Pharmacy and IMP Training

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PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

Previously covered at Pharmacy Induction

- Shipping
- Receipt of IMP
- Storage
- Temperature Monitoring
- Temperature Deviations
- Pharmacy File

Summary

- Prescriptions
- Labelling
- Dispensing
- Inventory
- Patient Returns
- Destruction
- Monitoring

Study Prescriptions

- The study drugs will be prescribed at the point of oral step-down.
- The doctor should attach the patient's individual visit schedule to the prescription to allow the pharmacist to check the prescription against the information on the schedule.
- Children will be prescribed the duration of antibiotics needed to complete the randomised total antibiotic course (starting at the time intravenous antibiotics were administered, excluding any antibiotics taken in the community prior to admission). For example:
  - A child randomised to total 8 days antibiotics who is well enough to start taking oral antibiotics after 3 days of intravenous antibiotics will receive 5 days oral antibiotics
  - A child who is randomised to total 4 days antibiotics who is well enough to start taking oral antibiotics after 2 days of intravenous antibiotics will receive 2 days oral antibiotics
- One extra dose should be prescribed to account for any lost or vomited doses.

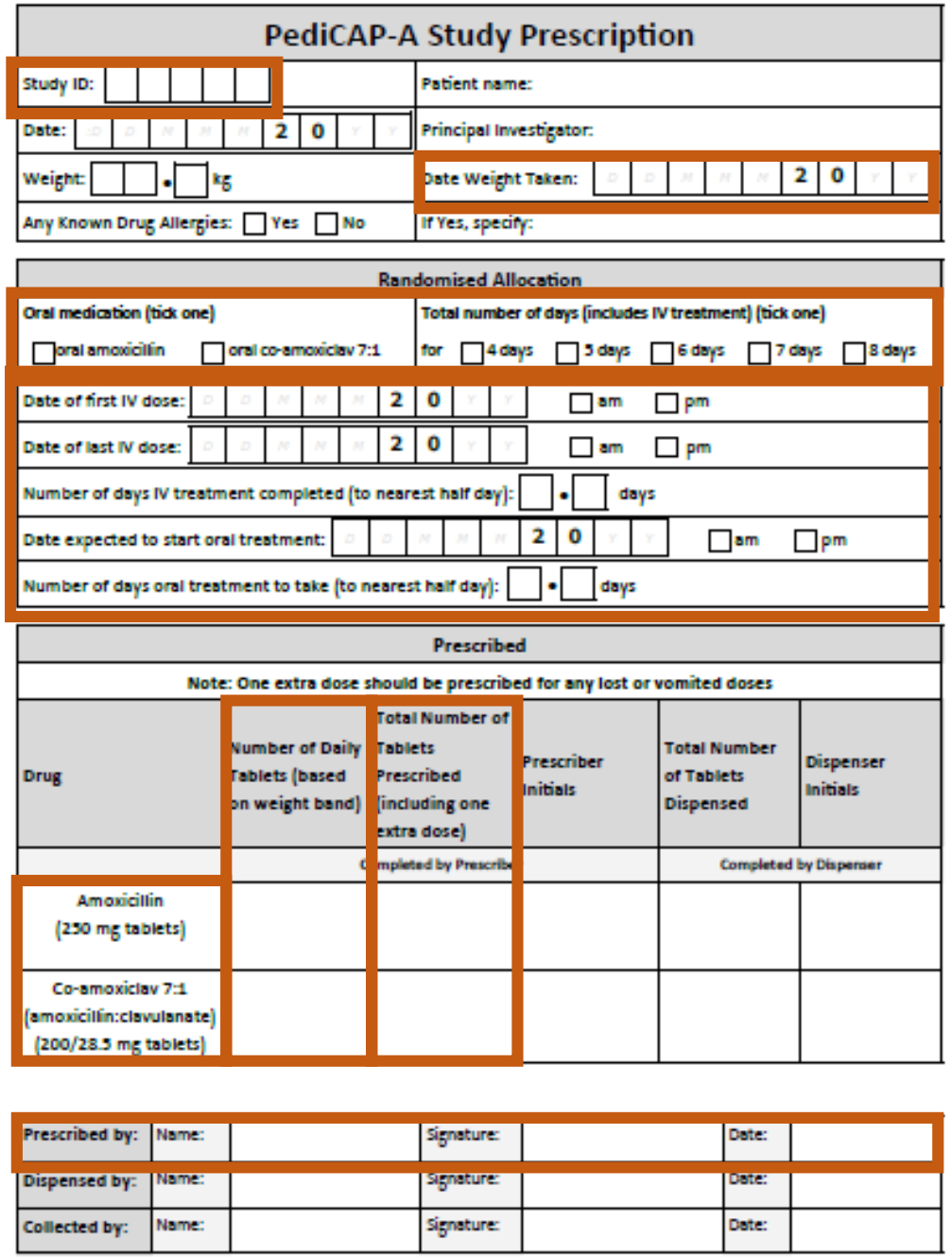
Checking the Prescriptions

Check that the randomised allocation matches the Individual Visit Schedule

