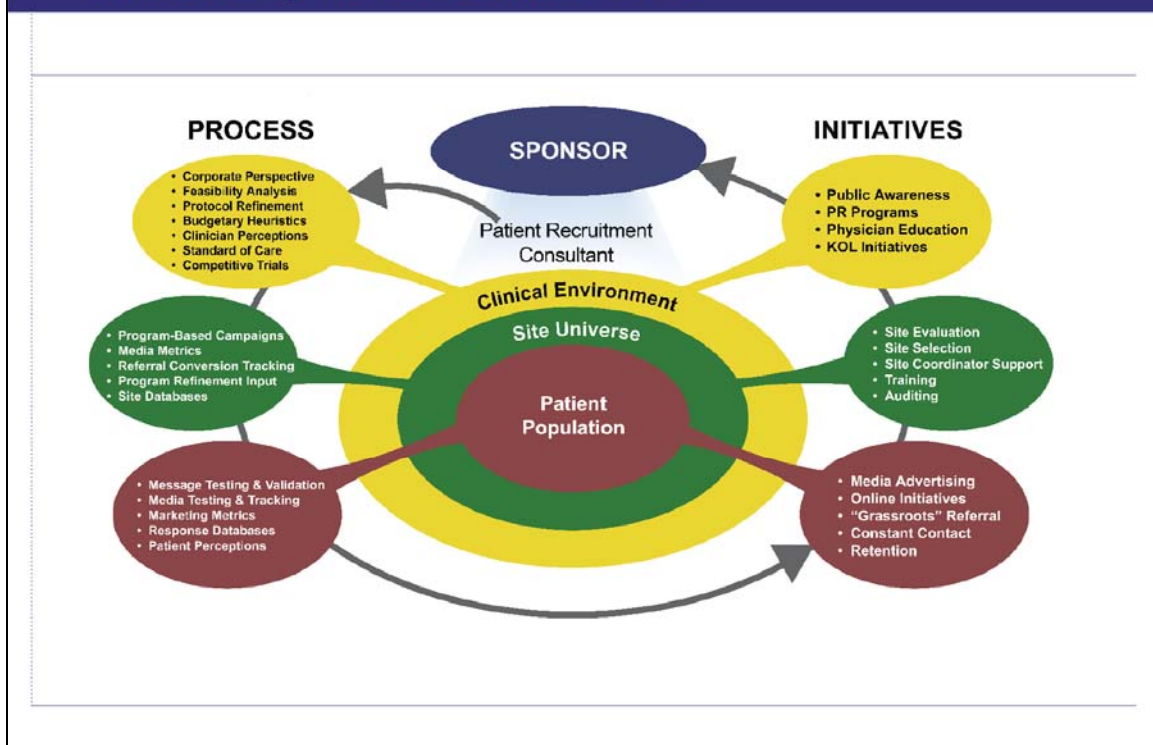
However, this problem can be significantly remediated through adoption of a new and forward-looking patient recruitment practice.

⇒ **A Sponsor-Integrated Solutions Model**

Not a “silver bullet” offering a simple solution to study patient recruitment problems, a new enrollment model recognizes the complex dynamics of trial enrollment as most efficiently solved via a *broad and externally-focused perspective*. The drivers (1. “Process” and 2. “Initiatives”) of such a staged-approach are summarized as follows:

