A RARE CRO

orphan reach™

Accelerating Orphan Drug Development

www.orphan-reach.com

Introducing orphan reach

from blockbuster drugs

to personalized medicine

RARE DISEASE FOCUS

With orphan reach we offer a global, dedicated and patient centric orphan drug development solution in support of accelerated access to orphan drugs.

PROVIDING YOUR BUSINESS THE RIGHT SUPPORT & RESOURCES YOU NEED

Rare diseases are not common business: with a paradigm shift from blockbuster drugs to personalized medicine, many new challenges have arisen and the biopharmaceutical industry has learned that patient focus is critical when working in the orphan drug domain. The integration of the broader contribution of patients and patient's representatives into developing and marketing an orphan drug has become a key success factor. As the industry heavily relies on collaboration of many parties, selecting the right service providers who recognize the importance of a patient focused approach is crucial.

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Who we are

orphan reach is the result of 14 years of international trial experience of QED Clinical Services, our founding parent company. Having started as a functional service provider for the pharmaceutical industry, QED quickly became a niche CRO known for rescuing clinical studies from other CROs where patient recruitment and retention were the main challenges.

Our team has conducted many of these projects in smaller patient populations, particularly in rare diseases where larger service providers struggled to find the optimal development strategy.

This obvious service gap has inspired us to tackle the challenges in the rare disease domain and to create orphan reach, the first niche CRO of its kind.

Why we're here

The purpose of orphan reach is to expedite the development of Orphan drugs and to facilitate patient access to treatments which can improve the quality of life of patients and patient's families.
By driving best practice we can provide continued, seamless, high quality support to biopharmaceutical companies throughout any stage of the orphan product development cycle, a service that has not previously been available.

Modular concept

CLINICAL DEVELOPMENT

We are an international Contract Research Organization (CRO) which has conducted clinical trials since 2002. A wealth of experience in rare indications combined with an innovative operational model provides global coverage and local expertise across all territories supported by a team of more than 1,000 staff members.

One of the advantages when engaging us lies in the fact that any country in the world can be accessed and clinical trials conducted to the highest standards.

The global operational model is fully scalable and has proven to work excellently particularly in trials involving few patients distributed over many countries. We have also shown to achieve major cost efficiencies for our clients as expensive and unnecessary overheads commonly found in global CROs targeting high volume studies can be avoided.

HOME VISITS

Making trials more acceptable for patients will have a positive impact on patient retention especially in a patient population affected by a rare and often debilitating disease. orphan reach offers qualified and trained nurses to fulfil this important role. Our nurses have the qualification to provide the following services at the patient's home:

Blood draws, PK sampling, QOL questionnaires, Physical assessments, Delivery of medication to the patient's home, Patient training, Infusions.

We offer this service in many countries globally adhering to the local regulations that apply for such service provision.

PATIENT TRAVEL

Travel to and from the investigational site during a clinical trial can become a major barrier for patients and their supporting families. With many children affected it becomes crucial to plan and organise properly based on their special needs and requirements.

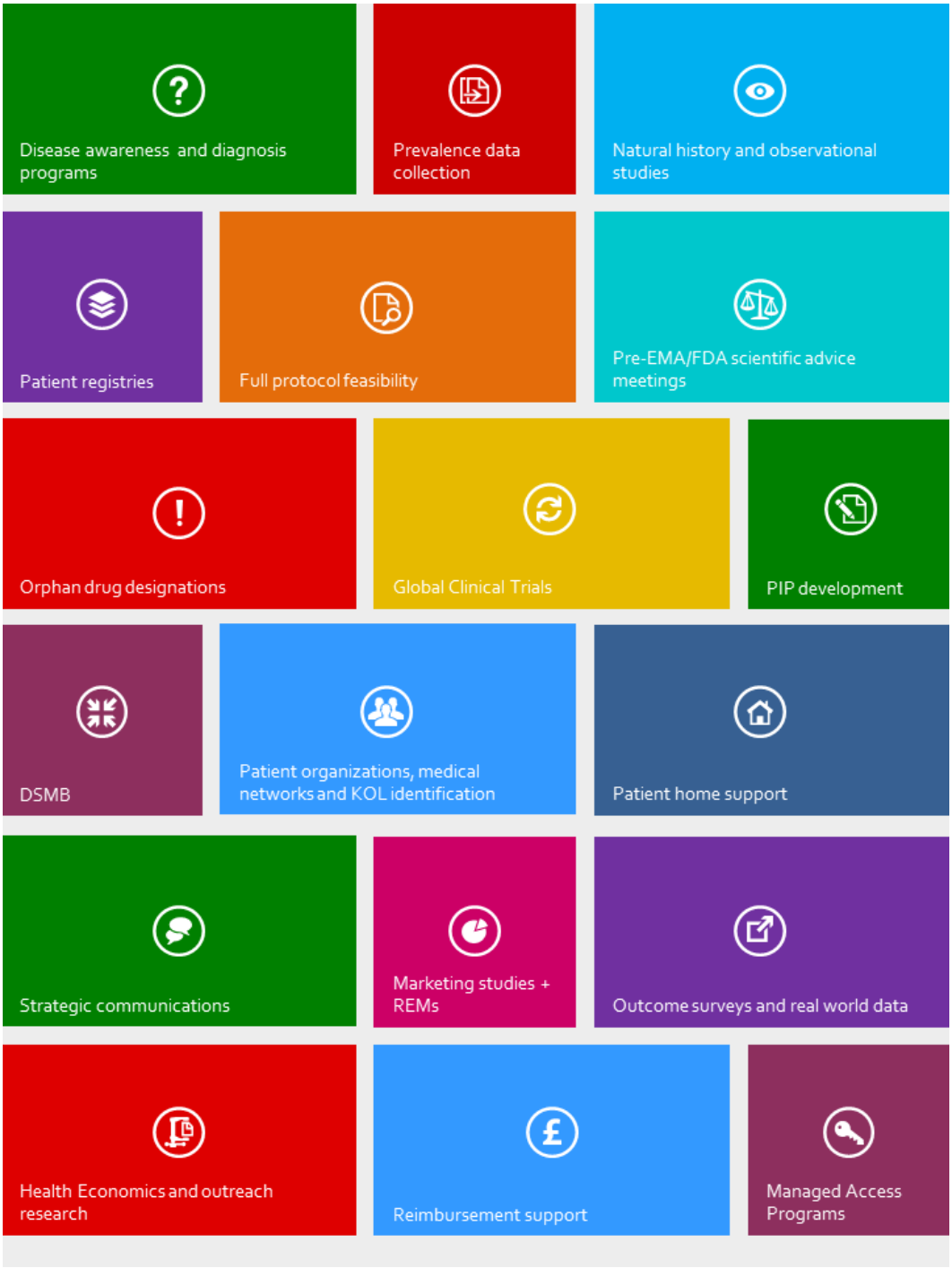
We are familiar with the confidential co-ordination of patient travel and expense management for clinical studies helping to make the drug approval process seamless. Whether travel, accommodation, ambulance charter or special care and assistance are needed, client needs can be met efficiently based on a proven history of providing efficient and effective solutions to reduce Sponsor and Investigator administration.

