Strategies to Collaboratively Manage Protocol Deviations in Multi-Site Clinical Trials: Site Perspectives

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NATIONAL DRUG ABUSE TREATMENT CLINICAL TRIALS NETWORK

Presentation Overview

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1) Site team perceptions of protocol deviations
2) Site procedures for reporting
3) Site feedback on revised process
4) Staff training

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Common Perceptions of Protocol Deviations

1. Poorly ***managed*** study
2. Poorly ***conducted*** study
3. Punishment or ***blame*** for staff

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My colleagues will view my study poorly.

Its all my fault.

I'm managing the study poorly.

Maybe others don't have to know.

I'm nervous to report this. What if I get in trouble?

I'm to blame.

Potential Consequences of Negative Perceptions

- ⬇ Decreased reporting
- ⬆ Toxic team dynamics
- ⬆ Repeated errors throughout trial
- ⬆ Potential to bleed into other trials

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Impact of Reporting Process

Discussion

- Lengthy discussions at team meeting
- Individual meetings for detailed discussion

Documentation

- Complicated documentation involving multiple team members
- Documentation across multiple systems: EDC, local logs, reporting to IRB

Timelines

- Confusion over reporting timelines
- Sense of urgency

Shifting Perceptions

- The purpose of identifying PDs is ***not*** to blame or punish.
  - ***Report*** and document deviations
  - ***Clarify*** results
  - ***Identify*** areas in need of retraining
  - ***Inform*** potential protocol modifications
  - ***Present*** to regulatory bodies for safety monitoring and data integrity

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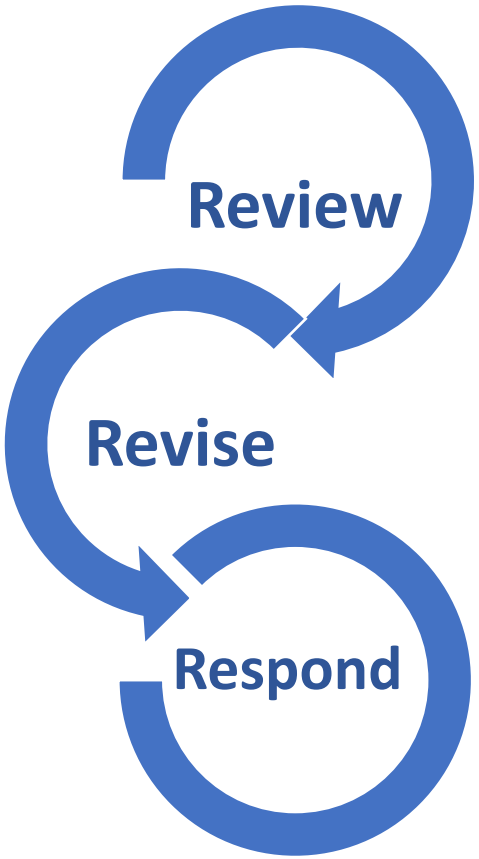
Site Engagement in Development



