

## **Presentations and Publications of the Tuberculosis Trials Consortium (as of May 8, 2013)**

### **I. Publications**

#### **1999**

Vernon A, Burman W, Benator D, Khan A, Bozeman L for the Tuberculosis Trials Consortium. Acquired rifamycin mono-resistance among patients with HIV-related tuberculosis treated with supervised once weekly rifapentine and isoniazid. Lancet 1999; 353:1843-47.

#### **2001**

TB Trials Consortium. The Tuberculosis Trials Consortium: A Model for Clinical Trials Collaborations. Public Health Reports 2001; 116 (Supplement 1):41-49.

#### **2002**

Centers for Disease Control & Prevention. Notice to Readers: Acquired Rifamycin Resistance in Persons with Advanced HIV Disease Being Treated for Active Tuberculosis with Intermittent Rifamycin-Based Regimens. Morb Mort Wkly Rep 2002; 51:214-5.

N Bock, T Sterling, CD Hamilton, C Pachucki, YC Wang, DS Conwell, A Mosher, M Samuels, and A Vernon and the TBTC. A prospective, randomized, double-blind study of the tolerability of rifapentine 600 mg, 900 mg and 1200 mg plus isoniazid in the continuation phase of tuberculosis treatment. Amer J Respir Crit Care Med 2002; 165: 1526-1530.

TB Trials Consortium. Once-weekly rifapentine and isoniazid versus twice-weekly rifampin and isoniazid in the continuation phase of therapy for drug-susceptible pulmonary tuberculosis: a prospective, randomized clinical trial. Lancet 2002; 360:528-34.

#### **2003**

Weiner M, Burman W, Vernon A, Benator D, Peloquin CA, Khan A, Weis S, King B, Shah N, Hodges T, TBTC. Low isoniazid concentrations and outcome of tuberculosis treatment with once-weekly isoniazid and rifapentine. Am J Respir Crit Care Med 2003; 167:1341-7.

Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A, TBTC. The effects of local review on informed consent documents from a multicenter clinical trials consortium. Clinical Trials 2003;24:245-55.

#### **2004**

Weiner M, Bock N, Peloquin CA, Burman WJ, Khan A, Vernon A, Zhao Z, Weis S, Sterling TR, Hayden K, Goldberg S, Tuberculosis Trials Consortium. Pharmacokinetics of rifapentine 600, 900 and 1,200 mg during once-weekly tuberculosis therapy. Am J Respir Crit Care Med 2004;169:1191-7.

Jasmer R, Bozeman L, Cave D, Saukkonen J, Schwartzman K, Metchock B, Burman W and the TB Trials Consortium (TBTC). Recurrent tuberculosis in the United States and Canada: relapse or reinfection? Am J Respir Crit Care Med 2004;170:1360-6.

## 2005

Bozeman L, Burman W, Metchock B, Welch L, Weiner M and the TB Trials Consortium (TBTC). Fluoroquinolone susceptibility among *Mycobacterium tuberculosis* isolates from the United States and Canada. *Clin Infect Dis* 2005;40:386-91.

Weiner M, Benator D, Burman W, Peloquin CA, Khan A, Vernon A, Jones B, Silva-Trigo C, Zhao Z, Hodge T and the Tuberculosis Trials Consortium. The association between acquired rifamycin resistance and the pharmacokinetics of rifabutin and isoniazid among patients with HIV-related tuberculosis. *Clin Infect Dis* 2005;40:1481-91.

Weiner M, Benator D, Peloquin CA, Burman W, Vernon A, Engle M, Khan A, Zhao Z, and the Tuberculosis Trials Consortium. Evaluation of the Drug Interaction between Rifabutin and Efavirenz in Patients with HIV Infection and Tuberculosis. *Clin Infect Dis* 2005; 41:1343–9

## 2006

Sterling TR, Zhao Z, Khan A, Chaisson RE, Schluger N, Mangura B, Weiner M, Vernon A for the Tuberculosis Trials Consortium. Mortality in a large tuberculosis treatment trial: modifiable and non-modifiable risk factors. *Int J Tuberc Lung Dis* 2006;10(5):542–549.

Burman W, Benator D, Vernon A, Khan A, Jones B, Silva C, Lahart C, Weis SE, King B, Mangura B, Weiner M, El-Sadr W, and the Tuberculosis Trials Consortium. Acquired Rifamycin Resistance with Twice-Weekly Treatment of HIV-related Tuberculosis. *Am J Respir Crit Care Med* 2006;173: 350-356.

Burman W, Goldberg S, Johnson JL, Muzanye G, Engle M, Mosher AW, Choudhri S, Daley CL, Munsiff SS, Zhao Z, Vernon A, Chaisson RE, and the Tuberculosis Trials Consortium. Moxifloxacin versus Ethambutol in the First 2 Months of Treatment for Pulmonary Tuberculosis. *Am J Respir Crit Care Med* 2006; 174:331–338.

Khan A, Sterling TR, Reves R, Vernon A, Horsburgh CR, and the Tuberculosis Trials Consortium. Lack of Weight Gain and Relapse Risk in a Large Tuberculosis Treatment Trial. *Am J Respir Crit Care Med* 2006;174:344–348.

