Standard Operating Procedure

Validation of Chemotherapy Protocols in ARIA (Wessex)

(SOP:CH003)

1. Objective

1.1 The purpose of this standard operating procedure (SOP) is to describe the procedure to be followed when validating chemotherapy protocols in ARIA in the Trusts formally part of the Central South Coast Cancer Network.

2. Scope

2.1. This SOP refers to all chemotherapy protocols including clinical trials and non-clinical trials.

3. Responsibility

3.1. The Aria lead pharmacist will be responsible for co-ordinating the production of the chemotherapy protocols as per SOP CH001.

3.2. The ARIA lead pharmacist will be responsible for maintaining the library of approved chemotherapy protocols as described in SOP CH001.

3.3. For non-trial prescriptions the ARIA electronic prescribing system manager, lead pharmacist and / or other suitably trained pharmacist or pharmacy technician will be responsible for building and validating all chemotherapy regimens on the Aria electronic prescribing system.

3.4 For trial prescriptions the ARIA electronic prescribing system manager, lead pharmacist and / or other suitably trained pharmacist or pharmacy technician will be responsible for building all chemotherapy trial regimens on the ARIA electronic prescribing system. A pharmacist will validate the regimen on ARIA. A Principal Investigator for that trial will also approve the prescriptions using test patients prior to their release for use on the system

3.5 The validation of the regimen on the electronic prescribing system must be conducted by someone different from the person who built the regimen on the system.

3.6 All regimens on ARIA, whether clinical trials or not, will be approved centrally by pharmacy and medical staff from any one of the acute Trusts that are part of the chemotherapy electronic prescribing system project. It remains the responsibility of each Trust to ensure the regimen is fit for use at their organisation. Each Trust must designate who holds this responsibility. For clinical trials this responsibility lies with the named principal investigator at that site.

3.7 Only one version of each protocol will be built and validated on the system for all to use. The protocols will be approved as described in this SOP and CH001.

3.8 The ARIA lead pharmacist will be responsible for ensuring all documentation in relation to the validation process is maintained.

4 Method

4.5 Ensure the validation documents "Validation Checklist for Regimens in 'PLANNER' (ARIA Version 13.6 - Adult Regimens Only)" and "Validation Checklist for Prescriptions in 'MANAGER' (ARIA Version 13.6 - Test Patients)" are completed during the validation process. This applies to the pharmacy staff validating the build information. Test patients should be assessed using the steps below.

4.6 Use the live system for all testing and log into manager. Change the location to RSH OP.

4.7 Open the relevant test patients (1, 2 and 3). All dummy patients used for testing Regimens in ARIA are to have their surnames starting with "xxzz" for easy identification, follow by the "Tumour site" eg xxzzLung

4.8 For quality assurance and ARIA system checking purposes, we need to present each patient/ regimen with small, medium and large surface areas in order to check for dose calculation and banding accuracy. To achieve this, we set up three dummy patients per regimen each with a different suffix at the end of the first name: -S for small, -M for medium and -L for large. Their NHS number will be identical but with a different suffix, ie. –S for small, -M for medium and –L for large (as below)

First name	NHS number
CarboNSCLC-S	Carbonsclcs

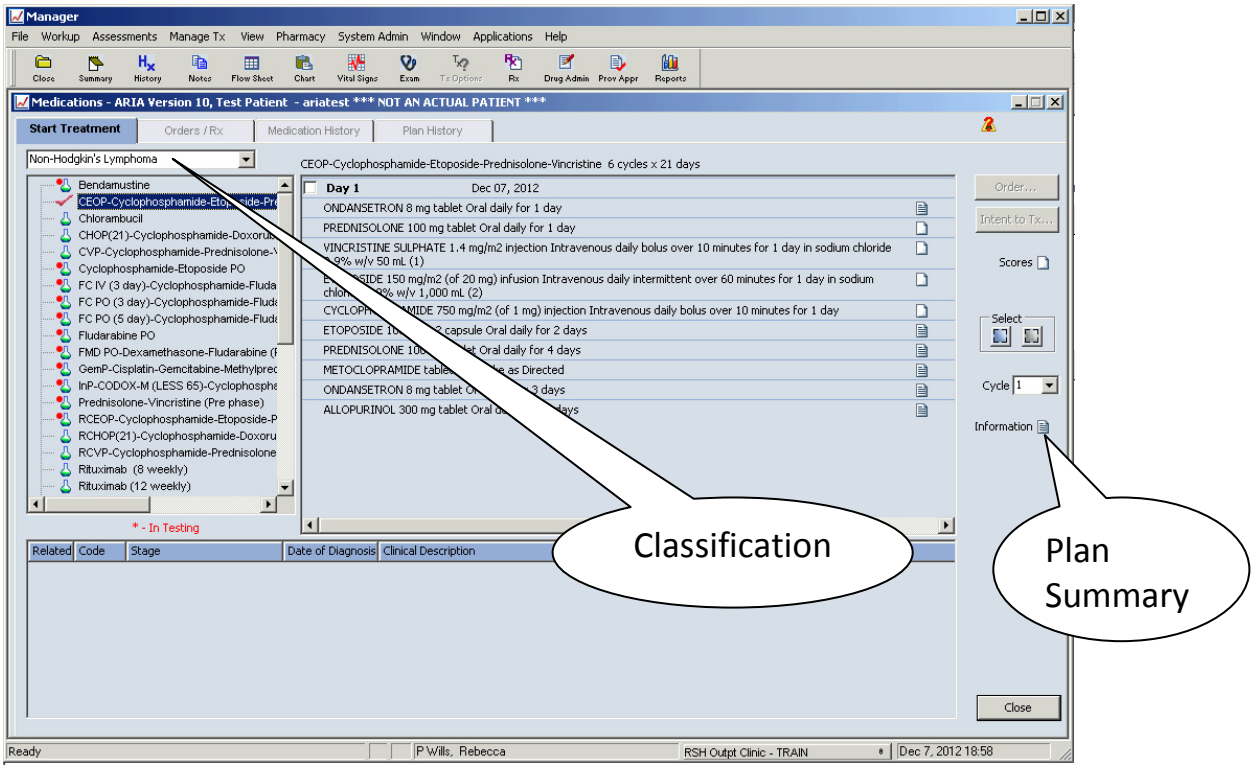
For your information, the surface areas details are as follows:

