

<p><i>Business Purpose</i></p>	<p>Pharmaceutical Company X has analyzed clinical trial data and recognized significant disparities in clinical research participation as a byproduct of systemic and institutional racism.</p> <p>COVID-19 vaccine and treatment development have greatly amplified the need for all communities to have the same opportunity to participate in research. To achieve better outcomes and health equity for historically underserved populations, Pharmaceutical Company X has committed to addressing the hidden, real-world reasons for such poor diversity in their clinical trials.</p> <p>This course will provide team members of Pharmaceutical Company X with a basic overview of unconscious systemic bias and its impact on clinical trial populations and outcomes. The course will also train the learner on the patient representativeness model as part of a company-wide initiative to increase diversity of trial participants. Lastly this course will provide team members with reasonable and actionable tasks that can be used towards the goal of increasing the diversity of clinical trial participants.</p> <p>Goal: Pharmaceutical Company X commits to a 30% increase in the number of people of color who participate in their clinical trials over the next five years.</p>
<p><i>Target Audience</i></p>	<p>Sponsors, Clinicians, and Clinical Trial Site/Study managers at Pharmaceutical Company X who will be recruiting participants for clinical trials.</p>
<p><i>Training Time</i></p>	<p>45 minutes</p>
<p><i>Training Recommendation</i></p>	<p>The recommendations for this training are:</p> <ul style="list-style-type: none"> <li>• This course is an eLearning module. This is the best format because it allows sponsors, clinicians, and site/study managers at Pharmaceutical Company X to access information at any time and any place.</li> <li>• This training is intended to show learners how to identify representativeness and optimal trial cite placement. This training will also introduce methods and awareness raising initiatives that will increase the percentages of people from diverse backgrounds who participate in clinical trials with Pharmaceutical Company X.</li> </ul>
<p><i>Deliverables</i></p>	<p>Complete Storyboard</p> <p>1 e-Learning course:</p> <ul style="list-style-type: none"> <li>• developed in Articulate Storyline</li> <li>• voice-over narration</li> <li>• approximately 15-20 slides</li> </ul>

<p><i>Learning Objectives</i></p>	<p>By the end of the module, learners will be able to:</p> <ul style="list-style-type: none"> <li>• identify steps in the patient representativeness model</li> <li>• recognize the critical importance of clinical trial site placement</li> <li>• describe methods of reimbursement costs for participants in clinical trials</li> <li>• provide examples of awareness raising initiatives to promote diverse participant engagement</li> </ul>
<p><i>Learner Outcomes</i></p>	<p>Learners will be able to apply the Patient Representativeness Model with the goal of increasing the number of people of color participating in clinical trials with Pharmaceutical Company X.</p>
<p><i>Training Outline</i></p>	<ol style="list-style-type: none"> <li>1) Cover Slide</li> <li>2) Navigation</li> <li>3) Objectives</li> <li>4) Solving Unconscious Systemic Bias in Clinical Trials             <ul style="list-style-type: none"> <li>▪ Build trust in diverse communities</li> <li>▪ Dispel long-held myths</li> <li>▪ Create relationships</li> <li>▪ Educate participants, families, communities, physicians</li> </ul> </li> <li>5) Representativeness Roadmap and Rubric             <ul style="list-style-type: none"> <li>▪ Define</li> <li>▪ Understand</li> <li>▪ Specify</li> <li>▪ Plan</li> <li>▪ Evaluate</li> <li>▪ Document</li> </ul> </li> <li>6) Strategies to Achieve Representativeness             <ol style="list-style-type: none"> <li>A. Clinical Trial Site Placement                 <ul style="list-style-type: none"> <li>▪ Selecting trial site placements</li> <li>▪ Centers of Excellence</li> <li>▪ Pairing Hospitals</li> </ul> </li> <li>B. Reimbursement Costs for Participants                 <ul style="list-style-type: none"> <li>▪ Equity</li> <li>▪ FDA</li> <li>▪ Appropriate Coverage</li> <li>▪ Explicit Written Policies</li> <li>▪ Prepaid Cards</li> </ul> </li> <li>C. Awareness Raising Initiatives                 <ul style="list-style-type: none"> <li>▪ Building Community &amp; Local Partnerships</li> <li>▪ Providing Educational Activities</li> </ul> </li> </ol> </li> </ol>

	<ul style="list-style-type: none"><li>▪ Advertising Strategies</li><li>▪ Integrating Research into Everyday Life</li></ul> <p>7) Review</p> <p>8) Knowledge Check</p>
<p><i>Evaluation Plan</i></p>	<p>Learner Assessment:</p> <p>There is a graded 5-question quiz at the end of the course for learners to demonstrate that they remember the key strategies to increase diverse participant population in clinical trials.</p> <p>Learners must score 80 or above to pass and will have two attempts to answer each question correctly.</p> <p>If incorrect answers are submitted on the second attempt, learners will be given feedback that reminds them where in the course they can review that content.</p> <p>Training Evaluation:</p> <p>Increase the percentage of people of color who participate in clinical trials with Pharmaceutical Company X.</p> <p>Annual reviews of all clinical trials will include specific review of percentages of participants of color.</p>