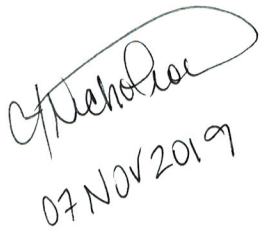
Carolina Clinical Research
Abigail Nicholson, CRC
Curriculum Vitae

PROFESSIONAL EXPERIENCE

Carolina Clinical Research
Site Director
9040 Nations Ford Road
Charlotte NC 28273
September 2019 - Present



Clinical Research of Gastonia
Regulatory Affairs Specialist
1010 X Ray Drive
Gastonia NC 28054
Phone: (704) 675-7144
April 2017- September 2019

Clinical Research of Gastonia
Regulatory Coordinator
Research Assistant
1010 X Ray Drive
Gastonia NC 28054
Phone: (704) 675-7144
April 2016- April 2017

Gastonia Pharmaceutical Research
Regulatory Coordinator
Administrative Assistant
442 East Long Avenue
Gastonia NC 28054
April 2015-November 2015

Certifications USA
Customer Support Manager
Charlotte NC
January 2014- March 2018

Olan Mills/Lifetouch Studios
Studio Manager
Eastridge Mall
254 N. New Hope Road
Gastonia NC 28054
2007-2012

Eckerd Pharmacy
Assistant Store Manager
Charlotte NC
2005-2007

Eckerd Pharmacy
Multi-Unit Photo Lab Manager
Charlotte NC
2001-2005

EDUCATION

Gaston College
Associate of Arts – Pre-Nursing Studies
Dallas, NC
May 2014

East Lincoln High School
Top 10% of Graduating Class
Denver, NC
May 2000

Certifications/Awards/Related Experience:

GCP Certified 2015-present
NIH Protecting Human Subjects 2015-2019
BLS CPR/AED Certified 2015-present
Clinical Research Coordinator 2019-present

RESEARCH EXPERIENCE

Regulatory Coordinator – Protocol D6571C00001. A 24 week treatment, multicenter, randomized, double blinded, double dummy, parallel-group, clinical trial evaluating the efficacy and safety of aclidinium bromide 400 µg/formoterol fumarate 12 µg fixed-dose combination BID compared with each monotherapy (aclidinium bromide 400 µg BID and formoterol fumarate 12 µg BID) and tiotropium 18 µg QD when administered to patients with stable chronic obstructive pulmonary disease. AstraZeneca AB, 2017.

Regulatory Coordinator – Protocol LAS-MD-45 (D6560C00002). Double-blind, Randomized, Placebo-controlled, Parallel-group, Phase IV Study to Evaluate the Effect of Aclidinium Bromide on Long-term Cardiovascular Safety and COPD Exacerbations in Patients with Moderate to Very Severe COPD (ASCENT COPD). AstraZeneca, 2017.

Regulatory Coordinator – Protocol D3251C00003. A Randomised, Double-blind, Chronic Dosing (56 week) Placebo-controlled, Parallel Group, Multicentre, Phase III Study to Evaluate the Efficacy and Safety of 2 Doses of Benralizumab (MEDI-563) in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with a History of COPD Exacerbations (GALATHEA). AstraZeneca, 2017.

Regulatory Coordinator – Protocol 460503. A Stage 1, Prospective, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Safety and Efficacy of Alpha1-Proteinase Inhibitor (A1PI) Augmentation Therapy in subjects with A1PI Deficiency and Chronic Obstructive Pulmonary Disease (COPD). Baxalta Innovations GmbH, 2017.

Regulatory Coordinator – Protocol 1237.19: A randomised, double-blind, active-controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD) exacerbation in patients with severe to very severe COPD. [DYNAGITO]. Boehringer Ingelheim, 2017.

Regulatory Coordinator -- Protocol 1218.22: A multicenter, international, randomized, parallel group, double-blind, placebo-controlled Cardiovascular Safety & Renal Microvascular outcome study with LINAgliptin 5mg once daily in patients with type 2 diabetes mellitus at high vascular risk. CARMELINA. Boehringer Ingelheim, 2017.

