

BUILDING & VALIDATING ADULT CHEMOTHERAPY REGIMENS AND SYMPTOM MANAGEMENT (SUPPORT) PLANS

OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when building and validating adult chemotherapy or other SACT regimens (referred to as chemotherapy regimens) and symptom management plans (referred to as support regimens) in the ARIA electronic prescribing system (referred to as ARIA).

SCOPE

This SOP applies to all adult chemotherapy and support regimens.

RESPONSIBILITIES

- Only specialist pharmacists and technicians who have received full training on the use of ARIA are authorised to build regimens.
- All regimens must be built in the Planner app of ARIA then fully tested and validated by a pharmacist, consultant and nurse before they can be approved for use. All regimen amendments must be re-validated by a pharmacist (as a minimum) before they can be approved for use.
- Only specialist pharmacists, nurses and consultants who have received full training on the use of ARIA are authorised to validate regimens. The validation of chemotherapy regimens must always be carried out by someone other than the person who built the regimen on ARIA Planner.
- The pharmacist validation should be completed in 2 stages by a pharmacist other than the builder. Planner should be checked first, then the consultant and nurse complete their validation, then the validating pharmacist completes their Manager validation checks
- Checklist 2 must be performed by the nominated consultant in the Manager app. The consultant will be expected to check the regimen details and prescribing functions. Consultants will need to use a different test patient for validation.
- Checklist 3 must be performed by a specialist nurse in the Manager app. The nurse will be expected to check the regimen for any nursing/administration-related issues. Nurses will need to use the same test patient set up by the validating consultant
- Any errors detected by the validating pharmacist in Planner must be referred back to the regimen builder for correction. Any errors detected by the validating consultant or nurse should be referred back to the validating pharmacist who should facilitate correction. Once corrected, the regimen must be tested again to ensure that the errors have been rectified. If a simple error is found, this can be rectified and re-checked at any time before approval. If a complex error is found that will impact on the rest of the validation procedure, the error must be rectified before continuing with the rest of the validation procedure.
- Each checklist must be signed by the validator to indicate a successful validation of the regimen and returned to the validating pharmacist.
- For network approved regimens, once completed, the validation checklists and completion notification form should then be forwarded to the system administrator. For non-network approved or off protocol regimens, the validation paperwork should be retained at Trust and a copy of the final approval form sent to the system administrator.
- The ARIA system administrator is responsible for allocating and overseeing the building and validation of all non-trial chemotherapy and support regimens in ARIA.

REFERENCE SOURCES

Ensure that you have access to the following, as you will require them during the regimen build & validation:

- K&M SACT protocol or other reference document for the regimen.
- Access to drug SPCs online at: <http://www.medicines.org.uk/emc/>.
- KMCCEP006 Regimen classification specification – Disease site and cancer categories
- KMCCEP012 ARIA test patient setup guide
- List of drugs needing accuracy check for % dose reductions.

BUILDING A REGIMEN:

Before starting the build, ensure all the drugs you require are present in the ARIA formulary. If they are not, request them on form *KMCCEP007 Adding, amending & deleting agents from the ARIA formulary* from system administrator. If you are unsure, contact the system administrator

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You can then choose to do one of the following:

- A. Build a new regimen from scratch:** Select “New” button to open up the “New Plan” window.
- B. Amend a regimen:** An existing regimen should be updated using the Amend button wherever possible however, if the Amendments Mandatory tick box is selected then DO NOT AMEND the regimen. Instead, click the “Copy” button and untick the Amendments Mandatory option, before proceeding with the changes.
- C. Copy a regimen:** Select this option if updating an approved regimen that has Amendments Mandatory ticked or if you wish to use the existing regimen to build a similar one. If you are unsure which option to choose, refer to the system administrator for advice

VALIDATING A REGIMEN

- A.** Validating pharmacist - Review the regimen build in Planner, following steps 1-10 below. If any errors are identified, these should be corrected by the regimen builder and re-checked by the validating pharmacist.
- B.** Once Planner checks have been completed and the test patient set up, inform the validating consultant that their validation can commence. Any errors identified that require correction should be forwarded to the builder via the validating pharmacist
- C.** Following consultant sign-off, validating pharmacist informs the validating nurse that validation can commence. Any errors identified that require correction should be forwarded to the builder via the validating pharmacist
- D.** On completion of consultant and nurse validations, the validating pharmacist must complete their checks of the regimen in Manager, following steps 12 onwards below
- E.** Once validation is complete, the regimen sign-off sheet *KMCCEP016 ARIA adult regimen validation and sign-off* should be completed and forwarded to the system administrator

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METHOD
ARIA PLANNER
LOG IN TO PLANNER

ENSURE THAT BOTH THE "FROM" AND "LOGIN TO" BOXES HAVE "MTW NHS TRUST" SELECTED FROM THE DROPDOWN MENUS.

OPEN PLAN WINDOW: IF THIS DOESN'T AUTOMATICALLY OPEN THEN SELECT "FILE - OPEN PLAN". THE OPEN PLAN WINDOW LISTS ALL REGIMENS THAT HAVE ALREADY BEEN BUILT UNDER THE PLAN TYPE SELECTED IN THE DROP-DOWN MENU. THE STATUS COLUMN WILL INDICATE WHETHER THEY ARE PENDING (I.E. STILL BEING BUILT), IN TESTING OR APPROVED.

BUILDER: SELECT NEW, AMEND OR COPY AS NECESSARY (see above for guidance)

VALIDATOR: Double click on the regimen you require then select 'Definition' from the tool bar

DO NOT COPY AND PASTE TEXT FROM WORD DIRECTLY INTO ANY WINDOW IN ARIA AS THIS WILL CAUSE A SYSTEM ERROR, INSTEAD, COPY FROM WORD INTO NOTEPAD THEN FROM NOTEPAD INTO ARIA. COMPLEX PRESCRIBING NOTES, I.E. TABLES, DIAGRAMS ETC, SHOULD NOT BE ENTERED INTO ARIA, INSTEAD, REFERENCE SHOULD BE MADE TO WHERE THEY CAN BE VIEWED E.G. KMCC SACT PROTOCOL

