PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

VACCINE DEVELOPMENT

PROVIDING COMPREHENSIVE SOLUTIONS IN A COMPLEX ENVIRONMENT

With more than 25 years of vaccine development experience for both government and commercial customers, PPD provides integrated clinical and laboratory vaccine expertise and global resources to advance our customers' vaccine programs.

VACCINE DEVELOPMENT PRESENTS UNIQUE NEEDS

PPD DESIGNS TARGETED STRATEGIES FOR SUCCESS

When developing a vaccine, working with a partner that understands the complexities of this important area of research is critical.

Large volumes of data must be processed over study peaks and troughs while maintaining data quality. Close collaboration with specialized laboratories is critical to ensure that sample processing, tracking and data reporting are well-coordinated to successfully complete vaccine studies.

Recruiting specific populations and ensuring subject retention to assess antibody persistence and long-term vaccine efficacy require a tailored approach to recruitment. Leveraging technology and employing up-to-date communications methods facilitates volunteer engagement and compliance with extended study visits over periods of years.

A DEDICATED AND EXPERIENCED TEAM TO ENSURE OPERATIONAL EXCELLENCE

- Knowledgeable experts with international regulatory expertise across a wide variety of vaccine product types, including genetically modified organisms (GMOs)
- Experience across a range of vaccine types and indications: vector/zoonotic, enteric, respiratory and sexually transmitted diseases

GLOBAL RESOURCES AND FLEXIBILITY TO DELIVER RAPID ENROLLMENT AND HIGH-QUALITY DATA

- PPD priority site network with over 450 experienced sites ready to go
- Proven regional enrollment strategies to maximize outcomes for seasonal projects and/or endemic diseases
- 32 depots across the globe for product and logistics management
- Near real-time data access and trend analysis to enable proactive study management through Preclarus®, our award-winning portfolio of technology solutions
- Pediatric investigator network (PIN) to ensure ready access to key opinion leaders (KOL)

