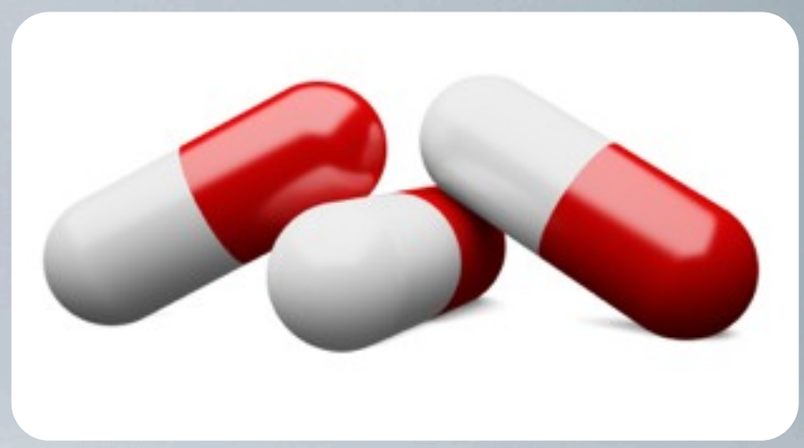

Safety Monitoring: The Patient Perspective

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CTTI CLINICAL TRIALS TRANSFORMATION INITIATIVE

Acknowledgments

Carrie Dombeck, MA
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Strategy

Sample beliefs and expectations of patients concerning AE monitoring and communication

Sample different ways AE monitoring is presented to subjects

Focus Group Study

Identify variety of beliefs and expectations

Goal is not to establish prevalence of beliefs and expectations

4 Groups

Clinical Trial Experience

No

- White (n = 5)
- African-American (n = 8)

Yes

- White (n = 6)
- African-American (n = 8)

Sample Characteristics

Age Mean (SD) Min - Max	34.4 (11.95) 22 - 60
Male gender (%)	48
Race (%) African-American White	 59 41
Education (%) ≤ High school diploma Some college Bachelor's degree Advanced degree	 30 22 26 22

Groups conducted at Duke's Social Science Research Institute

90 minute discussion

$100 compensation

Groups video recorded and transcribed

Discussion guide adjusted after each group

Understanding of Terms

medical or clinical research

clinical trial

blind or double-blind trial

role of investigator in a clinical trial

sponsor of a trial

adverse event

serious adverse event

IRB

DSMB

Sample Queries

How do investigators monitor patient safety?

Who should be responsible for monitoring?

What should be done when AEs occur?

How and when should other trial participants be informed?

Results

Preview of Findings

Satisfactory understanding of terms

Investigators should be told about all SAEs

Wide variability in whether and when trial participants should be told

Variability in how participants should be told

And a loud, surprising result . . .

Understanding

Pretty good

Understanding

Unfamiliar

IRB
DSMB

Understanding

Confusing

monitoring patients in multicenter or multinational trials

Reporting SAEs

Investigators should be told about *all* SAEs.

Notifying Research Participants

I need to know about every SAE, because it may affect me.

. . . when an SAE happens to a person like me

. . . when there is a trend of SAEs that are linked to the study drug.

Notifying Research Participants

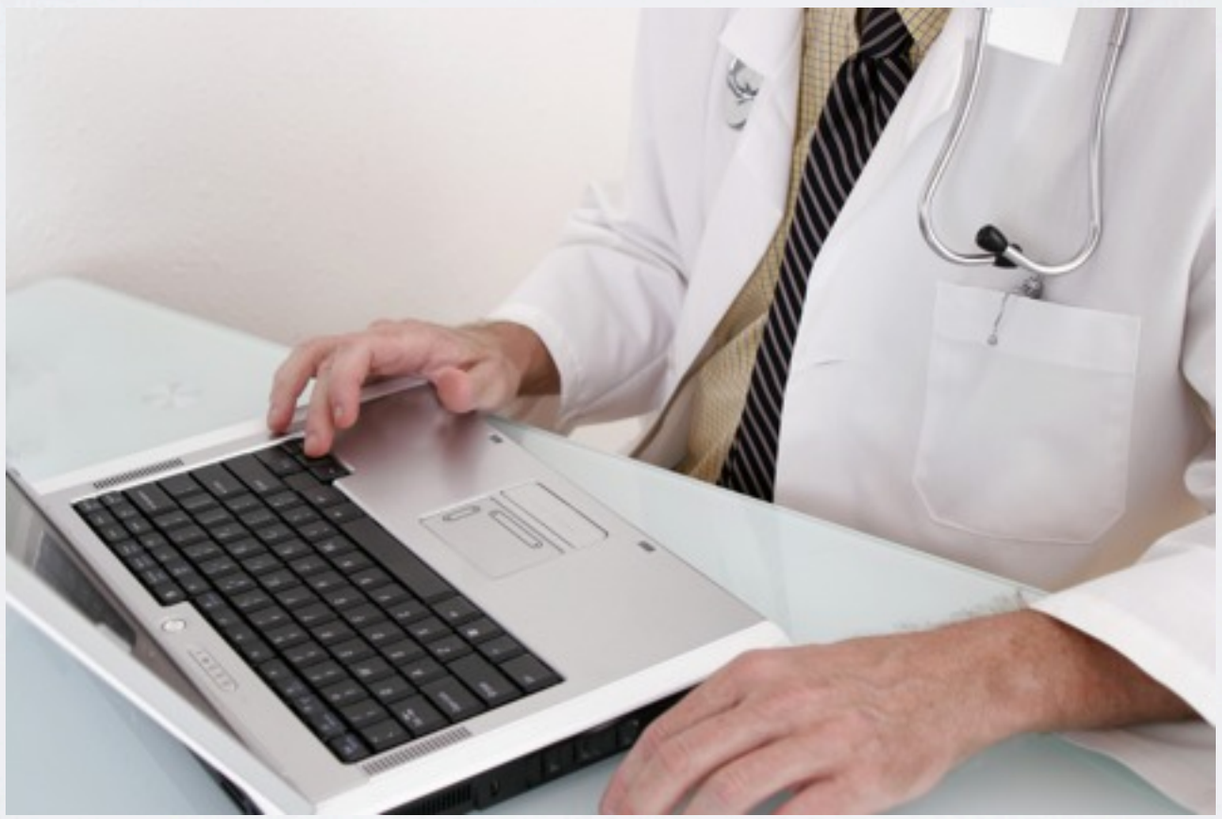
phone call within 24 hours after SAE is reported

