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The new EU clinical trials regulation

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The EU is introducing legislation aimed at harmonizing the way in which clinical trials conducted in the Europe are authorized and at improving the reliability of data generated in those trials. The Regulation replaces the EU Clinical Trials Directive (EUCTD), which was approved in 2001 and implemented in May 2004. The regulation will introduce and include a number of key provisions. There is an authorization procedure for clinical trials based on a single submission dossier via a single EU portal, an assessment procedure leading to a single decision on all aspects per member state, rules on the protection of subjects and informed consent, and transparency requirements. Other aspects include more detailed safety provisions, new indemnity provisions and a category for low interventional trials. The new regulation also intends to make it easier for Pharma companies to conduct multinational clinical trials. The talk will cover review the new Regulation, highlighting what will change from the Directive and advise companies how to gear up for its implementation.

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Culturally competent strategies for recruitment and retention of African-American populations into clinical trials

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Purpose: To identify successful recruitment strategies, challenges and best practices for researchers to engage African American communities in clinical studies taken into consideration target participants' culture and context.

Methods: We reviewed 50 studies conducted from 2001-2012 at an inner-city research center to determine the type, duration, anticipated enrollments and actual enrollments. Survey was sent to study coordinators to obtain data on recruitment and retention strategies, challenges and dropout rates. We also interviewed 25 study coordinators on challenges and strategies.

Results: Of the 50 studies, 24 had completed recruitment at the time of this report. The completed studies achieved a median recruitment rate of 88% [range: 50-110]. Successful recruitment and retention strategies included field-based strategy and snowballing. Major barriers were distrust, compensation, education disadvantage, lack of interest and inability to have study partner. Strategies to reduce barriers included providing informational sessions, disseminating newsletters about study outcomes. Best practices include being culturally sensitive including demonstrating a caring attitude and being responsive to participants needs.

Conclusions: Cultural competence is critical in order to design and implement successful recruitment strategies in this population. Research teams should comprise of multi-ethnic staff, involve the community, demonstrate trust and deliver concise education of the research endeavor.

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