• Overcome the challenges of early phase oncology studies with a global partner whose extensive experience, technology and partnerships, dedicated facilities, and global footprint can help to efficiently move your product to the next stage.
• Develop the right Phase I study designs to achieve early “go/no go” decisions and appropriate selection of tumor indication for later studies.

Strong Experience and Global Footprint
A significant percentage of PPD’s oncology business over the last five years has been driven by the delivery of more than 200 Phase I and II oncology studies conducted in all major early phase clinical research regions around the globe. Our extensive Phase I experience across a diverse range of malignancies and investigational products provides PPD with a strong foundation for partnering with biotech or pharma to develop innovative biologics or small molecule investigational products.

PPD has access to a network of oncology sites with broad capabilities in terms of early stage experience and clinical pharmacology expertise. At the same time, PPD targets countries and sites with robust Phase I capabilities in oncology to build collaborative partnerships to deliver future trial programs.

With capabilities spanning all phases of discovery and development, PPD’s laboratories have the scientific and regulatory knowledge to guide our clients’ biomarker strategies. Whether diagnostic, prognostic, staging, predictive, pharmacodynamics, theranostic or surrogate endpoint markers, PPD can help select the right approach to validation, develop methods under the appropriate regulatory guidelines, provide insight into how to effectively integrate safety and efficacy biomarkers into clinical development and help select the best technology platform to meet your needs.

Technology and Partnerships
In addition to our discovery, bioanalytical, central, cGMP and vaccines and biologics laboratories, we maintain the following partnerships and agreements in order to better support our clients’ needs:

• Anatomical and molecular pathology laboratories, which analyze tissue for histopathology and molecular pathologic processes using industry-leading histology and molecular techniques to define the role of biomarkers in disease processes.
• VirtualScopics, Inc., which provides image-based biomarker analysis across a broad range of therapeutic areas and modalities to assess risks regarding safety, toxicity and drug interactions. In addition, this partnership offers state-of-the-art data transfer capabilities partnership.
• FACTS™ Software, PPD is one of the very few CROs which have a license for the software, allowing us to create a more flexible, intuitive approach for study designs by simulating and comparing adaptive and rule based trials.
Progressive Phase I Approach
Critical elements of Phase I oncology development are novel study designs, which support establishing Maximum Tolerated Dose (MTD) as quickly and efficiently as possible, and determining the most appropriate indications for expansion.

- Innovative adaptive trial designs are used to focus on Continuous Reassessment Models (CRM) for Phase I studies. The introduction of CRM in establishing MTD has ensured an efficient approach for determining the most suitable dose or dose range for an expansion phase. This approach provides a greater probability of achieving the most appropriate dose when compared to the traditional 3 x 3 dose escalation.
- Bayesian statistical methods are used to model early data from Phase I research. These practices are applied to determine the dose levels most likely to be at the targeted toxicity rate.
- PPD’s Phase I and early Phase II experience is broad in terms of our use of advanced tissue analysis technologies to target therapies.

PPD also has strong expertise in the areas of early phase consultancy, full program design and development.

The Right Integrated Approach for Quick Data Decision Making
PPD gives clients access to innovative remote data capture technologies that provide real time data, efficient analytical approaches to data presentation, and quick decision making.

- Extensive Oracle® Clinical RDC, Medidata and Inform experience
- PPD Patient Profiles to review intra- and inter-patient tolerability profiles

PPD has broad experience with a variety of data processing and presentation software that is flexible enough to use our clients’ systems, if preferred.