Chart 1

## Integrated Communication Model Provides Optimal Recruitment ROI



### ⇒ Overview of the Model

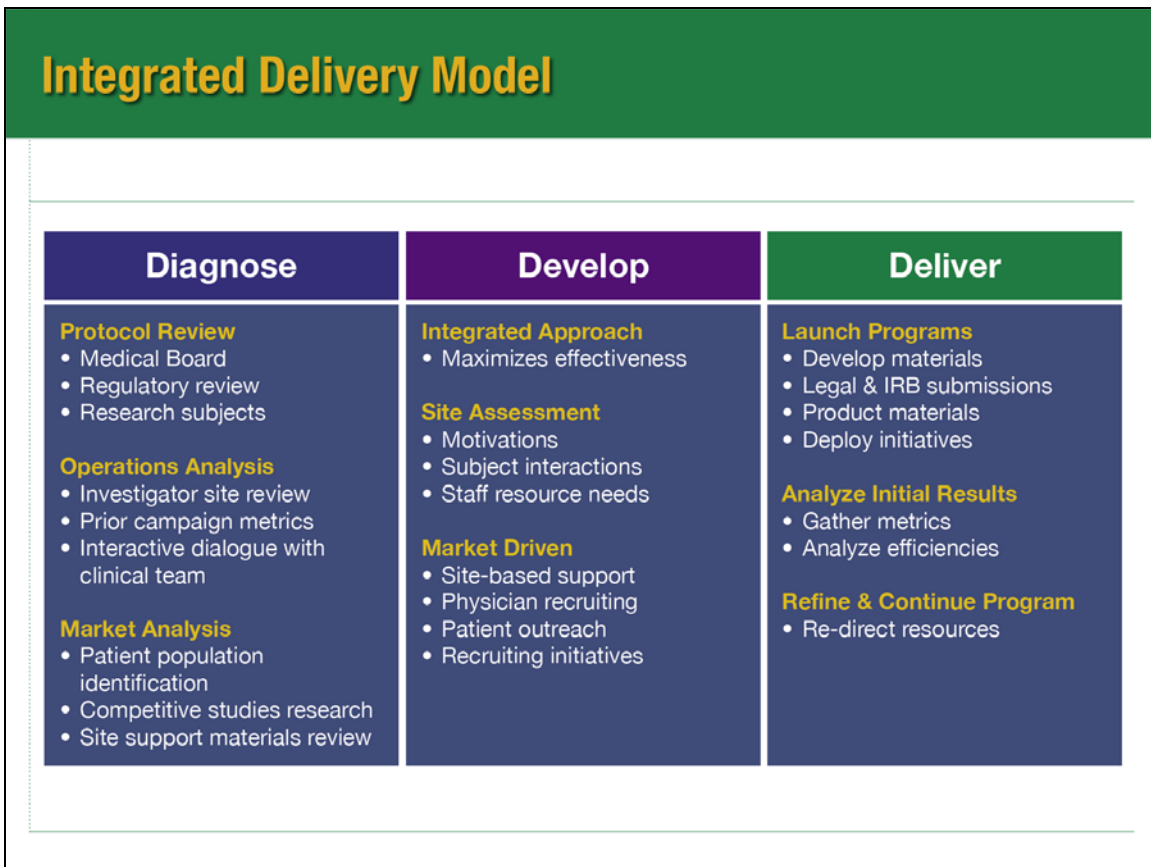
The Interactive Process Model utilizes a sequential three-part progression — captioned as “*Diagnose, Develop and Deliver*” – to build a *system* of research study enrollment effectiveness with application across multiple therapeutic areas. (See Chart 2 below).

These processes begin by seeking exhaustive understanding of the trial(s)’ position within its larger environment, though the following:

- Evaluation of subject population disease prevalence -- including geographic, demographic, psychographic indexes and/or seasonality drivers
- Consideration of the multitude of alternatives that prospective trial patients may compare to their participation in the trial

