Study: A5175 - A Phase IV, Prospective, Randomized, Open-Label Evaluation of the Efficacy of Once-Daily Protease Inhibitor- And Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Therapy Combinations For Initial Treatment Of HIV-1 Infected Individuals From Resource-Limited Settings (PEARLS) Trial
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5199 - International Neurological Study- A Stand Alone Study for Participants of A5175 (A Phase IV, Randomized, Open-Label Evaluation of the Efficacy of Once Daily Protease Inhibitor and Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Therapy Combinations for Initial Treatment of HIV-1 Infected Individuals from Diverse Areas of the World)
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5185 - Effect of Antiretroviral treatment of Genital Compartment virus in individuals initiating Potent Antiretroviral therapy from Resource limited settings.
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5207- Maintaining Options for Mothers Study (MOMS) – A Phase II Randomized Comparison of three Antiretroviral Strategies administered for 7 or 21 days to reduce the emergence of Nevirapine resistant HIV-1 following a single Intrapartum dose of Nevirapine
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5190- Assessment of Safety and Toxicity among Infants Born To HIV-1-Infected Women Enrolled in Antiretroviral Treatment Protocols in Diverse Areas of the World - A Limited Center Trial of the Adult AIDS Clinical Trials Group (AACTG) and the Pediatric AIDS Clinical Trials Group (PACTG), Conducted in Collaboration with the HIV Prevention Trials Network (HPTN)
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5221-STRIDE - A Strategy Study of Immediate Versus Deferred Initiation of Antiretroviral Therapy for AIDS Disease-Free Survival in HIV-Infected Persons Treated for Tuberculosis with CD4 < 250 Cells/mm3
Site Principal Investigator: Dr. N. Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5230 - A Pilot Study of Lopinavir/Ritonavir in Participants Experiencing Virologic Relapse on NNRTI-Containing Regimens
Principal Investigator: Dr. N. Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: A5265 - A Phase III, Open-Label, Randomized, Assessment-Blinded Clinical Trial to Compare the Safety and Efficacy of Topical Gentian Violet to that of Nystatin Oral Suspension for the Treatment of Oropharyngeal Candidiasis in HIV-1 Infected Participants in Non-U.S. Settings
Site Principal Investigator: Dr. N. Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Publications:

Study: A5271 - “Collection of Comparison Neurocognitive Data in Resource-Limited Settings”
Site Principal Investigator: Dr. N. Kumarasamy
Funding: ACTG/NIMH/NIAID/NIH
Status: Completed

Study: A5273 - Multicenter Study of Options for SEcond-Line Effective Combination Therapy (SELECT) A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)
Site Principal Investigator: Dr. N. Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed
Study: A5274/REMEMBER - Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens A Site-Limited Trial of the AIDS Clinical Trials Group (ACTG)
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: HPTN 052 - A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples
Site Principal Investigator: Dr.N.Kumarasamy
Funding: HPTN/NIAD/NIH
Status: Completed

Study: A5288 - Management Using the Latest Technologies in Resource-Limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)
Site Principal Investigator: Dr.N.Kumarasamy
Status: Completed

Publications:

Study: A5300/I2003 - Study of MDR TB Cases and their Household Contacts: Operational Feasibility to inform PHOENIX Trial Design
Site Principal Investigator: Dr.N.Kumarasamy
Funding: ACTG/NIAID/NIH
Status: Completed

Study: START-INSIGHT PROTOCOL - Strategic Timing of Antiretroviral Treatment
Site Principal Investigator: Dr.N.Kumarasamy
Funding: INSIGHT/NIAID/NIH
Status: Study ongoing

Study: Natural History of HIV disease in Southern India
Principal Investigator: Dr.N.Kumarasamy
Funding: Fogarty-Brown Univ/amFar/NIH
Status: Study ongoing
Study: TAHOD - The Treat Asia HIV Observational Database  
Site Principal Investigator: Dr. N. Kumarasamy  
Collaborators: Treat Asia  
Funding: Treat Asia/amFar/IeDEA/NIH  
Status: Study ongoing

