Dr. Keith Rodvold is currently approved by the U.S. FDA and is considered first-line for the treatment of uncomplicated cystitis as a one-time oral dose of 3 grams. In addition to this indication, fosfomycin is frequently utilized in the clinical arena for the treatment of complicated urinary tract infections and prostatitis, amongst other disease states.

Phase I Study to Evaluate Pharmacokinetics, Pharmacodynamics and Safety/Tolerability of Two Dosing Regimens of Oral Fosfomycin Tromethamine in Healthy Adult Participants (PROOF)

Principal Investigator: Keith Rodvold, PharmD

Treatment of cUTI in 2015 is challenging for a number of reasons including the potential risk of resistant gram-negative bacteria (e.g., ESBL-producing E. coli and Klebsiella pneumoniae). Fosfomycin tromethamine is currently approved by the U.S. FDA and is considered first-line for the treatment of uncomplicated cystitis as a one-time oral dose of 3 grams. In addition to this indication, fosfomycin is frequently utilized in the clinical arena for the treatment of complicated urinary tract infections and prostatitis, amongst other disease states.
The primary objectives of this project are 1) to assess the safety and tolerability of two different dosing regimens of oral fosfomycin tromethamine in healthy adults; and 2) to evaluate the steady-state pharmacokinetics and pharmacodynamics of the two different oral dosing regimens. To accomplish this PROOF is designed as a randomized, two-way crossover trial involving up to 24 randomized participants with an anticipated drop-out rate no higher than 25% to give a total of 18 evaluable healthy adult participants.

### 2015 Awards and Achievements

**John Bartlett, MD**  
4th C. Everett Koop Public Health Leadership Award

**Robert Bonomo, MD**  
Harrington Scholar-Innovators Award 2015

**Scott Evans**  
Mosteller Statistician of the Year 2015

**Robert Bonomo, MD**  
Nominated to serve as the chair for the Infectious Disease Society of America (IDSA) Committee for Practice Guidelines for the Diagnosis and Management of Complicated Intra-abdominal Infections in Adults and Children. 2015

**Robert A. Bonomo, MD**  
Nomination by the IDSA for membership on the Patient-Centered Outcomes Research Institute (PCORI) Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options. 2015

### Publications Update


