The YODA Project
Research Proposal Review

The following page contains the final YODA Project review approving this proposal.

The YODA Project
Research Proposal Review - Final
(Protocol #: 2015-0649)

Reviewers:

- ☒ Nihar Desai
- ☒ Cary Gross
- ☒ Harlan Krumholz
- ☒ Richard Lehman
- ☒ Joseph Ross

Review Questions:	Decision:
1. Is the scientific purpose of the research proposal clearly described?	Yes
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?	Yes
3. Can the proposed research be reasonably addressed using the requested data?	Yes, or it's highly likely
4. Recommendation for this data request:	Approve

Comments:

No additional comments.

The YODA Project
Research Proposal Review

Revisions were requested during review of this proposal.
The following pages contain the original YODA Project review and the original submitted proposal.

The YODA Project
Research Proposal Review - Revisions Requested
(Protocol #: 2015-0649)

Reviewers:

- ☒ Nihar Desai
- ☒ Cary Gross
- ☒ Harlan Krumholz
- ☒ Richard Lehman
- ☒ Joseph Ross

Review Questions:	Decision:
1. Is the scientific purpose of the research proposal clearly described?	No
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?	Yes
3. Can the proposed research be reasonably addressed using the requested data?	Unsure, further clarification from requestor is needed
4. Recommendation for this data request:	Not Approve

Comments:

Please clarify what population characteristics are of interest? Is the focus on demographic characteristics or clinical characteristics (or both), including disease severity.

Please clarify the approach that justifies the need for Individual-level Patient Data (IPD). If demographic and clinical characteristics will be examined independently, IPD would seem to be unnecessary and the trial population characteristics could be discerned from the CSR summary document. If a matrix of characteristics will be examined, that would require IPD but should be pre-specified.

Currently, no information is provided on how the metric (score) would be developed to quantify the population representativeness of each trial. Will different characteristics be weighted? How will the analysis be approached? The methods text does not adequately describe the planned work, both in terms of how the main outcome measure will be developed (the metric) or the statistical analysis plan.

It is unclear what you propose to measure. Specifically, you state that you will use metrics to compare characteristics of the study samples to the population in the data warehouse. However, you do not state which variables you will use, why the individual patient trial data are required (as opposed to simply applying trial exclusion criteria to their data warehouse sample, or how you will construct your metrics.

Further clarification of your main study outcome - your "quantitative metric" - is warranted.

Please clarify the trials, disease states, and corresponding data you would use for the comparison.

While all of the trials you and your team requested are available for sharing, approximately half of the trials have not yet been anonymized, reviewed for privacy, and uploaded on the secure data sharing server managed by SAS. This work requires substantial time and resources and will take some time, at least 6 months.

Principal Investigator

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2015-0649

General Information

Key Personnel (in addition to PI): **First Name:** Anando
Last name: Sen
Degree: PhD
Primary Affiliation: Columbia University

Are external grants or funds being used to support this research?: No external grants or funds are being used to support this research.
yoda_project_coi_form_for_data_requestors_2015.pdf
yoda_project_coi_form_for_data_requestors_2015-signed_sen.pdf

Certification

Certification: All information is complete; I (PI) am responsible for the research; data will not be used to support litigious/commercial aims.
Data Use Agreement Training: As the Principal Investigator of this study, I certify that I have completed the YODA Project Data Use Agreement Training

Associated Trial(s): NCT00307684 - An Open International Multicentre Long-Term Follow Up Study to Evaluate Safety of Prolonged Release OROS Methlyphenidate in Adults With Attention Deficit Hyperactivity Disorder
NCT00326300 - An Open-Label, Dose-Titration, Long-Term Safety Study to Evaluate CONCERTA (Methylphenidate HCL) Extended-release Tablets at Doses of 36 mg, 54 mg, 72 mg, 90 mg, and 108 mg Per Day in Adults With Attention Deficit Hyperactivity Disorder
NCT00246220 - A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study To Evaluate the Safety And Efficacy Of Prolonged Release OROS Methylphenidate Hydrochloride (18, 36 and 72 mg/Day), With Open-Label Extension,
NCT00036374 - A Randomized, Double-Blind Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate for the Treatment of Patients With Polyarticular Juvenile Rheumatoid Arthritis

