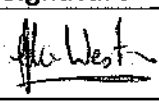
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_023

SOP Title: Pharmacy involvement in clinical trial site initiation visit

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		05/03/2018
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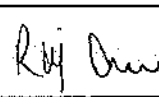
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	9/2/16
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for pharmacy involvement in site initiation of a clinical trial
1.2 Covers the procedures to follow at site initiation visit (SIV), including:

- arranging SIV appointment
- items to discuss at SIV

2. DEFINITIONS

SIV – Site initiation visit

3. PROCEDURE and RESPONSIBILITIES

3.1 Arranging site initiation visit (SIV)

3.1.1 Liaise with the local research team and contact the sponsor (directly or via the local research team) to arrange a date for the site initiation visit.

3.1.2 Establish with the sponsor the time required to conduct the SIV and allocate the time accordingly.

3.1.3 As a minimum, the pharmacist/technician delegated the task of trial set-up for the trial concerned should attend the SIV.

3.1.4 Book a suitable venue for the visit.

3.1.5 Record the SIV date and venue into the diary.

3.1.6 Invite all other relevant members of the team.

3.2 At the site initiation visit (SIV): face to face

3.2.1 Prior to the SIV, the pharmacist/technician delegated the task of trial set-up for the trial concerned should prepare a list of outstanding items requiring further information or clarification from the sponsor.

3.2.2 At the SIV, introduce all team members in attendance and the sponsor's representative.

3.2.3 Allow the sponsor's representative to present and provide information relating to the clinical trial.

3.2.4 Discuss any outstanding items arising out of step 3.2.1.

3.2.5 Remind the sponsor's representative of the pharmacy clinical trial service, including but not limited to:

- Storage facilities
- Temperature monitoring system
- Pharmacy site file documentation (e.g. trial specific pharmacy instructions, clinical trial prescription)
- Disposal/destruction of clinical trial medication processes
- Pharmacy staff training
- Curriculum vitae (CV) and Good Clinical Practice (GCP) certificates
- Monitoring visits arrangement
- Pharmacy contact details

3.2.6 Where requested by the sponsor's representative, conduct a tour of the pharmacy facilities.

3.2.7 Confirm with the sponsor's representative the process for site activation and establish whether there are any outstanding items before the site can open for recruitment.

3.2.8 Evidence of pharmacy attendance at the SIV must be documented and countersigned by the sponsor's representative. Use documentation provided by the sponsor where provided, and if unavailable, use the *Pharmacy SIV attendance log* (Form 06). File a copy of the documentation in the relevant section of the pharmacy site file.

3.2.9 Request for a copy of the sponsor's training slides where used, and file in the relevant section of the pharmacy site file.

3.2.10 Following the SIV, action any follow up items required.

3.3 At the site initiation visit (SIV): conducted by telephone

3.3.1 Follow steps 3.2.1 to 3.2.5.

3.3.2 Follow steps 3.2.7 to 3.2.10. For step 3.2.8, request the sponsor's representative to send through documentation to confirm that the SIV has been conducted by telephone including details of all in attendance.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensure procedures are in place
2			
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Site initiation visit attendance log (Form 06)

5. TRAINING

6. REFERENCES

For more detailed guidance/reference, refer to:

- Section 7.5.2 of the MHRA Good Clinical Practice Guide, 2012.