Regulatory Coordinator – Protocol DS8500-A-U202. A Randomized, Double-Blind, Placebo Ccontrolled With Active Comparator, 12-Week Study of DS-8500a in Subjects With Type 2 Diabetes Mellitus on Metformin. Daiichi Sankyo, 2016.

Regulatory Coordinator – Protocol MEA117113: Mepolizumab vs. Placebo as add-on treatment for frequently exacerbating COPD patients characterized by eosinophil level. GSK, 2017.

Regulatory Coordinator – Protocol MEA117106: Mepolizumab vs. Placebo as add-on treatment for frequently exacerbating COPD patients. GSK, 2017.

Regulatory Coordinator – Protocol CTT116855: A Phase III, 52 week, randomized, double-blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease. GSK, 2017.

Regulatory Coordinator – Protocol 205165. A Phase III, 4-week, randomised, double-blind study to compare 'closed' triple therapy (FF/UMEC/VI), 'open' triple therapy (FF/VI + UMEC) and dual therapy (FF/VI) in subjects with chronic obstructive pulmonary disease (COPD). GSK, 2016.

Regulatory Coordinator – Protocol 205076. A Phase II, multicenter, randomized, double-blind (sponsor-unblind), placebo- controlled, parallel group trial to evaluate the efficacy and safety of Sirukumab in subjects with severe, poorly controlled asthma. GSK, 2017.

Regulatory Coordinator – Protocol 201749. A 24-week treatment, multi-center, randomized, double-blind, double-dummy, parallel group study to compare Umeclidinium/Vilanterol, Umeclidimium, and Salmeterol in subjects with chronic obstructive pulmonary disease (COPD). GSK, 2017.

Regulatory Coordinator – Protocol 201546. A repeat-dose study of batefenterol/FF (GSK961081/GW685698) compared with placebo in the treatment of COPD. GSK, 2016.

Regulatory Coordinator – Protocol INS-212. A Randomized Open-Label, Multicenter Study of Liposomal Amikacin for Inhalation (LAI) in Adult Patients with Nontuberculous Mycobaterial (NTM) Lung Infections caused by Mycobacterium avium Complex (MAC) that are Refractory to Treatment. Insmed Incorporated, 2017.

Regulatory Coordinator – Protocol CLCZ696B2320. A multicenter, randomized, double-blind, active-controlled study to evaluate the effects of LCZ696 compared to valsartan on cognitive function in patients with chronic heart failure and preserved ejection fraction. Novartis Pharmaceuticals, 2017.

Regulatory Coordinator – Protocol CQAW039A2307. A 52-week, multicenter, randomized, double-blind, placebo controlled study to assess the efficacy and safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe asthma. Novartis Pharmaceuticals, 2017.

Regulatory Coordinator – Protocol CQVA149A2349. A multi-center, randomized, double-blind, double-dummy, active controlled, 2-period cross-over study to assess the efficacy, safety and tolerability of indacaterol maleate/glycopyrronium bromide compared to umeclidinium bromide/vilanterol in COPD patients with moderate to severe airflow limitation. Novartis Pharmaceuticals, 2017.

Regulatory Coordinator – Protocol PT009002. A Randomized, Double-Blind, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of PT009 Compared to PT005, PT008, and Open-label Symbicort® Turbuhaler®, as an Active Control, on Lung Function over a 24-Week Treatment Period in Subjects with Moderate to Very Severe COPD. Pearl Therapeutics, 2017.

Regulatory Coordinator – Protocol PT010008. A Randomized, Double-Blind, Parallel-Group, 52-Week, Chronic-Dosing, Multi-Center Study to Assess the Safety and Tolerability of PT010, PT009 and PT003 in Subjects with Moderate to Very Severe Chronic Obstructive Pulmonary Disease. Pearl Therapeutics, 2017.

Regulatory Coordinator – Protocol PT010006. A Randomized, Double-Blind, Parallel-Group, 24-Week, Chronic-Dosing, Multi-Center Study to Assess the Efficacy and Safety of PT010, PT003, and PT009 Compared with Symbicort® Turbuhaler® as an Active Control in Subjects with Moderate to Very Severe Chronic Obstructive Pulmonary Disease. Pearl Therapeutics, 2017.