NCT00036439 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis
NCT00096655 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis
NCT00207675 - A Randomized, Multicenter, Open-label Study to Evaluate the Safety and Efficacy of Anti-TNF a Chimeric Monoclonal Antibody (Infliximab, REMICADE) in Pediatric Subjects With Moderate to Severe CROHN'S Disease
NCT00094458 - Multicenter, Randomized, Double-Blind, Active Controlled Trial Comparing REMICADE® (infliximab) and REMICADE plus Azathioprine to Azathioprine in the Treatment of Patients with Crohn's Disease Naive to both Immunomodulators and Biologic
NCT00336492 - A Phase 3, Randomized, Open-label, Parallel-group, Multicenter Trial to Evaluate the Safety and Efficacy of Infliximab (REMICADE) in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis
NCT00264537 - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Methotrexate-naïve Subjects with Active Rheumatoid Arthritis
NCT00264550 - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy
NCT00265083 - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Ankylosing Spondylitis
NCT00299546 - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously in Subjects with Active Rheumatoid Arthritis and Previously Treated with Biologic Anti
NCT00361335 - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Intravenously, in Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy
NCT00487539 - A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis
NCT00488319 - A 2-Year, Open-Label, Single-Arm Safety Study of Flexibly Dosed Paliperidone Extended Release (1.5-12 mg/day) in the Treatment of Adolescents (12 to 17 Years of Age) With Schizophrenia
NCT01248780 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Golimumab in the Treatment of Chinese Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy
NCT01248793 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Golimumab in the Treatment of Chinese Subjects with Ankylosing Spondylitis
NCT01009047 - A Randomized, Multicenter, Double-Blind, Active-Controlled, Flexible-Dose, Parallel-Group Study of the Efficacy and Safety of Prolonged Release Paliperidone for the Treatment of Symptoms of Schizophrenia in Adolescent Subjects, 12 to 17 Ye
NCT00645099 - A Prospective Randomized Open-label 6-Month Head-To-Head Trial to Compare Metabolic Effects of Paliperidone ER and Olanzapine in Subjects With Schizophrenia
NCT00518323 - A Randomized, Multicenter, Double-Blind, Weight-Based, Fixed-Dose, Parallel-Group, Placebo-Controlled Study of the Efficacy and Safety of Extended Release Paliperidone for the Treatment of Schizophrenia in Adolescent Subjects, 12 to 17 Yea
NCT01606228 - An Open-Label Prospective Trial to Explore the Tolerability, Safety and Efficacy of Flexibly-Dosed Paliperidone ER among Treatment-Naive and Newly Diagnosed Patients with Schizophrenia
NCT00334126 - A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Paliperidone ER Compared to Quetiapine in Subjects With an Acute Exacerbation of Schizophrenia
NCT00645307 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study With an Open-Label Extension Evaluating Extended Release OROS® Paliperidone in the Prevention of Recurrence in Subjects With Schizophrenia - Open Label Phase
NCT00650793 - A Randomized, DB, PC and AC, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Extended Release OROS Paliperidone (6, 9, 12 mg/Day) and Olanzapine (10 mg/Day), With Open-Label Extension, in the T
NCT00589914 - A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexible Doses of Paliperidone Palmitate and Flexible Doses of Risperidone Long-Acting Intramuscular Injection in Subjects With Schizophrenia
NCT00604279 - A Randomized, Open-Label, Parallel Group Comparative Study of Paliperidone Palmitate (50, 100, 150 mg eq) and Risperidone LAI (25, 37.5, or 50 mg) in Subjects with Schizophrenia