Check that the drug prescribed matches the randomised allocation

Check that the prescriber is listed on the Signature and Delegation Log and has been assigned the responsibility for prescribing

Check that the number of daily tablets is correct for the patient's weight (check dosing table in Pharmacy Manual or protocol)



PediCAP-A Study Prescription

Study ID: | Patient name:

Date: 20 | Principal Investigator:

Weight: . kg | Date Weight Taken: 20

Any Known Drug Allergies: Yes No | If Yes, specify:

Randomised Allocation

Oral medication (tick one): oral amoxicillin; oral co-amoxiclav 7:1

Total number of days (includes IV treatment) (tick one): for 4 days; 5 days; 6 days; 7 days; 8 days

Date of first IV dose: 20 am pm

Date of last IV dose: 20 am pm

Number of days IV treatment completed (to nearest half day): . days

Date expected to start oral treatment: 20 am pm

Number of days oral treatment to take (to nearest half day): . days

Prescribed

Note: One extra dose should be prescribed for any lost or vomited doses

Drug	Number of Daily Tablets (based on weight band)	Total Number of Tablets Prescribed (including one extra dose)	Prescriber Initials	Total Number of Tablets Dispensed	Dispenser Initials
	Completed by Prescriber			Completed by Dispenser	
Amoxicillin (250 mg tablets)					
Co-amoxiclav 7:1 (amoxicillin:clavulanate) (200/28.5 mg tablets)					

Prescribed by:	Name:		Signature:		Date:
Dispensed by:	Name:		Signature:		Date:
Collected by:	Name:		Signature:		Date:

Check that the Study ID has been completed

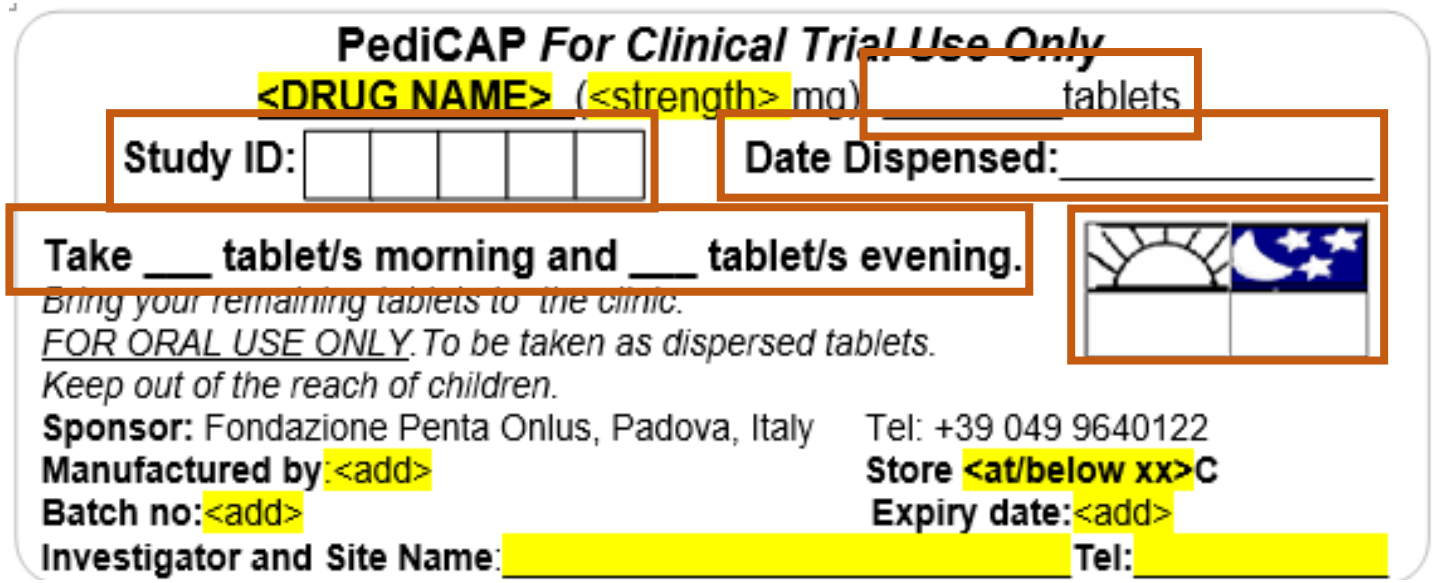
Check that the weight has been taken on the same day that the prescription was written

Check that the number of days oral treatment to take has been calculated correctly based on the randomised allocation and date of first IV dose.

Check that that total number of tablets prescribed includes one extra dose. Use dosing tool to check final number

Re-labelling

- The study drugs will need to be re-packaged and re-labelled upon receipt of a study prescription.
- Original drug packs will need to be split.
- The PediCAP sample labels should be used.
- These can be prepared in advance.