Regulatory Coordinator – Protocol PT010005. A Randomized, Double-Blind, Multi-Center, Parallel Group Study to Assess the Efficacy and Safety of PT010 Relative to PT003 and PT009 on COPD Exacerbations over a 52-Week Treatment Period in Subjects With Moderate to Very Severe COPD

Regulatory Coordinator – Protocol SEP091-402. A Comparative Effectiveness and Safety Study of Arformoterol Tartrate Inhalation Solution and Tiotropium Bromide on Re-hospitalization in Chronic Obstructive Pulmonary Disease (COPD) Subjects (a Phase 4 study). Sunovion, 2017.

Regulatory Coordinator – Protocol TD-4208-0126. A Phase 3, 12-week, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Study of Nebulized TD-4208 in Subjects with Chronic Obstructive Pulmonary Disease. Theravance BioPharma, 2017

Regulatory Coordinator – Protocol 201378. A Randomized, Double-Blind, Double-Dummy, Parallel Group, Multicenter Study of Once Daily Fluticasone Furoate/Vilanterol 100/25 mcg Inhalation Powder, Twice Daily Fluticasone Propionate/Salmeterol 250/50 mcg Inhalation Powder and Twice Daily Fluticasone Propionate 250 mcg Inhalation Powder in the Treatment of Persistent Asthma in Adults and Adolescents Already Adequately Controlled on Twice-Daily Inhaled Corticosteroid and Long-Acting Beta2 Agonist. GSK, 2016.

Regulatory Coordinator – Protocol WB29804. Phase II, randomized, double-blind, placebo-controlled, parallel-group clinical trial of lebrikizumab in patients with Chronic Obstructive Pulmonary Disease (COPD) and a history of exacerbations who are treated with inhaled corticosteroid (ICS) and at least one long-acting bronchodilator inhaler medication. This study will be conducted to assess the safety, efficacy, and patient-reported outcome (PRO) measures. Hoffman-La Roche, 2015

Regulatory Coordinator – Protocol TD-4208-0128. A Phase 3, 52-week, Randomized Active-Controlled Parallel-Group Study to Evaluate the Safety and Tolerability of Nebulized TD-4208 in Subjects with Chronic Obstructive Pulmonary Disease. Theravance BioPharma, 2015

Regulatory Coordinator – Protocol PT003014. A Randomized, Double-Blind, Chronic Dosing (24 Weeks), Placebo-Controlled, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe COPD, Compared With Placebo (PINNACLE 4). Pearl Therapeutics, 2015.

Regulatory Coordinator – Protocol NN9535-4269. A 30 week, confirmatory, randomized, double-blind, placebo-controlled, multicentre, multinational, two-arm, parallel-group trial to determine efficacy and safety of semaglutide once-weekly versus placebo as add-on to SGLT-2i in subjects with type 2 diabetes mellitus

Regulatory Coordinator – PT009003-00: A Randomized, Double-Blind, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of PT009 compared to PT005 in Subjects With Moderate to Very Severe COPD

Regulatory Coordinator – Novartis Pharmaceuticals trial entitled: A 2-treatment period, randomized, placebo-controlled, multicenter parallel-group study to assess the safety of QAW039 when added to existing asthma therapy in GINA steps 3, 4 and 5 patients with uncontrolled asthma
Protocol No.: CQAW039A2315

Regulatory Coordinator – An 8-week, randomized, double-blind, placebo and active-controlled, parallel group, dose ranging study to evaluate the efficacy and safety of 3 doses of CHF 718 pMDI (beclomethasone dipropionate) in asthmatic subjects
Clinical Study Code: CCD-05993AA3-01

Regulatory Coordinator – A 6-week, randomized, double-blind, placebo and active-controlled, parallel group, dose ranging study to evaluate the efficacy and safety of 4 doses of CHF 5259 pMDI (glycopyrronium bromide) in subjects with Chronic Obstructive Pulmonary Disease (COPD)
Clinical Study Code: CCD-05993AA3-02

Regulatory Coordinator – 1245.110/ A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF).

Regulatory Coordinator – 1245.121/ A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with reduced Ejection Fraction (HFrEF).