Study: TApHOD - The Treat Asia Pediatric HIV Observational Database  
Site Principal Investigator: Dr. N. Kumarasamy  
Collaborators: Treat Asia  
Funding: Treat Asia/amFar/NIH  
Status: Study ongoing

Study: Optimizing HIV Care in Less Developed Countries  
Site Principal Investigator: Dr. N. Kumarasamy  
Collaborators: Dr. Kenneth Freedberg, Dr. Rochelle Walensky, Dr. Kenneth Mayer-Harvard University  
Funding: CEPAC/ MGH/ NIH  
Status: Study ongoing

Study: Randomized Control Trial of Structured Interrupted Generic Antiretroviral Therapy (SIT) versus Continuous Therapy (CT) in HIV-infected Individuals  
Principal Investigators: Dr. N. Kumarasamy, Dr. Timothy Flanigan, Dr. Kenneth Mayer  
Collaborators: Brown University  
Funding: Fogarty/Brown University/NIH  
Status: Completed

Study: Prevalence and Incidence of Sexually Transmitted Infections among South Indians at Increased Risk of HIV Infection  
Principal Investigators: Dr. N. Kumarasamy, Dr. Kenneth Mayer  
Collaborators: Brown University  
Funding: Fogarty/Brown University/NIH  
Status: Completed

Study: Correlates of ART Adherence in Chennai  
Principal Investigators: Dr. N. Kumarasamy, Dr. Steve Safren  
Collaborators: Fenway Centre, Boston; Brown University, RI  
Funding: Fogarty/Brown University, RI, USA  
Status: Completed
**Study:** GSK TB 014 Project - A Phase II, Double Blind (Observer-Blind), Randomised, Controlled Study To Evaluate The Safety, Reactogenicity And Immunogenicity of GSK Biologicals’ Candidate Tuberculosis Vaccine (M72/As01e) When Administered Intramuscularly According To A 0,1 Month Schedule To HIV-Positive Adults Living In A TB Endemic Region  
**Principal Investigator:** Dr.N.Kumarasamy  
**Funding:** GSK  
**Status:** Study Completed

**Principal Investigators:** Dr.N.Kumarasamy, Dr.Joel Palefsky, Dr.S.Poongulali  
**Collaborators:** UCSF, CA, USA  
**Funding:** AMC/NCI/Publications  
**Status:** Study Completed and analysis ongoing

**Study:** SECONDLINE STUDY- A Randomised Open-Label Study comparing the Safety and Efficacy of Ritonavir boosted Lopinavir and 2-3N(T)RTI Backbone versus Ritonavir boosted Lopinavir and Raltegravir in Participants Virologically Failing First-Line NNRTI/2N(T)RTI Therapy  
**Principal Investigators:** Dr.N.Kumarasamy, Dr.Mark Boyd  
**Collaborators:** Kirby Institute, UNSW, Sydney  
**Funding:** Kirby Institute, UNSW, Sydney  
**Status:** Completed

**Study:** HIVIND - The Antiretroviral Roll out for HIV in India – Strengthening Capacity to Promote Adherence and Patient follow-up in the Context: A Research Plan for a Two-Centre, Randomized, Controlled, Open Trial in South India to Study an Innovative approach to Promote Adherence in HIV + Indian Patients  
**Principal Investigator:** Dr.N.Kumarasamy, Dr.Anita Shet, Dr.Vinod Diwan  
**Collaborators:** Karolinsk Institute, Sweden; St.Johns Medical Collge, Bangalore  
**Funding:** EU/ Karolinka Institute, Sweden  
**Status:** Study Completed.
**Study:** WRHI001-GATES- A Randomized, Double-Blind, Multi-Centre, Parallel-Group Phase 3b Study To Demonstrate Non-Inferiority Of Stavudine (20 Mg Twice Daily) Compared With Tenofovir Disoproxil Fumarate (300 Mg Once Daily) When Administered In Combination With Lamivudine And Efavirenz In Anti Retroviral-Naive Patients Infected With HIV-1

