BUILDING & VALIDATING ARIA SACT AND SUPPORT REGIMENS

OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when building and validating adult and paediatric SACT regimens (referred to as SACT 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 the creation and updating of all adult and paediatric SACT and support regimens including clinical trials

RESPONSIBILITIES

- Requests for new regimens and regimen amendments should be made by or via the relevant NOG or HOG, or following an update to a K&M SACT protocol.
- The ARIA system administrator is responsible for allocating and overseeing the building and validation of all regimens in ARIA and storing all associated documents.
- Regimen building must only be undertaken by a technician or pharmacist who was received and completed the necessary ARIA training
- Regimen validations must only be undertaken by staff who have received and completed the necessary ARIA training and who have not built the regimen.

PROCESS

1. PLAN THE BUILD

1.1. Decide how to build the regimen from the following options. If you are unsure which option to choose, refer to the system administrator for guidance.

1.1.1. Build a new regimen from scratch: Select “New” button to open up the “New Plan” window.

1.1.2. Amend a regimen: An existing regimen should be updated using the Amend button wherever possible however, if the Amendments Mandatory tick box is selected on the current live regimen then DO NOT AMEND the regimen. Instead, click the “Copy” button and untick the Amendments Mandatory option, before proceeding with the changes.

1.1.3. 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.

1.2. Decide if the regimen will be built and validated under a full validation or a minor validation as outlined below. If you are unsure which option to choose, refer to the system administrator for guidance.

1.2.1. FULL VALIDATION: A full validation must be performed on all regimens built from scratch and on regimens created by copying or amending a live regimen that have had changes made to the SACT drug(s)

1.2.2. MINOR AMENDMENT VALIDATION: A minor amendment validation can be performed on regimen updates or regimens copied from a current live regimen where the changes fall within the steps listed in checklist 8 Where required changes fall outside these steps, a full validation must be performed

1.3. Decide if the regimen should be built as a SACT or support regimen. Regimens that contain SACT drugs should be built as SACT regimens and those that don’t contain SACT drugs should be built as support regimens. Exceptions to this are when a SACT regimen will be used for substitution into another SACT regimen. In this case, the new regimen which will be used as a substitute will need to be built as a support regimen. Also, if the SACT regimen will be needed in addition to an existing SACT regimen for prescribing to patients with more than one cancer diagnosis then the new regimen will be built as a support regimen. If you are unsure which option to choose, contact the KMCC system administrator

1.4. Ensure all the drugs you require are present in the ARIA formulary. If they are not, request them on form *KMCCEP013 Request to add a drug to the ARIA formulary* from KMCC system administrator

2. BUILD THE REGIMEN

2.1. **Full validations** Build the regimen following the Method detailed in table 1

2.2. **Minor amendment validations**

2.2.1. Each permitted change is listed on checklist 8. The application is listed first (A. in example), followed by the window and tab name (B. in example) with a reference to the corresponding section of the building and validating ARIA regimens SOP (C. in example) which details the changes that can be made.

2.2.2. If the required changes fall in to the stated sections of checklist 8 then this SOP may be followed. If any of the required changes are not listed in checklist 8 then a full validation will need to be performed instead.

2.2.3. Each change made should be detailed on checklist 8 (D. in example) by the builder and the section ticked (E. in example) to indicate this. If a change has not been made on a listed section, leave this blank.

TABLE 1

Build SOP ref	DESCRIPTION OF CHANGE (state details of change made in the box)	Tick if changed
A. PLANNER CHECKS		
B. DEFINITION (MODIFY PLAN)		
1.1.1	**C.** Amendment to the plan name (only for copied regimens) **D.** Changed to BRE-101	**E.** ✔

2.2.4. Once all changes have been applied the builder should complete and sign the first part of checklist 8

3. VALIDATE THE REGIMEN

3.1. Full validations – K&M SACT and support regimens

3.1.1. **Pharmacist Planner check:** The pharmacist can now check the regimen build in Planner following the method detailed in table 1 below. Any amendments required should be sent to the builder for correction. Once complete, inform the KMCC administrator who will facilitate the super-user validation

3.1.2. **Second validator check:** The second validator check checks the regimen details, prescribing functions and drug administration as specified in checklist 2 for SACT regimens or checklist 3 for support regimens. The second validator will need to use a specific test patient for validation, as assigned by the KMCC administrator. Any amendments required should be sent to the builder for correction. Once complete, return the completed and signed validation checklist to the KMCC administrator who will facilitate the pharmacist Manager check

3.1.3. **Pharmacist Manager check:** The second part of the validation checks the regimen build in Manager following the method outlined in table 2 below. Once completed, return the completed and signed validation checklist and associated documents to the KMCC administrator who will inform the KMCC system administrator of validation completion

3.2. Full validations – Clinical trials, paediatrics and non-K&M SACT and support regimens

3.2.1. **Pharmacist Planner check:** The pharmacist can now check the regimen build in Planner following the method detailed in table 1. Any amendments required should be sent to the builder for correction. Once complete, inform the KMCC administrator who will facilitate the consultant and nurse validations

3.2.2. **Consultant check:** The consultant validation must be performed by a consultant specialising in the tumour site that the regimen treats. This validation checks the regimen details and prescribing functions, as specified in checklist 4 for SACT regimens or checklist 5 for support regimens. Consultants will need to use a specific test patient for validation, as assigned by the KMCC administrator. Any amendments required should be sent to the builder for correction. Once complete, return the completed and signed validation checklist to the KMCC administrator who will facilitate the nurse validation

3.2.3. **Nurse check (This step is not performed for clinical trial regimens):** The nurse validation must be performed by a specialist SACT or oncology nurse. The validation checks the regimen for any nursing/administration-related issues, as specified in checklist 6. Nurses will use the same test patient as the validating consultant. Any amendments required should be sent to the builder for correction. Once complete, return the completed and signed validation checklist to the KMCC administrator who will facilitate the pharmacist Manager check.

3.2.4. **Pharmacist Manager check:** The second part of the validation checks the regimen build in Manager following the method outlined in table 2. Once completed, return the completed and signed validation on table 3 and associated documents to the KMCC administrator who will inform the KMCC system administrator of validation completion

3.2.5. **For clinical trial builds:** Validations will be completed by the clinical trial pharmacist or specialist pharmacist who is overseeing the setup of the study. This is immediately followed by a validation by Principal Investigator (consultant leading on the study). There is no validation carried out by a nurse for clinical trial builds. Checks must be performed in the same way as for non-clinical trial builds with the nuances of the study being validated by a person well versed in the clinical trial protocol.

3.3. Minor amendment validations

3.3.1. The validating pharmacist will check the sections changed as indicated by the builder in checklist 8, in both Planner and Manager. When testing the amendments in Manager, the test patient from the original validation should be used. The regimen can be discontinued and re-prescribed but orders from the previous regimen should never be amended, deleted or errored.

3.3.2. On Completion of regimen validation, the pharmacist should then sign checklist 8 and return to the system administrator

4. APPROVE THE REGIMEN FOR USE

4.1. The KMCC system administrator or KMCC administrator file all validation documents in document management system

4.2. The KMCC system administrator or, in their absence an appropriately trained pharmacist will make the regimen live for use on ARIA following checklist 7 for full validations or checklist 9 for minor validations.

LIMITATIONS

Inpatient haematology regimens which include complex hydration and/or drugs to be administered continuously across more than one calendar day cannot be built in ARIA. Such treatments should be available as a paper protocol for prescribing for individual patients. Refer to KMCC system administrator for guidance if needed. Ensure that the total duration of the Internal agents does not exceed 10 hours a day for day case regimen

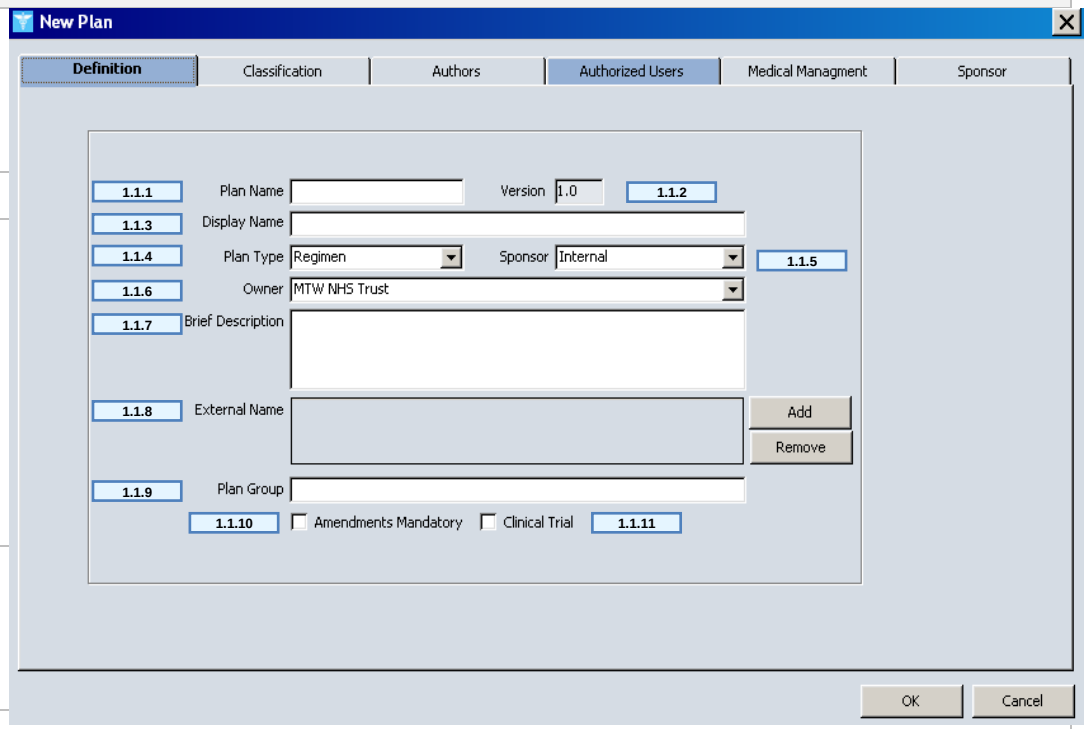
REFERENCE SOURCES

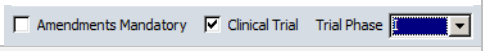
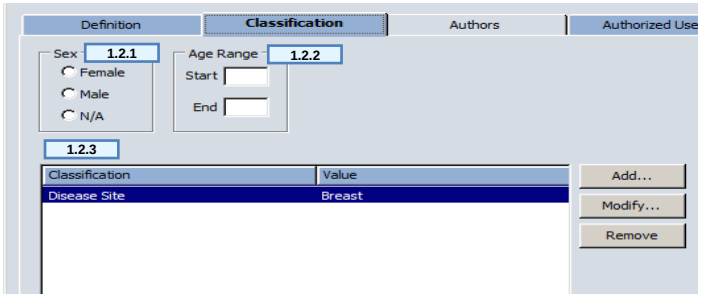
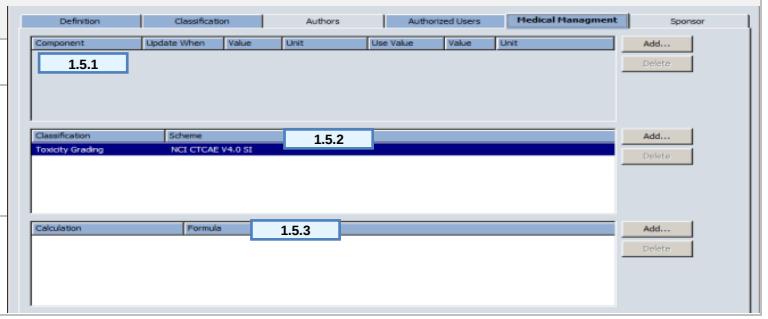
Ensure that you have access to the following, as you will require them during the regimen build & validation:

- K&M SACT protocol or other reference document for the regimen.
- KMCCEP006 ARIA regimen classification guide for adult regimens
- KMCCEP001 ARIA regimen building and validation process following protocol approval

