Bioteching in action

Four ways to increase rare disease drug development success

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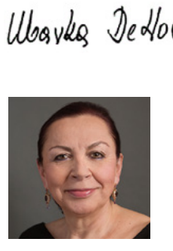
Rare diseases currently affect 3.5%-5.9% of the world's population, estimated to be more than 300 million people.

There are more than 7,000 identified rare diseases today, 71.9% of which are genetic. And only around 5% of rare diseases have treatments. Development is complex and presents specific challenges. For example, many rare disease patients are children, since nearly 70% of rare diseases are exclusively pediatric-onset. The patient pool is often very limited for any one disease, and patients are often geographically dispersed, highlighting the importance of selecting a development partner with strong patient recruitment and global operational capabilities.

In this eBook, Parexel Biotech shares insights on maximizing the chances of success in rare disease drug development, providing our perspectives on four of the most significant challenges:

- Easing trial burdens on sites, and enhancing the clinical staff experience
- Ensuring that pediatric trials are ethical and feasible for patients and families
- Getting to market faster and stronger with natural history studies and real-world evidence
- Learning from past successes and failures in orphan indications

We hope you find these articles helpful on your journey.



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Insights

High-quality natural history studies are a strategic asset for rare disease development

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Call it what you will — natural history study, epidemiological study, observational study, disease registry, non-interventional study, or real-world evidence (RWE) study. These terms describe the same thing: a study of the demographics and the course of a disease as it is currently treated from its pathological onset through recovery or death. Rare disease drug developers with access to data from a high-quality natural history study can make better strategic decisions, inform more efficient development paths, and deliver better products to patients.

For rare diseases, high-quality natural history studies can have an outsized impact on the overall development strategy. That's because little is known about the exact course of many rare diseases. But companies must balance data quality, time, and cost when deciding how to design and conduct a natural history study. There are three main types (Table 1):

1. Medical literature search, supplemented by interviews with key opinion leaders (KOLs)
2. Retrospective analysis of secondary datasets, such as that of Kaiser Permanente's integrated healthcare delivery network
3. Prospective research engaging sites, enrolling patients and following them over time, asking questions of scientific merit, and collecting the answers

The power of a prospective RWE study

As soon as a company has identified a compound with biological activity in a rare disease, it's time to plan a natural history study. For rare diseases, collecting natural history data is as essential as preclinical work or a Phase I trial. It's not just nice-to-have context; it's the starting point for efficient development. Natural history data can inform pivotal development decisions if the study is conducted in parallel with the clinical program. The FDA's 2019 Draft Guidance on Rare Disease Natural History Studies illustrates what agency reviewers consider best practices.

Prospective, longitudinal studies capture the most detailed and highest-quality data about patient demographics, disease course, and the current standard of care (SOC). As a result, they can be a valuable investment (Table 1). A high-quality retrospective data study is the next best thing for companies that cannot undertake a prospective study.

The RWE captured during a natural history study can boost the chances of a clinical trial succeeding. In recent years, the quality and standardization of secondary databases have improved — and will continue to be aided by advances in information technology. For example, in the EU, the EMA launched the Data Analysis Real World Interrogation Network (DARWIN EU) to access databases that collect real-world data on "diseases, populations and the uses and performance of medicines." Such a tool could allow physicians treating rare diseases to make their data public and foster collaboration.

The holy grail: an external control arm

For rare and ultra-rare diseases, especially rapidly advancing conditions in children, it is often unethical, impractical, or untimely to enroll a concurrent placebo or SOC arm. But when sponsors conduct single-arm studies in a small number of patients, regulators are left without a comparator against which to estimate a drug's risk-benefit profile.

External control arms (ECAs) can be constructed from natural history data, but it can be challenging to combine disparate databases and to match patients one-to-one on a large number of covariates in a clinical trial. One way to ensure quality is to apply epidemiologic principles of observational research to the ECA study design, methods, and operations and then systematically evaluate and resolve potential biases.