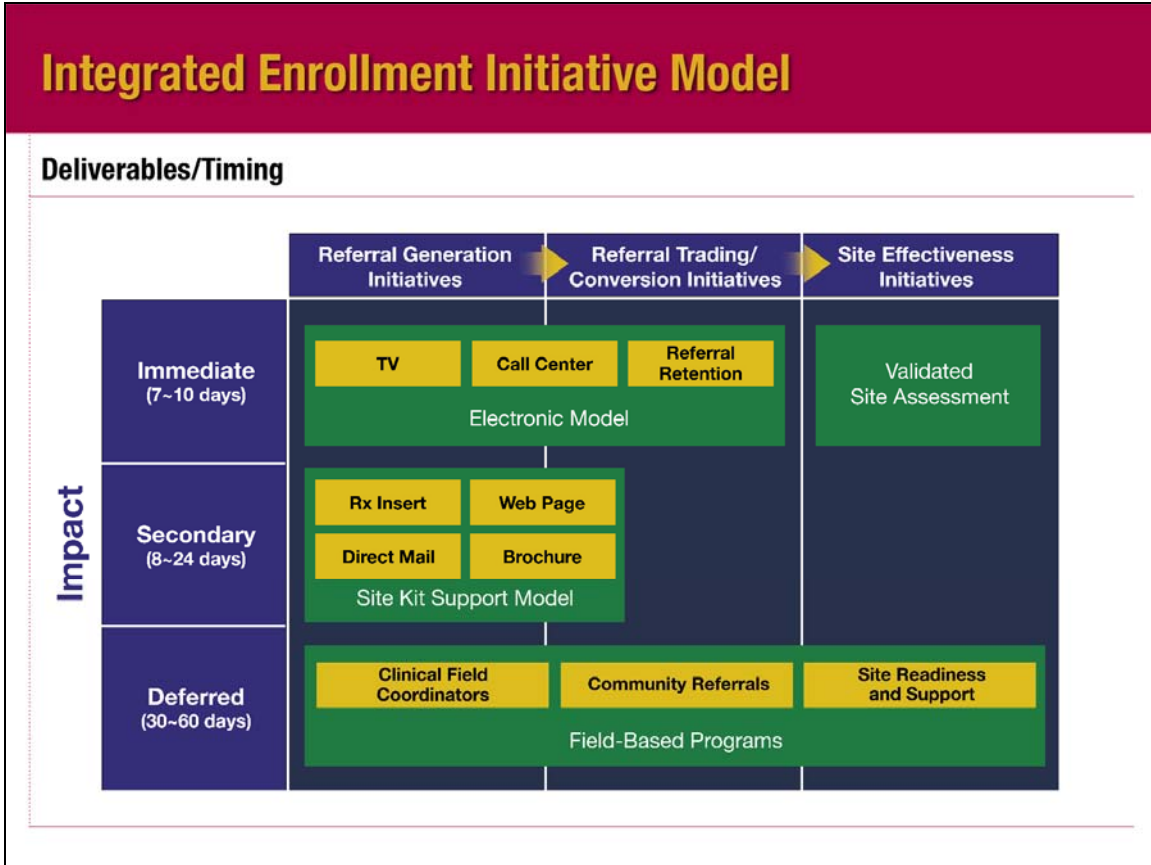
- Review of qualitative and quantitative research on what IRB-acceptable messages will be best received by patient, clinicians, caregivers and referral sources
- Ranking of “competitive” trials as to Principal Investigator perception of scientific value, grant amount, global vs. domestic execution, scale, protocol difficulty, and research referral network contribution
- Assessment of sites to identify which of them have historically *proven* their abilities to screen and randomize patients to similar protocols and determine the *needs* of others to enable best serving potential participants

Chart 2



The above scenario is based upon an interactive relationship between all client trial managers, internal cross-study teams, and external consultants-including the CRO. The process assumes a high data-sharing index to contribute the prior experience to the subject study via which stakeholders work together to further evaluate protocol feasibility, identify the best-matched investigative sites to the study (from an enrollment perspective), seek out and remediate “process” challenges, and analyze competition for the study. The resulting recruitment strategy is developed based on those catchment points researched to be most responsive in reaching patients who may best benefit from the trial: The campaigns’ “integrated components” may include patient or site education; a referral contact campaign to prospective subjects through caregivers, institutions or family members; and/or a media campaign tied to patient-direct motivation for participation. The deliverables of such a staged-approach is summarized in Chart 3. From there, the model proposes joint “real time” analysis of outcomes to continuously refine the approach and redirect resources to deliver continuous trial enrollment improvement.