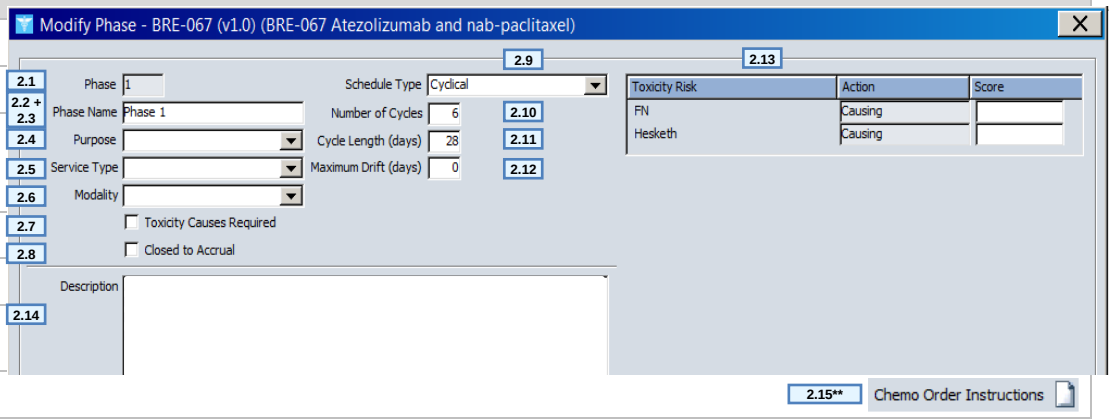
METHOD

TABLE 1: 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:** BEFORE COMMENCING VALIDATION, ENSURE YOU ARE IN RECEIPT OF A COMPLETED CHECKLIST 1, THEN DOUBLE CLICK ON THE REGIMEN YOU REQUIRE THEN SELECT 'DEFINITION' FROM THE TOOL BAR	
DO NOT COPY AND PASTE TEXT FROM WORD OR PDF DIRECTLY INTO ANY WINDOW IN ARIA AS THIS WILL CAUSE A SYSTEM ERROR. INSTEAD, COPY FROM WORD OR PDF INTO NOTEPAD THEN FROM NOTEPAD INTO ARIA. TABLES AND DIAGRAMS SHOULD NOT BE ENTERED INTO ARIA, INSTEAD REFERENCE SHOULD BE MADE TO WHERE THEY CAN BE VIEWED E.G. K&M 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. For Clinical Trials the plan name should be a short-hand identifier for the trial, regimen name and/or arm.
1.1.2.	**Version**: This is automatically created and updated by ARIA.
1.1.3.	**Display Name**: This is the regimen name that will be seen by system users in Manager and can contain a maximum of 80 characters. For network approved regimens, the full K&M SACT protocol name should be entered here as it is written on the protocol. For off-protocol/non-NOG/HOG approved, the display name will be assigned by the ARIA system administrator. For Clinical Trials the Display name must include the trial short title with word "Clinical Trial" as a suffix, the Arm name (if relevant) and regimen name e.g. ICON-9 clinical trial - Arm 1 – Olaparib + Cediranib Maintenance.
1.1.4.	**Plan Type**: Select "Regimen" if you are building a SACT regimen or "Symptom Mgmt" if you are building a support regimen. For Clinical Trials all builds will be 'Regimen' unless there is a specific need for a trial specific symptom management build. The need for this must be decided by the Principal Investigator and Clinical Trial Pharmacist.
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** (SACT regimens only): This box must be left unticked for all SACT regimens including clinical trials. 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**: Tick If building a Clinical Trial regimen; the phase of the trial should also be selected from the dropdown. 
1.2.	**Classification tab**
1.2.1.	**Sex**: Ensure "N/A" radio button is selected when building, this appears blank when validating
1.2.2.	**Age Range**: Leave all boxes blank.
1.2.3.	**Classification:** In the classification box, click on the "Add" button on the right then: • For SACT regimens – All regimens will need a disease site but not all wil require a cancer category. Refer to *KMCCEP006 Regimen classification specification – Disease site and cancer categories* document for instructions on which are required for your regimen. Select "Disease Site" from the Classification dropdown box then the relevant cancer disease site(s) from the Value dropdown box. 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. • For Clinical Trial regimens - The disease site should be selected as per the standard builds above. When selecting Cancer Categories for clinical trials, the 'Clinical Trials –…' category must be selected for the disease area the clinical trial is studying. e.g. a CT NSCLC lung cancer regimen would have the categories: Disease Site – Lung and Cancer Category – Clinical Trial NSCLC. 
1.3.	**Authors tab:** Leave blank.
1.4.	**Authorized Users tab:** This will contain the name of the regimen builder. Other authorised users must be added by clicking on the "Add" button on the right. The following users must be added: Caroline Waters, Hayley Paddock, Michelle Archer and Helen Downs, as well as the Varian access user Ks VMS. The validating pharmacists name should NOT appear in this tab at this stage. Contact the system administrator and ask to be removed from the list should your name be present before continuing
1.5.	**Medical Management tab (SACT regimens only)**
1.5.1.	**Component**: This should be left blank in all cases
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". For clinical trial regimens use the CTCAE version referred to in the protocol. If the protocol CTCAE version is not available on ARIA, the latest version of CTCAE on ARIA must be used.
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. Other formulas 

	may be required for clinical trial regimens where this has been previously agreed with PI in line with a clinical trial protocol.
1.6.	**Medical Management tab (support regimens): Leave blank.**
1.7.	**Sponsor tab:** Leave blank.
BUILDER: SELECT OK TO COMPLETE AND EXIT **VALIDATOR**: SELECT CANCEL TO LEAVE WINDOW CLICK ON 'GO TO' IN PLAN AGENDA SCREEN	
2.	**VIEW/MODIFY PHASE WINDOW**
2.1.	**Phase**: Automatically numbered as "1".
2.2.	**Phase Name (SACT regimens)**: Leave as "Phase 1".
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 regimen here. Maximum 20-character limit
2.4.	**Purpose**: Leave blank.
2.5.	**Service Type**: Leave blank
2.6.	**Modality**: Select "Radiation" for chemo-radiation regimens. Leave blank for all other regimens.
2.7.	**Toxicity Causes Required**: Leave this box unticked.
2.8.	**Closed to Accrual**: Leave this box unticked.
2.9.	**Schedule Type**: "Cyclical" should be selected for most SACT and support regimens that are repeated at regular intervals for a given number of cycles which, when prescribed, can be increased or decreased as necessary. "Linear" applies to treatment courses consisting of a single cycle that will not be repeated or amended. "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. "Linear" and "Linear – Neg. days" cannot be used on support regimens.
2.10.	**Number of Cycles**: Enter the number of cycles the regimen should contain as specified on the K&M SACT protocol. If the number of cycles isn't fixed, set up according to the list below: • Regimens for multiple indications with a differing range of cycles depending on indication, should be set up for the lowest number of cycles • Regimens which continue until disease progression should be set up for 12 months worth of cycles • Regimens which contain combination treatment cycles followed by single agent cycles until disease progression should be set up with the number of cycles stated on the protocol for the combined treatment, followed by 12 months worth of cycles of the single agent treatment.
2.11.	**Cycle Length (days)**: Specify the cycle length (in days) required for the regimen. ARIA cannot accommodate cycles with differing length in a single regimen so a different regimen will have to be built for each part which is of a different cycle length to the last. e.g. induction cycles of 28 days, consolidation cycles of 21 days and maintenance cycles of 28 days. 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 the cycle start doesn't fall on a weekend. In such cases, a note should be added to the Admin tab textbox (see 4.2) stating "DISPENSE 30 DAYS SUPPLY". For clinical trials refer to the clinical trial protocol for cycle length.
2.12.	**Maximum Drift (days)**: Leave as "0" days.



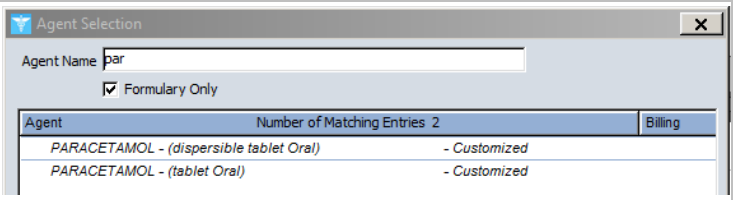
2.13.	**Toxicity Risk scores**: Leave blank
2.14.	**Description box**: Leave blank
2.15.	**Chemo Order Instructions**: Leave blank.

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

As detailed in the steps below, add NB Monitoring parameters as the first agent then add subsequent drugs as per the order of administration on the reference document, and their agent category, without regard for the day they are due as this will be set later in scheduling. Add all pre-meds first, then all treatment drugs, then all TTO drugs. When adding the agents, bear in mind that the lower the number, the higher the place the drug will appear when prescribed so a drug in position 2 will appear for administration before the drug in position 3 if they are scheduled on the same day.

3.1. **Agent Selection** Leave the "Formulary Only" box ticked and then type in the first 3 letters of the agent name. "NB Monitoring parameters" should be the first agent on all regimens, as this will contain all as the essential prescribing and monitoring guidance. Select required agent from the list then click OK. This will take you to the Add Agent window. Additional NB Monitoring Parameters may be added if the combination of drugs changes e.g. When building a regimen containing 6 cycles of immunotherapy with chemotherapy followed by single agent immunotherapy cycles until disease progression, add the initial NB Monitoring Parameters with all monitoring information in for use with cycles 1-6 then add an additional NB Monitoring Parameters entry for cycle 7 onwards with guidance for the immunotherapy treatment only



When building a clinical trial regimen, the NB monitoring parameters should only specify the location of the local reference protocol for the regimen, it is not necessary to also enter the details into the ARIA agent.

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 Internal agent will be scheduled on more than one day in a cycle then this should be added as a single agent entry then scheduled on multiple days. If more than one 'Internal' drug is administered more than once in a day then a different drug entry per dose will be required to ensure that the correct administration sequence is given. In addition, if the dose of a drug changes within the regimen, a different agent entry will need to be added for each dose.

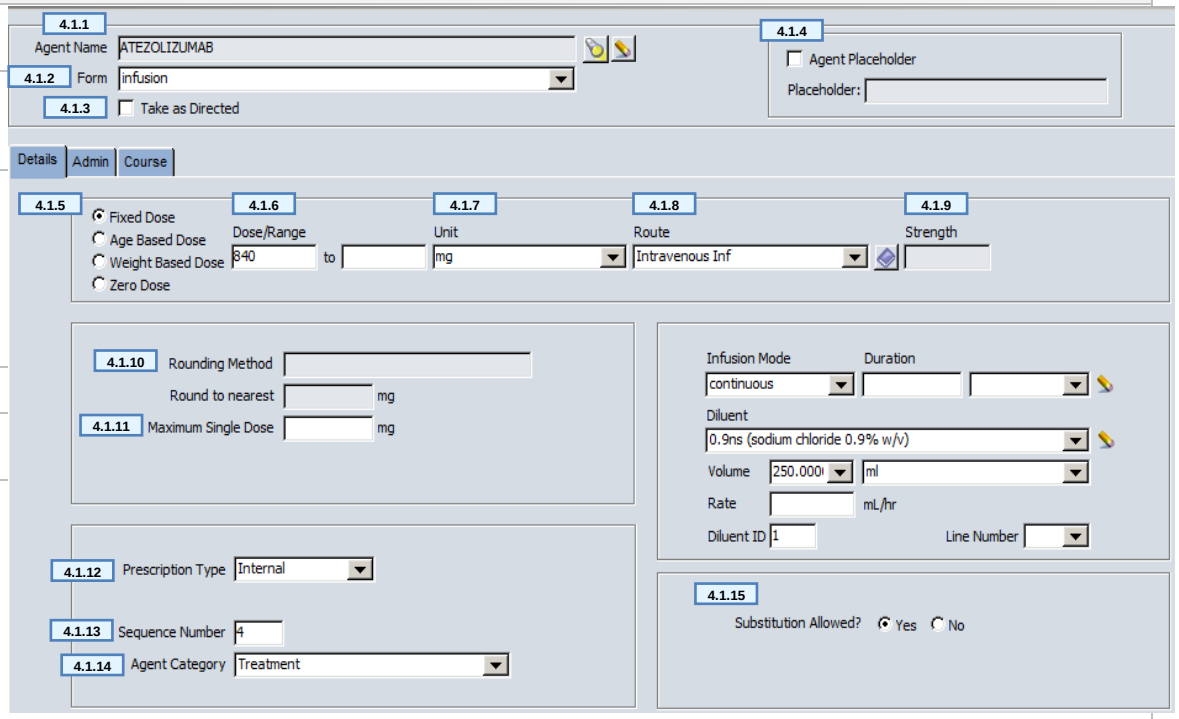
When adding agents for clinical trials, all Investigational Medicinal Products (IMP) supplied or reimbursed by the sponsor must include the suffix (Trial). e.g. Lenalidomide (Trial). If the required agent is a novel drug not on the formulary or is on the formulary and does not have the suffix (Trial) then a *KMCCEP013 Request to add a drug to the ARIA formulary* form must be completed and sent to the KMCC e-prescribing team for adding to the system. For all non-IMPs or standard of care stock, the standard agent file should be used. Agents should be added multiple times to a regimen when different strengths/ doses are required; to enable each strength or dose be scheduled at the right times within the regimen.

NB notes: An NB Reminder note should be added for all protocol instructions that are not attached to an agent, see screenshot below as an example of the protocol layout and how it is then built in ARIA. The only NB notes in use are NB Monitoring parameters (see above for guidance on required information) and NB Reminder for all other information e.g. pre-and post treatment line flushes, details of observation period between treatment drugs.

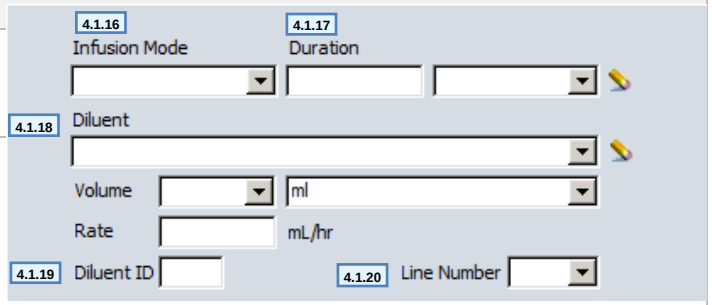
Paracetamol	1g	PO	stat	Given at least 30 minutes before the obinutuzumab infusion.
Chlorphenamine	4mg	PO	stat	
Ensure adequate hydration is given 12-24 hours prior to starting obinutuzumab infusion to patients with lymphocyte counts > 25 x 10^9/L to reduce the risk of TLS.				
OBINUTUZUMAB	1000mg	IV inf	See below	In 250ml Sodium Chloride 0.9%. Flush line pre and post infusion with Sodium Chloride 0.9%

PARACETAMOL 1,000 mg tablet Oral
CHLORPHENAMINE 4 mg tablet Oral
NB Reminder 1 unknown Not Assigned
OBINUTUZUMAB 1,000 mg infusion Intravenous Inf in sodium chloride 0.9% w/v 250 ml (2)

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 drug form will automatically be selected from the dropdown box, based on your previous selection from the formulary. This field should not be amended.
4.1.3	**Take as Directed**: This box should be left unticked whenever possible as ticking it disables the dose/range and unit boxes preventing doses from being automatically calculated. For drugs with varibale doses and/or frequency e.g. loperamide, this box will have to be ticked as such complex instructions cannot be accommodated in the predefined fields.
4.1.4	**Agent Placeholder**: Leave this box unticked.
4.1.5	**Dose type radio buttons:** Always leave the "Fixed Dose" radio button selected
4.1.6	**Dose/Range**: Enter the dose in the first Dose/Range box or for a range, enter a value in each box to show dose from and dose to. Capecitabine expressed on the reference protocol as a total daily dose divided into two administrations should be built as half the total daily dose then scheduled BD. 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. Filgrastim must be built as a 'Fixed dose' of 5mcg/kg. A dose banding table has been applied in Security to band the dose to 300mcg or 480mcg, as appropriate. Fluorouracil 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. NB notes (NB Monitoring parameters or NB Reminder) 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". Vincristine for adult patients 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). Vincristine for paediatric patients should be built as per reference protocol.
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**: This 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**: Leave the rounding boxes blank unless the protocol specifies a different rounding or banding schedule should be used, instead of the NHSE ones set up in Security. Dose banding tables should be added to all Cytarabine **Injection** entries where the standard dose is calculated. Cytarabine infusion entries are already banded at Security level. To