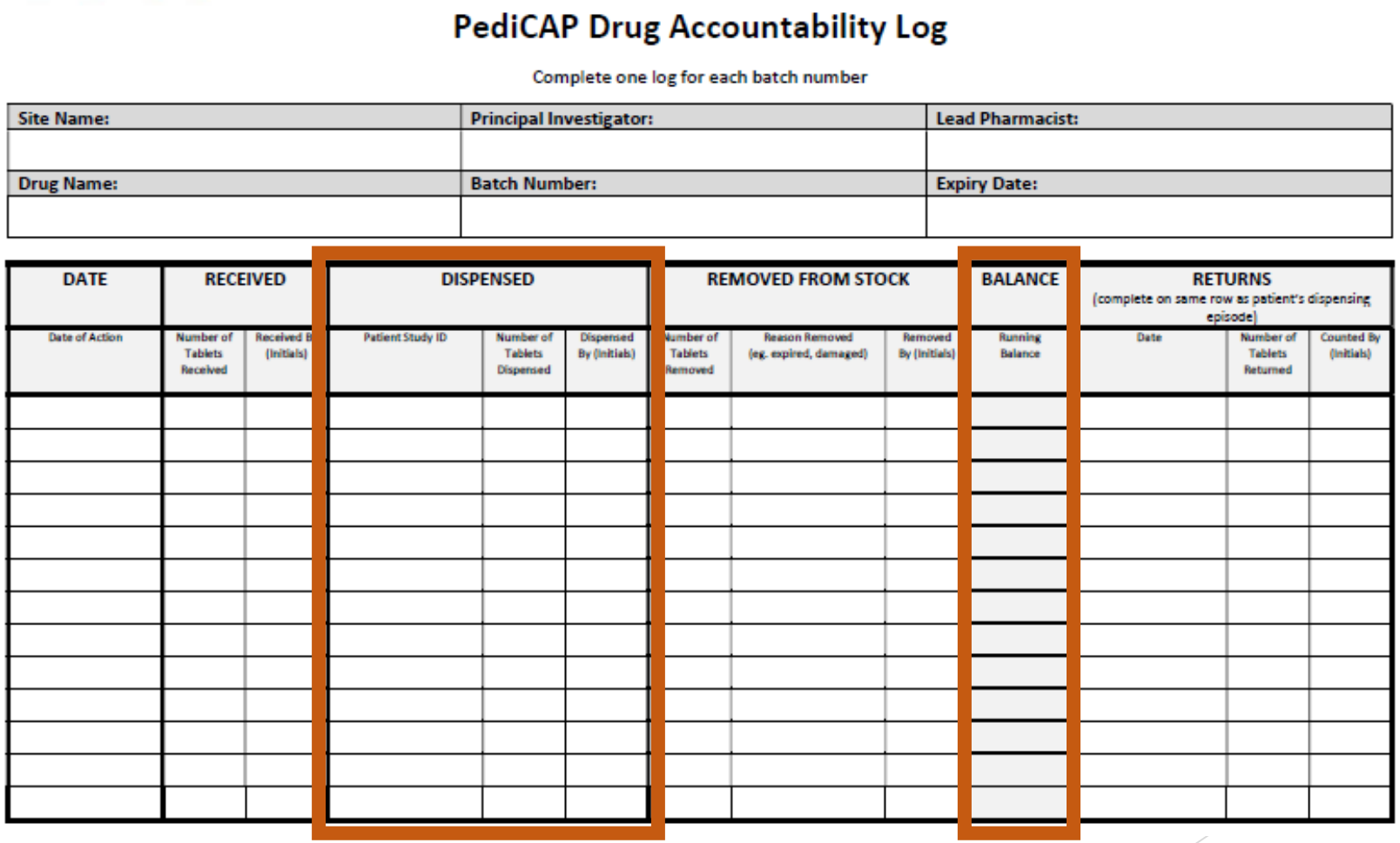


Before printing, fill in the highlighted sections.

Upon receipt of a prescription, complete the remaining details by hand

Dispensing

- Each dispensing episode should be recorded on the PediCAP Drug Accountability Log



PediCAP Drug Accountability Log

Complete one log for each batch number

Site Name:	Principal Investigator:	Lead Pharmacist:
Drug Name:	**Batch Number:**	**Expiry Date:**

DATE	RECEIVED		DISPENSED			REMOVED FROM STOCK			BALANCE	RETURNS (complete on same row as patient's dispensing episode)		
Date of Action	Number of Tablets Received	Received By (Initials)	Patient Study ID	Number of Tablets Dispensed	Dispensed By (Initials)	Number of Tablets Removed	Reason Removed (eg. expired, damaged)	Removed By (Initials)	Running Balance	Date	Number of Tablets Returned	Counted By (Initials)

Each log should be used until the running balance is 0 and there is no more dispensable stock left of that batch number. If the log becomes full, start a new log and ensure to complete the page numbers in the footer.

The running balance should be updated with each entry on to the log.

It should always be an accurate representation of the number of tablets in dispensable stock.

Inventory

- An inventory of all study drug stock should be completed monthly using the PediCAP Monthly Inventory template.
- Send copies of the Inventory logs to MRC CTU every 3 months.

Enter all drugs on to one log

Enter all drugs in dispensable stock at the time of conducting the inventory check

PediCAP Monthly Drug Inventory

Complete this inventory check form at the end of each month. Send MRC CTU copies of the checks every 3 months.