An even better approach is to design a high-quality prospective natural history study that can serve as an ECA, providing data that regulators and Health Technology Assessment (HTA) agencies can use to evaluate efficacy. There is a clear patient benefit, since it allows every patient to receive active treatment in a clinical trial rather than be allocated to a placebo control regimen.

"For rare diseases, history data is not just nice-to-have context; it's the starting point for efficient development."

Get to market faster and stronger

Robust natural studies have the potential to get new rare disease drugs to the patients who need them sooner. And there's a greater chance of getting reimbursement for those new products because the unmet needs and healthcare burden have been better quantified.

Table 1. Three primary ways to collect RWE on the natural history of a rare disease

Approach	Pros	Cons	Potential Uses
Medical literature search[1] and KOL interviews	Least expensive Fast • Captures public data on what is generally known about the rare disease • May provide a rough estimate of prevalence, incidence, disease duration, and overall survival rates • Identifies KOLs and initiates a relationship	Scarce peer-reviewed data on rare and ultra-rare diseases KOLs may have diagnosed and treated very few patients May not elucidate current SOC Published journal articles may be outdated No way to access patient data or capture missing data	• Inform protocol design • Aid market forecasting • Identify KOLs
Retrospective database analysis[2]	Lower cost than a prospective study Fast • Allows more granular look at data than literature review • Quantifies size and geography of rare disease population • May provide insight on current SOC and patient care pathways in different healthcare systems	• Must pay an access fee per database • May need to access many databases to get enough patient data • Need deep epidemiological expertise to differentiate between high- and low-quality data sources • Flawed data sources may be uninterpretable or misleading • Data coding and terminology may differ between sources, limiting interpretability	• Inform protocol design • Aid market forecasting • Outline patient care pathway
Prospective site-based (or direct-to-patient) cohort study[3]	• Yields high-quality and interpretable data • Captures current SOC data by region and locality • Quantifies target rare disease demographics precisely • Identifies potential biomarkers and endpoints/surrogate endpoints • Identifies PROs and QOL scales relevant to patients and caregivers • Engages patient advocacy groups • Builds relationships for future clinical trials	• More expensive than literature review or database analysis • Takes longer to complete (months to years, depending on the disease) • Requires expertise to design and execute rigorous study • To reap the rewards, it must be initiated early in development	• Optimize protocol design • Precisely forecast market size and subpopulations • Gather local/regional SOC and healthcare burden data to support reimbursement • Prepare and socialize investigators and sites • Speed patient recruitment through PAG partnerships • Serve as an external control arm for a clinical trial • Help fulfill post-marketing requirements

1 Includes peer-reviewed and non-peer-reviewed literature
2 Includes integrated healthcare delivery networks with electronic health records (EHRs), national or disease registries, insurance claims databases, population health surveys, etc.
3 Prospective NH studies can be entirely observational (noninterventional) or minimally interventional (with added diagnostics, procedures, or patient-reported outcomes). They can be cross-sectional (snapshot in time of an acute medical event, such as a stroke) or longitudinal (patient is followed for prespecified time periods and disease progression is tracked).

Ethical and practical considerations for conducting rare disease trials in children

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Global Head of Pediatrics

When Mateo* was diagnosed with Langerhans cell histiocytosis (LCH), a rare childhood cancer, his mother spent endless hours scouring the internet for information. She had encountered a common reality: Mateo's doctor had never heard of the disease or seen any patients. She embarked on the long rare disease journey that so many parents and caregivers face: deciphering the technical jargon of medical journals, connecting with members of the rare disease community, learning how clinical research works, and handling a clinical trial with multiple site visits and procedures, all while dealing with the day-to-day issues and comorbidities of the disease.

This mother's journey underscores how rare disease clinical research differs from other therapeutic areas. Since 70% of rare diseases are exclusively pediatric-onset, studies often revolve around the lives of very young children and their families. Trial designers must add protocol-specific activities to the already challenging lives of these patients and caregivers without creating any unnecessary burdens. And they have to accommodate broadly geographically dispersed patients. We asked Parexel's global head of pediatrics, Shipra Patel, M.D., how to design ethical and feasible rare disease trials for children.

