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**Commitment to Patient Recruitment Critical to Meeting Clinical Study Enrollment Goals**

***First Quest for Consensus Conference Explores Solutions  
to the Industry's Biggest Challenges***

PHILADELPHIA (March 16, 2009) – Repeated failed behaviors by study sponsors, complex and unrealistic protocols and flawed feasibility assessments of study sites are the three primary obstacles to meeting patient recruitment goals for clinical studies. That was the conclusion reached by the 25 pharmaceutical clinical experts and specialty service providers who attended the first “Quest for Consensus” conference, held Thursday, March 5, in Philadelphia.

Conference attendees further agreed that the patient recruitment function requires the same level of commitment from study sponsors as other critical functions of clinical trial execution, and that earlier, end-to-end planning will help avoid costly rescue missions and missed timelines.

“Quest for Consensus — Searching for Patient Recruitment Solutions” was a full-day conference sponsored by the Fleishman-Hillard Clinical Trials Division, which specializes in patient recruitment and retention services. The conference used interactive discussion and consensus-building techniques to identify the three biggest challenges and then strategize solutions for each challenge. The conference was attended by clinical operations and other experts from large to mid-sized pharmaceutical companies, patient recruitment niche providers and others involved in clinical research.

Keynote speaker Ken Getz, senior research fellow at Tufts Center for the Study of Drug Development, set the stage for the discussion by pointing out that less than 10 percent of clinical research studies are completed on time. Investigative site operating challenges, lack of public awareness and support of clinical research studies, negative and often unbalanced media coverage, poor public perceptions of the pharmaceutical industry and increasingly complex study protocols are considerable barriers to improving patient recruitment, he said.

Conference attendees agreed on three solutions to help overcome the biggest issues:

### **Fix Ineffective Processes at the Sponsor Level**

- Companies need to **establish and remain committed to dedicated departments and resources for patient recruitment planning and execution**. Companies must develop budgets to support the patient recruitment function early in the planning process to avoid costly rescue missions.
- Sponsors need to **employ “patient recruitment monitors”** to assist study sites and relieve traditional clinical research associates (CRAs) of this responsibility. The group unanimously agreed CRAs are overburdened and not always properly trained for their increasingly varying responsibilities, recruitment often included. These monitors would serve to engage and educate study site staff and help them take full advantage of patient recruitment resources.
- Sponsors should incorporate strong educational recruitment program discussions into the traditional **investigator/coordinator meetings, as well as hold meetings dedicated to patient recruitment**. The recruitment foci should be held at the beginning of the study and again six to 12 months later and be geared toward educating investigators and coordinators about effective patient recruitment strategies and tactical implementation.

### **Simplify Complex Protocols**

- **Determining if potential volunteers are willing to participate in a study based on the planned eligibility criteria**, number of site visits, medical tests and other factors was the No. 1 solution to simplifying protocol development. Doing so will identify potential recruitment issues before the protocol is submitted for approval. Gaining patient feedback can be accomplished through focus groups and online surveys, the group agreed.
- **Conducting simulations of the actual operations against the protocol at the study site**, among key opinion leaders, investigators and coordinators also can serve as test-cases to help ensure that the required study procedures can actually be performed at those sites. This will help avoid unrealistic procedure scheduling or timeframes and study site resource issues.
- **Engaging in earlier strategic planning** to assess whether current resources by the study sponsor match the needs of the study based on protocol’s timelines can help ensure that the actual implementation timelines are realistic.

### **Improve Site Selection Process**

**Create better tools and processes during the site selection assessment**. Paper-based systems are inadequate, and the content of site feasibility questionnaires often is insufficient to effectively forecast site performance. Internet-based tools, questionnaires and processes that more easily identify unsuitable sites were among the tools discussed.

- **Budget for resources to conduct face-to-face study site assessments**, giving those critiquing the potential sites greater perspective on potential site issues.
- **Develop an industry-sponsored, shared database** where all sponsors can access information about the past performance of study sites.

“The conference determined that there are indeed challenges to improving patient recruitment that is so critical to successful medical research, but that the pharmaceutical industry is anxious to collaborate to overcome them,” said John D. McAnulty, senior vice president and partner with

the Fleishman-Hillard Clinical Trials Division. “The candor and innovative thinking that occurred at this conference made it a success and highly rated by those in attendance.

“To our knowledge, this is the first patient recruitment conference of its kind. It was far more collaborative and interactive than simply having a conference with speakers. The participants were the speakers, sharing their experiences, challenges and ideas for solutions,” McAnulty continued.

The Fleishman-Hillard Clinical Trials Division plans to develop a summary report of the conference for distribution to a broad list of clinical research industry executives in the coming days.

### **About Fleishman-Hillard Clinical Trials Division**

Fleishman-Hillard Clinical Trials Division provides full-service marketing communications expertise to reach and motivate audiences for specific clinical research studies, using online and offline communications research and strategies. The division has more than a dozen years of experience in patient recruitment for the pharmaceutical, biotech and device industries. For more information visit [www.clinical.fleishmanhillard.com](http://www.clinical.fleishmanhillard.com).

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