

# Publications and Presentations of the Tuberculosis Trials Consortium

(2011-2016)

October 3, 2016

## I. Publications

2016

- Study 34 - ACTG 5295 Luetkemeyer AF, Firnhaber C, Kendall MA, Wu X, Mazurek GH, Benator DA, Arduino R, Fernandez M, Guy E, Johnson P, Metchock B, Sattler F, Telzak E, Wang YF, Weiner M, Swindells S, Sanne IM, Havlir DV, Grinsztejn B, Alland D; AIDS Clinical Trials Group A5295 and Tuberculosis Trials Consortium Study 34 Teams. Evaluation of Xpert MTB/RIF Versus AFB Smear and Culture to Identify Pulmonary Tuberculosis in Patients With Suspected Tuberculosis From Low and Higher Prevalence Settings. *Clin Infect Dis*. 2016 May 1;62(9):1081-8. PMID: 26839383. PMCID: PMC4826450 [Available on 2017-05-01]
- Study 26 - Non-completion Treatment Moro RN, Borisov A, Saukkonen J, Khan A, Sterling TR, Villarino ME, Scott NA, Shang NA, Kerrigan A, Goldberg SV. Factors Associated with Non-completion of Latent Tuberculosis Infection Treatment: Experience from the PREVENT TB Trial in the United States and Canada. *Clinical Infectious Disease*, 2016.
- Study 26 - HIV Seropositive Sterling TR, Scott NA, Miro JM, Calvet G, La Rosa A, Infante R, Chen MP, Benator DA, Gordin F, Benson CA, Chaisson RE, Villarino ME; Tuberculosis Trials Consortium, the AIDS Clinical Trials Group for the PREVENT TB Trial (TBTC Study 26 ACTG 5259). Three months of weekly rifapentine plus isoniazid for treatment of M. tuberculosis infection in HIV co-infected persons. *AIDS*. 2016 Mar 17. [Epub ahead of print]. PMID: 26990624

2015

- Study 26A Bliven-Sizemore EE, Sterling TR, Shang N, Benator D, Schwartzman K, Reves R, Drobeniuc J, Bock N, Villarino ME, The TBTC. Three months of weekly rifapentine plus isoniazid is less hepatotoxic than nine months of daily isoniazid for ltb. *The International Journal of Tuberculosis and Lung Disease* 2015;19:1039-1044.
- S29: Evaluation of Consent Process Chapman KN, Pevzner E, Mangan JM, Breese P, Lamunu D, Shrestha-Kuwahara R, Nakibali JG, Goldberg SV. Evaluation of the informed consent process of a multicenter tuberculosis treatment trial. *AJOB Empirical Bioethics* 2015;6:31-43.
- Study 29X Dorman SE, Savic RM, Goldberg S, Stout JE, Schluger N, Muzanyi G, Johnson JL, Nahid P, Hecker EJ, Heilig CM, Bozeman L, Feng P-JI, Moro RN, MacKenzie W, Dooley KE, Nuermberger EL, Vernon A, Weiner M, and the Tuberculosis Trials Consortium. Daily rifapentine for treatment of pulmonary tuberculosis. A randomized, dose-ranging trial. *American journal of respiratory and critical care medicine* 2015;191:333-343.
- Study 29 - Biomarkers Jayakumar A, Vittinghoff E, Segal MR, MacKenzie WR, Johnson JL, Gitta P, Saukkonen J, Anderson J, Weiner M, Engle M, Yoon C, Kato-Maeda M, Nahid P, Tuberculosis Trials Consortium. Serum biomarkers of treatment response within a randomized clinical trial for pulmonary tuberculosis. *Tuberculosis (Edinb)* 2015;95:415-420.
- Study 26HS Sterling TR, Moro RN, Borisov AS, Phillips E, Shepherd G, Adkinson NF, Weis S, Ho C, Villarino ME, for the Tuberculosis Trials Consortium. Flu-like and other systemic drug reactions among persons receiving weekly rifapentine plus isoniazid or daily isoniazid for treatment of latent tuberculosis infection in the prevent tuberculosis study. *Clinical Infectious Diseases* 2015;61:527-535.
- Study 26 - TB Pediatric Villarino ME, Scott NA, Weis SE, Weiner M, Conde MB, Jones B, Nachman S, Oliveira R, Moro RN, Shang N, Goldberg SV, Sterling TR, for the International Maternal Pediatric Adolescents Aids Clinical Trials Group, and the Tuberculosis Trials Consortium. Treatment for preventing tuberculosis in children and adolescents: A randomized clinical trial of a 3-month, 12-dose regimen of a combination of rifapentine and isoniazid. *JAMA pediatrics* 2015;169:247-255.