Chart 3



⇒ **Shared Success**

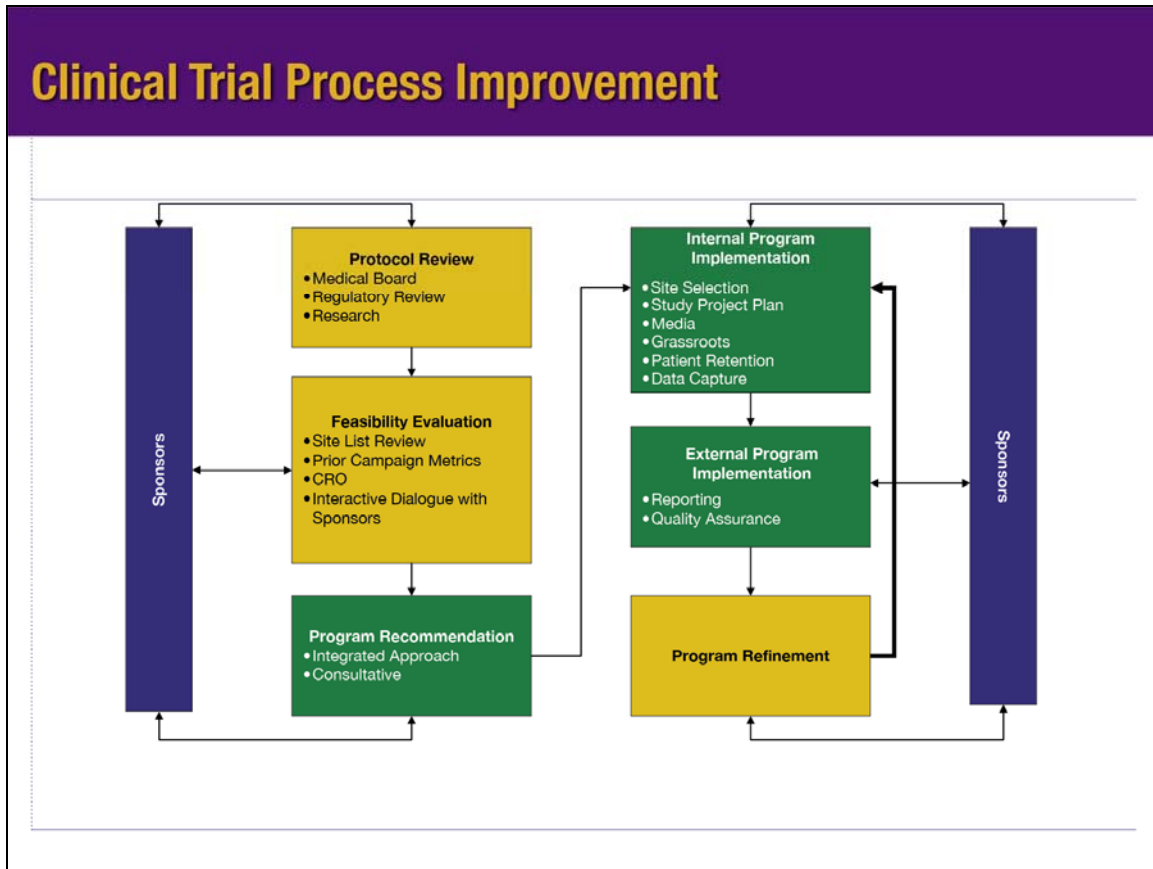
The interactive relationship between sponsor and support team(s) as empowered task forces is essential as these teams are jointly responsible for establishing and reaching consensus-based goals (ideally from the broader perspective of the subject drug’s overall position within the pharmaceutical sponsor’s portfolio); allocating and tracking financial resources for recruitment initiatives; and measuring outcomes by empirical process. Or, as Frederick R. Bode, MD, a Clinical Scientist with Hoffman-LaRoche comments about the critical importance of remaining in frequent contact with investigative sites during the trial: "To believe that a study, once it starts, is on autopilot is a definite mistake."

The outcome of the IPM approach is that by implementing a best practices recruitment process, enrollment timelines are met with a greater degree of predictability, enabling clinical programs to move toward completion and regulatory submission more quickly and within budget.

⇒ **The Adoption Process**

Because the IPM model impacts every aspect of subject recruitment and seeks to establish early and ongoing communication among all players -- sponsor, recruitment consultant, contract research organization, clinical investigators, and, most importantly, study volunteers -- it represents a radical departure from fragmented (but historically-accepted) patient recruitment processes. Rapid process change is challenging to implement for all but the most adventurous early adopters<sup>2,3</sup> so an incremental implementation may be the road of choice for some<sup>4</sup>.