*The patient's name has been changed to protect their identity.

What makes pediatric rare disease trials unique?

For many rare diseases with no effective therapies or cures, investigational treatments may provide the only source of hope to parents searching for ways to improve their child's quality of life. As a result, families of children with rare conditions are often deeply engaged with their patient communities and track the latest clinical trials and developments in detail. They travel long distances and go to great lengths to participate in clinical trials that might benefit their children and the broader rare disease community.

During the informed consent process, investigators must discuss potential risks, benefits, and study procedures while sensitively managing the family's expectations and misconceptions. Educational, clear, and transparent clinical trial materials can establish realistic expectations.

How do you design and conduct an ethical rare disease trial for children?

First, it is essential to make a trial for a rare childhood disease patient- and family-centric. Children and families living with rare diseases cannot take on the additional burden of a clinical protocol laden with nice-to-have endpoints. Trial designers must take extra time to streamline and optimize designs, paring down data gathering and site visits to the minimum sufficient to generate interpretable safety and efficacy data.

Second, the trial must address details and nuances to reduce patient and family burden. For example, blood draws may seem like a routine, low-burden activity, but they can be painful and traumatic for children, especially in some rare skin disorders. Protocols should only include necessary blood draws. Trial designers can modify protocols to ensure that the required trial data measurements and assessments are reasonable.

> "Trial designers must take extra time to streamline and optimize designs, paring down data gathering and site visits to the minimum sufficient to generate interpretable safety and efficacy data."

High-burden clinical trials remain a significant problem despite an industry-wide focus on patient centricity. In a recent Parexel-CISCRP survey, 59% of parents whose child participated in a clinical trial said it was "very" or "somewhat disruptive" to their daily routine. They cited traveling to sites, lab work, length of the study visit, health questionnaires, and diagnostic tests as the heaviest burdens.

Ethical conduct of clinical research in the pediatric rare disease setting consists of rigorous protocol optimization; respect for the specific physical, mental, and emotional burdens of the condition studied; transparency about the aims and limitations of clinical research; and compassion.

Can new technologies and decentralized trial techniques make rare disease pediatric trials more ethical?

Newer technologies like eConsent, apps, mobile devices, and telemedicine have great potential for rare disease pediatric studies. For example, eConsent is an effective tool for enabling parents and caregivers in complex situations (such as divorced couples living far apart or guardian grandparents who can't travel) to consent to trials. Sponsors can make a trial's requirements easier to understand by presenting information in videos or interactive multimedia. Remote technologies, however, may not work across borders because of different national regulations, such as the EU's data privacy laws.

Well-designed apps cleared by regulators, institutional review boards, and ethics committees can better engage and retain younger patients. Giving a clinical trial game-like elements can increase compliance and make it easier for patients and caregivers to keep a diary. But they require reliable internet access, patients must own or receive a device to run them, and they may need technical support.

Telemedicine can reduce the travel burden on families and cut the number of missed workdays for parents and school absences for children. It can be effective if it builds the same trust and confidence that in-person visits usually establish. Also, a home nursing network near the patient is critical to ensuring study compliance and safeguarding data quality.

> "During the informed consent process, investigators must discuss potential risks, benefits, and study procedures while sensitively managing the family's expectations and misconceptions."

Want to run a patient-centric rare disease trial? Be site-centric

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Patient- and site-centricity go hand in hand. Hospitals, clinics, and dedicated research sites are on the front lines of recruiting patients to participate in clinical trials. Developers who work to lessen the burdens on sites and enhance clinical staff experience will run more successful clinical trials. Most sites don't enroll many patients in rare disease trials, yet they still bear significant logistical and administrative burdens. They don't just participate for a return on investment. Their motivation is often altruistic; they want to help patients by offering the investigative drug — which may be the only care option — or publishing in the field to improve awareness and information sharing.