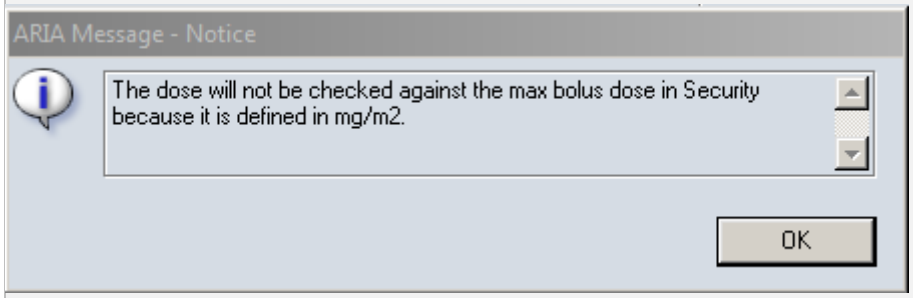
	add a different banding or rounding schedule, select "Dose Banded" from the Rounding Method dropdown box, then click on the red icon and click on the "Add" button to add each line of the dose banding table as required (see *KMCCEP029 Adding dose banding tables to ARIA*).
4.1.11.	**Maximum Single Dose**: A value should be entered here if specified on the protocol and if the agent is not a flat dose. For dose banded drugs, ensure the maximum dose corresponds to a dose band as per the entry in Security. If not, the equivalent dose band should be entered here, with a note added to the admin tab that the protocol maximum dose is NNmg, banded to NNmg on ARIA. Refer to KMCC system admin if unsure. Maximum single doses should not be entered for drugs marked as 'Take as directed'.
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" and 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.
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 only be entered once then scheduled for the appropriate days in Schedule Events window. 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. If building a clinical trial and adding multiple strengths of the same drug to facilitate titration these should be added consecutively in the relevant sequence in order to ensure they appear on ARIA correctly when scheduled.
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 an NB note, select "Not Applicable".
4.1.15.	**Substitution Allowed?**: Leave the Yes radio button selected.
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.	
4.1.16.	**Infusion Mode**: Selected from the dropdown box: "continuous" should be selected for infusions and "bolus" selected for bolus injections. If the infusion mode is not clearly specified on SACT protocol, use "bolus" for durations of less than 10 minutes and "continuous" for durations of 10 minutes or greater.
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 protocol 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 4.2). For Fluorouracil pumps, 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.
4.1.18.	**Diluent and Volume**: These should be selected from the dropdown boxes if required. If the SACT protocol 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 4.2). The Rate field is automatically calculated if both the duration and volume fields have been populated.
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.
4.1.20.	**Line Number**: This box should be left blank unless the protocol 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.
4.2.	**Admin tab:** Any additional administration instructions that are included on the protocol but are not specified in the Details tab of the agent entry or in the agent scheduling should be entered here.
4.2.1.	• DO NOT DUPLICATE AGENT OR SCHEDULING INFORMATION HERE that will be stated in the details and/or scheduling windows • For drugs marked as 'Take as directed' full details of dose, frequency, duration and additional notes should be entered



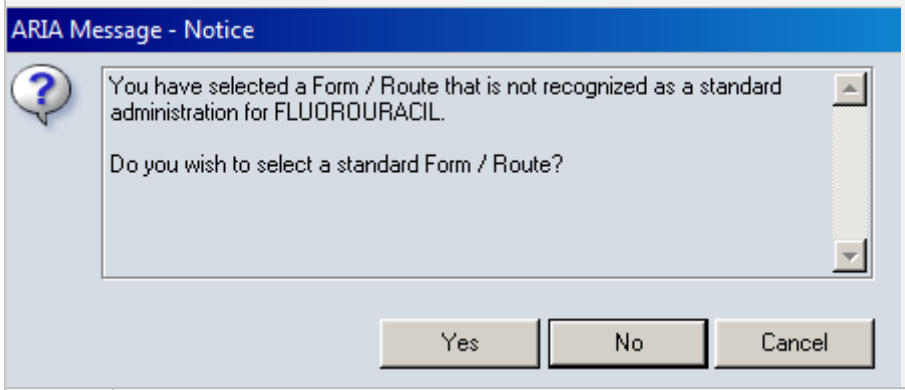
- For oral SACT drugs with treatment days followed by a rest period within a single cycle, this should be stated in the admin tab as 'Regimen standard schedule……'
- For ALL vinca alkaloids the following must be stated: "FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY ANY OTHER ROUTE."
- For Pick-Up Internal drugs which start on a day other than day 1, enter the actual start day in the admin instructions.
- Administration times for drugs on an in-patient regimen should be entered here if stated on the protocol, e.g. T=0.
- Do not enter any information in tabular form.
- If a maximum dose has been entered in the agent details, this must also be stated in the admin instructions.
- The protocol standard vincristine 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 a line is entered for staff to enter the brand supplied
- For Pick-Up Internal drugs which on the protocol state 'Dispense on cycle 1 then only if required', this statement must be added to the admin tab
- For clinical trials, specific details as per protocol must be added for each study medication. In addition to this pharmacy details for dispensing should be added here as well if accountability logs or specific vial/kit/pack must be selected. e.g. Pharmacy: Select specific vial numbers and complete accountability log.

4.3. **Course tab:** Leave blank.

SELECT OK TO COMPLETE THE AGENT ENTRY THEN REPEAT POINT 4 AS NECESSARY UNTIL ALL REQUIRED AGENTS HAVE BEEN ADDED. ONCE COMPLETED SELECT CLOSE TO RETURN TO THE PLAN AGENDA UPON SELECTING OK, THE FOLLOWING MESSAGES MAY APPEAR



THIS WARNING INDICATES THAT THE DRUG ADDED HAS DOSE BANDING SET ON IT
SELECT OK IN ALL CASES

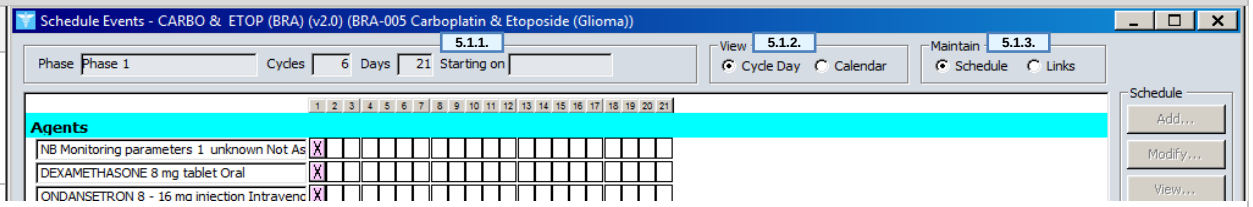


THIS WARNING INDICATES THAT THE ORIGINAL DRUG ENTRY HAS BEEN MODIFIED FOR LOCAL USE
SELECT NO IN ALL CASES

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

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

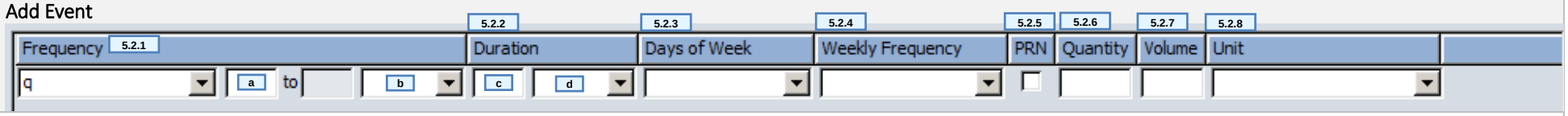
5.	SCHEDULE EVENTS
5.1.	Schedule Events Window
5.1.1.	**Starting On box**: The dropdown box should be left blank at this point. If specific days are selected in the scheduling agents window then the start day will be automatically entered here (see 5.2.3).
5.1.2.	**View box**: Cycle Day radio button should always be selected.
5.1.3.	**Maintain box**: Schedule radio button should always be selected.



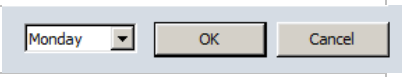
EACH AGENT NOW NEEDS TO BE SCHEDULED ON THE DAYS IT WILL BE GIVEN. CLICK ON THE RELEVANT TREATMENT DAY BOX ALONGSIDE THE FIRST AGENT AND THEN CLICK THE ADD BUTTON TO OPEN THE ADD EVENT WINDOW.

PICK-UP INTERNAL DRUGS THAT START ON A DAY OTHER THAN DAY 1 MUST BE SCHEDULED ON DAY 1 IRRESPECTIVE OF THE ACTUAL START DAY TO ENABLE THEM TO BE MARKED AS GIVEN TO THE PATIENT. THE ACTUAL START DAY MUST THEN BE STATED IN THE ADMIN TAB. ON CLINICAL TRIAL BUILDS, THE NB MONITORING PARAMETERS ENTRY MUST BE SCHEDULED FOR EACH DAY THE PATIENT WILL ATTEND SITE FOR ADMINISTRATION TO ENSURE TRIAL SPECIFIC CHECKS ARE DONE EACH TIME.

5.2.	Add Event



5.2.1.	**Frequency:** Select from drop down list. These boxes are disabled for drugs marked 'take as directed'. Do not use the frequency "mane", as it will cause a system error, instead use 'every am'. For doses using the frequency of 'q' for 'every', boxes a and b will also become available to enter a number and a interval type e.g. hours For Internal drugs given as a single dose per day, including fluorouracil pumps, select 'once'
5.2.2	**Duration:** Enter numerical duration value in box c and interval type in box d. For all Internal drugs given as a single dose per day, enter 1 in box c and doses in box d. Filgrastim must be scheduled on day 1 for the specified duration - or 5 days, if not specified – irrespective of the actual start day.
5.2.3	**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 to select the 'Starting on' day. Select Monday in all cases. This will then also appear in the 'Schedule Events' window.
5.2.4	**Weekly Frequency:** Select from drop-down list if required
5.2.5	**PRN:** Tick if drug is PRN, disabled for "Take as directed" drugs
5.2.6	**Quantity:** Leave blank
5.2.7	**Volume:** Leave blank
5.2.8	**Unit:** Leave blank



5.3	 **Cyclical tick box**: This box allows you to specify if the drug will be cyclical and given on the selected day on every cycle, or non-cyclical and given on the selected day on specified cycles only. Leave the cyclical box ticked for drugs that will be given on the selected day at every cycle. For Pick-Up Internal drugs that are dispensed on cycle 1 then only if required, schedule these

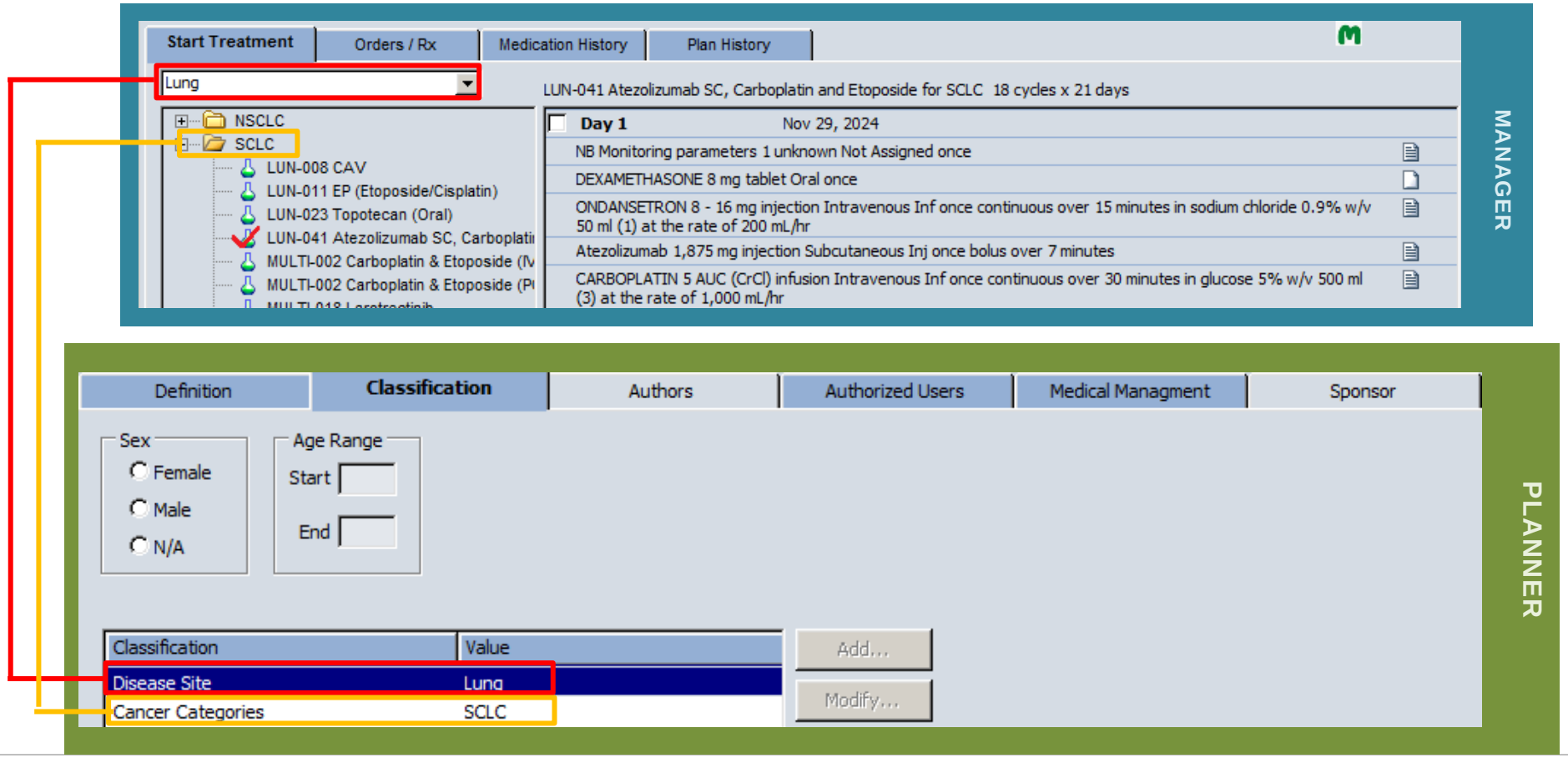
	as cyclical to enable them to be dispensed at any cycle, if required. If any part of an agents scheduling will be non-cyclical then all the events for that agent will need to be non-cyclical. For example, if a drug is required on day 1 of all cycles but only on day 8 of cycles 1 & 2, the day 1 scheduling should be made non-cyclical but the drug scheduled on every cycle. If the drug will not be given at every cycle, un-tick the cyclical tick box and specify the cycle number that treatment will be given on using the "Add" button that appears at the bottom.
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. TAKE A SCREENSHOT OF THE LIST(S) AND SEND TO THE KMCC SYSTEM ADMINISTRATOR AND ADMINISTRATOR. THIS LIST WILL THEN BE SENT TO THE VALIDATING NURSE FOR REFERENCE	
SELECT OK TO COMPLETE THE SCHEDULING FOR THE AGENT THEN REPEAT POINT 5 UNTIL ALL AGENTS HAVE BEEN SCHEDULED THEN SELECT CLOSE TO RETURN TO THE PLAN AGENDA	
6.	**TESTS: LEAVE BLANK**
7.	**TOXICITIES: LEAVE BLANK**
8.	**TREATMENT MANAGEMENT RULES (SUPPORT REGIMENS ONLY): LEAVE BLANK**
SELECT PLAN DETAILS THEN SUMMARY	
9.	**PLAN SUMMARY WINDOW**
9.1.	Enter a plan summary to include the following
	Non-Trial regimen • Regimen name and indication • Treatment intent • Treatment drugs, doses, maximum dose if stated, routes and days • Cycle length and course duration • Details of previous or subsequent regimens if complete treatment not in a single regimen • Signpost to full protocol • Reference(s) document name, version and owner, or website link and date accessed • Change control form number (if applicable)
	Clinical Trial regimens • Trial name with clinical trial suffix-Arm name (if applicable)-regimen name • Trial Protocol version the regimen has been built from and standard version control statement: *The regimen on Aria is based on the protocol version below. This information and regimen on Aria will only be updated in response to protocol amendments when that amendment affects either the chemotherapy regimen or supportive treatment that form the Aria prescription. This page will not be updated in response to other protocol amendments e.g. inclusion criteria that do not affect the drugs.* ***It is the responsibility of the PI at each site to ensure this prescription is suitable for use at their site***. • EudraCT number or ISRCTN number for the trial • Protocol long title • Protocol short title • IMP drug names, doses, frequency and routes • Cycle length and duration of treatment for the individual regimen • Intent for use: a summary of the purpose of the regimen e.g. to assess efficacy and safety of arm A vs arm B
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:**
10.1.	**Institutions tab**: Select either the "TEST LOCATION – OUTPATIENT" location for adult regimens or "TWH Paed – TEST LOCATION" for paediatric regimens.
10.2.	**Users tab:** Leave all users un-ticked

