

The Patient Recruitment Process: A Science and an Art

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Objectives

- Describe how scientific and artistic principles apply to the patient recruitment process
 - Discuss growing use of informatics, a scientific, evidence-based method for site selection and investigator selection
 - Highlight the value of early planning as a technique with promise for meeting enrollment targets on time and within budget
 - Spot a trend toward greater collaboration among recruitment providers
 - Discuss the emergence of patient recruitment forums and associations within the patient recruitment industry
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Introduction

A new multi-center phase III osteoporosis study is about to begin across the United States. The sponsor is in the process of selecting eighty investigative sites, with an enrollment target of twenty-five volunteers for each site. At the end of the selection process, the site selector has chosen a mix of sites with varied experience in conducting osteoporosis studies. For some, this new trial does not seem substantially different from the ten osteoporosis trials they have conducted in the recent past. For other sites, osteoporosis is a fairly new therapeutic area and is one in which they are looking to expand their service offerings. Whether the site is experienced in osteoporosis studies, or just getting started, it will be expected to reach its enrollment goal.

How this hypothetical sponsor and the eighty sites go about meeting the enrollment targets underscores how the recruitment process is evolving toward greater sophistication. Sponsors, investigative sites and recruitment providers are introducing elements of art and science into their planning strategies. Metrics are being used increasingly to document success of various recruitment initiatives, such as site selection and media choices, for the recruitment campaign. Recruitment providers are starting to collaborate to offer a comprehensive array of recruitment services. The investigator meeting may become a forum for soliciting investigator opinion about the structure of recruitment campaigns. A look at changing recruitment practices and processes is the subject of this chapter.

A Science and an Art

Recruitment processes are becoming more professional and systematic as they incorporate elements of scientific and artistic discipline. The intricate balance between the two is basic to the practice of medicine, and to the related field of clinical trials, which includes patient recruitment. In exploring how science and art complement each other in the context of patient recruitment, it is useful to establish working definitions of both.

Science can be defined as the observation, identification, description, experimental investigation and theoretical explanation of phenomena.^{1,2} Science is deeply rooted in a scientific method designed to test a hypothesis, measure results from the testing, and ultimately drawing a conclusion (see Table 1). Experiments should also be reproducible by other experimenters to establish validity.

Table 1: The Scientific Method

- Observe and describe a phenomenon or group of phenomena
- Formulate a hypothesis to explain the phenomena
- Use the hypothesis to predict the existence of other phenomena, or to predict quantitatively the results of new observations (deductive reasoning)
- Perform experiments to test the predictions, and collect and analyze data, possibly resulting in modifying hypothesis and retesting it
- Derive conclusion

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Art has many definitions reflecting the broad-based use of the term. Fine and performing arts may be regarded as the conscious production or