Session IV: Use of E-Consent Technology in the Informed Consent Process

Kevin Hudziak, Eli Lilly & Co.

March 10, 2015
Session IV Objectives

- Discuss the advantages and challenges to use of e-consent technology in the informed consent process
- Solicit feedback on proposed recommendations related to e-consent technology in the informed consent process
Proposed E-Consent Recommendations

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Please watch this video to learn important information about the study. You can pause the video or go back to re-play part or all of the video at any time. Please make sure the volume is turned up so you can hear the audio. You can change the volume by dragging the slider that appears when you tap the video.

After you've finished watching the video, please touch Continue.

Introduction

We are asking you to take part in a research study. This research study will test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the U.S. Food and Drug Administration (FDA). This drug is made by the company that makes Trimycin, a drug used to lower blood pressure. People who enter into this study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is an FDA-approved drug to lower blood pressure.

Glossary

Hydrochlorothiazide - a water pill, is used to treat high blood pressure and fluid retention caused by various conditions.
Advantages and Opportunities

- Better meets research participant needs (flexible)
  - Customized to user preference or ability
  - Embedded education
  - Multi-media formats (text, video, audio)
- Facilitates interactions between research participants and investigative site staff
  - Knowledge checks/metadata
  - Video content reinforces key info/consistent across sites
  - Difficult content can be tagged
  - Remote trials
Once I decide to participate in the study, I can stop ...

- only when the study is over
- after being in the study for at least one year
- whenever I choose
- at week 30
Advantages and Opportunities

- Facilitates interactions between sponsor, ethics committees, and sites
  - Version control
  - Integration into electronic data capture systems or other existing systems and processes
  - Improved storage capabilities
  - Enhanced ability to track individual consent selections
  - Decreases opportunity for generating fraudulent data

- Supports process-improvement models
  - Metadata can be powerful
  - Opportunity to drive content and quality improvement (ICP)
Metadata Examples

- Signatures
- Average Time with ICF
- Average Age
- Sites

Count Summary
- Patients consented (current version)
- Patients who need to re-consent
- Patients not yet consented
- Patients discontinued
- Empty seats
- Total seats

Timeline

Top Sites

Patients consented in last week: 1
Average time to consent (en only): 1m 29s
Potential/Perceived Barriers

- Research participant
  - Potential lack of familiarity with technology
  - May prefer paper

- Regulatory/IRB
  - Concerns about security and/or confidentiality
  - Lack of understanding of concepts
  - Sometimes no well-established review and approval process

- Sponsor
  - Cost – eICD specialty companies and equipment
  - OCM…paper works
Potential/Perceived Barriers

- Quality assurance
  - No established or widely-adopted methods for assessing quality
  - Unique elements like multi-media and metadata

- Overall
  - Global acceptance of electronic signatures
  - Availability of contemporaneous copies
Conclusions – eConsent can be superior if...

- **Participant**
  - Improved Comprehension
  - Improved Satisfaction and Decision-Making

- **Site**
  - Improved Enrollment
  - Improved Retention

- **Sponsor**
  - Improved Protocol Compliance
  - Improved ability to track, analyze, document, audit, and quickly amend the consent process

Process, Training, and Implementation
Recommendations

- Convene cross-enterprise stakeholder group to recommend quality guidelines
- Develop tools and training
- Create a forum to support stakeholder communication re: common pitfalls and mitigations
- Conduct interventional trials to evaluate study feasibility, participant comprehension, decision-making, and satisfaction using a standard set of metrics
- Fund research projects to identify, implement, and assess best practices

Proposed E-Consent Recommendations
E-Consent Work Group

- Steve Cummings (UCSF)
- Eric Delente (Enforme Interactive)
- Cheryl Grandinetti (FDA)
- Zachary Hallinan (CISCRP)
- Peter Hassett (Enforme Interactive)
- Kevin Hudziak (Eli Lilly & Co.)
- Jane Perlmutter (Patient Advocate)
- Seth Schulman (Pfizer, Inc.)
Panel Discussion

- Alison Cooper
  - Operations Director, Texas Diabetes and Endocrinology

- Ellen Kelso
  - Executive Director, Chesapeake IRB

- Steve Mikita
  - Patient Advocate

- Leonard Sacks
  - Acting Deputy Director of Medical Policy, CDER, FDA
Day 1 Summary

Jennifer Lentz, Eli Lilly & Co.

March 10, 2015
Wrap-Up

- Literature Review & Expert Interviews Results
- The Informed Consent Process
- Training on Conducting the Informed Consent Process
- Use of E-Consent Technology in the Informed Consent Process
Insert reception info

Tomorrow we will begin at 8:30am

Breakfast will be served tomorrow beginning at 7:30am