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How did you learn about the YODA Project?: Internet Search

Conflict of Interest

https://yoda.yale.edu/wp-content/uploads/2025/05/coi.pdf
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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

1. NCT00575055 - ELN115727-302 - A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) In Patients With Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein E4 Carriers
2. NCT00574132 - ELN115727-301 - A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) In Patients With Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein E4 Non-Carriers
3. NCT00253201 - GAL-USA-1 - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease
4. NCT00304629 - GAL-USA-3 - Long Term Safety and Efficacy of Galantamine in Alzheimer's Disease (Extension INT-8)
5. NCT00253227 - GAL-INT-2 - Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial
6. - GAL-INT-3 - Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease
7. - GAL-INT-7 - Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease
8. NCT00261573 - GAL-INT-6 - The Safety and Efficacy of Galantamine in the Treatment of Vascular and Mixed Dementia
9. NCT00253188 - GAL-INT-1 - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease
10. NCT00253214 - GAL-INT-10 - Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation
11. NCT00236574 - CR003145 // GAL-INT-11 - A Randomized Double Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease
12. NCT00236431 - GAL-INT-18 - A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease

13. - GAL-MVD-302 - Galantamine treatment of vascular dementia: a randomized trial
14. NCT00679627 - GALALZ3005 - A Randomized, Double-Blind, Placebo-controlled Trial of Long-term (2-year) Treatment of Galantamine in Mild to Moderately-Severe Alzheimer's Disease
15. NCT00216593 - GAL-ALZ-302 (PMID # 19042161-CR003940) - Treatment of Severe Alzheimer's Disease in a Residential Home, Nursing Home, or Geriatric Residential Setting: Evaluation of Efficacy and Safety of Galantamine Hydrobromide in a Randomised, Doubleblind, Placebo-Controlled Study
16. NCT00645190 - GAL-CHN-T100 - A Randomized, Double Blind, Active Control, Flexible Dose, Multicenter Study to Evaluate Galantamine HBr in the Treatment of Alzheimer's Disease:Safety and Effectiveness of an Immediate-release Table Formulation.
17. - GAL-USA-10 - Placebo-controlled evaluation of galantamine in the treatment of Alzheimer's disease: Evaluation of safety and efficacy under a slow titration regimen
18. - GAL-93-01 - A group comparative, placebo-controlled, double-blind trial of the efficacy and safety of galantamine hydrobromide, 7.5 mg (6 mg galantamine base) TID, 10 mg (8 mg galantamine base) TID and 15 mg (12 mg galantamine base) TID taken orally for 12 weeks in patients with a diagnosis of senile dementia of the Alzheimer's type
19. - RIS-INT-83 - Efficacy and safety of a flexible dose of risperidone versus placebo in the treatment of psychosis of Alzheimer's disease. A double-blind, placebo-controlled, parallel-group study.
20. NCT00034762 - RIS-USA-232/CR002764 - Efficacy And Safety Of A Flexible Dose Of Risperidone Versus Placebo In The Treatment Of Psychosis Of Alzheimer's Disease
21. NCT00086112 - RIS-ANX-301 - A Double-blind, Randomized, Prospective Study to Evaluate Adjunctive Risperidone Versus Adjunctive Placebo in Generalized Anxiety Disorder Sub-optimally Responsive to Standard Psychotropic Therapy
22. NCT00299715 - R076477-BIM-3001 - 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 Mixed Episodes Associated With Bipolar I Disorder
23. NCT00309699 - R076477-BIM-3002 - 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 Treatment of Acute Manic and Mixed Episodes Associated With Bipolar I Disorder
24. NCT00309686 - R076477-BIM-3003 - 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 and Mixed Episodes Associated With Bipolar I Disorder
25. NCT00490971 - R076477BIM3004 - A Randomized, Double-Blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Extended-Release Paliperidone as Maintenance Treatment After an Acute Manic or Mixed Episode Associated With Bipolar I Disorder
26. NCT00391222 - RISBMN3001 - 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 Disorder
27. NCT00076115 - RIS-BIM-301 - 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 Bipolar I Disorder
28. NCT00132678 - RISBIM3003 - 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
29. NCT00094926 - RIS-BIP-302 - 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
30. NCT00253162 - RIS-INT-69 - 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

31. NCT00249236 - RIS-IND-2/CR006064 - The Efficacy And Safety Of Flexible Dosage Ranges Of Risperidone Versus Placebo In The Treatment Of Manic Or Mixed Episodes Associated With Bipolar I Disorder
32. NCT00250367 - RIS-INT-46/CR006058 - The Safety And Efficacy Of Risperdal (Risperidone) Versus Placebo As Add-On Therapy To Mood Stabilizers In The Treatment Of The Manic Phase Of Bipolar Disorder
33. NCT00253149 - RIS-USA-102/CR006040 - The Safety And Efficacy Of Risperdal (Risperidone) Versus Placebo Versus Haloperidol As Add-On Therapy To Mood Stabilizers In The Treatment Of The Manic Phase Of Bipolar Disorder
34. NCT00257075 - RIS-USA-239/CR006052 - The Efficacy And Safety Of Flexible Dosage Ranges Of Risperidone Versus Placebo In The Treatment Of Manic Episodes Associated With Bipolar I Disorder
35. - RIS-USA-240 - The efficacy and safety of flexible dose ranges of risperidone vs. Placebo or divalproex sodium in the treatment of manic or mixed episodes associated with bipolar 1 disorder
36. NCT00246246 - RIS-BIP-301 - A Randomized, Open-label Trial of RISPERDAL(R) CONSTA(TM) Versus Oral Antipsychotic Care in Subjects With Bipolar Disorder
37. NCT00237289 - CR002653 (CAPSS-168) - Topiramate Versus Placebo as add-on Treatment in Patients With Bipolar Disorder in the Outpatient Setting
38. NCT00240721 - TOPMAT-PDMD-005 (CR002248) - 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-Label Extension
39. NCT00037674 - TOPMAT-PDMD-004 - 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-Label Extension
40. NCT00035230 - TOPMAT-PDMD-008 - 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
41. - TOPMAT-PDMD-006 - 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
42. NCT00249158 - RIS-AUS-5/CR006010 - Risperidone in the Treatment of Behavioural and Psychological Signs and Symptoms in Dementia (BPSSD): a Multicentre, Double-blind, Placebo-controlled Parallel-group Trial
43. - RIS-BEL-14 - Risperidone in the treatment of behavioural disturbances in patients with Alzheimer's dementia: a double-blind placebo-controlled trial
44. NCT00249145 - RIS-INT-24/CR006046 - Risperidone in the Treatment of Behavioral Disturbances in Demented Patients: an International, Multicenter, Placebo-controlled, Double-blind, Parallel-group Trial Using Haloperidol as Internal Reference
45. NCT00253123 - RIS-USA-63/CR006022 - A Randomized, Double-Blind, Placebo-Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects With Dementia
46. - RIS-USA-70 (EXTENSION OF RIS-USA-63) CR003361, RIS-USA-T216 - An open-label, long-term study of risperidone for the treatment of behavioral disturbances in patients with dementia
47. NCT02417064 - ESKETINTRD3001 - A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression
48. NCT02418585 - ESKETINTRD3002 - A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression
49. NCT02422186 - ESKETINTRD3005 - A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Intranasal Esketamine Plus an Oral Antidepressant in Elderly Subjects With Treatment-resistant Depression
50. NCT02497287 - ESKETINTRD3004 - An Open-label, Long-term, Safety and Efficacy Study of

