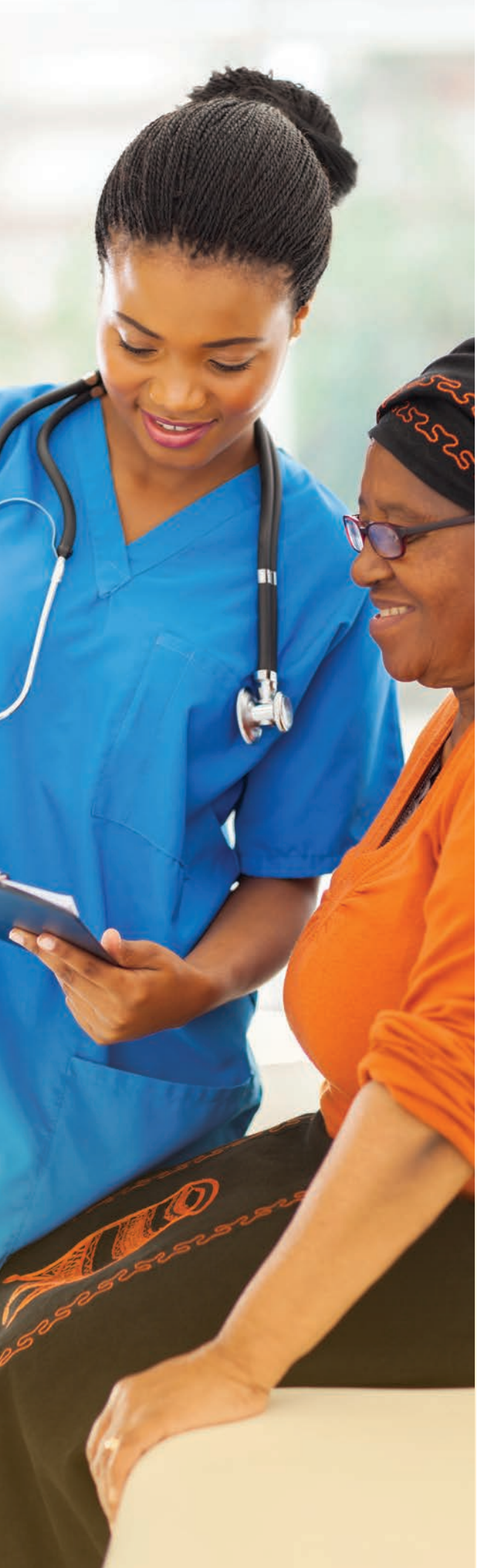
PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

HEMATOLOGY | ONCOLOGY



PROVEN CAPABILITIES TO SUPPORT AND ADVANCE ONCOLOGY RESEARCH

- Industry-leading expertise and strategies to support development of targeted therapies and cancer immunotherapies
- Translational research approaches, including use of broad tumor profiles, biomarkers and efficient adaptive trial designs
- Proven capability to design and operationalize adaptive and other innovative trial designs

PPD ALSO PROVIDES:

- Deep research experience in solid tumors, hematology, hematologic malignancies, cancer-related pain and supportive care
- Access to adult and pediatric hematology/oncology cooperative study groups and specialty organizations
- Investigator support, development and management for National Cancer Institute (NCI) proposals

More than **14 million cancer diagnoses** are made each year globally,* and **worldwide oncology sales** are expected to reach **$190 billion by 2022.****

THE STAKES HAVE NEVER BEEN HIGHER.

*SOURCE: World Health Organization **SOURCE: EvaluatePharma

An increasingly competitive marketplace, rising cost pressures and an ever-changing global regulatory environment make it crucial to find a partner who understands the unique complexities and opportunities of this therapeutic area.

THE ADVANTAGE OF PPD'S GLOBAL PRODUCT DEVELOPMENT TEAM

Our global product development team includes experienced hematologists and oncologists. An integral part of our medical organization, this group is comprised of experienced drug development professionals who work with our clients and clinical operations team to provide global medical, scientific, regulatory and product development expertise.

EARLY DEVELOPMENT ONCOLOGY GROUP

Phase I oncology trials are not the same as Phase I trials in other therapeutic areas. To address the differences and support the intensive nature of these studies, we have a dedicated team within hematology/oncology. Our experts manage the resources associated with early phase oncology trials to nurture those trials through completion.

EARLY PHASE ONCOLOGY SITES

PPD has established relationships with a global group of sites for early oncology development. These sites achieve excellence in delivery across solid and hematologic malignancies and varying dose escalation study designs. These sites combine academic and non-academic sites with investigators who contribute expertise in complex study execution and enrollment in a competitive environment.

Berry Consultants Partnership

PPD partners with Berry Consultants, a statistical consulting group specializing in the Bayesian approach and adaptive clinical trial design for pharmaceutical and medical device research and development. Together we are able to help clients plan for and effectively realize the benefits of adaptive trial design.

