

John Dillinger and Clinical Trials

The landscape of drug development has changed considerably in the last few decades. Initially driven by disease and unmet needs, advances in molecular biology have provided us with hundreds of thousands of molecules that may have useful biologic action. The potential therapeutic consequences of these manufactured or farmed substances now drives the clinical investigative pathway. Pharmaceutical pipelines have expanded and the financial pressures of new drug development have stimulated industry to rapidly move these potential “Blockbuster” molecules into human trials. Clinical trials require the co-operation of physicians and their patients, and there is significant demand, both local and internationally, for interested investigators and qualified human subjects.

It is difficult for the new physician to ignore the educational and therapeutic opportunities in the drug development arena. Once largely the role of the university centers, nonacademic researchers are now partnering with industry to assist with the large trials necessary to introduce new therapies in a safe and timely manner.

Should the new physician consider clinical trials as a part of their practice? Definitely! There is no other industry where we can be exposed to “scientific method”. Those of us who have been in practice for 20 years realize that only a small part of our practice is ‘evidence based’. If we only offered proven therapies with peer reviewed support, there’d be little to do. Clinical trials enhance our practices and a clear understanding of the rigors of scientific protocols keep our critical minds focused. When possible, direct involvement with this type of activity is to be encouraged. Participation in most clinical trials make us better physicians, and can help our patients.

There are certain skills necessary to be a principal investigator, and these are easily acquired. Also, the addition of a trials nurse can invigorate a practice and provide a bridge from patient to doctor, not available in the solo practice. Attendance at meetings provide us with specific educational perks and an opportunity to network with like minded colleagues. Finally, our patients love the opportunity to be involved in something a bit different and potentially beneficial.

With so much to do just providing care to our patients, why add another chore? In addition to the educational infusion, it can replace some of the more mundane aspects of clinical practice and keep us excited about our work. I remember the first sildenafil trials and the excitement my staff felt when we realized the impact this was going to have on urologic practice.

Today, clinical trials can be successfully carried out in non-teaching hospitals. Industry has realized the advantages of the high recruitment and superior quality of research that can be achieved in the community setting in accordance with the highest of GCP (Good Clinical Practice) standards. The old model of clinical work is changing and a broader involvement by practicing physicians has exposed industry to our strong relationship with our patients and our ability to enroll them in clinical trials. Why should only patients in large metropolitan areas have access to new therapies? Education through exposure to trial work translates to a better understanding of the disease in question and provides more rapid uptake once the therapy is available.

Why would industry move out of the institutions and into small, community practices? To paraphrase John Dillinger’s famous quote, “It’s where the patients are”.

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