AbbVie's Clinical Trial Diversity and Inclusion Journey – External Workforce Pathway

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Training Program For Research-Limited Sites in the US

Definition of Research-Limited Site	A research-limited site may be defined as (but is not limited to): • An investigator who has served as PI for ≤ 2 interventional industry-sponsored clinical trials • A research coordinator who is new to research • A new research center that may not have established, robust SOPs These sites should also have the potential ability to enroll diverse patients in clinical trials
Format	• Live, facilitator-led, interactive virtual sessions • 18-hour training delivered over 2 days • Training followed by mock trial assessment
Content (10 Modules)	1. Research Terminology 2. ICH GCP 3. FDA Regulations 4. Protocol Execution 5. AE and SAE Evaluation 6. Good Documentation Practices and Standards 7. Strategies for Recruitment and Retention 8. Monitoring and Site Expectations 9. Overall Operations from Feasibility to Close Out 10. Informed Consent Process and Documentation
Mock Trial Assessment	Assessment will determine research-readiness and cover: • Informed Consent • Following GCP • Assessment of AEs • Administration of IP/other study procedures • Data Collection