



LaRed Quarterly Progress Report

Q3 _ 01-Jul-2020 to 30-Sep-2020

Goal 1: Enhance and maintain a sustainable clinical research network	
Obj.1.1 Expand collaborative partnerships with other institutions and agencies (e.g. Public Health Institute)	
Q1	<ul style="list-style-type: none"> ▪ Dr. Ruiz-Palacios, Dr. Regalado, Dr. Montenegro and Dr. Sepulveda met with the Health Secretary of the state of Chiapas to formalize the collaboration. ▪ Discussions ongoing to implement IVIG study for adults and children with the INSIGHT network.
Q2	<ul style="list-style-type: none"> ▪
Q3	<ul style="list-style-type: none"> ▪ Ongoing discussions and preparations to implement the following interventional COVID studies: <ul style="list-style-type: none"> ○ INSIGHT 013 ITAC (Hospitalized IVIG) ○ INSIGHT 014 TICO (Monoclonal Antibodies) ▪ The LaRed sites considered for these studies are INCMNSZ, INER, HGG. An evaluation was conducted to determine the possibility of including additional sites. The anticipated start date of these studies would be Q4 2020.
Q4	<ul style="list-style-type: none"> ▪
Obj. 1.2 Leverage LaRed's capabilities to attract new investigators and engage in collaborative research activities	
Q1	<ul style="list-style-type: none"> ▪
Q2	<ul style="list-style-type: none"> ▪ Initiation of activities at Hospital Gea González and inclusion of new site to implement COVID study (ies). ▪ LaRed-CC coordinated efforts to request LaRed sites to complete a survey for potential participation in ACTIV – COVID studies. During this quarter, 7 out of 10 sites have answered the questionnaires. ▪ On 14-May-2020 a teleconference was held between U.S embassy, LaRed leadership and Mexican Government (The Ministry of Foreign Affairs) to strengthen ACTT clinical trial collaboration.
Q3	<ul style="list-style-type: none"> ▪ Dr. Nestor has been appointed as Sub-Investigator for the ACTT-3 study.
Q4	<ul style="list-style-type: none"> ▪
Obj. 1.3 Strengthen effective communications among LaRed members at all levels (maybe via LaRed-CC, Newsletters, periodic flyers, dedicated follow-up calls/work sessions of pending	
Q1	<ul style="list-style-type: none"> ▪ Facilitated an Adhoc virtual meeting with LaRed SSC to inform them of initiation of COVID-19 study and way forward.
Q2	<ul style="list-style-type: none"> ▪ Execution of Communication Plan for ACTT trial to optimize efficiencies among entities (DMID/EMMES/LaRed sites/LaRed-CC/LBR/SSS etc.) ▪ Facilitated several ad-hoc virtual meetings with LaRed SSC to share progress and status of COVID-19 studies that are being implemented by LaRed at partnering sites. These meetings were held on 08-May-2020 & 26-Jun-2020. ▪ In an effort to keep the partners engaged, the LaRed Director, leadership and CC continue to inform and seek feedback from LaRed partners about their interest and participation in future studies. A proposal was presented by Dr. Yuri Roldan: <ul style="list-style-type: none"> ○ Convalescent Plasma for Treatment of Hospitalized Patients with Laboratory Confirmed SARS-CoV-2 Infection.
Q3	<ul style="list-style-type: none"> ▪ LaRed CC coordinated various leadership conference calls to discuss the plans to expedite the implementation of COVID studies at LaRed sites: <ul style="list-style-type: none"> ○ LaRed Governing Board Meeting convened on 30-Jul-2020 & 09-Aug-2020 ○ LaRed Mx weekly Leadership calls ▪ LaRed Scientific Steering Committee met virtually on 08-July-2020 to inform LaRed about the scientific portfolio and its priorities.
Q4	<ul style="list-style-type: none"> ▪
Obj. 1.4 Leverage opportunities to seek grants and funding from other sources (e.g. Dr. Lipkin initiative)	
Q1	<ul style="list-style-type: none"> ▪
Q2	<ul style="list-style-type: none"> ▪ Discussions are in progress to engage INSIGHT for future COVID-19 observational and interventional studies by leveraging warm base / LaRed's existing capacity.
Q3	<ul style="list-style-type: none"> ▪
Q4	<ul style="list-style-type: none"> ▪
Challenges:	
Modifications/Changes:	