NCT00590577 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia
NCT00111189 - A Randomized Double-blind Placebo-controlled Parallel Group Study Evaluating Paliperidone Palmitate in the Prevention of Recurrence in Patients With Schizophrenia. Placebo Consists of 20% Intralipid (200 mg/mL) Injectable Emulsion
NCT00210717 - A Randomized, Double-Blind, Parallel Group, Comparative Study of Flexibly Dosed Paliperidone Palmitate (25, 50, 75, or 100 mg eq.) Administered Every 4 Weeks and Flexibly Dosed RISPERDAL CONSTA (25, 37.5, or 50 mg) Administered Every 2 Wee
NCT00119756 - A Randomized, Crossover Study to Evaluate the Overall Safety and Tolerability of Paliperidone Palmitate Injected in the Deltoid or Gluteus Muscle in Patients With Schizophrenia
NCT00210548 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia
NCT00101634 - A Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq, 50 mg eq, and 100 mg eq) of Paliperidone Palmitate in Patients With Schizophrenia
NCT00391222 - A Randomized, Double Blind, Placebo and Active Controlled Parallel Group Study to Evaluate the Efficacy and Safety of Risperidone Long-acting Injectable (LAI) for the Prevention of Mood Episodes in the Treatment of Subjects With Bipolar I
NCT00034749 - The Efficacy and Safety of Risperidone in Adolescents With Schizophrenia: a Comparison of Two Dose Ranges of Risperidone
NCT00076115 - Research on the Effectiveness of Risperidone in Bipolar Disorder in Adolescents and Children (REACH): A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy and Safety of Risperidone for the Treatment of Acute Mania in Bipola
NCT00132678 - A Randomized, Double-blind, Placebo-controlled Study to Explore the Efficacy and Safety of Risperidone Long-acting Intramuscular Injectable in the Prevention of Mood Episodes in Bipolar 1 Disorder, With Open-label Extension
NCT00094926 - A Prospective, Randomized, Double-blind, Placebo-controlled Study of the Effectiveness and Safety of RISPERDAL CONSTA Augmentation in Adult Patients With Frequently-relapsing Bipolar Disorder
NCT00210782 - A Double-blind Trial Comparing the Efficacy, Tolerability and Safety of Monotherapy Topiramate Versus Phenytoin in Subjects With Seizures Indicative of New Onset Epilepsy
NCT00210535 - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Topiramate for the Prophylaxis of Migraine in Pediatric Subjects 12 to 17 Years of Age
NCT00210860 - An Open-label Study of the Safety and Efficacy of Topiramate for Migraine Prophylaxis: Extension Study to CAPSS-277
NCT00714688 - A Multicentre, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate Efficacy and Safety of Prolonged Release (PR) OROS Methylphenidate (54 and 72 mg/Day) in Adults With Attention Deficit/Hyperactivi
NCT00866996 - A Multi-center Randomized Parallel Group Study Evaluating Treatment Outcomes of Concerta (Extended Release Methylphenidate) and Strattera (Atomoxetine) in Children With Attention-deficit/Hyperactivity Disorder
NCT00269815 - Long-term Safety and Effectiveness of OROS (Methylphenidate HCl) in Children With ADHD
NCT00397033 - A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Two Dosages of Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder
NCT00412373 - A Randomized, Double-blind, Placebo-controlled, Parallel- Group Study to Evaluate the Efficacy and Safety of Flexible-dose Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder
NCT00236444 - Risperidone in the Prevention of Relapse: a Randomized, Double-blind, Placebo-controlled Trial in Children and Adolescents With Conduct and Other Disruptive Behavior Disorders
NCT00236470 - Risperidone in the Treatment of Children and Adolescents With Conduct and Other Disruptive Behavior Disorders - an Open Label Follow-up Trial of CR002020
NCT00250354 - The Safety And Efficacy Of Risperidone Versus Placebo In Conduct Disorder In Mild, Moderate And Borderline Mentally Retarded Children Aged 5 To 12 Years
NCT00266552 - The Safety And Efficacy Of Risperidone Versus Placebo In Conduct Disorder and Other Disruptive Behavior Disorders In Mild, Moderate And Borderline Mentally Retarded Children Aged 5 To 12 Years
NCT00237289 - Topiramate Versus Placebo as add-on Treatment in Patients With Bipolar Disorder in the Outpatient Setting
NCT00240721 - A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-Week Study Of The Safety And Efficacy Of Two Doses Of Topiramate For The Treatment Of Acute Manic Or Mixed Episodes In Subjects With

