

Ways to Address RE-AIM Issues in Efficacy and Effectiveness Studies

RE-AIM Element	Efficacy Trials (Phase III Research)	Effectiveness Trials in Defined Populations (Phase IV Research)
Reach Strategies	<p>Specified inclusion criteria or purposeful selection, but participants will be volunteers in a specific research setting</p> <p>Report exclusion and participation rates, dropouts, and representativeness</p>	<p>Include all relevant members of a defined population</p> <p>Report exclusions, participation rates, drop-outs and representativeness</p>
Efficacy or Effectiveness Strategies	<p>Measure outcomes using intent to treat assumptions and a high level of rigor</p> <p>Assess both positive (anticipated) and negative (unintended) outcomes</p>	<p>Same as above, though measures are usually more limited</p> <p>More likely to include economic outcomes</p>
Adoption Strategies	<p>Have potential adoptees assess fit of prototype intervention to their setting</p> <p>Include "proxy measures" of adoption -such as participation among those staff members of a system who will participate in the study</p>	<p>Assess willingness of stakeholders from multiple settings to adopt and adapt the program</p> <p>Report on representativeness of settings, participation rate and reasons for declining</p>
Implementation Strategies	<p>Collect data on likely treatment demands</p> <p>Evaluate delivery of intervention protocol by different intervention agents (usually research staff)</p>	<p>Assess staff ability to implement key components of the intervention in routine practice</p> <p>Evaluate consistency of intervention delivery by agency staff who are not part of research team</p>
Maintenance Strategies	<p>Assess recidivism among participants</p> <p>Engage potential community settings in strategic planning efforts</p> <p>Document extent to which research protocol is retained by setting/agency once the formal study is completed</p>	<p>Assess continuation of program over time, and especially after research phase concludes</p> <p>Systematically program for and evaluate the level of institutionalization of the program elements after formal study assistance is terminated</p>