1. NEW PLAN WINDOW
1.1. Definition tab

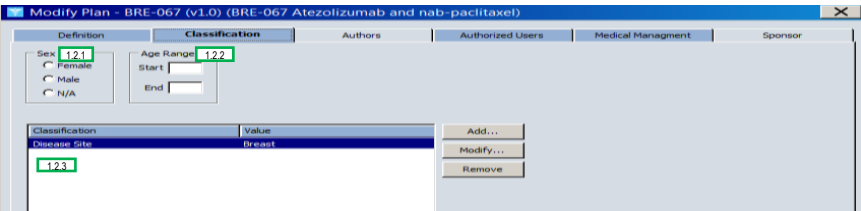
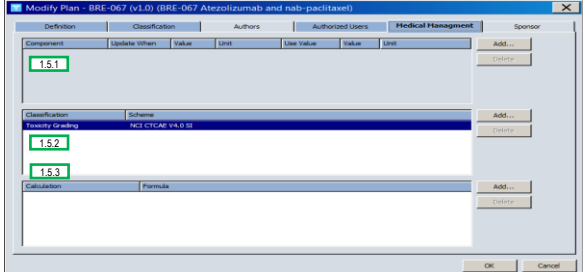
- 1.1.1. Plan Name:** This box can only contain up to 20 characters and must be unique. The K&M SACT protocol number must be entered. On leaving the new plan window, this can then not be changed so ensure it is entered correctly
- 1.1.2. Version:** The version number in this box will be automatically created and updated by ARIA.
- 1.1.3. Display Name:** This box will allow you to enter more information than the plan name box (80 character limit). This name is displayed in most user windows in Manager. The K&M SACT protocol number must be entered first followed by the protocol name, e.g. BRE-009 FEC75 (refer to protocol or KMCC regimen list). For new regimens that do not yet have a protocol number, one will be created by KMCC team. The protocol name should be entered in normal sentence case unless the regimen name is an acronym, e.g. CTD. For off-protocol/non-NOG approved, the display name will be assigned by the ARIA system administrator.
- 1.1.4. Plan Type:** Select "Regimen" if you are building a chemotherapy regimen. Select "Symptom Mgmt" if you are building a support regimen.
- 1.1.5. Sponsor:** Select "Internal" from dropdown box.
- 1.1.6. Owner:** Select "MTW NHS Trust" from dropdown box.
- 1.1.7. Brief Description:** Enter "See Plan Summary".
- 1.1.8. External Name:** Leave this box blank.
- 1.1.9. Plan group:** Leave this box blank.
- 1.1.10. Amendments Mandatory** (chemotherapy regimens only): This box must be left unticked for all standard regimens. When ticked, any future amendments to the regimen will be applied to all patients being treated with the regimen, including those patients already prescribed the regimen.
- 1.1.11. Clinical Trial:** Only tick if you are building a clinical trials regimen. When this box is ticked, an additional dropdown box will appear for entering the Trial Phase number (if applicable).

The screenshot shows the 'New Plan' window with the 'Definition' tab selected. The form contains the following fields and controls:

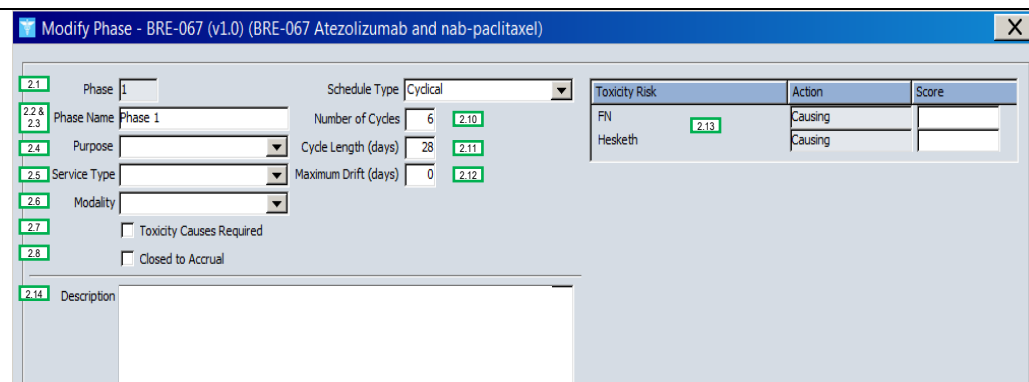
- Plan Name:** Text input field (1.1.1)
- Version:** Text input field with '1.0' (1.1.2)
- Display Name:** Text input field (1.1.3)
- Plan Type:** Dropdown menu with 'Regimen' selected (1.1.4)
- Sponsor:** Dropdown menu with 'Internal' selected (1.1.5)
- Owner:** Dropdown menu with 'MTW NHS Trust' selected (1.1.6)
- Brief Description:** Text area (1.1.7)
- External Name:** Text input field with 'Add' and 'Remove' buttons (1.1.8)
- Plan Group:** Text input field (1.1.9)
- Amendments Mandatory:** Checkbox (1.1.10)
- Clinical Trial:** Checkbox (1.1.11)

Buttons for 'OK' and 'Cancel' are located at the bottom right of the window.

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1.2.	Classification tab:	
	<p>1.2.1. Sex: Ensure "N/A" radio button is selected when building, this appears blank when validating</p> <p>1.2.2. Age Range: Leave all boxes blank.</p> <p>1.2.3. Classification: In the classification box, click on the "Add" button on the right then:</p> <ul style="list-style-type: none"> For chemotherapy regimens - Select "Disease Site" from the Classification dropdown box then the relevant cancer disease site(s) from the Value dropdown box as stated in the regimen classification document. If the regimen is used to treat more than one disease site, this process must be repeated for every disease site. If the disease site has a sub-category, e.g. NSCLC, this also needs to be added by selecting "Cancer Categories" from the Classification dropdown box then selecting the relevant sub-category from the Value dropdown box For support regimens - Select "Problems" from the Classification dropdown list then select the relevant symptom from the "Value" dropdown list. 	
1.3.	Authors tab: Leave blank.	
1.4.	Authorized Users tab: This will contain the name of the regimen builder. Other authorised users may be added by clicking on the "Add" button on the right. The user "Vms, Ks" must always be added to allow Varian Medical Systems access. Add the appropriate users for the type of regimen you are building – <i>KMCCEP024 ARIA authorised users register</i>	
1.5.	Medical Management tab (chemotherapy regimens only)	
	<p>1.5.1. Component: This is usually left blank, unless specific deviations are required from Security set-up, e.g. for clinical trials. This setting may be used to specify different settings, e.g. for GFR. BSA is capped in Security for all regimens at 2m². It is not possible to set a different BSA cap or to uncap a regimen in this window</p> <p>1.5.2. Classification Scheme: This setting cannot be changed after clicking 'OK', so ensure that you select the correct one at this stage. For non-trial regimens Add Toxicity Grading scheme of "NCI CTCAE v4.0 SI"</p> <p>1.5.3. Calculation Formula: This box is used to select a specific formula for BSA or GFR calculation for a regimen that will override the standard formulae set up in the Security module. The default formulae set up at Security level are Cockcroft & Gault for GFR calculation and Mosteller for BSA calculation.</p>	
1.6.	Medical Management tab (support regimens): Leave blank.	
1.7.	Sponsor tab: Leave blank.	
<p>BUILDER: SELECT OK TO COMPLETE AND EXIT VALIDATOR: SELECT CANCEL TO LEAVE WINDOW CLICK ON 'GO TO' IN PLAN AGENDA SCREEN</p>		
2.	VIEW/MODIFY PHASE WINDOW	
	<p>2.1. Phase: Automatically numbered as "1".</p> <p>2.2. Phase Name (chemotherapy regimens): Leave as "Phase 1".</p> <p>2.3. Phase Name (support regimens): This is the name the prescriber will see when they select the regimen. Enter the name of the support drug here. Maximum 20 character limit</p> <p>2.4. Purpose: Leave blank.</p> <p>2.5. Service Type: Leave blank.</p> <p>2.6. Modality: Select "Radiation" for chemo-radiation regimens. Leave blank for all other regimens.</p> <p>2.7. Toxicity Causes Required: Leave this box unticked.</p>	