Intranasal Esketamine in Treatment-resistant Depression
51. NCT02493868 - ESKETINTRD3003 - A Randomized, Double-blind, Multicenter, Active-Controlled Study of Intranasal Esketamine Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression
52. NCT02133001 - ESKETINSUI2001 - A Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Who Are Assessed to be at Imminent Risk for Suicide
53. NCT03039192 - 54135419SUI3001 - A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Subjects Assessed to be at Imminent Risk for Suicide
54. NCT03097133 - 54135419SUI3002 - A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Subjects Assessed to be at Imminent Risk for Suicide
55. NCT02918318 - 54135419TRD2005 - A Randomized, Double-blind, Multicenter, Placebo-controlled Study to Evaluate the Efficacy, Safety and Tolerability of Fixed Doses of Intranasal Esketamine in Japanese Subjects With Treatment Resistant Depression
56. NCT01627782 - KETIVTRD2002 - A Double-blind, Randomized, Placebo-controlled, Parallel Group, Dose Frequency Study of Ketamine in Subjects With Treatment-resistant Depression
57. NCT01640080 - ESKETIVTRD2001 - A Double-Blind, Double-Randomization, Placebo-Controlled Study of the Efficacy of Intravenous Esketamine in Adult Subjects With Treatment-Resistant Depression
58. NCT00246233 - 42603MDD3001 (CON-CAN-3) - A Double-blind, Placebo-controlled, Randomized Trial to Evaluate the Safety, Tolerability and Efficacy of CONCERTA(R) (Methylphenidate Hydrochloride) Augmentation of SSRI/SNRI Monotherapy in Adult Patients With Major Depressive Disorder.
59. NCT00044681 - RIS-INT-93 - A Study to Evaluate the Efficacy, Safety and Maintenance Effect of Risperidone Augmentation of SSRI Monotherapy in Young and Older Adult Patients With Unipolar Treatment-Resistant Depression
60. NCT00095134 - RIS-DEP-401 - A Double-Blind Study Comparing Adjunctive Risperidone Versus Placebo in Major Depressive Disorder That Is not Responding to Standard Therapy
61. NCT01998958 - ESKETINTRD2003 - A Double-Blind, Doubly-Randomized, Placebo-Controlled Study of Intranasal Esketamine in an Adaptive Treatment Protocol to Assess Safety and Efficacy in Treatment-Resistant Depression (SYNAPSE)
62. NCT03434041 - ESKETINTRD3006 - A Randomized, Double-blind, Multicenter Active-controlled Study to Evaluate the Efficacy, Pharmacokinetics, Safety and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression
63. NCT00642278 - 28431754DIA2001 - 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 Inhibitor JNJ-28431754 With Sitagliptin as a Reference Arm
64. NCT01106625 - 28431754DIA3002 - 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 Glycemic Control on Metformin and Pioglitazone Therapy
65. NCT01064414 - 28431754DIA3004 - 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 Diabetes Mellitus Who Have Moderate Renal Impairment
66. NCT01081834 - 28431754DIA3005 - 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 Controlled With Diet and Exercise
67. NCT01106677 - 28431754DIA3006 - 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 Inadequate Glycemic Control on Metformin Monotherapy

68. NCT00968812 - 28431754DIA3009 - 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 Not Optimally Controlled on Metformin Monotherapy
69. NCT01106651 - 28431754DIA3010 - 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 Inadequately Controlled on Glucose Lowering Therapy
70. NCT01106690 - 28431754DIA3012 - 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 Glycemic Control on Metformin and Sulphonylurea Therapy
71. NCT01137812 - 28431754DIA3015 - 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 Control on Metformin and Sulphonylurea Therapy
72. NCT01809327 - 28431754DIA3011 - A Randomized, Double-Blind, 5-Arm, Parallel-Group, 26-Week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in Combination With Metformin as Initial Combination Therapy in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control With Diet and Exercise
73. NCT01381900 - 28431754DIA3014 - A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 18-Week Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Alone or in Combination With a Sulphonylurea
74. NCT01340664 - 28431754DIA2003 - 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 Glycemic Control on Metformin
75. NCT02025907 - 28431754DIA4004 - A Randomized, Double-blind, Placebo Controlled, 2-arm, Parallel-group, 26-week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sitagliptin Therapy
76. NCT01032629 - 28431754DIA3008 - A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ-28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus
77. NCT01989754 - 28431754DIA4003 - A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus
78. NCT02065791 - 28431754DNE3001 - A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy
79. NCT03267576 - 28431754DIA4026 - Canagliflozin Continuous Glucose Monitoring (CANA CGM) Trial: A Pilot Randomized, Double-Blind, Controlled, Crossover Study on the Effects of the SGLT-2 Inhibitor Canagliflozin (vs. the DPP-4 Inhibitor Sitagliptin) on Glucose Variability in Mexican Patients With Type 2 Diabetes Mellitus Inadequately Controlled on Metformin
80. NCT00231530 - TOPMAT-OBDM-003 - A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients on a Controlled Diet
81. NCT00231673 - TOPMAT-NP-005 - A Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Effect of Topiramate on Electrophysiological Parameters in Subjects With Diabetic Peripheral Polyneuropathy
82. - 02-161 - Tolerability and Multiple-Dose Pharmacokinetics of Acetaminophen (Paracetamol) At and Above the Currently Recommended Maximum Daily Dose
83. 97-024 - 97-024 - Multiple-Dose Pharmacokinetic Study of an Ibuprofen-Psuedoephedrine HCl Suspension in Children, Aug 1999.
84. NCT01173562 - MEBENDAZOLGAI3002 - An Open-Label, Single-Dose Study to Assess the