Sandman L, Mosher A, Khan A, Tapy A, Condos R, Ferrell S, Vernon A, and the Tuberculosis Trials Consortium. Development and Implementation of a Quality Assurance Program in a Large Clinical Trials Consortium: Experience of the Tuberculosis Trials Consortium. *Contemp Clin Trials* 2006;27:554-60.

## 2007

Conwell DS, Mosher A, Khan A, Tapy J, Sandman L, Vernon A, Horsburgh CR and the TB Trials Consortium (TBTC). Factors Associated with Loss to Follow-up in a Large Tuberculosis Treatment Trial (TBTC Study 22). *Contemp Clin Trials* 2007;28:288-94.

Benator DA, Weiner M, Burman WJ, Vernon AA, Zhao ZA, Khan AE, Jones BE, Sandman L, Engle M, Silva-Trigo C, Hsyu PH, Becker MI, and Peloquin CA, for the Tuberculosis Trials Consortium. Clinical evaluation of the nelfinavir – rifabutin interaction in patients with tuberculosis and human immunodeficiency virus infection. *Pharmacotherapy* 2007 Jun;27(6):793-800.

Peloquin CA, Durbin D, Childs J, Sterling TR, Weiner M. Stability of anti-tuberculosis drugs mixed in food. *Clin Infect Dis* 2007 Aug 15;45(4):521.

Weiner M, Burman W, Luo CC, Peloquin CA, Engle M, Goldberg S, Agarwal V, Vernon A and the Tuberculosis Trials Consortium. Effects of rifampin and multidrug resistance gene polymorphism on concentrations of moxifloxacin. *Antimicrob Agents Chemother* 2007 Aug;51(8):2861-6. Epub 2007 May 21.

Burman W, Weis S, Vernon A, Khan A, Benator D, Jones B, Silva C, King B, Lahart C, Mangura B, Weiner M, el-Sadr W. Frequency, severity and duration of immune reconstitution events in HIV-related tuberculosis. *Int J Tuberc Lung Dis* 2007;11:1282-9.

Breese PE, Burman WJ, Goldberg S, Weis S. Education Level, Primary Language, and Comprehension of the Informed Consent Process. *Journal of Empirical Research on Human Research Ethics* 2007: 69-79.

## 2008

Hamilton CD, Stout JE, Goodman PC, Mosher A, Menzies R, Schluger NW, Khan A, Johnson JL, Vernon AN and the Tuberculosis Trials Consortium. The Value of End-of-Treatment Chest Radiograph in Predicting Pulmonary Tuberculosis Relapse. *Int J Tuberc Lung Dis* 2008 Sep;12(9):1059-64.

## 2009

Dorman SE, Johnson JL, Goldberg S, Muzanye G, Padayatchi N, Bozeman L, Heilig CM, Bernardo J, Choudhri S, Grosset JH, Guy E, Guyadeen P, Leus MC, Maltas G, Menzies D, Nuermberger EL, Villarino M, Vernon A, Chaisson RE; Tuberculosis Trials Consortium. [Substitution of moxifloxacin for isoniazid during intensive phase treatment of pulmonary tuberculosis.](#) *Am J Respir Crit Care Med.* 2009 Aug 1;180(3):273-80. Epub 2009 Apr 30.

Burman WJ, Bliven EE, Cowan L, Bozeman L, Nahid P, Diem L, Vernon A; Tuberculosis Trials Consortium. [Relapse associated with active disease caused by Beijing strain of \*Mycobacterium tuberculosis\*.](#) *Emerg Infect Dis.* 2009 Jul;15(7):1061-7.

## 2010

Stout JE, Kosinski AS, Hamilton CD, Goodman PC, Mosher A, Menzies D, Schluger N, Khan A, Johnson JL; the Tuberculosis Trials Consortium. [Effect of Improving the Quality of Radiographic Interpretation on the Ability to Predict Pulmonary Tuberculosis Relapse\(1\).](#) *Acad Radiol.* 2010 Feb;17(2):157-62. Epub 2009 Nov 11.

Kim EY, Nahid P, Hopewell PC, Kato-Maeda M. [Novel hot spot of IS6110 insertion in \*Mycobacterium tuberculosis\*.](#) *J Clin Microbiol.* 2010 Apr;48(4):1422-4. Epub 2010 Feb 10.

Nahid P, Bliven EE, Kim EY, Mac Kenzie WR, Stout JE, Diem L, Johnson JL, Gagneux S, Hopewell PC, Kato-Maeda M; Tuberculosis Trials Consortium. [Influence of \*M. tuberculosis\* lineage variability within a clinical trial for pulmonary tuberculosis.](#) *PLoS ONE.* 2010 May 20;5(5):e10753.

