

Getting clinical trials off to a good start



PAREXEL[®]
Right where you need us[™]

The issues of slow patient recruitment and poor retention are perpetual problems for the pharmaceutical industry.

Delays caused by recruitment affect most studies – often by many months, costing hundreds of thousands of dollars. Recognizing this issue, PAREXEL has developed a world-class suite of products and processes that are focused on achieving Last Patient In (LPI) targets.

PAREXEL is making patient recruitment and retention strategy, planning and execution more effective for clinical trial sponsors through a comprehensive offering that includes an expert recruitment team supported by new technology that substantially improves patient recruitment performance.

In order to streamline and analyze all the disparate factors across the organization that can impact Last Patient In recruitment goals, PAREXEL has created a unique, global organization called the Start-up and Accelerated Recruitment Team (START). START relies upon a new suite of proprietary technologies and data assets to more accurately plan for recruitment milestones.

The new Scenario Planning and Recruitment Calculator (SPARC™) integrates data from across the organization to help drug sponsors avoid costly delays due to slow recruitment or poor patient retention.

With this data, START is also able to implement pre-planned contingencies based upon ongoing information, avoiding potential problems before they become serious.

It's all about the data

Access to the right data allows trial sponsors to more accurately address two vital questions about patient recruitment:

- What are the likely enrollment rates for a particular trial?
- What are the best countries, sites, and investigators to select to achieve the required recruiting objectives?

A critical aspect of PAREXEL's expanded recruitment capabilities is an enhanced investigator database that is used in conjunction with the SPARC tool to plan trials and identify high potential investigators. Investigator databases are often limited to lists of contact information, trial participation and therapeutic specialty. PAREXEL enhances these basic data with comprehensive information on patient enrollment success and other historic recruiting performance indicators including information on recruitment issues

encountered during similar studies in the past. This information concerning the feasibility or difficulty of patient recruitment for specific types of patients, indications, or sites directly impacts the accuracy of projected enrollment rates and other recruiting assumptions. PAREXEL has the right data assets to support your decision making during feasibility studies and site selection and to impact patient recruiting and, most importantly, your ability to make the right decisions about trial staffing, budget, and timelines.

Analysis, analysis, analysis

While accurate data is essential, it is only one part of the equation to enhance patient recruiting. A sponsor must also have the appropriate data modeling and management tools in place to leverage the data. Inappropriate modeling tools will fail to account for enrollment variables that affect every trial and every site. PAREXEL's START utilizes comprehensive analytic tools and contingency strategies to ensure realistic predictions and enable changes to be made quickly and easily if a site is not performing as planned.



Using the advanced tools of SPARC – combined with accurate historical data – models can be created that recognize important recruiting variables, such as:

- Differences in enrollment rates among various countries, sites, and investigators
- Variations in time for different sites to get up to speed
- Common site activation delays;
- First “month” of study that is not a full 30 days
- Impact of seasonal variations and holidays on recruiting rates

By understanding and accounting for these variables, a sponsor will be able to more accurately predict patient recruiting timelines and allocate resources more efficiently.

Contingency planning

Many sponsors rely on “rescue” contingency plans that are implemented only after patient recruiting issues develop at a specific site, rather than building proactive contingency planning into their core development programs. Such reactive plans can cost the sponsor, at a minimum, several months of lost time.

PAREXEL’s START helps build strategic contingency planning into

the core recruiting plan. Signs of trouble can often be detected at a site well before or directly after the FPI stage – such as delays in getting a site up and running, or the ratio of patients being screened to those enrolled. Without this proactive contingency strategy in place to detect and address issues from the beginning of the recruitment process, the response may come too late to avoid costly recruiting delays.

A proactive contingency strategy for patient recruiting requires both management processes and performance monitoring. The key for contingency management is to embed the processes into the earliest stages of the core recruitment strategy and submitting them for IRB/EC review and approval in advance. This step can pay significant benefits by avoiding the months-long delays that would otherwise occur if the material has to be created and reviewed after recruitment is underway.

PAREXEL has the right data and the right tools to help sponsors more accurately predict, monitor, and manage patient recruiting, while avoiding expensive and risky trial delays. We can help you reduce costs and bring new products to market faster – improvements that are invaluable in today’s highly competitive pharmaceutical marketplace.

Your advantages with PAREXEL:

Patient and site analysis

- Internal PAREXEL site identification and quality databases
- Site recruitment qualification visits
- Patient-focused market research
- Ongoing site-, country-, and trial-level analysis
- Feasibility databases (MedStat, Verispan, GEMS)

Site management

- Customer site-specific recruitment plan
- Site education and patient triage materials
- Study newsletters
- Site recruitment/retention training
- Ongoing CRA calls to the clinical sites
- PI/CC teleconferences and focus groups
- PI/CC teleconferences
- CRA/MD booster visits

Patient outreach and retention

- Site-based patient collateral
- Interactive and broadcast patient outreach
- Referring physician outreach
- Patient pre-qualification

“Successfully achieving LPI milestones requires using all of the levers that PAREXEL, as a global CRO, has at its fingertips. Our expanded patient recruitment services let sponsors harness experience from some of the industry’s strongest recruitment specialists and the power of a solid technology platform that streamlines the entire process.”

Mark A. Goldberg, M.D., Chief Operating Officer

The Scenario Planning and Recruitment Calculator (SPARC)

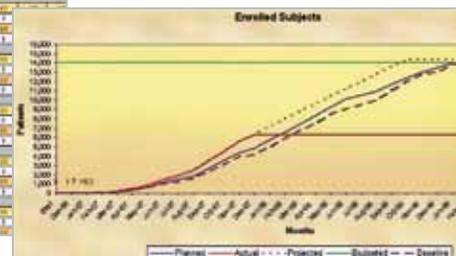
Enables more accurate estimation and management of LPI

This screenshot displays a complex data table with multiple columns including Country, Site, and various recruitment metrics. It represents the 'Country-level estimation' view.

Country-level estimation

This screenshot shows a detailed view of recruitment data for individual sites, including columns for Site Name, Status, and enrollment figures. It represents the 'Site-level estimation' view.

Site-level estimation



Trial-level estimation



PAREXEL patient recruitment provides

- Advanced planning to identify potential patient populations and sites most likely to succeed in meeting enrollment goals
- Supportive patient recruitment material to sites
- Vigorous site management during enrollment
- Detailed escalation plans combined with regular ongoing, site-, country-, and trial-level screening and enrollment analysis to identify recruitment challenges early on
- Preparation for rapid implementation of escalation plans
- Initiation of previously identified clinical sites in countries that are enrolling well
- Application of additional site management resources to poorly performing sites
- Launch of appropriate direct-to-patient outreach campaigns

Contingency-based escalation should be embedded in all recruitment strategies

Progress toward LPI should be monitored from before FPI to ensure contingency plans are launched when necessary



PAREXEL
Right where you need us™

195 West Street
Waltham, MA 02451
USA
+1 781 487 9900

The QUAYS
101-105 Oxford
Uxbridge
Middlesex UB8 1LZ
United Kingdom
+44 1 895 238000

3F, No. 510, Sec. 5
Chung-Hsiao E. Rd
Taipei, Taiwan 11077
+886 2 2727 1100

Kayaba-cho First Bldg.
1-17-21, Shinkawa, Chuo-ku
Tokyo, 104-0033
Japan
+81 3 3537 5900