Safety of 500-mg Mebendazole Chewable Formulation in Children 2 to 10 Years of Age, Inclusive

85. NCT00236665 - TOPMAT-OBHT-001 - A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese Patients With Mild to Moderate Essential Hypertension
86. NCT00207727 - C0743T06 - A Phase II, Double-blind, Placebo-Controlled, Randomized, Dose-ranging Study of Multiple Subcutaneous Injections of Human Monoclonal Antibody to IL-12p40 (CNTO1275) in Subjects With Relapsing-remitting Multiple Sclerosis
87. NCT00113815 - TOPMATPEP3001 - A Randomized, Double-Blind, Placebo-Controlled, Fixed Dose-Ranging Study to Assess the Safety, Tolerability, and Efficacy of Topiramate Oral Liquid and Sprinkle Formulations as an Adjunct to Concurrent Anticonvulsant Therapy for Infants (1-24 Months of Age) With Refractory Partial-Onset Seizures
88. NCT01483599 - CNTO1959PSO2001 - 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 (X-PLORE)
89. NCT02203032 - CNTO1959PSO3003 - A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Guselkumab for the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis and an Inadequate Response to Ustekinumab
90. NCT02207231 - CNTO1959PSO3001 - Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis
91. NCT02207244 - CNTO1959PSO3002 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis With Randomized Withdrawal and Retreatment
92. NCT02905331 - CNTO1959PSO3006 - A Phase 3, Multicenter, Randomized, Double-blind Placebo-controlled Study Evaluating the Efficacy and Safety of CNTO 1959 (Guselkumab) Delivered Via a SelfDose (TM) Device in the Treatment of Subjects With Moderate to Severe Plaque-Type Psoriasis
93. NCT02325219 - CNTO1959PSO3004 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of CNTO 1959 (Guselkumab) in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis
94. NCT02951533 - CNTO1959PSO3008 - Multicenter, Randomized, Open-Label, Efficacy Assessor-Blinded, Active Comparator-Controlled Phase 3b Study to Compare the Efficacy of Guselkumab to Fumaric Acid Esters (Fumaderm Initial/ Fumaderm) for Adult Patients With Moderate to Severe Plaque Psoriasis Who Are Candidates for and Naive to Systemic Treatment
95. NCT03090100 - CNTO1959PSO3009 - A Phase 3, Multicenter, Randomized, Double-blind Study Evaluating the Comparative Efficacy of CNTO 1959 (Guselkumab) and Secukinumab for the Treatment of Moderate to Severe Plaque-type Psoriasis
96. NCT00106834 - CR003130 / C0168T38 - A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Infliximab Induction and Maintenance Therapy in Patients With Moderate to Severe Plaque Psoriasis
97. NCT00230529 - CR003124 / C0168T31 - A Phase II, Multicenter, Randomized, Double-blind, Placebo-controlled Trial Evaluating the Efficacy and Safety of Infliximab (REMICADE) Induction Therapy in Patients With Plaque-type Psoriasis
98. NCT02295865 - 38518168PSO2001 - A Phase 2 Multicenter, Randomized, Double-blind, Placebo-Controlled, Trial to Evaluate Toreforant (JNJ-38518168) for the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis
99. NCT01009086 - CNTO1275PSA3001 /// PSUMMIT I - A Study of the Safety and Effectiveness of Ustekinumab in Patients With Psoriatic Arthritis
100. NCT01077362 - CNTO1275PSA3002 /// PSUMMIT II - A Study of the Safety and Efficacy of Ustekinumab in Patients With Psoriatic Arthritis With and Without Prior Exposure to Anti-TNF Agents
101. NCT00267969 - C0743T08 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo Controlled Trial Evaluating the Efficacy and Safety of Ustekinumab (CNTO 1275) in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis
102. NCT00307437 - C0743T09 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-

