

Methods to Reduce Systemic Implicit Bias in Clinical Trials – Storyboard

Notes for Reviewers:


- Please focus on the accuracy and completeness of the content during this review cycle. “Page breaks” for the online course will be adjusted after the content is edited.
- Questions for reviewers are indicated with **green highlighting**. All questions will need to be resolved before programming can begin.
- Remember, the text in the left column will be narrated audio.
 - There will be “connecting” words and phrases that would not appear in a written procedure. If the wording seems awkward to you, try reading the text aloud to see how it fits, then make changes if it still seems necessary.
 - Formatting is merely to aid the voiceover talent: remember, learners will hear – not see – this text.
 - Capitalization is not important in the left column, but is very important in the next column, “Visual/Text.”

Pharmaceutical Company X has analyzed clinical trial data and identified significant disparities in clinical research participation as a byproduct of systemic and institutional racism.


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.

Target Audience: Sponsors, Clinicians, and Clinical Trial Site/Study managers at Pharmaceutical Company X who will be recruiting participants for clinical trials.

Terminal Objective: 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.

1.1 Title Slide		
Narration	Visual/Text	Functionality
<p>Welcome to the Methods to Reduce Systemic Implicit Bias in Clinical Trials eLearning course. Please click "Begin", for information on how to navigate the course.</p>	<p>IMG: Woman looking at a collage of diverse people while seeing herself reflected.</p>  <p>Header: Welcome to Methods to Reduce Systemic Implicit Bias in Clinical Trials. OT: A course to help <i>recognize</i> and <i>resolve</i> unconscious bias in clinical trials. BEGIN button</p>	<p>Learner will advance by clicking BEGIN.</p>


1.2 Navigation		
Narration	Visual/Text	Functionality
<p>Please take a moment to familiarize yourself with the navigational features of this course.</p> <p>If you want to navigate to a different section in the course, Select the menu button. Do you want to see definitions of content specific vocabulary? Select the glossary button. Do you want to review the additional information for the course? Select the resources button. To move backward and forward in the course, simply select the previous and next buttons. Select the next button now.</p>	<p>Header: Course Navigation OT: MENU: Use the menu tab to check your progress in the course. You must complete all modules before you can progress to the final. GLOSSARY: Use the glossary tab to find definitions of content specific vocabulary. RESOURCES: Use the resources tab to review additional information for the course. PREV/NEXT: Use these to navigate in sequence back-and-forth between pages.</p>	<p>ANIM: Descriptions of navigation features (MENU, GLOSSARY, RESOURCES, PREV/NEXT) slide in timed with narration.</p>

1.3 Objectives		
Narration	Visual/Text	Functionality
<p>At the conclusion of this course, you will be able to:</p> <p>Identify the steps in the patient representativeness model.</p> <p>Recognize the critical importance of clinical trial site placement.</p> <p>Describe methods of reimbursement costs for participants in clinical trials. And</p> <p>Provide examples of awareness raising initiatives to promote diverse participant engagement.</p> <p>Please click NEXT to continue.</p>	<p>Header: Objectives</p> <p>IMG: Icons for each objective</p>  <p>OT:</p> <p>At the end of this course, you will be able to:</p> <ul style="list-style-type: none"> • identify steps in the patient representativeness model • recognize the critical importance of clinical trial site placement • describe methods of reimbursement costs for participants in clinical trials • provide examples of awareness raising initiatives to promote diverse participant engagement 	<p>ANIM: Each icon slides in timed with narration.</p>


1.4 Impact of Unconscious Systemic Bias		
Narration	Visual/Text	Functionality
<p>A lack of diverse community involvement early in clinical trial development process impacts a multitude of decisions that affect racial and ethnic minorities.</p>	<p>Header: Unconscious Systemic Bias</p> <p>IMG: Black father and two sons</p> <p>OT: What can we do to stop disparities in clinical trials during the time of COVID-19?</p>	<p>Image fades in</p>