Regulatory Coordinator – A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients with Severe Asthma Uncontrolled on Standard of Care Treatment. D3250C00045

Regulatory Coordinator – Protocol No:D5970C00002; Protocol Title: A Randomised, Double-Blind, Double-Dummy, Multicentre, Parallel Group Study to Assess the Efficacy and Safety of glycopyrronium/Formoterol Fumarate fixed-dose combination relative to Umeclidinium/Vilanterol fixed dose combination over 24 Weeks in patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (AERISTO), IND# 107739

Regulatory Coordinator – 206901: A randomized, open-label, cross-over, placebo inhaler study to evaluate the correct use of ELLIPTA™ dry powder inhaler (DPI) compared to DISKUS™ DPI used in combination with HandiHaler™ DPI in participants with Chronic Obstructive Pulmonary Disease (COPD). PHASE IV

Regulatory Coordinator – ABS-COPD-30065: A 12-Week, Open-Label Study to Evaluate the Relationship Between Use of Albuterol eMDPI, an Inhaled Short-Acting Beta Agonist "Rescue" Agent with an eModule, and Exacerbations in Patients (40 Years of Age or Older) with Chronic Obstructive Pulmonary Disease

Regulatory Coordinator – Protocol: 15-006
A Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in Subjects with Narcolepsy with Cataplexy

Regulatory Coordinator – PT001102: A Randomized, Double-Blind, Parallel Group, Multi-Center 24-Week Study Comparing the Efficacy and Safety of Three Doses of PT001 to Placebo and Open-label Spiriva Respimat in Subjects With Persistent Asthma

Regulatory Coordinator – Menlo Therapeutics Inc.: MTI-110 - A randomized, double-blind, placebo-controlled study of the efficacy, safety, and tolerability of serlopitant for the treatment of refractory chronic cough

Regulatory Coordinator – ES2016-01 Blood Sample Collection in Subjects with Pulmonary Nodules or CT Suspicion of Lung Cancer

Regulatory Coordinator – Protocol: 42847922ISM2005. "A Multicenter, Double-Blind, Randomized, Parallel-Group, Active- and Placebo Controlled Polysomnography Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42847922 in Subjects with Insomnia Disorder"

Regulatory Coordinator – Janssen Protocol 63623872FLZ3002.
A Phase 3 Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Non-hospitalized Subjects With Influenza A Infection who Are at Risk of Developing Complications

Regulatory Coordinator – D5180C00007 A Multicentre, Randomized, Double-Blind, Placebo Controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Tezepelumab in Adults and Adolescents with Severe Uncontrolled Asthma (NAVIGATOR)

Regulatory Coordinator – GSK 205715. Protocol 205715: A Phase III, randomized, double-blind, active controlled, parallel group study, comparing the efficacy, safety and tolerability of the fixed dose combination FF/UMEC/VI with the fixed dose dual combination of FF/VI, administered once-daily via a dry powder inhaler in subjects with inadequately controlled asthma.

Regulatory Coordinator – GSK 207626. A Phase IV, 12 week, randomised, double-blind, double-dummy study to compare single inhaler triple therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI), with tiotropium monotherapy based on lung function and symptoms in participants with chronic obstructive pulmonary disease (Protocol #207626)

Regulatory Coordinator – MNK 14344100. MNK14344100: A Phase 4 Multicenter, Randomized, Double Blind, Placebo Controlled Pilot Study to Assess the Efficacy and Safety of H.P. Acthar® Gel in Subjects with Pulmonary Sarcoidosis

Regulatory Coordinator – Volcano-2. A Double-Blind, Randomized, Placebo Controlled Study of the Efficacy and Safety of Three Doses of Orvepitant in Subjects with Chronic Refractory Cough. VOLCANO-2

Regulatory Coordinator – AT251-G-17-006: A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of JTT-251 Administered for 24 Weeks to Participants with Pulmonary Arterial Hypertension (RELIEF-PAH)

Regulatory Coordinator – ATA101-PN-001: A Dose Escalation Study to Assess the Efficacy and Safety of ATA-101 in Subjects with Refractory Chronic Cough

