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

Kevin Hudziak, Eli Lilly & Co.

March 10, 2015

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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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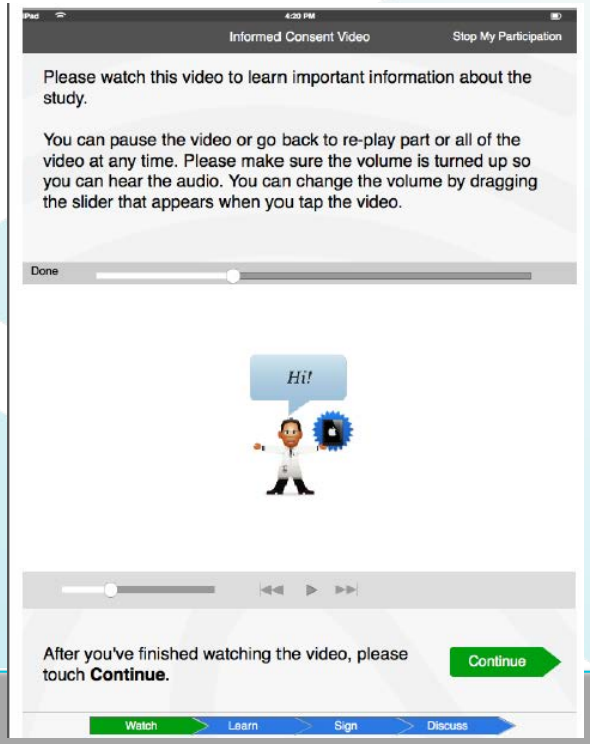
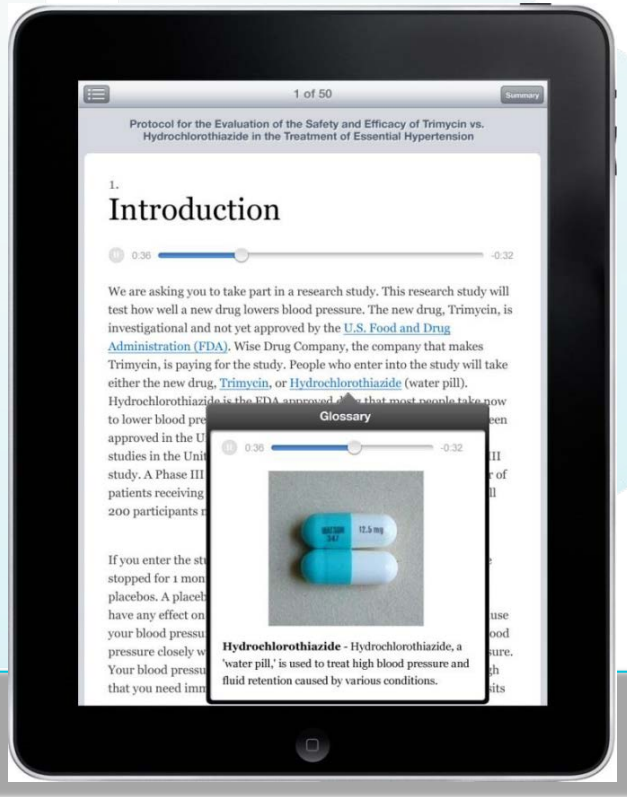
eConsent Definition