Bipolar I Disorder With An Optional Open-La
NCT00638690 - A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy
NCT00540449 - A Phase III, Randomized, Double-blind Trial of TMC278 25 mg q.d. Versus Efavirenz 600mg q.d. in Combination With a Fixed Background Regimen Consisting of Tenofovir Disoproxil Fumarate and Emtricitabine in Antiretroviral-naive HIV-1 Infecte
NCT00543725 - A Phase III, Randomized, Double-blind Trial of TMC278 25mg q.d. Versus Efavirenz 600mg q.d. in Combination With a Background Regimen Containing 2 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors in Antiretroviral-naive HIV-1 Infected
NCT00642278 - A Randomized, Double-Blind, Placebo-Controlled, Double-Dummy, Parallel Group, Multicenter, Dose-Ranging Study in Subjects With Type 2 Diabetes Mellitus to Evaluate the Efficacy, Safety, and Tolerability of Orally Administered SGLT2 Inhibit
NCT01106625 - A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemi
NCT01064414 - A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, 26-Week, Multicenter Study With a 26-Week Extension, to Evaluate the Efficacy, Safety and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabete
NCT01081834 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin as Monotherapy in the Treatment of Subjects With Type 2 Diabetes Mellitus Inadequately Co
NCT01106677 - A Randomized, Double-Blind, Placebo and Active-Controlled, 4-Arm, Parallel Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequ
NCT00968812 - A Randomized, Double-Blind, 3-Arm Parallel-Group, 2-Year (104-Week), Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-28431754 Compared With Glimepiride in the Treatment of Subjects With Type 2 Diabetes Mellitus
NCT01106651 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin Compared With Placebo in the Treatment of Older Subjects With Type 2 Diabetes Mellitus In
NCT01106690 - A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemi
NCT01137812 - A Randomized, Double-Blind, Active-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin Versus Sitagliptin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Con
NCT00207662 - ACCENT I - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long-term Treatment of Patients With Moderately to Severely Active Crohn's Disease
NCT00207766 - ACCENT II - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long Term Treatment of Patients With Fistulizing CROHN'S Disease
NCT00004941 - A Placebo-controlled, Repeated-dose Study of Anti-TNF Chimeric Monoclonal Antibody (cA2) in the Treatment of Patients with Enterocutaneous Fistulae as a Complication of Crohn’s Disease
NCT00269867 - A Placebo-Controlled, Double-Blinded, Randomized Clinical Trial of Anti-TNF Chimeric Monoclonal Antibody (cA2) in Patients With Active Rheumatoid Arthritis Despite Methotrexate Treatment
NCT00236028 - A Randomized, Double-blind, Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate Compared With Methotrexate Alone for the Treatment of Patients With Early Rheumatoid Arthritis
NCT00236509 - A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate in the Prophylaxis of Migraine
NCT00231595 - A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate in the Prophylaxis of Migraine
NCT00236561 - A Randomized, Double-Blind, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of Two Doses of Topiramate Compared to Placebo and Propranolol in the Prophylaxis of Migraine
NCT00216606 - A Randomized Double-Blind Placebo Controlled Trial to Investigate the Efficacy and Tolerability of Topiramate in the Prophylaxis of Chronic Migraine
NCT00212810 - TOPAMAX (Topiramate) Intervention to Prevent Transformation of Episodic Migraine: The

