STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_002

SOP Title: Pharmacy green light - readiness to dispense

Role	Name	Signature	Date
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SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	12-Jan-2015
3	1-June-2018	Reviewed to ensure still applicable to current practice	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for providing confirmation of pharmacy readiness to dispense

1.2 Covers the procedures to follow for providing confirmation of pharmacy readiness to dispense when initiating a new clinical trial, including:

- when to provide confirmation
- how to provide confirmation

2. DEFINITIONS

MHRA – Medicines and Healthcare Products Regulatory Agency

IMP – Investigational medicinal product

3. PROCEDURE and RESPONSIBILITIES

3.1 When to provide confirmation

3.1.1 Obtain a blank copy of the *Pharmacy green light - readiness to dispense checklist* (Form 07).

3.1.2 Complete the checklist accordingly, including but not limited to:

- Confirm approvals have been received from MHRA, Ethics committee and Trust R&D department.
- Confirm a clinical trial authorisation (CTA) been granted for the clinical trial as evidence by a copy of the CTA authorisation letter.
- Confirm receipt of the protocol (latest version and amendments) and Investigator brochure.
- Confirm the pharmacy site file is in place with the relevant up to date documentation including QP certificate of release.
- Confirm the pharmacy working documents file is in place including trial specific pharmacy instructions, clinical trial prescription and accountability logs.
- Confirm approval of trial specific pharmacy instructions as evidenced by the required signatories on the trial specific pharmacy instructions.
- Confirm training of relevant pharmacy staff on the trial specific pharmacy instructions as evidence by signatories on the *Pharmacy training log* (Form 01)
- Confirm receipt of clinical trial medication and that the products are in good condition and suitable for dispensing (In some circumstances, clinical trial medication may only be shipped upon participant screening/randomisation in the trial).

- Confirm code breaking procedure for the trial is in place (if applicable)

3.1.3 If any of the items listed above are not present, contact the principal investigator (PI), R&D department or the sponsor.

3.1.4 Sign and date the *Pharmacy green light - readiness to dispense checklist* (Form 07) to provide verification that the check has been completed.

3.1.5 In situations where clinical trial medication is only shipped upon participant screening/ randomisation in the trial, communicate the situation clearly to the PI and research team, and ensure good communication is maintained following participant screening/randomisation in case of any clinical trial medication shipment issues requiring re-scheduling of visits.

3.2 How to provide confirmation

3.2.1 When all the steps in section 3.1 have been completed, send an email to the principal investigator and the research team to provide confirmation of 'pharmacy green light - readiness to dispense'.

3.2.2 File a copy of the confirmation email and the completed *Pharmacy green light - readiness to dispense checklist* in the relevant section of the pharmacy site file.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Clinical trials pharmacist is responsible for ensuring all documentation is in place before IMP is dispensed.
2			
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Pharmacy green light - readiness to dispense checklist (Form 07)

5. TRAINING

- ICH-GCP training.
- An understanding of dispensing procedures.
- An understanding of the protocol procedures to write dispensing instructions which comply with protocol.
- An understanding of trial legal requirements needed before commencement of trial.

6. REFERENCES

For more detailed guidance/reference, refer to:

- Section 1.5.2 and 6.3.4 of the MHRA Good Clinical Practice Guide, 2012.