NAME:Valeria Cavalcanti Rolla

eRA COMMONS USER NAME (credential, e.g., agency login):VALERIA.ROLLA

POSITION TITLE:Senior Researcher and Head of the Clinical Research Laboratory on Mycobacteria at the National Institute of Infectious Diseases Evandro Chagas, FIOCRUZ, Rio de Janeiro, Brazil

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Universidade Gama Filho, UGF, Rio de Janeiro, Brazil	Graduation	1983	Medicine
Universidade Gama Filho, UGF, Rio de Janeiro, Brazil Brasil.	Residence	1984	Internal Medicine
Hospital Universitário Antonio Pedro, HUAP, Rio de Janeiro, Brazil	Residence	1985-1986	Infectious Disease
National Institute of Infectious Diseases Evandro Chagas	Public Server	1989	Infectious Disease
Institut Pasteur, Paris France	Specialist in Tropical Microbiology	1994	Tropical Microbiology
Instituto Oswaldo Cruz – Fiocruz – Rio de Janeiro, Brazil	PhD in Science	1999	Parasite Biology

A. Personal Statement

I am a Senior Researcher and Head of the Clinical Research Laboratory on Mycobacteria at the National Institute of Infectious Diseases Evandro Chagas at FIOCRUZ in Rio de Janeiro, Brazil. I have served as the Principal Investigator on many international and national tuberculosis and HIV/AIDS projects. I am also a member of the National HIV/AIDS Committee, head of the TB-HIV branch of the Brazilian TB network (Rede-TB), and a member of the National Tuberculosis Advisory Committee and Working Group. Recently, in collaboration with Dr Liane de Castro at INI, my research has been focused on studying genetic factors associated with treatment failure, adverse events, and drug metabolism. FIOCRUZ is a well-established institution and provides excellent infrastructure for clinical research, including laboratory space, personnel, and institution collaborators.

In the RePORT-Brazil project, I serve as the Brazilian Principal Investigator and oversee the formation of the TB cohort. For the new proposal, I will also serve as the Brazilian PI, working closely with RePORT Brazil co-PI involved in the proposal and Timothy R. Sterling, at Vanderbilt University. I will provide oversight and guidance in the execution of this project at all sites in Brazil, and ensure that the data collection is harmonized within all sites. I will also supervise the Fiocruz Project Coordinator and oversee enrollment, regulatory submissions, and administrative issues and procedures.

1. Menzies D, Adjobimey M, Ruslami R, Trajman A, Sow O, Kim H, Obeng Baah J, Marks GB, Long R, Hoeppner V, Elwood K, Al-Jahdali H, Gninafon M, Apriani L, Koesoemadinata RC, Kritski A, Rolla V, Bah B, Camara A, Boakye I, Cook VJ, Goldberg H, Valiquette C, Hornby K, Dion MJ, Li PZ, Hill PC, Schwartzman K, Benedetti A. Four Months of Rifampin or Nine Months of Isoniazid for Latent Tuberculosis in Adults. N Engl J Med. 2018 Aug 2;379(5):440-453. doi: 10.1056/NEJMoa1714283. PubMed PMID: 30067931.

2. Demitto FO, Schmaltz CAS, Sant'Anna FM, Arriaga MB, Andrade BB, Rolla VC.Predictors of early mortality and effectiveness of antiretroviral therapy in TB-HIV patients from Brazil. PLoS One. 2019;14(6):e0217014. doi: 10.1371/journal.pone.0217014. eCollection 2019. PubMed PMID: 31170171; PubMed Central PMCID: PMC6553696.
3. Hamilton CD, Swaminathan S, Christopher DJ, Ellner J, Gupta A, Sterling TR, Rolla V, Srinivasan S, Karyana M, Siddiqui S, Stoszek SK, Kim P. (2015). RePORT International: Advancing Tuberculosis Biomarker Research Through Global Collaboration. Clin Infect Dis. 2015 Oct 15;61Suppl 3:S155-9. PMCID: PMC4583572
4. Schmaltz CA, Sant'Anna FM, Neves SC, VelasqueLde S, Lourenço MC, Morgado MG, **Rolla VC**, Lopes GS (2009). Influence of HIV infection on mortality in a cohort of patients treated for tuberculosis in the context of wide access to HAART, in Rio de Janeiro, Brazil. J Acquir Immune DeficSyndr. Dec;52(5):623-8. PubMed PMID: 19730270.