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: LOG IN TO MANAGER AND VISIT THE FOLLOWING WINDOWS TO CHECK THE ACCURACY OF YOUR REGIMEN BUILD. THE FOLLOWING SCREENSHOTS WILL SHOW WHICH PLANNER WINDOW IS USED TO POPULATE WHICH MANAGER WINDOW. ONCE BUILDING IS COMPLETED AND CHECKED, FILL OUT, SIGN AND SUBMIT A BUILDERS CHECKLIST TO THE KMCC ADMINISTRATOR

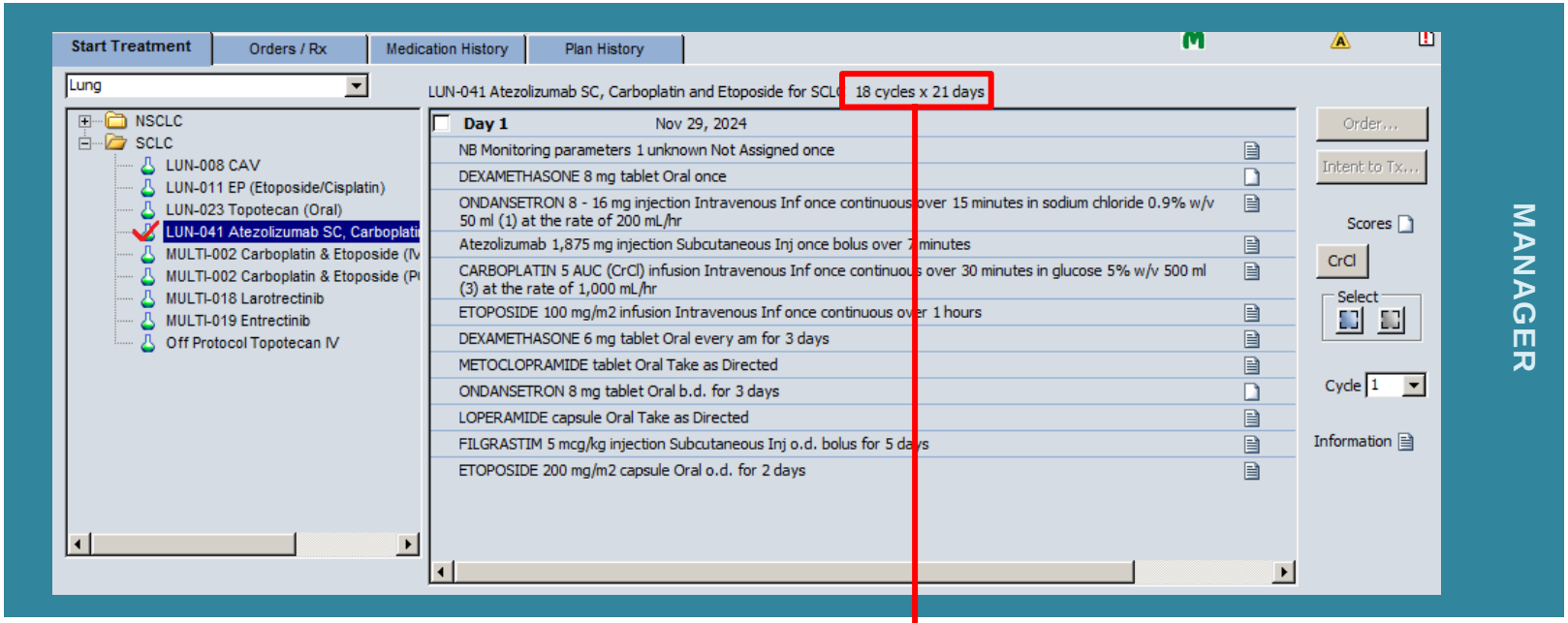
Check the disease site and cancer category (if applicable) are correct

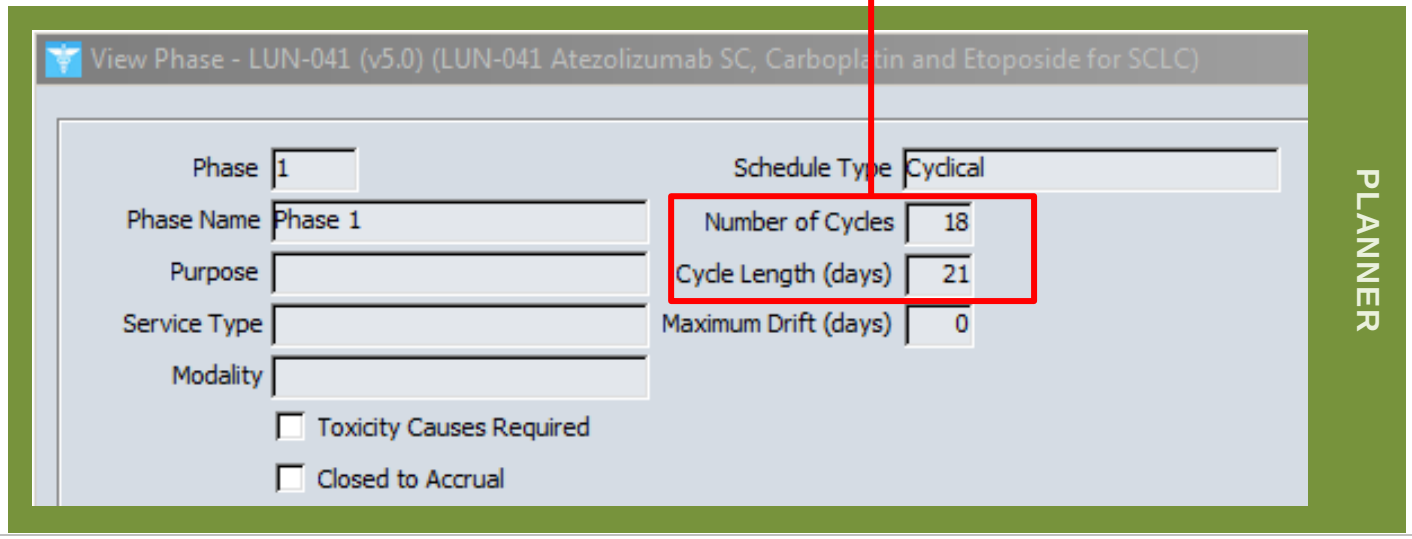
11.1



11.2

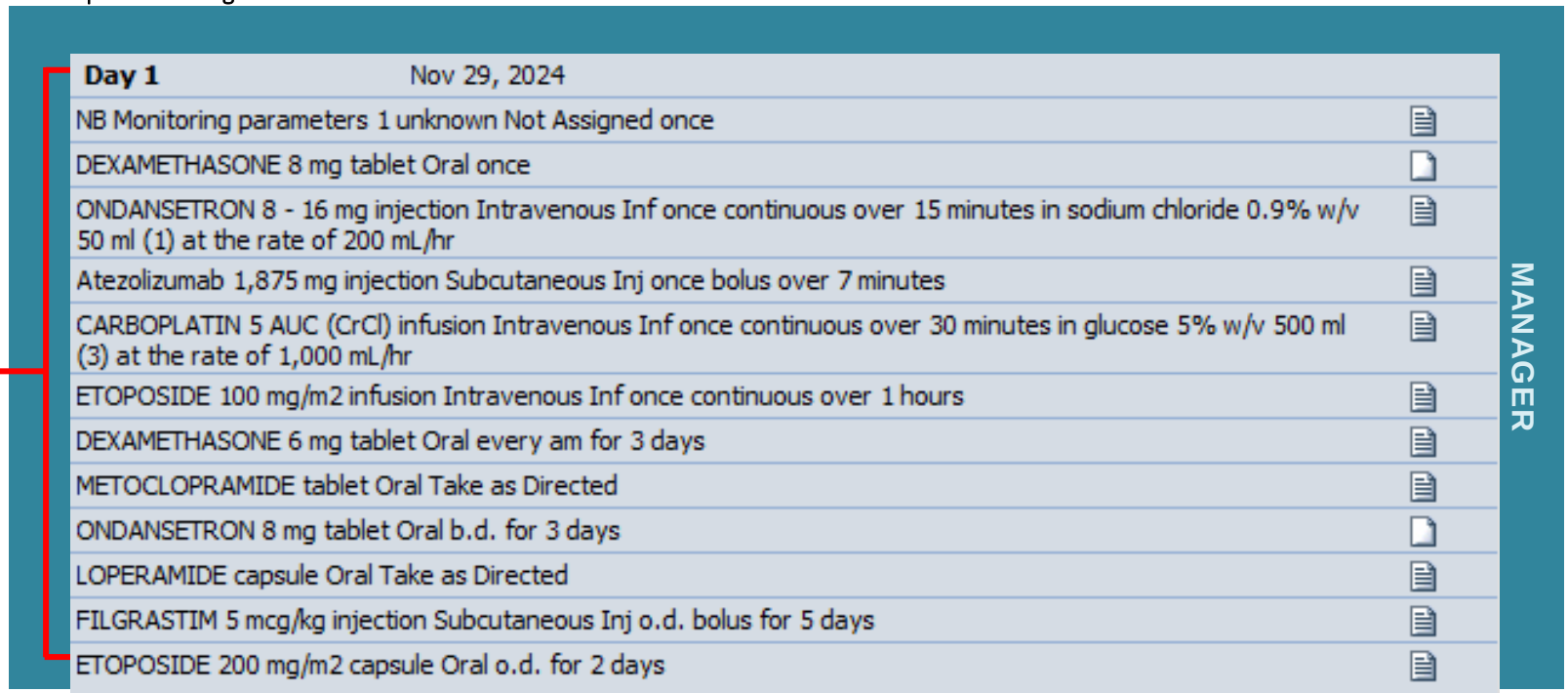
Check the number of cycles and cycle interval are correct

