

Implementation Readiness Checklist

Milestone	Completed
<i>Recruitment plans are finalized</i>	
All sites identified (documentation of site commitment)	
Methods for accurately identifying participants validated	
All agreements for necessary subcontracts in place (including DUAs if applicable)	
<i>Ethical/regulatory aspects are addressed</i>	
Coordinated IRB oversight in place	
Finalized plans for informed consent or waiver of informed consent	
Finalized data and safety monitoring plan	
<i>Intervention is fully developed and finalized</i>	
Finalized intervention (including materials and training at sites) ready for site implementation	
Finalized protocol is IRB approved (informed consent and data collection forms, if applicable)	
<i>Data collection methods are adequately tested</i>	
Validated methods for extracting and harmonizing electronic health record information	
Validated study surveys, interviews, or other data collection modes	
Demonstrated quality assurance and harmonization of data elements across healthcare systems/sites	
Statistical and data analysis methods have been adequately developed and recorded	
<i>Budget is realistic, feasible, and accounts for potential changes</i>	
<i>Trial registration is updated to reflect any changes to study protocol (including changes to outcome measures and analytic plan)</i>	

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