B. Positions and Honors

Positions and Employment

1989-2002 Chief of the Infectious Diseases Service INI –Fiocruz, Rio de Janeiro
2000-2004 Chief of the Infectious Deases Department INI –Fiocruz, Rio de Janeiro
2004-present Head of the Clinical Research Laboratory on Mycobacteria, INI - FIOCRUZ, Rio de Janeiro, Brazil

Other Experience and Professional Memberships

2005-present Advisor of the National DST AIDS program, Brazil
2009-2014 Advisor of the National TB program, Brazil
2010- present Stakeholder of the TB Alliance
2014- present Member of the National TB-HIV working group, Brazil

Honors

2008 Honor, Advisor of the top 10 Scientific Initiation student in Fiocruz (Rafael Laucas Pereira)

C. Contribution to Science

1. Protease inhibitor and rifampicin interactions. CDC guidelines did not include recommendations for the use of both HIV-1 protease inhibitors and rifampicin for treatment of HIV and TB until 2000. Few studies had been performed evaluating the interactions between these two classes of medications. Braziloffersboth therapies free of charge to patients (TB and HIV medication)and there is an increased need to evaluate these regimens. I have studied the interactions between rifampicin and ritonavir/saquinavir (400-400mg) in Brazilian TB-HIV patients. Based on the results of these studies, thesedrugs were recommended in the Brazilian national treatment guidelines as an option for patients with contra-indications to efavirenz and persons who had already failed efavirenz. I also designed a PK study to evaluate lopinavir/r in double dose (800mg/200mg) with concomitant rifampicin. The results showed that this therapy is very difficult to manage, andis associated with adverse events. But this regimen is sometimes useful in patients who require a low pill burden, given the increased number of pills when rifampin is replaced with rifabutin. This last study was used to support the Brazilian AIDS program decisionto include this regimen as part of the options for treatment of HIV-related TB (2012).

    a. **Rolla VC**, da Silva Vieira MA, Pereira Pinto D, Lourenço MC, de Jesus Cda S, Gonçalves Morgado M, Ferreira Filho M, Werneck-Barroso E. (2006). Safety, efficacy and pharmacokinetics of ritonavir 400mg/saquinavir 400mg twice daily plus rifampicin combined therapy in HIV patients with tuberculosis. ClinDrug Investig. 26(8):469-79. PubMed PMID: 17163279

b. de Castro L, do Brasil PE, Monteiro TP, **Rolla VC**. (2010) Can hepatitis B virus infection predict tuberculosis treatment liver toxicity? Development of a preliminary prediction rule.Int J Tuberc Lung Dis. Mar;14(3):332-40. PubMed PMID: 20132625.

c. Sant'Anna FM, Velasque L, Costa MJ, Schmaltz CA, Morgado MG, Lourenço MC, Grinsztejn B, **Rolla VC** (2009). Effectiveness of highly active antiretroviral therapy (HAART) used concomitantly with rifampicin in patients with tuberculosis and AIDS. Braz J Infect Dis. Oct;13(5):362-6. PubMed PMID: 20428637.

d. SchmaltzCA, Santoro-Lopes G, Lourenço MC, Morgado MG, VelasqueLde S, **RollaVC**. Factors impacting early mortality in tuberculosis/HIV patients: differences between subjects naïve to and previoiusly started on HAART. PLoS One. 2012;7(9):e45704.

2. Paradoxical reactions (e.g., due to immune reconstitution inflammatory syndrome; IRIS) in TB patients under adequate anti-TB therapy after the introduction of HAART. The description of this syndrome is variable and its incidence and severity depend on the geographic region and population described.The clinical manifestation can include lymph node enlargement and fever, which can occur weeks after HAART initiation. We have been studying IRIS since the year 2000 among our TB-HIV patients, describing lymph node enlargement that could result in deep venous thrombosis, high reactivity to PPD and excellent response to steroids in high doses. We have identified the clinical manifestations and risk factors in the population of Rio de Janeiro. This was a small study with the first cases detected in our clinic. However,this paper was one of the most referenced articles. After this first description, we have followed almost 100 antiretroviral therapy-naïve patients during TB-HIV therapy, after initiation of HAART with efavirenz (a nested study in a clinical trial). We (MarizaMorgado's group from Oswaldo Cruz Institute and my group) evaluated the immune response by evaluating cytokines, interferon, and ELISPOT (not yet published). These studies allowed us to observe the low incidence of IRIS among our population (which is very different from otherstudies) and collaborate with the Pasteur institute to study potential biomarkers that are able to predict the occurrence of the syndrome. In Brazilian guidelines, IRIS is addressed, and the use of corticosteroids is based on our experience.

