

## Pulmonary Arterial Hypertension in Eastern Europe Case Study

### Study Overview:

Pharm-Olam was selected to provide development services for a Phase III study, which was designed to address the efficacy and safety of a compound for pulmonary arterial hypertension patients. This study originally required 670 patients across the globe, but the enrollment was later increased to 1,150 due to study design changes. Pharm-Olam played an integral part in the enrollment of the additional patients, providing 45% more patients than originally tasked.

### Pharm-Olam was responsible for:

- Recruiting 192 patients, 45% more than the originally requested amount
- Management of 17 sites located in Russia, Belarus, and Ukraine
- Provided regulatory, project management and monitoring services

### Lessons Learned:

Further review of this study provided several lessons learned

for future studies in Pulmonary Arterial Hypertension studies. The primary lesson learned was that recruitment is a significant challenge for sites that did not have prior Pulmonary Arterial Hypertension experience. Sites that were well known in this area performed significantly better than non-experienced sites.

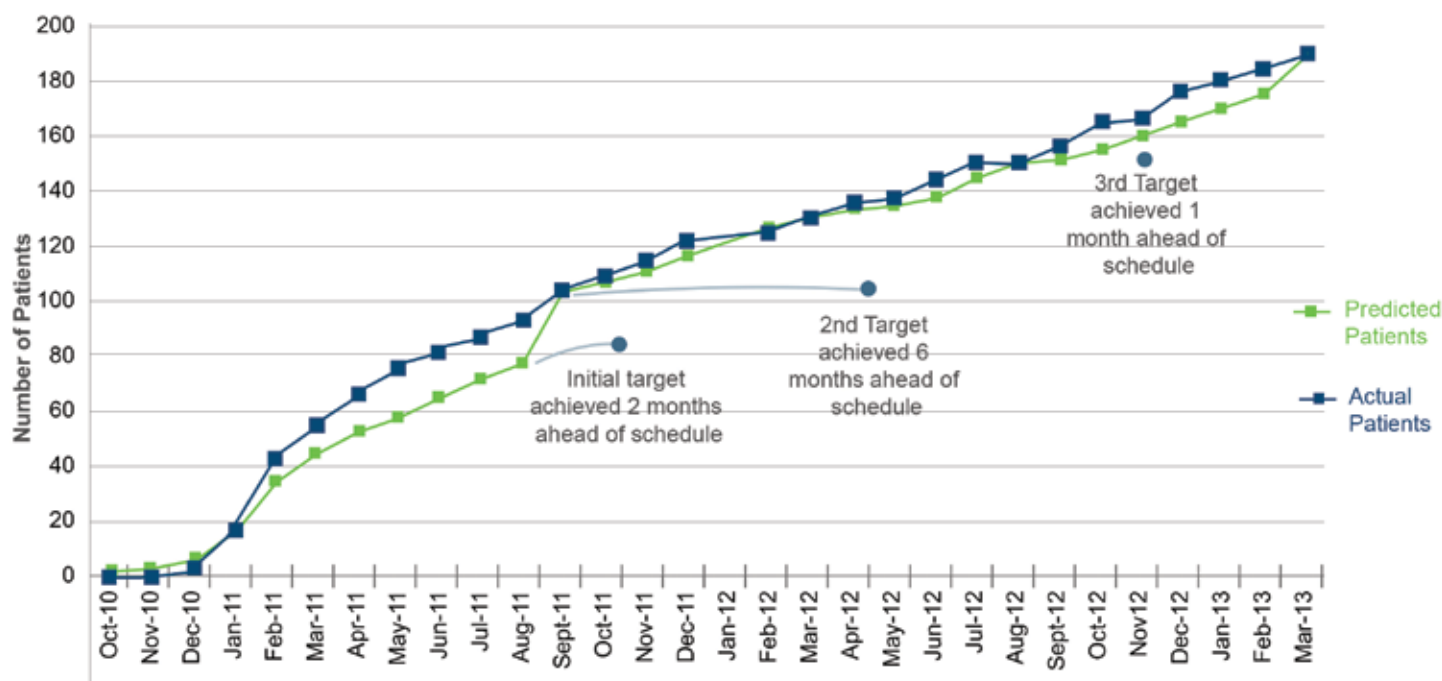
Another lesson learned was that detailed feasibility and careful, realistic planning from the study start is a key to future success. The time spent on providing detailed feasibility reports allowed Pharm-Olam to shorten start-up times and to quickly obtain eligible patients for the study. As seen in the following chart Pharm-Olam achieved their patient target ahead of schedule in each of the three enrollment requests from the Sponsor.

### Success in Eastern Europe:

Analysis of the delivered data highlighted the advantages of recruiting patients in Eastern Europe, as evidenced by the lowest number of queries/re-queries per patient, the highest recruitment rates, and one of the lowest screen failure rates were all achieved in this region by Pharm-Olam.

Query Rates by Region:

Region	Sites	# Randomized	# Average Query rate per Patient
USA & Canada	49	193	9.6
Latin America	15	110	10.4
Western Europe	73	371	10
Asia/ Asia Pacific	31	290	8.9
Eastern Europe	17	192	5.5
TOTALS	185	1156	8.8



Comparison of Regional Study Statistics:

Country	Sites	Avg Months Recruitment	Avg RR	Screened / Randomized		SF Rate
USA & Canda	49	34	0.11	253	193	23.7%
Latin America	15	34	0.22	118	110	6.8%
Western Europe	73	32	0.16	446	381	16.8%
Asia / Asia Pacific	31	32	0.29	328	290	11.6%
<b>Eastern Europe</b>	<b>17</b>	<b>31</b>	<b>0.36</b>	<b>206</b>	<b>192</b>	<b>6.8%</b>
TOTALS	185			1351	1156	14.4%

#### Conclusion:

Pharm-Olam's global reach was used to supplement the extensive number of patients required in this global study. Pharm-Olam has relationships with high-performing sites and investigators that enable sponsors to meet their recruitment

goals while ensuring timelines and budget requirements are being met. If you require assistance in supplemental recruitment or enrolling patients in a rare disease for an upcoming study, contact Pharm-Olam today to discuss solutions for your unique needs.



#### Pharm-Olam International, LTD

450 North Sam Houston Parkway E.,  
Suite 250  
Houston, TX 77060  
T: +1 713.559.7900  
F: +1 713.559.7901

[www.pharm-olam.com](http://www.pharm-olam.com)  
[info@pharm-olam.com](mailto:info@pharm-olam.com)

#### Pharm-Olam International (UK) Ltd.

The Brackens, London Road  
Ascot, Berkshire, SL5 8BJ, UK  
T: +44 (0) 1344 891121  
F: +44 (0) 1344 890335