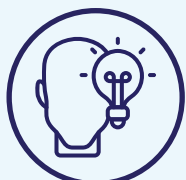


Strategic Regulatory and Development Consulting



Evidera, a PPD business, brings the insight and guidance you need to optimize your product's success from discovery through post-approval with:



More than 25 years' experience and diverse therapeutic expertise to help you anticipate and plan for opportunities and overcome challenges



Direct access to industry-leading experts in the design and execution of full product development programs



Close consultation to develop customized plans that increase efficiency and reduce risk, helping you maximize your product's value

Direct Access to Industry Experts

Our team is comprised of physicians, scientists, regulatory professionals, and biostatisticians with extensive small and large molecule development experience. These experts have significant knowledge of state-of-the-art pre-clinical, clinical, regulatory, biostatistical, manufacturing, and commercial strategies and can provide expert consultation at any phase in development, ranging from first-in-human testing through registration, including post-approval studies and product optimization strategies.


Product Development Consulting


With a long and successful history of consulting, our experts have broad therapeutic knowledge and in-depth understanding of all aspects of product development planning in all major therapeutic areas. Our expertise includes:

- Development of cross-functional, integrated product development plans
- Development of minimum and target product profiles and associated clinical development plans
- Development and implementation of biomarker and companion diagnostic strategies
- Development of global or regional regulatory strategies
- Development and implementation of cell and gene therapy strategies
- Process development design of manufacturing strategies for large and small molecules
- Design of clinical trials including in-depth knowledge of relevant indication specific endpoints and use of traditional and novel statistical approaches
- Development of medical devices
- Development of pharmaceutical products in rare diseases and pediatric indications
- Design of comprehensive pre-clinical toxicology plans

Your Advantage

Evidera gives you the advantage to succeed no matter your scenario.

 Virtual entities as well as small or emerging biotechnology pharmaceutical and diagnostic/device companies can take advantage of our development strategy and experience with regulatory agencies.

 For larger pharmaceutical and biotechnology companies we can address gaps in strategic resourcing, enhance existing resources, or engage in longer-term joint development and planning activities as part of joint development teams.

 Customized services are available for small and large molecules, devices, cellular therapies, and companion diagnostics.

Expect Excellence

As part of PPD, we can provide the global infrastructure, experience, and insight to expedite complex multinational product development programs leading to successful marketing approvals. When you consult with us, you can expect:

- ✔ Cutting-edge biostatistical experience
- ✔ Deep medical and therapeutic expertise
- ✔ Global regulatory experience in major and emerging markets
- ✔ Transparency and collaboration
- ✔ Flexible partnership approaches
- ✔ Cross-functional product development leadership and program management