ORPHAN STRATEGY

We work with a world renowned team of independent consultants in the US and Europe to assist our Sponsors in finding the right orphan product strategy.

Navigating in a regulatory and commercial environment that is constantly changing requires a tailored approach that is in tune with our clients' goals.

Services



PROVIDING CLINICAL DEVELOPMENT SERVICES ACROSS THE GLOBE

orphan reach have an established presence in more than 50 countries and provide integrated drug development solutions from obtaining orphan drug designation through to conducting post marketing surveillance studies. We are familiar with local regulations in all countries across the globe and maintain excellent relationships with local authorities.

Every Patient Counts

patient centric

approach

NATURAL HISTORY

We evaluate the current literature and available epidemiological data. We also identify appropriate thought leaders and interact with patient societies for the purpose of natural history studies are key initial steps in advocacy development. At the end of the process we publish the findings from natural history and epidemiological studies. If there is not sufficient natural history data available, we conduct additional natural history studies.

PATIENT RECRUITMENT

We nurture excellent global contacts with Clinical Research Networks, indication specific Investigator Networks and Patient Advocacy Groups. We also engage referral sites, pre-identify patients at site and use relationship marketing experts. Combining the various measures in an effective way helps us to meet or exceed patient inclusion timelines.

PEDIATRIC RESEARCH

We focus on the specific requirements of each study and the relevant patient groups, if children are involved in clinical trials. Our team of pediatric specialists is very familiar with the strict regulatory requirements and ensures that these requirements are met and the interests of this vulnerable patient group are kept at the forefront of all trial considerations.

Our Pediatrics research experience includes:

- A proven track record of 98 studies ranging from phase I to phase IV, observational studies across 25+ countries
- Recruited more than 50,000 children
- 11 studies in pediatric orphan diseases

PATIENT RETENTION AND COMPLIANCE

With very few patients, the integrity and completeness of data from each patient assumes even greater importance. We employ many methods to retain patients and maintain compliance. Focussed training of sites and patients is provided to increase retention and compliance supported by experienced Senior CRAs at a site level. Engaging patient advocacy groups, providing home healthcare by trained nurses and patient & family travel support are all additional efforts to ensure a smooth data collection according to the planned study timelines.

ADVOCACY GROUPS

We are connected to most of the patient advocacy groups through organizations like NORD and EURORDIS and also engage on a national level. This way we obtain valuable advice on practical considerations from a patient's perspective (e.g. protocol feasibility, drug application etc.).

ATTENTION TO DETAIL

Our global, patient centric approach differentiates orphan reach from other CROs.

It allows Sponsors to choose a nimble CRO with attention to small patient populations without the need to rely on CROs mainly operating in the field of common diseases involving larger patient pools.

ORPHAN INDICATION EXPERTISE

AA Amyloidosis
Acromegaly
Adrenoleukodystrophy
ATTRV30M amyloidosis
Atypical Hemolytic-Uremic Syndrome
Central Precocious Puberty
Ch. Thromboembolic Pulm. Hypertension
Congenital Fibrinogen Deficiency
Cushing's Syndrome
Cystic Fibrosis
Duchenne Muscular Dystrophy
Dysfibrinogenemia
Erythropoietic Protoporphyria
Fabry's Disease
Follicular Lymphoma
Gaucher Disease
Glanzmann Thrombasthenia
Hemophilia
Hairy Cell Leukemia
Hashimoto Thyroiditis
Hereditary Angioedema
Hereditary ATTR amyloidosis
Huntington's Disease
Hypofibrinogenemia
Idiopathic Thrombocytopenic Purpura
Lamellar ichthyosis
Leishmaniasis
Macroadenoma in acromegalic patients
Mastocytosis
Mucocutaneous candidiasis
Mucopolysaccharidosis Type I
Neurogenic Bladder
Primary Biliary Cirrhosis
Tuberculosis
Vitiligo
Von Willebrand Disease
Wegener Granulomatosis

Making a difference is important to us. In a world with more than 7,000 rare diseases for which only 200 treatments are available there is still a lot to do. Extraordinary concerted efforts from many different stakeholders are required to accelerate the process of bringing urgently needed new medicines to the market.

We invite you to join forces with the first of its kind CRO focused exclusively on orphan drugs and rare diseases.

Please contact our Business Development team to discuss your company's needs: **info@orphan-reach.com**

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