

Special issues in clinical trials of new anti-infective drugs for the treatment of sexually transmitted diseases. Infectious Diseases Society of America and the Food and Drug Administration.

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Several special issues arise in relation to clinical trials of therapy for sexually transmitted diseases. These issues include the desirability of including adolescents and both pregnant and nonpregnant women in the trial, the use of unapproved control regimens, problems with antimicrobial susceptibility testing due to inadequate methodology and the need for prompt treatment, the need to assess agents for treatment of syndromes of unknown microbial etiology, toxicity considerations related to the use of single-dose regimens, management of the sexual partners of the participants in the trial, analysis of data despite the high frequency of minor protocol violations, sexual reexposure to infection during the trial, and the potential for loss, alteration, or falsification of data because of the relative simplicity of the usual protocol design and the diagnostic reliance on specimens that are routinely discarded.