2014

- Study 29PK/29X PK Egelund EF, Weiner M, Singh RP, Prihoda TJ, Gelfond JAL, Derendorf H, Mac Kenzie WR, Peloquin CA. Protein binding of rifapentine and its 25-desacetyl metabolite in patients with pulmonary tuberculosis. *Antimicrobial agents and chemotherapy* 2014;58:4904-4910.
- NAA2m Heilig CM, Feng P-JI, 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. *Tuberculosis* 2014;94:317-322.

- NAA2m Joloba ML, Johnson JL, Feng PJ, Bozeman L, Goldberg SV, Morgan K, Gitta P, Boom HW, Heilig CM, Mayanja-Kizza H, Eisenach KD. What is the most reliable solid culture medium for tuberculosis treatment trials? *Tuberculosis (Edinb)* 2014;94:311-316.
- Study 29 - Biomarkers Nahid P, Bliven-Sizemore E, Jarlsberg LG, De Groote MA, Johnson JL, Muzanyi G, Engle M, Weiner M, Janjic N, Sterling DG, Ochsner UA. Aptamer-based proteomic signature of intensive phase treatment response in pulmonary tuberculosis. *Tuberculosis*. 2014;94(3):187-96.
- Study 29B Parsons TL, Marzinke MA, Hoang T, Bliven-Sizemore E, Weiner M, Mac Kenzie W, Dorman SE, Dooley KE. Quantification of rifapentine, a potent anti-tuberculosis drug, from dried blood spot samples using liquid chromatographic-tandem mass spectrometric analysis. *Antimicrobial agents and chemotherapy* 2014;58(11):6747-57.
- Study 24 Reves, R., C. M. Heilig, J. M. Tapy, L. Bozeman, R. P. Kyle, C. D. Hamilton, N. Bock, M. Narita, D. Wing, E. Hershfield, S. V. Goldberg and T. T. Consortium (2014). 'Intermittent tuberculosis treatment for patients with isoniazid intolerance or drug resistance.' *The International Journal of Tuberculosis and Lung Disease* 18(5): 571-580.
- Study 29B Savic RM, 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. *Antimicrobial agents and chemotherapy*. 2014;58(6):3035-42.
- Study 26 Cost Effectiveness Shepardson D, MacKenzie WR. Update on cost-effectiveness of a 12-dose regimen for latent tuberculous infection at new rifapentine prices. *The international journal of tuberculosis and lung disease*. 2014;18(6):751.
- Kolwijck E, Friedrich SO, Karinja MN, van Ingen J, Warren RM, Diacon AH. Early stationary phase culture supernatant accelerates growth of sputum cultures collected after initiation of anti-tuberculosis treatment. *Clinical Microbiology and Infection* 2014;20:O418-O420.
- Study 29PK RR Weiner M, Egelund EF, Engle M, Kiser M, Prihoda TJ, Gelfond JA, Mac Kenzie W, Peloquin CA. Pharmacokinetic interaction of rifapentine and raltegravir in healthy volunteers. *The Journal of antimicrobial chemotherapy* 2014;69:1079-1085.
- Study 26PK Weiner M, Savic RM, Kenzie WRM, Wing D, Peloquin CA, Engle M, Bliven E, Prihoda TJ, Gelfond JAL, Scott NA, Abdel-Rahman SM, Kearns GL, Burman WJ, Sterling TR, Villarino ME, for the Tuberculosis Trials Consortium PREVENT TB Pharmacokinetic Group. Rifapentine Pharmacokinetics and Tolerability in Children and Adults Treated Once Weekly With Rifapentine and Isoniazid for Latent Tuberculosis Infection. *Journal of the Pediatric Infectious Diseases Society*. 2014 January 16, 2014.