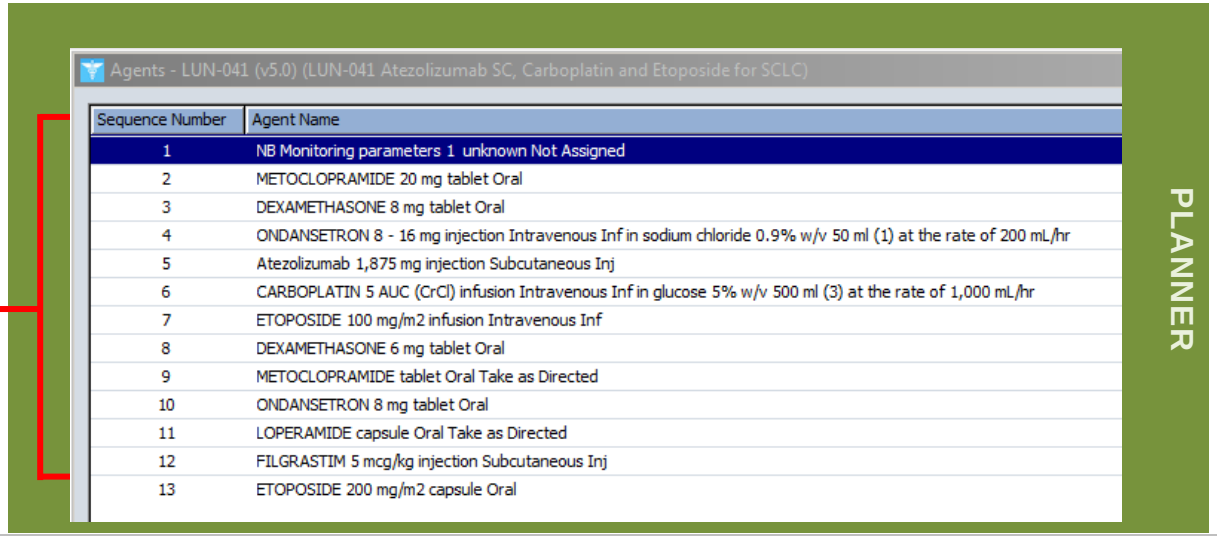




11.3

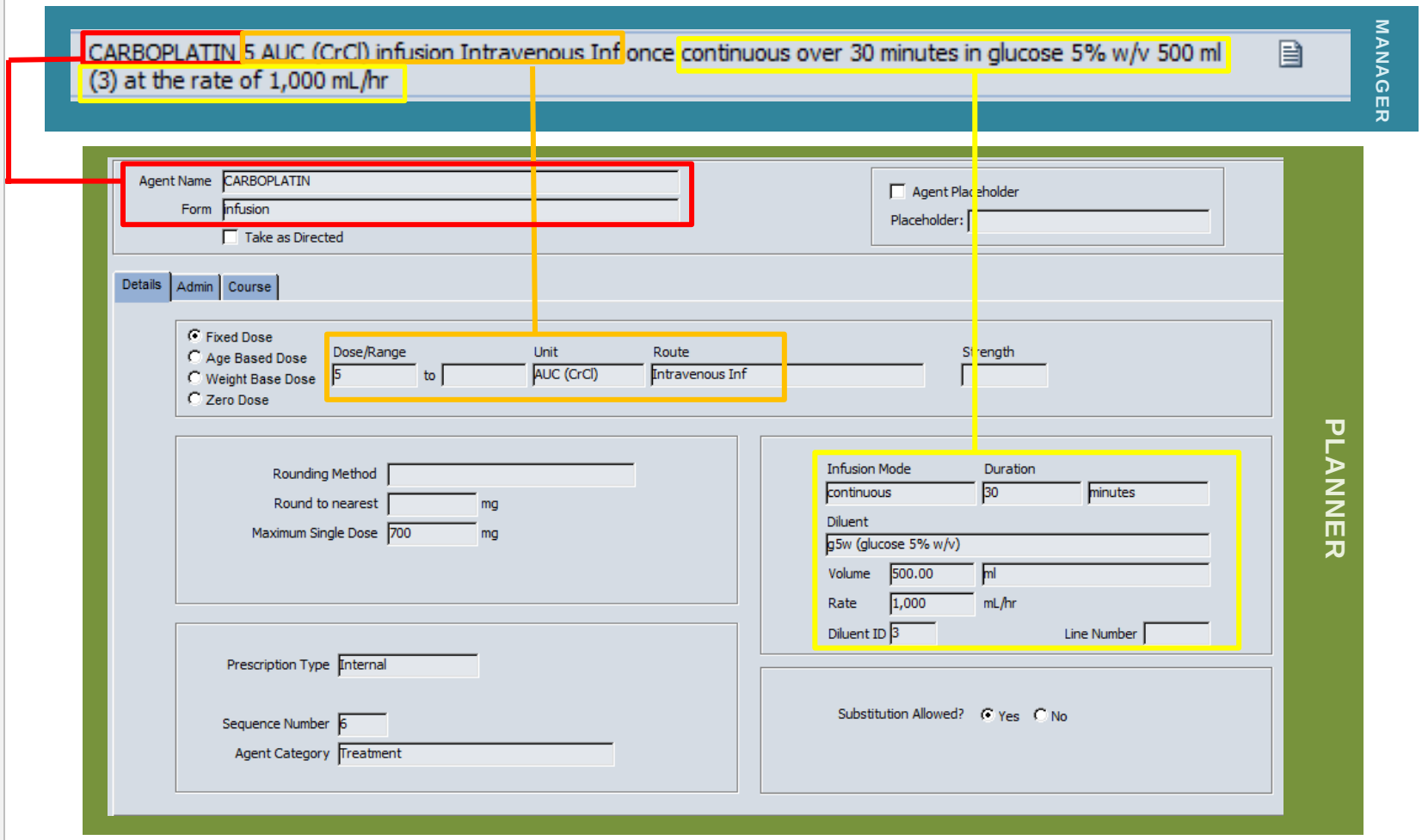
Check the sequence of drugs is correct

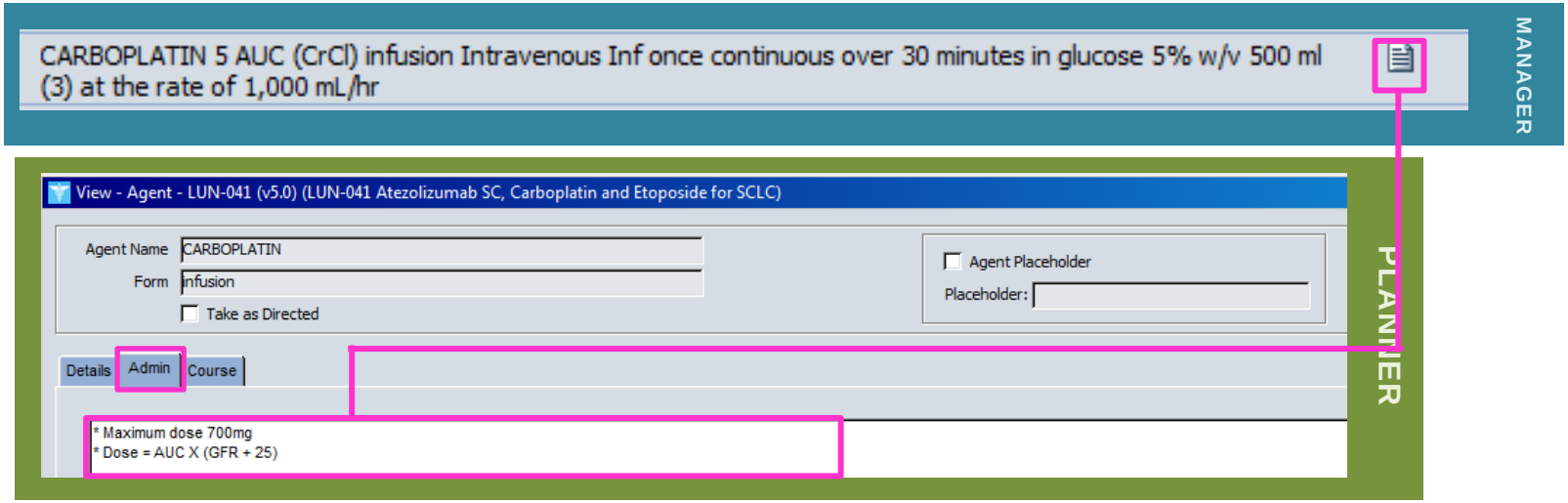




11.4

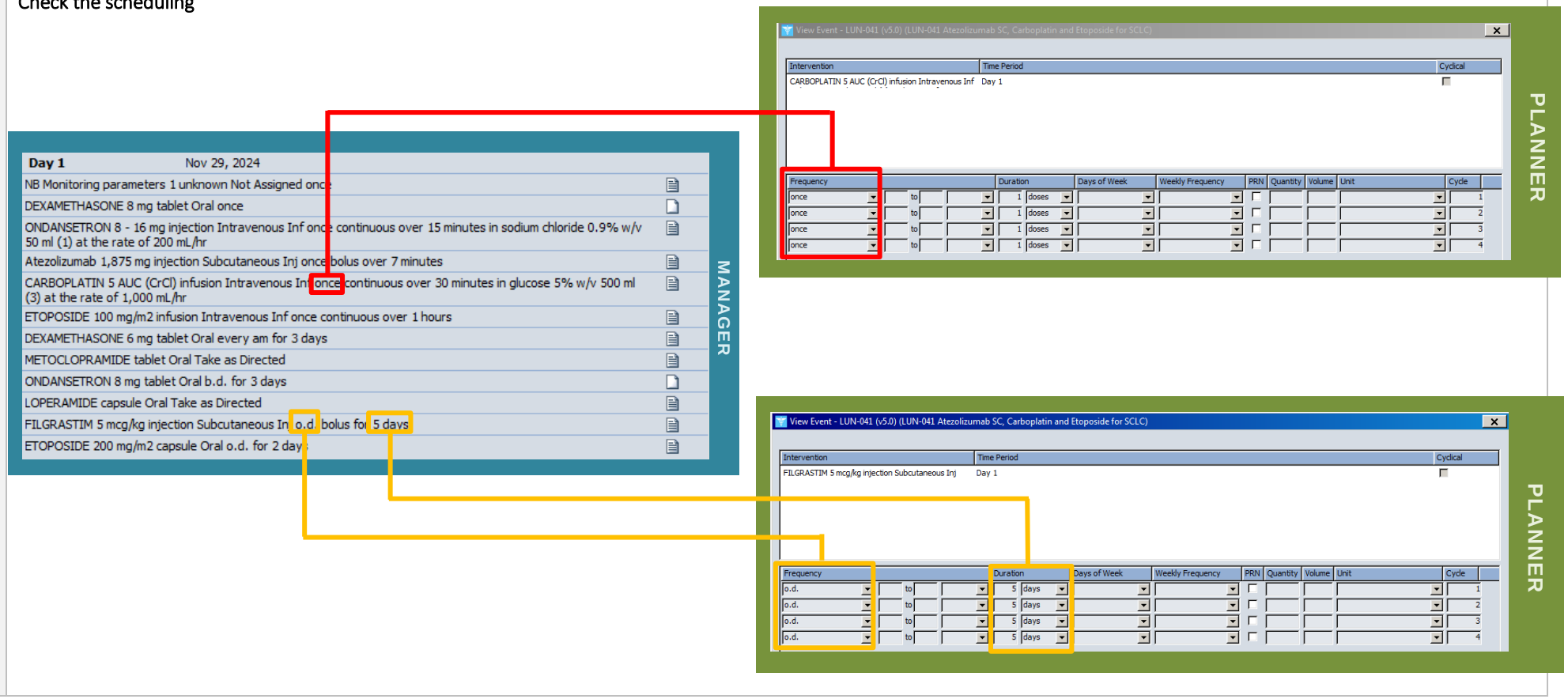
Check the drug details from the Details tab are correct




MANAGER
CARBOPLATIN 5 AUC (CrCl) infusion Intravenous Inf once continuous over 30 minutes in glucose 5% w/v 500 ml (3) at the rate of 1,000 mL/hr
PLANNER
View - Agent - LUN-041 (v5.0) (LUN-041 Atezolizumab SC, Carboplatin and Etoposide for SCLC)
Agent Name CARBOPLATIN
Form infusion
Take as Directed
Agent Placeholder
Placeholder:
Details
Admin
Course
* Maximum dose 700mg
* Dose = AUC X (GFR + 25)