email, within 2-3 days

next clinic visit

. . . the physician talks to the investigator, the investigator talks . . . well, that's a mass e-mail. That's one day.

That's a couple hours everyone could be notified.



Concerns about Independence / COI

Who polices the investigators when SAEs occur? *"... because there's a lot of money on the line for this drug to get passed."*

What happens to research personnel salaries if study is ended early due to SAEs?

Sponsor should not be responsible for monitoring or reporting safety, because of a conflict of interest.

Summary of Findings

Decent understanding of terms

Investigators should be told about all SAEs

Wide variability in whether and when trial participants should be told

Variability in how participants should be told

Serious concerns about financial conflicts of interest in monitoring and reporting

Consent Document Review

Sample ways in which AE monitoring and reporting is described to potential research participants at Duke

Provide point of reference for focus group results

Consent Document Review

Prospective RCTs coordinated by the Duke Clinical Research Institute

Identified and coded language about SAE disclosure

Readability diagnostics

Sample of Consent Documents

Funding	N=15
Federal	4
Commercial	9
Combination	2
Phase	
I/II	1
II	5
III	9

All forms contained language regarding monitoring and communicating safety information

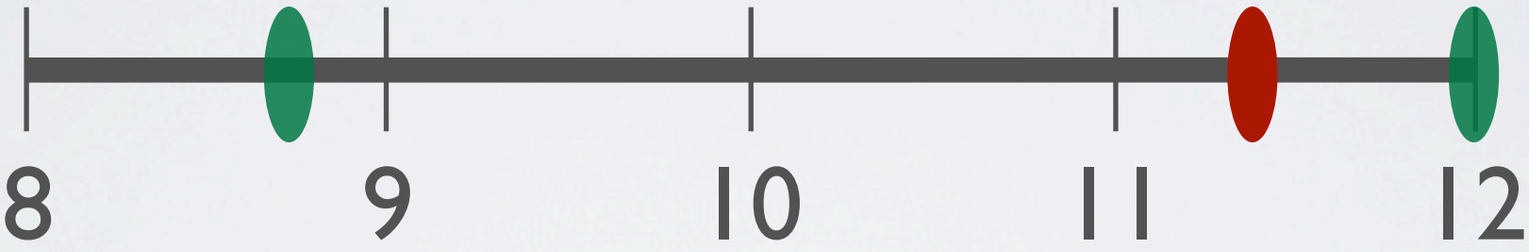
Sample:

"You will be told of important new findings or any changes in the study or procedures that may affect you or your willingness to continue in the study."

Location of Language

Section of Consent Document	N=15
Risks or Side Effects	9
Participation	3
New Information	3
Introduction	1
Rights	1
Other	1

Readability of AE-related Language



Grade-Level Equivalent

Content of the Language

Content Code	N = 15
New Information	15
Significant information	6
Affect willingness to participate	15
Timeframe	
“as soon as possible”	4
“in a timely manner”	4
Not specified	7

DCRI ICF Template 8/2010

NEW FINDINGS

If important new findings come up that might change your decision to be in this study, you will be given information about those findings as soon as possible. If you choose to stay in the study, you may be asked to sign a new version of the consent form.

3 Conclusions

1. Increase understanding about clinical trials and how risks are managed.

2. Language in consent forms should reflect reality.

3. Need to address conflicts of interest to restore/maintain trust.

Cannot assume disclosure is sufficient

Make the system trustworthy

Tell patients why it's trustworthy

Conclusions

1. Increase understanding about clinical trials and how risks are managed.

2. Language in consent forms should reflect reality.

3. Need to address conflicts of interest to restore/maintain trust.