Topiramate INTREPID Study
NCT00210912 - A Comparison of the Efficacy and Safety of Topiramate Versus Placebo for the Prophylaxis of Chronic Migraine
NCT00037674 - A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-Week Study of the Safety and Efficacy of Two Doses of Topiramate for the Treatment of Acute Manic or Mixed Episodes in Patients With Bipolar I Disorder With an Optional Open-La
NCT00035230 - A Randomized, Double-Blind, Multicenter, Placebo-Controlled 12-Week Study of the Safety and Efficacy of Topiramate in Patients With Acute Manic or Mixed Episodes of Bipolar I Disorder With an Optional Open-Label Extension
A Randomized, Double-Blind, Multicenter, Placebo-Controlled, 21-Day Study of the Safety and Efficacy of Topiramate for the Treatment of Acute Manic or Mixed Episodes in Subjects With Bipolar I Disorder With an Optional Open-Label Extension
NCT00210886 - A Multicenter, Double-blind, Randomized Study to Compare the Efficacy and Safety of Levofloxacin 750 mg Once Daily for Five Days Versus Ciprofloxacin Twice Daily for Ten Days in the Treatment of Complicated Urinary Tract Infection and Acu
NCT00253201 - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease
NCT00304629 - Long Term Safety and Efficacy of Galantamine in Alzheimer's Disease (Extension INT-8)
NCT00253227 - Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial
NCT00882908 - A Phase IIb, Randomized, Double-Blind, Placebo-Controlled Trial to Investigate the Efficacy, Tolerability, Safety and Pharmacokinetics of TMC435 as Part of a Treatment Regimen Including Peginterferon Alfa-2a and Ribavirin In Treatment-Naiv
NCT00980330 - A Phase IIb, Randomized, Double-Blind, Placebo-Controlled Trial to Investigate the Efficacy, Tolerability, Safety and Pharmacokinetics of TMC435 as Part of a Treatment Regimen Including PegIFNa-2a and Ribavirin in HCV Genotype 1 Infected S
NCT01289782 - A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety and Tolerability of TMC435 vs Placebo as Part of a Treatment Regimen Including Peginterferon ?-2a and Ribavirin in Treatment-naïve, Genotyp
NCT01290679 - A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety and Tolerability of TMC435 Versus Placebo as Part of a Treatment Regimen Including Peginterferon ?-2a (Pegasys®) and Ribavirin (Copegus®)
NCT01281839 - A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety and Tolerability of TMC435 vs Placebo as Part of a Treatment Regimen Including Peginterferon ?-2a and Ribavirin in Hepatitis C, Genotype 1 I
NCT00216502 - Long Term Treatment With Galantamine In Dementia
NCT00799409 - The ABC Study: A Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral, and Cognitive Effects of CONCERTA on Older Children With ADHD
NCT00799487 - Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children With ADHD (The ABC Study)
Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease
Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease
NCT00202865 - Evaluation of Low Dose Infliximab in Ankylosing Spondylitis (CANDLE)
NCT00537316 - Efficacy & Safety of Infliximab Monotherapy Vs Combination Therapy Vs AZA Monotherapy in Ulcerative Colitis (Part 1) Maintenance Vs Intermittent Therapy for Maintaining Remission (Part 2)
NCT01385202 - THERMOCOOL® SMARTTOUCH™ Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation
NCT00449644 - A Phase II, Placebo-controlled, Double-blind, Randomized Trial to Evaluate the Anti-bacterial Activity, Safety, and Tolerability of TMC207 in Subjects With Newly Diagnosed Sputum Smear-positive Pulmonary Infection With Multi-drug Resistan
NCT00910871 - A Phase II, Open-label Trial With TMC207 as Part of a Multi-drug Resistant Tuberculosis (MDR-TB) Treatment Regimen in Subjects With Sputum Smear-positive Pulmonary Infection With MDR-TB.
NCT00249132 - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients
NCT00265096 - A Multicenter, Randomized, Double-blind, Placebo controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously in Subjects with Active Psoriatic Arthritis
NCT01009086 - A Study of the Safety and Effectiveness of Ustekinumab in Patients With Psoriatic Arthritis
NCT01077362 - A Study of the Safety and Efficacy of Ustekinumab in Patients With Psoriatic Arthritis With and Without Prior Exposure to Anti-TNF Agents
NCT00216476 - CONSTATRE: Risperdal® Consta® Trial of Relapse Prevention and Effectiveness
NCT00216580 - An Open-label Trial of Risperidone Long-acting Injectable in the Treatment of Subjects With