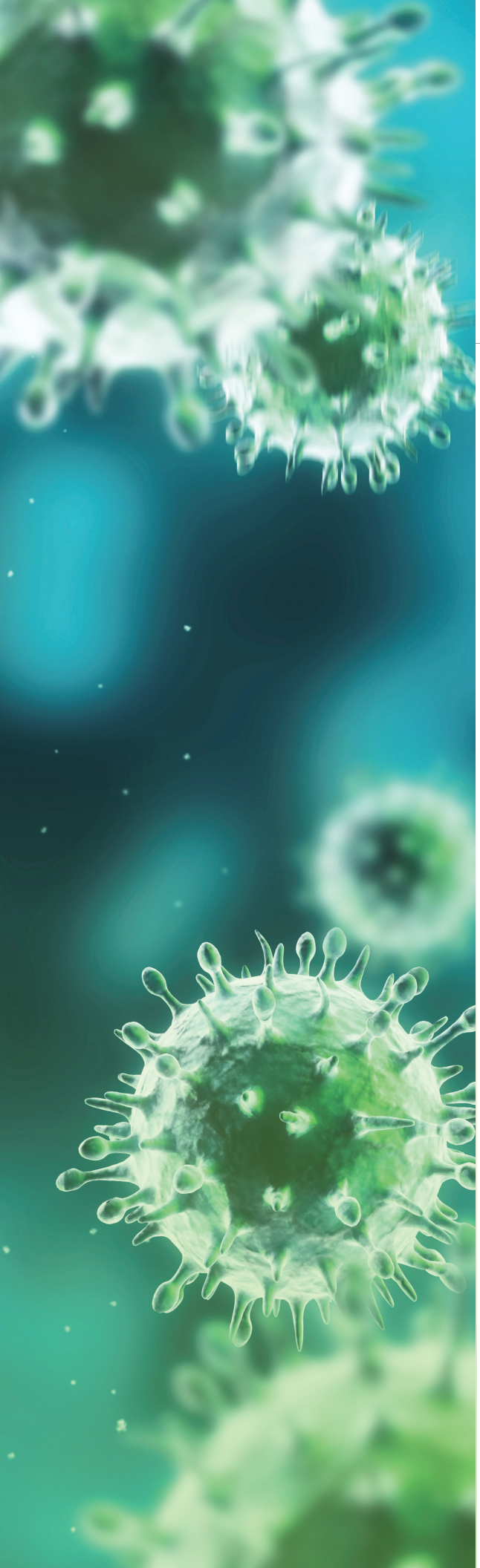
600+
STAFF with VACCINES experience

204
STUDIES in the past five years

450+
PRIORITY NETWORK SITES

~100
MEGA-TRIALS successfully completed

5,000+
PATIENTS in each mega-trial

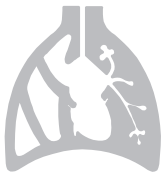


GLOBAL VACCINE EXPERIENCE AND RESOURCES

Expertise spanning a broad range of indications

Vector/Zoonotic

Dengue, malaria, West Nile, Zika, Chikungunya, Japanese Encephalitis, rabies, yellow fever



Respiratory

RSV, SARS/MERS, pandemic flu, seasonal flu, meningococcal, pneumococcal, tuberculosis, pertussis, strep A/B, diphtheria

Enteric

Rotavirus, norovirus, *E. coli*, Shigella, typhoid, cholera, *C. difficile*

Sexually transmitted

HIV, HPV, CMV, herpes, chlamydia, hepatitis B

Other

Hepatitis, rubella, measles, mumps, MMR, varicella, tetanus, polio, HIB, *Staph. aureus*

DELIVERING GLOBAL VACCINE EXPERIENCE AND RESOURCES

Clinical Vaccine Expertise

In the past five years, we have supported more than 145 vaccine trials globally for pharmaceutical companies and U.S. government agencies. This experience allows PPD to offer full-service vaccine capabilities and distinctive expertise across a wide spectrum of vaccine programs including:

- **Early-phase vaccine development** in normal, healthy volunteers and patient populations to evaluate safety and immunogenicity endpoints
- **Pivotal, field-efficacy studies** in selected geographies and targeted populations
- **Rapid site startup and capacity** to support large vaccine trials
- **Broad experience** with cold-chain management, serology specimen chain-of-custody and unique logistics of vaccine studies
- **Real-time data access** to facilitate data analytics and safety trend analysis

Our vast global footprint enables rapid deployment of teams to support the staffing needs of vaccine studies, including separate unblinded teams.

REGULATORY EXPERTISE

PPD has knowledgeable regulatory experts who understand vaccine regulatory requirements across regions and countries. These specialists lead development of study-specific regulatory submission plans, identify potential issues upfront and ensure a robust data package is submitted to the relevant regulatory authorities. They actively manage the submission process to ensure timely study startup and execution.

Pediatric Vaccine Mega-trial Case Study

Background

Double-blind, placebo-controlled, Phase III study for new flavivirus vaccine

Objective

Enrollment target 20,100 subjects, aged 4-16 years, in seven months. Two vaccination visits per subject and ongoing monitoring for febrile events (possible flavivirus infection).

Strategy

- Detailed resource planning to include onboarding training, communication and buddying
- Proactive management of peaks and troughs through use of front-loading staffing models and CRA swat team
- Eight countries, 26 sites, 87 clinical staff
- Supplement risk-based monitoring with the use of remote site monitoring and data analytics

Results

- Enrollment of 20,100 subjects completed five days ahead of target
- Approximately 81,000 subject visits with 94 percent source verification completed in the first year
- More than 27,600 subject visits with 94 percent case report form (CRF) review completed in the first year
- 70 percent of queries closed in less than 15 days

RAPID RECRUITMENT AND PATIENT ACCESS FOR VACCINE TRIALS

Leading Vaccine Recruitment and Enrollment Expertise

We leverage our broad vaccine experience to provide a comprehensive enrollment solution for faster feasibility, subject recruitment and execution for clinical trials globally.

Our global footprint, experienced trial management teams and known investigator sites provide clients with quick access to sites, including those with specialty populations. We also have developed unique strategies that minimize enrollment time and maximize subject follow-up.