**Site Principal Investigator:** Dr.N.Kumarasamy

**Collaborators:** Dr.Francois Venter,WITS,Johannesburgh; Dr.Andrew Kambugu,IDI,Kampala

**Funding:** Gates Foundation

**Status:** Study Completed and analysis ongoing

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**Study:** K23- Impact of Malaria Co-Infection on HIV-Associated Neurocognitive Disorders

**Principal Investigators:** Dr.N.Kumarasamy, Dr.Ajay Bharti

**Collaborators:** UCSD,CA,USA

**Funding:** CFAR/UCSD/NIH

**Status:** Completed

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**Study:** REACH TIBOTECH: Malaria and HIV Co-infection in Southern India

**Principal Investigators:** Dr.N.Kumarasamy, Dr.Ajay Bharti

**Collaborators:** UCSD,CA,USA

**Funding:** Tibotech

**Status:** Completed

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**Study:** UNITE: A Randomized, Controlled Trial To Assess The Impact Of TAMA (Health IT System) On Treatment Effectiveness In HIV-1Infected Subjects Initiated On First-Line Antiretroviral Therapy

**Principal Investigators:** Dr.N.Kumarasamy, Dr.Anirudha Joshi

**Funding:** Janssen

**Status:** Study Completed

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**Study:** HIV Tropism study - A Multicenter, Cross-sectional Survey of HIV-1 Viral Co-receptor Tropism in Patients infected with Clade C HIV-1 at select sites in India

**Site Principal Investigator:** Dr.N.Kumarasamy

**Funding:** Pfizer

**Status:** Completed

**Study:** A4001050 - A Multi-Centre, Open Label, Expanded Access Trial of Maraviroc  
**Site Principal Investigator:** Dr. N. Kumarasamy  
**Funding:** Pfizer  
**Status:** Completed

**Study:** ARIEL/TMC 114-TIDP29-C228-A Phase II, Open-Label Trial to Evaluate Pharmacokinetics, Safety, Tolerability and Antiviral activity of DRV in combination with Low Dose Ritonavir (DRV/RTV) in Treatment-experienced HIV-1 Infected Children from 3 Years to <6 Years of age  
**Site Principal Investigator:** Dr. N. Kumarasamy  
**Funding:** Tibotec  
**Status:** Completed

**Study:** Continued Access to Darunavir/Ritonavir (DRV/RTV) in HIV-1 Infected Children and Adolescents aged 3 Years and above (TMC114-TiDP29-C32), Protocol Amendment Gen-III, Issued Date October 9, 2012; Amendment Type: Non-Substantial  
**Site Principal Investigator:** Dr. N. Kumarasamy  
**Funding:** Tibotec  
**Status:** Ongoing

**Study:** TMC278-TiDP6-C215 - A Phase III, Randomized, Double-blind Trial Of TMC278 25 mg q.d. Versus Efavirenz 600 mg q.d. In Combination With a Background Regimen Containing 2 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors In Antiretroviral-Naive HIV-I Infected Subjects  
**Site Principal Investigator:** Dr. N. Kumarasamy  
**Funding:** Tibotec  
**Status:** Completed

**Study:** ACH443-015 Achillion: A Phase II, Randomized, Blinded, 12-Week Comparison of Elvucitabine in Combination with Efavirenz and Tenofovir Versus Lamivudine in Combination with Efavirenz and Tenofovir in HIV-1 infected, Treatment-naive Subjects, with an 84-Week Extension Treatment Period  
**Site Principal Investigator:** Dr. N. Kumarasamy  
**Funding:** Achillion  
**Status:** Completed
Study: Changes in HIV Viral Load in Patients Undergoing Treatment for Filarial Infection
Principal Investigators: Dr. N. Kumarasamy, Dr. Tom Nutman, Dr. Sowmya Swaminathan
Collaborators: NIRT, Chennai; LIP/NIAID/NIH
Funding: NIAID/NIH
Status: Completed

Principal Investigator: Dr. N. Kumarasamy, Dr. Saravanan, Dr. Rami Kantor & Dr. Charles Carpenter
Funding: CFAR/Brown University
Status: Completed.