controlled Trial Evaluating the Efficacy and Safety of CNTO 1275 in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis
103. NCT01550744 - CNTO1275PSO3009 - A Phase 3b, Randomized, Double-blind, Active-controlled, Multicenter Study to Evaluate a "Subject-tailored" Maintenance Dosing Approach in Subjects With Moderate-to-Severe Plaque Psoriasis
104. NCT00723528 - JNS009-JPN-02 - A Placebo-Controlled Double-Blind Comparative Study of CNTO1275 in Patients With Plaque Type Psoriasis
105. NCT00320216 - C0379T04 - A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel Study of Single and Multiple Dose Regimens With Subcutaneous CNTO 1275 (Human Monoclonal Antibody to IL-12) in Subjects With Moderate to Severe Psoriasis
106. NCT00454584 - C0743T12 - A Phase 3, Multicenter, Randomized Study Comparing CNTO 1275 and Etanercept for the Treatment of Moderate to Severe Plaque Psoriasis
107. NCT00747344 - C0743T25 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Korean and Taiwanese Subjects With Moderate to Severe Plaque-type Psoriasis
108. NCT01008995 - C0743T23 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Chinese Subjects With Moderate to Severe Plaque-type Psoriasis
109. NCT01059773 - CNTO1275PSO4004 - An Exploratory Trial to Assess Naturalistic Safety and Efficacy Outcomes in Patients With Moderate to Severe Plaque Psoriasis Transitiioned to Ustekinumab From Previous Methotrexate Therapy (TRANSIT)
110. NCT01090427 - CNTO1275PSO3006 - A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the of Efficacy and Safety of Ustekinumab in the Treatment of Adolescent Subjects With Moderate to Severe Plaque-type Psoriasis (CADMUS)
111. NCT02698475 - CNTO1275PSO3013 - A Phase 3 Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Ustekinumab in the Treatment of Moderate to Severe Chronic Plaque Psoriasis in Pediatric Subjects Greater Than or Equal to 6 to Less Than 12 Years of Age
112. NCT00319111 - AC-052-370 (BENEFIT OL) - Long-term Open-label Extension Study in Patients With Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH) Who Completed Protocol AC-052-366 (BENEFIT)
113. NCT00303459 - AC-052-414 (COMPASS-2) - Effects of Combination of Bosentan and Sildenafil Versus Sildenafil Monotherapy on Morbidity and Mortality in Symptomatic Patients With Pulmonary Arterial Hypertension - A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group, Prospective, Event Driven Phase IV Study
114. NCT00433329 - AC-052-419 - COMPASS 3: An Open-label, Multi-Center Study Employing a Targeted 6-Minute Walk Test (6-MWT) Distance Threshold Approach to Guide Bosentan-Based Therapy and to Assess the Utility of Magnetic Resonance Imaging (MRI) on Cardiac Remodeling
115. NCT00091715 - AC-052-364 - A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Bosentan in Patients With Mildly Symptomatic Pulmonary Arterial Hypertension (PAH)
116. NCT00319267 - AC-052-365 - An Open Label, Multicenter Study to Assess the Pharmacokinetics, Tolerability, and Safety of a Pediatric Formulation of Bosentan in Children With Idiopathic or Familial Pulmonary Arterial Hypertension
117. NCT00313222 - AC-052-366 - Prospective, Randomized, Placebo-controlled, Double-blind, Multicenter, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of Bosentan in Patients With Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
118. NCT00319020 - AC-052-367 - An Open Label, Long-term, Safety, and Tolerability Extension Study Using the Pediatric Formulation of Bosentan in the Treatment of Children With Idiopathic or Familial Pulmonary Arterial Hypertension Who Completed FUTURE 1
119. NCT01223352 - AC-052-373 - An Open-label, Prospective Multicenter Study to Assess the Pharmacokinetics, Tolerability, Safety and Efficacy of the Pediatric Formulation of Bosentan Two Versus Three Times a Day in Children With Pulmonary Arterial Hypertension
120. NCT01338415 - AC-052-374 - A Prospective, Multicenter, Open-label Extension of FUTURE 3 to Assess the Safety, Tolerability and Efficacy of the Pediatric Formulation of Bosentan Two Versus Three Times a Day in Children With Pulmonary Arterial Hypertension
121. NCT00660179 - AC-055-302 - A Multicenter, Double-blind, Randomized, Placebo-controlled,

Parallel Group, Event-driven, Phase III Study to Assess the Effects of Macitentan (ACT-064992) on Morbidity and Mortality in Patients With Symptomatic Pulmonary Arterial Hypertension

122. NCT01743001 - AC-055-305 - A Multi-center, Double-blind, Randomized, Placebo-controlled, Parallel-group, Phase 3 Study to Evaluate the Effects of Macitentan on Exercise Capacity in Subjects With Eisenmenger Syndrome
123. NCT02070991 - AC-055G201 - A Prospective, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group, 12-week Study to Evaluate the Safety and Tolerability of Macitentan in Subjects With Combined Pre- and Post-capillary Pulmonary Hypertension (CpcPH) Due to Left Ventricular Dysfunction
124. NCT02382016 - AC-055-404 - A Randomized, Double-blind, Placebo-controlled, Prospective, Multicenter, Parallel Group Study to Assess the Safety and Efficacy of Macitentan in Patients With Portopulmonary Hypertension
125. NCT03359291 - AC-055-122 - A Single-center, Open-label, One-sequence, Two-treatment Study to Investigate the Effect of Macitentan at Steady State on the Pharmacokinetics of Rosuvastatin in Healthy Male Subjects.
126. NCT01106014 - AC-065A302 - A Multicenter, Double-blind, Placebo-controlled Phase 3 Study Assessing the Safety and Efficacy of Selexipag on Morbidity and Mortality in Patients With Pulmonary Arterial Hypertension
127. NCT02471183 - AC-065A304 - Multicenter, Open-label, Single-group Study to Assess the Tolerability and the Safety of the Transition From Inhaled Treprostinil to Oral Selexipag in Adult Patients With Pulmonary Arterial Hypertension
128. NCT03078907 - AC-065A404 - A Multi-center, Double-blind, Placebo-controlled Phase 4 Study in Patients With Pulmonary Arterial Hypertension to Assess the Effect of Selexipag on Daily Life Physical Activity and Patient's Self-reported Symptoms and Their Impacts
129. NCT00488319 - R076477PSZ3002 - 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
130. NCT01009047 - R076477PSZ3003 - 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 Years of Age
131. NCT00645099 - R076477SCH3020 - A Prospective Randomized Open-label 6-Month Head-To-Head Trial to Compare Metabolic Effects of Paliperidone ER and Olanzapine in Subjects With Schizophrenia
132. NCT00518323 - R076477PSZ3001 - 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 Years of Age
133. NCT00334126 - R076477SCH3015 - 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
134. NCT00086320 - R076477-SCH-301 - A Randomized, Double-blind, Placebo-controlled, Parallel-group Study With an Open-label Extension Evaluating Paliperidone Extended Release Tablets in the Prevention of Recurrence in Subjects With Schizophrenia
135. NCT00650793 - R076477-SCH-703 - 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 Treatment of Subjects With Schizophrenia - Open Label Phase
136. NCT00397033 - R076477SCA3001 - 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
137. NCT00412373 - R076477SCA3002 - 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
138. NCT00752427 - R076477-SCH-702 - 24 week extension of NCT00085748: A Randomized, 6-Week Double-Blind, Placebo-Controlled Study With an Optional 24-Week Open-Label Extension to Evaluate the Safety and Tolerability of Flexible Doses of Paliperidone Extended

