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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eConsent Definition

- Delivered via electronic media
- Interactive
- May contain multi-media function (video, audio)
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
Question 2 of 4

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
- [x] whenever I choose
- [ ] at week 30

You may have some side effects from taking these drugs. The side effects of Trinycin are headaches, feeling drowsy, and feeling tired. About forty percent (40%) of people who take Trinycin have reported feeling drowsy and tired. About twenty percent (20%) of people who take Trinycin have headaches. Hydrochlorothiazide can cause the following side effects: low blood potassium; a rise in blood uric acid and blood sugar; and a lowering of red and white blood cells. About eighty percent (80%) of people who take Hydrochlorothiazide have these problems. There may also be risks that are unknown at this time. You will be given more information if other risks are found.
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

8

Patients consented

1

Patients consented in last week

1m 29s

Average time to consent (en only)

Count Summary

- 18 Patients consented (current version)
- 1 Patients who need to re-consent
- 5 Patients not yet consented
- 3 Patients discontinued
- 113 Empty seats
- 128 Total seats

Top Sites

Timeline

0 1 2 3 4

Patient Consent

Date

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
Housekeeping

- Insert reception info
- Tomorrow we will begin at 8:30am
- Breakfast will be served tomorrow beginning at 7:30am