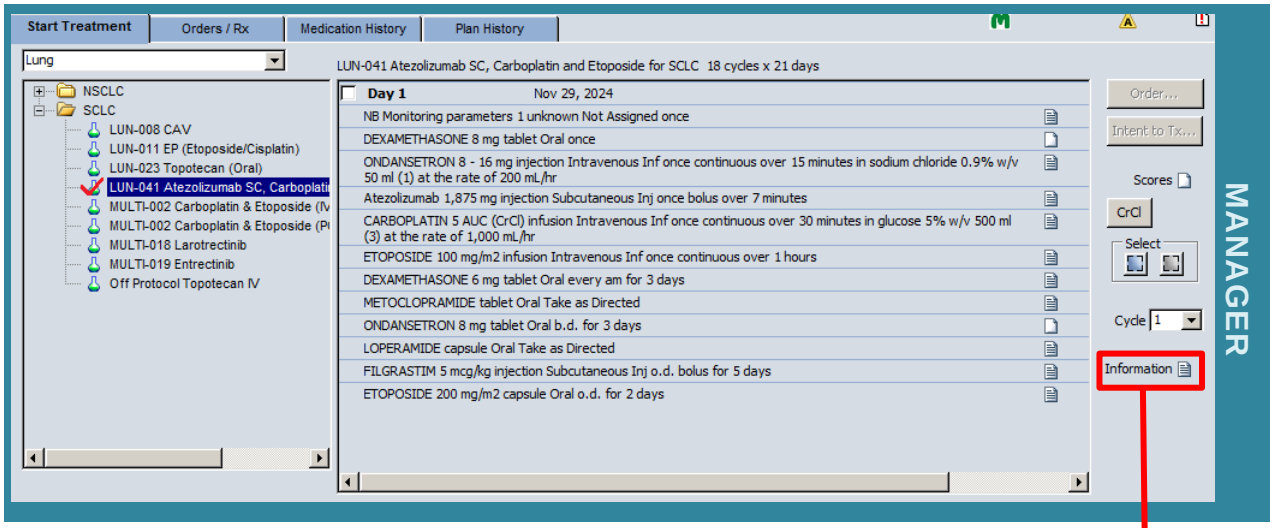
11.5

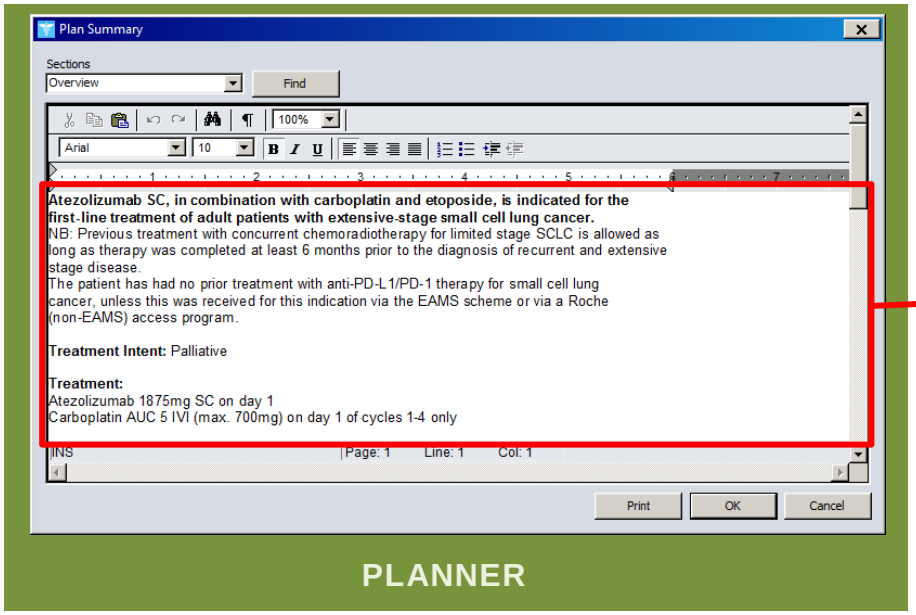
Check the scheduling

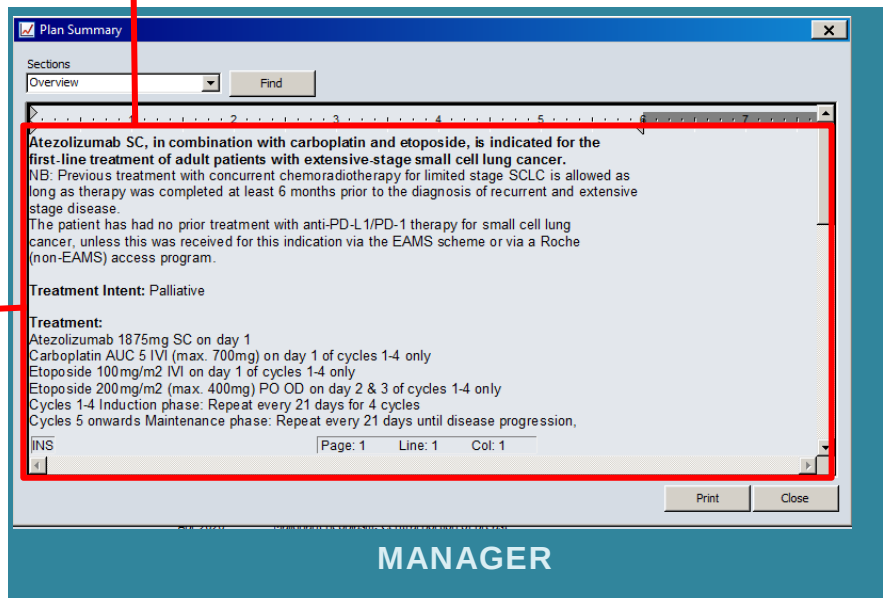


11.6

Check the Plan Summary







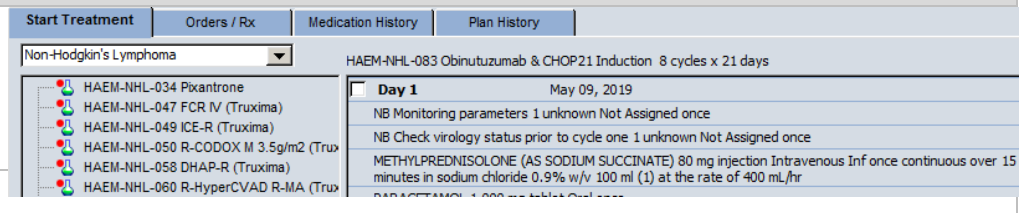
VALIDATING PHARMACIST: INFORM THE KMCC ADMINISTRATOR THAT THE VALIDATION CAN NOW BE SENT TO THE CONSULTANT. IF THE REGIMEN BEING VALIDATED IS A SUPPORT REGIMEN THAT WILL BE USED IN COMBINATION WITH A CHEMO REGIMEN, INFORM THE KMCC ADMINISTRATOR WHO WILL FACILITATE ACCESS

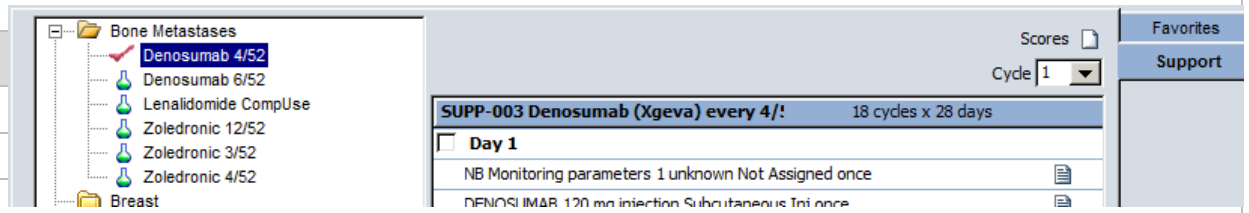
CHECKLIST 1: BUILDERS CHECKLIST					
REGIMEN NAME					
REGIMEN VERSION		TEST PATIENT			Click or tap to enter a date.
REFERENCES INCLUDING VERSIONS					

START TREATMENT WINDOW	CYCLE(S) & DAY(S) TESTED Always check cycle 1 all days then also any subsequent cycles which differ from the first				AMENDMENTS/COMMENTS
Disease site, cancer category, number of cycles and cycle length					
Drugs sequence					
Drug name, form, dose and frequency					
Admin instructions (where appropriate)					
Treatment days/cycles					
Plan summary					

I CONFIRM THAT I HAVE COMPLETED THE BUILDING OF THIS REGIMEN AND IT CAN NOW BE SENT FOR PHARMACIST VALIDATION			
Regimen build completed by		Signed	
Designation		Click or tap to enter a date.	

TABLE 2: PHARMACIST VALIDATION ARIA MANAGER	
LOG INTO ARIA MANAGER AT "TEST LOCATION - OUTPATIENT" LOCATION FOR ADULT REGIMENS OR "TWH PAED – TEST LOCATION" FOR PAEDIARIC REGIMENS. CREATE A TEST PATIENT (SEE *KMCCEP012 ARIA TEST PATIENT SET UP GUIDE*). ENTER VITAL SIGNS FOR THE LARGE PATIENT THEN OPEN THE MEDICATIONS WINDOW	
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. 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 13 BELOW. THE FOLLOWING TESTS NEED ONLY BE PERFORMED ON THE SUPPORT REGIMEN DRUGS 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.	
12.	**CHEMOTHERAPY REGIMENS – START TREATMENT TAB**
12.1.	Check that the regimen appears in the correct folder(s) in Manager based on the indication specified in the reference protocol and the regimen classification guide e.g. Disease site lung and cancer category NSCLC For Clinical Trials ensure that the regimen appears in the correct Clinical Trial dropdown for the disease being selected.
12.2.	Next to the drop-down menu bar check that the cycle length is correct.
12.3.	Check that the standard number of cycles is correct
13.	**SUPPORT REGIMENS – FAVORITE AGENTS SELECTION**
13.1.	Check that the support regimen appears in the correct folder
13.2.	Check that the cycle length is correct
13.3.	Check that the standard number of cycles is correct
ORDER YOUR REGIMEN FOR THE TEST PATIENT. IF CYCLE 1 CONTAINS MULTIPLE TREATMENT DAYS, ALL DAYS SHOULD BE ORDERED	
14.	**DOSE CALCULATION MANAGEMENT WINDOW (If there are no calculated doses (flat dose only) with NO permitted dose reductions, omit test 14)**
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
14.2.	Uncap the BSA by selecting 'Use Actual'.
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.	**REVIEW PRESCRIPTION DETAILS WINDOW**
CHECK THAT THE FOLLOWING ARE CORRECT AGAINST THE REFERENCE PROTOCOL AND YOUR OWN CALCULATIONS	





15.1	**Drug sequence:** Are all the agents still in the correct sequence for administration? For regimens with more than one scheduled treatment day, all 'Internal' agents are listed first, followed by all 'Pickup - Internal' agents.
15.2	**Drug details:** Are all the agents correct in terms of routes of administration, diluents, infusion volumes and durations?
15.3	**Admin instructions:** For each agent that has text present in the Admin Instructions, as indicated by the lined paper symbol, check that this is correct
15.4	**Doses:** 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. For Clinical Trials ensure that any regimens built with edited dose calculations are correct and match what is setup in the planner.

15.5	**Banding and rounding:** 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.

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 AND CHECK THAT THE APPROPRIATE DOSE BANDING OR ROUNDING HAS BEEN APPLIED. If A maximum dose has been specified in the drug entry in Planner, this may override the dose banding. Document any discrepancy on the validation form.

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.

16.	APPROVAL POP-UP WINDOWS (If applicable. Doesn't appear for all regimens)
16.1.	**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 table 3. 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.
16.2.	**Prescription Approval/Printing window** appears, check that all of the information is correct then click the Approve button.

PHARMACY APPROVE THE ORDER BY CLICKING ON THE 'APPROVE' BUTTON ON THE RIGHT, TICKING THE BOX FOR THE APPROPRIATE ORDER, THEN CLICKING APPROVE AGAIN.

CLICK ON THE 'DISPENSE' BUTTON ON THE RIGHT HAND SIDE OF THE SCREEN IN THE ORDERS/RX TAB.

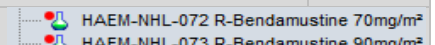
17.	PRESCRIPTION DISPENSING WINDOW
17.1.	Check all the information in the Prescription Dispensing window is correct.
17.2.	Are all the agents listed?
17.3.	Are all the agents marked correctly as Internal or Pickup – Internal? Pick-up External should not be used.
17.4.	Are all the agents to be dispensed in Aseptics correctly marked to indicate this?

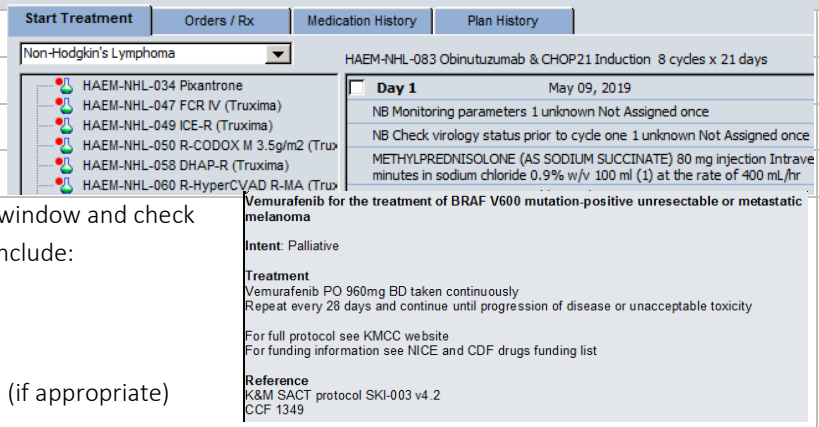
CLICK ON THE BLUE  ICON IN THE TOP LEFT-HAND CORNER OF THE DISPENSING WINDOW TO HIGHLIGHT ALL DRUGS, THEN CLICK ON THE 'DISPENSE' BUTTON AT THE BOTTOM OF THE WINDOW, AND THEN CLICK ON 'APPROVE'.	
CLOSE THE DISPENSING WINDOWS AND RETURN TO ORDERS/RX. HIGHLIGHT THE APPROPRIATE ORDER THEN SELECT THE PRINTER SYMBOL. TICK TO PRINT INTERNAL, PICK-UP INTERNAL (AS APPROPRIATE) AND PRINT ADMINISTRATION INSTRUCTIONS AND PRINT TO PDF. CHECK THE DOCUMENTS AND SUBMIT WITH OTHER VALIATION PAPERWORK	
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 18 IF THE REGIMEN CONTAINS ONLY PICK-UP INTERNAL AGENTS CLICK ON THE OTHER ADMINISTRATION TAB AND GO TO POINT 19	
18.	**DAILY ADMINISTRATION TAB**
18.1.	Are all the Internal agents listed in the correct sequence for administration?
18.2.	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.
19.	**OTHER ADMINISTRATION TAB**
19.1	Are all the Pick-up Internal agents listed? They will be shown in alphabetical order per treatment day.
IF THE REGIMEN CONSISTS OF CYCLES SET UP DIFFERENTLY (E.G. FEC-T), EACH DIFFERENT CYCLE MUST BE TESTED BY REPEATING SECTIONS 14 ONWARDS	
COMPLETE TABLE 3 AND RETURN TO SYSTEM ADMINISTRATOR	

CHECKLIST 2: SECOND VALIDATOR VALIDATION OF CHEMOTHERAPY REGIMEN					
Regimen name		**Regimen version**		**Regimen Date**	Enter Date
Test Patient name		**Cycles to be ordered**		**Cycles to be checked**	
References used					

LOG IN TO ARIA MANAGER AT "TEST LOCATION – OUTPATIENTS" AND OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN GO TO THE "RX" ICON

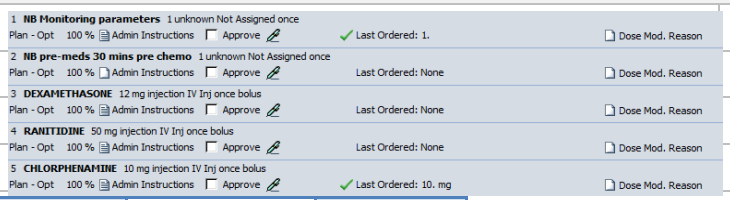
An agent list and event list will be supplied with the validation paperwork. The list of agents will show how many drugs are in the regimen and the event list will show how often they are scheduled. All drugs must be fully checked on the first occasion that they appear following the steps below. On subsequent occurences, only their scheduling and position in the prescription being correct as per the reference protocol needs to be checked as all other information will remain the same regardless of when it is scheduled. For example, if there is a single gemcitabine drug entry and gemcitabine is scheduled on days 1, 8, 15 & 22 of the cycle, the drug details and admin instructions need to be checked on day 1, then only the scheduling and drug position needs to be checked on day 8, 15 & 22

