

# Virtual Clinical Trials: A Regulator's Perspective

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September 24, 2020

ASA Biopharmaceutical Section: Regulatory-Industry Workshop



# DISCLAIMER

This presentation represents my views and does not represent FDA position or policy.

# OVERVIEW

**1** Examples of Virtual Studies

**2** Thoughts on Virtual Clinical Trials



1

# VIRTUAL CLINICAL TRIALS (VCTS)

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- Definitions vary, from fully online only trials, to traditional trials with online recruitment
- Given the prevalence and adoption of technology, expect all clinical trials to incorporate some aspects

# VCTs: MY EXPERIENCE

*As a statistician* for the Women's Health Update

- Multi-year, longitudinal observational study of young adult women's health behaviors
- Focused on mental health and health risk behaviors (e.g. drinking, drug use, etc.)

# VCTs: MY EXPERIENCE

*As a participant* in a local survey of transit use

- Week-long tracking of all travel via smartphone app
- Daily brief questionnaires about demographics, transportation, etc.

# VCTs: EXAMPLES

- Several studies of nutritional supplements
  - Glucosamine for knee osteoarthritis (2004)
  - Kava & valerian for anxiety, insomnia (2005)
- REMOTE (2014)
  - Tolterodine ER (4mg) in women with overactive bladder





# VCTs: REGULATORY EXAMPLE

Orri, M., Lipset, C. H., Jacobs, B. P., Costello, A. J., & Cummings, S. R. (2014). Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial. *Contemporary clinical trials*, 38(2), 190-197.

## REMOTE Trial

- Effectiveness and safety of tolterodine ER (4mg) in women with overactive bladder
- Randomized, double-blind, placebo-controlled, parallel group study

# VCTs: REGULATORY EXAMPLE

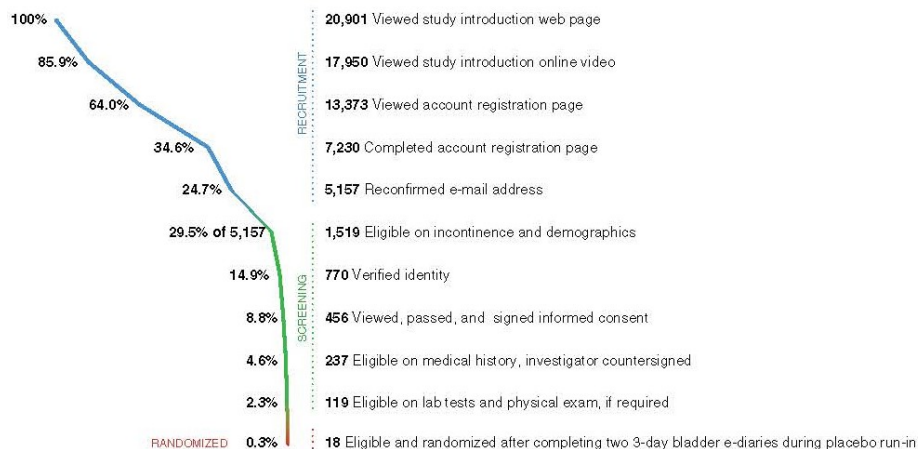
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- Recruitment: online
- Enrollment: online with lab or clinic visit
- Randomization: 2:1 active to placebo
- Stages
  - 2-week single-blind placebo run-in
  - 12-week double-blind treatment period

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- Aim: 283 participants
- Actual: 18 participants
- Terminated early





2

# THOUGHTS ON VCTS

# VCTs: RECRUITMENT/RETENTION

- May reduce or remove some barriers, but introduce others or have no effect
  - Geographic, time, schedule requirements
  - Internet access, technological literacy
- May increase or decrease retention

# VCTs: DATA QUALITY

- Nonsensical Data: implausible records, might be caught by software
- Missing Data: may have more or less, with different mechanisms
- Suspect Data: data that seems unlikely or incorrect but cannot be confidently identified as such

# VCTs: TECHNOLOGY

Need to develop infrastructure to provide

- IT support
- Privacy
- Security

to ensure participation and high quality data

# CONCLUSIONS

- Incorporating technology in clinical trials could be an exciting opportunity to improve the quality of trials
- Need to carefully design and implement and not assume technology imparts certain strengths (or weaknesses)





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