Manna MR Research

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CURRICULUM VITAE

ACADEMIC BACKGROUND

1. 2010 Certification in Family Medicine from the College of Family Physicians of Canada
2. 2003 – 2004 Rotating Internship – Ministry of Health (MOH) Hospital – Amman, Jordan
3. 2002 – 2003 Rotating Internship – College of Medicine/Baghdad University - Baghdad Medical City
4. 1996 – 2002 Bachelor of Medicine & Bachelor of Surgery (MB ChB) – Baghdad University

ADDITIONAL TRAINING & CERTIFICATIONS

- Introduction to Clinical Research – Self Instruction Manual
- Overview of ICH GCP
- Clinical Trial Ethics
- Clinical Investigator Obligations & Qualification, Resources, IRBs/IECs
- Subject Informed Consent & Protocol Compliance
- Patient Recruitment & Retention Training
- Source Documentation
- Data Privacy
- Investigational Product, Randomization & Unblinding & Source Documents & Case Report Form Completion
- Safety – Adverse Events & Serious Adverse Events Reporting
- Safety Reporting, Financial Disclosure, & Study Closeout, Trial Termination, and Record Retention
- Liver Safety Training
- Non-compliance, Scientific Misconduct and Fraud & Monitoring and Preparing for Audits and Inspections
- Pharmacogenetics for Investigator Site Staff
- The European Clinical Trial Directives
- Part C Division 5, of the Canadian Food & Drug Regulations Certification
- Health Canada Drugs and Health Products – Summary Report of Inspections of Clinical Trials Conducted from April 2004 – March 2011
- National Institute of Health (NIH) Web-based Training Course "Protecting Human Research Participants"
- Guidance for Industry – Investigator Responsibilities – Protecting the Rights, Safety, & Welfare of Study Subjects
- FDA Readiness Training
- sPGA, PASI, BSA, NAPSI, PSSI, PPPASI
- Static 6-Point Physician Global Assessment Certificate
- Tophi Measurement
- CGI-S, CGI-I, SCID-CT, C-SSRS, , HAMD-D-17
- Basic Life Support Health Care Provider Course (BLS)
- Advanced Cardiovascular Life Support Provider Course (ACLS)
- Pediatric Advanced Life Support Provider Course
- Advanced Trauma Life Support (ATLS)
- Acute Musculoskeletal Limb Support (AMLS)

ADDITIONAL TRAINING & CERTIFICATIONS CONTINUED

- Advanced Life Support in Obstetrics (ALSO)
- Airway Interventions & Management in Emergencies (AIME)
- Casting and Splinting Techniques in the Emergency Department (CASTED)
- Learning Essential Approaches to Palliative and End-of-Life Care
- Intralinks
- Pearls.ce (Evidence-based Practice Reflection Exercise) – The College of Family Physicians of Canada.
- Quality Improvement & Innovation Partnership – Wave 4 Advanced Access & Efficiency in Primary Care – Learning Session 1 & 2 – Health Quality Ontario
- IV/WRS
- Self-Monitored Blood Glucose
- Leeds Enthesitis Index (LEI) and Leeds Dactylitis Index-Basic (LDI-Basic)
- Electronic Document Exchange (eDX) Training
- Assessment of Enthesitis and Dactylitis in Psoriatic Arthritis
- Assessment of Synovitis in Psoriatic Arthritis – Joint Count
- Inhaler and Novel Dry Powder Inhaler Use
- Serious Adverse Event Reporting and RDE2OCEANS (e-N@ble v3) Training
- Intralinks Training for Investigator/Sub-Investigator(s)
- eResearch Technologies – Masterscope ® CT: Site Personnel Training
- Introduction to the ClinPhone IVRS/IWRS
- COWS Training
- DataLabs v5.0 Investigator Training
- ClinTrakEDC Training
- InForm
    - InForm v4.5 – Modules
    - InForm Version 4.6 Gap Training for Investigator Site Staff
    - EDC InForm v4.6
    - InForm 4.6 Training for Investigators
    - InForm 4.6 – Inv Data Entry
    - InForm GTM 6.0 for PI (Signature)
    - Become EDC InFormed for Investigators Data Entry and Approve
    - Safety Information Form in InForm for Site Staff v2
- eResearch Technologies – Query Management Portal: Site Personnel Training
- ePRO Training for PHT\s StudyWorks Tool, LogPad Tool
- Meaning of Electronic Signature and Security Requirements
- Medidata Rave
    - Medidata Rave ® 5.6 Certified Clinical Research Coordinator
    - Medidata EDC System: Site Training (EDC-CRC Ver 1.0)
    - Rave 5.6 EDC Essentials for Investigators
    - Investigator Rave Training Version 3.0
    - Data Management Medidata Rave
- OC RDC (SITE) Training (4.6.2)
- Vitalograph Spirometry, FeNO and e-Diary Training
- TrialMax Training

