**VALIDATION AND COMPLETION OF MINOR AMENDMENTS TO ARIA REGIMENS**

**Objective**

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when applying minor amendments to 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) including clinical trials. All chemotherapy and support regimens will be built in the ARIA Planner app, then tested and validated in the Planner and Manager apps.

**Scope**

This SOP applies to the update or creation of new regimens from an already approved and active ARIA regimen, where the required changes fall in to the stated sections listed in the ‘Build SOP ref column’ of the checklist. Further information on permitted changes in each section can be found in the corresponding section of the Building and validating ARIA regimens SOP. All other changes should be validated using the full validation process as outlined on the ARIA regimen validation SOP.

**Responsibilities**

* Requests for amendments should be made by or via the relevant NOG, HOG or following an update to a K&M SACT protocol then submitted to the system administrator.
* The ARIA system administrator is responsible for allocating and overseeing the building and validation of all chemotherapy and support regimens in ARIA as stated in **ARIA Regimen Building and Validation Process Following Protocol Approval**.
* The following checklist should be completed by the technician or pharmacist who makes the changes to the regimen on ARIA then the changes must be validated by a second pharmacist.
* When updating an approved regimen, if Amendments Mandatory is ticked on the current Approved regimen, the regimen MUST be copied then re-built to remove this tick and NOT amended. If the changes to the copied regimen meet the criteria of a minor amendment then this SOP may be followed.
* When a chemotherapy regimen is copied to create a support regimen, or to remove the Amendments Mandatory tick, this SOP should also be used to document that process.
* The completion checklist should be completed by the technician or pharmacist who makes the regimen live.

**Method**

* Each permitted change is listed on Table 1. The application is listed first (A. in example below), followed by the window and tab name (B. in example below) with a reference to the corresponding section of the building and validating ARIA regimens SOP (C. in example below) which details the changes that can be made.
* If the required changes fall in to the stated sections of Table 1 then this SOP may be followed. If any of the required changes are not listed in Table 1 then a full validation will need to be performed instead.
* Each change made should be detailed on Table 1 (D. in example below) by the builder and the section ticked (E. in example below) to indicate this. If a change has not been made on a listed section, leave this blank.

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| **TABLE 1** |
| **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)** |  ✔  |
|  Changed to BRE-101 |

**A.**

**B.**

**E.**

**C.**

**D.**

* Once all changes have been applied the builder should complete and sign the first part of Table 3
* The validating pharmacist will check the sections changed in Planner as indicated by the builder in Table 1, then check these changes in Manager as per Table 2
* 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.
* On Completion of regimen validation, the pharmacist should then complete the second part of Table 3 and send this form to the system administrator
* The system administrator, upon receipt of completed SOP, will then make the regimen live for use as per Table 4

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Regimen name** | Click or tap here to enter text. | **Regimen****version** | Click or tap here to enter text. | **Regimen Date\*** | Regimen Date |
| **Copied regimen name** (if applicable) | Click or tap here to enter text. | **Regimen****version** | Click or tap here to enter text. | **Regimen Date\*** | Regimen Date |
| **Test patient name from full validation** | Click or tap here to enter text. | **CCF number and/or KMCC protocol version** | Click or tap here to enter text. | **Build SOP version** | Click or tap here to enter text. |

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| **TABLE 1** |
| **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)** |   |
| Click or tap here to enter text. |
| **1.1.3** | **Amendment to the display name**  |   |
| Click or tap here to enter text. |
| **1.1.4** | **Plan Type** Change when copying a regimen to create a support regimen |   |
| Click or tap here to enter text. |
| **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’ |   |
| Click or tap here to enter text. |
| **1.4** | **Change to Authorized Users** |   |
| Click or tap here to enter text. |
| **MODIFY PHASE** |
| **2.14** | **DescriptIon Box:** If text is present it should be deleted |   |
| Click or tap here to enter text. |
| **2.3** | **Phase Name:** Complete only for support regimens |   |
| Click or tap here to enter text. |
| **2.6** | **Change to modality**  |   |
| Click or tap here to enter text. |
| **2.10** | **Change number of cycles** Regimens with cyclical agents only. Amend / check under modify phase.  |   |
| Click or tap here to enter text. |
| **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 |   |
| Click or tap here to enter text. |
| **3.1** | **Add drugs**To add non-SACT drugs to a regimen. If a SACT drug needs to be added then a full regimen validation will be required |   |
| Click or tap here to enter text. |
| **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 doses require a full validation.  |   |
| Click or tap here to enter text. |
| **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 |   |
| Click or tap here to enter text. |
| **ENSURE EXTRA TEST SPECIFIED BELOW IS COMPLETED DURING MANAGER CHECKS** |
| **4.1.16– 4.1.20** | **Changes to the diluent details within Details Tab**Including diluent, infusion mode, volume, duration and rate. |   |
| Click or tap here to enter text. |
| **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. |   |
| Click or tap here to enter text. |
| **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 |   |
| Click or tap here to enter text. |
| **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. |   |
| Click or tap here to enter text. |
| **10.1** | **Change regimen access to only TEST LOCATION – OUTPATIENTS for adult regimens or TWH Paed – TEST LOCATION for paediatric regimens. Complete for ALL regimens** |   |
| **TABLE 2** |
| **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:**Click or tap here to enter text. |
| **TABLE 3** |
| **Builder (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 or tap to enter a date. |
| **I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS** |
| **Validated by (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 or tap to enter a date. |

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| **TABLE 4** |
| **DOCUMENTATION CHECKS** Signed documents received | **✓ when completed** |
| Screenshots from pharmacist  |   |
| Prescription print-out (not always needed for minor amendment) |   |
| 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 |   |
| **For network approved regimens:** 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 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 | 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 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** | 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 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** |

\* 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