<p>You may be asking yourself, "What can we do to stop disparities in clinical trials during the time of covid Nineteen?"</p> <p>For starters, we can: Begin the process to eradicate unconscious bias, start to build trust in diverse communities, Work to dispel long-held myths, begin to create meaningful and lasting relationships, and find effective ways to educate patients, family members, and physicians. Let's continue by looking at representativeness in clinical trials.</p> <p>Please click NEXT to continue.</p>	<ul style="list-style-type: none"> • Eradicate unconscious bias • Build trust in diverse communities • Dispel long-held myths • Create relationships • Educate patients, family members, and physicians <p>Let's continue by looking at representativeness in clinical trials.</p>	<p>Each bullet point slides in timed with narration</p>
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1.5 Solving Unconscious Systemic Bias		
Narration	Visual/Text	Functionality
<p>"Representativeness" means enough people from diverse backgrounds are included in trials, to ensure those enrolled represent the target population for whom the treatment is intended.</p>	<p>Header: Representativeness IMG: Black grandmother and grandson at kitchen sink, circles that say Definition, Who, How OT: <i>Click each button to learn more.</i></p> <p>Definition: Representativeness means enough people are included in a trial to ensure that those enrolled can speak on behalf of the target population.</p> <p>Who: Representativeness refers to "who" and "how many" individuals to include to, as closely as possible, represent the broader target patient population.</p> <p>How: We achieve representativeness by using the following roadmap while planning and conducting clinical trials.</p>	<p>ANIM: Direction fly in</p> <p>INTERACTION: When clicked each circle will have text appear to expand on the information.</p> <p>Learner must click each circle to continue.</p>


1.6 Understanding Representativeness		
Narration	Visual/Text	Functionality
<p>Establishing strong patient representativeness requires using process measurements to assess how close a trial has gotten to the target measures.</p> <p>Click on each segment of the circle to reveal more information about each step.</p>	<p>Header: Representativeness Roadmap and Rubric</p> <p>IMG:</p>  <p>OT: Establishing strong patient representativeness requires using process measurements. <i>Click each segment of the circle to read more information about each step.</i></p> <p>Layer 1: Define: The objective, goal, or research question is critical to defining what “good” patient representativeness means for that engagement. The method(s) used to engage patients (e.g., focus groups, surveys, individual discussions, or patient preference studies) should also be considered when defining patient representativeness and a “representative sample” for that engagement activity.</p> <p>Layer 2: Understand: Prior to the engagement, we must understand as much about the total patient population of interest to avoid missing critical details (including inadvertently ignoring relevant smaller subpopulations) that can impact how to define a target population.</p> <p>Layer 3: Specify: Defining the optimal target population – or the patient population that the desired “representative sample” should represent – is key to achieving patient representativeness.</p>	<p>INTERACTION: When clicked each topic will have text appear to expand on the information.</p>

	<p>Layer 4: Plan: For each patient engagement effort, clearly defining and developing a plan for achieving the minimum target(s) should be outlined prior to the engagement and <i>with</i> patient input.</p> <p>Layer 5: Evaluate: Any plan for achieving patient representativeness should include continual assessment and refinement. As in the beginning, patients should be involved in the refining of any plans, definitions, or minimum targets throughout the entire engagement, and their input should be integrated into decision-making and evaluations.</p> <p>Layer 6: Document: It is important that stakeholders document the processes and outcomes of defining a target(s) and creating achievement and assessment plans, recording their processes of defining, achieving, and assessing patient representativeness for each engagement. This will help in articulating their rationale and ensure processes are understandable to others.</p>	
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1.7 Clinical Trial Site Placement		
Narration	Visual/Text	Functionality
<p>Without adequate participation of ethnic/racial minorities in our clinical trials, we miss the Opportunity to understand how the therapy works in minority patients, whether it is safe, and how much drug is needed to be efficacious. Conversely, these potential participants continue to look in from the outside and feel disaffected (if they are even aware of the research).</p>	<p>Header: Importance of Clinical Trial Site Placement</p> <p>IMG:</p>  <p>2nd IMG: Photo of outside of a hospital</p> <p>OT:</p>	<p>ANIM: Onscreen text and image of young men fades in.</p> <p>Image of hospital fades in.</p>


