The YODA Project
Research Proposal Review

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

The Yale University Open Data Access (YODA) Project
Yale University Center for Outcomes Research and Evaluation (CORE)
1 Church Street, Suite 200, New Haven, CT 06510

The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4754)

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 Yale University Open Data Access (YODA) Project
Yale University Center for Outcomes Research and Evaluation (CORE)
1 Church Street, Suite 200, New Haven, CT 06510

The YODA Project
Research Proposal Review - Revisions Requested
(Protocol #: 2021-4754)

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?	Unsure, further clarification from requestor is needed
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:

Investigators have requested access to 66 different trials in order to examine the utility of Desirability of Outcome Ranking (DOOR) in measuring the risk-benefit profile of antipsychotic treatment in schizophrenia. I found this proposal difficult to evaluate, as it was short on detail. I was left with little understanding of DOOR as a measure, whether it had already been developed, how it is developed, and how it will be applied to each of the 66 trials. These trials are quite heterogeneous, examining different populations who were treated for different periods of time and who were assessed on the basis of different primary and secondary efficacy and safety endpoints. Is DOOR determined for each trial, separately? Far more detail is needed to better understand the authors planned use of these data.

Principal Investigator

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General Information

Key Personnel (in addition to PI):
First Name: Xin
Last name: Zhou
Degree: PhD
Primary Affiliation: Yale University

Are external grants or funds being used to support this research?: No external grants or funds are being used to support this research.
How did you learn about the YODA Project?: Email/Newsletter/Flier

Conflict of Interest

https://yoda.yale.edu/system/files/radhakrishnan_coi.pdf
https://yoda.yale.edu/system/files/xin_coi.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

1. 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
2. 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
3. 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
4. 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
5. 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

6. 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
7. 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
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. NCT00034749 - RIS-USA-231 - The Efficacy and Safety of Risperidone in Adolescents With Schizophrenia: a Comparison of Two Dose Ranges of Risperidone
17. 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
18. 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
19. NCT00236444 - CR002020 (RIS-INT-79) - Risperidone in the Prevention of Relapse: a Randomized, Double-blind, Placebo-controlled Trial in Children and Adolescents With Conduct and Other Disruptive Behavior Disorders
20. NCT00266552 - CR006019 (RIS-USA-93) - 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
21. NCT00249132 - RIS-INT-3 - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients
22. NCT00216476 - RISSCH3001 - CONSTATRE: Risperdal® Consta® Trial of Relapse Prevention and Effectiveness
23. NCT00216580 - RIS-PSY-301 - An Open-label Trial of Risperidone Long-acting Injectable in the Treatment of Subjects With Recent Onset Psychosis
24. NCT00378092 - CR011992, RISSCH3024 - A Prospective Study of the Clinical Outcome Following Treatment Discontinuation After Remission in First-Episode Schizophrenia
25. 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
26. 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
27. 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
28. 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
29. NCT00078039 - R076477-SCH-303 - Trial Evaluating Three Fixed Dosages of Paliperidone Extended-Release (ER) Tablets and Olanzapine in the Treatment of Patients With Schizophrenia
30. 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
31. 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
32. 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
33. NCT00253136 - RIS-USA-121/CR006055 - Risperidone Depot (Microspheres) vs. Placebo in the Treatment of Subjects With Schizophrenia
34. RIS-USA-72 - The safety and efficacy of risperidone 8 mg qd and 4 mg qd compared to placebo in the treatment of schizophrenia
35. NCT01529515 - R092670PSY3012 - A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects With Schizophrenia
36. NCT01193153 - R092670SCA3004 - A Randomized, Double-Blind, Placebo-Controlled, Parellel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder
37. 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
38. 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
39. 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
40. NCT00645307 - R076477-SCH-701 - 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
41. 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
42. NCT00249223 - RIS-INT-61 - Risperidone Depot (Microspheres) vs. Risperidone Tablets - a Non-inferiority, Efficacy Trial in Subjects With Schizophrenia
43. 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
44. 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
45. 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
46. NCT01051531 - R092670SCH3009 - Safety, Tolerability, and Treatment Response of Paliperidone Palmitate in Subjects With Schizophrenia When Switching From Oral Antipsychotics
47. NCT01527305 - R092670SCH4009 - An Open-Label, Prospective, Non-Comparative Study to Evaluate the