Yamshchikov AV, Kurbatova EV, Kumari M, Blumberg HM, Ziegler TR, Ray SM, Tangpricha V. [Vitamin D status and antimicrobial peptide cathelicidin \(LL-37\) concentrations in patients with active pulmonary tuberculosis.](#) *Am J Clin Nutr.* 2010 Jul 7. [Epub ahead of print]

Weiner M, Peloquin C, Burman W, Luo CC, Engle M, Prihoda TJ, Mac Kenzie WR, Bliven-Sizemore E, Johnson JL, Vernon A. [The effects of tuberculosis, race and human gene \*SLCO1B1\* polymorphisms on rifampin concentrations.](#) *Antimicrob Agents Chemother.* 2010 Jul 26. [Epub ahead of print]

Weiner M, Prihoda TJ, Burman W, Johnson JL, Goldberg S, Padayatchi N, Duran P, Engle M, Muzanye G, Mugerwa RD, Sturm AW. Evaluation of time to detection in broth culture as an endpoint for tuberculosis trials. *J Clin Microbiol.* In press.

## 2011

Mac Kenzie WR, Heilig CM, Bozeman L, Johnson JL, Muzanye G, Dunbar D, Jost, Jr KC, Diem L, Metchock B, Eisenach K, Dorman S, Goldberg S. Geographic Differences in Time to Culture Conversion in Liquid Media: Tuberculosis Trials Consortium Study 28. Culture Conversion Is Delayed in Africa. *PLoS ONE* 2011;6:e18358.

Sterling TR, Villarino ME, Borisov AS, Shang N, Gordin F, Bliven-Sizemore E, Hackman J, Hamilton CD, Menzies D, Kerrigan A, Weis SE, Weiner M, Wing D, Conde MB, Bozeman L, Horsburgh CR Jr, Chaisson RE; TB Trials Consortium PREVENT TB Study Team. [Three months of rifapentine and isoniazid for latent tuberculosis infection.](#) *N Engl J Med.* 2011 Dec 8;365(23):2155-66.

Heilig CM, Chia D, El-Sadr WM, Hirsch-Moverman Y, Mac Kenzie WR, Saukkonen J, Villarino ME, Padayatchi N. Justifying research risks in a clinical trial for treatment of multidrug-resistant tuberculosis. *IRB:Ethics & Human Research.* 2011;33:10-17.

Nahid P, Saukkonen J, Mac Kenzie W, Johnson JL, Phillips PJ, Andersen J, Bliven E, Belisle J, Boom H, Luetkemeyer A, Campbell T, Eisenach K, Hafner R, Lennox J, Makhene M, Swindells S, Villarino E, Weiner M, Benson C, Burman W. Tuberculosis Biomarker and Surrogate Endpoint Research Roadmap. *Am J Respir Crit Care Med.* 2011 Jul 14.

## 2012

Dooley KE, Bliven-Sizemore EE, Weiner M, Lu Y, Nuermberger EL, Hubbard C, Fuchs EJ, Melia MT, Burman WJ, Dorman SE. Safety and pharmacokinetics of escalating daily doses of the antituberculosis drug rifapentine in health volunteers. *Clinical Pharmacology & Therapeutics.* 2012;91:881-8.

Bliven-Sizemore EE, Johnson JL, Goldberg S, Burman WJ, Villarino ME, Chaisson RE, Consortium FT. [Effect of HIV infection on tolerability and bacteriologic outcomes of tuberculosis treatment.](#) *Int J Tuberc Lung Dis.* 2012;16:473-9.

Goodridge A, Cueva C, Lahiff M, Muzanye G, Johnson JL, Nahid P, Riley LW. Anti-phospholipid antibody levels as biomarker for monitoring tuberculosis treatment response. *Tuberculosis.* 2012;92:243-7.

Dorman SE, Goldberg S, Stout JE, Muzanye G, Johnson JL, Weiner M, Bozeman L, Heilig CM, Feng PJ, Moro R, Narita M, Nahid P, Ray S, Bates E, Haile B, Nuermberger EL, Vernon A, Schluger NW, the Tuberculosis Trials Consortium. Substitution of Rifapentine for Rifampin during intensive phase treatment of pulmonary tuberculosis: Study 29 of the Tuberculosis Trials Consortium. *J Infect Dis.* 2012;206:1030-1040.

Chigutsa E, Meredith S, Wiesner L, Padayatchi N, Harding J, Moodley P, Mac Kenzie WR, Weiner M, McIlleron H, Kirkpatrick CM. Population pharmacokinetics and pharmacodynamics of ofloxacin in South African patients with multidrug-resistant tuberculosis. *Antimicrob Agents Chemother.* 2012;56:3857-63.

Padayatchi N, Mac Kenzie WR, Hirsch-Moverman Y, Feng PJ, Villarino ME, Saukkonen J, Heilig CM, Weiner M, El-Sadr WM. Lessons from a randomised clinical trial for multidrug-resistant tuberculosis. *Int J Tuberc Lung Dis* 2012;16:1582-7.

Lamunu D, Chapman KN, Nsubuga P, Muzanyi G, Mulumba Y, Mugerwa MA, Goldberg S, Bozeman L, Engle M, Saukkonen J, Mastranzio S, Mayanja-Kizza H, Johnson JL. Reasons for non-participation in an international multicenter trial of a new drug for tuberculosis treatment. *Int J Tuberc Lung Dis* 2012;16:480-5.