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Goal 2: Conduct clinical research to promote the generation of knowledge and disseminate results	
Obj.2.1 Engage LaRed PIs to explore new concepts and develop new protocols	
Q1	<ul style="list-style-type: none"> ▪ SPRINT-SARI protocol- Site PIs met to discuss the study chair, site staff, new LaRed sites at Tapachula and Oaxaca. ▪ ACTT 20-0006 protocol. - LaRed Leadership, LaRed-CC & SSS Staff achieved in 25 calendar days: ▪ Sites and Staff selection and qualification to conduct the protocol ▪ Translation Eng-Spa-Eng (as applicable) of protocol essential and all other related documents ▪ IRB & COFEPRIS Protocol dossier submission and approval.
Q2	<ul style="list-style-type: none"> ▪ ACTT-1 20-0006 protocol was successfully implemented at 2 sites: (INCMNSZ & INER). ▪ ACTT-1 20-0006 protocol successfully closed with 10 participants enrolled (6 at INCMNSZ & 4 at INER) ▪ ACTT-2 20-0006 protocol versions 3, 4 & 5 were finalized, translated, submitted and approved by IRB & COFEPRIS. ▪ ACTT-2 20-0006 protocol Ver 6.0 amendment submitted and approved by IRB & COFEPRIS <ul style="list-style-type: none"> ○ 68 participants enrolled (45 at INCMNSZ & 23 AT INER). ▪ Process to evaluate LaRed participation in the INSIGHT protocols has been completed. The Observational Study protocol (ICON 011) & its ICF have already been translated. Awaiting formal confirmation of participating LaRed sites for 011 and other INSIGHT trials.
Q3	<ul style="list-style-type: none"> ▪ Zik02 approval by COFEPRIS on 12-Aug-2020. ▪ Dr. Sepulveda & Ruiz-Palacios are drafting the originally conceptualized "Febrile Study" that served as the basis for the concept of "Syndromic Protocol" and will allow the inclusion of COVID data. ▪ ACTT-2 20-0006 Protocol <ul style="list-style-type: none"> ○ Successfully closed with 68 participants enrolled (44 at INCMNSZ & 24 at INER) ○ All queries generated in this study were completed and answered in a timely manner. ▪ ACTT-3 20-0006 Protocol <ul style="list-style-type: none"> ○ IRB & COFEPRIS Protocol Ver 7.0 amendment dossier submission and approval. ○ HGG SQV to evaluate implementing INSIGHT 011 ICOS Study at their hospital. ▪ ACTIV Clinical Trial Survey" for feasibility of COVID studies at HGAV, INP, HIM & HRAE Tapachula was completed. ▪ INSIGHT COVID Studies: the feasibility and regulatory processes were performed for the following trials: <ul style="list-style-type: none"> ○ 011 ICOS Observational Study <ul style="list-style-type: none"> ▪ On 24-Sep-2020 Dr. Lourdes Guerrero & Dr. John Powers integrated the FLU PRO study in INSIGHT 011. This research proposal titled: "Prospective comprehensive systematic evaluation of the symptoms of COVID-19 using a validated Patient Reported Outcome Instrument FLU-PRO", short title: COVID-19 Symptoms using FLU-PRO, was submitted for consideration by the INSIGHT Scientific Steering Committee. ○ 013 IVIG Inpatient Trial ○ 014 Monoclonal Antibodies Inpatient Trial
Q4	<ul style="list-style-type: none"> ▪
Obj. 2.2 Refine and implement the process to get timely, effective and compliant approval of a new concept/protocol by the SSC	
Q1	<ul style="list-style-type: none"> ▪ Developed a user-friendly tool to review, provide feedback, and vote on scientific concept proposals that are presented to the SSC.
Q2	<ul style="list-style-type: none"> ▪
Q3	<ul style="list-style-type: none"> ▪
Q4	<ul style="list-style-type: none"> ▪
Obj. 2.3. Refine and implement processes to allow timely and effective implementation of protocols	
Q1	<ul style="list-style-type: none"> ▪ LaRed Leadership met with COFEPRIS & CCINSHAE Commissioners to expedite review & approval for ACTT 20-0006 protocol. ▪ Second phase (F2F) LaRed Sites staff Training Program has been completed for CDMX, SLP and Oaxaca Site's Staff.
Q2	<ul style="list-style-type: none"> ▪ LaRed leadership continues to strengthen ties with COFEPRIS. As a result of this, LaRed was able to expedite the review & approval of ACTT 20-0006 protocol amendments.
Q3	<ul style="list-style-type: none"> ▪ LaRed-CC is working diligently with all collaborators to find effective solutions and approaches to make translation of study documents, submission of protocol amendments, and ensuring the correct versions are submitted to COFEPRIS so that the study implementation can be done as quickly as possible.
Q4	<ul style="list-style-type: none"> ▪