- 2.8. Closed To Accrual:** Leave this box unticked.
- 2.9. Schedule Type:** "Cyclical" should be selected for most chemotherapy and support regimens that are repeated at regular intervals for a given number of cycles. "Linear" applies to treatment courses consisting of a single cycle that will not be repeated. "Linear - Neg. Days" should only be selected for bone marrow transplant regimens or any other regimens that may require treatment on negative day numbers. If "Linear - Neg. Days" is selected, enter the Starting Day for the cycle, e.g. Day -5, instead of the Number of Cycles.
- 2.10. Number of Cycles:** Specify the number of cycles required for the regimen.
 - If the KMCC SACT protocol states a range for number of cycles, select the lower figure when building your regimen, unless the regimen is for chemoradiotherapy (e.g. 2-3 cycles) where the higher number of cycles should be entered.
 - If the regimen contains cytotoxic chemotherapy of indefinite duration, set up as 6 cycles (unless the proforma states a different figure). MAb monotherapies or combinations with longer fixed durations, e.g. trastuzumab 18 cycles, should be set up for the full course.
 - Palliative MAb or TKI monotherapies (i.e. excluding cytotoxic chemotherapy) with no fixed duration should be set up with a standard duration of 12 cycles.
 - Chemo and MAb combination treatments should be set up for the full duration or up to a years treatment, whichever is less
- 2.11. Cycle Length (days):** Specify the cycle length (in days) required for the regimen. If the Kent & Medway SACT proforma does not specify the length of a cycle (e.g. some haematology regimens), set cycle length as 28 days. If the protocol states a cycle length of 30 days, the regimen must be built as a cycle length of 28 days so that subsequent cycle treatment days are scheduled for the same day of the week and do not fall on a weekend. A protocol would usually only specify a duration of 30 days if the pack size of the treatment contained 30 days' supply, e.g. erlotinib. If this is the case, then a note should be added to the Admin tab textbox (see 3.2) when building the agent stating "DISPENSE 30 DAYS SUPPLY".
- 2.12. Maximum Drift (days):** Leave as "0" days.
- 2.13. Toxicity Risk scores:** Leave blank.
- 2.14. Description box:** Leave blank.
- 2.15. Chemo Order Instructions:** Leave blank.

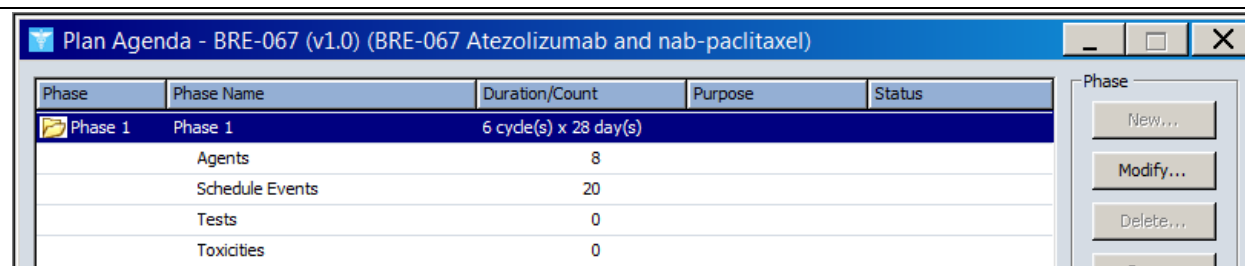


SELECT OK TO SAVE AND CLOSE THE WINDOW
DOUBLE-CLICK ON AGENTS TO OPEN THE AGENTS WINDOW. SELECT 'NEW' TO ADD AN AGENT

3. AGENTS

3.1. Agent Selection

Leave the "Formulary Only" box ticked and then type in the first 3 letters of the agent name. All matching entries will be listed in the Agent box (those in upper case are from First Data Bank whereas agents in lower case have been created manually and will not have interaction/allergy functionality). "NB Monitoring parameters" should be the first agent as the essential prescribing and monitoring guidance must be entered in the Admin tab textbox (see 4.2). Add subsequent agents ensuring they will appear in the correct order in



Manager and include all pre-medications and supportive medicines that are required. If an agent will be required more than once in a regimen, e.g. vinorelbine day 1 and day 8, then this should be built as one agent where possible and scheduled twice for day 1 and day 8. There may occasionally be instances where an agent must be built more than once within a regimen, e.g. if the dose, directions or admin notes are different depending on the day of treatment. Select required agent from the list then click OK. This will take you to the Add Agent window. Ensure that the total duration of the Internal

agents exceeds 10 hours a day for day case regimen

4. **ADD/VIEW / MODIFY AGENT**

4.1. **Details Tab**

4.1.1. Agent Name: This will show the agent name as selected on the previous screen.

4.1.2. Form: The form for the drug will automatically be selected from the dropdown box, based on your previous selection from the formulary.

4.1.3. Take as Directed: Whenever possible this box should be left unticked as ticking this box disables the dose/range and unit boxes so doses will not be calculated, e.g. day 2-3 oral etoposide.

Circumstances when the box will have to be ticked include drugs with variable doses, e.g. metoclopramide TDS for 3 days then PRN. When the box is ticked, full instructions regarding dose and administration day would then need to be typed in the Admin tab textbox (see 3.2).

4.1.4. Agent Placeholder: Leave this box unticked.


4.1.5. Dose: Ensure the "Fixed Dose" radio button is selected then enter the required dose. Filgrastim must be built as a 'Fixed dose' of 5mcg/kg. A dose banding table has been applied at Security level in order to round the calculated dose to 300mcg or 480mcg, as appropriate. Carboplatin should be set up with the dose unit selected as "AUC (CrCl)". Prescribers will manually amend to "AUC (EDTA)" at the prescribing stage if/when an EDTA result is available. Vincristine should be set as a flat dose of 2mg for all regimens that currently stipulate a calculated dose of 1.4 or 1.5mg/m² (the calculated dose must be entered in the admin notes). 5-FU pumps should be set up with the total dose to be infused as mg/m² with the duration entered in the infusion mode duration box below. Warning notes marked as Internal, e.g. NB Monitoring parameters, should be set up as a 'Fixed Dose' of 1, with the Unit dropdown box left blank and the Route dropdown box should be set as "Not Assigned".