Regulatory Coordinator -- 200879 : A Phase IIb, Randomized (Stratified), Double-Blind (Sponsor open), Parallel-Group, Placebo-Controlled, Dose-Finding Study of Nemiralisib (GSK2269557) Added to Standard of Care (SoC) Versus SoC Alone in Participants Diagnosed with an Acute Moderate or Severe Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

Regulatory Coordinator -- Protocol: JZP080-301: A Double-blind, Placebo-controlled, Randomized Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in the Treatment of Idiopathic Hypersomnia (IH) with an Open-label Safety Extension

Regulatory Coordinator -- CQAW039A2316: A 12-week, multi-center, randomized, double-blind, placebo controlled study to assess the efficacy and safety of QAW039 when added to standard-of-care asthma therapy in patients with uncontrolled asthma

Regulatory Coordinator -- MK7264-027 A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 12-Month Study to Evaluate the Efficacy and Safety of MK-7264 in Adult Participants with Chronic Cough (PN027)

Regulatory Coordinator – Novum CLR_17_08: A Randomized, Single-Dose, Double-Blind, Double-Dummy, Four-Period, Four-Sequence, Four-Treatment, Placebo and Active Controlled, Comparative, Multiple-Center, Crossover-Design, Bronchoprovocation Study to Evaluate the Pharmacodynamic Equivalence of Albuterol Sulfate Inhalation Aerosol, eq 90 mcg base (Sun Pharmaceuticals Industries Limited) to PROAIR® HFA (albuterol sulfate) Inhalation Aerosol, eq 90mcg base (Teva Respiratory, LLC) in Subjects With Stable, Mild Asthma

Regulatory Coordinator – SUN CLR_16_33: A Randomized, Multi-Center, Investigator-Masked, Parallel Group, Equivalence Study of Once Daily Brimonidine Tartrate Ophthalmic Suspension Compared with Three Times Daily Alphagan® P in Subjects with Open Angle Glaucoma or Ocular Hypertension.

Regulatory Coordinator – Theravance 0173: A Phase 2 Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Induction Therapy with 2 Doses of TD-1473 in Subjects with Moderately-to-Severely Active Crohn's Disease

Regulatory Coordinator -- Novartis Pharmaceuticals trial CQGE031C2302 entitled: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

Regulatory Coordinator – Theravance 0164: 0164: A 3-Year Multi-Center, Long-Term Safety (LTS) Study to Evaluate the Safety and Tolerability of TD–1473 in Subjects with Ulcerative Colitis

Regulatory Coordinator – Theravance 0157: A Phase 2b/3 Multi-Center, Randomized, Double-Blind, Multi-Dose,Placebo-Controlled, Parallel-Group Set of Studies to Evaluate the Efficacy and Safety of Induction and Maintenance Therapy with TD–1473 in Subjects with Moderately-to-Severely Active Ulcerative Colitis

Regulatory Coordinator – Avillion: A Long-term, Randomized, Double-blind, Multicenter, Parallel-Group, Phase III Study Evaluating the Efficacy and Safety of PT027 Compared to PT007 Administered as Needed in Response to Symptoms in Symptomatic Adults and Children 4 Years of Age or Older with Asthma (MANDALA) / AV003

Regulatory Coordinator – Verona: RPL554-CO-205, "A Phase II, Randomized, Double-Blind, Placebo Controlled Dose Ranging Study to Assess the Effect of RPL554 Added on to Tiotropium in Patients with COPD "

Regulatory Coordinator – Seer: A Prospective Blood Sample Collection Study to Develop and Validate a Panel of Protein-based Biomarkers in Patients with Pulmonary Nodules

Regulatory Coordinator – Pfizer: A Placebo Controlled, Double Blind, Randomized, Parallel Group Pilot Study to Evaluate the Efficacy of Dextromethorphan Hydrobromide on Acute Cough in a Pediatric Population

Regulatory Coordinator – Innolife: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of INL1 (Trientine) in Patients with Heart Failure and Reduced Ejection Fraction

Regulatory Coordinator – Teva CompleWare: A Randomized, Blinded, Parallel Group, Placebo-Controlled, Multiple Dose, Multicenter Study to Compare the Therapeutic Equivalence of Fluticasone Propionate Pressurized Metered Dose Inhaler, 110 mcg, to Flovent® HFA 110 mcg, in Adult Subjects with Asthma (TPI-18-03)

