**EXPAND RFP**

**EXPanding reAl world experieNce with Dovato**

**Concept Template**

Concept pages should have 1-inch margins & Normal style 10-point Arial font, single spaced and should be no more than 4 pages in length. Concepts must include the Level 1 Heading sections identified below. If section is “not applicable to the type of study, enter “N/A” under the heading. Level 1 Headings should not be modified. Level 2 headings can be added as appropriate.

**All concepts submitted must include the sections below**

# Title of Research Project

Provide a descriptive title for the topic your study addresses. Note: This title should align with the title entered on the ISR portal.

# Study Background and Rationale

*Explain the significance of the proposed study and how it will support one or more of the RFP’s priority areas. The rationale should also include relevant background information to support the proposed study and a brief review of any other studies completed or being conducted that address the priority area. This section should be no longer than 150 words.*

# Purpose Statement

*Please state what the study is expected to demonstrate, and how this study will address the Priority Area(s) you selected. This section should be no longer than 50 words.*

# Objectives and Endpoints

*Please list below your anticipated primary and secondary objectives, how you intend to measure these and at what timepoints.*

## Primary Objective and Endpoints

*List*

## Secondary Objectives and Endpoints

*List*

# Methods

**a. Type of Study**

Please state if this will be an: interventional study, prospective observational study, retrospective observational study, implementation science study or dissemination research study, or other (please specify). Please refer to the application guide for more details.

**b. Study Design**

*Describe and justify the type of study you are proposing. For example, state type of design, comparison groups, main tests, or procedures, primary and secondary, outcome variables, study duration, and study outline. State whether the design is case-control, cohort, case-cohort, case-crossover, systematic review, meta-analysis, etc. and whether the participants are followed retrospectively or prospectively. Any comparison groups should also be described. This should be no longer than 150 words.*

**c. Study Population**

*A brief description of the participant population to be studied including a brief discussion of any specific inclusion/exclusion criteria that may affect enrollment.*

**d. Data Source**

If applicable, please describe the source of data that will be used for this study (e.g. databases, etc.).

**e. Interventions**

Outline the interventions planned which may include study-administered medications, patient reported outcome measures, other surveys, implementation science frameworks & strategies, etc. This should be no longer than 150 words.

# Statistical Plan

**a. Sample Size**

*Provide the target sample size for the primary objective. Justify the total sample size based on statistical power to test the primary hypothesis (and important secondary hypotheses, if relevant) using the stated primary and/or secondary outcome variables.*

**b. Statistical Analyses**

*Outline the statistical analyses planned for the primary endpoints and key secondary endpoints.*

# Reporting Timeframes

Please provide estimated timings for achievement of key milestones in study (e.g. enrollment duration, completion of primary analyses, etc.).

# References

Please list up to 5 key references.