4.1.6. Dose/Range: For a single dose, enter it in the dose box; for a range, enter a value in each box to show dose from and dose to

4.1.7. Unit: Enter as per protocol e.g. mg/kg, mg/m², etc.

4.1.8. Route: This will auto-populate based on the settings for the chosen drug and MUST NOT be altered.

4.1.9. Strength dropdown box is usually left blank and cannot be manually entered. The box is only populated if the drug had more than one strength available during agent selection e.g. Co-codamol 8/500 or 30/500

4.1.10. Rounding: The rounding boxes are normally left blank, as the dose-banding or rounding is set up at Security level. This section may be completed if a regimen needs to override the standard set-up. A different dose banding table can be set up at regimen level for an agent, if required. In order to do so, select "Dose Banded" from the Rounding Method dropdown box, then click on the  icon and click on the "Add" button to add each line of the dose banding table as required (see *KMCCEP025 Adding dose banding tables to ARIA*). When adding new tables, the 'addition of dose banding tables' SOP should be used

	<p>4.1.11. Maximum Single Dose: A value should be entered here if the drug appears on the maximum dose spreadsheet (see reference list) and the agent is a flat dose. Maximum single doses should not be entered for drugs marked as 'Take as directed'.</p> <p>4.1.12. Prescription Type: Select "Internal" for all preparations that are administered on the ward. Select "Pickup - Internal" for all preparations that are to be supplied to the patient to take home. If Pickup - Internal is selected, leave Record Dose dropdown box as "No Dose Recordings". Also leave Refill box unticked. For regimens with 'Internal' agents, "NB Monitoring Parameters" must be designated an 'Internal' agent. For regimens with only 'Pickup - Internal' agents, "NB Monitoring Parameters" must be set up as a 'Pickup - Internal' agent.</p> <p>4.1.13. Sequence Number: The sequence number will determine the order of administration for all drugs entered for the regimen. Where possible, an agent should be entered once when building the regimen and then scheduled for the appropriate days in Schedule Events window. If you are building a regimen where the same drug appears multiple times, e.g. cytarabine, BD for 10 days, for ADE, the sequence number may not be the same for every dose, depending on when other drugs are given. Therefore, it may be necessary to build an agent more than once so that each has a different sequence number. E.g. cytarabine would be built twice – once for am dose and once for pm dose – to allow other drugs to be inserted between the two doses. If you forget to add in a drug during your regimen build, all subsequent sequence numbers must be amended in reverse order before the drug can be added in at the vacant position.</p> <p>4.1.14. Agent Category (chemo regimens only): Select the correct category for the drug from the dropdown list, e.g. treatment, hydration, etc. When adding a warning note, select "Not Applicable".</p> <p>4.1.15. Substitution Allowed?: Leave the Yes radio button selected.</p>
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FOR INFUSIONS/INJECTIONS A SET OF BOXES WILL APPEAR, CONTINUE TO POINT 4.1.16 FOR INSTRUCTIONS ON COMPLETION. FOR ALL OTHER PREPARATIONS, GO TO POINT 4.2.

	<p>4.1.16. Infusion Mode: Selected from the dropdown box: "continuous" should be selected for infusions and "bolus" selected for bolus injections. If infusion mode is not clearly specified on SACT proforma, use "bolus" for durations of less than 10 minutes and "continuous" for durations of 10 minutes or greater.</p> <p>4.1.17. Duration: Enter duration of infusion (where required). The first box is where the numerical field is entered and the second dropdown box is where the units are selected. If the SACT proforma specifies a range for the infusion duration, e.g. bevacizumab, then this field should be left blank and the full infusion details entered in the Admin tab textbox (see 3.2). For <u>5-FU pumps</u>, enter the infusion mode and duration in hours or days. If you decide to delete the infusion mode or duration after entering, select the 'eraser' icon to the right of the dropdown box.</p> <p>4.1.18. Diluent and Volume: These should be selected from the dropdown boxes if required. If the SACT proforma specifies a range for the diluent volume, e.g. oxaliplatin, then this field should be left blank and the full infusion details entered in the Admin tab textbox (see 3.2). The Rate field is automatically calculated if both the duration and volume fields have been populated.</p> <p>4.1.19. Diluent ID: This box must be completed with a number if a diluent is required. This number should be sequential in terms of the order that the agents are administered in. If two or more agents are to be diluted and administered in the same infusion bag then each agent should be given the same Diluent ID number.</p> <p>4.1.20. Line Number: This box should be left blank unless the regimen states a specific line that the drug needs to be administered by if a double or triple lumen line is used and drugs are incompatible.</p>	
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4.2.	<p>Admin tab: Additional administration instructions should be entered here as stated on the KMCC SACT protocol.</p> <ul style="list-style-type: none"> For ALL drugs marked as 'Take as directed', enter FULL directions in this field, as specified in the KMCC SACT treatment protocol. For all other drugs, ensure that no information is duplicated in the admin tab that will be provided by the scheduling (e.g. dose, frequency, duration). For ALL <i>vinca alkaloid</i> agents the following must be stated: "FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY ANY OTHER ROUTE." For <i>filgrastim</i> and other drugs to be started after day 1, enter the actual start day in the admin instructions. Administration times for in-patient regimens should be entered here, if appropriate, e.g. T=0. <u>Do not</u> enter any information in tabular form. <u>If a maximum dose is specified in the agent details this must be also be stated in the admin instructions.</u> The original <i>vincristine</i> dose, e.g. 1.4mg/m², must be entered in this section in all cases where vincristine has been built as a flat dose of 2mg. For drugs with a specified brand e.g. biosimilars, ensure the brand is stated here
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4.3.	Course tab: Leave blank.
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SELECT OK TO COMPLETE AGENT THEN REPEAT POINT 4 AS NECESSARY UNTIL ALL REQUIRED AGENTS HAVE BEEN ADDED THEN SELECT CLOSE TO RETURN TO THE PLAN AGENDA

4.4. **Reminders (support regimens only):** Leave blank

SCHEDULE EVENTS WINDOW: DOUBLE-CLICK ON SCHEDULE EVENTS TO ENTER SCHEDULE EVENTS WINDOW.

5. SCHEDULE EVENTS

5.1. Schedule events window

5.1.1. **Starting On box:** The dropdown box should be left blank at this point. If specific days are selected in the scheduling agents window then the start day will be automatically entered here (see 5.2.2).