Study: HIV and Ocular manifestations
Principal Investigators: Dr. N. Kumarasamy, Dr. J. Biswas
Funding: Sankara Nethrlaya
Status: Ongoing

Study: HIV and Oral manifestations
Principal Investigators: Dr. N. Kumarasamy, Dr. Ranganathan
Collaborators: Ragas Dental College, Chennai Dental Research Foundation
Funding: Ragas/Chennai Dental Research Foundation
Status: Ongoing

Study: Detection of Herpes viruses in Oral Fluids from HIV Positive patients in Chennai, India
Principal Investigators: Dr. Ranganathan, Prof Newell W Johnson, Mr. David Speicher, Dr. Kumarasamy
Collaborators: Ragas Dental College, Griffith University, Australia
Funding: Australia
Status: Completed and analysis ongoing

Study: Impact of Alcohol on HIV transmission and ART adherence
Principal Investigators: Dr. N. Kumarasamy, Dr. Maria Ekstrand
Collaborators: UCSF
Funding: NIAAA/NIH
**Study:** Immune Activation in Virologically Suppressed persons with HIV who are on ART  
**Principal Investigators:** Dr.N.Kumarasamy, Dr.Murugavel, Dr.Savita Pahwa  
Collaborators: University of Miami, Florida, USA  
**Funding:** ICMR/NIH  
**Status:** Study Completed and analysis ongoing

**Study:** HPV Co-infection among HIV positive women in Chennai: A Pilot study  
**Principal Investigator:** Dr.Poongulali Selvamuthu, Dr.Lyn Menezes, Dr.N.Kumarasamy  
**Funding:** USF  
**Status:** Completed

**Study:** Anemia and Nutrition among Children with Perinatally Acquired HIV Infection in South India  
**Principal Investigators:** Dr.Poongulali, Dr.Anita Shet, Dr.N.Kumarasamy  
Collaborators: St.Johns, Bangalore; NIRT, Chennai  
**Funding:** ICMR  
**Status:** Completed

**Study:** HPV-019 PRI - A Phase IV, Observer-Blind, Randomized, Controlled, Multicentric Study to Assess the Safety and Immunogenicity of GSK Biologicals’ HPV -16/18 L1 VLP AS04 Vaccine (Cervarix) Administered Intramuscularly According to A 3-Dose Schedule (Month 0, Week 6, Month 6) in Human Immunodeficiency Virus-Infected (HIV+) Female Subjects Aged 15-25 Years, as Compared to Merck’s HVP 6/11/16/18 Vaccine (Gardasil)  
**Principal Investigators:** Dr.S.Poongulali, Dr.N.Kumarasamy, Dr. Sudharsan, Dr.S.Poongulali  
**Funding:** GSK  
**Status:** Study Completed and analysis ongoing

**Study:** GIVCYT- Ganciclovir—Intravitreous Versus Systemic—Cytomegalovirus Retinitis Trial  
**Principal Investigators:** Dr.Jyotirmay Biswas, Dr.John Kempen, Dr.N.Kumarasamy, Dr. Sudharsan, Dr.S.Poongulali  
**Funding:** Sanakara Nethralaya  
**Status:** Completed
Study: Menstrual Irregularities in Indian Women with HIV: Is immunologic status a factor?
**Principal Investigators:** Dr. Poongulali Selvamuthu, Dr. Krutika Kuppali
**Funding:** Observational
**Status:** Completed