We asked two experts from our Site Alliance program — a global network of more than 500 research and healthcare institutions that Parexel partners with to conduct clinical trials — to offer best practices for conducting site-centric trials.

Since 2013, Parexel has been developing long-term strategic relationships with the most experienced multitherapeutic research and healthcare institutions under the name of the Site Alliance program to partner in successful projects delivery and make the company easy to work with for sites. Currently, there are 500+ alliance institutions, representing 20,000+ investigators all over the world. Site Alliances are actively managed by Parexel dedicated Site Alliance Managers (SAMs), who have in-depth knowledge of clinical trials processes. They work closely with an appointed single point of contact (SPOCs) from alliance institutions and facilitate protocol assessments, site start-up activities, and patient recruitment strategies across all projects conducted with the investigators from alliance institutions.

What challenges do you encounter with protocol designs?

In rare diseases, the relationships between physicians, site staff, patients, and families are intimate; communication is direct and close as they work together to diagnose and treat conditions. For example, a treating physician may see just one or two patients with a rare disease at any given time — and will likely know their names and family situations. In contrast, a diabetes specialist may be treating dozens of patients.

As a result, when we evaluate sites for inclusion in rare disease trials, we don't rely on standard performance metrics such as cycle times and past enrollment rates. Instead, we try to engage with the site staff early to get a sense of their expertise, assess their relationships with patients, and ask for their feedback on protocol design and strategy. If a site does not think that the investigational therapy or study is beneficial for their patients or is too burdensome, it is not likely to participate. We explore ways to involve site staff and patients in reducing a trial's burdens before the protocol is finalized.

Treat sites and institutions as research partners

A site-centric approach requires eliciting feedback from the staff and taking action, addressing their concerns as expeditiously and effectively as possible. For example, at Parexel Biotech, we use more digital devices, new and advanced risk-based monitoring systems, and platforms. We never assume site staff will welcome these new technologies and systems.

Before we adopt new trials methodologies, medical devices, or remote tools, we discuss them with research partners who collaborate with us through our Site Alliance program. We consult with expert councils at sites, a nurse advisory panel (see box), and site and patient advisory groups.

For example, when the COVID-19 pandemic hit, we met with sites and patient advisors in the United States and Europe to discuss overcoming the dual challenges of ensuring patient safety and continuity of treatment in clinical trials. Patients and sites shared their concerns related to COVID-19, which included reduced contact with physicians due to lockdowns, constrained site resources, and delays in the shipment and distribution of investigational drugs. Advisors' feedback differed depending on the therapeutic area; patients and providers in oncology, diabetes, respiratory, and rare disease trials had different priorities. Gathering all the insights helped us do a better job of adapting studies for each community. Working as partners with research sites and utilizing these modifications to complete ongoing trials helped everyone move through the pandemic.

Build hub sites to expand patient access to trials

Many rare disease trials seek to enroll newly diagnosed, treatment-naïve patients. Because most rare diseases represent unmet needs, clinical trials are often the only treatment option for these patients. Yet many physicians are not aware of ongoing trials or new treatment approaches, especially for conditions they rarely encounter.

Suppose doctors, general practitioners, and specialists offered clinical trial participation to their patients at the point of diagnosis. In that case, investigators could recruit more eligible rare disease patients faster through referral programs or networking. For this to happen, more physicians and nurses — not just those in research facilities or rare disease centers of excellence — need to know about ongoing clinical trials and routinely offer them as a care option for patients.

At Parexel, we established a rare disease resource center to bring together representatives of patient organizations, health and research professionals, employees, and volunteers at one site. Our Site Alliance team works on special site networks that revolve around a "flagship site," which connects researchers with the physicians who have access to patients and could participate in screening activities and decentralized medical procedures.