### 2013

- Study 29 - Biomarkers De Groote 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.
- Study 22 - Symptoms and microbiological ly- Trx response 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.
- NAA2m Nyendak MR, Park B, Null MD, Baseke J, Swarbrick G, et al. (2013) Mycobacterium tuberculosis Specific CD8+ T Cells Rapidly Decline with Antituberculosis Treatment. *PLoS ONE* 8(12): e81564.
- Study 26 Cost Effectiveness Shepardson D, Marks SM, Chesson H, Kerrigan A, Holland DP, Scott N, et al. Cost-effectiveness of a 12-dose regimen for treating latent tuberculous infection in the United States. *Int J Tuberc Lung Dis*. 2013;17(12):1531-7.

### 2012

- Study 27/28 HIV Bliven-Sizemore EE, Johnson JL, Goldberg S, Burman WJ, Villarino ME, Chaisson RE, for the Tuberculosis Trials Consortium. Effect of HIV infection on tolerability and bacteriologic outcomes of tuberculosis treatment. *Int J Tuberc Lung Dis*. 2012;16:473-9.
- Study 30PK 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.
- Study 29B 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 healthy volunteers. *Clinical Pharmacology & Therapeutics*. 2012;91:881-8.

- Study 29 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.
- Study 29 - Biomarkers 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.
- Study 28 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.
- Study 30 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.

## 2011

- Study 30 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.
- Study 28 - Africa difference 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.
- Study 29 - Biomarkers 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.
- Study 26 - Main Study - Adults 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, for the TB Trials Consortium PREVENT TB Study Team\*; 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.

## Selected Guideline Publications Influenced by TBTC Work

Centers for Disease Control & Prevention. Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection. *Morb Mort Wkly Rep* 2011;60:1650-1653.

Centers for Disease Control & Prevention. Treatment of Tuberculosis. *Morb Mort Wkly Rep* 2003; 52 (No. RR-11)

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.

## II. Presentations and Abstracts

### 2016

- Study 33- Cost Effectiveness Holland DP, Sheehan D, Wright A, Scott N, Belknap R, Borisov A for the Tuberculosis Trials Consortium. iAdhere Study: Cost-Effectiveness of Self-Administered Isoniazid/Rifapentine for Treatment of Latent Tuberculosis Infection in the United States. Abstract presented at American Thoracic Society conference, San Francisco, CA, May 13-18, 2016.
- Early treatment response in adult TB/HIV patients, Soweto Martinson N, Gordhan B, Friederich S, Otjombe K, Letutu M, Waja Z, Lebina L, Msandiwa R, Chaisson RE, Kana B, Diacon A. Are smear-negative, HIV-infected, TB patients appropriate participants for clinical trials of novel TB regimens?. 21th International AIDS Conference (AIDS 2016) Durban, South Africa, 18-22 July 2016
- Study 26 Pregnancy Moro RN, Scott NA, Vernon A, Goldberg SV, Schwartzman K, Narita M, Machado ES, Schluger NW, Lopez M, Leung CC, Chaisson RE, Belknap RW, Sanchez J, Villarino E, Sterling T. Pregnancy Safety Assessment of 3 Months of Once-Weekly Rifapentine and Isoniazid and 9 Months of Daily Isoniazid: a Post-hoc Analysis of the PREVENT TB and the iAdhere Trials. American Thoracic Society (ATS) 2016 – San Francisco, CA - May 14 – 18. Poster and oral presentation.

