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# **Real-World Evidence for Regulatory Decision-making**

**May 7, 2019, 8:00am-4:00pm**

**RTI International**

**Abstract Submission Form**

**Instructions**: Abstracts are invited from students, post-docs and junior investigators (terminal degree award 2010 or later) on topics related to real world data (including e.g., comparison of alternative data sources, data quality, validation) and real-world evidence regarding the safety and/or effectiveness of healthcare interventions (e.g., medications, procedures, devices). Comparisons of methods for designing or analyzing such studies are also of interest.

The maximum character count for the abstract is 2,350 characters (spaces are not counted). The character count includes the abstract title and body, and also includes the required headers: Title, Background, Objectives, Methods, Results, Conclusions.

To submit an abstract, please fill out all fields in the tables below following the guidelines on Page 2. Save the document as *BERD\_Abstract\_[last name of contact PI].doc*, and email your abstract to [ahaydon@med.unc.edu](mailto:ahaydon@med.unc.edu). Abstracts are due by 5pm on March 18, 2019.

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| Authors and Affiliations |  |

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| Title |  |
| Background |  |
| Objectives |  |
| Methods |  |
| Results |  |
| Conclusions |  |

**Additional Guidance**

**ABSTRACT BODY**

The below information provides you with the expectations regarding content of your submission under the five major headings: Background, Objectives, Methods, Results, and Conclusions.

1. **Background**: One or two sentences that describe the clinical (or other) importance of the study question.
2. **Objectives**: The main objective(s) or study question should be explicitly stated (e.g., "To determine the rate of"). If study was to test an a priori hypothesis, it should be stated.
3. **Methods**: Should include statements that address: Design: Basic study design, source population, follow-up; For new analyses of existing data the data-set should be disclosed; statement of criterion standard if study of screening or diagnostic test and any blinding; analysis type (e.g., cost-effectiveness, costbenefit, etc.) if an economic analysis. Matching and selection of controls, if relevant, also should be included.
   * **Setting**: To assist readers in determining the relevance of the findings to their own circumstances, the setting or source population should be described including statements regarding generalization to a larger or more representative population. This may include eligibility, inclusion/exclusion criteria, and for surveys and follow-up studies should include the number eligible versus the number/proportion remaining in the analysis.
   * **Exposures or interventions**: Explicit naming of medications or other interventions. Non-proprietary names should be used.
   * **Main outcome measures**: The primary and secondary outcome measurement(s) as determined prior to data collection. If hypothesis was formulated after data collection, this should be stated.
   * **Statistical analysis**: The statistical methods should be described.

1. **Results**: The main outcomes of the study should be provided and quantified, including confidence intervals and/or other significance tests. If differences are not significant, the clinically important difference sought should be stated and the confidence interval for the difference between the groups should be given. When risk changes or effect sizes are reported, absolute values should be included so that the reader can determine the absolute as well as relative impact of the result. Screening and diagnostic test studies should report sensitivity, specificity, and likelihood ratio and if predictive value or accuracy is given, prevalence or pretest likelihood should be provided.
2. **Conclusions**: Only those conclusions that are directly supported by the reported data should be provided, along with their implications (avoiding speculation and overstatement of findings). Emphasis should be given equally to positive and negative findings of equal scientific merit.