- 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

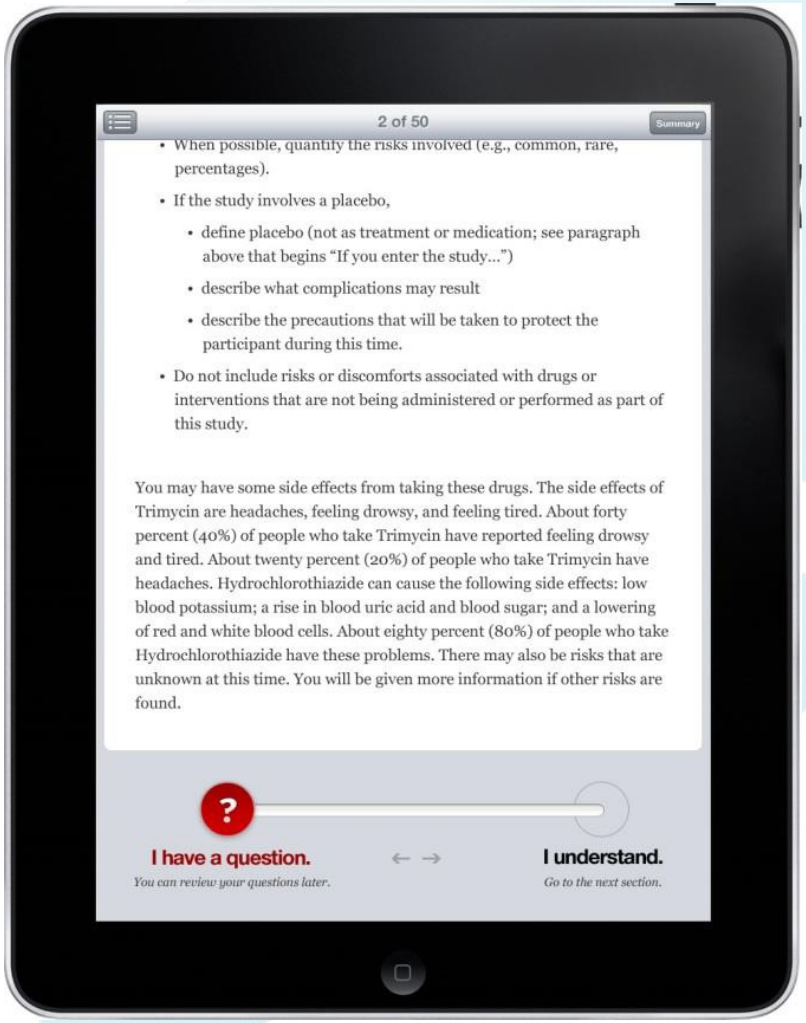
Examples

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
- whenever I choose
- at week 30