Berry Consultants

A HEMATOLOGY AND ONCOLOGY RESEARCH LEADER

PPD has a broad spectrum of experience managing clinical trials in complex indications such as benign hematologic disorders, hematologic malignancies and oncology diseases, including rare tumor types and supportive care indications in patients with cancer.

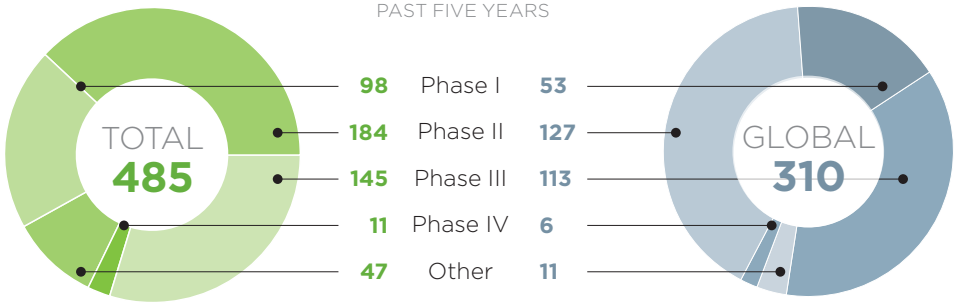
~500
STUDIES

108,000+
PATIENTS

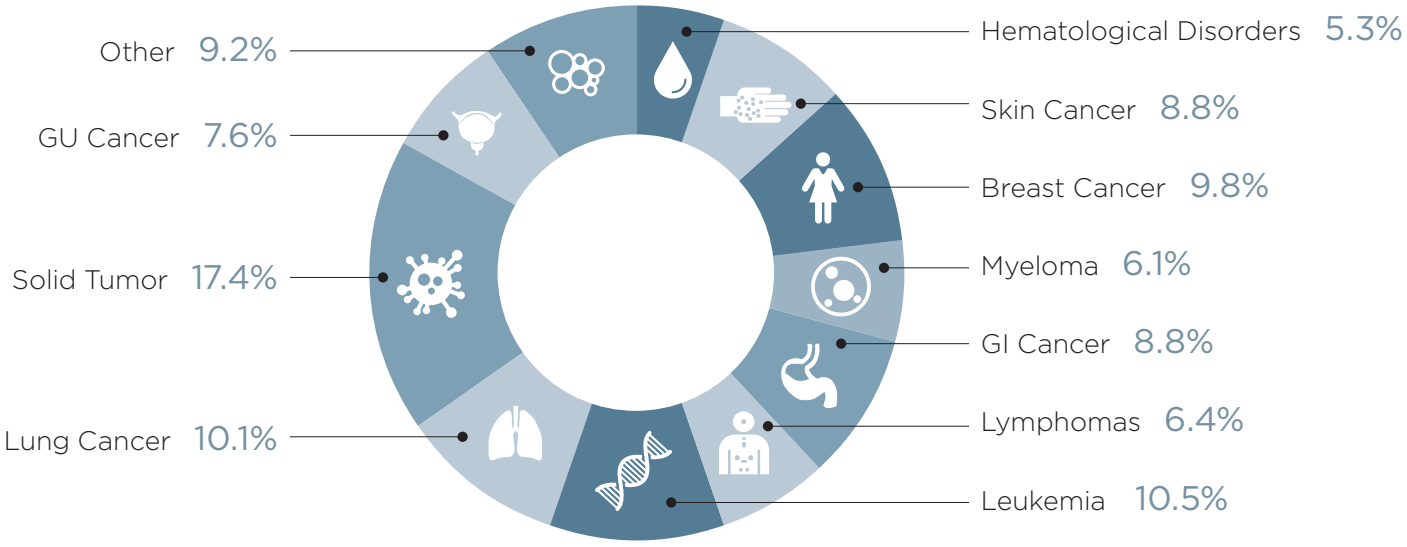
27,000+
SITES

1,300+
REAL-WORLD AND POST-APPROVAL STUDIES (INCLUDES EVIDERA)

ONCOLOGY CLINICAL EXPERIENCE BY PHASE
PAST FIVE YEARS



A CLOSER LOOK AT PPD'S ONCOLOGY EXPERIENCE



Immuno-oncology Center of Excellence

PPD is a leader in immuno-oncology innovation, having conducted more than 120 immuno-oncology programs that include checkpoint inhibitors, immune modulators, monoclonal antibodies, cancer vaccines, adoptive cell therapy and cytokines. Our Immuno-oncology Center of Excellence is a knowledge center for project teams and clients regarding the competitive environment and efficient adaptive designs and the dynamic regulatory landscape that has evolved with these new and exciting immunotherapies.

