Sleeping with the Enemy?

By Ruben Mesa, MD

Financial disclosure forms, conflict-of-interest disclosures, disclosure slides before every presentation… The complex love-hate relationship between clinical investigators, academic institutions, and the pharmaceutical industry has never been a bigger issue for hematology. In an era where government support of research is very challenging to obtain, the need for industry support of clinical trials has never been greater. Indeed, even clinical trials in the cooperative group structure, despite group support by NIH, frequently require collaborative industry support before they can become a reality. The ASH annual meeting this year is devoting two key sessions to explore the complexity of these issues.

Today at 9:30 a.m., a Special Session on Practical and Ethical Issues Arising During the Conduct of Pharmaceutical-Industry-Sponsored Research will be led by Dr. Charles Schiffer of the Karmanos Cancer Institute. He will be joined by an energetic expert panel, which includes Dr. Frank Giles, a phase I and novel therapy expert from San Antonio Institute for Drug Development; Dr. Richard Schilsky, from the University of Chicago Pritzker School of Medicine; and Dr. David Parkinson, from Biogen Idec. The panel will focus discussion around three critical topics: 1) conflict of interest inherent in pharmaceutical-industry sponsored research, 2) authorship and publications, and 3) problems encountered during design and conduct of trials. The planned open discussion will tackle tough issues such as investigator objectivity, consulting activities by investigators, clinical trial data ownership, manuscript authorship, and clinical trial management. The symbiotic relationship between "big pharma" and academic clinical research has never been more evident, with the majority of clinical trials presented at this year's ASH annual meeting sponsored, at least in part, by for-profit companies.

The second ASH colloquium on clinical research challenges will be an Education Session (offered today at 7:30 a.m. and 4:00 p.m.) on "Pitfalls of Clinical Trials and Their Interpretation." Chaired by Dr. Mark Crowther, of St. Joseph's Hospital in Hamilton, Ontario, Canada, this discussion will spotlight the potentially premature impact that clinical trials may have on practice. Dr. Michael DeBaun (Washington University School of Medicine), drawing on his experience with large trials in sickle cell patients, will highlight the potential limitations of applying data obtained from a narrow study cohort to broader clinical groups. Keeping with this theme, Dr. Marcie Tomblyn, of the University of Minnesota, will examine the pattern of extrapolating data from limited phase II clinical trials in ways that alter standard care. Finally, Dr. Deborah Cook, of McMaster University, will examine the opportunities and problems that result from using systematic reviews and meta-analyses to justify changing clinical practice.

In the fast-paced world of clinical investigation, keeping up with evolving treatment guidelines, deciphering clinical trial outcomes, measuring the impact of conflict of interest on trial outcomes and on reporting these outcomes, and managing clinical uncertainty will continue to challenge us all. Indeed, the need for a positive and collaborative relationship between pharma and academic hematology will likely remain essential for therapeutic progress. This year's special sessions will serve as a starting point for the ongoing conversation on these issues in years to come.