

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	
<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 the 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	
<i>Budget is realistic, feasible, and accounts for potential changes</i>	