		ACTION	✓ or ✖
Select the tumour site folder then the regimen to be tested by clicking on it once. The required regimen will have a red dot next to it to indicate that it is in testing			
A.	1.2.3	Does the regimen appear in the correct folder(s)?	
B.	2.11	Next to the drop down menu bar check that the cycle length is correct?	
C.	2.10	Is the standard number of cycles correct?	
D.	5	Do all treatment days appear and are the appropriate drugs listed for each day?	
E.	4.2	Click on the Information text box on the right-hand side to open up the Plan Summary window and check that all of the information is correct and matches the treatment protocol. This should include: • Regimen name, indication and intent • Treatment drugs, doses, maximum dose if stated, routes and days • Cycle length and course duration • Details of previous/subsequent/alternative regimens to complete treatment course (if appropriate) • Signpost to full protocol and funding information • References and change control (if appropriate)	



ORDER ALL TREATMENT DAYS OF CYCLE 1 FOR THE TEST PATIENT, THEN CHECK THE FOLLOWING ARE CORRECT FOR EACH DRUG

F.	3.1	Drug name, form and route	
	5.2.1	Frequency	
	4.1.18	Diluent and diluent volume	
	4.1.17	Infusion duration	



	4.1.6	Dose and dose calculation	
	4.1.10	Dose rounding and/or banding	
G.	Is all the information from the protocol present or signposted, in the drug entry, scheduling and plan summary?		
COMPLETE THE 'ORDERED BY' as Dr MD Varian, 'START ON' (ENTER TODAY'S DATE), 'LINE OF TX', 'TX INTENT' AND 'TX USE' FIELDS, THEN CLICK 'APPROVE ALL' TO APPROVE THE TREATMENT CYCLE.			
H.	In the 'Treatment' tab, does the approved cycle appear as ordered		
I.	If the cycle consists of multiple treatment days are these scheduled at the correct intervals?		
ORDER EACH CYCLE AND DAY AS SPECIFIED ABOVE AND REPEAT THE CHECKS SPECIFIED IN SECTIONS F AND G FOR EACH CYCLE AND DAY			
ENSURE A BREAK IS TAKEN BEFORE CONTINUING THE VALIDATION			
OPEN THE DRUG ADMINISTRATION WINDOW AND COMPLETE THE FOLLOWING CHECKS ON THE CYCLES AND DAYS SPECIFIED ABOVE FOR CYCLES TO BE ADMINISTERED: COMPLETE STEPS J-P AND FOR CYCLES TO BE TESTED: COMPLETE STEPS J-O			
DAILY ADMININSTRATION TAB			
J.	Are all the drugs listed in the correct sequence for administration?		
K.	For each drug, are the following details correct, where applicable? Form, Administration route, Frequency, Diluent type and volume, Infusion duration		
L.	If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions		
OTHER ADMINISTRATION TAB			
M.	Are all the Pick-up Internal (TTO) drugs listed here? They will be shown in alphabetical order per treatment day		
N.	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		
O.	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).		
IN THE "DAILY ADMINISTRATION" AND "OTHER ADMINISTRATION" WINDOWS RECORD EACH AGENT DUE ON CYCLE 1 DAY 1 AS ADMINISTERED BY SELECTING EACH AGENT, CLICKING ON THE "RECORD" BUTTON, ENTERING AN ADMINISTRATION TIME AND CLICKING ON THE "APPROVE" BUTTON.			
MEDICATION HX TAB			
P.	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			

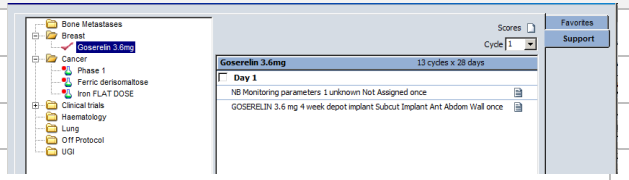
FOR NEW REGIMENS, COMPLETE AND SUBMIT A KOMS NEW EVENT REQUEST FORM			
I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS			
VALIDATION COMPLETED BY		SIGNED	
DESIGNATION		DATE	

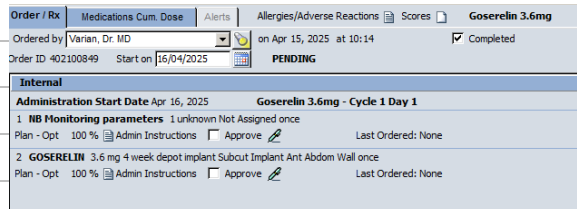
CHECKLIST 3: SECOND VALIDATOR VALIDATION OF SUPPORT REGIMEN					
Regimen name		**Regimen version**		**Regimen Date**	Enter Date
Test Patient name		**Cycles to be ordered**		**Cycles to be checked**	
References used					

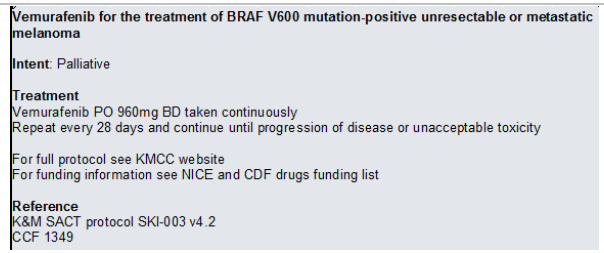
LOG IN TO ARIA MANAGER AT "TEST LOCATION – OUTPATIENTS" AND OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN GO TO THE "RX" ICON SELECT THE ORDERS/RX TAB, ADD Dr MD VARIAN INTO THE 'ORDERED BY' FIELD THEN SELECT THE 'NEW' BUTTON

An agent list and event list will be supplied with the validation paperwork. The list of agents will show how many drugs are in the regimen and the event list will show how often they are scheduled. All drugs must be fully checked on the first occasion that they appear following the steps below. On subsequent occurences, only their scheduling and position in the prescription being correct as per the reference protocol needs to be checked as all other information will remain the same regardless of when it is scheduled. For example, if there is a single gemcitabine drug entry and gemcitabine is scheduled on days 1, 8, 15 & 22 of the cycle, the drug details and admin instructions need to be checked on day 1, then only the scheduling and drug position needs to be checked on day 8, 15 & 22

		ACTION	✓ or ✘
SELECT THE FAVORITES BUTTON, SELECT "SUPPORT" THEN CLICK ONCE ON THE REQUIRED PLAN			
A.	1.2.3	Does the regimen appear in the correct folder(s)?	
B.	2.11	Next to the drop down menu bar check that the cycle length is correct?	
C.	2.10	Is the standard number of cycles correct?	
D.	5	Do all treatment days appear and are the appropriate drugs listed for each day?	
ORDER ALL TREATMENT DAYS OF CYCLE 1 FOR THE TEST PATIENT, THEN CHECK THE FOLLOWING ARE CORRECT FOR EACH DRUG			
E.	3.1	Name, form and route	
	5.2.1	Frequency	
	4.1.18	Diluent and diluent volume	
	4.1.17	Infusion duration	
	4.1.6	Dose and dose calculation	
	4.1.10	Dose rounding and/or banding	
COMPLETE THE 'ORDERED BY', 'START ON' (ENTER TODAY'S DATE), 'LINE OF TX', 'TX INTENT' AND 'TX USE' FIELDS, THEN CLICK 'APPROVE ALL' TO APPROVE THE TREATMENT CYCLE.			
F.		In the 'Treatment' tab, does the approved cycle appear as ordered	
G.		If the cycle consists of multiple treatment days are these scheduled at the correct intervals?	





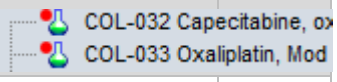
H.	4.2	Click on the Information text box on the right-hand side to open up the Plan Summary window and check that all of the information is correct and matches the treatment protocol. This should include: • Regimen name, indication and intent • Treatment drugs, doses, maximum dose if stated routes and days • Cycle length and course duration • Details of previous/subsequent/alternative regimens to complete treatment course (if appropriate) • Signpost to full protocol and funding information • References and change control (if appropriate)	
ORDER EACH CYCLE AND DAY AS SPECIFIED ABOVE AND REPEAT THE CHECKS SPECIFIED IN SECTION E FOR EACH CYCLE AND DAY			
ENSURE A BREAK IS TAKEN BEFORE CONTINUING THE VALIDATION			
OPEN THE DRUG ADMINISTRATION WINDOW AND COMPLETE THE FOLLOWING CHECKS ON THE CYCLES AND DAYS SPECIFIED ABOVE FOR CYCLES TO BE ADMINISTERED: COMPLETE STEPS I-O AND FOR CYCLES TO BE TESTED: COMPLETE STEPS I-M			
DAILY ADMININSTRATION TAB			
I.	Are all the drugs listed in the correct sequence for administration?		
J.	For each drug, are the following details correct, where applicable? Form, Administration route, Frequency, Diluent type and volume, Infusion duration		
K.	If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions		
OTHER ADMINISTRATION TAB			
L.	Are all the Pick-up Internal (TTO) drugs listed here? (drugs will appear in alphabetical order)		
M.	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		
N.	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).		
IN THE "DAILY ADMINISTRATION" AND "OTHER ADMINISTRATION" WINDOWS RECORD EACH AGENT FOR THE CYCLE STATED ABOVE AS ADMINISTERED BY SELECTING EACH AGENT, CLICKING ON THE "RECORD" BUTTON, ENTERING AN ADMINISTRATION TIME AND CLICKING ON THE "APPROVE" BUTTON.			
MEDICATION HX TAB			
O.	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			

FOR NEW REGIMENS, COMPLETE AND SUBMIT A KOMS NEW EVENT REQUEST FORM			
I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS			
VALIDATION COMPLETED BY		SIGNED	
DESIGNATION		DATE	

CHECKLIST 4: ARIA CONSULTANT VALIDATION OF SACT REGIMEN					
Regimen name	Click or tap here to enter text.	**Regimen version**		**Regimen Date**	**Enter Date**
Test Patient name	Click or tap here to enter text.	**Cycles to be ordered**	Click or tap here to enter text.		
References used	Click or tap here to enter text.				

LOG IN TO ARIA MANAGER AT EITHER THE "TEST LOCATION – OUTPATIENT" LOCATION FOR ADULT REGIMENS OR "TWH PAED – TEST LOCATION" FOR PAEDIATRIC REGIMENS AND OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN GO TO THE "RX" ICON

An agent list and event list will be sent along with the validation paperwork. The list of agents will show how many drugs are in the regimen and the event list will show how often they are scheduled. All drugs must be fully checked on the first occasion that they appear following the steps below. On subsequent occurences, only their scheduling and position in the prescription being correct as per the reference protocol needs to be checked as all other information will remain the same regardless of when it is scheduled. For example, if there is a single gemcitabine drug entry and gemcitabine is scheduled on days 1, 8, 15 & 22 of the cycle, the drug details and admin instructions need to be checked on day 1, then only the scheduling and drug position needs to be checked on day 8, 15 & 22

	ACTION	✓ or ✖
	Select the tumour site folder then the regimen to be tested by clicking on it once. The required regimen will have a red dot next to it to indicate that it is in testing 	
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 THE REGIMEN FOR THE 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	
	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.	
I.	In the 'Treatment' tab, does the approved cycle appear as ordered	
J.	If the cycle consists of multiple treatment days are these scheduled at the correct intervals?	
	IF THE REGIMEN CONSISTS OF CYCLES SET UP DIFFERENTLY EACH DIFFERENT CYCLE MUST BE TESTED BY ORDERING EACH CYCLE AND REPEATING SECTIONS F-J FOR ALL CYCLES SPECIFIED ABOVE	

ERRORS/COMMENTS	Click or tap here to enter text.

I confirm that the regimen has passed all required tests

Validation Completed by	Click or tap here to enter text.	**Signed**	Click or tap here to enter text.
Designation	Click or tap here to enter text.	**Date**	

CHECKLIST 5: ARIA CONSULTANT VALIDATION OF SUPPORT REGIMEN					
Regimen name	Click or tap here to enter text.	**Regimen version**		**Regimen Date**	**Enter Date**
Test Patient name	Click or tap here to enter text.	**Cycles to be ordered**	Click or tap here to enter text.		
References used	Click or tap here to enter text.				

LOG IN TO ARIA MANAGER AT EITHER THE "TEST LOCATION – OUTPATIENT" LOCATION FOR ADULT REGIMENS OR "TWH PAED – TEST LOCATION" FOR PAEDIATRIC REGIMENS AND OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN GO TO THE "RX" ICON

SELECT THE ORDERS/RX TAB THEN 'NEW' BUTTON
FROM THE NEW PRESCRIPTION WINDOW COMPLETE THE "ORDERED BY" FIELD BY SELECTING DR. MD VARIAN

An agent list and event list will be sent along with the validation paperwork. The list of agents will show how many drugs are in the regimen and the event list will show how often they are scheduled. All drugs must be fully checked on the first occasion that they appear following the steps below. On subsequent occurences, only their scheduling and position in the prescription being correct as per the reference protocol needs to be checked as all other information will remain the same regardless of when it is scheduled. For example, if there is a single gemcitabine drug entry and gemcitabine is scheduled on days 1, 8, 15 & 22 of the cycle, the drug details and admin instructions need to be checked on day 1, then only the scheduling and drug position needs to be checked on day 8, 15 & 22

	ACTION	**✓ or ✖**
	SELECT THE FAVORITES BUTTON, SELECT "SUPPORT" THEN CLICK ONCE ON THE REQUIRED PLAN	
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?	
	ORDER THE REGIMEN FOR THE 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	
E.	Are all doses, flat and calculated, correct according to the protocol?	
F.	If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions	
	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.	
G.	In the 'Treatment' tab, does the approved cycle appear as ordered	
H.	If the cycle consists of multiple treatment days are these scheduled at the correct intervals?	
I.	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 EACH DIFFERENT CYCLE MUST BE TESTED BY ORDERING EACH CYCLE AND REPEATING SECTIONS F-J FOR ALL CYCLES SPECIFIED ABOVE	

ERRORS/COMMENTS	Click or tap here to enter text.

