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Common Findings related to Investigational Product (IP) Management

Scenario

Site ABC is conducting multiple oncology trials and one of the breast cancer Investigator- initiated trial (IIT) involves IV Trastuzumab and PO Tucatinib was selected by the institution for monitoring.

Here are some of the monitoring findings with regards to IP Labelling & Accountability and proposed corrective actions and preventive actions by the study team:

Finding	Corrective Action	Preventive Action	Remarks
Date of expiry of IV Trastuzumab was not labelled on the infusion bag.	To label the expiry date-on all infusion bag before dispensing the drugs to treatment area for administration.	To have a checklist to counter check against all necessary information to be included on drug label before dispensing.	We have to ensure the drug administered to patient is within the allowed timeframe per study protocol & pharmacy manual.
The phrase 'For Clinical Trial / Research Use Only' or similar wordings were not stated on the IP label for PO Tucatinib.	To amend the master IP label to include the respective wordings so that the same issue will not occur on all the other IP labels.	To have a checklist to counter check against all necessary information to be included on drug label before dispensing	This phrase is to alert all that this is an IP and hence can only be used on research patient only. This phrase may be printed in red font for immediate attention.
Accountability for PO Tucatinib did not tally with the number of returned drug tablets in the IP bottle for subjects 0012, 0017 and 0019.	To check again the accountability log against the returned drug bottles and do the correction.	To always have 2 pharmacists to do the accountability check to ensure the entry on accountability log is accurate. Study coordinator may assist to record the number of tablets returned by patient for pharmacist's reference if possible.	Accountability check is one of the most important element in clinical trial drug compliance check to make sure patient is compliant with the IP drug-taking. Overdose and underdose are categorized as major non-compliance as they may lead to safety concern.

Reference

1. NHG PCR SOP 501-B06 IP Accountability

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