| Contract No. | **HHSA290201500011I** | | | | |
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| Task Order No. | **10** |  |  |  |  |
| EPC | **RTI-UNC** | |  |  |  |
| Project Title | **Drug Therapy for Early Rheumatoid Arthritis in Adults** | | | | |
| **Standard Category** | **Abbrev.** | **Standard** | **Is this standard applicable to this SER update?** | **List sections and pages of the SER report where you address this standard** | **If applicable, describe how and why the SER update deviated from this standard?** |
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| **Cross-Cutting Standards** | | | | | |
| Standards for Formulating Research Questions | RQ-1 | Identify Gaps in Evidence | Yes | Intro: pages 3-4 |  |
| RQ-2 | Develop a Formal Study Protocol | Yes | Published Protocol on AHRQ EHC website |  |
| RQ-3 | Identify Specific Populations and Health Decision(s) Affected by the Research | Yes | Intro: pages 4-6;  Methods: page 7 |  |
| RQ-4 | Identify and Assess Participant Subgroups | Yes | Intro: page 5;  Methods: page 7 |  |
| RQ-5 | Select Appropriate Interventions and Comparators | Yes | Intro: pages 2-6;  Methods: pages 7-8 |  |
| RQ-6 | Measure Outcomes that People Representing the Population of Interest Notice and Care About | Yes | Intro: pages 4-6;  Methods: pages 7-8, 10-11 |  |
| Standards Associated with Patient-Centeredness | PC-1 | Engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context. | Yes | Front Matter: page iii; page 7  Appendix J | Refers to the PCORI Stakeholder Call in December 2016 that gathered stakeholder groups and technical experts to define the scope of this review. |
| PC-2 | Identify, Select, Recruit, and Retain Study Participants Representative of the Spectrum of the Population of Interest and Ensure that Data Are Collected Thoroughly and Systematically from All Study Participants | N/A |  | Systematic review with no primary data collection. |
| PC-3 | Use Patient-Reported Outcomes When Patients or People at Risk of a Condition Are the Best Source of Information | N/A |  | Systematic review with no primary data collection. However, we used patient-centered outcomes data for KQ2 whenever our included studies reported them. |
| PC-4 | Support dissemination and implementation of study results | N/A |  | Systematic review with no primary data collection. |
| Standards for Data Integrity and Rigorous Analyses | IR-1 | Assess Data Source Adequacy | Yes | Methods: pages 8-13 |  |
| IR-2 | Describe Data Linkage Plans, if Applicable | N/A |  | No data linkage required. |
| IR-3 | A priori, Specify Plans for Data Analysis that Correspond to Major Aims | Yes | Methods: pages 12-13 |  |
| IR-4 | Document Validated Scales and Tests | Yes | Methods: pages 10-11;  Appendix F |  |
| IR-5 | Use Sensitivity Analyses to Determine the Impact of Key Assumptions | Yes | Methods (high ROB): page 12;  Results: page 41;  Discussion: page 115;  Appendix I |  |
| IR-6 | Provide Sufficient Information in Reports to Allow for Assessments of the Study’s Internal and External Validity | Yes | Methods: pages 11-12, 14;  Discussion: pages 125-126;  Appendix D |  |
| Standards for Preventing and Handling Missing Data | MD-1 | Describe in Protocol Methods to Prevent and Monitor Missing Data | Yes | Methods (handsearching, gray literature, SEADs): pages 9, 11-12 |  |
| MD-2 | Describe Statistical Methods to Handle Missing Data in Protocol | N/A |  | Standard does not apply. |
| MD-3 | Use Validated Methods to Deal with Missing Data that Properly Account for Statistical Uncertainty Due to Missingness | Yes | Methods (imputation plan for missing network meta-analysis data): page 12 |  |
| MD-4 | Record and Report All Reasons for Dropout and Missing Data, and Account for All Patients in Reports | N/A |  | Standard does not apply. |
| MD-5 | Examine Sensitivity of Inferences to Missing Data Methods and Assumptions, and Incorporate into Interpretation | N/A |  | Standard does not apply. |
| Standards for Heterogeneity of Treatment Effect (HTE) | HT-1 | State the Goals of HTE Analyses | Yes | Methods: page 12;  Discussion: page 128 |  |