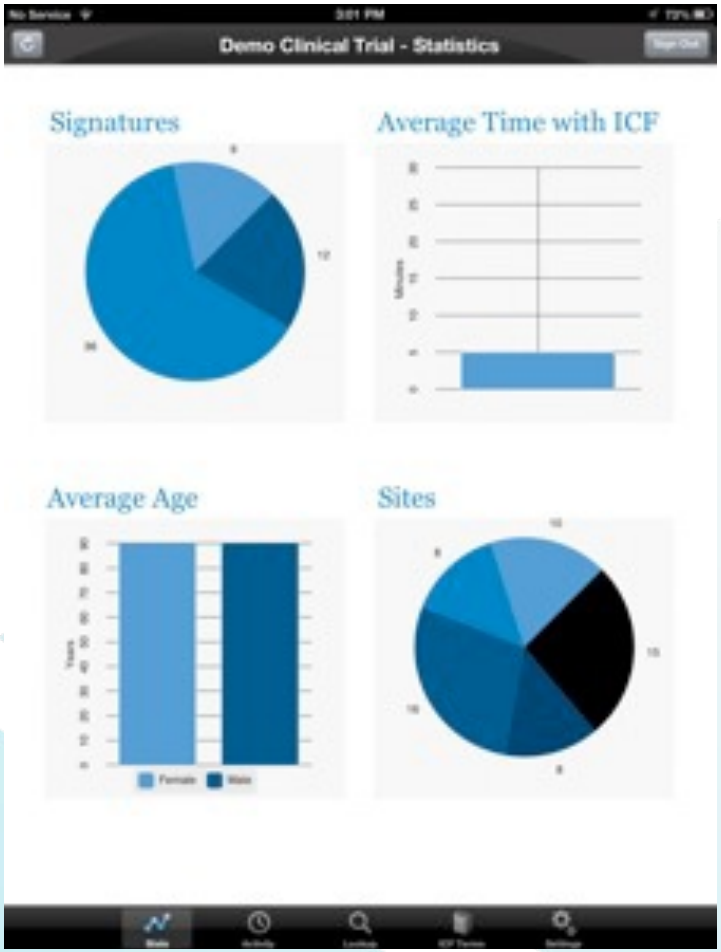
Continue

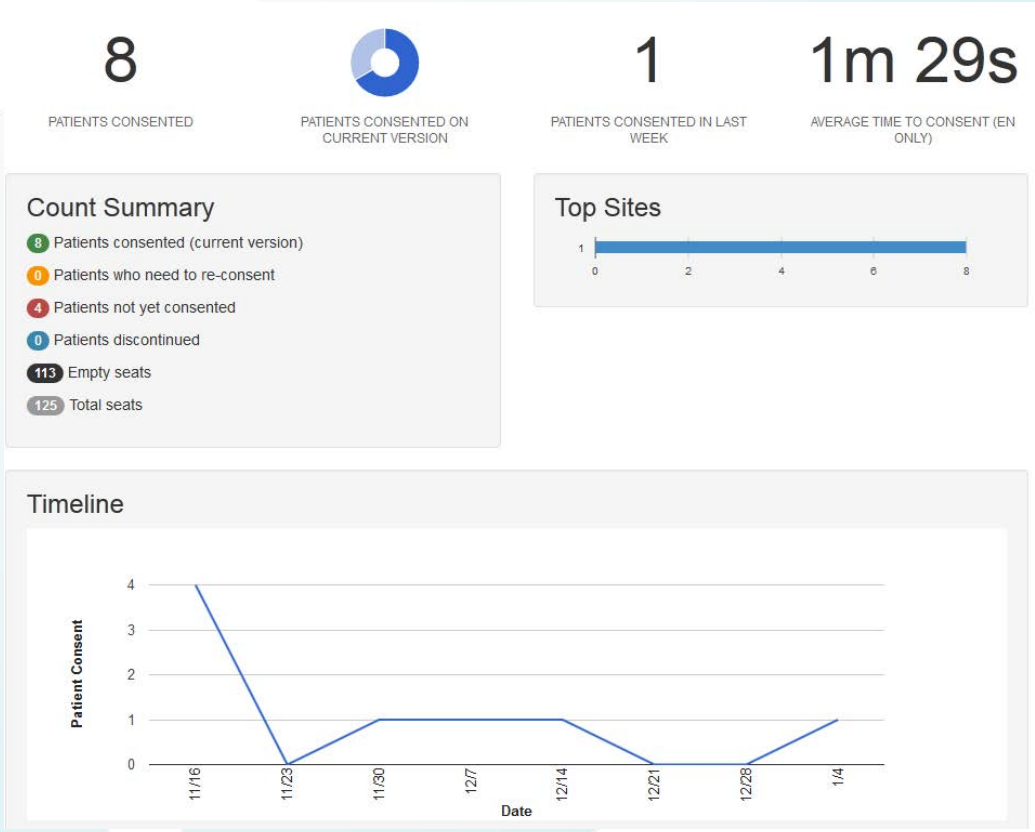


Advantages and Opportunities

- 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



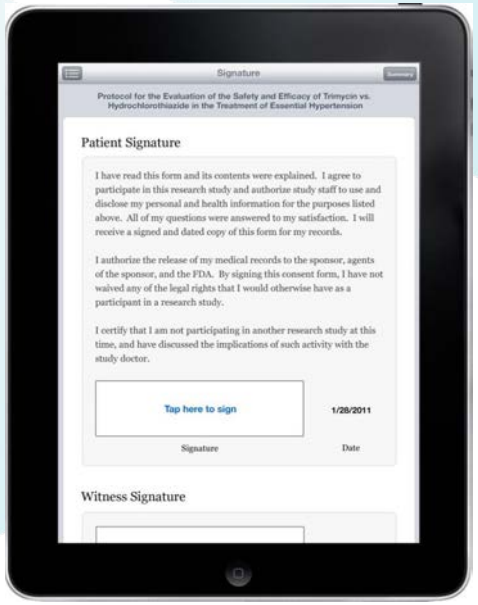


Potential/Perceived Barriers

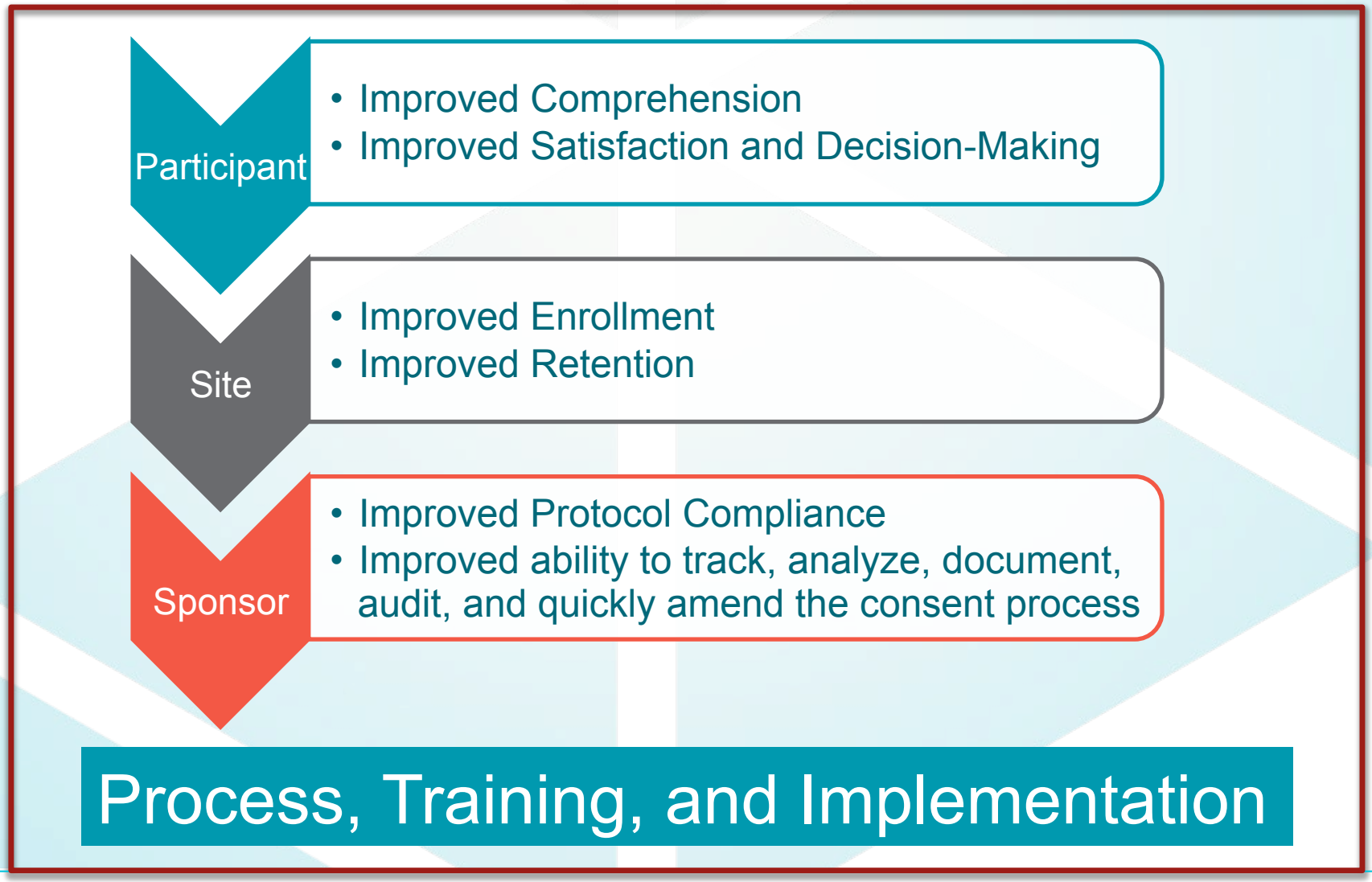
- Research participant
  - Potential lack of familiarity with technology
  - May prefer paper
- Regulatory/IRB
  - Concerns about security and/or confidentiality
  - Lack of understanding of concepts
  - Sometimes no well-established review and approval process
- Sponsor
  - Cost – eICD specialty companies and equipment
  - OCM…paper works