	Small	Medium	Large
Height (cm)	150	170	190
Weight (kg)	50	68	120
Surface Area m^2	1.43	1.79	2.47

4.9 Place patient on test regimen. With the medication screen open at start treatment page:

4.5.1 Check that the regimen appears for the appropriate disease **classification.**

4.5.2 For standard regimens the information box (**plan summary**) should either be absent or empty. For clinical trials check that, as a minimum, the trial title, version number and date, EUDRACT number and sponsor appear and that all details are correct.

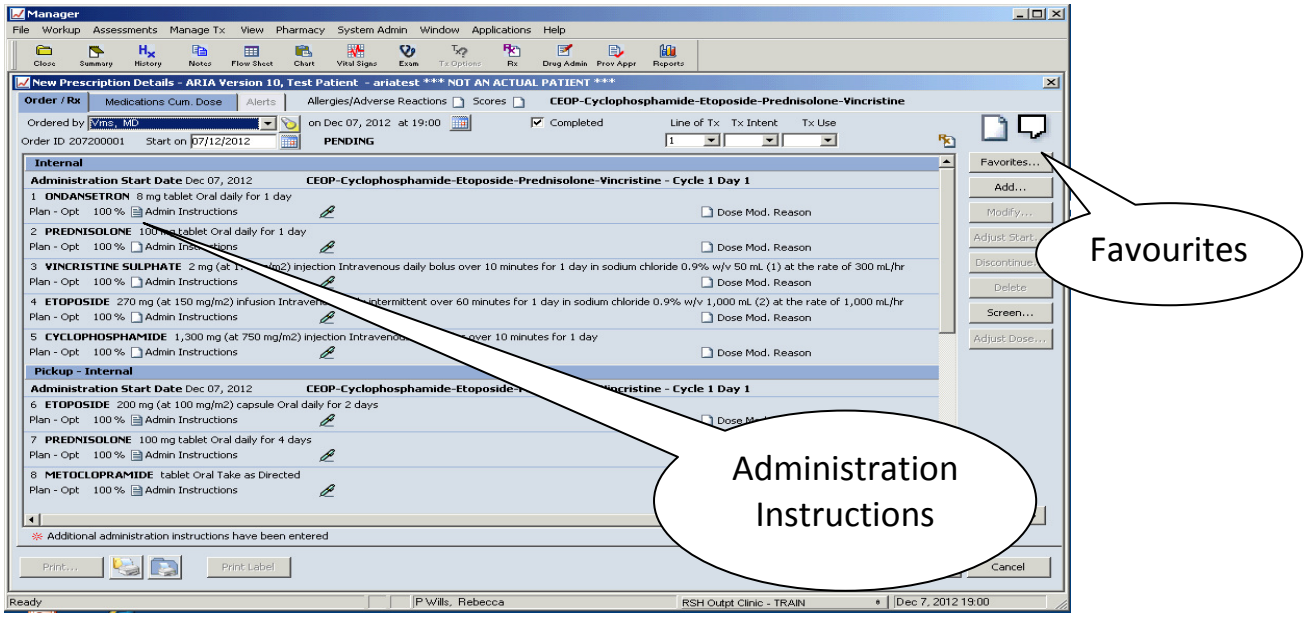


4.10 Order the regimen

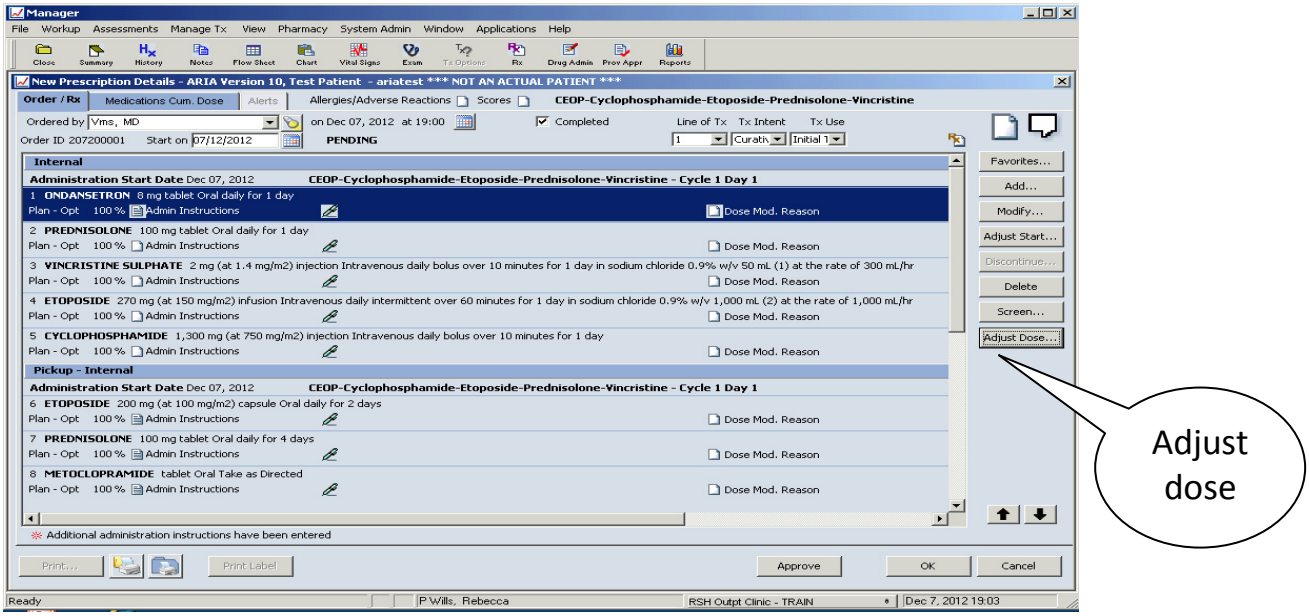
4.10.1 Check all **drugs,** doses, route, and **administration** instructions are correct as CSCCN protocol.