5.1.2. **View box:** Cycle Day radio button should always be selected.

5.1.3. **Maintain box:** Schedule radio button should always be selected.

EACH AGENT NOW NEEDS TO BE SPECIFIED AS TO WHICH DAYS IT WILL NEED TO BE GIVEN ON. CLICK ON THE RELEVANT TREATMENT DAY BOX ALONGSIDE THE FIRST AGENT AND THEN CLICK THE ADD BUTTON TO OPEN THE ADD EVENT WINDOW.

5.2. Add event

5.2.1. **Frequency and Duration:** These should be selected from the relevant dropdown boxes (disabled for "Take as directed" drugs). Do not use the frequency "mane", as it will cause a system error. All other dropdown boxes are usually left blank. The PRN box may be ticked if required (disabled for "Take as directed" drugs) and Quantity can also be specified if deemed necessary. All internal agents, given as a single dose per day, should be scheduled 'once' for 1 dose. Internal agents must be scheduled as a separate event for each day that treatment is to be administered, e.g. 'Once for 1 dose', 'bd for 1 day' etc. 5-FU pumps must be scheduled 'once' for '1 doses' on the stated start day. Filgrastim must be scheduled OD on day 1 for the specified duration - or 5 days, if not specified - irrespective of the actual start day (the start day is to be stated in the Admin tab).

5.2.2. **Days of Week:** Select appropriate day(s) of the week from the drop down list (Pick-up Internal drugs only). Once selected, an additional box will appear at the bottom of the screen to select the 'Starting on' day. Select Monday in all cases. This will then also appear in the 'Schedule Events' window. I

5.2.3. **Cyclical tick box:** If treatment will not be repeated every cycle, un-tick the Cyclical tick box and specify cycle number that treatment will be given on. For TTOs that are dispensed on cycle 1 then only if required, schedule as cyclical to enable these to be dispensed at any cycle, as required. Non-cyclical drugs can be added to more than one cycle by clicking on the "Add" button that appears at the bottom once the cyclical tick box is un-ticked. If any part of an agents scheduling will be non-cyclical then all the events for that agent will need to be non-cyclical

VALIDATOR: CLICK ON THE "LIST" BUTTON ON THE RIGHT AND CHECK THAT THE EVENT LIST IS DISPLAYING CORRECTLY. THIS LIST WILL SHOW YOU HOW EACH DRUG IS SCHEDULED FOR THIS REGIMEN. SELECTING "CYCLICAL" WILL BRING UP LIST OF ALL AGENTS THAT HAVE BEEN SCHEDULED CYCLICALLY. SELECTING "NON-CYCLICAL" WILL BRING UP LIST OF ALL AGENTS THAT HAVE BEEN SCHEDULED NON-CYCLICALLY. PRINT ALL LISTS AND ATTACH TO THIS DOCUMENT.

SELECT OK TO COMPLETE THE SCHEDULING FOR THE AGENT THEN REPEAT POINT 5 AS NECESSARY UNTIL ALL REQUIRED AGENTS HAVE BEEN SCHEDULED THEN SELECT CLOSE TO RETURN TO THE PLAN AGENDA

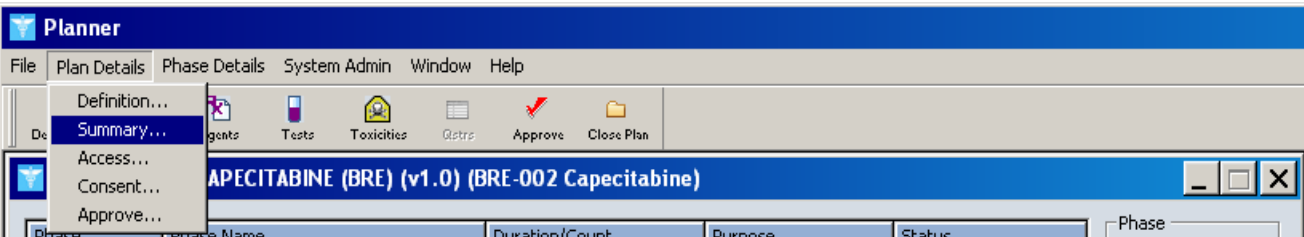
6. **TESTS: THIS WILL BE LEFT BLANK.**

7. **TOXICITIES: THIS WILL BE LEFT BLANK.**

8. **TREATMENT MANAGEMENT RULES (SUPPORT REGIMENS ONLY): THIS WILL BE LEFT BLANK**

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SELECT PLAN DETAILS THEN SUMMARY

9.	PLAN SUMMARY WINDOW:
	<p>Enter a plan summary to include the following: Regimen name and indication, treatment drugs, doses, routes and days, treatment intent, cycle length and course duration, signpost to full protocol, references (including change control). but will be accessible on the KMCC website or in the SPC and the reference should be stated here, e.g. "Refer to KMCC website for dose reduction guidelines".</p> 
10.	PLAN ACCESS WINDOW: SELECT "PLAN DETAILS" THEN "ACCESS" FROM THE MENU AT THE TOP OF THE SCREEN. THIS WINDOW WILL ALLOW YOU TO SPECIFY WHO AND WHERE WILL HAVE ACCESS TO THE REGIMEN THAT YOU HAVE BUILT:
	<p>10.1. Institutions tab: Select only the "TEST LOCATION – OUTPATIENT" location. 10.2. Users tab: Leave all users un-ticked</p>
11.	APPROVE PLAN: SELECT APPROVE FROM THE TOOLBAR THEN THE ANALYSE BUTTON AT THE BOTTOM OF THE SCREEN TO CHECK FOR ANY ERRORS IN THE SET-UP. IF NO PROBLEMS ARE HIGHLIGHTED, CLICK ON THE APPROVE FOR TESTING BUTTON.

