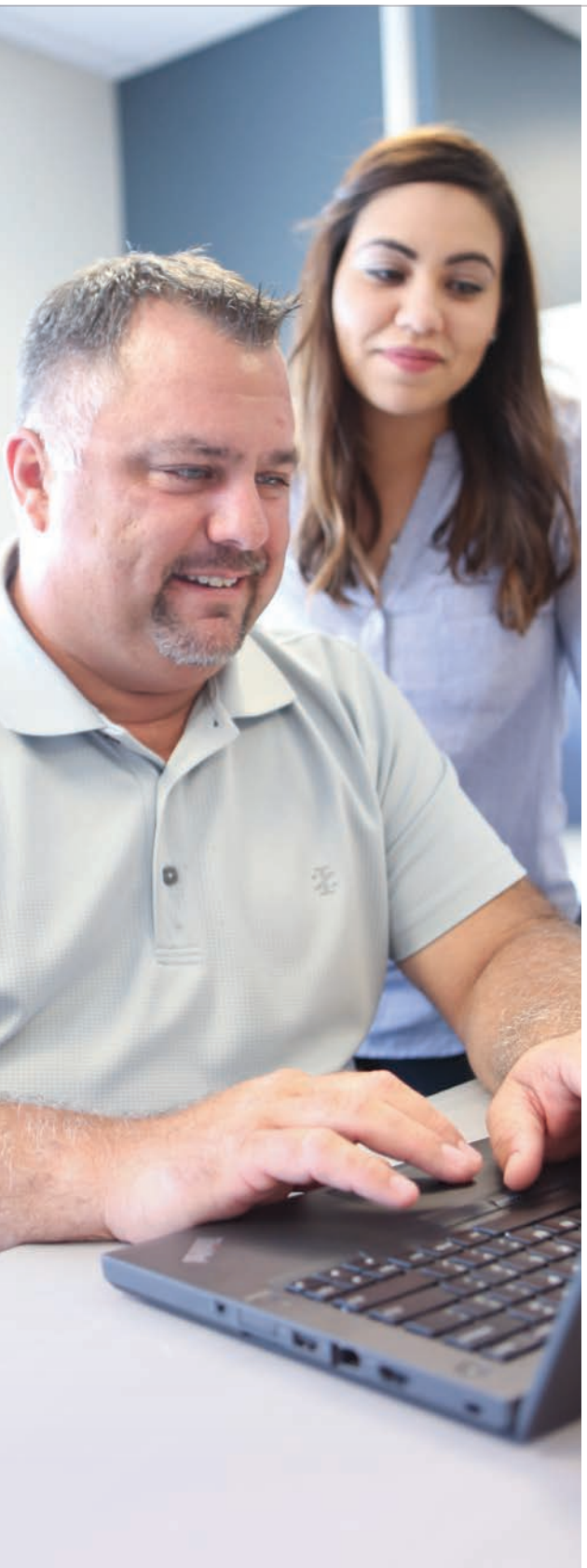
PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

REGULATORY AFFAIRS

FLEXIBLE, INNOVATIVE REGULATORY SERVICES



PPD offers unmatched scientific, regulatory and operational expertise and the global reach to help you navigate regulatory approval and market access for your product. Our strategic regulatory services span the full spectrum of activities and technical functions including regulatory development, licensing and lifecycle management, regulatory strategy input and full-service regulatory partnerships. Our end-to-end solutions assure regulatory compliance throughout the product lifecycle while helping to advance global product development.