<p>We must start selecting clinical trial sites that are inclusive of diverse patient populations.</p>	<ul style="list-style-type: none"> • Pre-COVID-19, the percentage of African Americans and Hispanics/Latinx participating in clinical trials was 14 percent and 7.6 percent, respectively. • We continue to struggle creating racially and ethnically balanced clinical drug participation. • We must select clinical trial sites that are inclusive of diverse patient populations. 	
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1.8 Site Placement		
Narration	Visual/Text	Functionality
<p>[1] There is often a disconnect between where patients with the disease reside and clinical trial site placement, especially for racial and ethnic minority populations. Solutions may include centers of excellence and pairing hospitals. Click each button to learn more.</p> <p>[2] Sponsors could partner with organizations such as BIO, C.T.T.I., Pharma, and TransCelerate to create centers of excellence at smaller community hospitals with large populations of ethnic/racial minority physicians and patients.</p> <p>[3] Pairing community hospitals with major hospital institutions would arm community hospitals with the same standard of care, availability of clinical trials, patient referral programs, and increased diversity choices and participation as preeminent institutions.</p>	<p>Header: Clinical Trial Site Placement</p>  <p>IMG:</p> <p>OT:</p> <p>Base Layer: There is a disconnect between where patients with the disease reside and clinical trial site placement, especially for racial and ethnic minority populations.</p> <p>(Buttons)</p> <p>Centers of Excellence Pairing Hospitals</p> <p>Layer 1: Sponsors could partner with larger organizations to create centers of excellence at smaller community hospitals with large populations of ethnic/racial minority patients.</p> <p>Layer 2: Same standard of care</p> <ul style="list-style-type: none"> • Availability of clinical trials • Patient referral programs • Increased diversity choices and participation 	<p>ANIM: Buttons fade in.</p> <p>INTERACTION: When clicked each topic will have text appear to expand on the information.</p> <p>Learner must click each button to move forward.</p>

1.9 Knowledge Check		
Narration	Visual/Text	Functionality
<p>[1] Let's check your knowledge. Michelle works for a biopharmaceutical company that wants to understand the impact of a rare disease on patients' lives. The company has little experience with the disease or therapeutic area.</p> <p>What should Michelle suggest in this early-stage engagement, pre-clinical work to ensure that there will be diverse patient representativeness in the trial?</p> <p>Select all that apply.</p> <p>[A] Yes! Bringing together the strengths of a community setting, such as understanding the culture and the relationships within the community will facilitate greater representativeness.</p> <p>[B] Yes! Using the Patient Representativeness Roadmap and Rubric can guide our decision-making on representativeness for clinical trials.</p> <p>[C] Yes! It is time to partner with hospitals with large populations of ethnic and racial minority physicians and patients. This will allow us to create representativeness in clinical trial education and referral programs.</p>	<p>Header: Knowledge Check</p> <p>IMG: Women's facial expression and body language changes based on answer learner clicks on.</p>  <p>OT:</p> <p>[1] Michelle works for a biopharmaceutical company that wants to understand the impact of a rare disease on patients' lives. The company has little experience with the disease or therapeutic area.</p> <p>[2] What should Michelle suggest in this early-stage engagement, pre-clinical work to ensure that there will be diverse patient representativeness in the trial?</p> <p>[3]</p> <p>A. "We could partner with a major hospital institution that has paired with a community hospital where it is manageable for racial and ethnic minorities to participate."</p>	<p>[1] Fade in.</p> <p>[2] Fade in.</p> <p>[3] Fade in.</p> <p>INTERACTION: Scenario based multiple select knowledge check question. Learners will select what they think is the best course of action for avatar Michelle to suggest to her biopharmaceutical company. There are multiple correct answers with feedback explaining each choice.</p>

