parexel BIOTECH

Accelerating, guiding and simplifying biotech drug development

Helping you deliver medical breakthroughs. Because patients can't wait.

At Parexel Biotech, we focus on meeting your patients' needs. The most critical and innovative new therapies, and those for rare and untreated diseases, are in the biotech pipeline. We have tailored biotech-specific solutions that connect essential services supported by dedicated experienced leadership and resources. Patients are waiting for more effective and better-tolerated therapies and our mission is to help you deliver them. From development strategy, meeting clinical development timelines, optimizing product and pipeline value, to navigating competitive, regulatory and reimbursement landscapes, we connect essential capabilities with a passionate, can-do culture to bring success for you while delivering better healthcare for patients.

With Heart

Your challenges

- Navigating complex **competitive, regulatory and reimbursement** landscapes
- Managing complex **funding** environment and limited resources
- Defining the right **development** and post-launch path
- Orchestrating increasing **trial complexity** and associated **site burden**
- Applying the latest drug development **innovations** to improve the likelihood of launch
- The need to **demonstrate** proof-of-concept
- Identifying the **optimal protocol design**
- Selecting the **right sites** for **optimized** patient **recruitment**

A strong plan helps you hit your targets

Smart, early planning is essential. Considering the needs of your key stakeholders, investors, regulators, payers, physicians and patients can optimize your development program to save time and resources. We'll help you map out your development journey to identify potential risks and how to avoid them.

We'll help you reach your goals faster. How we do it:

- Assign a dedicated point of contact to meet project timelines
- Invest dedicated resources in emerging and mid-size sponsors
- Deliver executive sponsorship to support ongoing success
- Provide access to specialized resources from world-class experts, including former regulators
- Develop an integrated, customized strategy to minimize complexity, accelerate timeliness and reduce fixed costs
- Leverage adaptive, synthetic and/or flexible trial designs for maximum efficiency
- Apply industry-leading translational medicine expertise*
- Implement innovative patient-centric solutions** and the latest thinking around real-world data and evidence

* including quantitative clinical development, biomarkers and genomics (enabling delivery of precision medicine), and bioanalysis
** e.g., hybrid or virtual trials

We offer guidance and experience with flexibility

You're driven by the goal to make life better for your patients. We're here to help make sure that happens.

Here's what we can do:

- Give you strategic guidance
- Innovate and streamline your development program
- Extend your reach
- Integrate your approach
- Navigate therapeutic areas
- Mitigate your risks

Biotech is a fast-growing, competitive environment

The R&D pipeline keeps on growing, year on year...[1]

170% increase in number of drugs in R&D pipeline between 2001 and 2019

...and investment in biotech is growing[2]

179% increase in amount invested via venture financing between 2001 and 2019

80.5% biotech's share of the overall pipeline in 2019

Sources: 1. Citeline Annual Report, March 2019. 2. Venture Financing WW 2010-2019.

Parexel has the expertise to guide you to make the most of this growing market

- 60+ former regulators from around the world
- 1,000+ regulatory experts, 110 countries covered
- 100+ marketing applications and submissions (NDA, BLA, ANDA, MAA, JNDA, 501(k), etc.) per year
- Health Advances: 25 years, 2500 projects, 140 employees, $75 billion of client transactions
- 652 studies, incorporating 135K+ patients and 15K+ sites[1]
- 80+ meetings with global Regulatory Authorities (FDA, EMA, PMDA, NMPA, etc.) per year

Source: 1. GXDB – Data 2012-2018 (Project: Clinical studies only)

We'll put our heart and soul into helping you solve your challenges – at every step

It's now more difficult and expensive than ever to get a molecule to market. A tragic fact that means some worthy drugs never make it to the patients who need them. That's why at Parexel Biotech, we focus on finding ways to simplify and speed up development in order to reduce costs.

While there's always more to do, here's how we're doing so far:

12%
faster start-up
than other CROs from final protocol available to first site initiated*

13%
shorter cycle
than industry average from final protocol available to database lock*

9%
faster turnaround times
than industry average from database lock to clinical study report approval*

Up to
20%
efficiency generated
in developing evidence platforms for compounds while identifying new value opportunities*

*Source: KMR Group – Clinical Group 2015-2017.

Our operating model

We tailor our services for you, keeping our operational structure lean and our processes flexible, to reduce cost and improve efficiency.

Parexel Biotech Operating Model

- Dedicated Leadership
- Dedicated Resources
- Lean Operational Structure
- Flexible Processes

Integrated Delivery Model: one Team – one Voice – one Vision – one Parexel

- Project Level › Project Leader
- Account Level › Client Delivery Director

Parexel Biotech Culture: making a difference for patients – *With Heart*

Like our hearts, our offices are in the right places

- **Asia Pacific**
  20+ offices
  8,000+ employees
- **Europe**
  30+ offices
  5,500+ employees
- **Latin America**
  3+ offices
  600+ employees
- **Middle East & Africa**
  5+ offices
  400+ employees
- **North America**
  10+ offices
  3,500+ employees

With Heart

We're always available for a conversation

To learn more about Parexel's Biotech services, please contact:

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