GLOBAL REGULATORY INTELLIGENCE AND INFORMATION

REGULATORY DEVELOPMENT EXPERTISE AND GLOBAL STRATEGIES

NEW PRODUCT LICENSING AND MARKET EXPANSION

MARKETED PRODUCT LIFECYCLE MANAGEMENT AND COMPLIANCE

AD-HOC CLIENT SUPPORT AND SPECIALIST CONSULTING

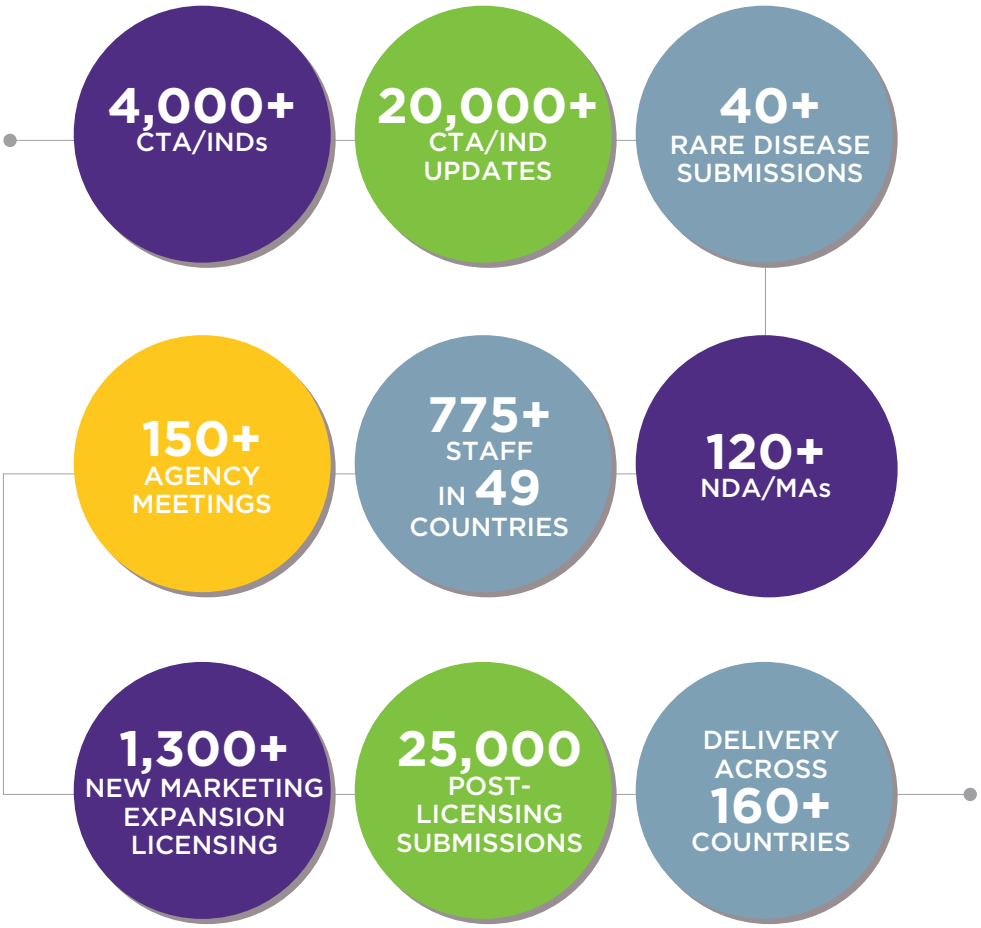
EXPERIENCE DELIVERS QUALITY RESULTS

PPD's regulatory team is comprised of dedicated and experienced experts committed to delivering high-level results for clients. Our team of more than 775 members in 49 countries have a broad range of experience in commercial and market access environments. Additionally, regulatory team members have a range of backgrounds, with many holding a Ph.D., M.D., or M.B.A, and our senior staff members have an average of 22 years of experience in the pharmaceutical and medical device industries and 16 years in regulatory affairs.

775+ members

in **49** countries

average **22** years of industry experience



Our industry-leading regulatory experts have extensive experience in global product development and global regulatory strategies in all phases and multiple pharmaceutical and medical device platforms. We provide flexible, comprehensive consulting and delivery services including:

- Clinical trial and marketing applications
- Medical devices and diagnostics
- Publishing and submissions
- Lifecycle and compliance management
- Strategic consulting and intelligence, including
  - Preclinical and chemistry manufacturing and controls expertise
  - Vaccines, biosimilars and biologics
  - Pediatric and orphan drug experience
  - Innovative and advanced therapies and diagnostics
  - Generics

FULL SPECTRUM OF FLEXIBLE SOLUTIONS

Our wide-range of regulatory services provide strategic and technical expertise focused on delivery excellence. These services include:

Regulatory affairs

Development, new product licensing and market expansion, marketed product lifecycle management and compliance, navigation of complex global regulatory landscapes, leveraging established relationships with regulators and industry stakeholders

Regulatory intelligence

Environment monitoring, assessment and strategic application, compliance with applicable regulations, review and benchmark of competitive products, development of risk mitigation strategies

Regulatory science and innovation

Using current regulatory framework and proactive flexible approaches, influencing of future paradigms

