North Carolina Regulatory Affairs Forum
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Clinical Data Disclosure: A Regulatory and Standards Update

Presenter: John C. McKenney, Sr.
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Date & Time:	**Thursday, 20 September 2007** Networking reception 5:30 – 6:30 p.m. Seminar 6:30 - 8:00 p.m.
Location:	Elion-Hitchings Building (GSK Campus) 3030 E. Cornwallis Road Durham, NC 27709-3398

The pace of change in the field of Clinical Trial Registries and Results Databases has increased dramatically in 2007. The push for publication of initiated trials and completed trial results on publicly accessible web sites is coming from many quarters: U.S. and international regulatory authorities, state lawmakers, the World Health Organization, and medical journal editors, to name a few. The pressure on pharmaceutical trial sponsors has never been greater. If the FDA Modernization Act of 2007 is passed, that pressure may soon extend to medical device trial sponsors as well. The State of Maine regulation governing prescription drug clinical trial reporting went into effect in March of this year, and several more states have clinical data disclosure legislation pending.

This presentation will provide a brief introduction into the history and key drivers that have shaped the rapidly evolving state of clinical data disclosure. The main focus of the presentation will be a survey of the current state of the environment, including updates on the legal, regulatory, standards and enforcement activities affecting trial sponsors in this complex and confusing domain. Participants should gain a clearer understanding of the factors behind the push for public disclosure, and an appreciation of what sponsors must do to ensure they are on track with current requirements and expectations.

This seminar is FREE to current NCRAF members; $20 for non-members;
Advance registration is STRONGLY recommended!

Register by Monday, Sept. 17 on our website: **www.ncraf.org**