



Regulatory affairs

Regulatory affairs



Flexible, innovative regulatory services

The PPD™ clinical research business of Thermo Fisher Scientific 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

Our regulatory team is comprised of dedicated and experienced experts committed to delivering high-level results for clients. Our team of more than 390 members in 38 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 24 years of experience in the pharmaceutical and medical device industries and 18 years in regulatory affairs.

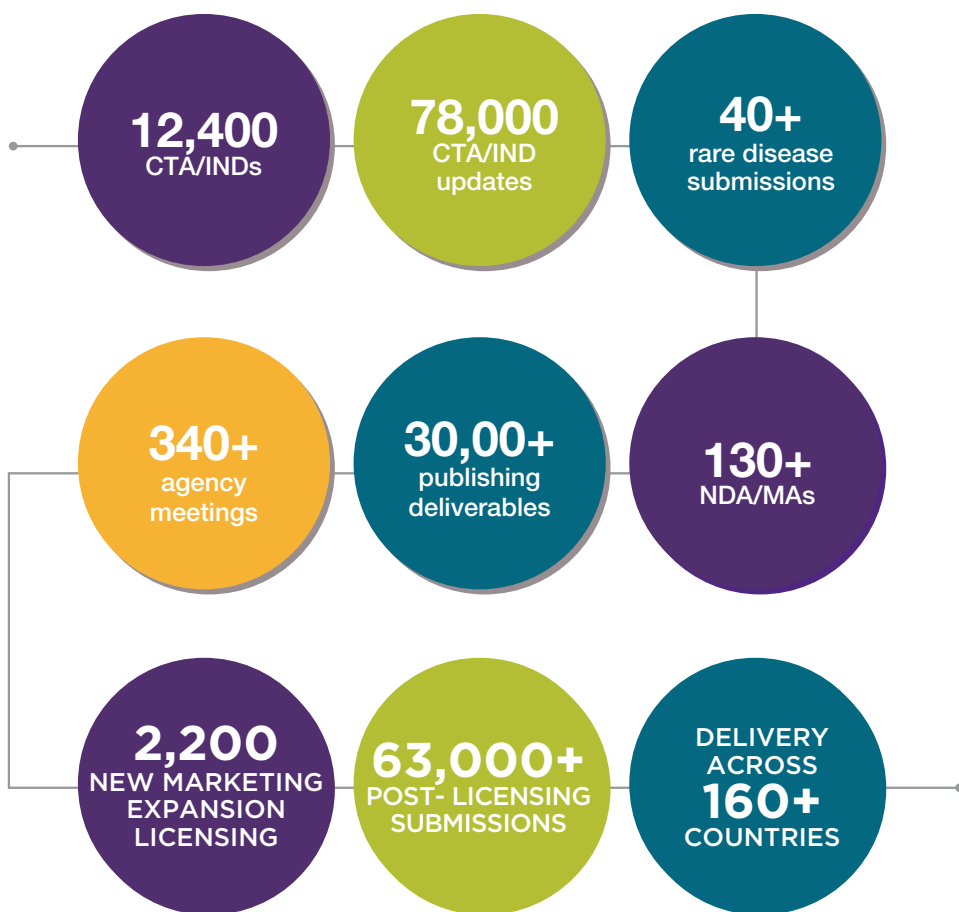
390+ 
members

 in **38**
countries

average 
24 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

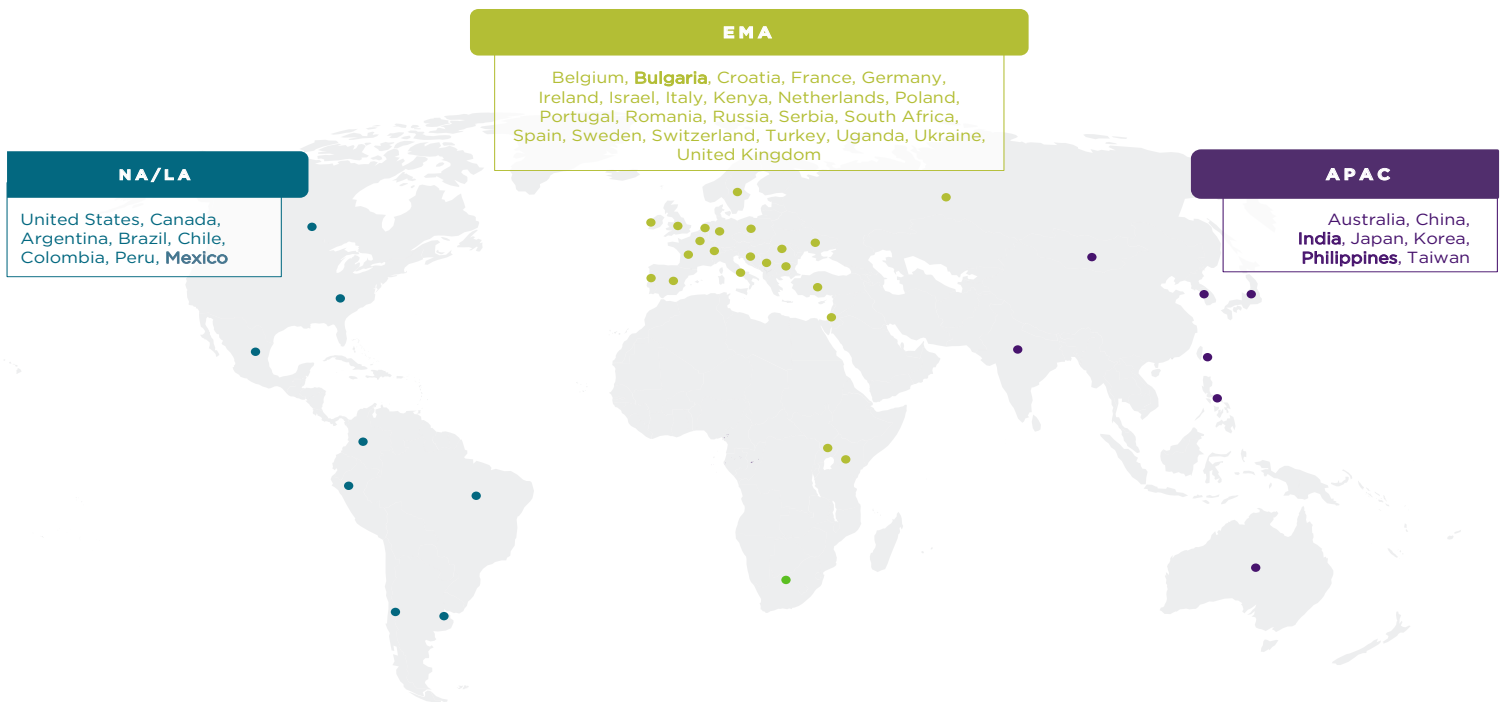
Rapid and seamless deployment of staff in global locations.