BUILDER: TEST YOUR REGIMEN IN MANAGER BY ORDERING FOR A TEST PATIENT

VALIDATING PHARMACIST: SET UP A TEST PATIENT FOR THE CONSULTANT& NURSE VALIDATIONS AND ADD NAME TO CHECKLIST.
 IF THE REGIMEN BEING VALIDATED IS A SUPPORT REGIMEN THAT WILL BE USED IN COMBINATION WITH A CHEMO REGIMEN, AN APPROPRIATE APPROVED REGIMEN WILL NEED TO BE PRESCRIBED. FIRSTLY, ENABLE ACCESS TO THE CHEMO REGIMEN IN THE TEST LOCATION. CLICK ONCE ON THE REGIMEN ON THE OPEN PLAN WINDOW THEN SELECT 'ACCESS' AND TICK 'TEST LOCATION – OUTPATIENTS'.
 IN MANAGER, PRESCRIBE THE CHEMO REGIMEN FOR THE TEST PATIENT, SPECIFYING DR MD VARIAN AS THE PRESCRIBER AND LEAVE THE ORDER PENDING

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PHARMACIST VALIDATION	
ARIA MANAGER	
LOG INTO ARIA MANAGER AT “TEST LOCATION - OUTPATIENT” AND CREATE A TEST PATIENT (SEE <i>KMCCEP012 ARIA TEST PATIENT SET UP GUIDE</i>). ENTER VITAL SIGNS FOR THE LARGE PATIENT THEN OPEN THE MEDICATIONS WINDOW	
<p>a) FOR CHEMOTHERAPY REGIMENS: SELECT THE RELEVANT CANCER DISEASE SITE FOR THE REGIMEN THAT YOU WILL BE TESTING AND HIGHLIGHT THE REGIMEN. CONTINUE TO POINT 12.</p> <p>b) FOR SUPPORT REGIMENS USED IN COMBINATION WITH A CHEMOTHERAPY REGIMEN, SELECT THE SAME CHEMOTHERAPY REGIMEN AS SET UP FOR THE CONSULTANT FROM THE RELEVANT DISEASE SITE FOLDER AND ORDER, THEN FOLLOW POINT c) BELOW. THE FOLLOWING TESTS NEED ONLY BE PERFORMED ON THE SUPPORT REGIMEN DRUGS</p> <p>c) FOR SUPPORT REGIMENS USED AS A STAND-ALONE TREATMENT, GO TO ORDERS/RX TAB THEN SELECT ‘NEW’ BUTTON. FROM THE NEW PRESCRIPTION WINDOW COMPLETE THE “ORDERED BY” FIELD BY SELECTING DR. MD VARIAN THEN SELECT THE FAVORITES BUTTON, SELECT “SUPPORT” THEN CLICK ONCE ON THE REQUIRED PLAN. GO TO POINT 13.</p>	
12.	<p>CHEMOTHERAPY REGIMENS – START TREATMENT TAB</p> <p>12.1. Check that the regimen appears in the correct folder(s) in Manager based on the indication specified in the treatment protocol, e.g. lung → NSCLC etc.</p> <p>12.2. Next to the drop down menu bar check that the cycle length is correct.</p> <p>12.3. Check that the standard number of cycles is correct</p>
13.	<p>SUPPORT REGIMENS – FAVORITE AGENTS SELECTION</p> <p>13.1. Check that the support regimen appears in the correct folder</p> <p>13.2. Next to the support regimen name, check that the cycle length is correct</p> <p>13.3. Check that the standard number of cycles is correct</p>
ORDER YOUR REGIMEN FOR THE TEST PATIENT. IF CYCLE 1 CONTAINS MULTIPLE TREATMENT DAYS, ALL DAYS SHOULD BE ORDERED If there are no calculated doses (flat dose only) with NO permitted dose reductions, omit test 16	
14.	<p>DOSE CALCULATION MANAGEMENT WINDOW</p> <p>14.1. For regimens with calculated doses, check that the BSA is capped in the Dose Calculation Management window. This window should automatically open when you first order the regimen. If it does not, then click on the icon in the top right-hand corner.</p> <p>14.2. Uncap the BSA by selecting ‘Use Actual’</p>
FOR EACH OF THE INDIVIDUAL AGENTS IN THE REGIMEN, CHECK THE FOLLOWING: (NB: If a support regimen is prescribed in combination with an approved chemotherapy regimen, only the agents in the support regimen should be checked)	
15.	<p>REVIEW PRESCRIPTION DETAILS TAB</p>

<p>15.1. Are all the agents still in the correct administration sequence as shown in Planner? For regimens with more than one scheduled treatment day, all 'Internal' agents are listed first, followed by all 'Pickup - Internal' agents.</p> <p>15.2. Are all the agents correct in terms of routes of administration, diluents, infusion volumes and durations?</p> <p>15.3. For each agent click on the Administration Instructions box and check that the administration instructions are correct</p> <p>15.4. Are all the doses that have been calculated by the system based on either BSA/weight/CrCl etc. correct and match what is specified in the regimen and set up in Planner.</p> <p>15.5. If any of the drugs are dose banded or rounded, check that the dose is as expected". The dose banding table can be viewed by clicking on the icon.</p>	
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TAKE A SCREENSHOT OF THE REGIMEN AT 100% dose and actual BSA

CLICK ON THE ICON IN THE TOP RIGHT-HAND CORNER AND SELECT 'USE CAP' TO APPLY TO 2M² DOSE CAP

HIGHLIGHT AN AGENT AND CLICK ON THE 'ADJUST DOSE' BUTTON. REDUCE DOSES TO 10% ON ALL CALCULATED DOSES, IF APPLICABLE. NOTE: EACH DRUG MUST BE DOSE-REDUCED INDIVIDUALLY (DO NOT USE THE 'CHANGE CHEMO' OR 'CHANGE ALL' BUTTONS). IF THE REGIMEN CONSISTS OF FLAT DOSE(S) WITH INCREMENTAL DOSE REDUCTIONS, ENTER THE REDUCED DOSE IN THE 'ADMIN' FIELD).

16. ADJUST DOSE WINDOW


- 16.1.** If an agent appears more than once in the regimen (e.g. for days 1 & 8), does a message appear to ask if you would like the dose reduction applied to all orders? This message should appear if the agent is identical for all occurrences in a cycle. If the warning does not appear, is it because the agent varies for different days/times and is this justified? For fixed dose oral drugs with multiple daily doses (e.g. sorafenib) ensure that specified incremental dose reduction(s) can be applied. (This message box will not appear for agents of differing route/formulation (e.g. etoposide IV and oral).)
- 16.2.** Are all calculated doses correct and rounded/banded/capped, as applicable?
- 16.3.** For flat dose regimens, the reduced dose should not be rounded or banded and must be correct based on the available formulations.

TAKE A SCREENSHOT OF THE ADJUST DOSE WINDOW WITH THE REDUCED DOSES THEN SELECT CANCEL TO EXIT WINDOW WITHOUT SAVING DOSE REDUCTIONS

APPROVE THE PRESCRIPTION BY CLICKING ON THE 'APPROVE ALL' BUTTON AT THE BOTTOM OF THE SCREEN (THE BLANK DROPDOWN BOXES AT THE TOP OF THE WINDOW NEED TO BE POPULATED FIRST. USE DR MD VARIAN FOR 'ORDERED BY'). CHECK EACH WINDOW THAT POPS UP DURING THE PRESCRIPTION APPROVAL STAGE.