Recent Onset Psychosis
NCT00253162 - The Efficacy And Safety Of Flexible Dose Ranges Of Risperidone Versus Placebo Or Haloperidol In The Treatment Of Manic Episodes Associated With Bipolar I Disorder.
NCT00378092 - A Prospective Study of the Clinical Outcome Following Treatment Discontinuation After Remission in First-Episode Schizophrenia
NCT00299715 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response, Multicenter Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended-Release Paliperidone in the Treatment of Subjects With Acute Manic and Mi
NCT00309699 - A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed, Extended-Release Paliperidone Compared With Flexibly-Dosed Quetiapine and Placebo in the T
NCT00309686 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed Extended-Release Paliperidone as Adjunctive Therapy to Mood Stabilizers in the Treatment of Acute Manic
NCT00752427 - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Tolerability of Extended Release OROS Paliperidone in Geriatric Patients
NCT00077714 - A Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 2 Fixed Dosages of Paliperidone Extended Release Tablets and Olanzapine, With Open-label Extension, in t
NCT00083668 - A Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Paliperidone Extended Release (ER) Tablets and Olanzapine, With Open-label Extension,
NCT00074477 - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 and 100 Mg-eq of Paliperidone Palmitate in Patients With Schizophrenia
NCT00211133 - A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Impact of Maintaining Hemoglobin Using Eprex (Epoetin Alfa) in Metastatic Breast Carcinoma Subjects Receiving Chemotherapy
NCT00270127 - Double-Blind, Placebo-Controlled Study to Assess the Effect of Early Intervention and/or Treatment With Epoetin Alfa on Anemia in Cancer Patients Receiving Non-Platinum-Containing Chemotherapy
NCT00270166 - A Placebo-Controlled Study on the Effect of Epoetin Alfa in Patients With Malignancy Receiving Chemotherapy
NCT00270049 - The Effect of Subcutaneous r-HuEPO in Patients With Chronic Lymphocytic Leukemia
NCT00270101 - A Placebo-Controlled Study on the Effect of r-huEPO in Patients With Multiple Myeloma Followed by an Open-Label Extension
NCT00270283 - A Double-Blind, Placebo-Controlled Study With Open-Label Follow-up to Determine the Safety and Efficacy of Subcutaneous Doses of r-HuEPO in AIDS Patients With Anemia Induced by Their Disease and AZT Therapy
NCT00091910 - A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of Epoetin Alfa in Critically Ill Subjects
NCT00078039 - Trial Evaluating Three Fixed Dosages of Paliperidone Extended-Release (ER) Tablets and Olanzapine in the Treatment of Patients With Schizophrenia
Efficacy in the rHuEPO (Epoetin Alfa) in the Critically Ill Patient: A Randomized, Double Blind, Placebo-Controlled trial
NCT00653952 - A Phase 3, Randomized, Open-Label, Comparative Study of CAELYX® versus Paclitaxel HCl in Patients with Epithelial Ovarian Carcinoma Following Failure of First-Line, Platinum-Based Chemotherapy
A Phase 3, Randomized, Open-Label, Comparative Study of DOXIL/CAELYX® versus Topotecan HCl in Patients with Epithelial Ovarian Carcinoma Following Failure of First-Line, Platinum-Based Chemotherapy
What type of data are you looking for?: Individual Participant-Level Data, which includes Full CSR and all supporting documentation

Research Proposal

Project Title

Population Representativeness of Clinical Trial Study Samples

Narrative Summary:
Population representativeness of clinical trial study samples directly influences the generalizability of clinical trial

results. We aim to develop a multivariate representativeness measure to quantify the population representativeness of the study samples of each clinical trial. We will compare the clinical trial study samples to real-world patients using this measure.

Scientific Abstract:
Background:
The lack of population representativeness in clinical trial study samples has been a persistent problem that has been observed across disease domains. Numerous studies have shown the differences between real-world patients and clinical trial study samples. This problem is significant in that the lack of population representativeness can compromise the generalizability of clinical trial results and lead to unforeseen adverse events among the real-world patients. It is imperative to improve the transparency of the population representativeness of clinical trial samples using systematic analyses.

Objective:
Our study aims to develop a quantitative metric that is able to quantify the population representativeness of each trial using multiple study traits while accounting for their dependencies and relevancies.

Study Design:
We will design and validate the population representative metric by comparing patient-level clinical trial sample to real-world target populations made available by electronic health records. For each trial, we will identify the real-world target population in our institution's clinical data warehouse, which contains 4.5 million patients' 20 years of data. We will profile the study samples and the target population for each trial and measure the representativeness of study sample of the target population.

Participants:
all enrolled patients in the trials.

Main outcome measures:
a score of population representativeness of each trial

Statistical analysis:
our metric for representativeness is statistically-based

Brief Project Background and Statement of Project Significance:
In every study, investigators need to extrapolate study results from the Study Sample, which comprises all the individuals enrolled in a study, to the Target Population, which comprises all individuals for whom a treatment may be considered for its intended purpose. The Sample population is recruited from and is a subset of a Study Population, which is defined by the eligibility criteria and comprises all individuals who would be eligible to enroll in that study. Thus the population representativeness of the Study Population is a function of the eligibility criteria and directly influences the generalizability of the study results. Ideally, the definition of the study population should be optimized to reflect the target population. Since it is impossible to accurately profile the Target Population A, we can approximate A by profiling all the members of A who have EHR data, which we call Target Population with EHRs.