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 us throughout the world.



Countries in **BOLD**: Our 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.

Actionable regulatory intelligence



Effectively monitoring the regulatory landscape

RegView is a one-stop regulatory intelligence platform that enables our staff to source global regulatory intelligence to better support clients. The platform contains regulations and guidance, as well as best practices based on our experience, and is used to support clinical trial, marketing authorization, lifecycle management, safety reporting and CTMS document requirements. In addition, 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.

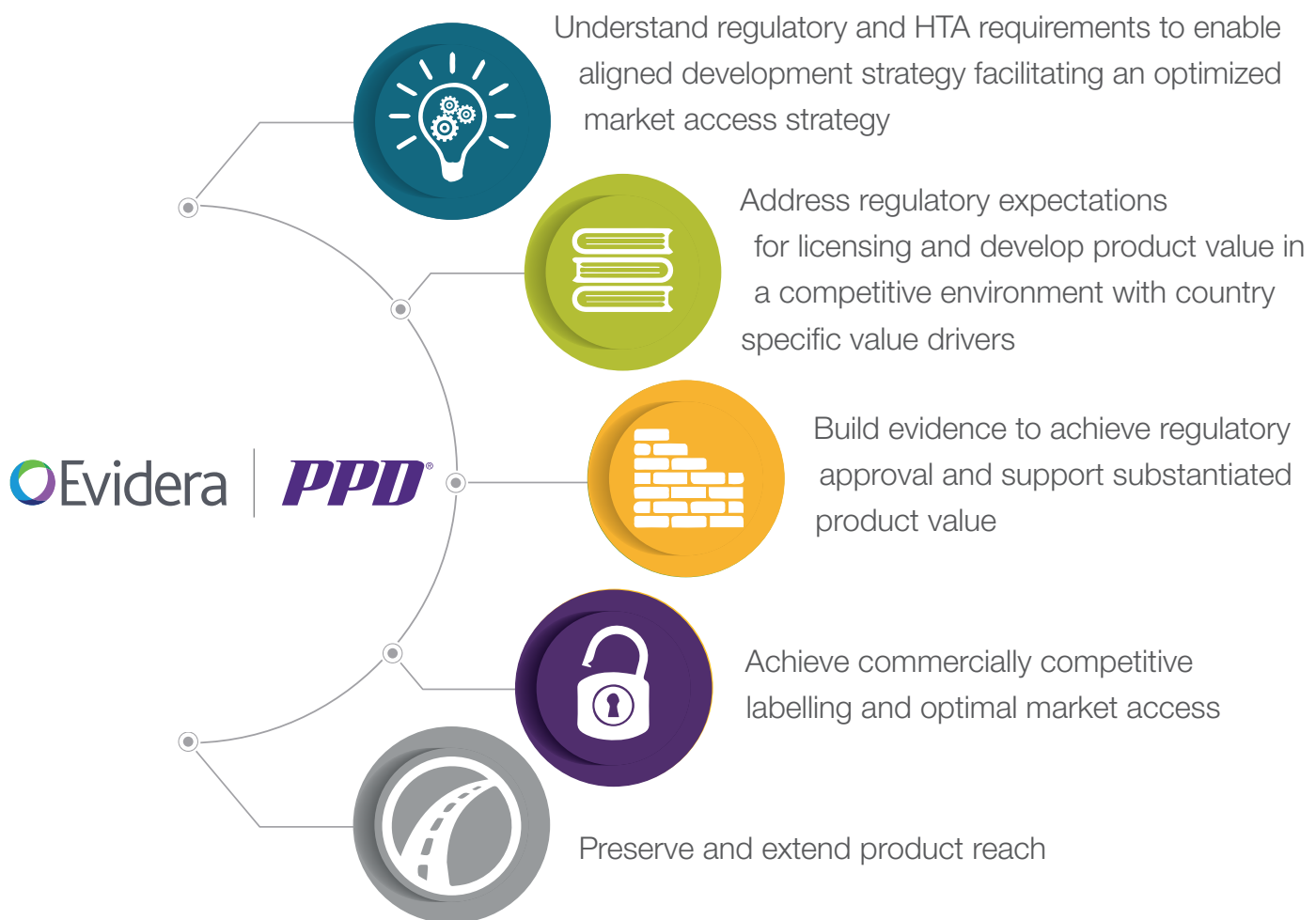
13,500+
 regulatory overview summaries

in **180+**
countries 

with **400+**
contributors 

Optimizing product registration and market access

As our dedicated real-world research and market access business, Evidera 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.



 Learn more at thermofisher.com/ppd

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