17. APPROVAL POP-UP WINDOWS

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	<p>17.1. First databank interaction screening window Check that the Summary tab in the window lists all agents built into the regimen. Any agents excluded from the screening process will have the symbol ✖ next to their name. This is expected for NB notes, but if any drugs have the symbol next to their name, please document on <i>KMCCEP016 ARIA adult regimen validation and sign-off</i>. Note: It is not necessary to check the clinical accuracy of the screening information. Click on the Accept button once you have checked the Summary tab.</p> <p>17.2. Prescription Approval/Printing window appears, check that all of the information is correct then click the Approve button.</p>
<p>PHARMACY APPROVE THE ORDER BY CLICKING ON THE 'APPROVE' BUTTON ON THE RIGHT, TICKING THE BOX FOR THE APPROPRIATE ORDER, THEN CLICKING APPROVE AGAIN.</p>	
<p>CLICK ON THE 'DISPENSE' BUTTON ON THE RIGHT HAND SIDE OF THE SCREEN IN THE ORDERS/RX TAB.</p>	
18.	PRESCRIPTION DISPENSING WINDOW
	<p>18.1. Check all the information in the Prescription Dispensing window is correct.</p> <p>18.2. All agents are listed.</p> <p>18.3. Are all agents marked correctly as Internal or Pickup - Internal?</p> <p>18.4. Are all agents to be dispensed in Aseptics correctly marked to indicate this?</p>
<p>CLICK ON THE BLUE  ICON IN THE TOP LEFT-HAND CORNER OF THE DISPENSING WINDOW TO HIGHLIGHT ALL DRUGS, THEN CLICK ON THE 'DISPENSE' BUTTON AT THE BOTTOM OF THE WINDOW, AND THEN CLICK ON 'APPROVE'.</p>	
<p>CLOSE THE DISPENSING WINDOWS AND RETURN TO ORDERS/RX. HIGHLIGHT THE APPROPRIATE ORDER THEN SELECT THE PRINTER SYMBOL.. TICK TO PRINT INTERNAL, PICK-UP INTERNAL (AS APPROPRIATE) AND PRINT ADMINISTRATION INSTRUCTIONS. CHECK THE PRINT OUTS, SIGN, DATE AND SUBMIT WITH OTHER VALIATION PAPERWORK</p>	
<p>CLOSE THE DISPENSING WINDOW THEN CLICK ON THE 'DRUG ADMIN' BUTTON ON THE TOOLBAR TO ACCESS THE NURSING SCREEN. IF THE REGIMEN INCLUDES INTERNAL AGENTS THEN CLICK ON THE DAILY ADMINISTRATION TAB AND CONTINUE TO POINT 19 IF THE REGIMEN CONTAINS ONLY PICK-UP INTERNAL AGENTS CLICK ON THE OTHER ADMINISTRATION TAB AND GO TO POINT 20</p>	
19.	DAILY ADMINISTRATION TAB
	<p>19.1. Are all the Internal agents listed in the correct sequence for administration?</p> <p>19.2. If the regimen includes Internal agents being given on different days in the cycle check that the drug is listed under each appropriate date in the Admin Date box.</p>
20.	OTHER ADMINISTRATION TAB
	<p>Are all the Pick-up Internal agents listed? (they will be in alphabetical order per treatment day)</p>
<p>IF THE REGIMEN CONSISTS OF CYCLES SET UP DIFFERENTLY (E.G. FEC-T), EACH DIFFERENT CYCLE MUST BE TESTED BY REPEATING SECTIONS 14 ONWARDS</p>	
<p>COMPLETE <i>KMCCEP016 ARIA adult regimen validation and sign-off</i> AND RETURN TO SYSTEM ADMINISTRATOR</p>	

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ARIA CHECKLIST: CONSULTANT VALIDATION - CHEMOTHERAPY REGIMENS

Regimen name		Regimen version		Regimen Date	
Test Patient name		Cycles to be ordered			
References used					

LOG IN TO ARIA MANAGER AT "[TEST LOCATION - OUTPATIENT](#)" AND OPEN THE RECORD OF THE TESTPATIENT STATED ABOVE THEN GO TO THE "Rx" ICON

ACTION	✓ or X
a) Does the regimen appear in the correct folder(s)?	
b) Next to the drop down menu bar check that the cycle length is correct?	
c) Is the standard number of cycles correct?	
d) Do all treatment days appear and are the appropriate drugs listed for each day?	
e) Click on the Information text box  on the right-hand side to open up the Plan Summary window. Check that all of the information is correct and matches the treatment protocol. This should include: Regimen name and indication, Treatment drugs, doses, routes and days, Treatment intent, Cycle length and course duration, References (including change control), Signpost to full protocol	
ORDER YOUR REGIMEN FOR TEST PATIENT, THEN CHECK THE FOLLOWING	
f) For each drug, are the following details correct, where applicable? Form, Administration route, Frequency, Diluent type and volume, Infusion duration	
g) Are all doses, flat and calculated, correct according to the protocol?	
h) If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions 	
TAKE A SCREENSHOT OF THE REGIMEN AT 100% AND SAVE IN A WORD DOCUMENT	
HIGHLIGHT AN AGENT AND CLICK ON THE ADJUST DOSE BUTTON. APPLY A DOSE REDUCTION TO ALL <u>SACT</u> DRUGS. EACH DRUG MUST BE DOSE-REDUCED INDIVIDUALLY (<u>DO NOT</u> USE THE 'CHANGE CHEMO' OR 'CHANGE ALL' BUTTONS).	
i) Have the dose reductions been calculated and capped/banded/rounded appropriately?	
TAKE A SCREENSHOT OF THE REGIMEN AT THE REDUCED DOSE AND SAVE IN A WORD DOCUMENT	
COMPLETE THE 'ORDERED BY', 'START ON' (ENTER TODAY'S DATE), 'LINE OF TX', 'TX INTENT' AND 'TX USE' FIELDS, THEN CLICK 'APPROVE ALL' BUTTON TO APPROVE THE TREATMENT CYCLE.	
j) In the 'Treatment' tab, does all the information appear as ordered, for cycle 1?	
k) If the regimen consists of multiple treatment days are these scheduled at the correct intervals?	
l) Has the dose reduction been carried forward correctly to all unordered cycles?	
IF THE REGIMEN CONSISTS OF SEVERAL CYCLES SET UP DIFFERENTLY (E.G. FEC-T), EACH DIFFERENT CYCLE MUST BE TESTED BY ORDERING EACH CYCLE AND REPEATING SECTIONS 3-5.	
ERRORS/COMMENTS	

I confirm that the regimen has passed all required tests			
Validation Completed by		Signed	
Designation		Date	


ARIA CHECKLIST: CONSULTANT VALIDATION – SUPPORT REGIMENS

Regimen name		Regimen version		Regimen Date	
Test Patient name		Cycles to be ordered			
References used					