<p>[D] Unfortunately, this model can perpetuate the inclusion of the same “TYPE” of patient participants being recruited for trials and can cause a crucial lack of representativeness.</p>	<p>B. “We could utilize the Patient Representativeness Roadmap: Define, Understand, Specify, Plan, Evaluate, and Document.”</p> <p>C. “We could partner with organizations such as TransCelerate to create centers of excellence in rural and urban centers.”</p> <p>D. “We could continue working with hospitals where we have long standing relationships and a history of high recruitment and retention.”</p> <p>(Layer 1 Answer A) Feedback Yes! Bringing together the strengths of a community setting, such as understanding the culture and the relationships within the community will facilitate greater representativeness.</p> <p>(Layer 2 Answer B) Feedback Yes! Using the The Patient Representativeness Roadmap and Rubric can guide our decision-making on representativeness for clinical trials.</p> <p>(Layer 3 Answer C) Feedback Yes! It is time to partner with hospitals with large populations of ethnic/racial minority physicians and patients. This will allow us to create representativeness in clinical trial education and referral programs.</p> <p>(Layer 4 Answer D) Feedback</p>	
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	<p>Unfortunately, this model can perpetuate the inclusion of the same “type” of patient participants being recruited for trials and can cause a crucial lack of representativeness.</p>	
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1.10 Reimbursement Costs for Participants in Clinical Trials		
Narration	Visual/Text	Functionality
<p>Layer 1 The graph below is from The NMQF Diverse Cancer Communities Working Group survey from 2019 and asked about the degree to which major innovative cancer sponsors have a standard approach to coverage or reimbursement of patients care during clinical trials. The results?</p> <p>“Well, it depends.” This response can no longer be accepted.</p> <p>Layer 2 Appropriate reimbursement for patient logistical and medical expenses *MUST* be a priority, not an afterthought. We must start with appropriate coverage of costs that allows patients to participate. At the core, true engagement of diverse communities starts with fairness and equitable implementation. We cannot achieve trial diversity and representativeness without appropriate, ethical reimbursement.</p>	<p>Header: Reimbursement Costs for Participants in Clinical Trials</p> <p>Layer 1 IMG: Graph demonstrating lack of reimbursement for participants in trials.</p> <p>Layer 1 OT: Appropriate reimbursement for patient logistical and medical expenses must be a priority, and not an afterthought.</p> <p>Layer 2 IMG: </p> <p>Layer 2 OT: True engagement of diverse communities starts with fairness and equitable implementation.</p>	<p>ANIM: Graph fades out and image of family fades in.</p> <p>Layer 2 reveal timed with narration. No action required from learner.</p>

1.11 Reimbursement is Critical		
Narration	Visual/Text	Functionality
<p>Reimbursement of Participant Costs is Critical. We must start with appropriate coverage of costs that allows patients to participate. Click on each box below to learn about the steps that can be taken to mitigate participant costs in clinical trials.</p>	<p>Header: Why Reimbursement of Participant Costs is Critical IMG: 6 different images that correspond to the steps that can be taken to mitigate participant costs in clinical trials. OT: Click on each box below to learn about the steps that can be taken to mitigate participant costs in clinical trials.</p>	<p>INTERACTION: When clicked each topic will have text appear to expand on the information.</p> <p>Learner must click each step to advance.</p>
<p>1.11a Step 1 Fairness and Equity:</p> <ul style="list-style-type: none"> • Appropriate reimbursement for patient logistical and medical expenses is a priority. • It is well documented that populations with low socioeconomic status (SES) are not engaged in clinical trials in the U.S. • Limited engagement because of onerous compensation processes or policies is a trust issue. • At the core, true engagement of diverse communities starts with fairness 	<p>OT Layer 1: Step 1 Fairness and Equity:</p> <ul style="list-style-type: none"> • Reimbursement is a priority. • Populations with low socioeconomic status (SES) are not engaged in clinical trials. • Limited engagement is a trust issue. • True engagement of diverse communities starts with fairness and equitable implementation. 	<p>ANIM:</p>
<p>1.11b OT Layer 2: Step 2 The FDA:</p> <ul style="list-style-type: none"> • The FDA does not consider as undue influence reimbursement for reasonable travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging. 	<p>OT Layer 2: Step 2 The FDA:</p> <ul style="list-style-type: none"> • The FDA supports reimbursement for trial related travel expenses. • Don't let FDA compliance stand in the way of appropriately reimbursing participants. 	

<ul style="list-style-type: none"> • Sponsors, clinicians, and site managers should not let FDA compliance and approval stand in the way of appropriately reimbursing participants in clinical trials. 	<ul style="list-style-type: none"> • The FDA supports ethical reimbursement. 	
<p>1.11c Step 3 Appropriate Coverage:</p> <ul style="list-style-type: none"> • People should decide whether to participate in a trial based on what it means to them, their family, and their community. • Out-of-pocket expenses should not be a barrier to trial participation. <p>We cannot achieve trial diversity and representativeness without appropriate and ethical reimbursement.</p>	<p>OT Layer 3: Step 3 Appropriate Coverage:</p> <ul style="list-style-type: none"> • People should decide whether to participate in a trial. • Expenses shouldn't be a barrier to participation. • Diversity and representativeness won't be achieved without reimbursement. • Get input from diverse populations about the expenses associated with being in a trial. 	
<p>1.11d Step 4 Discuss and Cover</p> <ul style="list-style-type: none"> • Discuss with your IRB the importance of standardization of appropriate coverage costs to patients. • Cover all patient out-of-pocket expenses based on the principle that it should not cost the patient more to be in a clinical trial. This expectation should be discussed with patients during the recruitment phase. 	<p>OT Layer 4: Step 4 Discuss and Cover</p> <ul style="list-style-type: none"> • Work with your IRB to standardize appropriate coverage costs. • It should not cost the patient more to be in a clinical trial. • To build trust during the recruitment phase, discuss reimbursement of costs with patients. 	
<p>1.11e Step 5 Explicit Written Policies:</p> <ul style="list-style-type: none"> • You must have explicit, written, approved policies regarding reimbursement for trial participants. 	<p>OT Layer 5: Step 5 Explicit Written Policies:</p> <ul style="list-style-type: none"> • Reimbursement policies must be explicitly written and approved. 	