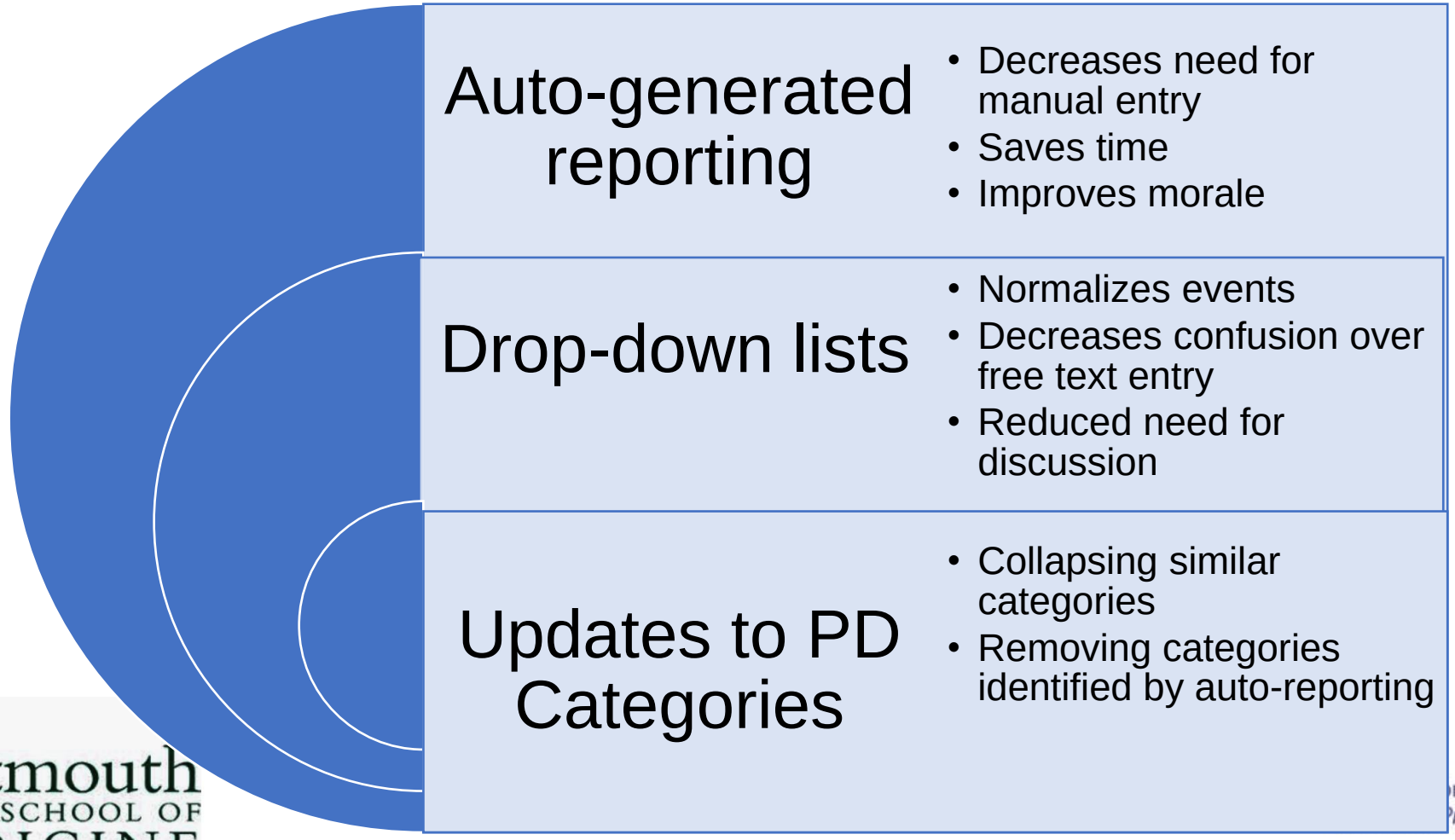
1) Emmes team ***reviewed*** the existing process
2) Emmes team ***revised*** the reporting system
3) Presented revisions to external stakeholders for ***response*** and feedback

Site Engagement

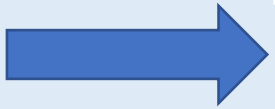
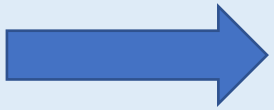
Feedback provided:

- Clarifying language
- Feedback on most common PDs encountered
- Commentary on common corrective action plans and staff retraining

Streamlined Process



Changing the Conversation

I'm to blame.		*This has happened to others before*.
I'm managing my study poorly.		*This doesn't mean I'm bad at my job.*
I'm nervous to report this. What if I get in trouble?		*There is a well-established process for reporting events like these.*
Maybe others don't have to know.		*I'm confident that we can report this event correctly and efficiently*.

Staff Training

- Training on protocol deviations is critical for ***all levels*** of the research team
- Important that all team members share the same understanding regarding identifying, reporting, resolving, and preventing PDs
- Encourage **supportive leadership** and **open communication**
- Avoid punitive response to PDs to encourage identification

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Conclusion

- Original reporting process captured numerous minor protocol deviations which could otherwise be captured using system reports.
- A post-mortem approach highlighted significant means for leveraging the EDC system
- Utilize existing system design and data collection to streamline the process
- Involve multiple stakeholders in planning stages to create digital solutions to identify PDs as early as possible
- Streamlining reporting has numerous benefits for site teams, improvements to team morale and site productivity.

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Thank you!

Questions?