

## Effective RWD-Supported Discussions of Eligibility Criteria

CTTI recommends planning for iterative discussions about eligibility criteria as these and other interrelated considerations evolve over the course of designing a clinical trial. The following checklist can help sponsors ensure productive discussions.

Factor	Detailed Considerations
<b>Engage a cross-functional team</b>	<p>In utilizing real-world data (RWD) to inform trial eligibility criteria, the ideal team will be multi-disciplinary and cross-functional. Examples of important perspectives include:</p> <ul style="list-style-type: none"> <li>▶ <b>Clinical</b></li> <li>▶ <b>Operations</b></li> <li>▶ <b>Informatics</b></li> <li>▶ <b>Epidemiology</b></li> <li>▶ <b>Patients</b></li> <li>▶ <b>Investigators / Key Opinion Leaders (KOLs)</b></li> </ul>
<b>Define fundamental parameters</b>	<p>CTTI recommends that discussions of eligibility criteria begin early in the study design process. Information necessary for a productive discussion includes:</p> <ul style="list-style-type: none"> <li>▶ <b>Study synopsis.</b> This should include study objectives / key endpoints and high-level eligibility criteria, which provide a framework to help focus any data analyses.</li> <li>▶ <b>Likely operational challenges.</b> Work across the study team to understand important feasibility considerations for the study.</li> </ul>
<b>Adjust study design and mitigate risks</b>	<p>Insights from RWD can help sponsors understand and plan for:</p> <ul style="list-style-type: none"> <li>▶ <b>Risks associated with non-negotiable eligibility criteria.</b> If analysis of RWD identifies potential recruitment challenges associated with non-negotiable eligibility criteria, it will be important to develop recruitment plans that mitigate risks to the success of the study (e.g., by increasing the number of recruitment sites).</li> <li>▶ <b>Impact of negotiable eligibility criteria on study feasibility.</b> <ul style="list-style-type: none"> <li>○ Use a range of information to inform decision-making, and assess whether findings are directionally similar.</li> <li>○ Data visualizations that support interactive discussions are valuable. Visualizations should quickly convey key information and be understandable to all team members.</li> </ul> </li> <li>▶ <b>Other factors impacting study feasibility</b>, such as new treatments becoming available and their potential impact (e.g., see <a href="#">Case Study: Solving Mid-Study Recruitment Challenges for Phase Ib/II Breast Cancer Trial</a>).</li> </ul>