<ul style="list-style-type: none"> • Make the policies available to all trial sites and investigators to ensure study budgets and implementation are consistent with the guidance. • Assume there are real costs to patients, families, and caregivers to engaging in clinical trials. • Engage with diverse and vulnerable populations for input regarding expenses and costs. 	<ul style="list-style-type: none"> • Make reimbursement policies available to all stakeholders to ensure study budgets and implementation are consistent. • There are <i>real</i> costs to patients, families, and caregivers who engage in clinical trials. 	
<p>1.11f Step 6 Prepaid Cards:</p> <ul style="list-style-type: none"> • Consider a prepaid card for all participants. • Prepaid cards are an efficient way to apply the policy. • Prepaid cards are not dependent on a patient asking for support. • Prepaid cards do not require a clinical monitor to make a determination in a timely manner. 	<p>OT Layer 6: Step 6 Prepaid Cards:</p> <ul style="list-style-type: none"> • Are for all participants. • Are efficient. • Aren't dependent on a patient asking for support. • Don't require a clinical monitor to make a determination in a timely manner. 	


1.12 Awareness Raising Initiatives		
Narration	Visual/Text	Functionality
<p>Hopefully you are beginning to wonder How to Promote Diverse Participant Engagement. Below is a checklist for those who design and implement clinical trials. Click the boxes to the left to learn how to raise awareness about clinical trials in areas with diverse populations.</p>	<p>Header: How to Promote Diverse Participant Engagement</p> <p>IMG:</p>  <p>OT: Awareness Raising Initiatives</p>	<p>INTERACTION: When clicked each box will have a checklist appear to expand on the information and offer actionable tasks.</p>

	<p>This is a model checklist for those who design and implement clinical trials.</p> <p>Click the boxes to the left to learn how to raise awareness about clinical trials in areas with diverse populations. <i>(Boxes)</i> Build Community and Local Partnership Provide Educational Activities Advertising Strategies Integrate Research into Everyday Life</p> <p>OT Layer 1: Build Community and Local Partnership</p> <ul style="list-style-type: none">• Reach out to local institutions, groups, community leaders, and clinicians.• Hire and train community members as staff.• Attend and integrate into community events as possible. <p>OT Layer 2: Provide Educational Activities</p> <ul style="list-style-type: none">• Host a luncheon, expo, or health fair for the community.• Provide onsite, educational programs and print materials. <p>OT Layer 3: Advertising Strategies</p> <ul style="list-style-type: none">• Create understandable, health literate study materials in languages relevant to the target population.• Place study adverts in locations frequented by target study population.• Consider all places media outlets: radio, tv, internet, and social media. <p>OT Layer 4: Integrate Research into Everyday Life</p>	
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	<ul style="list-style-type: none"> • Consider decentralizing the trial to ease direct participation requirements. • Provide necessary provisions to encourage participation (i.e., transport or refunds) and reduce burdens. • Create community advisory boards to inform research design and outcomes. 	
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1.13 Knowledge Check		
Narration	Visual/Text	Functionality
<p>[1] It is time to test your knowledge of reimbursement strategies and diverse participant engagement strategies in clinical trials. Drag and drop each strategy into the category to which it belongs and then click submit.</p> <p>[2] That is incorrect. Please try again.</p> <p>[3] Unfortunately, that is incorrect. Please take a moment to review the correct answers now.</p> <p>[4] That's right! You selected the correct response. Well done!</p>	<p>Header: Knowledge Check</p> <p>IMG: Two computer screens one labeled Methods of Reimbursement Strategies and the other Diverse Patient Engagement Strategies.</p> <p>OT [1]:</p> <ul style="list-style-type: none"> • Hire and train community members as staff • Provide transport and refunds to ease financial burden • Host a lunch or health fair for the community or hospital • Consider prepaid cards for all participants • Use all media outlets: radio, TV, Internet, social media • Have policies in place to cover patient out of pocket expenses <p>OT [2]: That is incorrect. Please try again.</p> <p>OT [3]: Incorrect: Correct Answer Methods of Reimbursement</p> <ul style="list-style-type: none"> • Provide transport and refunds to ease financial burden 	<p>INTERACTION: Learners will drag and drop the correct answers to the appropriately labeled computer.</p> <p>Learners will click submit to submit their response.</p> <p>Learners will be given two opportunities to get the correct answer.</p> <p>[2] If the first answer submitted is incorrect, learners will click Try Again.</p> <p>[3] If the learner is incorrect a second time, they will click Continue to proceed.</p>