Efficacy and Safety of Paliperidone Palmitate in Subjects With Acute Schizophrenia
48. NCT01299389 - PALM-JPN-4 - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of JNS010 (Paliperidone Palmitate) in Patients With Schizophrenia
49. NCT01258920 - PALM-JPN-5 - A Long-Term, Open-Label Study of Flexibly Dosed Paliperidone Palmitate Long-Acting Intramuscular Injection in Japanese Patients With Schizophrenia
50. NCT00216671 - RISSCH4045 - Early Versus Late Initiation of Treatment With Risperdal Consta in Subjects With Schizophrenia After an Acute Episode
51. NCT00369239 - RISSCH4043 - Is Premorbid Functioning a Predictor of Outcome in Patients With Early Onset Psychosis Treated With Risperdal Consta?
52. NCT00216632 - RISSCH4026 - Treatment Success in Patients Requiring Treatment Change From Olanzapine to Risperidone Long Acting Injectable (TRESOR)
53. 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
54. NCT01050582 - RISNAP4022 - Evaluation of Growth, Sexual Maturation, and Prolactin-Related Adverse Events in the Pediatric Population Exposed to Atypical Antipsychotic Drugs
55. 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
56. NCT00236457 - RIS-INT-62 - Randomized, Multi-center, Open Label Trial Comparing Risperidone Depot (Microspheres) and Olanzapine Tablets in Patients With Schizophrenia or Schizoaffective Disorder
57. NCT00236587 - RIS-USA-265 - An Open Label, Long Term Trial of Risperidone Long Acting Microspheres in the Treatment of Patients Diagnosed With Schizophrenia
58. 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
59. 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
60. NCT00299702 - RISSCH4060 - A 2-year, Prospective, Blinded-rater, Open-label, Active-controlled, Multicenter, Randomized Study of Long-term Efficacy and Effectiveness Comparing Risperdal® Consta® and Abilify® (Aripiprazole) in Adults With Schizophrenia
61. N/A - RIS-INT-85 - Open-label Study Exploring a Switching Regimen From Depot Neuroleptics to Risperidone Depot Microspheres
62. NCT00034775 - RIS-USA-259 - Open-Label Trial Exploring A Switching Regimen From Oral Neuroleptics, Other Than Risperidone, To Risperidone Depot Microspheres
63. NCT00460512 - R076477SCH3017 - An Open-label Prospective Trial to Explore the Tolerability, Safety and Efficacy of Flexibly Dosed Paliperidone ER in Subjects With Schizophrenia
64. NCT00566631 - R076477SCH3018 - Tolerability, Safety and Treatment Response of Flexible Doses of Paliperidone ER in Acutely Exacerbated Subjects With Schizophrenia
65. 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
66. 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

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

Research Proposal

Project Title

Harnessing clinical trial data to inform real-world clinical decision making in the treatment of schizophrenia

Narrative Summary:

Randomized clinical trials (RCT) provide rich data related to safety and efficacy of pharmacological agents. This is often at variance with real-world data since patients in the real-world i.e. (real-world data (RWD)) are not constrained by RCT design. Even when the results of RCT and RWD are consistent, they often do not apply directly to an individual patient who presents before a physician. We attempt to overcome these challenges by use of a novel statistical technique, Desirability of Outcome Ranking (DOOR), to better inform clinical-decision making in the treatment of schizophrenia.

Scientific Abstract:

Background: Randomized clinical trials (RCT) provide rich data related to safety and efficacy of pharmacological agents. This is often at variance with real-world data since patients in the real-world i.e. (real-world data (RWD)) are not constrained by RCT design. Even when the results of RCT and RWD are consistent, they often do not apply directly to an individual patient who presents before a physician.
Objectives: To examine the utility of Desirability of Outcome Ranking (DOOR) in measuring the risk-benefit profile of antipsychotic treatment in schizophrenia.
Study Design: Randomized control trial data will be reanalyzed using Desirability of Outcome Ranking (DOOR), a measure that combines clinically-relevant risks and benefits.
Participants: Subject-level data from randomized, placebo-controlled studies of risperidone and paliperidone in schizophrenia patients.
Main Outcome Measures: Utility of DOOR in characterizing treatment responders/non-responders and overall concordance with results of trial using traditional outcome measures.
Statistical Analysis: We will re-analyze the trial data using DOOR for finer gradations of composite outcomes. DOOR probability, proportion in favor of treatment, and win ratio will be used to compare treatments. Their 95% confidence intervals will be estimated by bootstrap.