### 2015

- ALT kinetic biomarker for hepatotoxicity Divya R, Janice W, Ruth M, Pei-Jean F, Stefan G, Jussi JS. Patterns of alanine transaminase rise in tuberculosis drug-induced hepatotoxicity. B50 Diagnosis and Treatment of Active Tuberculosis Disease. Denver, CO: American Thoracic Society; 2015. p. A3318-A3318.
- S33 Motivations to Enroll Chapman KN, Borisov A, Engle M, Belknap R, Goldberg S, Wing D, and Joan Mangan. (2014) The iAdhere Study: Reasons patients declined or accepted study participation. [Abstract]. The International Journal of Tuberculosis and Lung Disease. CDC ATS Late Breaker 2015 poster presentation, Denver, CO, May, 2015.
- Study 34 - ACTG 5295 Luetkemeyer A, Firnhaber C, Kendall M, Wu X, Benator D, Mazurek G, Havlir D, Grinsztejn B, Alland D, on behalf of the ACTG A5295/TBTC 34 Study teams(8). Xpert MTB/RIF versus AFB smear to determine respiratory isolation of U.S. TB suspects. Presented at CROI 2015, Seattle, Washington.
- Study 26 - Non-completion Treatment Moro R., Saukkonen J., Khan A., Sterling T., Scott N., Kerrigan A., and Borisov A. Factors associated with non-completion of latent tuberculosis infection (LTBI) treatment: experience from the randomized PREVENT TB trial in the United States and Canada. Poster presentation at the 2015 National Tuberculosis Conference. Atlanta U.S., June 8-11. 2015 TB Poster Award at the at 2015 National Tuberculosis Conference.
- Studies 27, 28, 29, 29X Adverse Events Moro RN, Borisov A, Johnson JL, Leung CC, Chang KC, Martinson N, Goldberg, SV. Ethnic Differences in Neutrophil Counts and Neutropenia Reporting in Two International Trials of Rifapentine and Rifampicin for Tuberculosis Treatment. Presented as a poster three times: 1. 18th Annual Conference of The Union North America Region, International Union Against Tuberculosis and Lung Disease, February 2015, Vancouver, Canada. 2. The National Tuberculosis Conference. Atlanta, GA June 2015 3. International Society for Pharmacoeconomics Conference. 31st ICPE. Boston, MA August 2015
- Study 33- I Adhere Robert Belknap, Andrey Borisov, David Holland, Pei-Jean Feng, Joan-Pau Millet, Neil Martinson, Alicia Wright, Michael P. Chen, Joan A. Cayla, Jose M. Miro, and the TBTC. Adherence to Once-weekly self-administered rifapentine for latent TB: iAdhere. CROI 2015 late-breaker poster presentation, Seattle, WA. February 24-26th, 2015.
- Study 33- I Adhere Robert Belknap, Andrey Borisov, David Holland, Pei-Jean Feng, Joan-Pau Millet, Neil Martinson, Alicia Wright, Michael P. Chen, Joan A. Cayla, Jose M. Miro, and the TBTC. Adherence to Once-weekly self-administered rifapentine for latent TB: iAdhere. CDC ATS Late Breaker 2015 poster presentation, Denver, CO, May, 2015.
- Markers of Trx response in children, Stellenbosch & Kisumu Walters E, van der Zalm M, Demers AM, Bosch C, Schaaf HS, Palmer M, Gie RP and Hesselning AC. Bacteriological response to treatment in children with confirmed intrathoracic tuberculosis. Union 2015, Cape Town, South Africa.