	<ul style="list-style-type: none"> • Consider prepaid cards for all participants • Have policies in place to cover patient out of pocket expenses <p>Diverse Patient Engagement Strategies.</p> <ul style="list-style-type: none"> • Hire and train community members as staff • Host a lunch or health fair for the community or hospital • Use all media outlets: radio, TV, Internet, social media <p>OT [4]: That's right! You selected the correct response.</p>	<p>[4] If the learner is correct, they will click Continue to proceed.</p>
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1.14 Review		
Narration	Visual/Text	Functionality
<p>[1] Let's review! When moving forward in the planning phases of clinical trials, please take the following objectives into consideration to mitigate the effects of unconscious systemic bias.</p> <p>[2] The Patient Representativeness Model. Use the model as a roadmap during planning stages. Remember the mnemonic: Do-U-SPED.</p> <p>[3] Clinical Trial Site Placement. Placement of trials needs to be easily accessible for ALL patients.</p> <p>[4] Reimbursement Costs.</p>	<p>Header: Review</p> <p>IMG:</p>  <p>OT:</p> <p>[1] When moving forward in the planning phases of clinical trials, please take the following objectives into consideration to mitigate the effects of unconscious systemic bias.</p> <p>[2] The Patient Representativeness Model. Use the model as a roadmap during planning stages. Remember the mnemonic: Do-U-SPED.</p> <p>[3] Clinical Trial Site Placement.</p>	<p>ANIM:</p> <p>Image fades in. Text boxes fade in timed with narration.</p> <p>User clicks Next to continue.</p>

<p>One suggestion is to consider providing patients with pre-paid cards to offset costs.</p> <p>[5] Awareness Raising Strategies. Use social media to ensure diverse populations are aware of trials.</p>	<p>Placement of trials needs to be easily accessible for ALL patients.</p> <p>[4] Reimbursement Costs. One suggestion is to consider providing patients with pre-paid cards to offset costs.</p> <p>[5] Awareness Raising Strategies. Use social media to ensure diverse populations are aware of trials.</p>	
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1.15 Assessment		
Narration	Visual/Text	Functionality
<p>You will now take a short assessment. The following three slides contain questions that will assess your knowledge of methods to solve unconscious systemic bias in clinical trials. You must score 80% or above to successfully complete this module. When you are ready, click NEXT to begin the assessment.</p>	<p>Header: Assessment</p> <p>IMG:</p>  <p>OT: The following slides contain questions that will assess your knowledge of methods to solve unconscious systemic bias in clinical trials.</p>	<p>Learner will click Next to begin assessment.</p>

1.16 Question 1		
Narration	Visual/Text	Functionality
	<p>Header: Question 1</p> <p>OT: Site Placement What is the best solution to help diversify clinical trial site placement?</p>	<p>INTERACTION: Learner will select best answer from 4 choices.</p> <p>Learners will be given two chances to select the correct answer.</p>

