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Innovations In Trial Design

Sandra F. Reilley, M.D. CPI

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Trial Design and the FDA

FDA 483 Observation: An investigation was not conducted in accordance with the signed statement of investigator and investigational plan



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Trial Design and the FDA

The problem?

Subject enrolled with sponsor approval
of a BMI that was out of the range of
the I/E



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A New Day Has Come



- Waivers or Exemptions from Inclusion/Exclusion Criteria are no longer tolerated by the FDA
- I/E language must include the flexibility that has been granted with waivers



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Solution: Wording of I/E

- ❖ Unless deemed NCS by the investigator
- ❖ Approximately
- ❖ Unless sponsor's medical monitor and investigator agree that enrollment would pose no increased risks to subject
- ❖ Clinically significant history
- ❖ Relevant to study
- ❖ Recent history of (within 6 mo or 1 yr)



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Solution: Blanket Statement

- ❖ Inclusion/Exclusion criteria is to screen for appropriate subjects to enroll in this study. If a subject does not fall within the parameters of one or more of these criteria, the subject may be included in the study if both the Investigator and sponsor Medical Monitor agree that the deviation is not clinically relevant within the context of this study.



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“Windows” for timed procedures

- Avoid strict definitions that lead to reportable deviations
- Use words like “expectation”
- Report actual times of PK draws and procedures
- Define windows for safety issues only



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