Elevate the role of site relationship managers

Clinical trials pose complex logistics and operations challenges, and there are always problems that need to be resolved. Sponsors or CROs managing a trial need talented relationship managers who can handle the moving parts and find solutions. Dedicated, knowledgeable staff who operate at institutional rather than project level can review all active trials, accelerate study start-ups, discuss enrollment challenges and concerns, and troubleshoot problems. They can also update sites regarding new trials.

For example, decentralized trials (DCTs) require new methodologies, including remote monitoring, telemedicine, and access to real-world data. A site relationship manager can help introduce and utilize DCT technologies and procure technical support for research institutions and site networks. This role demands a portfolio of skills, including extensive clinical trial knowledge, strategic thinking, relationship-building, and a customer service orientation.

Focusing on sites helps us make the trial process easier for physicians and nurses. That in turn improves the patient experience and increases compliance, making the trial process more efficient and effective.

"When we evaluate sites for inclusion in rare disease trials, we don't rely on standard performance metrics, such as cycle times and past enrollment rates."

Harnessing the knowledge and insight of study nurses

Nurses and study coordinators have the most direct sightlines into their clinical trial patients' needs, preferences, and challenges. Yet, nurses and coordinators typically aren't included in the process of designing the trials they will help conduct. Parexel decided to change this model by creating a Nurse Advisory Panel comprised of 70 experienced research nurses and clinical research coordinators.

We invited nurses from sites in our Site Alliance program with clinical research experience ranging from five to more than 30 years across multiple therapeutic areas, including oncology, rare disease, and cardiology. Study nurse advisors on our panel told us there were three things they needed:

1. Diaries and questionnaires translated into multiple languages
2. Simpler recruitment tools
3. Better communication about study progress

We've learned to communicate with sites early in the protocol development process so they can suggest changes to make studies more site- and patient-centric. Better protocols can reduce barriers to patient enrollment, ease patient and site burdens, and limit protocol amendments by doing it right the first time.

To create more rare disease drugs, learn from the past

Lucas Kempf, M.D.
Vice President, Regulatory

To speed the development of treatments for rare diseases, regulatory agencies, patient advocacy organizations, and industry need to collaborate to create a cohesive, reinforcing framework that allows developers to learn from past successes and failures in orphan indications. Lucas Kempf, former director of the rare disease program at the FDA's Office of New Drugs, has overseen dozens of rare disease regulatory submissions and offers advice on how sponsors can avoid repeating common mistakes.

In 2020, for the first time, a majority (55%) of new drug and biologic approvals were orphan-designated (Table 2). The numbers have been trending up for years. A recent study commissioned by the National Organization for Rare Disorders (NORD) found the FDA approved 599 orphan products between 1983 and July 2020.

Despite these successes, there remain thousands of rare diseases without any effective treatments. An analysis of 2006-2015 clinical development success rates showed about 75% of rare disease drugs that enter Phase I trials fail to reach the market. Here are five lessons from past experience that could help improve the odds.

Substantiate novel biomarkers

In 2020, 78% (25/32) of the orphan drugs and biologics approved by the FDA were targeted therapies (Table 2). Using biological markers to develop and deliver targeted treatments works; one recent study found clinical trials using biomarkers are twice as likely to succeed as those that don't. But for rare diseases, there often are no qualified biomarkers for screening or diagnosing patients, predicting their disease course, or measuring their response to treatments.

