LEGAL DIVISION

Electronic Informed Consent
Perspectives from a Sponsor's Experience

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Overview

- Overview of REMOTE study
- Electronic Consent
  - Benefits
  - Challenges
- Lessons learned

Pfizer REMOTE Study - Background

- **Study: Research on Electronic Monitoring of OAB Treatment Experience ("REMOTE")**

- **Primary end point: Compare the efficacy of Detrol® LA (tolterodine tartrate) ER to placebo in subjects with overactive bladder after 12 weeks of treatment using an innovative web-based trial design**

- **Objective: Mimic a previously completed trial to replicate the results and validate this novel approach**

Pfizer REMOTE Study - Background

- Advance FDA feedback obtained
- IRB Review: Western IRB & UCSF IRB
- Principal Investigator: Dr. Stephen Bent, UCSF
- Electronic Consent Platform: Mytrus, Inc.
- Single clinical coordinating center
- Open to participants from 10 states

Pfizer REMOTE Study - Background

Innovative Approach:

- **Web-based recruitment**
- **Web-based consent process**
- **Web-based screening**
- **Mobile phone based efficacy assessment (e-diary)**
- **Study drug delivery by overnight courier (signature receipt required)**
- **Interactive data capture via secure website**
- **Virtual site visits: patient will not attend investigator / site for visits**
- **Study physician /call center available 24/7 by email & phone**

Pfizer REMOTE Study - Background

Enrollment Challenges:

- **Target Enrollment:** 600 patients
- **Enrollment Open:** March 3, 2011
- **Enrollment Closed:** April 15, 2012
- **Participants Screened:** 237
- **Participants Randomized:** 18
- **Participants Discontinued:** 2
- **Participants Completed:** 16

REMOTE Study - Unique Hurdles

- **Patchwork of State & Federal Requirements**
- **Local Practice of Medicine / Licensing aspects**
- **Telemedicine Laws**
- **Dispensation of Study Drug**

Electronic Consent Benefits & Challenges

Electronic Consent - Benefits

- Potential advantages for compliance and quality
- Efficiency and Flexibility
- Ability to monitor and track subject review of consent
- Ability to verify/capture subject understanding via online testing
- Active participation in consent process by subjects potentially enhances engagement and understanding
- Potentially more effective in capturing subject options within consent

Electronic Consent - Challenges

- Development of consent platform and process is resource intensive
- Confirmation of subject identity/age/location
- Amendments to consent possibly complicated
- May require new areas of understanding/competency
- Non-standard approaches may complicate regulatory/ethics review process
- Inter-relationships between various state and federal requirements

Lessons Learned

REMOTE - Lessons Learned

- Web-based approach efficient for reaching subjects
- Percentage of Subjects actually enrolled was low
- Difficult to draw conclusions from single study
- Substantial up-front investment required
- Regulatory framework does not contemplate web-based IND research

Questions?