

## List of Clinical Trials Approved by the NBRHC REB as of January 6, 2022

- **M15-991** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to assess the Efficacy and Safety of Risankisumab in subjects with moderately to severely active Crohn's Disease who failed prior biologic Treatment (Dr. Scott Shulman)
- **M16-000:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease Who responded to Induction Treatment in M-16-006 or M15-991 (Dr. Scott Shulman)
- **M16-006** A Multicenter, Randomized, double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Crohn's Disease (Dr. S. Shulman)
- **747-304:** Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicentre Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (Dr. S. Gauthier)
- **M16-067:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Ulcerative Colitis Who Have Failed Prior Biologic Therapy (Dr. S. Shulman)
- **M14-433:** A Multicenter, Randomized, Double Blind, Placebo- Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease who Have Inadequately Responded to or are Intolerant to Conventional Therapies but have not Failed Biologic Therapy. (Dr. S. Shulman)
- **M16-066:** A Multi, Randomized, Double-Blind, Placebo- Controlled 52-week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis Who Responded to Induction Treatment in M16-067 or M16-065 (Dr. S. Shulman)
- **M14-430:** A Multicenter, Randomized, Double-Blind, Placebo Controlled Maintenance and Long Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease, who completed the M14-431 or M14-433 Studies (Dr. S. Shulman)

- Enhancing Evidence-based Practice for Youth and Emerging Adults with Early Psychosis: Implementation and Evaluation in Diverse Service Settings. (Dr. A. Voineskos)
- **PN-943-03** A Phase 2 Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center Study to Evaluate the Safety and Efficacy of Oral PN-943 in Subjects with Moderate to Severe Active Ulcerative Colitis (Dr. S. Gauthier)
- **I6T-MC-AMAM** - A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled, Treat-Through Study to Evaluate the Efficacy and Safety of Mirikizumab in Patients with Moderately to Severely Active Crohn's Disease (Dr. S. Gauthier)
- **M20-259** - A Phase 3, Multicenter, Randomized, Efficacy Assessor-Blinded Study of Risankizumab Compared to Ustekinumab for the Treatment of Adult Subjects With Moderate to Severe Crohn's Disease Who Have Failed Anti-TNF therapy (Dr. S. Shulman)