## 2014

- Study 29 - GeneXpert A Jayakumar, R Savic, CK Everett, D Benator, JL Davis, D Alland, CM Heilig, M Weiner, A Kerrigan, C Zamudio, SV Goldberg, WC Whitworth, and P Nahid; Tuberculosis Trials Consortium. Rifamycin Exposure Predicts MTB Clearance As Measured By Quantitative Xpert MTB/RIF Assay. Keystone Symposium. 2014. Accepted for poster presentation.
- S33 Motivations to Enroll Chapman KN, Borisov A, Engle M, Belknap R, Goldberg S, Wing D, and Joan Mangan. (2014) The iAdhere Study: Reasons patients declined or accepted study participation. [Abstract]. The International Journal of Tuberculosis and Lung Disease. Poster Discussion at the 45th Union World Conference in Barcelona, Spain (November 2014)
- Study 34 - ACTG 5295 AF Luetkemeyer, C Firnhaber, MA Kendall, X Wu, D Benator, GH Mazurek, B Metchock, P Johnson, S Swindells, I Sanne, DV Havlir, B Grinsztejn, D. Alland, ACTG A5295/TBTC 34 Study teams. Performance of Xpert MTB/RIF testing for M.tuberculosis(TB) detection in HIV+ and HIV- pulmonary TB suspects in low versus high TB prevalence settings: the ACTG 5295/TBTC 34 Study. Presented July 2014 International AIDS Society Meeting.
- ALT kinetic biomarker for hepatotoxicity Reddy D, Minter M, Moro R, Feng P, Goldberg S, Saukkonen J, TBTC. Time-based analysis for alanine transaminase monitoring to detect hepatotoxicity during tuberculosis treatment; American Thoracic Society Conference, Poster Presentation, San Diego, May 2014
- Study 29 - GeneXpert Jayakumar A, Everett C, Benator D, Davis JL, Alland D, Heilig CM, Weiner M, Kerrigan K, Zamudio C, Goldberg SV, Whitworth WC, and Nahid P; Tuberculosis Trials Consortium. Quantitative Xpert MTB/RIF to assess tuberculosis treatment response: timing to predict eight week culture conversion. American Thoracic Society International Meeting, 2014. Abstract accepted.
- Study 26 - Non-completion Treatment Moro R, Borisov A, Saukkonen J, Khan A, Shang N, Villarino E, Sterling T, Scott N, Efron A, Kerrigan A, and Goldberg S. Factors Associated with Non-completion of Latent Tuberculosis Infection (LTBI) Treatment: Reasons other than Adverse Events (AE) The TB Trials Consortium PREVENT TB - Study 26. International Union Against Tuberculosis and Lung Disease-North American Union. Poster presentation, February 25-28th 2014, Boston, MA.
- Study 26 - Non-completion Treatment Moro R, Borisov A, Saukkonen J, Khan A, Shang N., Villarino E, Sterling T, Scott N, Efron A, Kerrigan A, and Goldberg S. Factors Associated with Non-completion of Latent Tuberculosis Infection (LTBI) Treatment: Reasons other than Adverse Events (AE) The TB Trials Consortium PREVENT TB - Study 26. International Union Against Tuberculosis and Lung Disease-North American Union. Oral presentation, March 1st 2014, Boston, MA.
- Studies 27, 28, 29, 29X Adverse Events Moro RN, Borisov A, Johnson JL, Leung CC, Chang KC, Martinson N, Goldberg, SV. Racial differences in neutrophil counts and reported neutropenia in two International TB Treatment Trials, Rifapentine- Rifampicin, TBTC Studies 29 and 29x. 45th Union World Conference on Lung Health, International Union Against Tuberculosis and Lung Disease, Poster presentation, October 30, 2014, Barcelona, Spain. (accepted but not presented; printed in abstract book)
- Study 26 - HIV Seropositive Sterling T, Benson C, Scott N, Miro J, Calvet G, Chaisson R, La Rosa A, Infante R, Chen M, Villarino E, and TBTC / ACTG. (2014 March). Three Months of Weekly Rifapentine + INH for M. tuberculosis Infection in HIV- Infected Persons. Poster presented at Conference on Retroviruses and Opportunistic Infections, Boston, MA.

## 2013

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.