4.11 Click on the "favourites" button

4.11.1 Check that the appropriate **support regimens** are available under the favourites and support tabs.

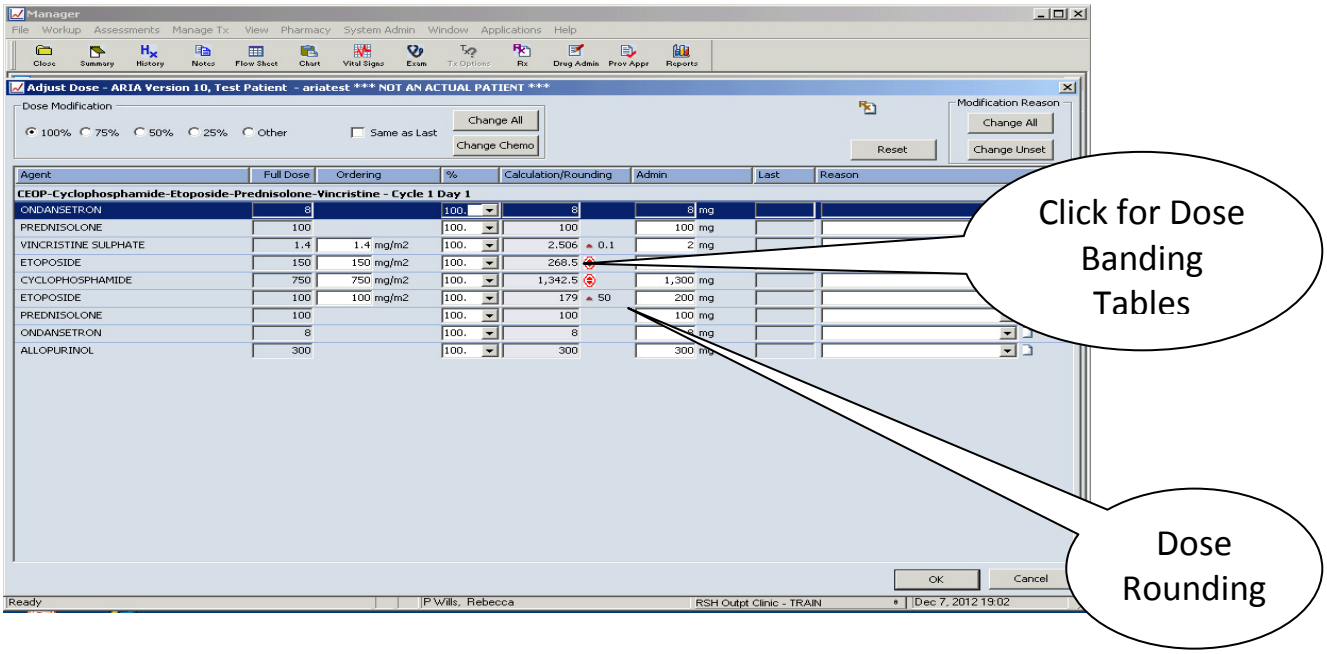


4.12 Highlight at least one agent on the list and click on the "adjust dose" button.

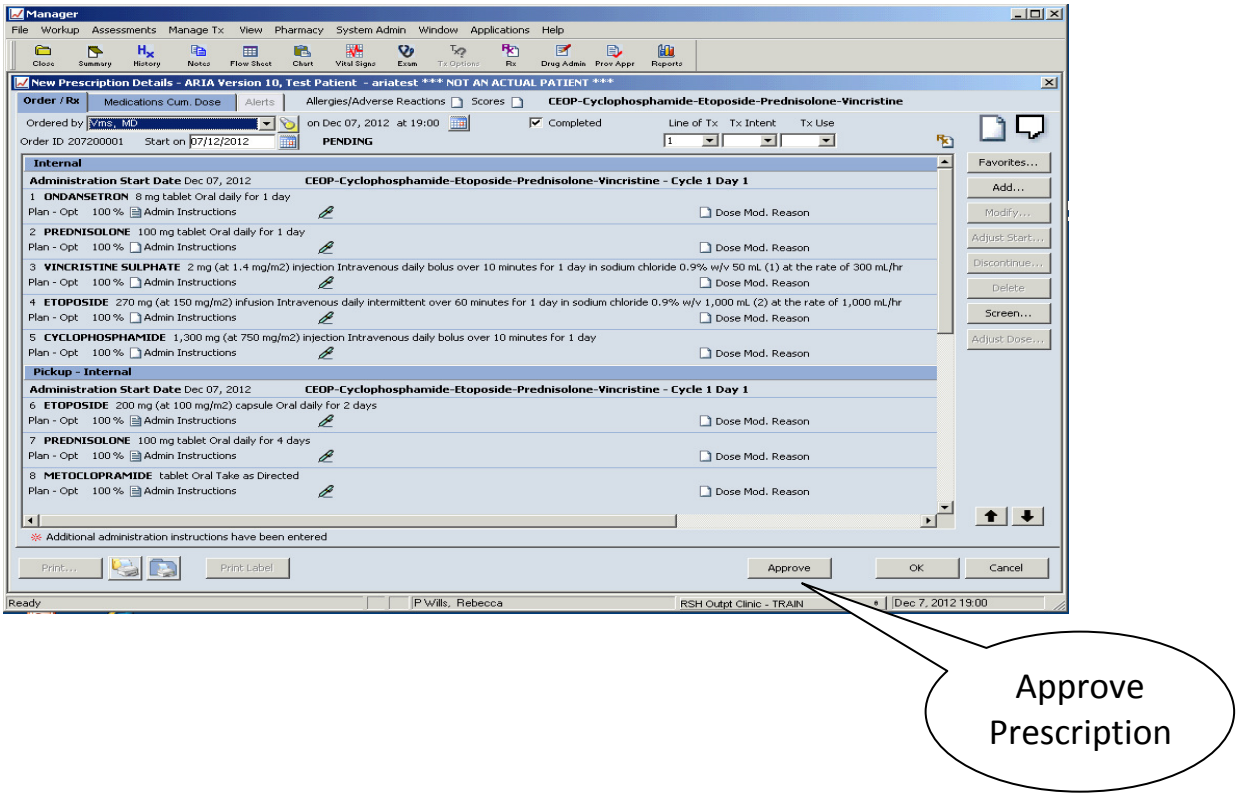


4.12.1 Check that the relevant dose banding tables and dose rounding values have been applied

4.12.2 Check that all the drugs can have **doses modified** as you would expect; the dose banding / dose rounding is working and that percentage reductions are correct. Use both the "Change all" and "Change chemo" buttons to check that only the relevant agent doses change.



