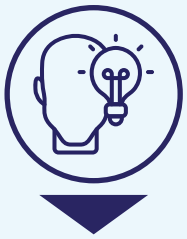
Strategic Regulatory and Development Consulting

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

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Specialization to Meet Industry Demands

Evidera offers specialized guidance to help clients successfully navigate challenges and realize opportunities across a wide range of therapeutic areas, including those with unique and complex development needs. We have established Centers of Excellence specifically focused on three key specialty areas to address strategic, operational, medical, and scientific challenges.

- **Rare Diseases and Pediatrics**
  - This team provides tailored thought leadership and innovation in the design and execution of rare diseases and pediatric trials and studies, as well as strategic insights to inform and optimize clinical, regulatory, and market access strategy development.
- **Immuno-oncology (IO)**
  - We foster innovative thinking and collaboration in IO trials, including the development and implementation of sufficient adaptive design approaches in early phase studies. Education is also a high priority to keep our staff updated on industry activity, such as current and expected IO drug approvals, recent clinical data, emerging classes of immunotherapy and combinations, regulatory strategies and considerations, and approaches for reducing development timelines.
- **Precision and Transformative Medicine** (including cell and gene therapies, biosimilars, and medical devices)
  - The emergence of innovative health technologies has the potential to fundamentally alter disease management. These new therapies, however, require special expertise to optimize their potential for approval and access. This cross-functional team of experts works with you on unique, end-to-end development strategies to demonstrate your product's effectiveness and value.

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**

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