Rapid response

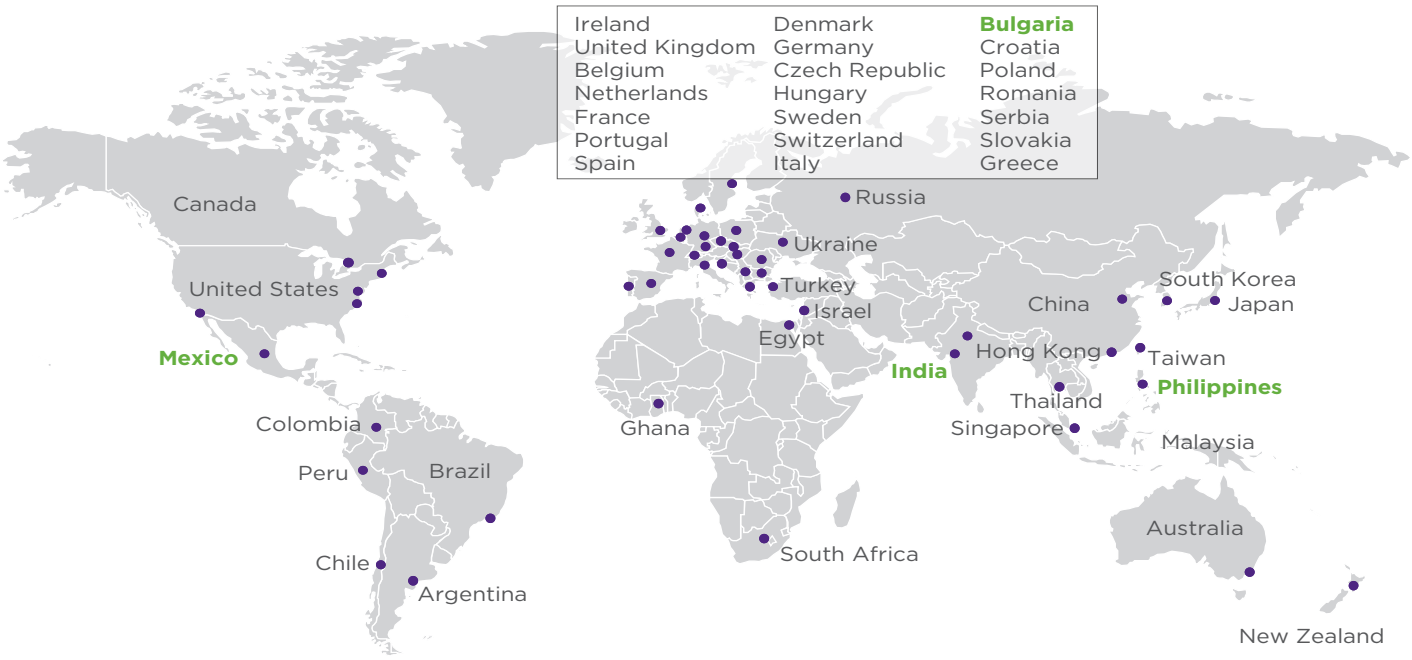
Rapid and seamless deployment of staff in global locations

Real world applicability

Alignment of regulatory and HTA, including opportunity for parallel advice, increasing payer and patient engagement, driving strategies for early access, adaptive/conditional licensing with robust post-approval framework