RESEARCH EXPERIENCE

Principal Investigator *2012 – Present*
Manna Research Inc. – Toronto, ON

- Consenting subjects
- Ultimate responsibility of the clinical trial, including medical management
- Familiarity with all protocols
- Identifying adverse events, expected, unexpected and serious
- Determine causality of all adverse events
- Liaison with ethics Review Board
- Liaison with sponsors and CROs
- Report SAEs and pertinent medical events to sponsor
- Report SAEs and other reportable items to ethics committee
- Overall conduct of the clinical trial
- Overall conduct of the all staff
- Blind breaking in collaboration with the sponsor
- Decides whether subjects continuation in the trial will benefit the subject
- Determines subject physical and mental eligibility to participate or discontinue in a trial
- Confirms that subject's continues to meet the protocol inclusion criteria in clinical trial
- Ensure Training of Sub Investigators and staff
- Dose titration of Investigational product
- Initiating/Ordering medication/device be administered
- Confirmation of subject's medical history
- Subject recruitment
- Data query acknowledgment and signature
- Working with knowledge and acceptance of all site SOPs
- Following ICH,GCP and Declaration of Helsinki guidelines
- Continuous Study related training, i.e. InForm, ICH/GCP, HAMD-D-17 & NIH
- Maintain up-to-date clinical trial related certificates as well as current medical licenses

CLINICAL EXPERIENCE

Family Physician *Feb 2013 – Present*
Kipling Heights Medical Center

Family Physician *(Full-Time) Dec 2011 – Dec 2012*
Bramalea Community Health Centre – Brampton, ON *(Part-Time) Dec 2012 – Present*

Family Physician - (*Part-Time)* *Apr 2012 – Apr 2013*
Bloom Clinic – Brampton, ON

CLINICAL EXPERIENCE CONTINUED

Family Physician *2005 – 2011*
Newfoundland & Labrador

- ***Senior Medical Officer/Senior Staff Physician*** *2006 – 2011*
  AM Guy Memorial Health Centre – Buchans, NL
- ***District Medical Officer*** *Apr 2006 – Dec 2006*
  Labrador South Health Centre – Forteau, Labrador

General Practitioner *Jun 2004 – Dec 2004*
Baghdad, Iraq

TEACHING EXPERIENCE

Supervisor
Family medicine resident, McMaster University *2012*

Preceptor
Two students in the Nurse Practitioner Program of Newfoundland and Labrador *2006 & 2007*

PROFESSIONAL COMMITTEES

Local Medical Advisory Committee

- AM Guy Memorial Health Centre – Buchans, NL *Dec 2006 – Dec 2011*
- Labrador South Health Centre – Forteau, Labrador *Apr 2006 – Dec 2006*
- Rufus Guinchard Health Centre – Port Saunders, NL *Oct 2005 – Apr 2006*

Rural Medical Advisory Committee *Jan 2008 – Dec 2011*
Central Health - NL

RESEARCH STUDIES

1. A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate Long-term Tolerability and Durable Efficacy of AMG 145 on LDL-C in Hypercholesterolemic Subjects
2. A Multicenter, Controlled, Open-label Extension (OLE) Study to Assess the Long-term Safety and Efficacy of AMG 145
3. A Double-blind, Randomized, Placebo and Ezetimibe-controlled, Multicenter Study to Evaluate Safety and Efficacy of Lipid Lowering Monotherapy With AMG 145 in Subjects With a 10-Year Framingham Risk Score of 10% or Less
4. A Randomized Double-blind Study to Evaluate the Safety and Efficacy of Denosumab Compared With Zoledronic Acid in Postmenopausal Women With Osteoporosis Previously Treated With Oral Bisphosphonates
5. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of LY2439821 to Etanercept and Placebo in Patients with Moderate-to-Severe Plaque Psoriasis
6. A phase 3B, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial of Linaclotide Administered Orally For 12 Weeks to Patients With Chronic Constipation And Prominent Abdominal Bloating At Baseline

