

REPRESENTATIVE EXPERIENCE Clinic Trial Support

IDIs & Focus Groups **KOL & Investigator Identification** Recruitment Support Site & Country Profiles

GlobalReach-SBI combines expertise in conducting IDIs and focus groups with expertise in profiling markets (clinical trial infrastructure, regulations and requirements) around the world. We assist pharmaceutical companies and clinical trial recruitment firms in shaping patient and investigator recruitment campaigns as well as in site selection. We are a member of The Patient Recruitment Global Alliance. If we can help you with KOL interviews or testing clinical trial recruitment materials, please contact us at 212-519-9220 or email info@qlobalreach-sbi.com.



Focus Groups and Patient Survey: Testing Patient Recruitment Materials on Five Continents

The Challenge: A pharmaceutical firm needed to test patient recruitment materials in preparation for an upcoming global clinical trial for a new Hepatitis C drug – on a tight deadline.

Our Approach: We conducted focus groups at several U.S. sites as well as in Germany, Malaysia, Mexico, and Australia. We also carried out a companion on-line survey in additional countries in Asia, the Pacific Rim, Europe, and the Americas. The focus groups and survey examined patient attitudes towards participation in clinical trials in general, as well as towards the proposed materials.

Result: Our research elicited unanticipated consumer reactions to the materials; we also discovered unmet patient needs, notably for some form of support group. We provided the client with a clear set of patient attitudes and reactions to their materials across several cultures, as well as with insights that would help the pharmaceutical company improve overall patient outreach while meeting their deadline.





Patient Recruitment Support: Rare Genetic Diseases

The Challenge: A biopharmaceutical firm was having trouble recruiting patients to its multi-center clinical trial for patients suffering from a very rare lysosomal storage disease.

Our Approach: As direct patient contact was not an option, we determined the best approach was to directly approach specialists who diagnose and treat patients with inherited metabolic disorders. In close collaboration with our partner, an internationally reputed patient recruitment firm we developed outreach materials. Through networking and detective-like sleuthing our network identified over 500 hundred specialist spread across Europe, Latin America and Oceania. Specialists included geneticists, specialists in inherited metabolic diseases including lysosomal storage disorders, neurologists, neuropediatricians and neuromuscular neurologists. We conducted an intensive outreach effort. Specialists were invited to participate in one-on-one interview or respond to an online questionnaire.

"The use of databases and Web outreach make a difference, but it is the in-country presence by those who intimately know and understand the healthcare landscape that tips the scales in our recruitment direction.

Té Revesz, GlobalReach-SBI, Member Patient Recruitment Global Alliance.

Result: Through our outreach effort, we were able to identified over 50 specialist currently treating patients diagnosed with the disorder and referred them to the geographically appropriate clinical trial site. Our client was able to meet its global patient recruitment target.



Country Assessment and IDIs: Siting Schizophrenia Trials

The Challenge: Our client needed to select the best sites from among 30 countries for upcoming Phase II and Phase III trials for two schizophrenia drugs. They wanted to gain an in-depth understanding of the challenges facing specialists treating schizophrenia patients in each of these countries and their concerns and capabilities with regard to clinical trial participation for themselves and their patients. Additionally, they wanted to identify potential investigators.

Our Approach: We identified leading specialists in the treatment of schizophrenia in each country and conducted hour-long indepth interviews with more than 100 of these key opinion leaders (KOLs). Our interviewers asked the KOLs to share their expertise with regard standards of care, benefits of and problems with current treatment regimens, clinical trial approval processes, and patient recruitment potential and practices.

We gave the client insights into the KOLs' expectations regarding patient attitudes toward treatment and trials as well as their perceptions concerning unmet needs. We also provided detailed background information on the KOLs; their research experience, professional associations and committee and other related activities.



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Over the years I've worked with many research companies. In

my experience, your company's

professionalism, consultative expertise, and tenacious pursuit of my research goals" has

always been second to none.
Global Operations Leader,

Patient Recruitment Firm

For each market, we profiled the healthcare infrastructure, disease incidence and prevalence, treatment modalities and accessibility, patient access to treatment, and current drug availability and costs.

<u>Result:</u> Our client used our finding to select the countries that would best support its upcoming trials and identify a group of committed investigators.



Global Survey of AIDS Drug Availability

<u>The Challenge:</u> A pharmaceutical firm needed to select sites for clinical trials from among over 45 countries for its new antiretroviral HIV medicine. As a first step it needed to understand the availability of AIDs medications already approved for in each market, as well as the distribution structure.

<u>Approach</u>: Our field research team interviewed medical and pharmaceutical associations, hospitals, pharmacists and distributors in each country. We determined availability and pricing of competitive branded and generic drugs in each country, identified manufacturers and distributors, and profiled drug reimbursement practices, government regulations, promotional practices. We provided the client with individual

<u>Result:</u> The pharmaceutical company combined our report with demographic and clinical trial site information it already had to narrow its target list to 10 prime targets.

profiles of each country, as well as with a comparative factor grid to help facilitate their decision making process.



Ethical Considerations for Patient Recruitment

<u>The Challenge:</u> The head of the international practice of a U.S.-based clinical trial recruitment firm wanted to build the company's client base in the European Union. His goal was to demonstrate that his firm's knowledge of and commitment to the highest ethical standards for patient recruitment.

<u>Approach</u>: We supported this effort by profiling and interviewing key members of national ethics committees, and by providing an analysis of evolving legal and ethical recruitment guidelines in Europe.

<u>Result:</u> Our client presented the findings at an international industry conference and used them as a tool to attract several new clients.



Practicing Rheumatologists in 30 Countries

<u>The Challenge:</u> Our client was planning to recruit rheumatoid arthritis patients in 30 countries for a multi-center, randomized, double-blind, placebo-controlled trial of a fully human anti-TNF monoclonal antibody. They had put together a creative brief for the U.S. and wished to obtain feedback from practicing rheumatologists in the other target countries before translating the creative brief for use outside North America.

<u>Our Approach and the Result:</u> We identified practicing rheumatologists and conducted in depth telephone or in-person interviews with three physicians per country on their assumptions on patient attitudes and on the most effective way physicians can position the study with their patients. The client used the results to tailor the creative briefs so they appeal most effectively to patients in the different counties.

KOL & PI: Practice Areas

In over 60 countries, we have identified, qualified & interviewed KOLs & investigators across a wide variety of practice areas, including:

- Cardiologists
- Clinical trial coordinators
- Dermatologists
- Gastroenterologists
- Geneticists
- Hospital administrators
- Infertility physicians
- Nephrologists
- Neurologists
- Neuropediatricians
- Oncologists

- Ophthalmology surgeons
- Pediatricians
- Pharmaceutical researchers
- Pharmacists
- Psychiatrists
- Psychologists
- Physiatrists
- Rheumatologists
- Thoracic surgeons
- Urogynecologists

Sample Therapeutic Areas

GlobalReach-SBI has completed single and multi-country country projects in a broad range of therapeutic areas, including:

- Acute Optic Neuritis
- ADHD
- AIDS
- Arthritis
- CardiologyDepression
- Dermatology- Psoriasis
- Dyslexia
- Epilepsy
- Growth hormone deficiency
- Hepatitis
- Infectious disease
- Lysosomal storage diseases
- Medical devices
- Microfracture Cartilage Injury
- Nephrology/Urology
- Oncology
- Rare diseases
- Respiratory
- Schizophrenia

^{*}Representative experience of our principals and associates