## 2013

Hales CM, Heilig CM, Chaisson R, Leung CC, Chang KC, Goldberg SV, Gordin F, Johnson JL, Muzanyi G, Saukkonen J, Vernon A, Villarino ME, Burman WJ. The association between symptoms and microbiologically defined response to tuberculosis treatment. *Ann Am Thorac Soc* 2013;10:18-25.

De Groot MA, Nahid P, Jarlsberg L, Johnson JL, Weiner M, Muzanyi G, Janjic N, Sterling DG, Ochsner UA. Elucidating novel serum biomarkers associated with pulmonary tuberculosis treatment. *PLoS One*. 2013 Apr 18;8(4):e61002.

## II. Presentations and Abstracts

### 1997

Bozeman L, Vernon A, Crawford J, Glickman S, Dansbury K, Villarino E and the USPHS Rifapentine Trials Group. Drug susceptibility testing (DST) of *M. tuberculosis* (M.TB) isolates from patients enrolled in a clinical trial. [abstract]. *Am J Respir Crit Care Med* 1997;155:A220.

Rifapentine Trial Group: Design of USPHS Study 22: A trial of once weekly isoniazid and rifapentine in the continuation phase of TB treatment.[abstract] *Am J Respir Crit Care Med* 1997;155:A255.

Vernon A, Villarino E, O'Brien R et al. Relapse with rifampin mono-resistant TB (RMR-TB) in HIV-positive TB patients treated with a once weekly rifapentine-containing regimen [abstract]. *Int J Tuberc Lung Dis* 1997;1 Suppl.A:S51-2.

### 1998

Benator D, Burman W, Chaisson R, and USPHS Study 22 Investigators. Acquired rifamycin mono-resistant tuberculosis among HIV-infected patients treated with once-weekly isoniazid and rifapentine. 5<sup>th</sup> Conference on Retroviruses and Opportunistic Infections. Chicago, IL, February 1998.

Vernon A, Khan A, Bozeman L, et al. Update on US Public Health Service (USPHS) Study 22: A trial of once weekly isoniazid (INH) & rifapentine (RFP) in the continuation phase of TB treatment [abstract]. *Am J Respir Crit Care Med* 1998;157:A467.

Vernon A. TB Clinical Trials in the US. Oral presentation, evening symposium, American Thoracic Society International Conference, Chicago, IL, April 1998.

### 1999

Burman W, Vernon A, Benator D for the TB Trials Consortium. Isoniazid, rifampin and rifapentine in human plasma: no need to add ascorbic acid to maintain stability. [abstract]. *Am J Respir Crit Care Med* 1999;159:A496.

Horsburgh CR, Reichman LB, Vernon A, Gordin F, Villarino ME, O'Brien R, for the TBTC Investigators. Establishment of the Tuberculosis Trials Consortium (TBTC). Invited presentation, 1999 American Thoracic Society International Conference, San Diego, CA.

Peloquin CA, Vernon A, Burman W, Benator D, for the TB Trials Consortium. Pharmacokinetics of rifapentine, rifampin, isoniazid in TB patients. [abstract]. *Am J Respir Crit Care Med* 1999;159:A416.

Bock N, for the Tuberculosis Trials Consortium. Safety and tolerability of once-weekly rifapentine/isoniazid (INH) vs. twice-weekly rifampin/INH in the continuation phase therapy of pulmonary tuberculosis in HIV-negative adults in USPHS Study 22. Poster presentation, 30<sup>th</sup> IUATLD World Conference on Lung Health, Madrid (Spain), September 1999.

### 2000

A Vernon for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary Results in HIV-negative Patients. Invited presentation at Rifapentine Evening Symposium, Meeting of the European Region of the IUATLD, Budapest (Hungary), April 2000.

A Vernon for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary Results in HIV-negative Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A252.

A Catanzaro, R Horsburgh for the TB Trials Consortium. TBTC Study 22: Risk Factors for Relapse with Once-weekly Isoniazid/rifapentine (HP) in HIV-negative TB Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A252.

F.Gordin, R.Chaisson for the TB Trials Consortium. TBTC Study 22: Risk Factors for Relapse with Twice-weekly Isoniazid/rifampin (HR) in HIV-negative TB Patients. [abstract]. *Am J Respir Crit Care Med* 2000;

161(suppl):A252.

Z. Taylor, Qualls N, Vernon A, Villarino E, O'Brien R. A prevention effectiveness study of rifapentine in the continuation phase of therapy for active pulmonary tuberculosis.[abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A524.

A. Khan, L. Sandman, A. Mosher, D. Pizzano for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary quality assurance results in HIV-negative Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A645.