7. A Multicenter, Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of Febuxostat and Allopurinol in Subjects with Gout and Cardiovascular Comorbidities

8. A Multicenter, Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of TAK-875 25 mg and 50 mg Compared to Glimepiride When Used in Combination with Metformin in Subjects with Type 2 Diabetes

9. Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Safety, Efficacy and Potential Pharmacokinetic Interaction of RDEA594 and Allopurinol in Gout Patients with an Inadequate Hypouricemic Response with Standard Doses of Allopurinol Phase 2 Allopurinol Combination Study

10. A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic Response to Standard of Care Allopurinol Combining Lesinurad with Allopurinol in Inadequate Responders (CLEAR 2)

11. A Long-Term Open-Label Extension Study for Subjects Completing a Phase 3 Efficacy and Safety Study of Lesinurad Monotherapy in Subjects with Gout

12. A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Febuxostat Compared to Febuxostat Alone at Lowering Serum Uric Acid and Resolving Tophi in Subjects with Tophaceous Gout

13. A Long-Term Open-Label Extension Study for Subjects Completing a Phase 3 Efficacy and Safety Study of Lesinurad Monotherapy in Subjects with Gout

14. A multicenter, randomized, double-blind, parallelgroup study to evaluate the efficacy and safety of the addition of umeclidinium bromide Inhalation Powder (62.5mcg) once-dailyto fluticasone propionate/salmeterol (250/50mcg) twice-daily, umeclidinium bromide Inhalation Powder (125mcg) once-daily to fluticasone propionate/salmeterol (250/50mcg) twice-daily versus placebo to fluticasone propionate/salmeterol (250/50mcg) twice-daily over 12 weeks in subjects with COPD.

15. 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Non-Insulin Antihyperglycemic Drugs with a 6-month Safety
Extension Period

16. A Multicenter Trial Comparing the Efficacy and Safety of Umeclidinium/Vilanterol 62.5/25 mcg Once Daily with Tiotropium 18 mcg Once Daily over 24 Weeks in Subjects with Chronic Obstructive Pulmonary Disease (COPD)

17. A 12-Week Dose-ranging Study to Evaluate the Efficacy and Safety of Fp Spiromax® (Fluticasone Propionate Inhalation Powder) Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Severe Persistent Asthma Uncontrolled on High dose Inhaled Corticosteroid Therapy

18. A 64-Week, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous SCH 900222/MK-3222, Followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis

19. A Placebo-Controlled, Randomized, Double-Blind, Parallel-Group, Dose-Finding Trial to Evaluate the Efficacy and Safety of TBS-2 Intranasal Testosterone Gel in Pre-Menopausal Women With Acquired Female Orgasmic Disorder

20. A randomized, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 ug and 5 ug Tiotropium Inhalation Solution delivered by the Respimat Inhaler with Tiotropium inhalation capsules 18 ug delivered by the HandiHaler

21. A Phase 3B, Randomised, double-blind, placebo-controlled, parallel-group trial of Linaclotide administered orally for 12 weeks to patients with Chronic constipation and prominent abdominal bloating at baseline

22. A 24-week, Multicentre, Randomised, Double-blind, Placebo-Controlled, International Phase III Study with a 28 week Extension Period to Evaluate the Safety and EFficacy of Dapagliflozin 10 Mg once daily in Patients with Type 2 Diabetes who have inadequate Glycaemic Control on a background combination of Metformin and Sulfonylurea (March 14, 2012 – September 4, 2013)

23. A Phase 2 Multicenter, Randomized, Placebo- and Active-Comparator-Controlled, Dose-Ranging Trial to Evaluate CNTO 1959 for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis (11 Sept 2011 – 11 Oct. 2013)

24. A Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Add-On Therapy with Saxagliptin and Dapagliflozin added to Metformin compared to Add-On Therapy with Saxagliptin in combination with Metformin

or Dapagliflozin in combination with Metformin in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin Alone (27Sep2012 – 17Mar2014)