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Obj. 2.4 Establish and implement a process that enables timely and effective communication of research findings/manuscripts	
Q1	<ul style="list-style-type: none"> ▪ LaRed-CC currently providing support to Dr. Jose Ramos to submit two manuscripts writing proposals. ▪ Monthly calls have been scheduled to follow-up and facilitate the completion and submission of multiple manuscripts (Zik01 and ILI002). ▪ <i>A Unique Immune Signature of Serum Cytokine and Chemokine Dynamics in Patients with Zika Virus Infection from a Tropical Region in Southern Mexico - Manuscript was published, Feb. 2020, International Journal of Infectious Diseases</i> ▪ LaRed-CC fully supported the review, completion of final version and submission of two manuscripts pending acceptance from journals: <ul style="list-style-type: none"> ○ <i>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 Mexico. Submitted March 2020, Journal International Journal of Infectious Diseases</i> ○ <i>Description of clinical and epidemiological characteristics of patients with probable Zika infection in Tapachula, Chiapas in Mexico (2016-2018): an observational, prospective cohort stud. Submitted Feb. 2020, Journal BMC Infectious Diseases.</i>
Q2	<ul style="list-style-type: none"> ▪ A zika study manuscript "<i>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</i>", was resubmitted and accepted to be published in: <i>International Journal of Infectious Diseases</i>.
Q3	<ul style="list-style-type: none"> ▪ A zika study manuscript "Comparison of clinical characteristics of Zika and dengue symptomatic infections and other acute illnesses of unidentified origin in Mexico": <ul style="list-style-type: none"> ○ 27-Aug-2020: Submitted to Clinical Infectious Diseases Journal (CIDJ) for publication. ○ 03-Sep-2020: CIDJ rejected this publication. ○ 05-Sep-2020: COS staff provided and updated a draft to meet "PLOS ONE - Neglected Tropical Diseases" journal requirements for submission. ○ 14-Sep-2020: Manuscript submitted for publication. Currently waiting for publication approval in this new journal.
Q4	▪
Challenges:	
Modifications/Changes:	

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

Obj.3.1 Develop and implement a quality management system

Q1	<ul style="list-style-type: none"> ▪ Developed Standard Operations Procedures (SOPs), Guidelines (GDL), Complementary and Freestanding Procedural Documents (CPDs & FPDs) on: <ul style="list-style-type: none"> ○ Abbreviations and Acronyms used by LaRed Staff ○ Definitions used by LaRed Staff ○ Writing Procedural Documents ○ Staff Performance Review ○ Document Naming ○ Trial Master File Index ○ Standard Logs used in clinical trials ▪ Translations and Version Tracking across LaRed Weekly F2F sessions with LaRed-CC and SSS staff to review action items and updates ▪ Weekly F2F training sessions with LaRed-CC and SSS staff on SOP's and several topics.
Q2	<ul style="list-style-type: none"> ▪ Supporting development and implementation of site-specific QA Checklist at active ACTT sites.
Q3	<ul style="list-style-type: none"> ▪ SQV SOP was developed, training was conducted and process was implemented at the LaRed, HGG site. ▪ Development of LaRed-CC procurement SOP is in progress.
Q4	▪
Obj. 3.2 Maintain a skilled workforce, provide and coordinate training opportunities for LaRed CC staff, site staff and PI's (technical skills)	