Villarino ME, O'Brien RJ for the TB Trials Consortium. TBTC Study22: Rifapentine Clinical Trial. Results in HIV-negative patients with pulmonary tuberculosis. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Catanzaro A, Villarino ME, for the TB Trials Consortium. Rate of and risk factors for relapse after once-weekly treatment with isoniazid and rifapentine for pulmonary tuberculosis. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Reichman LB, Villarino ME, for the TB Trials Consortium. Evaluation of the standard short course therapy (SSCT) for treatment of pulmonary tuberculosis (TB): results from TBTC Study 22. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Burman W, for the Tuberculosis Trials Consortium. Should tuberculosis treatment be extended in selected patients? Data from TBTC Study 22 and review of previous studies (poster). 38<sup>th</sup> Annual IDSA Meeting, New Orleans LA, Sept 7-10, 2000

Chaisson RE, El-Sadr W, for the TB Trials Consortium. Weekly Rifapentine and INH versus Twice Weekly Rifampin/INH in the Continuation Phase of Therapy for HIV Negative Patients with Pulmonary Tuberculosis (TB): Final Results; USPHS Study 22 (poster). ICAAC, 2000.

## 2001

Carol Dukes Hamilton, William N. Rom, for the TB Trials Consortium. Clinical Correlates of Sub-optimal Response to Tuberculosis (TB) Therapy in Humans (abstract). Keystone Symposium, February 2001.

Weiner M, Khan A, Benator D, Peloquin C, Burman W, and the TB Trials Consortium. Low Isoniazid (INH) Levels Are Associated with TB Treatment Failure/Relapse with Once-Weekly Rifapentine (RPT) and INH [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

Peloquin C, Benator D, Hayden K, Pizzano D, and the TB Trials Consortium. Low Rifapentine, Rifampin, & Isoniazid Plasma Levels Are Not Predicted by Clinical And Demographic Features [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

A. Vernon, D. Benator, N. Shah, T. Hodge and the TB Trials Consortium. N-Acetyl transferase type 2 Genotype Correlates with Treatment Failure or Relapse of Intermittent Isoniazid-containing Short-course Therapy [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

N. Bock, Sterling T, Pachucki C, Conwell D, Wang YC, for the TB Trials Consortium. Tolerability of Once-weekly Rifapentine 900 mg plus INH vs Once-weekly Rifapentine 600 mg plus INH during Continuation Phase Treatment of Pan-susceptible Tuberculosis in HIV-negative Adults [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A497. (poster).

Weiner M, Vernon A, Benator D, Khan A, Peloquin C, Hodge T and Burman W, for the TB Trials Consortium. Low Isoniazid Levels Are Associated with Tuberculosis Treatment Failure or Relapse with Once-Weekly, Short Course Rifapentine and Isoniazid [abstract]. *Int Journal TB and Lung Disease* 2001;5 (Supp 1):S120. Poster presented at 32<sup>nd</sup> World Conference of the International Union Against Tuberculosis and Lung Disease, Paris

FRANCE, November 2001.

Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A, for the TB Trials Consortium. The effects of local review on informed consent documents from a multicenter clinical trials consortium. Poster presented at the 15<sup>th</sup> Annual Applied Research Ethics National Association (ARENA) Meeting, Boston MA, December 2001.

## 2002

L Sandman, a Khan, A Mosher, J Tapy, A Vernon, and the TB Trials Consortium. Data Quality Assurance in the Tuberculosis Trials Consortium: A Partnership Approach. Submitted to 2002 Society for Clinical Trials conference, Arlington VA. *Controlled Clinical Trials* 2002; 23:63S (poster).

D Conwell, A Khan, J Tapy, L Sandman, A Mosher, S Barnes, M Bhattacharya, A Vernon, and the TB Trials Consortium (TBTC). Preventable Loss to Follow-Up (F/U) in a Large TB Treatment Trial (TBTC Study 22). Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A293. (poster).

A Khan, R Reves, T Sterling, A Vernon, S Weis, and the TB Trials Consortium (TBTC). Weight, Body Mass Index, and Treatment Outcome in a Large TB Treatment Trial (TBTC Study 22). Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A293. (poster).

L Bozeman, R Chaisson, G Dickinson, B Mangura, N Schluger, T Sterling, A. Vernon, Y-C Wang, and the TB Trials Consortium. Mortality in a Large TB Treatment Trial. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

L Bozeman, W Burman, F Gordin, B Metchock, C Peloquin, M. Weiner, and the TB Trials Consortium (TBTC). Fluoroquinolone Susceptibility Among Mycobacterium *tuberculosis* Isolates from the United States and Canada. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A18 (oral presentation).

M Bhattacharya, L Bozeman, W Burman, D Cave, B Metchock, J Tapy, A Vernon, C Woodley, and the TB Trials Consortium (TBTC). Usefulness of DNA fingerprinting of Mycobacterium *tuberculosis* in a large clinical trial of tuberculosis treatment. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

CA Peloquin, N Bock, M Weiner, A Vernon and TB Trials Consortium (TBTC). Pharmacokinetics of Rifapentine Used at High Doses in Patients with TB Disease. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

A Vernon, CR Horsburgh, B Burman, and the TB Trials Consortium. TBTC Study 22/Once-Weekly Isoniazid/Rifapentine (HP1) Vs Twice-Weekly Isoniazid/Rifampin (HR2) In HIV-Negative TB Patients. – In Whom Can Once-Weekly Therapy Be Safely Used? [abstract 146]. Program and Abstracts of the 4<sup>th</sup> World Congress on Tuberculosis, Bethesda MD, June 2002; 86.