Baertlein L, Moro RN, Borisov A, Goldberg S. Assessment of Severity Grading Differences Between Terms in Common Toxicity Criteria Used in Clinical Trials. Poster presentation: Drug Information Association's (DIA) Annual Meeting, Boston, MA, June 2013.

Chapman KN, Oramasionwu G, Mangan J. Pilot Evaluation of Latent Tuberculosis Infection (LTBI) Treatment Adverse Event Fact Sheet. Oral presentation & poster: National TB Controllers Association Conference, Atlanta, GA, June 2013,

Dooley K and Bliven-Sizemore E. Population pharmacokinetics of pyrazinamide. Presented at the Clinical Pharmacology of TB Drugs meeting, Sept 2013

Dorman S. Determining The Optimal Dose Of Rifapentine For Treatment Of Tuberculosis: How High Is High? Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

Ho C and Borisov A. Weekly INH/Rifapentine for LTBI: Initial Experiences and Future Prospects. Oral presentation: National TB Controllers Association Conference, Atlanta, GA, June 2013.

Moro RN, Dorman S, Schluger NW, Stout J, Muzanyi G, Phan H, Feng, P-I, Heilig C, Bozeman L, Goldberg SV, Tolerability And Safety Of Escalating Rifapentine (RPT) Doses During The First 2 Months Of Tuberculosis (TB) Treatment. Poster presentation: American Thoracic Society, May 20, 2013, Philadelphia, PA, Am J Respir Crit Care Med 187;2013:A6051.

Moro RN, Sterling TR, Borisov A, Phillips E, Shepherd G, Adkinson NF, Ho C, Weis SE, Villarino ME, and the Tuberculosis Trials Consortium. Other Drug-Associated Reactions (ODAR) Among Persons Receiving the 3 Month Regimen of Rifapentine plus Isoniazid for Treatment of Latent Tuberculosis Infection (LTBI). Poster presentation: American Thoracic Society & CDC Session, May 20, 2013, Philadelphia, PA,

Moro R. Safety of Once-weekly INH/Rifapentine- Update on Data from TBTC Study 26. Oral presentation: National TB Controllers Association Conference, Atlanta, GA, June 10, 2013.

Schluger NW and Dorman S. Effect Of Sequester On CDC Tuberculosis Research. Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

Sterling TR. Toxicity, Tolerability and Completion of The New Rifapentine-Based Weekly Treatment For LTBI. Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

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.

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. 6th International Workshop on Clinical Pharmacology of TB Drugs, Sept 2013

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. Gates sponsored TB Modeling and Analysis Consortium meeting in Beijing, China

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. CPTR meeting in Washington, DC - October, 2013

Dorman S and Goldberg S. Study 29X, Phase 2 clinical trial, is to compare tolerability and safety of arms containing escalating doses of rifapentine Presentation, INTER-TB, St. George's University, 25 October 2013

Dorman S and Goldberg S. Study 29X, Phase 2 clinical trial, is to compare tolerability and safety of arms containing escalating doses of rifapentine Presentation, International Union Against Tuberculosis and Lung Disease, November 2013

## 2012

Weiner M, Peloquin C, Engle M, Egelund E, Thomas P, Mac Kenzie W. The pharmacokinetic interaction between raltegravir and rifapentine in healthy volunteers. 19<sup>th</sup> Conference on Retroviruses and Opportunistic Infections. Seattle, WA. March 5-8, 2012.

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.

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). International AIDS Society, July 2012.

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.

## 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.

Reves R, Hamilton CD, Tapy J, Narita M, Kyle RP, Heilig C, Bozeman L, Goldberg S. Evaluating the efficacy and safety of intermittent tuberculosis treatment when isoniazid cannot be used (Study 24). Oral presentation at the American Thoracic Society International Conference. May 17, 2011.

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.

Peloquin C, Weiner M, Bliven-Sizemore E, Egelund E, Engle M, Johnson J, Nsubuga P, Mac Kenzie W. 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.

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