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SOP's

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Format

- 1. Quick basic intro to SOPs and how to write them.
- 2. Practical working session during which a specific SOP will be written by groups of you.

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What is an SOP?

- A detailed, written instruction to achieve uniformity of the performance of a specific function.

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Why are SOPs important?

- 1. By writing SOPs, an investigator is compelled to read and understand GCP regulations and to apply them for the site.

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Why are SOPs important?

- 2. They help to ensure consistency, compliance, accountability and efficiency of the study team when conducting trials.

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Why are SOPs important?

- 3. “Investigators who do not have clinical research SOPs run a high risk of GCP non-compliance and poor productivity.”*

- * Janet Zimmerman, Clinical Research Training Consultant, USA



Are SOPs a requirement?



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Are SOPs a requirement?

- The most frequent reported deficiencies during inspections are the lack of written SOPs and/or the failure to adhere to them.

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Writing an SOP



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Writing an SOP

- Step 1 – what topics do you need?
- Step 2 – what format should you use?
- Step 3 – train the study team on SOPs
- Step 4 – implement a review process

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SOP Topics

- SA GCP Guidelines – Section 4 (Investigator)
- Any activity that is part of the clinical research process at a site should be described in an SOP (including the writing of SOPs)
- Should SOP writing be a delegated duty?

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SOP Format

- Heading
- Effective date / amendment date
- Version controlled
- Introduction (including GCP)
- Purpose
- Description
- Approval signature

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SOP Training

- Its not enough to have a clean crisp SOP in the site file

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Reviewing SOPs

- A specific SOP is not a final document
- SOP review at least every 1-2 years
- SOP changes will be documented and version controlled

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Standard Operating Procedure

Title:	Date of original version	
	Revision date	
	SOP Number	
	Reason for change	

1. **Purpose**

2. **Background**

3. **Procedures**

<u>Approval and acceptance by:</u>	<u>Signature:</u>	<u>Date:</u>

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