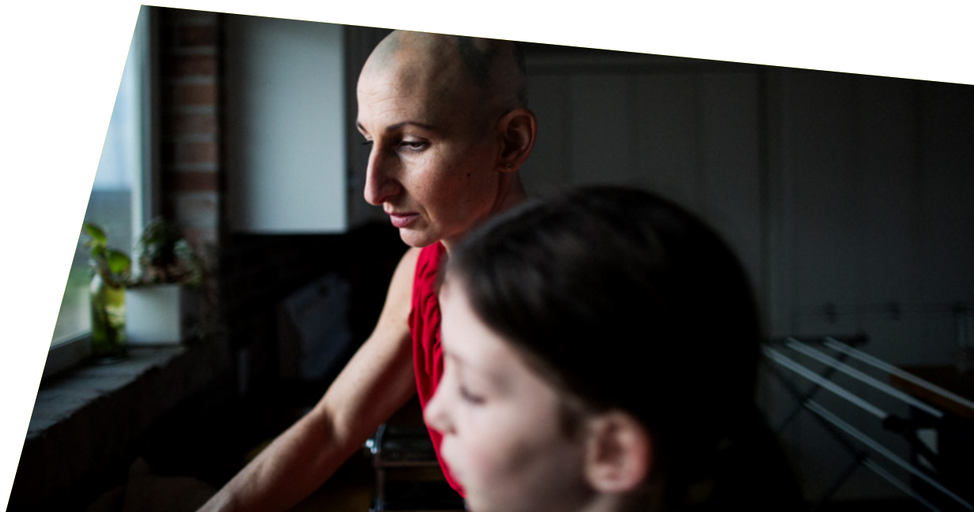
If a developer identifies a useful (or potentially useful) but unqualified biomarker, they must devise a biomarker strategy and test their arguments and data with regulators. The FDA is willing to engage early on using novel biomarkers as endpoints or even surrogates, and the EMA also offers early scientific advice on biomarker qualification.

For companies working on treatments for rare diseases, it's increasingly possible to receive guidance from senior regulatory staff — especially if a product is deemed a Breakthrough Therapy, a designation held by 67% (22/33) of FDA-approved orphan indications in 2020. While the FDA's Biomarker Qualification Program can be useful, it's best suited for projects with long time horizons; one-on-one negotiations with regulators are faster.

The goal for the regulator and the developer is to reach a tailored, science-based agreement that can reduce risk, guide rational development, support regulatory approval, and demonstrate value to payers, prescribers, and patients. Regulators can be convinced to consider unqualified biomarkers with sound science and data from well-designed studies — ideally supported by expert consensus on the biomarker's utility. The FDA looks to companies for leadership in novel approaches as long as they are well substantiated, so don't wait for regulators to take the lead.

Validate your assay

Once a company has decided to use a biomarker, it must choose the optimal assay and technology platform for clinical development. The technology platforms for biomarker testing are constantly evolving, not just for companion diagnostics (for patient selection) but also for complementary diagnostics (to improve disease management, early diagnosis, risk stratification, and monitoring).



Regulators evaluate assay technologies on a case-by-case basis; no assay is the preferred option. But assays always need to be of regulatory quality, and switching from a research-based test to a commercial assay midstream can cause problems. For example, one company recently began its clinical program using a research-based biomarker test, but while trials were in progress, they began using a newly available commercial assay. The result was a mixed bag of data — early studies that used the research assay and later studies that used the commercial assay. The company had to conduct a bridging study to prove the two assays performed equivalently.

Avoid leveraging a diagnostic test to measure endpoint changes without validating the reliability. For example, newborns are routinely screened for Wilson disease. This rare genetic disorder leads to a toxic buildup of copper and causes mental disabilities, behavioral problems, and eye and liver diseases. The assays used to diagnose Wilson disease (and other copper metabolism disorders) were not designed to measure quantitative copper levels reliably and have never been tested for sensitivity and specificity. Companies using some of these tests to measure activity in clinical trials had to re-validate the assays during development.

Design a high-quality natural history study

Getting the standard of care right is essential because you must demonstrate an incremental improvement over it to make your argument to payers. It's difficult and expensive to get the data after HTA agencies ask for it. It is much easier to gather it from natural history (NH) studies before clinical trials.

Data from an NH study should be used to precisely identify patients who will benefit most from treatment, especially if a drug is mechanistic. Enrolling only the patients most likely to demonstrate benefit on your chosen endpoints at the time points measured in your clinical trial can allow faster go/no-go decisions on product candidates. The FDA wrote its 2019 Draft Guidance on Rare Disease Natural History Studies after a decade of reviewing rare disease NDAs and BLAs with suboptimal NH studies. Regulators cannot rely on data from NH studies that have significant quality issues, and the draft guidance offers a road map for avoiding that problem.