25. A phase III randomized, double-blind, parallel group study to evaluate the efficacy and safety of once daily oral administration of BI 10773 25 mg/linagliptin 5 mg and BI 10773 10 mg/linagliptin 5 mg Fixed Dose Combination tablets compared with the individual components (BI 10773 25 mg, BI 10773 10 mg, and linagliptin 5 mg) for 52 weeks in treatment naïve and metformin treated patients with type 2 diabetes mellitus with insufficient glycaemic control (17Jun2013 – 28Oct2013)

26. A Double-Blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate Long-Term Tolerability and Durable Efficacy of AMG 145 on LDL-C in Hypercholesterolemic Subjects (11Jun 2012 – 4Apr2014)

27. "A Double-blind, Randomized, Placebo and Ezetimibe controlled, Multicenter Study to Evaluate Safety and Efficacy of Lipid Lowering Monotherapy With AMG 145 in Subjects With a 10-Year Framingham Risk Score of 10% or Less" **(**22Feb2013 – 27Feb2014)

28. The SPD489-322 Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (May 30, 2012 – Feb. 28, 2014)

29. A Phase III Randomized Double-Blind Placebo Controlled Trial to Evaluate the Efficacy and Safety of the Nitazoxanide and Nitazoxanide plus Oseltamivir in the Treatment of Acute Uncomplicated Influenza (Jan. 2,2014 – Jun. 26, 2014)

30. A Placebo-Controlled, Randomized, Double-Blind, Parallel-Group, Dose-Finding Trial to Evaluate the Efficacy and Safety of TBS-2 Intranasal Testosterone Gel in Women With Acquired Female Orgasmic Disorder (Jul. 31, 2012 – Apr. 14, 2014)

31. A Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination With an Antidepressant in the Treatment of Adults With Major Depressive Disorder With Residual Symptoms or Inadequate Response Following Treatment With an Antidepressant (Nov. 24, 2012 – Jun. 5, 2014)

32. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 24-Week Study to Evaluate the Efficacy and Safety of Daily Oral TAK-875 50 mg Compared With Placebo as an Add-On to Glimepiride in Subjects With Type 2 Diabetes (Dec. 17, 2013 – Jun. 17, 2014)

33. A Phase 3, Multicenter, Randomized, Double-Blind, Active-Controlled, 24-Week Study to Evaluate the Efficacy and Safety of Daily Oral TAK-875 50 mg Compared with Sitagliptin 100 mg When Used in Combination With Metformin in Subjects With Type 2 Diabetes (Sep. 12, 2013 – Jun. 25, 2014)

34. A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Assess the Efficacy and Safety of Lesinurad Monotherapy Compared to Placebo in Subjects with Gout and an Intolerance or Contraindication to a Xanthine Oxidase Inhibitor (Feb. 21, 2012 – Sept. 3, 2013)

35. A Phase 3 Efficacy and Safety Study for ALKS 5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-4 Study) (Aug. 22, 2014 – Dec. 22, 2014)

36. A Phase 3 Randomized Placebo Controlled Study to Evaluate the Efficacy and Safety of Abatacept Subcutaneous Injection in Adults with Active Psoriatic Arthritis (May 23, 2013 – Apr. 25, 2015)

37. A Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Tolerability, and Safety of NXN-426 in Patients with Post-Herpetic Neuralgia (PHN) (Apr. 25, 2013 – Aug. 18, 2014)

38. A Phase 3 Randomized, Double Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic Response to Standard of Care Allopurinol (Dec. 16, 2011 – Aug. 27, 2014)

39. A phase I/II observer-blind, randomized, controlled, multi-center trial to evaluate the safety and immunogenicity of different formulations of monovalent Influenza A/mallard/Netherlands/12/2000 NIBRG-63 (H7N1) vaccine manufactured in Quebec, Canada with and without AS03 adjuvant, given as a two-dose series to adults 21 to 64 years of age (Jul. 17, 2013 – Mar. 5, 2015)

40. A prospective, open label study evaluating the efficacy of two management strategies (pantoprazole 40 mg q.a.m. and taking Pradaxa with food (within 30 minutes after a meal)) on gastrointestinal symptoms (GIS) in patients newly on treatment with Pradaxa 150 mg b.i.d., 110 mg b.i.d. or

75 mg b.i.d. for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF) (Sep. 25, 2013 – Aug. 22, 2014)