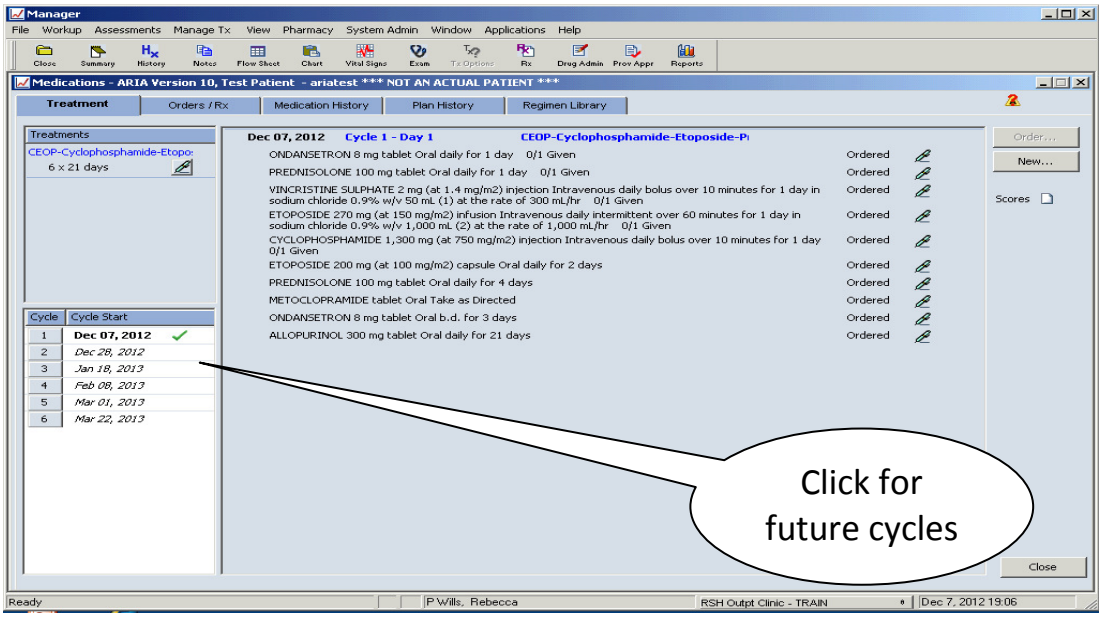
4.13 Approve cycle 1



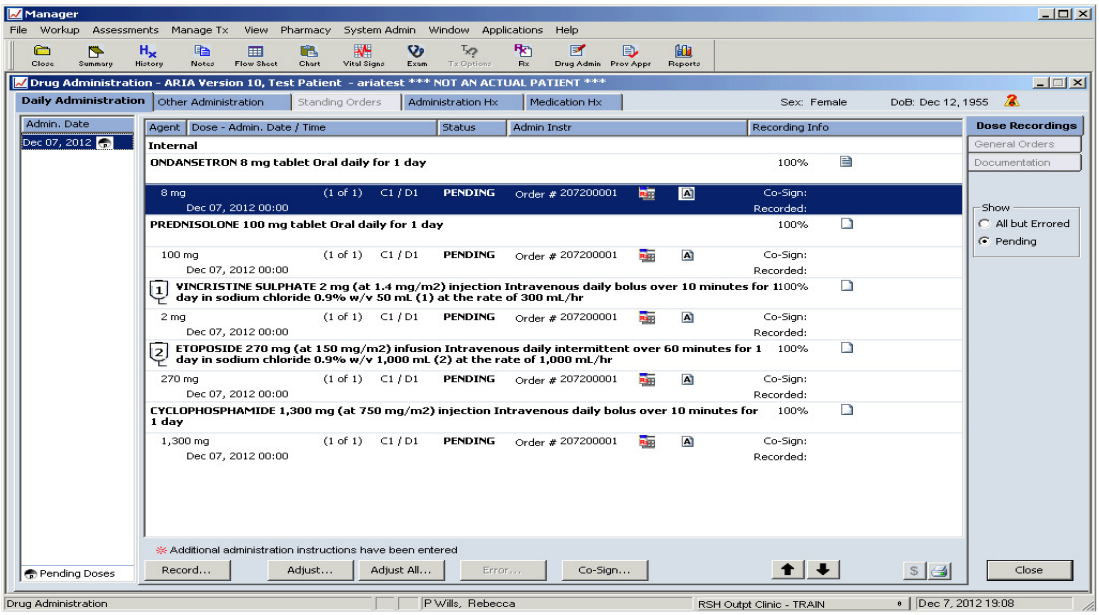
4.14 On the treatment tab check the following:

4.14.1 View all cycles on the "Treatment" tab and check that that the correct medications are present for the appropriate days of each cycle. Check **non-cyclical drugs** change as you would expect (e.g. doses of monoclonals change after cycle 1 if appropriate, drugs change on cycle 4 of FEC-docetaxel, etc.)