   a. Fernandes GC, Vieira MA, Lourenço MC, Gadelha AJ, Coura LC, **Rolla VC** (2002). Inflammatory paradoxical reaction occurring in tuberculosis patients treated with HAART and rifampicin. Rev Inst Med Trop Sao Paulo. Mar-Apr;44(2):113-4. PubMed PMID: 12048550

   b. Serra FC, Hadad D, Orofino RL, Marinho F,Lourenço C, Morgado M, **Rolla V**. (2007) Immune reconstitution syndrome in patients treated for HIV and tuberculosis in Rio de Janeiro. Braz J Infect Dis. Oct;11(5):462-5. PubMed PMID: 17962870.

   c. da Silva TP, Giacoia-Gripp CB, Schmaltz CA, Sant Anna FM, **Rolla V**, Morgado MG (2013). T Cell Activation and Cytokine Profile of Tuberculosis and HIV-Positive Individuals during Antituberculous Treatment and Efavirenz-Based Regimens. PLoS One. Jun 19;8(6):e66095. Print 2013. PubMed PMID: 23840403; PubMed Central PMCID: PMC3686825

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/48621488/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

Grant R01 AI20790-01A1 8/2013 – 7/2017
Predictors of treatment toxicity, failure, and relapse in HIV-related tuberculosis
A Pharmacogenetic study to achieve the drug metabolism profile of Brazilian patients for tuberculosis and antiretroviral drugs
Role: Principal investigator in Brazil
U$ 2,000,000

Grant U01 Al69923 - Regional Prospective Observational Research for TB (RePORT)-Brazil Supplement to Caribbean, Central and South America network for HIV epidemiology (CCASAnet)
Role Principal Investigator in Brazil
U$800,000

Grant 25029.000507/2013-07 (Rolla) 08/01/2013 – 06/30/2018
Brazilian Department of Science and Technology
Pesquisa Regional Prospectiva e Observacional em Tuberculose no Brasil (RePORT-Brasil).
Biorepository for futures studies in a cohort of 900 TB patients and 2700 contacts.
Role: Principal Investigator

Completed Research Support

Grant A06-295 (Rolla) 09/21/2012 – 12/30/2017
Miller School of Medicine, Miami University and Abbott Laboratories
Pharmacokinetic Study of Super-boosted Lopinavir/Ritonavir in Combination with Rifampin in HIV-1-infected Patients with Tuberculosis.
PK study with an increased dose of ritonavir (400mg) in a new formulation to access the PK of lopinavir in TB-HIV patients with contraindication to efavirenz
Role: Principal Investigator in Brazil

Grant 5U01 AL069923-08 (Sterling/Rolla) 08/01/2013 – 06/30/2016
Rede do Caribe, América Central e América do Sul de Epidemiologia do HIV (CCASAnet Report) – VUMC 41966 Regional ProspectiveObservationalResearch for Tuberculosis (RePORT-BRAZIL)
Biorepository for futures studies in a cohort of 900 TB patients and 2700 contacts. NIH grant
Role: Principal Investigator in Brazil
$ 1,500,000

Grant U2GPS001204 09/2009 – 09/2015
Centers for Disease Control and Prevention
LAM associated with smear microscopy for early detection of TB cases in the clinical routine of patients with tuberculosis associated with HIV and advanced immunodeficiency.
$200,000
Role: Principal Investigator

Grant 113/2013 (Rolla) 10/29/2013 – 02/30/2015
National Program of DST and AIDS
Factors associated with survival in TB-HIV patients
Study on survival of Tuberculosis and HIV patients
A cohort study to evaluate survival according to different baseline characteristics
Role: Principal Investigator

Grant TMC207-TiDP13-C208 10/10/2010 – 02/10/2012
Jansen-Cilag

TMC207-TiDP13-C208: Anti-bacterial Activity, Safety, and Tolerability of TMC207 in Participants with Multi-drug Resistant Mycobacterium Tuberculosis(MDR-TB).
Role: Principal Investigator in Brazil