Our core hypothesis is that the more accurately clinical investigators can characterize the target population as defined by EHR data -- the better informed and prepared they will be able to define eligibility criteria to construct the study population to appropriately represent the true Target Population. This research will help cultivate a new culture of clarity and transparency about eligibility criteria, in which investigators are expected and supported to explain and justify the rationale for their eligibility criteria choices. Such transparency will enable more effective measures to reduce clinical research biases and improve research reliability.

This research promises to improve the transparency of the population representativeness of clinical research eligibility criteria and hence reduce biases and improve research reliability, and enable early iterative in silico estimates of feasibility and population representativeness

Specific Aims of the Project:
The specific aims of this project are
(a) developing a multi-feature representativenss metric
(b) measure the population representativness of the study samples of the included 123 trials in the Yoda database

What is the purpose of the analysis being proposed? Please select all that apply. New research question to examine treatment safety
Participant-level data meta-analysis
Participant-level data meta-analysis uses only data from YODA Project

Research Methods

Data Source and Inclusion/Exclusion Criteria to be used to define the patient sample for your study:
Data sources:
1. all study samples in the Yoda database
2. EHR-based target population characteristics from our institutional clinical data warehouse

Main Outcome Measure and how it will be categorized/defined for your study:
population representativeness of each clinical trial

Main Predictor/Independent Variable and how it will be categorized/defined for your study:
None

Other Variables of Interest that will be used in your analysis and how they will be categorized/defined for your study:
None

Statistical Analysis Plan:
We will use a quantitative metric to analyze population representativeness

Project Timeline:
we expect to use 1 year to complete this project:

months 1-3: data collection
months 4-6: study sample and target population profiling
months 4-9: population represetnativess analysis and evaluation
months 6-12: publication

Dissemination Plan:
we will publish and presenting our methods in peer-reviewed mainstream informatics journals and conferences.

Bibliography:
Weng C,
Optimizing Clinical Research Participant Selection with Informatics,
Trends in Pharmacological Sciences 36 (2015), Cell Press, pp. 706-709. PDF

Ma H, Weng C,
Identification of Questionable Exclusion Criteria in Mental Disorder Clinical Trials Using a Medical Encyclopedia,
2016 Pacific Symposium on Biocomputing, in press. (Travel Awardee)

He Z, Chandar P, Ryan PB, Weng C,
Simulation-based Evaluation of the Generalizability Index for Study Traits,
AMIA Annu Fall Symp, 2015, in press. PDF (Distinguished Paper Award)

He Z, Wang S, Borhanian E, Weng C,
Assessing the Collective Population Representativeness of Related Type 2 Diabetes Trials by Combining Multiple Public Data Resources,
Proc of MedInfo’2015, Sao Paulo, Brazil, 19-23 August, accepted. PDF

He Z, Carini S, Sim I, Weng C,
Visual Aggregate Analysis of Eligibility Features in Clinical Trials,

Journal of Biomedical Informatics, 2015 Jan 20. pii: S1532-0464(15)00007-6. PMID: 25615940 PDF

He Z, Carini S, Hao T, Sim I, Weng C,
A Method for Analyzing Commonalities in Clinical Trial Target Populations,
Proc of AMIA 2014 Fall Symp, Nov 15-19, 2014, Washington DC, 1777-1786. PMID: 25954450

Weng C, Li Y, Ryan P, Zhang Y, Gao J, Liu F, Bigger JT, Hripcsak G,
A Distribution-based Method for Assessing The Differences between Clinical Trial Target Populations and Patient Populations in Electronic Health Records,
Applied Clinical Informatics, Vol. 5: Issue 2 2014, 463-479. PMID: 25024761 PDF

Weng C, Yaman A, Lin K, He Z,
Trend and Network Analysis of Common Eligibility Features for Cancer Trials in ClinicalTrials.gov,
Smart Health Lecture Notes in Computer Science Volume 8549, 2014, pp 130-141

* Hao T, Rusanov A, Boland MR, Weng C,
Clustering Clinical Trials with Similar Eligibility Criteria Features,
J Biomed Inform, 2014 Feb 1. pii: S1532-0464(14)00011-2. PMID: 24496068