Release in the Treatment of Geriatric Patients With Schizophrenia
139. NCT00077714 - R076477-SCH-304 - 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 the Treatment of Patients With Schizophrenia
140. NCT00083668 - R076477-SCH-305 - 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, in the Treatment of Patients With Schizophrenia
141. NCT00078039 - R076477-SCH-303 - Trial Evaluating Three Fixed Dosages of Paliperidone Extended-Release (ER) Tablets and Olanzapine in the Treatment of Patients With Schizophrenia
142. NCT00085748 - R076477-SCH-302 - A Randomized, 6-Week Double-Blind, Placebo-Controlled Study With an Optional 24-Week Open-Label Extension to Evaluate the Safety and Tolerability of Flexible Doses of Paliperidone Extended Release in the Treatment of Geriatric Patients With Schizophrenia
143. NCT01662310 - R076477-SCH-3041 - Paliperidone Extended Release Tablets for the Prevention of Relapse in Subjects With Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study
144. NCT00524043 - R076477SCH4012 - A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of a Fixed Dosage of 1.5 mg/Day of Paliperidone Extended Release (ER) in the Treatment of Subjects With Schizophrenia
145. NCT00105326 - R076477-SCH-1010/CR002281 - A Double-blind, Placebo-controlled, Randomized Study Evaluating the Effect of Paliperidone ER Compared With Placebo on Sleep Architecture in Subjects With Schizophrenia
146. NCT00645307 - R076477-SCH-701 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study With an Open-Label Extension Evaluating Extended Release OROS(R) Paliperidone in the Prevention of Recurrence in Subjects With Schizophrenia - Open Label Phase
147. NCT00460512 - R076477SCH3017 - An Open-label Prospective Trial to Explore the Tolerability, Safety and Efficacy of Flexibly Dosed Paliperidone ER in Subjects With Schizophrenia
148. NCT00566631 - R076477SCH3018 - Tolerability, Safety and Treatment Response of Flexible Doses of Paliperidone ER in Acutely Exacerbated Subjects With Schizophrenia
149. NCT00668837 - R076477-SCH-705 - Open Label Extension to R076477-SCH-305 to Evaluate the Safety and Tolerability of Paliperidone ER in Subjects With Schizophrenia
150. NCT00589914 - R092670PSY3006 - 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
151. NCT00604279 - R092670PSY3008 - 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
152. NCT00590577 - R092670PSY3007 - 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
153. NCT00111189 - R092670PSY3001 - 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
154. NCT00210717 - R092670PSY3002 - 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 Weeks in Subjects With Schizophrenia
155. NCT00119756 - R092670PSY3005 - 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
156. NCT00210548 - R092670PSY3003 - 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

157. NCT00101634 - R092670PSY3004 - 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
158. NCT00074477 - R092670-SCH-201 - 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
159. NCT01529515 - R092670PSY3012 - A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects With Schizophrenia
160. NCT01193153 - R092670SCA3004 - A Randomized, Double-Blind, Placebo-Controlled, Parellel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder
161. NCT01157351 - R092670SCH3006 - A Fifteen-month, Prospective, Randomized, Active-controlled, Open-label, Flexible Dose Study of Paliperidone Palmitate Compared With Oral Antipsychotic Treatment in Delaying Time to Treatment Failure in Adults With Schizophrenia Who Have Been Incarcerated
162. NCT01081769 - R092670SCH3005 - A 24-month, Prospective, Randomized, Active-Controlled, Open-Label, Rater-Blinded, Multicenter, International Study of the Prevention of Relapse Comparing Long-Acting Injectable Paliperidone Palmitate to Treatment as Usual With Oral Antipsychotic Monotherapy in Adults With Schizophrenia
163. NCT01281527 - R092670SCH3010 - A 6-month, Open Label, Prospective, Multicenter, International, Exploratory Study of a Transition to Flexibly Dosed Paliperidone Palmitate in Patients With Schizophrenia Previously Unsuccessfully Treated With Oral or Long-acting Injectable Antipsychotics
164. NCT01051531 - R092670SCH3009 - Safety, Tolerability, and Treatment Response of Paliperidone Palmitate in Subjects With Schizophrenia When Switching From Oral Antipsychotics
165. NCT01527305 - R092670SCH4009 - An Open-Label, Prospective, Non-Comparative Study to Evaluate the Efficacy and Safety of Paliperidone Palmitate in Subjects With Acute Schizophrenia
166. NCT01299389 - PALM-JPN-4 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of JNS010 (Paliperidone Palmitate) in Patients With Schizophrenia
167. NCT01258920 - PALM-JPN-5 - A Long-Term, Open-Label Study of Flexibly Dosed Paliperidone Palmitate Long-Acting Intramuscular Injection in Japanese Patients With Schizophrenia
168. NCT01515423 - R092670PSY3011 - A Randomized, Multicenter, Double-Blind, Non-inferiority Study of Paliperidone Palmitate 3 Month and 1 Month Formulations for the Treatment of Subjects With Schizophrenia
169. NCT02713282 - R092670SCH3015 - A 52-Week, Open-Label, Prospective, Multicenter, International Study of a Transition to the Paliperidone Palmitate 3-Month Formulation In Patients With Schizophrenia Previously Stabilized on the Paliperidone Palmitate 1-Month Formulation
170. NCT03345342 - R092670PSY3015 - A Double-blind, Randomized, Active-controlled, Parallel-group Study of Paliperidone Palmitate 6-Month Formulation
171. NCT01559272 - R092670PSY1005 - A Single-Dose, Open-Label, Randomized, Parallel-Group Study to Assess the Pharmacokinetics, Safety, and Tolerability of a Paliperidone Palmitate 3-Month Formulation in Subjects With Schizophrenia
172. NCT00034749 - RIS-USA-231 - The Efficacy and Safety of Risperidone in Adolescents With Schizophrenia: a Comparison of Two Dose Ranges of Risperidone
173. NCT00249132 - RIS-INT-3 - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients
174. NCT00216476 - RISSCH3001 - CONSTATRE: Risperdal(R) Consta(R) Trial of Relapse Prevention and Effectiveness
175. NCT00378092 - CR011992, RISSCH3024 - A Prospective Study of the Clinical Outcome Following Treatment Discontinuation After Remission in First-Episode Schizophrenia
176. NCT00088075 - RIS-SCH-302/CR003370 - A Randomized, Double-Blind, Placebo-Controlled Clinical Study of the Efficacy and Safety of Risperidone for the Treatment of Schizophrenia in