PPD PRIORITY VACCINE SITE NETWORK

PPD has streamlined site startup capabilities for vaccine studies by pre-identifying more than 450 high-quality vaccine sites, across all geographic regions. These 450 sites make up our priority vaccine site network. In addition to strong startup timelines, the regional diversity of the priority sites enables tailored enrollment solutions for seasonal respiratory studies.

PPD's site solution for vaccine studies also includes Acurian, PPD's leading patient recruitment offering, to provide comprehensive, integrated enrollment solutions for vaccine trials that target specific disease indications. This is particularly important for therapeutic vaccines.

Special Subject Populations

Many vaccines aim to prevent diseases in children, elderly and other vulnerable groups, so efficient targeting of specific populations is crucial. Our access to global populations, coupled with our ability to run large vaccine trials, enables PPD to offer well-designed study plans to meet the challenges of recruiting these defined populations. Additionally, as healthy, normal volunteers from disease-endemic areas with or without prior disease-exposure history are needed, having a global footprint with experience is paramount.

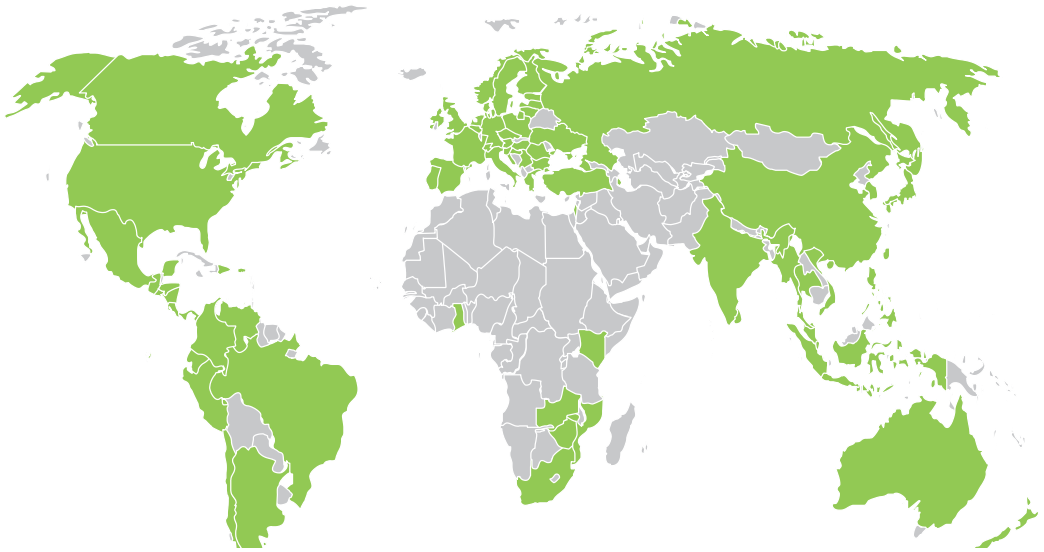
PPD HAS EXPERIENCE ACROSS MANY TARGET POPULATIONS, INCLUDING:

PEDIATRIC ADOLESCENT ELDERLY

For studies involving pediatric populations, we have a specialized approach for conducting assent discussions, developing appropriate literature, and educating parents and guardians to overcome possible barriers to enrollment.

Our cross-functional pediatric team offers strategic guidance to pediatric investigational plans (PIP) and individual studies required for vaccine development.

Countries where PPD has conducted vaccines studies in the past five years

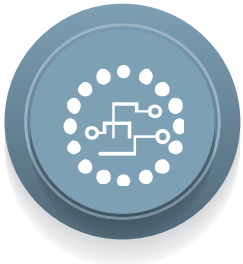


INTEGRATED TECHNOLOGY SOLUTIONS ENHANCE DATA QUALITY AND EFFICIENCY OF VACCINE STUDIES

Real-time Access to Clinical Trial Data

Vaccine studies produce large volumes of data that must be reviewed and analyzed in a short period of time. PPD leverages technologies that enable:

Collection of subject-level data, which facilitates real-time feedback on safety and immunogenicity measures and direct communication of key study assessments



An integrated technology platform that links data across sites and laboratories

Less frequent on-site monitoring visits and a remote monitoring approach with a customizable plan driven by continuous site-level risk assessment

Development of eSource solutions for sites, allowing for more immediate access to source documentation and facilitating remote source verification

Preclarus®, PPD's comprehensive data solution, provides real-time access to all clinical trial operations and subject data.