Leverage your pre-IND meeting

The traditional progression from Phase I to III clinical trials is giving way to seamless, flexible Phase I/II designs that can accelerate suddenly to an NDA submission. Compressed development elevates the role of early planning and intelligence gathering. For example, a pre-IND meeting with the FDA is no longer a cursory step on the road to initiating first-in-human trials. It is now a critical opportunity to ask questions and get high-quality answers that can improve the development plan for a rare disease drug.

> "A pre-IND meeting with the FDA is no longer a cursory step on the road to initiating first-in-human trials. It is now a critical opportunity to ask questions and get high-quality answers."

The FDA recognized how important high-quality pre-IND meetings are for rare diseases, and they wrote a draft guidance document on how to make them more efficient and productive. The initiative was prompted by an internal agency review of pre-IND meeting minutes from approved NDAs and BLAs for rare diseases. This "winner only" analysis concluded that the pre-IND packets submitted by companies were generally insufficient to glean good scientific advice and clarity on issues such as what was needed to validate biomarkers, what was feasible for trial designs, and how to power studies.

Better pre-IND meetings will lead to better scientific advice and shorter review times. Meticulous attention to preparing the pre-IND meeting dossier can make it the basis for a high-yield regulatory interaction.

Make patients your expert collaborators

Quite often, rare disease patients are the only true experts in their conditions and can offer insights that can't be gleaned from literature searches and interviews with KOLs. In some of these conditions, KOLs may have treated just four or five patients. Sponsors may get better information about what is clinically meaningful and feasible trial designs from talking directly with patients and their caregivers.

"Quite often, rare disease patients are the only true experts in their conditions and can offer insights that can't be gleaned from literature searches or KOLs."

Table 2. 2020 FDA orphan approvals by the numbers

55% (32/58) of FDA Novel Drug and Biologic approvals were orphan-designated[1]

32 new drugs and biologics approved in **33 orphan-designated indications**[2]

44% (14/32) developed by small firms, 41% by large firms, and 5 by medium firms[3]

52% (17/33) were for cancer, 24% (8) genetic disorders, 12% (4) infectious diseases, 9% (3) autoimmune diseases, 3% (1) metabolic/endocrine disease

78% (25/32) were targeted therapies

82% (27/33) received priority review, 67% (22) breakthrough therapy, 39% (13) accelerated approval, 39% (13) fast track

21% (7/33) earned a Rare Pediatric Disease Priority Review Voucher

1 In 2020, the Center for Drug Evaluation and Research (CDER) approved 31 orphan-designated products out of 53 novel drug approvals (58%), and the Center for Biologics Evaluation and Research (CBER) approved one orphan product out of five novel biologic approvals (20%). Therefore, 55% (32/58) of novel drugs and biologics were orphan-designated.
2 Includes 31 CDER approvals and one CBER approval (CAR T cell therapy Tecartus). One drug, Gavreto, was approved for two different orphan-designated cancers.
3 Small firm defined as <500 employees at the time of approval; midsize firm 500-2,000 employees; large firm >2,000 employees. Of 32 orphan drugs in 2020, 14 (44%) were developed by small companies, five (15%) were developed by midsize companies, and 13 (41%) were developed by large companies.

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Proactively

integrating clinical and regulatory strategies to streamline every step of the drug development journey

Keeping pace with the rapidly growing biotech environment requires the expertise to anticipate and adapt to development challenges before they happen. Parexel Biotech provides the experience and guidance you need to help you reach your development goals every step of the way. No matter the project, Parexel Biotech helps you put patients first with a delivery model that is fully integrated and adaptable from the very beginning. From there, your team will walk you step by step through every decision, touchpoint, and milestone along your clinical development journey, helping you achieve your most important endpoint — bringing your innovation from the lab to the patients who need it most, faster.

Get the flexibility and adaptability it takes to never stop bioteching. ›

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