Adolescents
177. - RIS-USA-1 (RIS-USA-9001) - Risperidone versus haloperidol versus placebo in the treatment of schizophrenia
178. NCT00253136 - RIS-USA-121/CR006055 - Risperidone Depot (Microspheres) vs. Placebo in the Treatment of Subjects With Schizophrenia
179. - RIS-USA-72 - The safety and efficacy of risperidone 8 mg qd and 4 mg qd compared to placebo in the treatment of schizophrenia
180. NCT00249223 - RIS-INT-61 - Risperidone Depot (Microspheres) vs. Risperidone Tablets - a Non-inferiority, Efficacy Trial in Subjects With Schizophrenia
181. NCT00216671 - RISSCH4045 - Early Versus Late Initiation of Treatment With Risperdal Consta in Subjects With Schizophrenia After an Acute Episode
182. NCT00369239 - RISSCH4043 - Is Premorbid Functioning a Predictor of Outcome in Patients With Early Onset Psychosis Treated With Risperdal Consta?
183. NCT00216632 - RISSCH4026 - Treatment Success in Patients Requiring Treatment Change From Olanzapine to Risperidone Long Acting Injectable (TRESOR)
184. NCT00236379 - RIS-USA-275 - A Six-month, Double-blind, Randomized, International, Multicenter Trial to Evaluate the Glucoregulatory Effects of Risperidone and Olanzapine in Subjects With Schizophrenia or Schizoaffective Disorder
185. NCT01050582 - RISNAP4022 - Evaluation of Growth, Sexual Maturation, and Prolactin-Related Adverse Events in the Pediatric Population Exposed to Atypical Antipsychotic Drugs
186. NCT00216528 - RIS-KOR-66 - A Prospective, Open-Label Study to Evaluate Symptomatic Remission in Schizophrenia With Long Acting Risperidone Microspheres (Risperdal Consta)
187. NCT00269919 - RIS-KOR-64 - Effect on Efficacy, Safety and Quality of Life by Long-Term Treatment of Long-Acting Risperidone Microspheres in Patients With Schizophrenia
188. NCT00992407 - RISSCH4178 - A Randomized, Open-label, Active-controlled Study to Evaluate Social Functioning of Long Acting Injectable Risperidone and Oral Risperidone in the Treatment of Subjects With Schizophrenia or Schizoaffective Disorder
189. NCT00236353 - RIS-USA-305 - An Open-label Study of the Efficacy and Safety of RISPERDAL Long-acting Microspheres (RISPERDAL CONSTA) Administered Once Monthly in Adults With Schizophrenia or Schizoaffective Disorder
190. NCT00495118 - RIS-INT-80 - Risperidone Depot (Microspheres) in the Treatment of Subjects With Schizophrenia or Schizoaffective Disorder - an Open-label Follow-up Trial of RIS-INT-62 and RIS-INT-85
191. NCT00236457 - RIS-INT-62 - Randomized, Multi-center, Open Label Trial Comparing Risperidone Depot (Microspheres) and Olanzapine Tablets in Patients With Schizophrenia or Schizoaffective Disorder
192. NCT00236587 - RIS-USA-265 - An Open Label, Long Term Trial of Risperidone Long Acting Microspheres in the Treatment of Patients Diagnosed With Schizophrenia
193. NCT00297388 - RIS-SCH-401 - A 52-wk Prospective, Randomized, Double-blind, Multicenter Study of Relapse Following Transition From Oral Antipsychotic Medication to 2 Different Doses (25 or 50 mg Every 2 Wks) of Risperidone Long-acting Microspheres (RISPERDAL CONSTA) in Adults With Schizophrenia or Schizoaffective Disorder
194. NCT00821600 - RIS-SCH-1012 - Single-Dose, Open-Label Pilot Study to Explore the Pharmacokinetics, Safety and Tolerability of a Gluteal Intramuscular Injection of a 4-Week Long-Acting Injectable Formulation of Risperidone in Patients With Chronic Stable Schizophrenia
195. NCT00299702 - RISSCH4060 - A 2-year, Prospective, Blinded-rater, Open-label, Active-controlled, Multicenter, Randomized Study of Long-term Efficacy and Effectiveness Comparing Risperdal(R) Consta(R) and Abilify(R) (Aripiprazole) in Adults With Schizophrenia
196. NCT00526877 - RISSCH4119 (RISC-TWN-MA10) - Evaluation of Efficacy and Safety of Long-acting Risperidone Microspheres in Patients With Schizophrenia or Schizoaffective Disorders, Who is Receiving Psychiatric Home-care Treatment, When Switching From Typical Depot or Oral Antipsychotics to Long-acting Risperidone Microspheres
197. NCT00061802 - RIS-SCP-402 - A Randomized, Double Blind Study to Evaluate the Efficacy and Safety of Two Atypical Antipsychotics vs. Placebo in Patients With an Acute Exacerbation of Either Schizophrenia or Schizoaffective Disorder
198. - RIS-INT-85 - Open-label Study Exploring a Switching Regimen From Depot Neuroleptics to Risperidone Depot Microspheres

199. NCT00034775 - RIS-USA-259 - Open-Label Trial Exploring A Switching Regimen From Oral Neuroleptics, Other Than Risperidone, To Risperidone Depot Microspheres

What type of data are you looking for?: Individual Participant-Level Data, which includes Full CSR and all supporting documentation

Research Proposal

Project Title

ALL-EMBRACED: clinicAL triaLs web-sErvice to Modify eligiBility cRiteria and pre-screening viA artifiCial intElligence methoDs

Narrative Summary:

Clinical trials (CT) are fundamental in the process of testing a drug or treatment. Today there is a duty to increase the inclusiveness of CTs, overcoming their main limitation: non-representative recruitment caused by inappropriate and restrictive inclusion criteria that results in the exclusion of many population sub-types. ALL-EMBRACED intends to propose solutions to this criticality through the development of a free of charge web platform, integrated with Artificial Intelligence (AI) and Machine Learning (ML) tools, in order to optimize the process of selection and recruitment of representative patients of the general population by clinicians and CT-managers.

Scientific Abstract:

Background: Traditional CTs often struggle with restrictive eligibility criteria, limiting the diversity of participants and making it difficult to generalize findings to broader populations.
Objective: Our project will investigate the impact of relaxing some eligibility criteria on the target CT population and will provide a new state-of-the-art pre-screening service based on AI methods.
Study Design: The project is structured in four Work-Packages (WPs). WP1 will create the IT infrastructure for the web platform, GDPR/HIPPA compliant and with a state-of-the-art data-encryption standard (SSH-256, AES-256). WP2 will collect micro-data and aggregated data from general population and CTs databases and create reliable synthetic data. WP3 will evaluate the relaxation of the eligibility criteria and biomarkers thresholds. WP4 will develop a web prototype for clinical and research settings.
Participants: Micro-data and aggregated data of the general population from national and international data repositories will be collected. We will also undertake a meticulous examination of the eligibility criteria and clinical outcomes from real world CTs databases.
Primary and Secondary Outcome Measure(s): With its new web-based tool, the project aims to improve the design and organization of CTs recruitment, reflecting in a more accurate way the population characteristics of the general population affected by the same pathology.
Statistical Analysis: Natural Language Processing (NLP) and ML techniques, Large Language Models and eXplainable AI techniques (SHAP) will be used during each WP.