PPD® LABORATORIES: A COMPLETE RANGE OF SOLUTIONS FOR HEMATOLOGY AND ONCOLOGY

Across every phase of pharmaceutical development, clients count on PPD® Laboratories' services and scientific expertise to deliver the data needed for fast, accurate decision-making.

Our hematology/oncology portfolio covers a wide range of disease mechanisms and targets. Our scientific leaders have extensive hematology/oncology research experience with small molecules, biologics, antibody-drug conjugates (ADCs), biomarkers, cell and gene therapies, and companion diagnostics.

Our strategic alliance with NeoGenomics Laboratories further extends our pathology and molecular capabilities to support complex oncology and immuno-oncology clinical trials.

PPD Laboratories helped develop **19 of the top 20** best-selling oncology drugs of 2018

EXPANSIVE ARRAY OF LAB SERVICES

- Bioanalytical Lab
- Biomarker Lab
- Central Lab
- Vaccine Sciences Lab
- GMP Lab

ACTIVATE AND ENROLL SITES FASTER

PPD delivers studies on time with our proven trial optimization methodology. Our four-part approach results in high-level site enrollment and performance, and includes:

Development Consulting and Early Engagement

Experts with deep therapeutic knowledge engage with clients before the study's protocol is developed or advise on an existing protocol to limit amendments and reduce costs.

Data-driven Analysis

Analytics and expert recommendations improve forecasting to optimize both the protocol and the trial and to mitigate risk before a study begins.

Investigator Feasibility and Site Selection

Sites and investigators with experience conducting similar studies and who are proven to recruit patients according to set timelines are recommended.

Continuous Feasibility and Optimization

A feedback loop is used to determine what parts of the trial optimization strategy are successful and what changes are needed to create time and cost savings.

Applying Adaptive Trial Design to Hematology and Oncology Trials

Adaptive trial design helps ensure potential issues are revealed earlier, enabling faster "go, no-go" decision-making and creating more confidence in outcomes. Adaptive trial design continues to see growing regulatory acceptability from the U.S. Food and Drug Administration. PPD's experience in planning and executing adaptive trial designs provides clients significant advantages that lead to safer, faster and more cost-effective outcomes.

ONCOLOGY ENROLLMENT ENHANCEMENT
THE JUST-IN-TIME APPROACH

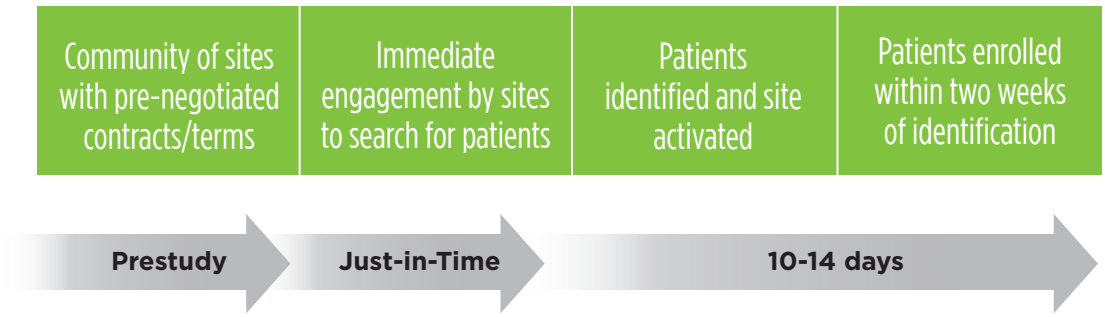
Oncology clinical trials represent a special challenge for biopharmaceutical companies. When oncology research sites enroll, it takes an average of more than eight months from protocol outreach to site activation. Some 60 percent of sites never enroll and 40 percent of ongoing trials never meet enrollment targets*.

300+
pre-qualified sites

1,000+
investigators

Oncology enrollment enhancement uses a just-in-time methodology to jump-start study enrollment. We provide confirmed availability of pre-identified patients from pre-qualified sites in our community of over 300 sites with over 1,000 research-experienced investigators. This turnkey service augments your traditional trial approach and provides the first study subject within two weeks of patient identification.

Zero
non-enrolling sites in the just-in-time community



* https://www.forbes.com/sites/judystone/2015/01/06/how-can-we-encourage-participation-in-clinical-trials/#1dc9f1ac4d0c

BENEFITS

Diversity
Just-in-time sites are concentrated in ethnically diverse areas

Patient-centric
Exposing more trial options to patients while allowing sites to focus on studies for which they have patients

Efficiency
Improved efficiencies/volume through protocol stacking

Performance
Opportunity to accelerate overall study performance

Risk Management
Mitigate risk from non-enrolling sites; risk mitigation strategy is available from day one

PPD®

For more information, please contact us at
+1 877 643 8773 or +1 919 456 5600.

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