	<p>A. Create and support centers of excellence in rural and urban centers.</p> <p>B. Continue working with hospitals where relationships have been formed.</p> <p>C. Pair community hospitals with other successful community hospitals.</p> <p>D. Seek out trial sites that have strong recruitment and retention numbers.</p> <p>(Incorrect Try Again) Sorry! Your answer is incorrect. Try Again. Remember that we are attempting to implement new methods to rectify old patterns that will lead to a more diverse patient population.</p> <p>(Correct) Congrats! Your answer is correct! Continue. Yes, creating and supporting centers of excellence in rural and urban centers will aid us in recruiting a diverse patient population.</p> <p>(Incorrect) Sorry. Your answer is incorrect. Continue. Please go back to the slides <i>Importance of Clinical Trial Site Placement</i> and <i>Clinical Trial Site Placement</i> and review what can be done to improve the diversity of patient populations in clinical trials.</p>	<p>Learners will click Continue to move on.</p> <p>Correct answer is A.</p>
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1.17 Question 2		
Narration	Visual/Text	Functionality
	<p>Header: Question 2</p> <p>OT: Awareness Raising Initiatives Connect the actions with the corresponding initiatives and click submit.</p>	<p>INTERACTION: Learner will drag answers to match actions to corresponding initiatives.</p>

	Initiatives	Actions	<p>Learners will be given two chances to select the correct answer.</p> <p>Note: In the table to the left the action is correctly matched to the corresponding initiative. In the training they will be randomized.</p> <p>Learner will click continue to move on.</p>
	Build Community and Local Partnerships	Hire and train community members as staff.	
	Provide Educational Activities	Host a luncheon, health fair, or expo for the community or hospital.	
	Advertising Strategies	Place study adverts in all media outlets: radio, TV, Internet, and social media.	
	Integrate Research into Everyday Life	Create community advisory boards to inform research design and outcomes.	
<p>(Incorrect Try Again) Sorry! Your answer is incorrect. Try Again. Remember that it is important to use a variety of strategies. There are multiple ways to raise awareness about trials in diverse communities. (Correct) Congrats! Your answer is correct! Continue. Yes! Please consider these methods the next time you are in the planning phases of a trial. These methods will help you generate a diverse population of participants. (Incorrect) Sorry. Your answer is incorrect. Continue. Please go back to the slide <i>Awareness Raising Initiatives to Promote Diverse Participant Engagement</i>. This slide suggests various methods for engaging a diverse participant population.</p>			

1.18 Question 3		
Narration	Visual/Text	Functionality
	<p>Header: Question 3</p> <p>OT: Patient Representativeness Roadmap What is the correct sequence of the steps in the Patient Representativeness Roadmap? Drag the steps into the correct sequence and click submit.</p> <ol style="list-style-type: none"> 1. Define a clear objective. 2. Understand the full population. 3. Specify minimum targets. 4. Plan to achieve the targets. 5. Evaluate progress made. 6. Document <p>(Incorrect Try Again) Sorry! Your answer is incorrect. Try Again. Remember the sequence involves process measurements that will allow us to assess how close a trial has come to target goals. There is a great deal of thought and design that comes before the implementation stage.</p> <p>(Correct) Congrats! Your answer is correct! Continue. Excellent! Using the Representativeness Roadmap will assist you in designing trials that are inclusive of diverse participant populations and have measurable methods of assessing target goals.</p> <p>(Incorrect) Sorry. Your answer is incorrect. Continue.</p>	<p>INTERACTION: Learner will drag answers into the correct sequence of steps.</p> <p>Learners will be given two chances to submit the correct answer.</p> <p>Note: In the list to the left the steps are in the correct order. In the training they will be randomized.</p> <p>Learner will click continue to move on.</p>

	Please go back to the slide <i>Understanding Representativeness</i> and review the Rubric and Roadmap that lays out the sequence for helping to ensure representativeness in trials.	
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1.19 Results		
Narration	Visual/Text	Functionality
<p>(Not pass) Unfortunately, you did not pass this course. Please go back and review the information presented and try again!</p> <p>(Pass) Congratulations! You have successfully passed this course. Continued focus and progress on increased participation of racial and ethnic minorities in clinical research is needed from multiple collaborative stakeholders to continue to improve our understanding of differences in risk and disease outcomes across populations ... so let's keep tackling together.</p>	<p>Header: Results</p> <p>OT: (Not pass) You did not pass this course.</p> <p>(Pass) Congrats! You passed this course!</p>	

1.20 Exit		
Narration	Visual/Text	Functionality
As we plan clinical trials, we have a responsibility to include diverse patient populations. We <i>*ALL*</i> deserve a chance to save our lives, and together, we can.	<p>HEADER: The Talmud says, "When you save one life, it is as if you saved the entire world."</p> <p>IMG:</p>	



OT:

Novel treatments that are tested in clinical trials belong to everyone who qualifies: women, men, ethnic and racial minorities, LGBTQ community members, the old and the young.