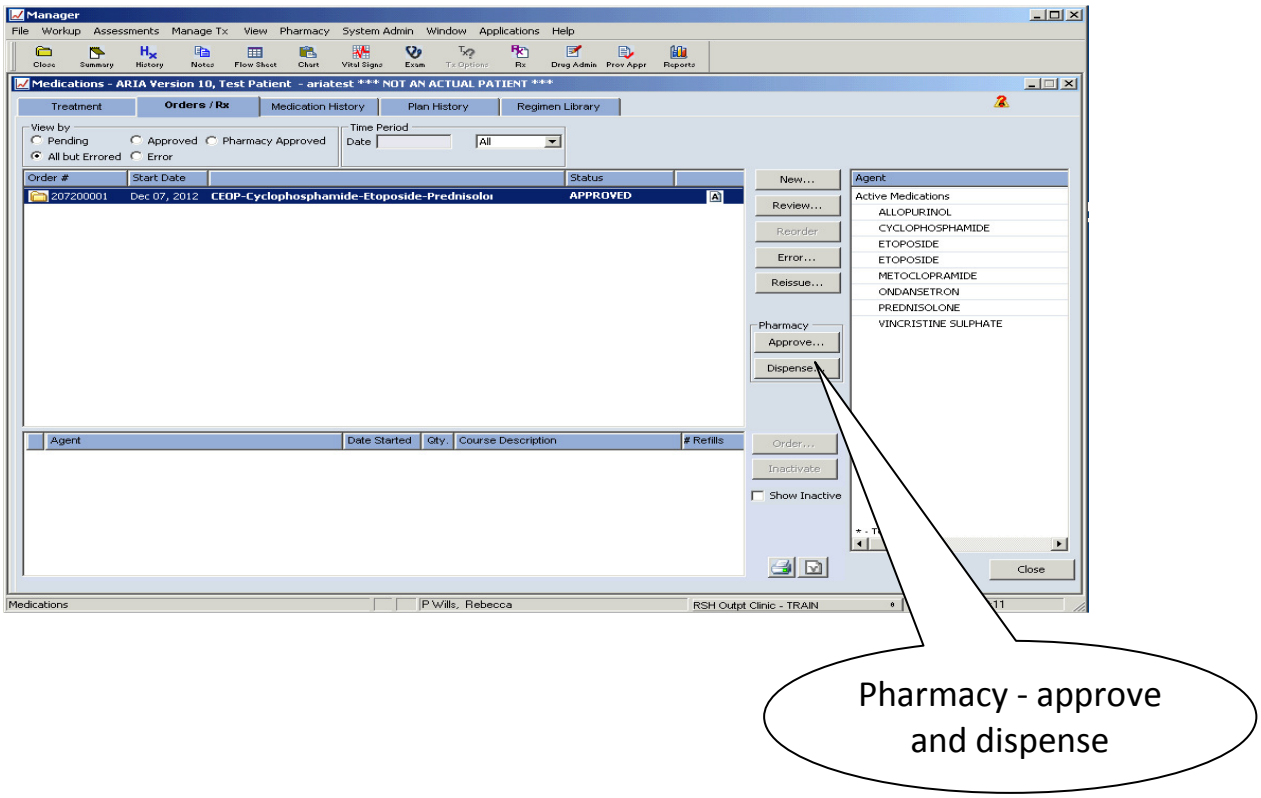
4.14.2 Check the default number of **cycles** and cycle frequency is correct.



4.15 Go to Drug Admin and check that all agents are listed in the correct order prior to dispensing



4.16 Go to the Orders/Rx tab and approve and dispense all medication. If there is more than one agent then change a diluent volume or dose and ensure it follows through to the drug administration as below.



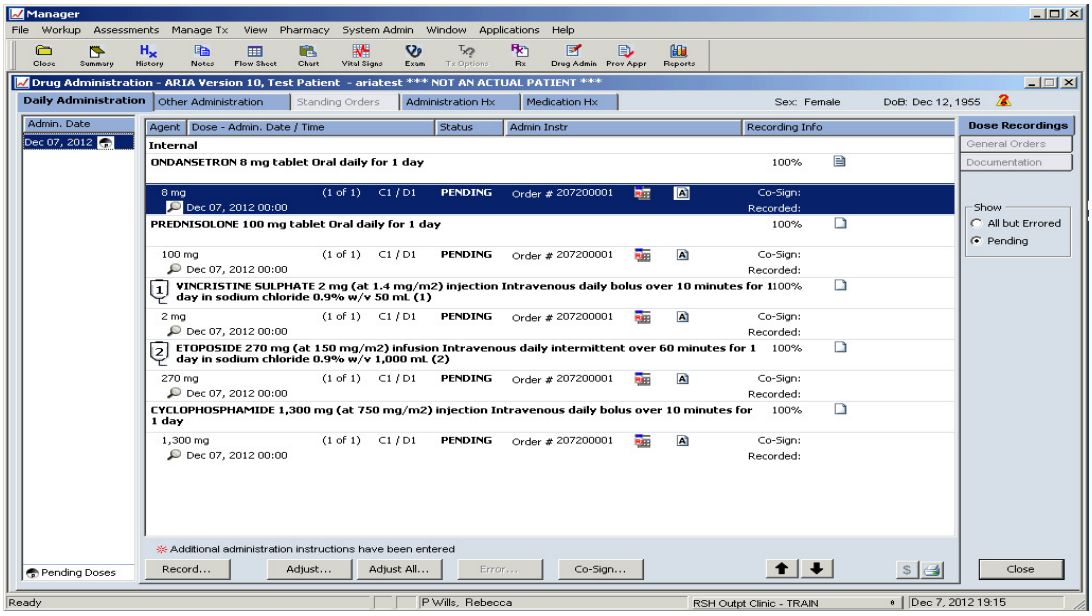
4.17 Return to "Drug Admin" screen and check the following for both the "Daily Administration" and "Other Administration" screens:

4.17.1 All required chemotherapy agents and other required drugs are present and in the correct order

4.17.2 The calculated **doses** are correct and banded as you would expect. (BSA may be confirmed via the Vital Signs button)

4.17.3 The administration route and details are correct.

4.17.4 The correct **administration instructions** have been entered where appropriate (administration instruction box)

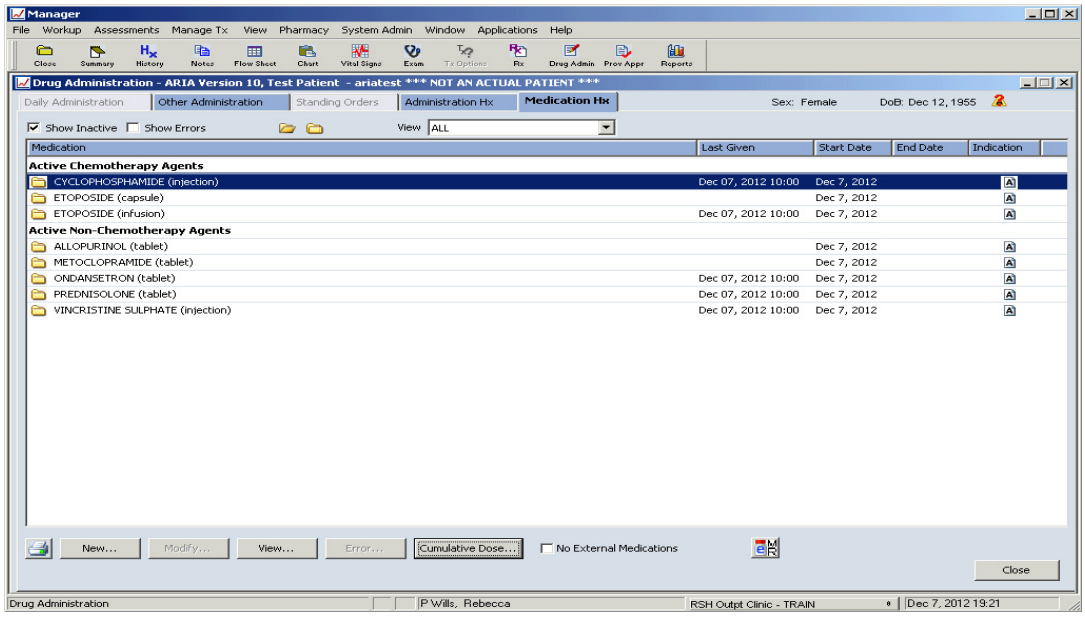


4.18 Administer the agents on the daily administration screen and check they disappear from the screen.

4.19 Once all drugs have been administered check the "Administration Hx" tab list all the relevant agents.

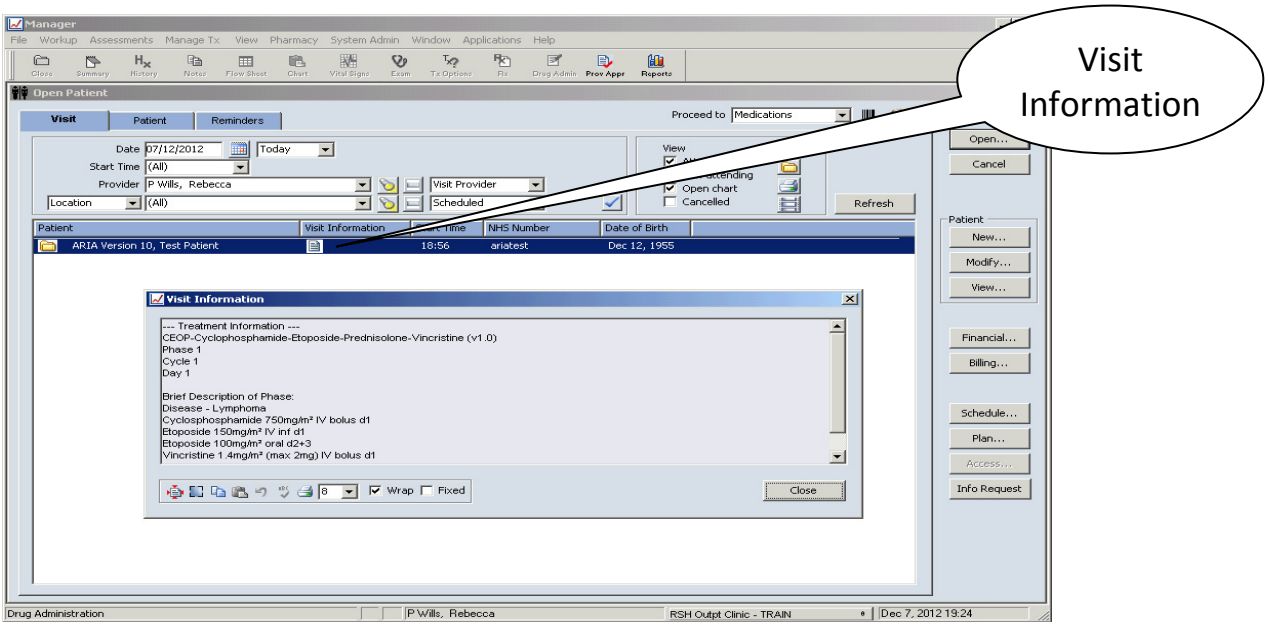
4.20 Check the "Medication Hx" tab and check that all chemotherapy appears under the "Active Chemotherapy Agents" descriptor and that all supportive treatments appear under "Active Non Chemotherapy Agents" descriptor.

