Research staff and their roles in ACTG studies

YRG CARE

CRS (affiliated to UCSD)
ACTG Network

- The mission of the AIDS Clinical Trials Group (ACTG) Network is:
- To develop and conduct scientifically rigorous translational research and clinical trials to (1) investigate the viral and immune pathogenesis of HIV-1 infection and its complications; (2) evaluate novel drugs and strategies for treating HIV-1 infection; (3) evaluate interventions and strategies to treat and prevent HIV-related co-infections and co-morbidity, and; (4) publish and disseminate results to improve care, and reduce or eliminate morbidity and mortality associated with HIV-1 infection and its complications.
- IDS
ACTG Network Structure

- Network PI Chair
- Vice Chair
- Network Leadership Steering Committee (LSC)
- Executive Committee (AEC)

Scientific Committees
- Scientific Agenda Steering Committee (SASC)

Clinical Trials Units & Clinical Research Sites

- Laboratory Steering Committee (LSC)
- Laboratory Structure (LNS)
- Statistical & Data Analysis Center (SDAC/DMC)

Resource Committees
- Underrepresented Populations Committee (UPC)

- Scientific Committees
- Optimization of Antiretroviral Therapy Committee (OPART)
- Translational Research & Drug Development Committee (TRADD)
- Optimization of Co-Infection & Co-Morbidity Management Committee (OPICAN)

- Laboratory Steering Committee (LSC)
- Virology Core
- Pharmacology Core
- Immunology Core
- Specimen & DNA Repositories
- Laboratory Technologists Committee (LTC)

- Resource Committees
- Site Operations Subcommittee

- Scientific Committees
- Hepatitis Committee (HFPC)
- ACTG/IMPAACT Women’s Health Inter-network Scientific Committee (WHISC)
- ART Prevention Science Committee
- Oral HIV/AIDS Research Alliance (CHARA) Subcommittee

- Scientific Committees
- ACTG Data Management Committee (DMC)
- Global Community Advisory Board Committee (GCAB)

- Scientific Committees
- Laboratory Evaluation Subcommittee (LES)
- Laboratory Structure (LNS)

- Scientific Committees
- Operations Center (OPS)
- Performance Evaluation Committee (PEC)

- Scientific Committees
- Network Leadership Steering Committee (LSC)
- Executive Committee (AEC)

- Scientific Committees
- Network PI Chair
- Vice Chair

- Scientific Committees
- Laboratory Steering Committee (LSC)
- Virology Core
- Pharmacology Core
- Immunology Core
- Specimen & DNA Repositories
- Laboratory Technologists Committee (LTC)
Location: YRG CARE, Chennai, India
YRG CARE, Chennai, India

- YRG is a not for profit established in 1993 by Dr. Suniti Solomon- she discovered the first case of HIV in India during her work as Professor of Microbiology in a leading teaching hospital at Chennai.
- YRG currently offers HIV related care to over 15000 patients, supported by a well equipped lab, team of clinicians and support staff.
- Over 20 different studies and projects are on at YRG- these range from bio medical, lab sciences, behavioral to community centered care for HIV patients with Government of India.
YRG CARE ACTG structure

- Site PI
- Study Coordinator
- Research nursing coordinator
- Research nurses
- IRB coordinator
- Data team
- Outreach supervisor
- Outreach team
- CAB coordinator
- Community education team
Process

- Each study protocol is presented to IRB, CAB and prior to this, study team discusses with site PI
- Each protocol is presented to the study team that reviews inclusion, exclusion criteria, feasibility of explaining study objectives to the community, obtaining consent for their participation, estimating possible risks of loss to follow up, kind of educational materials required for CAB, developing training materials for CAB, obtaining necessary inputs from CAB on recruitment and retention, following all ethical norms and ensuring CAB and communities understand the importance of complying with these norms.
ACTG-5207 study

- Intrapartum single dose NVP with a 21 day course of antiretroviral therapy results in less frequent selection of NVP resistance than with a 7 day course.

- The drugs used for tailing will not pick up any resistance of their own.
Study process

- Study design: phase 2, prospective, randomized, open label study evaluating the effectiveness of three different antiretroviral (ART) strategies for the prevention Nevirapine resistance.
- Objective: To determine whether a 21 day course of ART is more effective than a 7 day course.
- Duration: mothers will be followed up for 96 weeks and infants for 12 weeks
- Sample size: 420 mother infant pairs
- Inclusion and exclusion criteria
Role of research team in this study

- Site PI presented the protocol draft version to the team
- Team sees the importance of such a scientific pursuit
- Research team works with the PI to understand the research question and how this can be communicated effectively to the community and CAB
- Outreach team meets with CAB to discuss training needs for CAB members for effective understanding of this protocol.
- Also outreach team meets with key opinion leaders about the research question and study design
Role of research team in this study

- Discuss with PI about the feedback received from CAB and community members relating to this study
- Present key findings in a short document for PI to discuss with ACTG protocol team
- Responses received from the ACTG protocol team through site PI is then shared with CAB and community members
- Research team also works with site PI in developing appropriate informed consents, coordinates translations as needed and then develops Information materials needed for training CAB and disseminating information to the communities.
THANK YOU!!

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