Brief Project Background and Statement of Project Significance:

CTs must be designed and conducted to test the efficacy of drugs or diagnostic treatments. The eligibility criteria are essential requirements for the success of CTs [1,2] and have a direct impact on the results of each CT. Inappropriate eligibility criteria lead to insufficient recruitment, which is a major reason for the failure of many CTs. In a majority of therapeutic areas, a typical trial needs to double the planned enrollment period to reach the recruitment target, and even then, about of 40% of sites in a multicentre trial will enroll too few patients compared to what was planned, while 10% will not enroll a single patient. [3,4] In addition, recently the US Food and Drug Administration (FDA) has indicated that certain populations are generally excluded from CTs without sound clinical

rationale. Restrictive trials do not fully capture the efficacy and safety of the drug in the populations that will use the drug after approval [5]. Despite the FDA's proclaims, problems with CTs participation persist, and certain groups continue to be underrepresented. Excessively restrictive eligibility criteria, including modifying cut-offs values, limit patients' access to potentially beneficial treatments. In addition to the strict eligibility criteria, the pre-screening procedures also contribute to the unsatisfactory participation rates. Indeed, a considerable amount of time is required to identify the eligible patients ("pre-screening"), as much of the clinical information required for this process is available in the patient's EHR as unstructured free text or in scanned documents, that are not easily searchable by clinicians with existing technologies.[6] This factor can lead to distortions in terms of representativeness and inclusivity.
The key ambition for ALL-EMBRACED project is to create a unified framework that simultaneously combines and improves the capabilities that available tools capture separately, i.e.: CT design optimization and patient pre-screening. The ALL-EMBRACED unified framework will integrate a variety of data, including general population micro-data affected, real-world CT data and validated synthetic data. ALL-EMBRACED will utilize advanced AI algorithms to identify eligibility criteria that are most likely to safely expand CT access for patients without compromising the clinical outcomes. ALL-EMBRACED will use a dynamic and adaptive design that will allow refinement of future CT design based on analysis of retrospective similar CTs. ALL-EMBRACED will also propose adjustment of the eligibility rules to actively optimize the an in-fieri CT study, in case a CT is not be able to enroll the initially defined total number of patients, without compromising its clinical outcomes.
In the long run, the platform could grant to clinicians the selection of the most representative populations from the available EHRs that will be uploaded in the web-portal and that reflects the general population characteristics. The ALL-EMBRACED platform will be able to "converse" fluently in natural language with CT-Managers and Physicians, with a deep clinical understanding in pre-screening patients.

Specific Aims of the Project:

The ALL-EMBRACED project aims to revolutionize CT design with a focus on inclusivity, safety, and transparency through advanced AI technologies. The main goal of the project is to introduce a web-platform designed to craft CTs in a way that can reflect the diversity of the general population in most CTs. The tool will be completely free of charge for all end-users (i.e.: researchers, clinicians, and CT managers). Our ultimate goal is to propose an effective way to formulate more evidence-based criteria to speed up the CT process.
The overarching objectives are:
- Evaluation and optimization of eligibility criteria for any CTs
- Exploitation of AI/ML data-driven techniques
- Assessment of the safety implications of broadening eligibility criteria
- Web-platform prototype development
- Collaboration with experts to ensure the effectiveness of the prototype
- Dissemination of the project findings through peer-reviewed open-access publications, position papers, and presentations at national and European forums.
- Fostering the professional and training skills
The ALL-EMBRACED framework will be based on the principles of "Responsible Research and Innovation (RRI)" and "Findability, Accessibility, Interoperability, and Reusability" (FAIR) to ensure that the expected outcomes of the project are socially beneficial and inclusive, environmentally sustainable, and ethically justifiable.

Study Design:

Methodological research

What is the purpose of the analysis being proposed? Please select all that apply.

Research on clinical trial methods

Research on comparison group

Research Methods

Data Source and Inclusion/Exclusion Criteria to be used to define the patient sample for your study:

The ALL-EMBRACED framework will be multi-pathology, because it will be based on data concerning several Non-Communicable Diseases (NCD). In detail the ALL-EMBRACED will focused on: Choroidal Neovascularization; Diabetes Type 2; Hypertension (High Blood Pressure); Kidney transplant; Heart transplant; Liver transplant; Metabolic syndrome; Multiple Sclerosis; Partial Seizure; Psoriasis; Multi-site Seborrheic Dermatitis; AD Dementia; Mental Health disorders (Depression, Schizophrenia, BPD).
The data sources can be divided in two sections.
- The microdata and the aggregated data (prevalence, incidence, years lived with the disease) for the general population affected by NCDs, obtained from national and international repositories (e.g.: ISTAT, EUROSTAT, GBD/IHME).
- CT data, in particular eligibility criteria (both inclusion and exclusion) and outcome measures. IRCCS-FBF will provide individual outcome measurements for CTs conducted (e.g.: interventional and observational studies). The IPD data requested from YODA project will be added to this dataset. Additional data for CTs will be obtained from CT reports downloaded from clinical databases (clinicaltrials.gov and ISRCTN).

The creation of the synthetic datasets will be done via Synthea, a tool that can generate and make downloadable synthetic subjects for different pathologies, based on results from academic publications and statistical institutions. Individual data from the YODA project will not be used in the generation of synthetic data, but will only be used as comparative data to check the reliability of the Synthea's data. No individual data from YODA project will be downloaded or shared with external users, as also stated in the disclosure agreement. Additional information on this topic is provided in the supplementary document.