Brief Project Background and Statement of Project Significance:

Randomized clinical trials (RCT) provide rich data related to safety and efficacy of pharmacological agents. This is often at variance with real-world data since patients in the real-world i.e. (real-world data (RWD)) are not constrained by RCT design. Even when the results of RCT and RWD are consistent, they often do not apply directly to an individual patient who presents before a physician. We attempt to overcome these challenges by use of a novel statistical technique, Desirability of Outcome Ranking (DOOR), to better inform clinical-decision making in the treatment of schizophrenia. DOOR has proven utility in antimicrobial therapy in conjunction with partial credit scoring to allow for quantitative comparisons of the clinical desirability of treatment decisions (Claeys et al, 2021, Evans et al, 2020). In this proposal, we extend this novel statistical technique to clinical decision making in antipsychotic treatment of schizophrenia.

Specific Aims of the Project:

The specific aims of the project are:
a) Develop a Desirability of Outcome Ranking (DOOR) for schizophrenia trials
b) Examine the utility of DOOR in characterizing treatment responders/non-responders and overall concordance with results of trial using traditional outcome measures

What is the purpose of the analysis being proposed? Please select all that apply.
Participant-level data meta-analysis
Participant-level data meta-analysis using only data from YODA Project
Develop or refine statistical methods

Research Methods

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

Individual-level data from RCTs of risperidone and paliperidone in schizophrenia

Main Outcome Measure and how it will be categorized/defined for your study:

Desirability of Outcome Ranking (DOOR) will be defined a-priori from input from expert psychiatrists who have experience in treating patients with schizophrenia. The outcome is a composite outcome, combining the efficiency and safety measures together.

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

The predictor / independent variable is the treatment assignment (i.e drug vs placebo). The analysis will include the treatment assignment, age, gender, race/ethnicity, and other potential risk factors.

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

We will evaluate the heterogeneity of the composite outcomes in the subgroups of age, gender and race/ethnicity.

Statistical Analysis Plan:

We will generate tables that summarize the distribution and extent of missingness of potential risk factors, for example, age, gender, and race/ethnicity, overall and by treatment arm to assess for random baseline imbalances for the trial data.

Our interest is to compare the DOOR between two treatments. The DOOR probability, proportion in favor of treatment and win ratio will be estimated by making all possible pairwise comparisons between two treatment arms according to DOOR, and their 95% CI will be constructed using bootstrap.

We will also evaluate heterogeneity of the composite outcome in several pre-specified subgroups, for example, age, gender, and race/ethnicity. These are hypothesis generating analyses. We will use the method described above to evaluate the effect of treatments stratified by subgroup. All subgroup analyses will be clearly reported, including how subgroups will be defined, outcomes examined, and how both the point and interval estimates of treatment effects.
Software Used:
R
Project Timeline:

Estimation of key milestone dates for the proposed study:
1) Anticipated project start date = Nov-2021
2) Data analysis completion = May 2022
3) Dissemination of results= Nov 2022

Dissemination Plan:

Dissemination plan includes presentation at conferences (such as ASCP Annual conference, ISCTM annual meeting) and publication in peer-reviewed journals (such as Journal of Clinical Psychiatry).

Bibliography:

1. Claeys CK, Hopkins TL, Schlaffer K, Hitchcock S, Jiang Y, Evans S, Johnson JK, Leekha S. Comparing the Clinical Utility of Rapid Diagnostics for Treatment of Bloodstream Infections Using Desirability of Outcome Ranking Approach for the Management of Antibiotic Therapy (DOOR-MAT). Antimicrob Agents Chemother. 2021;65(9):e0044121.
2. Evans SR, Knutsson M, Amarenco P, Albers GW, Bath PM, et al. Methodologies for pragmatic and efficient assessment of benefits and harms: Application to the SOCRATES trial. Clin Trials. 2020 Dec;17(6):617-626.