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Networking to Enhance Development

A Conference By and For Research Coordinators

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How to Talk to Your PI and Other Partners About Good Clinical Practices: Non-compliance, Guidelines, or Inappropriate Issues

Presenters

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UW Medicine Division of Hematology

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Disclosures

- Cody Hammer consultant: GlycoMimetics, Inc.

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Learning Objectives

1 Develop methods and strategies of communicating non-compliance, guidelines, adverse events, or inappropriate issues with an investigator and partners

2 Understand different communication types and methods, use them to tailor communication with an investigator and partners

3 Develop methods to engage investigators and partners to learn GCP, review guidance, or change standard practices

How to prepare to speak with an investigator

The Toolbox

INVESTIGATE THE ISSUE

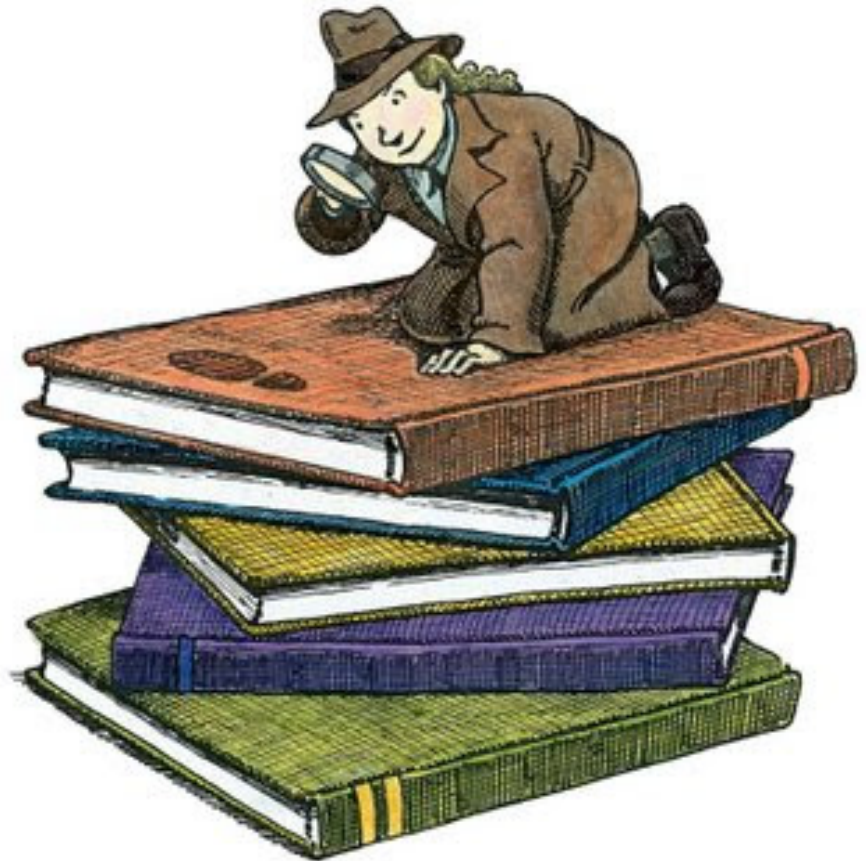**REVIEW POLICIES AND REGULATIONS**

DEVELOP A SOLUTION

PREPARE THE DISCUSSION

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Investigate

Determine the:

- **WHO**

- **WHEN**

- **WHERE**

- **WHY**

- **HOW**

Look for a system or process problem rather than just who caused the problem.

Review regulations, policies, and guidance

International	**Federal**	**State**	**Local**
International Conference of Harmonization, EMA, etc.	*FDA regulations and guidance, OHRP, NIH, etc.*	*Department of Health, etc.*	*Institutional/Company Policies Regulatory Board Policies Team/Group Standard practices.*
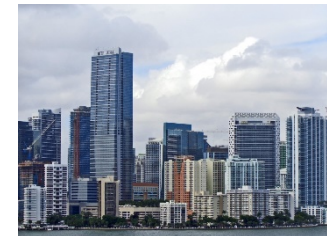
Violations of regulations, policies, and guidance should be presented with details about the event.

Develop a solution

SOLUTIONS SHOULD INCLUDE AN IMMEDIATE FIX AND A LONG-TERM PREVENTION OF THE PROBLEM

The solution does not just involve one individual it involves a team.

► Look for the immediate fix that will resolve the problem.

► Develop a process change that will resolve the problem in the future.

► Develop a system change that can prevent the issue.

► Train all personnel that could have made the error or that will be impacted by future changes to processes or systems.

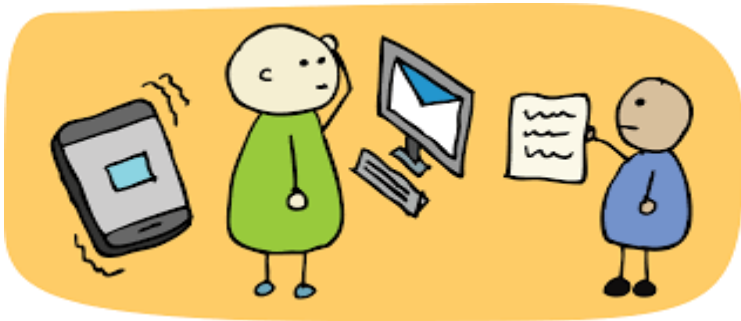# Prepare your discussion

KNOW YOUR AUDIENCE

Tailor your presentation to your audience and remove all emotion from the conversation.