Primary and Secondary Outcome Measure(s) and how they will be categorized/defined for your study:

ALL-EMBRACED focuses on improving eligibility criteria so that the CT population is representative of the general population. The IPD data requested from YODA project will be collected on several CTs where the clinical conditions of interest will be among these NCDs: Diabetes type II, hypertension, multiple sclerosis, partial seizure, psoriasis, (seborrheic) dermatitis, AD, dementia, bipolar disorder, depressive disorders, schizophrenia and schizoaffective disorder. The primary and secondary outcomes will vary depending on the different CT studies and the pathologies investigated. However, in general, the primary and secondary outcomes of these CTs concern the evaluation of the efficacy of a given drug (depending on the pathology) by performing clinical tests and monitoring contraindications in subjects to ensure their safety. The clinical tests, collected at different time points as biomarkers that mimic disease progression, are specific to each pathology, and allow comparison between CTs of the same NCD. An additional outcome is pharmacokinetics, which is tested with blood sample analysis.

Main Predictor/Independent Variable and how it will be categorized/defined for your study:

The inclusion and exclusion criteria of several CTs (similar in pathology and clinical endpoints, but different in eligibility criteria) will be our main predictors for ML and SHAP analysis and will allow defining how to broaden the criteria for future CTs.
Each NCD has specific neuropsychological scales that were collected at several time points and compared with the baseline measurements to evaluate the efficacy of the drug of interest. For example, in CTs concerning AD, the main biomarkers are ADAS-cog, MMSE, DAD and CIBIC scores. Psoriasis has different scales to be collected and evaluated, such as PASI, IGA, DLQI, PSSD and PGA. Relevant neuropsychological tests in CTs related to mental disorders are instead YMRS, MADRS, HAM-D, GAD and CGI.
Other independent variables, which are in common among the NCDs, include socio-demographic variables (e.g.: sex, age, education, physical activity, and others), clinical data (e.g.: BMI,

diastolic/systolic blood pressure, and others) and biological data (e.g.: TAU, ABETA, C-Protein, and others) from blood, urine or other sources. Clinical and biological data were usually collected to verify the insurgence of possible adverse events.

Other Variables of Interest that will be used in your analysis and how they will be categorized/defined for your study:

Other variables of interest can be instrumental derived biomarkers (e.g.: MRI post processing, EEG post processing, ECG post processing, and others). ECG, for example, is usually collected together with biological sample during physical examination and laboratory measurements for drug safety inspection.
The additional variables we will use are those related to the improvement of future CT. Indeed, it is also possible to extract features from similar CTs, aggregated according to the tested drugs, to the administration modalities and treatment duration.

Statistical Analysis Plan:

The ALL-EMBRACED project will make extensive use of classical statistical methods and ML tools. In a first step, normalization and scaling will be performed to account for different measurement units. In addition, the original CT population will be compared with the sociodemographical characteristics of the general population before starting any simulations to relax the eligibility criteria to increase the representativeness of a CT. This will be done using the Fisher's exact test, the Chi-squared tests, T-test, the Wilcoxon--Mann--Whitney test depending on the specific distributions of the samples and the typologies of the variables.
The most important aspects of originality of ALL-EMBRACED lies in the adoption of the "SHapley Additive exPlanations strategy" (SHAPLEY) libraries with regard to the eligibility criteria and the broadening of the threshold values.[10] The SHAPLEY technique has recently been proposed in the field of machine learning (ML) as a principled approach to quantify the marginal contribution of individual features and data. SHAPLEY is used in many ML tasks because it enables the explainability of models (e.g.: Logistic models, Generalized Liner Models, Support Vector Regressors, MLP-regressors, or others). The SHAPLEY value is a way to measure the contribution of each eligibility rule in the selection of the patients for a specific CT. It will be calculated by taking the average of the marginal contributions of the criterion to all possible subsets of the criteria. The marginal contribution of a criterion is computed by the difference in the outcome when the criterion is included in a subset and when it is not.[8] In this context, the SHAPLEY value will be used to evaluate the importance of different criteria for selecting patients for CTs. We will use a python library to estimate the SHAPLEY values using Monte-Carlo sampling, because calculating the values for all possible subsets of eligibility criteria would be computationally prohibitive, also on the HPC centre of the IRCCS-FBF.
The ALL-EMBRACED approach we will use is innovative because allows to reach the population representativeness using an explainable data driven approach, controlling for clinical outcomes and patient safety using multiple in-silico simulations.

Software Used:

Python

Project Timeline:

ALL-EMBRACED is a two-year project started in April 2025 and it is structured in four main Work-Packages (WP). WP1 (M0-M2) will create the IT infrastructure underpinning the web platform. WP2 (M0-M8) will aim to collect micro-data from the general population, "real-world" CT data and create possible synthetic data. WP3 (M6-M20) will be dedicated to identifying which are the eligibility criteria that can be relaxed and the threshold values of biomarkers expanded to increase the target population of a CT. This will be done through data-driven tools combining Natural Language Processing (NLP), ML, Large Language Model (GPT3.5 turbo), and eXplainable AI techniques. Finally, WP4 (M12-M24) will concern the development of a prototype able to perform the actions previously described with a continuous involvement of end users and patients. The final result will be a tool

usable both in clinical and research settings, completely free of charge for all end-users (i.e.: researchers, clinicians, and CT managers). Four deliverables are expected to be compiled in the second year of the project, describing the safety of broadening of inclusion criteria and thresholds, the pre-screening service and how the end-users (Physicians, CT-manager, CT-sponsor, general population) can benefit from all of ALL-EMBRACED services.

Dissemination Plan:

Our broad strategy is to disseminate findings and results through journal publications and oral-presentations as well as through open-source software repositories to ensure widespread access to our methods as well as open data (embracing the FAIR principle) to promote the reproducibility. Specific mechanisms we will use are: i) publications in prestigious journals, i.e.: Nature, Nature Comms, Journal of Biomedical Informatics -- we have a track record of publication in all these venues; ii) Presentations at conference, i.e.: European Congress of Clinical Investigation, International Conference on Harmonisation of Requirements for Registration of Pharmaceuticals for Human Use, and others; iii) Education and public engagement; iv) Software dissemination: we have a tradition of web-based dissemination of open-source software [11,12] and our group is available via GitHub; v) as ALL-EMBRACED services mature, we will seek follow-on funding for translational research to sustain the web-platform free of charge.

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Supplementary Material:

https://yoda.yale.edu/wp-content/uploads/2025/06/additional_text.pdf