Site Name:	Principal Investigator:	Lead Pharmacist:	Person Completing Inventory Check:	Date Inventory Check completed:

Drug name	Batch number	Expiry date	Number of tablets counted in dispensable stock	Number of tablets recorded on accountability log running balance	If discrepancy found, record reason and resolution	Confirm expired/damaged tablets separated and reconciled (Initials)	Check completed by (Initials)

Physically count the number of tablets

Check the number of tablets recorded of the accountability log running balance

If discrepancies are found, a re-count should be performed and/or the accountability log checked for errors

Record the reason and resolution on the log

If expired or damaged tablets are identified during the inventory check, they should be removed from dispensable stock and reconciled on the Drug Accountability Logs

PediCAP Drug Accountability Log

Complete one log for each batch number

Site Name:	Principal Investigator:	Lead Pharmacist:
Drug Name:	**Batch Number:**	**Expiry Date:**

DATE	RECEIVED		DISPENSED			REMOVED FROM STOCK			BALANCE	RETURNS (complete on same row as patient's dispensing episode)		
Date of Action	Number of Tablets Received	Received By (Initials)	Patient Study ID	Number of Tablets Dispensed	Dispensed By (Initials)	Number of Tablets Removed	Reason Removed (eg. expired, damaged)	Removed By (Initials)	Running Balance	Date	Number of Tablets Returned	Counted By (Initials)

Patient returns

- Patients will be asked to return any unused tablets when they come to clinic for their final visit at week 4.
- If returned to the nurse/doctor, they will pass these on to pharmacy.
- Returned tablets should never be re-dispensed and must be stored separately from dispensable stock.

DATE	RECEIVED		DISPENSED			REMOVED FROM STOCK			BALANCE	RETURNS (complete on same row as patient's dispensing episode)		
Date of Action	Number of Tablets Received	Received By (Initials)	Patient Study ID	Number of Tablets Dispensed	Dispensed By (Initials)	Number of Tablets Removed	Reason Removed (eg. expired, damaged)	Removed By (Initials)	Running Balance	Date	Number of Tablets Returned	Counted By (Initials)

Record the returned tablets on the Drug Accountability Log

Enter the tablets on the same line that the patient's dispensing episode is recorded.

Destruction

- IMP that has been returned, has expired, is damaged or is otherwise deemed unusable after quarantine should be destroyed.
- Drugs should be destroyed in batches.
- Destruction should be performed according to local procedures and GMP.
- At the end of the trial, all unused drugs must be destroyed within 60 days of the last study visit.
- To request a destruction, MRC CTU must be sent a PediCAP Drug Destruction Authorisation form.

PediCAP Drug Destruction Authorisation

Site Name:	Principal Investigator:	Lead Pharmacist:	Person Requesting Destruction:	Date Requested:

Drug Name	Batch Number	Expiry Date	Number of Tablets (Physical Count)	Reason for Destruction

MRC CTU Authorisation of Destruction

I.....(Print name and job title)

confirm that the above drugs are authorised for destruction.

Signature.....Date.....

Site Pharmacist Confirmation of Destruction

I.....(Print name and job title)

confirm that the drugs were destroyed according to GMP instructions

on.....(Date of destruction)

Signature.....Date.....

MRC CTU will review the form and approve the destruction by signing in the box at the bottom of the form

Once the destruction has been completed, the site pharmacist should sign in the other box provided

Send a copy of the fully signed form and any destruction certificates to MRC CTU.

Monitoring

- Local monitors will perform on-site monitoring visits every 3 months.
- We will aim for the first visit to take place as soon as possible after the first 5 patients have been randomised.
- MRC CTU monitors will aim to visit annually.
- All on-site visits will be arranged in advance and planned for a time that suits all parties.
- At each visit, monitors may look at all or some of the following:
  - Drug Accountability Logs
  - Pharmacy File – including essential documents, drug destruction forms
  - Temperature Logs
  - Physical stock count
- In the event that the coronavirus pandemic interrupts on-site monitoring, MRC CTU will increase their central monitoring activities and may request electronic copies of documents such as Drug Accountability Logs for review.