Chart 4



To deliver “real world” enrollment success, in balance with their scientific objectives, IPM recommends that *study protocols be written with an eye toward efficient subject recruitability*. (For what good is it to consider an esoteric clinical hypothesis, if the subjects to validate it cannot be obtained such that the study will ultimately be cancelled?!) As a part of the development process, it is wise that the protocol be “Reviewed by consultants experienced in the particular therapeutic area for feasibility of enrollment-as well as likely acceptability with ethics committees,” according to Dr. Bode. Peter DiBiaso, M.H.A., Director of Clinical Trial Recruitment Services at Pfizer, Inc., speaking about the importance of a recruitable protocol says, “The biggest shift in recent years is that there is a better appreciation of early planning at the protocol level for the

required elements of recruitment planning.” Javier Szwarcberg, M.D., M.P.H., Medical Product Leader at Sanofi-Aventis adds, “Very early in the development of the protocol, we think about the inclusion/exclusion criteria and how they will impact our ability to recruit. Once inclusion/exclusion criteria are drafted, we tend to examine them to assess if they will be easy for patients or if they will make the trial attractive to physicians.” Dr. Szwarcberg goes on to acknowledge: “If we don’t work hard to simplify the inclusion/exclusion criteria, it will be difficult to meet our timelines.”

Another key focus is on improving the *site selection process* so that Principal Investigators are selected based -- along with their ability to deliver consistent clinical data -- upon their experience in enrolling subjects for similar trials. With so many unknown study variables, predictions based on enrolling the desired number of subjects from PI’s internal databases often change significantly as more details become available: The more comprehensive IPM model is intended to increase projection accuracy to meet enrollment deadlines.

According to DiBiaso, Pfizer has embraced a collaborative approach and views the patient recruitment function as a shared responsibility between sponsor and sites, and it starts by the sponsor laying the groundwork upfront. “Sponsors need to do a better job of identifying the types of sites that they want to work with and then help the sites understand what the sponsor is looking for. Just trying to find out how many patients the site thinks it can enroll isn’t good enough. Prior to site selection, we sit down with the site to understand its capacity to enroll and the goals of the study. This is part of our plan

to do a much more robust job and a lot more due diligence at the front end. The greater the specificity of the questions we ask at the front end will hopefully pay off at the back end,” DiBiaso says.

⇒ **Gaining Momentum**

Clinical trial patient recruitment methods are experiencing lots of small changes, too (along with big ones as well), as momentum is built toward a tipping point. The days of viewing patient recruitment as an afterthought are numbered as the trend advances toward collaboration, information sharing and a sophisticated, proactive planning process.<sup>5,6</sup> While successfully started, turning this approach into industry-wide standard practice will take some doing. It will mean implementing process changes so recruitment and enrollment issues are routinely handled upfront in an organized, systematic fashion, while still allowing the unique features of individual trials to be recognized.

Today’s progressive Interactive Process Model offers a best practices approach to improving the many steps that comprise patient recruitment, i.e. protocol development, budgeting, site selection, media campaign, education and training, that will ultimately tip the scale toward more predictable and effective recruitment and enrollment practices. Which progressive pharmaceutical development organizations will be the next to add their weight to the tipping process?

*Frank S. Kilpatrick is President, Jeanne Floyd, Vice President/Chief Operating Officer, and Hershel Goulson, MBA, Client Services Manager of Healthcare Communications Group ([www.hcg.com](http://www.hcg.com));*

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<sup>1</sup> CenterWatch, 2001

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- <sup>2</sup> Maloy, J., *et.al.*, “Technology”, ACRP White Paper, 2003, *The Monitor*, Summer 2003, pp. 18 - 23.
- <sup>3</sup> Bleicher, P., “Clinical Trial Technology, At the Inflection Point”, *Biosilico*, Nov. 2003, Vol. 1, No. 5, pp. 163 - 168.
- <sup>4</sup> Bleicher, P., “Managing the Information Supply Chain in Clinical Trials, *European Pharmaceutical Contractor*, Summer 2003, pp. 42 - 49.
- <sup>5</sup> Anderson, D.L., *A Guide to Patient Recruitment and Retention*, Thomson CenterWatch, 2004, p. 6.
- <sup>6</sup> King, J., “10 Ways to Faster and Easier Patient Recruitment”, *R&D Directions*, April 2004., Vol. 10, No. 4, pp. 34 - 46.