LOG IN TO ARIA MANAGER AT “TEST LOCATION - OUTPATIENT” AND OPEN THE RECORD OF THE TESTPATIENT STATED ABOVE THEN GO TO THE “Rx” ICON

FOR SUPPORT REGIMENS THAT WILL BE PRESCRIBED WITH A CHEMO REGIMEN, SELECT THE ORDERS/RX TAB, HIGHLIGHT THE PENDING ORDER AND SELECT MODIFY

FOR SUPPORT REGIMENS THAT WILL BE PRESCRIBED ALONE SELECT THE ORDERS/RX TAB THEN ‘NEW’ BUTTON FROM THE NEW PRESCRIPTION WINDOW COMPLETE THE “ORDERED BY” FIELD BY SELECTING DR. MD VARIAN

ACTION	✓ or X
SELECT THE FAVORITES BUTTON, SELECT “SUPPORT” THEN CLICK ONCE ON THE REQUIRED PLAN	
a) Does the support regimen appear in the correct folder(s)?	
b) Next to the support regimen name, check that the cycle length is correct?	
c) Is the standard number of cycles correct?	
ORDER YOUR REGIMEN FOR TEST PATIENT, THEN CHECK THE FOLLOWING	
d) For each drug, are the following details correct, where applicable? Form, Administration route, Frequency, Diluent type and volume, Infusion duration	
f) Are all doses, flat and calculated, correct according to the protocol?	
g) If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions 	
TAKE A SCREENSHOT OF THE REGIMEN AT 100% AND SAVE IN A WORD DOCUMENT	
HIGHLIGHT AN AGENT AND CLICK ON THE ADJUST DOSE BUTTON. APPLY A DOSE REDUCTION TO ALL SACT DRUGS. EACH DRUG MUST BE DOSE-REDUCED INDIVIDUALLY (DO NOT USE THE ‘CHANGE CHEMO’ OR ‘CHANGE ALL’ BUTTONS).	
h) Have the dose reductions been calculated correctly, within 5% of the full ‘Admin’ dose, in each case? Please specify any errors or capped doses in the comments section.	
i) Have the dose reductions been calculated and capped/banded/rounded appropriately?	
TAKE A SCREENSHOT OF THE REGIMEN AT THE REDUCED DOSE AND SAVE IN A WORD DOCUMENT	
COMPLETE THE ‘ORDERED BY’, ‘START ON’ (ENTER TODAY’S DATE), ‘LINE OF TX’, ‘TX INTENT’ AND ‘TX USE’ FIELDS, THEN CLICK ‘APPROVE ALL’ BUTTON TO APPROVE THE TREATMENT CYCLE.	
j) In the ‘Treatment’ tab, does all the information appear as ordered, for cycle 1?	
k) If the regimen consists of multiple treatment days are these scheduled at the correct intervals?	
l) Has the dose reduction been carried forward correctly to all unordered cycles?	
m) Click on the green pen on the left of the screen next to the support regimen name and select ‘Show Summary’. Check that all of the information is correct and matches the treatment protocol. This should include: Regimen name and indication, Treatment drugs, doses, routes and days, Treatment intent, Cycle length and course duration, References (including change control), Signpost to full protocol	
IF THE REGIMEN CONSISTS OF CYCLES SET UP DIFFERENTLY (E.G. FEC-T), EACH DIFFERENT CYCLE MUST BE TESTED BY ORDERING EACH CYCLE AND REPEATING SECTIONS 3-5.	
ERRORS/COMMENTS	

I confirm that the regimen has passed all required tests


Validation Completed by		Signed	
Designation		Date	

ARIA CHECKLIST: NURSE VALIDATION

Regimen name		Regimen version		Regimen Date	
Test Patient name		Cycles to be administered			
References used					

LOG IN TO ARIA MANAGER AT “[TEST LOCATION - OUTPATIENT](#)” AND OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN GO TO THE MEDICATIONS WINDOW BY CLICKING ON THE “Rx” ICON

NOTE: IF YOU ARE VALIDATING A SUPPORT REGIMEN THAT HAS BEEN ORDERED WITH A CHEMOTHERAPY REGIMEN, THE VALIDATION CHECKS ONLY NEED TO BE COMPLETED ON THE SUPPORT REGIMEN AGENTS

ACTION		✓ or X
TAKE A SCREENSHOT OF THE ORDERS/RX TAB SHOWING THE REGIMEN THAT WILL BE VALIDATED		
OPEN THE DRUG ADMINISTRATION WINDOW AND COMPLETE THE FOLLOWING CHECKS AS APPROPRIATE		
DAILY ADMINISTRATION TAB		
a) Are all the drugs listed in the correct sequence for administration?		
b) For each drug, are the following details correct, where applicable? Form, Administration route, Frequency, Diluent type and volume, Infusion duration		
c) Are all doses, flat and calculated, correct according to the protocol?		
d) If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions 		
OTHER ADMINISTRATION TAB		
e) Are all the Pick-up Internal (TTO) drugs listed here? (drugs will appear in alphabetical order)		
f) Check that all drugs have the correct dose, form, route of administration, frequency, infusion rate, diluent information, and administration instructions (where applicable). If there is a stated maximum dose for a drug on the protocol, ensure this is also stated in the admin instructions		
g) If the regimen includes some Pickup - Internal agents being given on different days, e.g. Vinorelbine oral given on Day 1 and Day 8, check that all days of treatment are listed and that the information is correct, and the drug is being administered on the correct day(s).		
TAKE A SCREENSHOT OF THE “DAILY ADMINISTRATION” WINDOW AND THE “OTHER ADMINISTRATION” WINDOW IF DRUGS ARE PRESENT IN BOTH WINDOWS. REPEAT PROCESS FOR ALL DAYS OF THE REGIMEN (IF APPLICABLE).		
IN THE “DAILY ADMINISTRATION” AND “OTHER ADMINISTRATION” WINDOWS RECORD EACH AGENT AS ADMINISTERED BY SELECTING EACH AGENT, CLICKING ON THE “RECORD” BUTTON, ENTERING AN ADMINISTRATION TIME AND CLICKING ON THE “APPROVE” BUTTON.		
MEDICATION HX TAB		
h) Are all of the administered drugs listed in the appropriate sections, i.e. all anti-cancer drugs listed under ‘Active Chemotherapy Agents’ and all other supportive drugs and warning notes listed under ‘Active Non-Chemotherapy Agents’? NB: For support regimens, all agents become ‘Inactive Agents’ immediately after administration		
ERRORS/COMMENTS		

I confirm that the regimen has passed all required tests

Validation Completed by		Signed	
Designation		Date	