Benator D, Burman W, Vernon A, Weiner M, Villarino E, Jones B, Silva C, Weis S, Lahart C, King B, Mangura B, Weiner M, El-Sadr W and the TB Trials Consortium (TBTC). Acquired Rifamycin Resistance is Associated with Intermittent Treatment of Tuberculosis in Patients with Advanced HIV infection: Preliminary Results of TBTC Study 23 and review of previous studies [abstract]. Program and Abstracts of the 4<sup>th</sup> World Congress on Tuberculosis, Bethesda MD, June 2002; 12-13.

A Vernon, A Khan, B Burman, CR Horsburgh, and the TB Trials Consortium. TBTC Study 22: Risk Factors For Failure/Relapse With Once-Weekly Isoniazid/Rifapentine (Hp) Or Twice-Weekly Isoniazid/Rifampin (Hr) In Sputum Smear-Positive Hiv-Negative Tb Patients – An Analysis For Resource-Poor Settings. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S124.



W. Burman, D Benator, W Burman, A Vernon, M Weiner, E Villarino B Jones, C Silva, S Weis, C Lahart, B King, B Mangura, W El-Sadr and the Tuberculosis Trials Consortium (TBTC). Acquired Rifamycin Resistance Is Associated With Intermittent Treatment Of Tuberculosis In Patients With Advanced Hiv Infection: Preliminary Results Of TBTC Study 23. Oral presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S149-50.

M Weiner, A Khan, A Vernon, B Burman, B Jones for the Tuberculosis Trials Consortium. Epidemiologic and clinical factors associated with the endpoint of *M. tuberculosis* culture-positivity in sputa after two-months of therapy for pulmonary tuberculosis. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S189.

CA Peloquin, N Bock, M Weiner, A Vernon and the TB Trials Consortium (TBTC). Pharmacokinetics of Rifapentine Used at High Doses in Patients with TB Disease. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S128-9.

Sterling TR, Hackman J, Horsburgh CR, Chaisson RE, Wang YC, Quinn E, Hamilton CD, Gordin F, Khan A, Donovan C, Menzies RI, McSherry G, Villarino ME and the TB Trials Consortium. Design of Tuberculosis Trials Consortium Study 26: Once-weekly rifapentine (RPT) + isoniazid (INH) for 3 months vs. daily INH for 9 months for the treatment of latent TB infection. 4<sup>th</sup> World Congress on Tuberculosis. Washington, DC. June 3-5, 2002. Abstract # 143.

### 2003

Burman W, Welch L, Metchock B, Bozeman L, Weiner M and the Tuberculosis Trials Consortium. The frequency and genetic basis of fluoroquinolone resistance among *Mycobacterium tuberculosis* isolates [abstract]. In: Tuberculosis: integrating host and pathogen biology. Jan 25-30, 2003, Santa Fe. Keystone Symposium, page 100.

Burman W, Benator D, Vernon A, Khan A, El-Sadr W, Silva C, Lahart C, Mangura B, King B, Weiner M, Jones B and the TB Trials Consortium. Use of antiretroviral therapy during treatment of active TB with a rifabutin-based regimen: TBTC Study 23 [abstract 136]. Abstracts of the 10th Conference on Retroviruses and Opportunistic Infections, Boston MA, February 2003;106. (Oral Presentation)

Benator D, Peloquin C, Vernon A, Khan A, Jones B, Weis S, Weiner M, Burman B, TBTC. Low serum levels of isoniazid are associated with acquired rifamycin resistance among patients with HIV-related TB treated with largely twice-weekly rifabutin and isoniazid [abstract]. *Am J Respir Crit Care Med* 2003;167:A433.

Bock NN, Sterling TR, Khan A, Hamilton C, Pachucki C, Mosher A, Samuel M, Conwell D, Vernon AA, TBTC. Extension of continuation-phase therapy to reduce relapse rates among HIV-negative TB patients at thigh risk for relapse [abstract]. *Am J Respir Crit Care Med* 2003;167:A433.

Weiner M, Bock N, Peloquin CA, Bock N, Vernon A, Burman WJ, Khan A, Weis S, Sterling T, Hayden K, Goldberg S, Zhao Z, Tuberculosis Trials Consortium. Rifapentine Pharmacokinetics with 600, 900 or 1,200 mg Doses in Patients with Tuberculosis during Once-Weekly Continuation-Phase Therapy. *Int J Tuberc Lung Dis* 2003;7:S197.

### 2004

Weiner M, Peloquin C, Khan A, Vernon A, Engle M, Benator D, Fitzgerald M, Zhao Z, Burman B and the Tuberculosis Trials Consortium. Intermittent Rifabutin and Isoniazid with Daily Efavirenz in Combination with Two Nucleosides for Treatment of HIV Infection and Tuberculosis Disease (Abstract #761). Program and Abstracts of the 11<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, 2004;350.