- ► Does your audience prefer facts and data?

- ► Do they prefer solutions and knowing how this affects the project timeline?

- ► Do they usually respond emotionally?

- ► Do they care about personal relationships?

- ► Are they usually passive?

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Prepare your discussion

UNDERSTAND YOUR METHODS OF COMMUNICATION

Phone Calls & Pages

Text Messaging & Text Paging

Emails, Letters, & Reports

Face-to-face Discussions

Group Discussions & Presentations

Each method has its use, find which one is most appropriate for your discussion.

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Prepare your discussion

KEEP CALM AND CREATE A LIST OF IMPORTANT POINTS

Organizing your thoughts externally can benefit both you and the audience.

► What are the risks and benefits or pro and cons?

► What are the facts that your feel need to be conveyed?

► Do you have any questions that need to be answered?

► Do you have any answers to questions you know or suspect will be asked of you?

► Are you nervous?

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Now you're ready to talk!

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"Don't let perfect be the enemy of good"

- Aphorism commonly said be Elihu Estey, MD

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Case Study!

- **A Research Coordinator at a participating site of an IND exempt Sponsor-Investigator multicenter trial studying a marketed product in a new indication receives the newly minted manufacturer's IB 20 from the coordinating site.**

- **The RC promptly has the PI review the IB and it is determined there are no new or increased risk and no modifications of protocol or consent are indicated.**

- **RC submits to IRB and indicates no new or increased risk and no modifications required.**

- **IRB responds stating that the last manufacturer's IB on file is 14 and requests they supply 15-19 as well. These are supplied.**

- **IRB determines that due to the missing manufacturer's IBs 15-19, the participating site PI failed to adequately inform participants of changes in risk resulting in serious noncompliance and harm to research subjects. IRB reports PI to FDA and HHS**

What do you do next?

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GRAB THE TOOLBOX

INVESTIGATE THE ISSUE

REVIEW POLICIES AND REGULATIONS

DEVELOP A SOLUTION

PREPARE THE DISCUSSION

RESULTS

- Investigate:

  - PI disagrees with IRB

  - Sponsor-investigator's site never sent IBs 15-19

  - IBs 15-19 appear to already be incorporated in protocol and consent

- Relevant policies, guidance, and regulations:

  - FDA.gov IND Applications for Clinical Investigations: Regulatory and Administrative Components

  - E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry, section 7.1

  - 21 CFR 312.55 (a)

  - 21 CFR 312.55 (b)

  - Safety Reporting Requirements for INDs and BA/BE Studies Guidance for Industry and Investigators VI.B.1

- Solution:

  - Failed to find any pertinent safety information relative to trial patients missing from consent

  - Failed to identify any noncompliance

- Prepare discussion:

  - Formal letter

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Questions?

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References:

Investigate Picture:
http://3.bp.blogspot.com/_IxeuPtVnWsw/SAPMjmDrjEI/AAAAAAAAAms/jwZRfuR2_8w/s320/Investigate-books.jpg
International photo:
:http://3.bp.blogspot.com/_IxeuPtVnWsw/SAPMjmDrjEI/AAAAAAAAAms/jwZRfuR2_8w/s320/Investigate-books.jpg
Capital building photo:
http://3.bp.blogspot.com/_IxeuPtVnWsw/SAPMjmDrjEI/AAAAAAAAAms/jwZRfuR2_8w/s320/Investigate-books.jpg
Washington flag photo: https://upload.wikimedia.org/wikipedia/commons/thumb/5/54/Flag_of_Washington.svg/255px-Flag_of_Washington.svg.png
Local photo:
https://c.pxhere.com/photos/b7/95/miami_downtown_miami_tall_buildings_cityscape_city_florida_usa_america-617708.jpg!d
Solution picture: https://1.bp.blogspot.com/-1itpCJg1Lvw/VvTR8QstMMI/AAAAAAAAbsA/FuXXJ0fXF4Qd6GfW7kH9XOKDt9-ZdIjBQ/s1600/working-together-as-a-team-Working-Together-Small.jpg
Communication picture: https://res.cloudinary.com/people-matters/image/upload/w_624,h_351,c_scale,q_auto,f_auto/v1490162453/1490162452.jpg
Types of communication picture: https://ccmit.mit.edu/wp-content/uploads/2014/09/ps-ending-proper-comm.pngf
preparing for discussion picture: http://2.bp.blogspot.com/-rzVCD1EDFng/UO2SyPIdWeI/AAAAAAAAs8/proqEFYM_kQ/s1600/talking_points.png
Reported photo: https://www.shutterstock.com/image-vector/rubber-stamp-word-reported-inside-vector-368555396
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Thank You