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Q1	<ul style="list-style-type: none"> ▪ Clinical Operations Specialist and Information Technology Specialist have been selected as part of the LaRed CC and will be on board 04/16/20. ▪
Q2	<ul style="list-style-type: none"> ▪ Continue supporting training efforts on new versions of the protocol and EDC updates ▪ Initiated discussions to coordinate a protocol navigator training for LaRed-CC Clinical Operations Specialists at NIAID facilities. ▪ Onboarding Plan and training was completed by new LaRed-CC hires (COS & IT specialist). ▪ Hiring a Clinical Data Manager was re-discussed after multiple candidates' interview. As soon as a more refined plan is in place, the recruitment process will be resumed. ▪ Dr. Pilar Miyoko Martínez was hired as Study Coordinator assigned to Hospital General Dr. Manuel Gea Gonzalez. ▪ Central Pharmacist job description was finalized by LaRed-CC Manager, LaRed Director & SSS, so far, the position is open. ▪ IT Technician, Juana Flores was temporally contracted to support ACTT data entry activities for INCMNSZ.
Q3	<ul style="list-style-type: none"> ▪ Additional site staff hired to support LaRed studies. <ul style="list-style-type: none"> ○ INCMNSZ <ul style="list-style-type: none"> ▪ 2nd Study Coordinator: Dr. Cristina Fragoso ▪ Data Entry Specialist: Alejandra Flores ▪ Back up Pharmacist: Dr. Diana Paola Dávalos ○ INER <ul style="list-style-type: none"> ▪ 3rd Study Coordinator: Nancy Cervantes ▪ Pharmacists: <ul style="list-style-type: none"> ○ Dr. Odalis Rodríguez (Primary) ○ Areli Liliana Montes (Back up) ○ HGG <ul style="list-style-type: none"> ▪ Study Coordinator: Dr. David Barrón ▪ Onboarding Plan and training completed for HGG Study Coordinators. ▪ Hiring and study training of INCMNSZ Data Entry Specialist, Pharmacists (Primary & Back up) & INER Study Coordinator & Pharmacists (Primary & Back up) has been completed. ▪ LaRed-CC coordinated the prompt and efficient handling of staff shortages due to the heavy workload of studies at various LaRed sites and provided effective solutions to manage the gaps in staffing to ensure smooth running of the trials. ▪ LaRed-CC has also made provisions for staff to receive counseling during this difficult time. At first weekly and now biweekly sessions are scheduled for staff from Carlo Clerico on "Emotional Contention".
Q4	<ul style="list-style-type: none"> ▪
Obj. 3.3 Establish a data management center for LaRed	
Q1	<ul style="list-style-type: none"> ▪ LaRed leadership met with Dr. Enrique Graue, Dean of Universidad Autónoma de México in order to appoint key person to initiate discussions on a possible collaboration. ▪ Interviews for new Data Management Specialist to begin in April as original candidate declined position. ▪ Freezerworks Preparation and Upgrade Installation at CdMx and Tapachula Lab sites.
Q2	<ul style="list-style-type: none"> ▪ LaRed-CC SharePoint was re-structured to make navigation and use, more intuitive. ▪ Freezerworks was upgraded at INCMNSZ & HRAE-Tapachula Lab sites.
Q3	<ul style="list-style-type: none"> ▪
Q4	<ul style="list-style-type: none"> ▪
Obj. 3.4 Identify and formalize a rapid response team for LaRed	
Q1	<ul style="list-style-type: none"> ▪ Principal Investigators from INER and INCMNSZ were appointed to implement the ACTT study as part of LaRed's efforts to respond rapidly to the global COVID-19 pandemic. ▪ Sub-investigators and site support personnel from INER and INCMNSZ site laboratories and pharmacies were identified and trained for the ACTT study as part of LaRed's efforts to respond rapidly to the global COVID-19 pandemic.
Q2	<ul style="list-style-type: none"> ▪ Discussions currently ongoing with INSIGHT Washington ICC to begin processes for LaRed to work on INSIGHT COVID studies. ▪ LaRed CC has been successfully and seamlessly coordinating the shipment/receiving of drugs for the current COVID studies being implemented at LaRed sites.



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Q3	<ul style="list-style-type: none"> ▪ LaRed leadership is assessing and supplementing staff at the various sites based on the site/study needs to ensure responsibilities are carried out as per the demands of the COVID studies being implemented.
Q4	<ul style="list-style-type: none"> ▪
Obj. 3.5 Establish a process that enables enhancing accountability at all levels within LaRed (Leidos, SSS, NIAID, sites, LaRed CC).	
Q1	<ul style="list-style-type: none"> ▪ Developed LaRed Staff performance evaluation SOP and its corresponding tools. Implementation expected in Q3. ▪ LaRed-CC and SSS will work together on the “Protocol Concept Proposal Development”. ▪ Timesheets & Time Off Management System was implemented, and training coordinated for LaRed-CC. ▪ Supplies Management (Clinical and Office) “Inventory System” has been drafted.
Q2	<ul style="list-style-type: none"> ▪ Kick-Off between LaRed-CC and SSS on the “Protocol Concept Proposal Development”.
Q3	<ul style="list-style-type: none"> ▪ LaRed-CC is managing and ensuring all functional areas and entities are working in a coordinated manner, LaRed Leadership is closely monitoring the timelines and rapid amendments to protocols to efficiently implement these crucial studies.
Q4	<ul style="list-style-type: none"> ▪
Challenges:	
Modifications/Changes: Q1- Obj.3.2- Maintain a skilled workforce, provide and coordinate training opportunities for LaRed CC staff, site staff and PI’s (technical skills)- Propose to add language to obj. 3.2. Additional task- 3.2.2 Assess LaRed CC and site staffing needs and recruit appropriate staff required to execute LaRed's strategy.	