Benator DA, Weiner M, Burman WJ, Vernon A, Zhao Z, Khan A, Sandman L, Engle M, Silva C, Peloquin CA,

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Sterling TR, Borisov AS, Shang N, Bliven E, Chaisson RE, Gordin F, Hackman J, Hamilton CD, Horsburgh CR, Kerrigan A, Menzies D, Scott N, Villarino ME, and the Tuberculosis Trials Consortium. The PREVENT TB Study (TB Trials Consortium Study 26): 3 months of once-weekly rifapentine + INH vs. 9 months of daily INH for treatment of latent TB infection: First report of results of a multi-center, randomized clinical trial. Oral presentation at the Latebreaker Session, 2010 IUATLD meeting. November 15, 2010. Berlin

## 2011

Dooley KE, Bliven-Sizemore E, Weiner M, Nuermberger EL, Lu Y, Fuchs E, Burman WJ, Dorman S. A phase 1 dose escalation trial of the pharmacokinetics, safety, and tolerability of rifapentine dosed daily in healthy volunteers: preliminary results for TBTC Study 29B. Oral presentation at the American Thoracic Society International Conference. May 15, 2011. Denver, CO.

Weiner M, Peloquin C, Egelund E, Engle M, Bliven-Sizemore E, MacKenzie WR, Johnson JL, Nsubuga P, Prihoda TJ, Dorman S, Burman WJ. Rifapentine exposure in a trial of daily rifapentine compared to rifampin during the intensive phase of TB treatment. (Study 29 PK). Oral presentation at the American Thoracic Society International Conference. May 15, 2011. Denver, CO.

Sterling TR et al. The PREVENT TB Study (TB Trials Consortium Study 26): 3 months of once-weekly rifapentine + INH vs. 9 months of daily INH for treatment of latent TB infection: Final results. Oral presentation at the American Thoracic Society International Conference. May 16, 2011. Denver, CO.

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Bliven EE, Sterling TR, Shang N, Benator D, Schwartzman K, Reeves R, Drobeniuc J, Spradling PR, Villarino E, for the Tuberculosis Trials Consortium. Hepatitis C virus (HCV) infection and female sex are risk factors for treatment limiting hepatotoxicity in a large clinical trial of treatment of latent tuberculosis infection: results of a nested case-control study (Study 26A). Oral presentation at the American Thoracic Society International Conference. May 17, 2011. Denver, CO.

Dorman SE et al. A phase II study of a rifapentine-containing regimen for intensive phase treatment of pulmonary tuberculosis (Study 29). Oral presentation at the American Thoracic Society International Conference. May 17, 2011. Denver, CO.

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Modeling the pharmacokinetics of rifapentine in TB patients receiving 600 mg daily. 4<sup>th</sup> International Workshop on Clinical Pharmacology of TB drugs. 2011.

Dooley KE et al. Rifapentine and des-rifapentine population PK model. 4<sup>th</sup> International Workshop on Clinical Pharmacology of TB drugs. 2011.

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Chapman KN, Bessler P, Borisov A, Bozeman L, Dukes Hamilton CS, Hecker EJ, Kerrigan A, Menzies D, Moreno A, Saukkonen J, Goldberg S. Reasons for non-participation in an international multicenter trial of a new regimen for latent tuberculosis infection. Annual meeting of the American Thoracic Society, May 2012.

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Weiner M, Savic R, Wing D, Mac Kenzie WR, Peloquin CA, Engle M, Bliven E, Borisov A, Prihoda TP, Wing R, Abdel-Rahman SM, Kearns GL, Burman W, Sterling T, Villarino ME, and the Tuberculosis Trials Consortium Study 26PK Group. Rifapentine pharmacokinetics in children and adults receiving once weekly rifapentine and isoniazid for the treatment of latent tuberculosis infection. 5<sup>th</sup> International Workshop on Clinical Pharmacology of Tuberculosis Drugs. September 2012.

Sterling TR, Benson CA, Shang N, Villarino ME, the AIDS Clinical Trials Group, and the Tuberculosis Trials Consortium. Tolerability among HIV-infected persons of three months of once-weekly rifapentine + INH (3HP) vs. 9 months of daily INH (9H) for treatment of latent tuberculosis infection: The PREVENT TB Study (TBTC Study 26/ACTG 5259). IV Congreso Nacional de Gesida, Spain, November 2012.

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Villarino ME, Moro R, Borisov A, Adkinson NF, Phillips E, Shepherd G, Ho C, Weis SE, Sterling TR, and the Tuberculosis Trials Consortium. The rate and risk factors for drug hypersensitivity reactions among persons receiving 3 months of once-weekly rifapentine plus isoniazid for the treatment of latent tuberculosis infection (LTBI). Conference on Retroviruses and Opportunistic Infections, March 2013, Atlanta, GA.

Kolwijck E, Friedrich SO, Venter A, van Ingen J, Diacon AH. Effect of culture supernatant containing resuscitation-promoting factors on the growth of *M. tuberculosis* from sputum samples collected during antituberculosis treatment. European Society for Clinical Microbiology and Infectious Diseases, April 27-30, 2013, Berlin, Germany.