I confirm that the regimen has passed all required tests

Validation Completed by	Click or tap here to enter text.	**Signed**	Click or tap here to enter text.
Designation	Click or tap here to enter text.	**Date**	

CHECKLIST 6 ARIA NURSE VALIDATION					
Regimen name	Click or tap here to enter text.	**Regimen version**		**Regimen Date**	Enter Date
Test Patient name	Click or tap here to enter text.	**Cycles to be checked**		**Cycles to be administered**	
References used	Click or tap here to enter text.				

An agent list and event list will be sent along with the validation paperwork. The list of agents will show how many drugs are in the regimen and the event list will show how often they are scheduled. All drugs must be fully checked on the first occasion that they appear following the steps below. On subsequent occurences, only their scheduling and position in the prescription being correct as per the reference protocol needs to be checked as all other information will remain the same regardless of when it is scheduled. For example, if there is a single gemcitabine drug entry and gemcitabine is scheduled on days 1, 8, 15 & 22 of the cycle, the drug details and admin instructions need to be checked on day 1, then only the scheduling and drug position needs to be checked on day 8, 15 & 22

	ACTION	✓ or ✖
	OPEN THE RECORD OF THE TEST PATIENT STATED ABOVE THEN OPEN THE DRUG ADMINISTRATION WINDOW AND COMPLETE THE FOLLOWING CHECKS AS APPROPRIATE FOR CYCLES TO BE ADMINISTERED: COMPLETE STEPS A-G AND FOR CYCLES TO BE TESTED: COMPLETE STEPS A-F	
	DAILY ADMININSTRATION 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.	If there are any drug-specific administration instructions, check that they are correct by clicking on the Admin instructions	
	OTHER ADMINISTRATION TAB	
D.	Are all the Pick-up Internal (TTO) drugs listed here? (drugs will appear in alphabetical order)	
E.	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	
F.	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).	
	IN THE "DAILY ADMINISTRATION" AND "OTHER ADMINISTRATION" WINDOWS RECORD EACH AGENT FOR THE CYCLE STATED ABOVE AS ADMINISTERED BY SELECTING EACH AGENT, CLICKING ON THE "RECORD" BUTTON, ENTERING AN ADMINISTRATION TIME AND CLICKING ON THE "APPROVE" BUTTON.	
	MEDICATION HX TAB	
G.	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	Click or tap here to enter text.

FOR NEW REGIMENS, COMPLETE AND SUBMIT A KOMS NEW EVENT REQUEST FORM

I confirm that the regimen has passed all required tests

Validation Completed by	Click or tap here to enter text.	**Signed**	Click or tap here to enter text.
Designation	Click or tap here to enter text.	Date	

CHECKLIST 7: COMPLETION AND GO-LIVE FOR ARIA FULL VALIDATIONS					
Regimen name	Click or tap here to enter text.	**Version**	Click or tap here to enter text.	**Date***	Click here to enter a date.

DOCUMENTATION CHECKS Completed and signed documents received	✓ or ✖
ARIA building checklist	
ARIA regimen validation summary and sign-off received	
Screenshots from pharmacist	
Prescription print-out	
Event list from pharmacist	
Validation checklist from clinician	
Validation checklist from nurse (NA for clinical trials)	
Correct version of SOPs used	

All related CCFs returned and completed (check with system administrator if unsure)	CCF	Click or tap here to enter text.	

CONFIGURE ACCESS	
Check the regimen in the test location in Manager to ensure scheduling is still present. If not, refer back to validating pharmacist	
For network approved regimens: Check that the protocol is in the final folder and that there are no versions in draft in the document management system and that the correct version (the approved final draft or the approved final), as stated on the regimen work plan has been used for the build and validation. Update the references in Plan Summary with the final version number	Version from: Click or tap here to enter text. Version to: Click or tap here to enter text.
Update the authorised users with the lead EP pharmacist from each Trust, the KMCC pharmacists, the system administrator and the Varian user. For clinical trials regimens, also add each Trusts lead clinical trials pharmacist and their deputy	
For network approved regimens: Grant access to all locations as appropriate to the regimen type i.e. all non-test adult locations for an adult regimen and all non-test paediatric locations for a paediatric regimen. **For non-network approved regimens, including clinical trials:** ONLY grant access to locations within each Trust who have approved its use and as appropriate to the regimen type The lead e-prescribing or clinical trials pharmacist will be authorised to allow the use of a regimen within their Trust. In all cases, do not grant access at Radiation Scheduling location.	

MAKE REGIMEN LIVE		
Approve Plan - Click 'Analyse' and then 'Approve for use'		
If superseding a regimen, deactivate the previous version(s)	Version	Click or tap here to enter text.
In Manager, using XXAccess, Test for adult regimens and XXPaed, Test for paediatric regimens, check the regimen is available in one of the locations selected, as appropriate for the regimen type		
Check that the scheduling is still present for the regimen. If not, refer back to validating pharmacist		

CREATE AND FILE BACK-UP TEMPLATE
Non-MTW users ensure that the default printer is set to 'docu-printer' via File – Printer setup before proceeding **Run the report:** Manager - Reports – 'Prescriptions – Daily doses – Template – QA CUSTOM' - Enter *Plan Name* - 'Preview' then **Save the report:** For MTW users: Click the 'Export' icon. For non-MTW users: Click the 'Print' icon
Upload the template to the regimen library in the document management system.
For all network approved regimens: Inform the SACT Governance Group, as well as the HOG/NOG as appropriate **For off-protocol regimens:** Inform the local Trust pharmacy team and the prescribing clinician **For clinical trials regimens:** Inform the Principal Investigator and the lead Clinical Trials pharmacist at each Trust that the regimen is available at, who should then disseminate the information to the relevant teams

Print name	Click or tap here to enter text.	**Signed**	Click or tap here to enter text.
Designation	Click or tap here to enter text.	**Date:**	Click here to enter a date.

ONCE COMPLETED, SAVE THIS FORM WITH THE VALIDATION DOCUMENTS IN THE DOCUMENT MANAGEMENT SYSTEM

CHECKLIST 8: ARIA MINOR AMENDMENT VALIDATION					
Regimen name		Regimen version		Regimen Date*	Regimen Date
Copied regimen name (if applicable)		Regimen version		Regimen Date*	Regimen Date
Test patient name from full validation		CCF number and/or KMCC protocol version		Build SOP version	

Build SOP ref	DESCRIPTION OF CHANGE (state details of change made in the box)	Tick if changed
PLANNER CHECKS		
DEFINITION (MODIFY PLAN)		
1.1.1	**Amendment to the plan name (only for copied regimens)**	
1.1.3	**Amendment to the display name**	
1.1.4	**Plan Type:** Change when copying a regimen to create a support regimen	
1.1.7	**Brief Description:** Change or update to say See Plan Summary	
1.1.10	**'Amendments Mandatory' box must NOT be ticked** Check and action on ALL regimens	
1.2.3	**Change to Classification type box:** If copying a regimen to make a support regimen, remove disease site and cancer categories and add in appropriate 'Problem'	
1.4	**Change to Authorized Users**	
MODIFY PHASE		
2.14	**Description Box:** If text is present it should be deleted	
2.3	**Phase Name:** Complete only for support regimens	
2.6	**Change to modality**	
2.10	**Change number of cycles:** Regimens with cyclical agents only. Amend / check under modify phase.	
PRINT EVENT LIST IF A CHANGE HAS BEEN MADE TO THE NUMBER OF CYCLES		
ADD/VIEW/MODIFY AGENTS		
	Delete a drug: Non-SACT drugs can be deleted from a regimen. Scheduling must be deleted first, before the drug can be deleted	
3.1	**Add a drug:** To add non-SACT drugs to a regimen. If a SACT drug needs to be added then a full regimen validation will be required	
4.1.1 – 4.1.15 (except 4.1.11)	**Changes to the Details tab (except diluent details):** Dose changes are permitted on all non-SACT drugs. Changes to SACT drug doses or SACT drug sequence number require a full validation.	

4.1.11	**Maximum single dose:** Changes are permitted to all SACT and non-SACT drugs. Ensure value entered is also specified in the Admin tab and the Plan Summary	
4.1.16–4.1.20	**Changes to the diluent details within Details Tab:** Including diluent, infusion mode, volume, duration and rate.	
4.2	**Change to the free text within the Admin tab.** Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	
5	**Change to the scheduling:** Scheduling changes are permitted on all non-SACT drugs and schedule changes from 'days' to 'doses' is permitted on ALL SACT and non-SACT drugs. Any other changes to SACT drug scheduling require a full validation	
PLAN SUMMARY		
9	**Change to the free text within the Plan Summary**: Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	
10.1	**Change regimen access to <u>only</u> TEST LOCATION – OUTPATIENTS for adult regimens or TWH Paed – TEST LOCATION for paediatric regimens.** Complete for ALL regimens	

MANAGER CHECKS (Validating pharmacist only)

LOG INTO ARIA MANAGER AT "TEST LOCATION - OUTPATIENT" FOR ADULT REGIMENS OR TWH Paed – TEST LOCATION FOR PAEDIATRIC REGIMENS AND CREATE OR SELECT THE APPROPRIATE TEST PATIENT. OPEN THE MEDICATIONS WINDOW BY CLICKING ON THE "Rx" ICON ON THE TOOLBAR. SELECT THE RELEVANT CANCER DISEASE SITE FOR THE REGIMEN THAT YOU WILL BE TESTING. HIGHLIGHT THEN ORDER YOUR REGIMEN FOR THE TEST PATIENT

- 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.
- Are all the agents correct in terms of routes of administration, diluents, infusion volumes and durations?
- If a change has been made to the maximum dose of a drug, ensure the application of the cap has been challenged by attempting to prescribe a dose above the cap
- For each agent click on the Administration Instructions box and check that the administration instructions are correct

TAKE A SCREENSHOT OF THE CHANGE

Errors detected requiring correction (list test numbers) and errors found that were not covered in Checklist procedure:

Builder (Print Name)		**Signed**	
Designation		**Date:**	Click or tap to enter a date.

I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS

Validated by (Print Name)		**Signed**	
Designation		**Date:**	Click or tap to enter a date.

* Regimen date should be the date the regimen was first created.
This can be found in the Modify Plan window – Definition tab. Click on the Audit symbol and enter the created date

CHECKLIST 9: COMPLETION AND GO-LIVE FOR ARIA MINOR VALIDATIONS					
DOCUMENTATION CHECKS Signed documents received					✓ when completed
Screenshots from pharmacist					
Correct version of SOPs used					
All related CCFs returned and completed (check with system administrator if unsure)	CCF				
CONFIGURE ACCESS					
Check the regimen in the test location in Manager to ensure scheduling is still present. If not, refer back to validating pharmacist					
For network approved regimens: Check that the protocol is in the final folder and that there are no versions in draft in the document management system and that the correct version (the approved final draft or the approved final), as stated on the regimen work plan has been used for the build and validation					
For network approved regimens: Update the references in Plan Summary with the final version number	Version from		Version to		
Update authorised users with the lead EP pharmacist from each Trust, the KMCC pharmacists, the system administrator and the Varian user. For clinical trials regimens, also add each Trusts lead clinical trials pharmacist and their deputy					
For network approved regimens: Grant access to all locations as appropriate to the regimen type i.e. all non-test adult locations for an adult regimen and all non-test paediatric locations for a paediatric regimen. **For non-network approved regimens, including clinical trials:** ONLY grant access to locations within each Trust who have approved its use and as appropriate to the regimen type, and exclude any prescribers prohibited from using the regimen. The lead e-prescribing or clinical trials pharmacist will be authorised to allow the use of a regimen within their Trust. In all cases, do not grant access at Radiation Scheduling location.					
MAKE REGIMEN LIVE					
Approve Plan - Click 'Analyse' and then 'Approve for use'					
If amending or superseding a regimen, deactivate the previous regimen(s)/version(s)	Version				
In Manager, using XXAccess, Test for adult regimens and XXPaed, Test for paediatric regimens, check the regimen is available in one of the locations selected, as appropriate for the regimen type					
Check that the scheduling is still present for the regimen. If not, refer back to validating pharmacist					
CREATE AND FILE BACK-UP TEMPLATE					
Non-MTW users ensure that the default printer is set to 'docu-printer' via File – Printer setup before proceeding **Run the report:** Manager - Reports – 'Prescriptions – Daily doses – Template – QA CUSTOM' - Enter *Plan Name* - 'Preview' then **Save the report:** For MTW users: Click the 'Export' icon. For non-MTW users: Click the 'Print' icon					
Upload the template to the regimen library in the document management system.					
For all network approved regimens: Inform the SACT Governance Group, as well as the HOG/NOG as appropriate for the regimen. **For Off-protocol regimens:** Inform the local Trust pharmacy team and the prescribing clinician **For clinical trials regimens:** Inform the Principal Investigator and the lead Clinical Trials pharmacist at each Trust that the regimen is available at, who should then disseminate the information to the relevant teams					
Print name		**Signed**			
Designation			**Date:**	Click or tap to enter a date.	
ONCE COMPLETED, SAVE THIS FORM WITH THE VALIDATION DOCUMENTS IN THE DOCUMENT MANAGEMENT SYSTEM					
IF THIS VALIDATION HAS CREATED AN ENTIRELY NEW REGIMEN, ENSURE THE MTW KOMS TEAM ARE INFORMED AND PROVIDED WITH A NEW EVENT REQUEST					

TABLE 3: ARIA ADULT AND PAEDIATRIC REGIMEN VALIDATION SUMMARY AND SIGN-OFF				
Regimen name				
CCFs		Regimen version		Click here to enter a date.
References including versions				
Completed building checklist received?		Test patient		

PLANNER SECTIONS	AMENDMENTS/COMMENTS
New/view plan window	
View/modify phase window	
Agents	
Add/view/modify agent	
Schedule events	
Plan summary window	

MANAGER SECTIONS	CYCLE(S) TESTED				AMENDMENTS/COMMENTS
Review prescription details tab					
Adjust dose window					
Approval pop-up windows					
Prescription dispensing window					
Event list print outs					
Internal/pick-up internal agents prescription					

CONFIRM THAT I HAVE COMPLETED THE VALIDATION OF THIS REGIMEN AND IT CAN NOW BE MADE LIVE ON ARIA			
Validation Completed by		Signed	
Designation		Date	Click here to enter a date.
Superseded regimen(s)		Version(s)	
Regimen to be removed from Test location (if applicable)			