Potential/Perceived Barriers

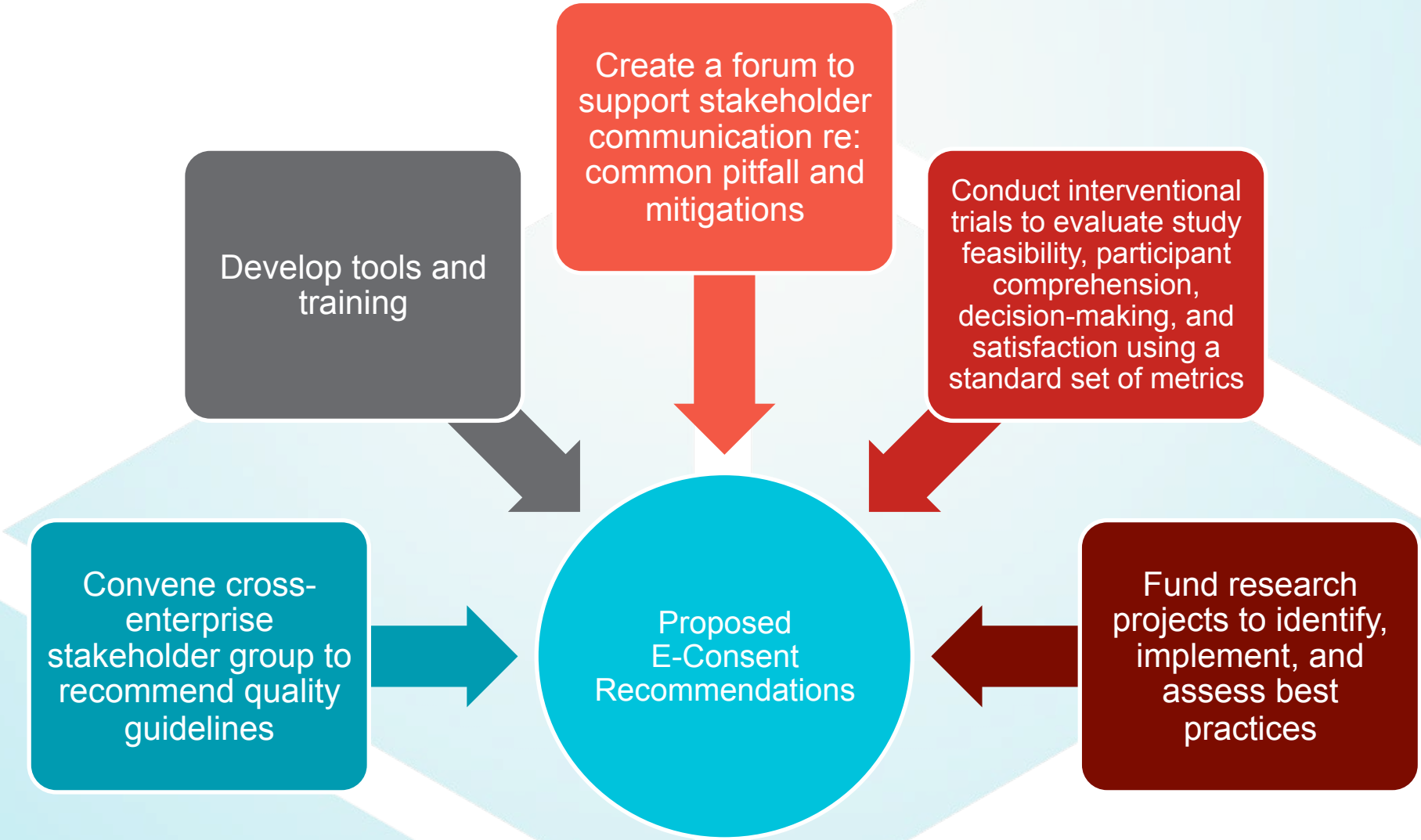
- Quality assurance
  - No established or widely-adopted methods for assessing quality
  - Unique elements like multi-media and metadata
- Overall
  - Global acceptance of electronic signatures
  - Availability of contemporaneous copies



Conclusions – eConsent can be superior if…



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.

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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