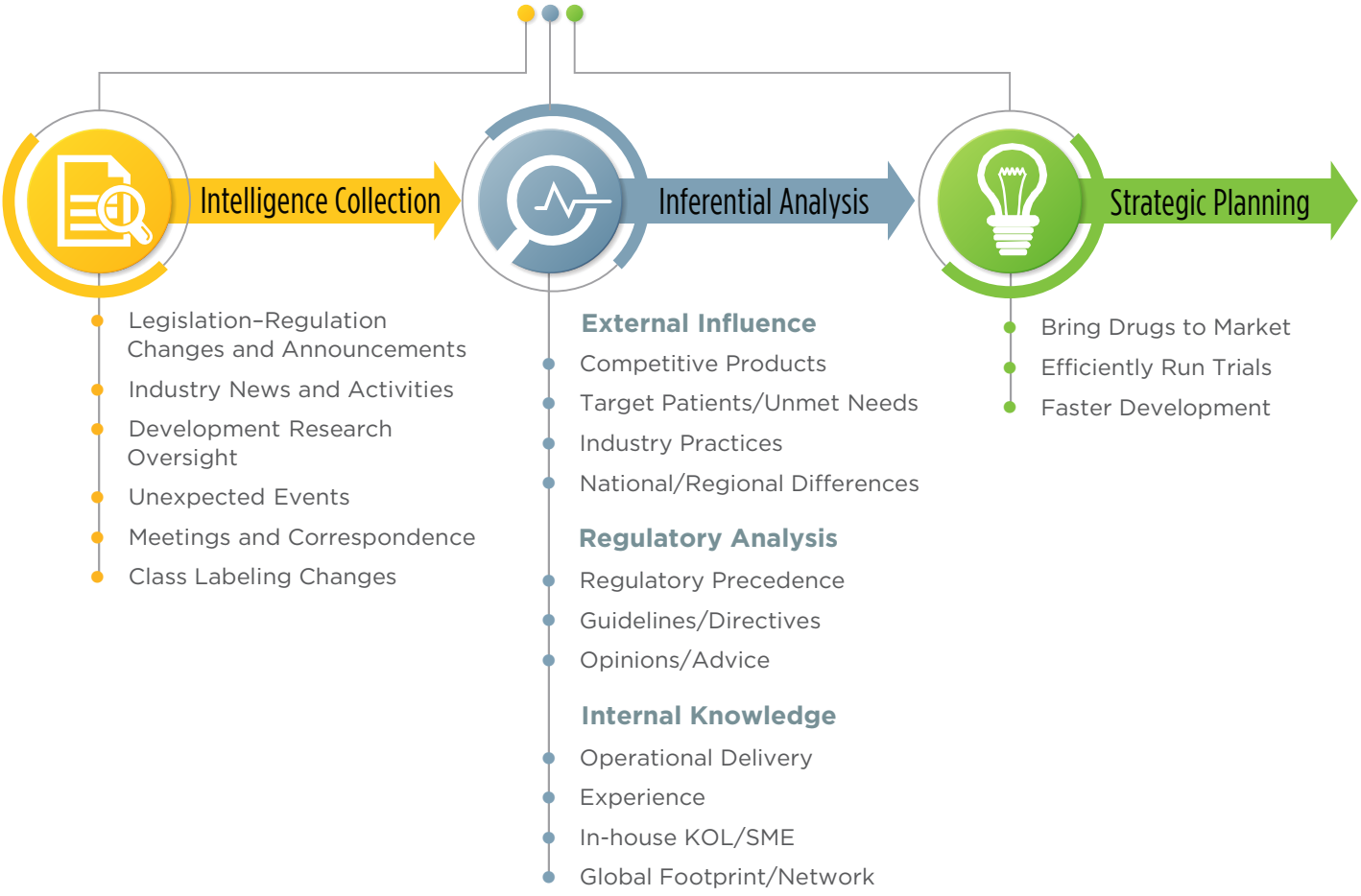
WIDE-REACHING GLOBAL FOOTPRINT

Our global reach and active regulatory agency network provide local coverage in key markets, enabling us to apply up-to-date, robust regulatory intelligence to product development and registration strategies. We develop preemptive solutions for potential regulatory hurdles and ensure the quality of submissions to worldwide agencies to maximize the likelihood of successful review. Our country regulatory agency network ensures appropriate country regulatory representation, response and action to support PPD throughout the world.



- PPD's FLEX units provide functional outsourcing as a customizable solution that focuses on high quality, measurable outcomes and cost savings. This dedicated business unit focuses on a full range of regulatory services, including regulatory strategy and document preparation, publishing and lifecycle management.
- Offices with regulatory affairs presence, including clinical trial application (regulatory authority and ethics committee) submission handling.

ACTIONABLE REGULATORY INTELLIGENCE



EFFECTIVELY MONITORING THE REGULATORY LANDSCAPE

PPD® RegView is a one-stop system that allows our regulatory team members to source actionable intelligence to better support clients. The system provides information on regulations, guidance and best practices, and is used to support clinical trials, marketing authorization, lifecycle management, safety reporting and CTMS document requirements. In addition, PPD® RegView is used to educate internal expert groups on the latest trends, including new developments in global and regional regulatory affairs and the competitive landscape.

13,000+
regulatory overview summaries

in **160+** **countries**

with **200+** **PPD contributors**

OPTIMIZING PRODUCT REGISTRATION AND MARKET ACCESS

As PPD's dedicated real-world research and market access unit, Evidera—Evidence, Value & Access by PPD delivers a solution to seamlessly integrate and align regulatory and peri- and post-approval research efforts, improving the ability to meet the evidence demands of regulators and payers. With an extensive global network of regulatory experts, industry leading global operations capabilities and unparalleled expertise and experience in health economics, outcomes research, market access, epidemiology, observational studies and non-registration interventional studies, we are able to design and implement comprehensive regulatory and market access strategies across the product lifecycle.

PPD®

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