| HT-2 | For all HTE Analyses, Pre-specify the analysis plan; for Hypothesis driven HTE Analyses, Pre-specify Hypotheses and supporting evidence base | Yes | Methods: page 12 |  |
| HT-3 | All HTE claims must be based on appropriate statistical contrasts among groups being compared, such as interaction tests or estimates of differences in treatment effect | Yes | Discussion (Limitations): pages 127-128 |  |
| HT-4 | For Any HTE Analysis, Report All Pre-specified Analyses and, at Minimum, the Number of Post-hoc Analyses, Including all Subgroups and Outcomes Analyzed | Partially | Methods: pages 12-13;  Results: KQ 1 (pages 27, 39-41, 42-56), KQ 3 (pages 94-111); KQ 4 (pages 112-114);  Discussion: pages 123-124, 125-126;  Appendix G; Appendix H; Appendix I | For systematic reviews, the analytic decisions are data-dependent. That is, we could pre-specify outcomes of interest, but we could not pre-specify whether meta-analyses were possible. |
| **Standards for Specific Study Designs and Methods** | | | | | |
| Standards for Data Registries | DR-1 | Requirements for the Design and Features of Registries | N/A |  | Standard does not apply. |
| DR-2 | Standards for Selection and Use of Registries | N/A |  | Standard does not apply. |
| DR-3 | Robust Analysis of Confounding Factors | N/A |  | Standard does not apply. |
| Standards for Data Networks as Research-Facilitating Structures | DN-1 | Requirements for the Design and Features of Data Networks | N/A |  | Standard does not apply. |
| DN-2 | Standards for Selection and Use of Data Networks | N/A |  | Standard does not apply. |
| Causal Inference Standards | CI-1 | Define Analysis Population Using Covariate Histories | N/A |  | Standard does not apply. |
| CI-2 | Describe Population that Gave Rise to the Effect Estimate(s) | N/A |  | Standard does not apply. |
| CI-3 | Precisely Define the Timing of the Outcome Assessment Relative to the Initiation and Duration of Exposure | N/A |  | Standard does not apply. |
| CI-4 | Measure Confounders before Start of Exposure. Report data on confounders with study results | N/A |  | Standard does not apply. |
| CI-5 | Report the assumptions underlying the construction of Propensity Scores and the comparability of the resulting groups in terms of the balance of covariates and overlap | N/A |  | Standard does not apply. |
| CI-6 | Assess the Validity of the Instrumental Variable (i.e. how the assumption are met) and report the balance of covariates in the groups created by the IV for all IV analyses | N/A |  | Standard does not apply. |
| Standards for Adaptive and Bayesian Trial Designs | AT-1 | Specify Planned Adaptations and Primary Analysis | N/A |  | Standard does not apply. |
| AT-2 | Evaluate Statistical Properties of Adaptive Design | N/A |  | Standard does not apply. |
| AT-3 | Specify Structure and Analysis Plan for Bayesian Adaptive Randomized Clinical Trial Designs | N/A |  | Standard does not apply. |
| AT-4 | Ensure Clinical Trial Infrastructure Is Adequate to Support Planned Adaptation(s) | N/A |  | Standard does not apply. |
| AT-5 | Use the CONSORT statement, with Modifications, to Report Adaptive Randomized Clinical Trials | N/A |  | Standard does not apply. |
| Standards for Studies of Diagnostic Tests | DT-1 | Specify Clinical Context and Key Elements of Diagnostic Test Study Design | N/A |  | Standard does not apply. |
| DT-2 | Study Design Should be Informed by Investigations of the Clinical Context of Testing | N/A |  | Standard does not apply. |
| DT-3 | Assess the Effect of Factors Known to Affect Diagnostic Performance and Outcomes | N/A |  | Standard does not apply. |
| DT-4 | Structured Reporting of Diagnostic Comparative Effectiveness Study Results | N/A |  | Standard does not apply. |
| DT-5 | Focus studies of diagnostic tests on patient centered outcomes, using rigorous study designs with preference for randomized controlled trials | N/A |  | Standard does not apply. |
| Standards for Systematic Reviews | SR-1 | Adopt the Institute of Medicine (IOM) standards for systematic reviews of comparative effectiveness research, with some qualifications. | Yes | Entire report (all pages) |  |