Study: HAART associated body composition and metabolic changes in HIV infected patients in South India
**Principal Investigators:** Dr. Suneetha Sagayam, Dr. Chrisdtine Wanke, Dr. N. Kumarasamy
**Collaborators:** Brown University, Tufts University, USA
**Funding:** Fogarty/Brown-Tufts Univ/NIH
**Status:** Completed

Study: Randomized Trial to Prevent Vascular Events in HIV – REPRIEVE (A5332)
**Site Principal Investigator:** Dr. N. Kumarasamy
**Funding:** NIH/National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases (NIAID)
**Status:** Ongoing

Study: Multicenter, non-randomized, non-controlled, open-label Phase IV trial to evaluate the safety, tolerability and Effectiveness of Dolutegravir 50 mg tablet of Emcure Pharmaceuticals along with other antiretrovirals among HIV-1 Infected participants’, NARI/01-2017
**Site Principal Investigator:** Dr. N. Kumarasamy
**Funding:** Emcure Pharmaceuticals Ltd
**Status:** Ongoing

Study: Open-Label Study with Rilpivirine in Treatment-naïve Indian Subjects With HIV-1 Infection to Determine Safety and Efficacy. RISE, Protocol TMC278HTX3001; Phase 3b
**Principal Investigator:** Dr. N. Kumarasamy
**Funding:** Johnson & Johnson Private Ltd
**Status:** Ongoing

Study: A phase IIIB/IV randomised open-label trial to compare dolutegravir + pharmaco-enhanced darunavir versus recommended standard of care antiretroviral regimens in patients with HIV infection who have failed recommended first line therapy, D2EFT: Dolutegravir and Darunavir Evaluation in adults Failing Therapy
**Site Principal Investigators:** Dr. Poongulali S and Dr. N. Kumarasamy
**Funding:** UNITAID/University of New South Wales, The Kirby Institute, Australia
Status: Yet to initiate

Study: Understanding tobacco use and cessation among HIV-care individuals in India
Principal Investigators: Dr. Gina Kruse and Dr. Poongulali.S
Funding: NIH/NIAID-Harvard University Center for AIDS Research
Status: Yet to initiate

Study: Towards a Functional cure for HBV: exploiting lessons from HIV-HBV co-infection-The COMMIT Cohort study
Site Principal Investigator: Dr.N.Kumarasamy
Funding: The National Health and Medical Research Council (NHMRC), Australia.

Publications:

More than 375 scientific manuscripts were published in peer reviewed medical journals from these research studies.
A full list of published work is available here:

Publications :


30) Purnima Madhivanan, Amutha Hari, N. Kumarasamy, A. Geetha, Kausalya, JS. Lambert, Suniti Solomon. Profile of HIV-infected pregnant women and the interventions to reduce
vertical transmission at a tertiary HIV care center in South India. The Journal of Obstetrics and Gynaecology of India. 2003


34) Thangam Menon, N. Kumarasamy, Shilpa Sarang, M. Palani Kumar, Suniti Solomon, SP Thyagarajan. Penicillium pubhregenum infection in an AIDS patient - First report from South India. Ind J Sexually Transmitted Diseases 2002.


41) N. Kumarasamy, Anish Mahajan, Timothy Flanigan, R. Hemalatha, Kenneth Mayer, Charles Carpenter, SP. Thyagarajan, Suniti Solomon. The Total Lymphocyte count (TLC) is a useful tool for Opportunistic infection prophylaxis in India and other resource- constrained countries. JAIDS 2002 .31:378-383.


46) Suniti Solomon, Jessica Buck, Sreekanth Chaguturu, AK Ganesh and N.Kumarasamy.


