PPD has recently completed recruitment on a large Phase III ovarian cancer study summarized below:

- 1,080 patients
- 32 countries
- 4 geographical regions (North America; Latin America; Europe, Middle-east, Africa (EMEA) and Asia Pacific)
- Average recruitment rate 0.135 (minimum by country: 0.05; maximum by country 0.35)

**KEY LESSON:**

In common with many oncology studies, this is an event driven study. As a consequence, the primary efficacy variable is based on an independent radiological review of tumor progression based upon RECIST criteria. Choosing a good radiological vendor and ensuring that the combined project team, including the chosen vendor, have thought through the logistical challenges of capturing, tracking, reconciling and managing this key data is essential for successful management of the study. Key elements for this success include the following:

- The radiological vendor should be willing to play an active and involved part in the combined project team.
- The CRO management team and CRAs need to be willing to collaborate with that vendor to offer a coordinated approach to communicating with the investigative sites and collecting the radiological data in a timely fashion.
- Consideration should be given to either choosing a CRO partner who can provide radiological services through a strategic partnership with a suitable vendor or who would be willing to subcontract those services rather than the radiological component be separately contracted by the sponsor. This contracting framework offers better assurance of coordinated and cohesive management of this data.

**VIRTUALSCOPICS, INC.**

VirtualScopics is an industry-recognized scientific leader in the field of imaging for oncology drug development. PPD and VirtualScopics have a strategic alliance to deliver a comprehensive set of clinical and medical imaging services that will enable our clients to make faster, more confident decisions regarding the development of the drug. This relationship will also broaden access to industry-best cycle times and consistent and reliable medical imaging information. Additional benefits include:

- Integrated technologies and processes (i.e., study start-up, site initiation, data management, project management) yielding reduced vendor management, improved communications, consolidated risk management and study efficiencies
- Harmonization of communications and reporting technologies
- Reduced execution time and study costs