

» On-Conversation with Dalvir Gill, PhD, President, Late Stage Development, PharmaNet



Dalvir Gill, PhD

For more than 20 years Dalvir Gill has been involved in all aspects of international clinical research. In the early 1990s, he played a key role in the development of sanofi-aventis' Taxotere® in breast and non-small cell lung cancer, and was also involved in the submissions of a number of other successful regulatory filings. In his current role as President, Late Stage Development at PharmaNet Development Group in Princeton, NJ, Dr. Gill has overall responsibility for Phase 2 to Phase 4 patient-based studies in oncology, as well as other therapeutic areas. OBR recently spoke to Dr. Gill to discuss the successful model PharmaNet employs for their oncology programs and how that model has been replicated by other CROs. Following is an excerpt of that discussion.

OBR: *What can you tell us about the role of CROs in oncology development and PharmaNet in particular?*

DG: The role of CROs in drug development has evolved. As pharmaceutical companies and biotechs continue to rationalize their infrastructures and portfolios we expect outsourcing in oncology to continue to grow for CROs capable of handling complex global studies. The development of oncologic drugs is so different from other therapeutic areas that you need specific approaches and specialized expertise. You cannot apply general techniques or utilize personnel with general experience to this arena. At PharmaNet, we have deliberately added significant scientific and medical expertise to complement the strong operational capabilities in our teams dedicated to the clinical development of oncologic drugs.

OBR: *Can you give us a few examples of this?*

DG: As a CRO, we've been involved in a significant number of oncology drug development programs, and we have an excellent track record in conducting programs for cutting-edge therapies that are currently on the market. Over the last few years, we have conducted global pivotal studies for

11 programs and of those at least 5 of those drugs have been approved and are on the market.

In addition, we have been awarded a number of programs for studies that will lead to future registration packages. These programs run into the hundreds of millions of dollars, and require deeper involvement and integration with the sponsor than for single-study programs. In the past, many of our awards have come from small to mid-sized companies, but as large pharmaceutical companies outsource more complex oncology programs, we are getting awarded more than our fair share. Just recently we were awarded a very large program by one of the largest pharmaceutical companies in the oncology arena.

OBR: *Things have changed so much in oncology drug development. From where we've been 10 to 15 years ago and where we're at today is vastly different. How do you see these changes affecting CROs?*

DG: The level of competition for specific patient populations around the world is more intense than it was 10 or 15 years ago. Today, there are so many more oncologic drugs in development that have the same target—from a molecular and stage of disease perspective. Approximately one third of all current drug development is in the oncology field which has resulted in fierce competition for eligible patients. More often than not, success of studies is highly dependent on the ability of the protocol to attract patients and the operational strategy implemented to maximize patient enrollment.

I also believe that the type of patients participating in clinical trials today are vastly more engaged and are far more savvy and informed in their decision making than they were years ago. Much of this change is due to the availability of information via the Internet.

With this increased competition for patients, CROs have to be more efficient in what they do. The speed in which they get an investigational site up and running, the efficiency of the contracting process, the collection of data, and the automation of data processes all have driven the



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dramatic shift from just 7 years ago. For example, less than 5% of our clients want paper-based studies compared to electronic capture studies. That shift alone is significant. With the financial pressures upon us, CROs have become more efficient in the actual implementation of clinical trials in order to succeed.

OBR: *How do you get a site up and running today?*

DG: One of the major challenges to get sites up and running quickly in the academic setting versus the community setting is the ability to contract with that investigational site or that institution quickly. We have approached contracting very specifically, because it is so critical to a study. Other aspects have improved, but not as much as the contracting process. We have personnel within PharmaNet that specialize in getting studies launched as quickly as possible. They assist the project team in overcoming common start-up challenges and this initiative has been a very successful venture for us. These specialized teams start up many studies each year and as such, have become experts in the launch phase of studies.

OBR: *Where does the community practice figure in all this?*

DG: Well, optimally, we need more community practices to encourage patients to get involved in clinical research. Statistics show that about 95% of cancer patients in the United States do not participate in clinical trials, but the numbers are probably similar in other parts of the developed world as well. Usually, patients come into these centers, get diagnosed, treated, and then proceed with a standard therapy. Many community centers just do not have the incentive to participate in clinical trials, but when they do participate, they are often highly productive, contribute eligible patients, and produce high quality data.

OBR: *What about academic centers?*

DG: Academic centers, on the other hand, play a slightly different role. Often in large clinical trials, we advise our clients to also use community centers along with large academic centers because that's where they will be able to get a significant number of study participants. Beyond participation in larger trails, academic centers do very well

in earlier studies with multiple interventions where the adverse event profile is complex and patients require close scrutiny. Academic centers also provide access to thought leaders and cutting-edge science for these more complex and early clinical trails.

OBR: *How is the role of biomarkers increasing in drug development?*

DG: Biomarkers are becoming more prevalent, and in the next 2 to 3 years are going to take off substantially in the clinical trial setting. The vast majority of pharmaceutical companies have invested in biomarker development in order to better target interventions. By using biomarkers to prescreen specifically targeted populations for studies, fewer people are being exposed to toxicities and the prospect for better patient outcomes increases. Trials may eventually become smaller and more targeted as biomarkers allow us to better define responsive patient populations.

With recent developments, it is clear that regulatory agencies and our clients want to see meaningful efficacy outcomes such as overall survival. We now know that improved overall survival does not require a phenomenal tumor response rate. Stabilizing the disease and the patient living longer is far more meaningful than a short response rate that does not impact survival. Biomarkers are good early indicators of efficacy. They can help us select patients that will benefit the most from a particular intervention. All of this improves our chances of success with a particular drug or clinical trial, with the goal of getting safe and effective therapies to patients. **OBR**

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