



Solving challenges for  
emerging companies

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

We all know how hard it is to bring a new drug to market. Yet, because of your passionate pursuit of a novel therapy, here you are. And that's why we're here, too. There's no doubt that the challenges for emerging biotech companies are big but we have the experience and capability to help make sure you get there.

*With Heart*



# Your challenges



Meeting **deadlines** having usable **data** and avoiding **re-work**



Optimizing the value of your **product** at every stage, whether you plan to partner, sell, or take your asset to market



Filling any **expertise** gaps you may have in the development process due to limited resources



Aligning your development plan with the desired **business outcomes**





»»» We offer guidance and  
experience with flexibility

You're driven by the goal of bringing life-saving drugs to market – as quickly as possible. We're here to help make sure that happens. We're not interested in the size of your company, but rather the size of your ambition.

Here's what we can do:

› **Give you strategic guidance**

You've got big decisions to make – for example, who to partner with, which indication to go for, potential mergers and acquisitions, how to raise capital, and competitive assessments. Let us develop strategies tailored to your specific goals backed by a proven track record of success.

› **Streamline your study**

We believe in starting with the end objective in mind. Our expert consultants include many former regulators, payers and business experts who can advise you on the most efficient course to help you optimize the value of your asset and reach your business goals as soon as possible.

› **Extend your reach**

Flexibility is key to successful drug development. So whether you need an expert touch here and there, or access to our full range of global clinical operations, we'll scale our approach accordingly, to ensure we are the perfect fit for you.

› **Integrate your approach**

For maximum efficiency and smooth communication, we can be your single partner, providing expert oversight across clinical development, regulatory and strategic consulting, and commercialization.

› **Navigate therapeutic areas**

Whatever your drug's mechanism of action or your therapeutic areas, our experience means we will have run trials with similar therapies, so let us ensure you get the right sites and the right protocol definition from the start.





## »»» A strong plan makes everything else work better

A go/no-go decision for your drug relies on the data you provide to investors, regulators, payers and providers. That's why smart, early planning is essential. This upfront work is vital but we'll help you map out your development journey to identify potential risks and how to avoid them, without slowing the process.



Our integrated approach can help you decide which way you want to go – fast.

We can help you:

- › Analyze the competitive landscape for unmet clinical needs
- › Conduct a disease incidence study to determine the viability of developing a therapy
- › Manage recruitment for early phase studies



**Remain independent**



**Seek a buyer**



**Pursue new funding**





Get early scientific advice from regulators to help gain approval.

**85%** of applications that followed scientific advice were approved

**41%** of applications without scientific advice were approved



Source: Hofer et al, 2015

Select the right trial type to increase likelihood of launch\*.

**21%** higher likelihood of launch using real-world data

**19%** higher likelihood of launch with patient-centric trials



**13%**

higher likelihood of launch with adaptive trials

\*Compared to traditional clinical trials.

Source: The Innovation Imperative: The Future of Drug Development, The Economist Intelligence Unit, 2018



»»» Your mission is to save lives.  
Ours is to make yours easier

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 bring the cost of new drugs down.

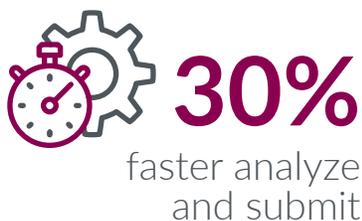
While there's always more to do, here's how we're doing so far:



First site initiated to last site initiated, compared to industry average\*



From first subject randomized to last subject randomized, compared to industry average\*



From database lock to clinical study report approved, compared to industry average\*

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



# Your Journey. Our Mission.®

»»» We're always available  
for a conversation

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