Regulatory Coordinator – BI Airwise: Pragmatic Randomized Clinical Trial in a Community-Based Setting Comparing Tiotropium bromide + Olodateral FDC (STIOLTO® RESPIMAT®) vs. ICS-LABA plus LAMA (Triple Therapy) in Patients with COPD

Regulatory Coordinator: Arena - APD371-202: A Phase 2, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of Olorinab in Subjects with Irritable Bowel Syndrome Experiencing Abdominal Pain

Regulatory Coordinator: Arena- APD334-301: A Phase 3, Randomized, Double Blind, Placebo Controlled, 52 Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis

Regulatory Coordinator: Arena- APD334-302: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 12-Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis

Regulatory Coordinator: Arena- APD334-303: An Open-Label Extension Study of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis

Regulatory Coordinator: GRANIT - AstraZeneca AB, D3741C00007, GRANIT, A Phase 2b Randomised, Double Blind, Placebo Controlled, Parallel Arm, Multi Centre Study to Assess Efficacy and Safety of Multiple Dose Levels of AZD7594 DPI Given Once Daily for twelve weeks, compared to placebo, in Asthmatics symptomatic on low dose ICS

Regulatory Coordinator: GSK LEGEND- GSK-206860: A Comparison of the Clinical Effectiveness of Inhaled Triple Therapy (Fluticasone Furoate / Umeclidinium Bromide / Vilanterol) in a Single Inhaler (TRELEGY™ ELLIPTA™) with Inhaled Non-ELLIPTA™ Multiple Inhaler Triple Therapies in COPD Patients in the US within a Usual Care Setting in a Prospective Pre-Post Study.

Regulatory Coordinator: Vedanta- VE303-002: A Double-Blind Placebo-Controlled Phase 2 Study of VE303 for Prevention of Recurrent Clostridium Difficile Infection

Regulatory Coordinator: Roche- GA29144: A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ETROLIZUMAB AS AN INDUCTION AND MAINTENANCE TREATMENT FOR PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE

Regulatory Coordinator: Roche- GA29145: AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE PREVIOUSLY ENROLLED IN THE ETROLIZUMAB PHASE III PROTOCOL GA29144

Regulatory Coordinator: Roche- GA28948: A PHASE III, RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY (INDUCTION OF

REMISSION) AND SAFETY OF ETROLIZUMAB COMPARED WITH ADALIMUMAB AND PLACEBO IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS WHO ARE NAIVE TO TNF INHIBITORS

Regulatory Coordinator: Roche- GA28949: A MULTICENTER, PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY (INDUCTION OF REMISSION) AND SAFETY OF ETROLIZUMAB COMPARED WITH ADALIMUMAB AND PLACEBO IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS IN PATIENTS NAÏVE TO TNF INHIBITORS

Regulatory Coordinator: Roche- GA28951: AN OPEN LABEL EXTENSION AND SAFETY MONITORING OF MODERATE TO SEVERE ULCERATIVE COLITIS PATEINTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES

Regulatory Coordinator: Sanofi PEDISTAD- Prospective, observational, longitudinal study in pediatric patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not medically advisable

Regulatory Coordinator: Sanofi- LPS15496: TITLE: EVALUATION OF BIOMARKERS OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT MEDICALLY ADVISABLE

Regulatory Coordinator: GSK Matinee- GSK 208657: A phase IIIA multi-center, randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels

Regulatory Coordinator: Novartis- CQBW251B2201: A phase IIB 24-week multi-center, double-blind, placebo-controlled dose range finding study to investigate the efficacy and safety of oral QBW251 in COPD patients on triple inhaled therapy (LABA/LAMA/ICS)

Regulatory Coordinator: OTSUKA- 341-201-00004: A Phase II, Multicenter, Randomized, Double-blind, Placebo-controlled, Proof-of-Concept Trial to Assess the Efficacy and Safety of Orally Administered OPS-2071 for 12 Weeks in Subjects with Crohn's Disease Showing Symptoms of Active Inflammation Despite Ongoing Treatment