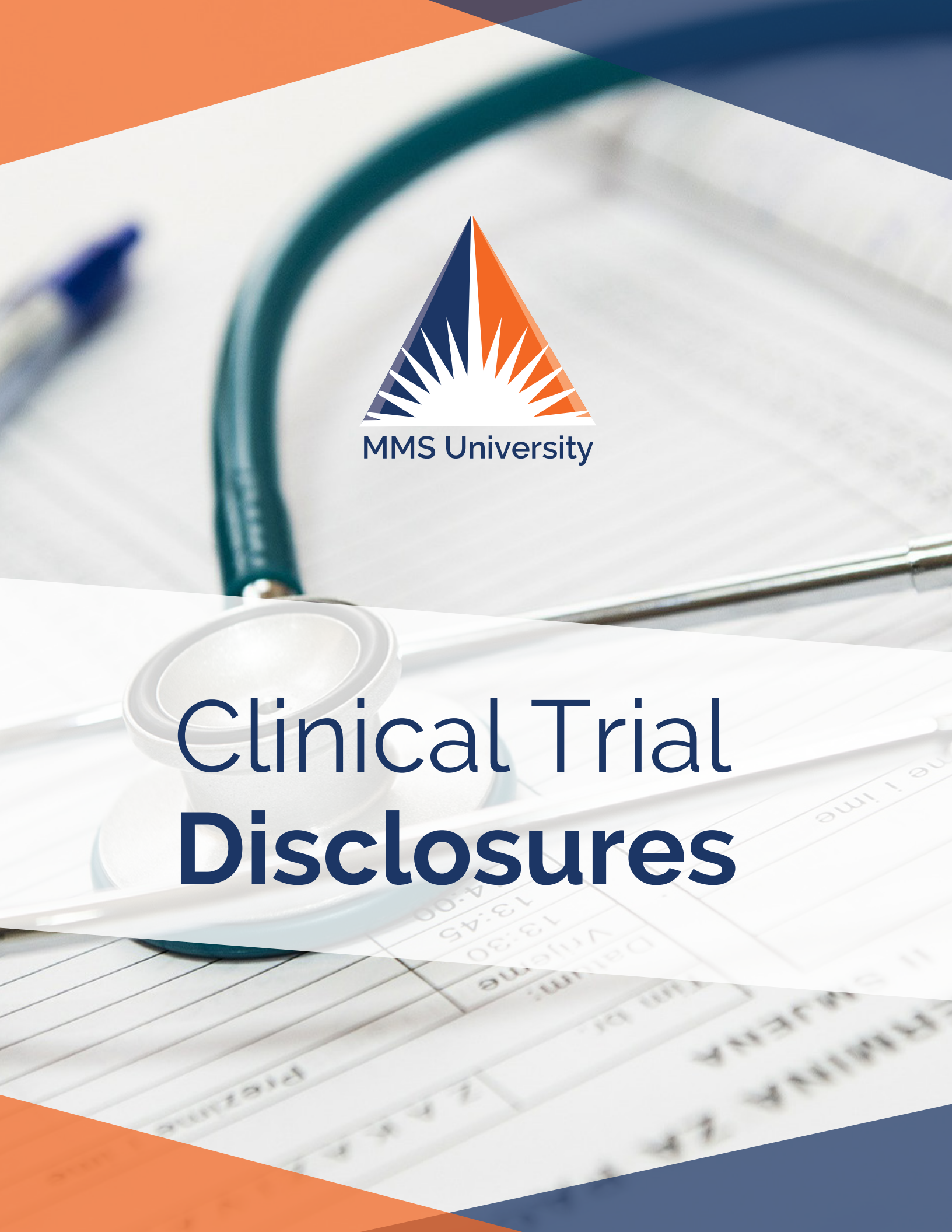

Clinical Trial **Disclosures**

CLINICAL TRIAL DISCLOSURES

Purpose of this Certificate Program

To train and educate professionals in the field of clinical trial disclosures for reporting to public registries mandated by law and regulated by health authorities.

Target Audience

Existing clinical research professionals wishing to specialize in trial disclosures.

Prerequisites

Minimum Expectations:
A BS in a life sciences field, graduate level education preferred.*

2 years' experience in a clinical research discipline facilitating clinical data and involvement with data systems is preferred.

*Degrees/diplomas from educational institutions outside the United States must be equivalent to degrees from U.S. educational institutions.

Intended Learning Outcomes

• Understand disclosure landscape, with an awareness of legal and ethical framework.

• Will possess the knowledge and ability to effectively conduct summarizations of different types of clinical trial protocols and results following registry guidelines.

• Competency in reviewing, interpreting, and summarizing Protocols, Clinical Study Reports, data tables, listings, and graphs.

• Understanding interface capabilities, technical components, and timelines for disclosing on domestic and international registries.

• Provided a perspective for operationalizing clinical trial disclosure workflow.

Description of Training Provided

This one of kind, 16-week course provides training and education for professionals in the field of clinical trial disclosure reporting. This is an evolving regulatory requirement in which the Life Science industry has struggled to maintain compliance; because of its complexities, outsourcing has increased. The skill sets required to learn and excel in disclosures are the focus of this program. This course will provide hands-on experience with writing and reporting to global registries with an emphasis on Clinicaltrials.gov (US) and EudraCT (EMA). Students will learn about the legal and ethical basis for disclosure of the clinical trial protocol and results, beginning with a comprehensive overview of Clinicialtrials.gov and EudraCT.

The course will define how to meet the technical requirements of the registries, to effectively summarize protocols and results. Other mandatory international registries will also be reviewed, and workflow processes and systems for operationalizing clinical trial disclosures will be demonstrated. This is an ideal course for the detail-oriented, regulatory-focused, compliance-minded scientist or aspirant within the pharmaceutical industry.

Duration: 16 weeks

Assessments

Knowledge checks will be performed through quizzes at the end of each session. Evaluation of student outputs will be performed through various assignments and exercises, concluding with a final examination. A minimum of 75 percentage points is required to pass the final examination and obtain certification.

About the Instructor

Mr. Joe Archer is the Associate Director, Trial Disclosure Services at MMS Holdings Inc., Canton, MI, USA, and responsible for providing disclosure, transparency, and consulting services to MMS sponsors across the globe. Mr. Archer has over 25 years of experience in clinical research and is a SME of processes and systems related to the reporting of clinical trial information to ClinicalTrials.gov, EudraCT, and additional registries globally. Prior to MMS, Mr. Archer was the Senior Manager, Clinical Trial Disclosures at GlaxoSmithKline from 2007 to 2011 where he provided operational development and compliance oversight of systems, processes, and quality control for disclosure of the company's protocols and results summary information. He has also held various positions of increasing responsibility in the Regulatory Quality Control and Strategic Operations divisions of INC Research, Pfizer, and Parke-Davis. Mr. Archer earned a Bachelor of Science degree in Health Care Administration from Eastern Michigan University.

Course fee: $2125 (USD)