



Red Mexicana de Investigación Clínica en Enfermedades Infecciosas Emergentes (LaRed)

2020 ACCOMPLISHMENTS



LaRed INCMNSZ, INER & LaRed-CC staff 2020

Goal 1: Enhance and maintain a sustainable clinical research network.

COLLABORATIONS

- LaRed leadership formalized the collaboration with Health Secretary of the state of Chiapas.
- LaRed is collaborating with INSIGHT network to implement several COVID-19 studies.
- LaRed is collaborating with the Division of Microbiology and Infectious Diseases (DMID), NIAID to implement the ACTT studies.

CAPACITY BUILDING

- 6 Pharmacists were hired to support LaRed sites at INCMNSZ, INER, GEA and HGAV (Oaxaca)
- 4 new Study Coordinators were onboarded to support the sites at INCMNSZ, INER, HGG and HGAV (Oaxaca)
- 2 Data entry Specialists were hired to support INCMNSZ, INER sites
- 2 Clinical Research Associates (monitors) were hired to support the LaRed-CC.

Goal 2: Conduct clinical research to promote the generation of knowledge and disseminate results.

STUDIES

- ACTT 1- Successfully closed with 10 participants enrolled: 06 at INCMNSZ & 04 at INER
- ACTT 2- Successfully closed with 68 participants enrolled: 44 at INCMNSZ & 24 at INER
- ACTT 3- Successfully closed with 57 participants enrolled: 31 at INCMNSZ & 26 at INER
- ACTT 4- IRB Protocol Ver 9.0 amendment approved. COFEPRIS Protocol Ver 9.0 amendment dossier submitted.
- INSIGHT COVID studies:
 - 011 ICOS Observational Study
 - IRB & COFEPRIS Protocol dossier submitted and approved
 - 013 ITAC Inpatient Trial
 - IRB Protocol dossier submitted and approved
 - COFEPRIS Protocol dossier submitted.
 - 014 TICO Monoclonal Antibodies Inpatient Trial
 - IRB Protocol dossier submitted and approved.

PUBLICATIONS & PRESENTATIONS

- Manuscript entitled: "Patterns of Signs, Symptoms and Laboratory Values Associated with Zika, Dengue and Undefined Acute Illnesses in a Dengue Endemic Region: Secondary Analysis of a Prospective Cohort Study in Southern México", was resubmitted and accepted for publication: International Journal of Infectious Diseases.
- On 03-Dec-2020 "Comparison of Clinical Characteristics of Zika and Dengue Symptomatic infections and Other Acute Illnesses of Unidentified Origin in Mexico" accepted for publication at PLOS Neglected Tropical Diseases.

Goal 3: Strengthen network capabilities to enable rapid response to emerging infectious diseases.

TRAINING & DEVELOPMENT

- 7 Standard Operating Proc. (SOPs), Guidelines & Procedural Documents were developed. LaRed staff received training on SOPs implementation.
- Site Qualification Visit (SQV) SOP was developed with training provided with full implementation of SOP during the LaRed during the HGG assessment.
- APEIC Regulatory workshop was coordinated and held for Clinical Operations Specialists (COS) & LaRed-CC administrative staff on 18-Nov-2020.
- The LaRed-CC COS team attended a Methodology course -Univariate inferential statistics and basic use of SPSS on 23-Nov-2020 to 04-Dec-2020
- 1st round Unanet training for CdMx LaRed sites staff & a refresher training for LaRed-CC staff was completed.



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Additional Information

ACTT Trials:

- A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults. Short Title: Adaptive COVID-19 Treatment Trial (ACTT)
- Funder and holder of US IND: National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
- Carried out by: Division of Microbiology and Infectious Diseases (DMID)

ICOS Study:

- An International Observational Study of Outpatients with SARS-CoV-2 Infection. Short Title: International SARS-CoV-2 Infection Observational Study (ICOS)

ITAC Study:

- An International Multicenter, Adaptive, Randomized Double-Blind, Placebo-Controlled Trial of the Safety, Tolerability and Efficacy of Hyperimmune Intravenous Immunoglobulin for the Treatment of Adult Hospitalized Patients at Onset of Clinical Progression of COVID-19. Short Title: Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC)
- Funder and holder of US IND: National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
- Carried out by: International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)