Preclarus facilitates prompt and ongoing study assessment and adjustment, which is critical for fast-paced vaccine trials. In addition to improving overall study management, access to near real-time data can effectively facilitate:

- Independent data monitoring committee (IDMC) reviews to observe safety trends
- Case definition and endpoint evaluation for field efficacy trials

Preclarus can be utilized by internal teams, sites and clients, and is particularly useful in cohort studies and ongoing safety evaluations by medical monitors.

HIGH-QUALITY, TARGETED MONITORING FOR VACCINE STUDIES

PPD utilizes Preclarus as part of its approach to risk-based monitoring, which includes on- and off-site monitoring to increase quality, decrease data review time and expedite decision-making.

Specifically, PPD's vaccine team uses the Preclarus patient data dashboard to create a customized profile of subjects across a wide range of clinical laboratory findings and to review safety trends for vaccine reactogenicity, labs and toxicity gradings, all of which are important for early phase vaccine research and dose escalation meetings.

PPD develops study-specific, risk-based monitoring strategies based on key site performance indicators. This propriety method allows CRAs to maximize their time on-site and focus holistically on site performance. In vaccine studies, this approach ensures PPD delivers cost savings in conjunction with quality data.

PPD® LABORATORIES AND VIRAL LAB PARTNERS DELIVER HIGH-THROUGHPUT, HIGH-QUALITY DATA

More than 25 Years of Specialized Vaccine Laboratory Experience

PPD® Laboratories offers a full range of vaccine testing services, with a focus on incorporating cost and operational efficiencies that move life-changing vaccines to market faster. **Our laboratory features:**

- More than 65,000 square feet of industry-leading laboratory space dedicated to supporting vaccine trials
- More than 410 scientists, including a dedicated research and development team
- Automated platforms, including:
  - TECAN EVO®, Hamilton® Microlab™ STAR
  - BD FACSCanto™
  - Multiplex assay platforms for serology, molecular genomics and functional, cell-based assays
- Successful U. S. Food and Drug Administration (FDA) submissions demonstrate a strong understanding of requirements to meet approval
- More than 25 years of experience developing and validating custom, proprietary assays for new vaccines
- Several assays available for use by all clients for concomitant testing

A TEAM OF BIOSTATISTICIANS

To complement our scientific expertise, the vaccine sciences lab has a team of biostatisticians with extensive experience supporting the development and operation of vaccine assays. The lab team has developed and validated a data processing tool for functional serial-dilution assays that delivers:

- Complete sample and reagent traceability
- Sample volume assessment at each step of the process
- Automated experimental design for error-proof serial dilution calculations for all studies, including complex, multiplexed assays
- Validated, electronic batch/run documentation and audit trail

VACCINE LAB CAPABILITIES

To complement our internal vaccine laboratory capabilities, PPD has identified several preferred lab vendors to ensure that global trials are supported by high-quality, high-throughput laboratory services around the globe and around the clock.

- Specialized facilities to meet biosafety level two (BSL2) and three (BSL3) requirements
- Bioassay services - virus microneutralization, ELISA, ELISPOT, cytokines, bactericidal assays, opsonophagocytic assays (OPA, MOPA) and cell-based/functional assays
- Molecular testing - qPCR, subtyping, resistance testing, sequencing, etc.
- Sample logistics, kits, manuals and training
- Biobanking and cryopreservation
- Diagnostic testing across a broad range of infectious disease indications including, but not limited to, RSV, influenza and flavivirus

PPD®

For more information, please contact us at
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