

## Acute Bacterial Skin and Skin Structure Infections

To successfully manage an Acute Bacterial Skin and Skin Structure Infection (ABSSSI) study, Pharm-Olam provided a complete enrollment solution for the management and data submission of this multi-region study. With the increase of ABSSSI diagnoses and ABSSSI-related hospitalizations, inconsistent treatment methods for those diagnosed, and resistance to previous standards of care makes this an important study for those in need. Pharm-Olam assisted the study sponsor in the protocol development according to the Guidance for Industry for ABSSSI released by the FDA in October 2013. This Guidance addresses the overall development program and clinical trial designs for systemic drugs to support an indication for the treatment of ABSSSI. Pharm-Olam has conducted a number of studies under this Guidance to select the right patient population, prior therapy exclusions, study design as well as stringent endpoints. Pharm-Olam delivered a total of 380 patients for this particular study within 9 months. The study was completed 2 months ahead of time.

### Study Overview:

- Phase III
- **Patients:** 380
- **Sites:** 53 in 11 countries - Bulgaria, Croatia, Georgia, Estonia, Hungary, Latvia, Romania, Russia, Serbia, South Africa, Ukraine
- Drug Approved by FDA and EMA
- **Design:** Randomized, double-blind, in subjects with gram-positive ABSSSI
- **Exclusion Criteria:** Prior antibiotic therapy with 14 days of randomization, gram negative bacteria
- **Enrollment:** June 2014 to February 2015
- **Services:** Regulatory, Monitoring, Project Management
- **Patient Reported Outcomes:** Pain assessment, SSTI-C questionnaire

### Top Performing Countries:

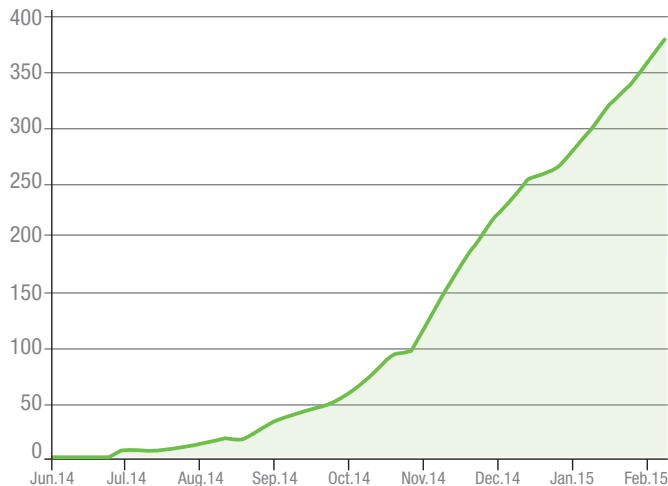
Country	Sites	Study Start-up	Recruitment Months	Patients Planned	Patients Randomized
Georgia	4	2.9	7.5	20	<b>31</b>
Latvia	5	4.3	6.0	50	<b>63</b>
Russia	7	6.1	2.5	40	<b>55</b>
S. Africa	10	5.9	3.8	15	<b>40</b>
Ukraine	7	5.0	4.7	45	<b>135</b>

### Study Challenge and Solution – Patient Recruitment

This study experienced slower than expected recruitment in certain regions, including North America. Pharm-Olam's involvement in this study was focused on the European enrollment initiative, which exceeded the recruitment numbers of the other regions. To encourage enrollment, Pharm-Olam installed a daily contact outreach program with the sites to motivate and provide continuing education on the study parameters. The study CRAs included in this study were highly experienced and dedicated, which ensured that their ongoing contact with the sites resulted in high enrollment rates and higher data quality.

During this study we experienced a highly successful enrollment rate in among the sites in Ukraine. To accommodate the higher than expected enrollment, Pharm-Olam installed a quick response program where CRAs and internal country teams were trained and assigned to assist with the monitoring of the patient data.

Patient Recruitment Timeline:



### Study Challenge and Solution – Drug Supply in Russia

This study presented a challenge in acquiring supplies of the comparator drug in Russia due to a general worldwide shortage of the comparator during the study timeline. To assist with the supply issues, the Pharm-Olam Russian team pro-actively identified the issue, and presented a solution of supplying all of the Russian sites the comparator generic drug in Russia to avoid any delays in the enrollment of patients. Russia contributed a total of 55 patients to the overall target.

### Sponsor Reference

“The Pharm-Olam Regulatory Team proved to be excellent liaisons in the coordination and execution of complex multi-national submissions with major regulatory authorities. The presence of actual regulatory-experienced specialists on the ground in the respective countries took the guess work out of what was required, how we needed to go about our submissions, and how quickly approval would be granted. In terms of moving ahead full-steam, we were always kept in the know as to the status of all submissions, which assisted greatly in meeting previously agreed to country start-up goals.”

“And the Pharm-Olam Monitoring Team served as our eyes and ears out in the field. They were key in ensuring the trial was executed with precision and the data obtained was top-quality. Not only did they monitor, but they served as excellent ambassadors on our behalf to support the sites in whatever capacity needed. They educated the sites; they motivated their sites to ensure they met study timelines; and they kept them on task and on target! Each member of the monitoring team represented our interests as if they were their own.”

—Global Clinical Trial Manager



**Pharm-Olam International, LTD**  
450 North Sam Houston Parkway E.,  
Suite 250  
Houston, TX 77060 USA  
T: 713.559.7900  
F: 713.559.7901

**Pharm-Olam International (UK) Ltd.**  
The Brackens, London Road  
Ascot, Berkshire, SL5 8BJ, UK  
T: +44 (0) 1344 891121  
F: +44 (0) 1344 890335