### III. Manuscripts and Presentations/Abstracts submitted or in preparation

#### A. Manuscripts

Shepardson D, Marks S, Chesson H, Kerrigan A, Holland DP, Scott N, Tian X, Borisov AS, Shang N, Heilig CM, Sterling TR, Villarino ME, Mac Kenzie WR. Cost-effectiveness of 12 weekly doses of directly observed rifapentine and isoniazid for the treatment of latent tuberculosis infection in the United States. Submitted.

Nyendak MR, Park B, Null MD, Baseka J, Swwarbrick G, Mayanja-Kizza H, Nsereko M, Johnson DF, Gitta P, Okwera A, Goldberg S, Bozeman L, Johnson JL, Boom WH, Lewinsohn DA, Lewinsohn DM, for the Tuberculosis Research Unit and the Tuberculosis Trials Consortium. Mycobacterium tuberculosis specific CD8+ T cells rapidly decline with antituberculosis treatment. In prep.

Weiner M, Egelund E, Engle M, Kiser M, Prihoda T, Peloquin CA, Mac Kenzie WR. The pharmacokinetic interaction between raltegravir and rifapentine in healthy volunteers. Submitted.

Bliven-Sizemore EE, Johnson JL, Goldberg S, Borisov A, Burman WJ, Dorman SE, Chaisson RE, Saukkonen JJ, and the Tuberculosis Trials Consortium. Hepatotoxicity in two phase 2 international multi-center trials of treatment for tuberculosis disease. Submitted.

Reves R, Heilig CM, Tapy J, Bozeman L, Kyle RP, Hamilton CD, Bock N, Narita M, Wing D, Hershfield E, Goldberg S, and the Tuberculosis Trials Consortium. Intermittent treatment for tuberculosis in patients not receiving isoniazid because of intolerance or drug resistance. Manuscript submitted to IJTLD April 2013.

Nahid P, Bliven-Sizemore, Jarlsberg LG, De Groote MA, Johnson JL, Muzanyi G, Weiner M, Janjic N, Sterling DG, Ochsner UA. Proteins predictive of intensive phase treatment response in Ugandan pulmonary tuberculosis patients, using multiplexed, aptamer-based proteomic technology. Manuscript submitted to JID May 2013.

Savic R, Lu Y, Bliven-Sizemore E, Weiner M, Nuermberger E, Burman W, Dorman SE, Dooley KE. Population pharmacokinetics of rifapentine and desacetyl rifapentine in healthy volunteers: nonlinearities in clearance and bioavailability. Manuscript submitted to AAC April 2013.

Heilig CM, Feng PJ, Joloba ML, Johnson JL, Morgan K, Gitta P, Boom WH, Mayanja Kizza H, Eisenach KD, Bozeman L, Goldberg SV. How we determined the most reliable solid medium for studying treatment of tuberculosis.

Joloba ML, Johnson JL, Feng PJ, Bozeman L, Goldberg SV, Morgan K, Gitta P, Boom WH, Heilig CM, Mayanja-Kizza H, Eisenach KD. What is the most reliable solid culture medium for tuberculosis treatment trials?

#### B. Presentations and Abstracts

Frick M, Lessem E, McKenna L, Menon L, Ruiz Mingote L, Namutamba D, Hamilton CD, The Community Research Advisors Group. Measuring the impact of community advisory groups on TB clinical trials: a case study from the TB Trials Consortium. Abstract submitted the Union meeting to be held 30 Oct -3 Nov 2013.

Denti P, Lu Y, Bliven-Sizemore E, Dooley KE. A semi-physiological model for rifampicin and rifapentine induction on midazolam pharmacokinetics. Abstract submitted to the Population Approach Group in Europe meeting to be held June 11-14 2013.

Alsultan A, Dooley KE, Weiner M, Whitworth W, Mac Kenzie WR, Peloquin CA, Tuberculosis Trials Consortium. Population pharmacokinetics of pyrazinamide in patients with tuberculosis. Abstracted submitted to the meeting of the American College of Clinical Pharmacology to be held 22-24 September 2013.

Moro R, Dorman SE, Schluger N, Stout J, Feng PJ, Heilig C, Bozeman L, Goldberg SV. Tolerability and safety of escalating rifapentine doses in intensive phase tuberculosis treatment. Submitted to CROI 2013.

Moro R, Dorman SE, Schluger N, Stout J, Feng PJ, Heilig C, Bozeman L, Goldberg SV. Tolerability and safety of escalating rifapentine doses in intensive phase tuberculosis treatment. Submitted to Union meeting 2013.

Weiner M, Savic R, Mac Kenzie W, Johnson JL, Engle M, Nsubuga P, Phan H, Gelfond J, Peloquin C, Dorman S, for the Tuberculosis Trials Consortium. Rifapentine exposure at higher daily doses in patients during intensive phase treatment for tuberculosis. Submitted to CROI 2013.

Everett CK, Benator D, Davis JL, Alland D, Heilig CM, Persing DH, Tnover FC, Weiner M, Kerrigan A, Zamudio C, Goldberg SV, Whitworth WC, Nahid P, and the TB Trials Consortium. Automated quantitative PCR using Xpert MTB/RIF to monitor tuberculosis treatment. Submitted to ATS meeting May 2013.