74) Tokugha Yepthomi, Snigdha Vallabhaneni, Sreekanth Chaguturu, Suniti Solomon, Timothy P. Flanigan, **N. Kumarasamy**. Neurologic Manifestations of Human Immunodeficiency Virus in Chennai, India (Submitted)


84) Anitha Cecelia, Priya Christy Bai, S.Anand, Jayakumar, T.Gurunathan, Suniti Solomon, **N.Kumarasamy**. Usefulness of observational database to study the impact of


150) Olivia Keiser; Hannock Tweya; Andrew Boulle; Paula Braitstein; Mauro Schechter; Martin Brinkhof; François Dabis; Suely Tuboi; Eduardo Sprinz; Mar Pujades; Alexandra Calmy; N. Kumarasamy; Denis Nash; Andreas Jahn; Andrew P McPhail; Ruedi Lüthy; Robin Wood; Matthias Egger. Switching to second-line ART in resource-limited settings: Comparison of programmes with and without viral load monitoring. AIDS 2009 (In press)


153) Melissa A. Bender, N. Kumarasamy, Kenneth H. Mayer, Bingxia Wang, Rochelle Walensky, Timothy Flanigan, Bruce Schackman, Callie A. Scott, Zhigang Lu, Kenneth A. Freedberg, for the CEPAC-International investigators. Potential Cost-Effectiveness of
Tenofovir as First-Line Antiretroviral Therapy in India. Clinical Infectious Diseases 2010. Feb 1;50(3):416-25


220) Saran Vardhanabhuti; Edward P. Acosta; Heather J. Ribaudo; Patrice Severe; Umesh Laloo; N Kumarasamy; Frank Taulo; Joseph Kabanda; Olola Oneko; Prudence Iwe; Pradeep Sambarey; Ellen S. Chan; Jane Hitti; Francis Hong; Deborah McMahon; David W. Haas; the A5207 Study Team. Clinical and Genetic Determinants of Plasma Nevirapine Exposure following an Intrapartum Dose to Prevent Mother-to-Child Transmission. Journal of Infectious Diseases 2013; doi: 10.1093/infdis/jit223.


300. Singini I, Campbell TB, Smeaton LM, Kumarasamy N, La Rosa A, Taejareonkul S, Safren SA, Flanigan TP, Hakim JG, Hughes MD; ACTG A5175/PEARLS Study Team.


308. De La Mata NL, Ahn MY, **Kumarasamy N**, Ly PS, Ng OT, Nguyen KV, Merati TP, Pham


321. Amole CD, Middlecote C, Prabhu VR, Kumarasamy N. Can the generic antiretroviral industry support access to a universal antiretroviral regimen? Curr Opin HIV AIDS. 2017 Apr 24. PMID: 28441147


Contribution to Book Chapters:

1. A Colour Guide- HIV Disease in India
2. Treatment Guidelines- HIV Disease in India.
3. HIV Disease in India-Handbook for Dental Professionals.
5. Ocular lesions in AIDS in India.
9. The HIV Pandemic: local and global implications
15. WHO Consolidated Treatment Guidelines on the use of Antiretroviral Drugs for treating and preventing HIV infection-June 2013.
17. WHO Consolidated Treatment Guidelines on the use of Antiretroviral Drugs for treating and preventing HIV infection- Dec 2015.
Outcome of the studies carried out at CART Clinical Research Site, VHS Infectious Diseases Medical Centre:

More than 375 manuscripts are published in peer reviewed medical journals.

1) Described the Clinical spectrum and Natural History of HIV disease in Southern India
2) Studied the safety, tolerability, efficacy and effectiveness of Generic antiretroviral drugs in Indian patients
3) Documented the Impact of antiretroviral therapy - ↓OIs and ↓death
4) Described the short term and long adverse effects of Antiretrovirals (ARVs) in Indian patients and Studied the pattern of genotypic mutations among patients failing Antiretroviral Therapy.
5) Randomized Clinical trials carried out at the site answered- When & what to start ART and When and what to switch to?
   - Safety and efficacy of newer Antiretrovirals (ARVs)
   - Usage of antiretrovirals in prevention
6) Documented the cost effectiveness of various interventions in persons with HIV disease.