Occassionally if a new agent has been added or an existing agent customised it will appear in the wrong category, as can be seen here with vincristine. If this is the case check the agent status with the ARIA system manager, if the agent status cannont be changed make a note on the validation paperwork



4.21 If there are agents that are scheduled for subsequent days or cycles that do not appear in the prescription(s) tested so far, repeat the process by approving a treatment day/cycle containing one or more of these agents and follow steps 4.6 onwards.

4.22 Close the patient and go to the "Visit" screen. Click the "Visit Information" box. Check the plan name, version number and **brief description** are correct for this regimen.



DOCUMENT CONTROL

Version Number	Description of Change	Amended By	Date
4.0	ARIA changed to capitals throughout Section three (responsibilities) updated Location added in section 4.6	Dr Deborah Wright Pharmacist	16/05/18
3.0	Updated for Aria version 13.6 Reformatted Header updated Checklists transferred into document CH003 Requirement for second check on plan summary removed References to version 10 removed Document ownership section added	Rebecca Wills E-Prescribing Pharmacist	22/02/16
2.0	Additional step added at 4.17: "If there are agents that are scheduled for subsequent days or cycles that do not appear in the prescription(s) tested so far, repeat the process by approving a treatment day/cycle containing one or more of these agents and follow steps 4.6 onwards." Agent tables – Errors column –"overleaf" replaced with "below"	Rebecca Wills CSCCN Electronic Prescribing Pharmacist	22/01/13
1.5	Updated for ARIA version 10 Document control table added and footer updated Amendments to SOP Screenshots updated throughout 3.5 "(Appendix 2)" removed 4.1 "(Appendix 2)" replaced with ""Checklist for Validation of Treatment Regimens in ARIA Version 10" and "Pharmacist Checklist for CSCCN Chemotherapy Regimens in Aria"" 4.4 NHS number quoted changed from "LUNG00001S" to "Carbonsclcs" Large patient increased to 190cm, 120kg, BSA 2.47m^2 4.5.2 "protocol and correct version are present in the information box" changed to "disease site and website address is present in the information box (plan summary). For clinical trials check that, as a minimum, the trial title, version number and date, EUDRACT number and sponsor appear and that all details are correct" Favorites information moved from 4.8 to 4.7 Dose adjust information moved from 4.7 to 4.8. 4.8.1 Additional statement added "Check that the relevant dose banding tables and rose rounding values have been applied" 4.8.2 "Use both the "Change all" and "Change chemo" buttons to check that only the relevant agent doses change" added 4.10 Section reworded. Additional check added "the plan summary can be viewed by clicking on the pen icon and selecting "Show summary". Original 4.11 moved to 4.12 4.11 Step added "Go to Drug Admin and check that all agents are listed in the correct order prior to dispensing" Original 4.12 moved to 4.17 4.12 Statement added "Please note attempting to move the drug order in the dispensing screen, using the arrow keys, often results in an error message – this is a known fault in version 10."	Rebecca Wills CSCCN Electronic Prescribing Pharmacist	20/01/13

	4.13 Point 4.13.2 removed, point 4.13.6 incorporated into pions 4.14 and 4.15 4.16 regarding medication history added Amendments to Pharmacist checklist: Protocol – Title changed to "Plan Summary", reference to protocol and protocol version removed, replaced with "disease site and website address or trial protocol summary". Drugs – "Trial" added. Support medicines – moved to number 4. Dose adjustment moved to number 5 "dose adjust button" replaced with "both the "change chemo" and "change all" buttons". Non-cyclical drugs – information in brackets removed. Plan summary – added at number 8. Check visit information – moved to number 12 Extra line added to small and medium patient tables Error table removed		
1.4	Additional lines added to tables	Dr Deborah Wright CSCCN Lead Pharmacist	01/12/10
1.3	Administration details added	Dr Deborah Wright CSCCN Lead Pharmacist	02/06/10
1.2	Point 8 added	Dr Deborah Wright CSCCN Lead Pharmacist	06/05/10
1.1	Medication Hx added	Dr Deborah Wright CSCCN Lead Pharmacist	24/02/10

This SOP has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. This document has been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospital NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust