

Checklist for Verification of Treatment Regimens in ARIA Version 10

| Regimen's Name and Disease Site | Internal Name/ Version | Date Regimen Last Updated |
|---|------------------------|---------------------------|
| The regimen above has been checked against (Tick as appropriate): <input type="checkbox"/> CSCCN Protocol, version number: <input type="checkbox"/> Other, please specify and cross reference: | | |
| Entered By: | Signature: | Date |
| Checked By: | Signature: | Date: |

To access the regimen for testing log into "CSCCN" in Medonc Planner. In the "Open Plan" window select: Plan Type - "Regimen" or "Symptom Mgmt." and Plan Status - "In Testing" and "Active". Highlight the plan for testing and double-click or click the "open" button.

| PLAN AGENDA WINDOW – DEFINITION (from the toolbar click the "Definition" button) | Correct (✓) Incorrect (X) |
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| DEFINITION TAB: | |
| • Plan name (20 character limit - NOTE unable to have 2 plans with the same name therefore may have extra spaces in title) | |
| • Display name | |
| • Version number (check version is the same as stated above) | |
| • Plan type (should be "regimen" or "symptom management") | |
| • Sponsor (should always be "internal") | |
| • Owner (should always be "CSCCN") | |
| • Brief description (correctly describes agents, doses, administration route, frequency and duration) | |
| • Clinical Trial (should NOT be selected) | |
| • Amendments Mandatory (should NOT be selected) NB only applicable to regimen | |
| CLASSIFICATION TAB: | |
| • Sex (Should always be N/A) | |
| • Age range (should always be blank) | |
| • Classification type – check the following classifications have been selected correctly | |
| ➤ Disease site | |
| ➤ Cancer categories (includes OPCS codes, disease sub categories and trial status where applicable) | |
| ➤ Problems (NB only applicable to symptom management) | |
| AUTHORS TAB: | |
| • There should be no entries in this field | |
| AUTHORIZED USERS TAB: | |
| • This list should consist of the following names only; Kimber Donna, P Basker Nanda, P Burgin Ali, P Harrison Liz, P Robertson Debra, | |

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| P:CH003 | Version: 2.0 | Issue Date: Jan 2010 | Rev Date: Jan 2015 |
| Written: D Kimber CSCCN E-Prescribing System Manager | Approved: Dr D Wright CSCCN Lead Pharmacist | Date of Amendments: February 2010, May 2010, July 2010, August 2010, Sept 2010, November 2010, May 2012, June 2012, Jan 2013, Jan 2013 | |

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| P Wills Rebecca , Wright (IP) Debbie, Vms Ks | | | |
| MEDICAL MANAGEMENT TAB: | | | |
| <ul style="list-style-type: none"> Classification – Toxicity Grading - NCI CTCAE v4.0 (SI units) should be selected | | | |
| <ul style="list-style-type: none"> Estimated GFR – only selected if a formula other than Cockcroft & Gault is required | | | |
| SPONSOR TAB: | | | |
| <ul style="list-style-type: none"> There should be no entries in this field | | | |
| PLAN AGENDA WINDOW – MODIFY PHASE (click on the “Modify” button in the “Plan Agenda” window) | | | Correct (√) Incorrect (X) |
| <ul style="list-style-type: none"> Phase (should always be phase 1) | | | |
| <ul style="list-style-type: none"> Phase name (Should be Phase 1 for a regimen or a description for a symptom management plan) | | | |
| <ul style="list-style-type: none"> Purpose (should always be blank or N/A) | | | |
| <ul style="list-style-type: none"> Service type (should always be blank) | | | |
| <ul style="list-style-type: none"> Modality (should always be blank) | | | |
| <ul style="list-style-type: none"> Toxicity cause required (should NOT be selected) | | | |
| <ul style="list-style-type: none"> Closed to accrual (should NOT be selected) | | | |
| <ul style="list-style-type: none"> Schedule type (ensure correct schedule type has been selected) | | | |
| Dependent on the schedule type please complete the following: | | | |
| CYCLICAL (√) or (X) | LINEAR (√) or (X) | LINEAR-NEG DAYS (√) or (X) | AD HOC (√) or (X) |
| Cycle length (days): | Length (days): | Length (days): | Length (days): |
| Number of cycles: | Max. Drift (days): (Should always be “0”) | Starting day: | Max. Drift (days): (Should always be “0”) |
| Max. Drift (days): (Should always be “0”) | | Max. Drift (days): (Should always be “0”) | |
| <ul style="list-style-type: none"> Description (correctly describes agents, doses, administration route, frequency and duration) | | | |
| <ul style="list-style-type: none"> Toxicity Risk (NO scores should be selected) | | | |
| <ul style="list-style-type: none"> Chemo order instructions (should always be blank) | | | |
| PLAN AGENDA WINDOW – AGENTS (from the toolbar click the “Agents” button to view all the agents attached to this regimen) | | | Correct (√) Incorrect (X) |
| <ul style="list-style-type: none"> Check that all of the regimen's drugs specified as per the CSCCN protocol are listed in the “Agents” window | | | |
| <ul style="list-style-type: none"> Check that all of supportive care drugs and pre and post hydration are included as per the CSCCN protocol summary page | | | |
| <ul style="list-style-type: none"> Ensure that all drugs are listed in the correct administration order and amend the sequence number if needed (using plan utilities) | | | |
| <ul style="list-style-type: none"> IMPORTANT – all drugs must be in UPPER CASE (as taken from First Data Bank). For investigational or unlicensed drugs please check spelling and entry of drug. Specify total number of agents on this list: | | | |
| <ul style="list-style-type: none"> Double click on each individual agent to open and then list each individual agent in table 1 on Page 5 and table 2 on Page 6 and repeat for each agent. | | | |
| PLAN AGENDA WINDOW – TESTS/TOXICITIES (from the toolbar click the “Tests” and “Toxicities” buttons) | | | Correct (√) Incorrect (X) |
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| <ul style="list-style-type: none"> • Tests (there should be NO "Selected Tests") • Toxicities (there should be NO "Selected Toxicities") | |
| PLAN AGENDA WINDOW – SCHEDULE (from the tool bar click the "Schedule" button.) | Correct (√) Incorrect (X) |
| <ul style="list-style-type: none"> • Starting on (this field should be blank except where the regimen includes an agent scheduled for specific days e.g. M/W/F) • View ('cycle day' should always be selected) • Maintain ('schedule' should always be selected) | |
| Click on the "List" button to view how drugs are scheduled for this regimen. | |
| <ul style="list-style-type: none"> • Select 'Cyclical' to bring up a list of ALL agents that have been scheduled cyclically. Complete table 1 on Page 5 to indicate whether each agent is scheduled correctly. Print the cyclical list and attach it to this document. • Select 'Non-cyclical' to bring up a list of ALL agents that have been scheduled non-cyclically. Complete table 1 on Page 5 to indicate whether each agent is scheduled correctly. Print the non-cyclical list and attach it to this document. | |
| PLAN DETAILS MENU – Summary (from the "Plan Details" menu select Summary to open the "Plan Summary" window) | Correct (√) Incorrect (X) |
| <ul style="list-style-type: none"> • The "Plan Summary" window shows free-typed information about the regimen. This should contain the link to the correct protocol on the CSCCN website or reference the trial protocol. | |
| PLAN DETAILS MENU – Access (from the "Plan Details" menu select Access to open the "Plan Access for Institution/User" window) | Correct (√) Incorrect (X) |
| <ul style="list-style-type: none"> • Institutions tab (check that the relevant institutions have been selected) <ul style="list-style-type: none"> ○ For adult regimens this includes all institutions except "PIAM Brown" ○ For paediatric regimens select "PIAM Brown" and "RSH Outpt Clinic" only • User tab (check that all users have access to the regimen – i.e. none are ticked) | |
| TESTING THE REGIMEN IN ARIA | Correct (√) Incorrect (X) |
| Follow the Validation of CSCCN Chemotherapy Protocols in Aria (SOP:CH003) and review this regimen using the appropriate number of test patients. (For most regimens this will involve 3 test patients but for simple regimens where the doses for all agents are flat only one patient need be completed) | |

Once the test patients have been completed successfully and all necessary amendments made return to the regimen in planner. In the "Plan Agenda" window click the "Approve" button, then click "Analyse", then "Approve for Use".

APPROVED FOR USE IN ARIA

| Print | Signature | Date | Occupation |
|-------|-----------|------|------------|
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DOCUMENTATION

The completed form must be returned to the CSCCN system manager along with the check list for testing chemotherapy regimens and validation prescriptions within two weeks of regimen approval. A message must be broadcast to all users of the system as soon as the regimen has been approved for use stating either that the regimen has been added to Aria or an update implemented (with a brief description of the update).

| | Date Sent / Sign | | Date Received / Sign | |
|--|------------------|------|----------------------|------|
| | Date | Sign | Date | Sign |
| Message Broadcast on Aria | Date | Sign | | |
| Checklist for Verification | Date | Sign | Date | Sign |
| Checklist for Prescription Verification (S / M / L) | Date | Sign | Date | Sign |
| Test Prescriptions (S / M / L) Only the L prescription need be printed | Date | Sign | Date | Sign |

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Checklist for verification of Treatment Regimens in ARIA Version 10 – Table 1 Agents and their Schedule

| AGENT | | | | | SCHEDULE | | | | | | | |
|--------------------------------|------|-------------|------------|------------|--|----------|---|---|---------------|-----------------|-----------|----------|
| DRUG (AGENT) NAME, DOSE & FORM | SEQ# | DETAILS TAB | ADMIN TAB | COURSE TAB | Tick to indicate how each agent has been scheduled | | Indicate if agent has been entered correctly (√) or incorrectly (X) | Check the following for each agent and indicate if correct (√) or incorrect (X) | | | | |
| | SEQ# | (√) or (X) | (√) or (X) | (√) or (X) | (√) or (X) | Cyclical | | Non-cyclical | Treatment Day | Treatment Cycle | Frequency | Duration |
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Checklist for verification of Treatment Regimens in ARIA Version 10 – Table 2 Agents Details
Insert a (√), (X) or (N/A) in each box

| DRUG (AGENT) NAME, DOSE & FORM | Agent Placeholder (not selected) | Fixed dose (always selected) | Form, Dose/Range and Units correct | Route | Strength (if Dose banded) | Rounding Method (if applicable) | Max Single dose (if applicable) | Prescription type (internal or pick-up internal only) | Record Dose (for pick-up only – “no dose recordings” selected) | Refill (for pick-up only – not selected) | Agent Category correct (treatment/hydration etc) | Infusion Mode | Duration | Diluent | Volume | Diluent ID | Line No – should be blank | Substitution allowed – always YES |
|--------------------------------|----------------------------------|------------------------------|------------------------------------|-------|---------------------------|---------------------------------|---------------------------------|---|--|--|--|---------------|----------|---------|--------|------------|---------------------------|-----------------------------------|
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DOCUMENT CONTROL

Checklist for Verification of Treatment Regimens in ARIA Version 10

| Version Number | Description of Change | Amended By | Date |
|----------------|---|--|-------------------------------|
| 2.0 | Plan details menu – Access – Institutions tab: “For adult regimens this includes all institutions except “PIAM Brown”, For paediatric regimens select “PIAM Brown” and “RSH Outpt Clinic” only ” added Testing the regimen in Aria – Option for one patient testing for regimens with flat doses added | Rebecca Wills CSCCN Electronic Prescribing Pharmacist | 22 nd January 2013 |
| 1.9 | Title changed to ARIA Version 10 Instructions on how to access regimen added “Modify Plan Window” title changed to “Plan Agenda Window – Definition” with associated information Definition Tab: “Billable plan” removed, “Amendments mandatory” added, “symptom management” included as an option for the plan type. Classification Tab: Disease stage, cell categories, Tx line, Tx intent removed. Coding included in under cancer categories with disease sub categories and trial status added. “Problems” added Authorised User Tab: P Burgin Ali added, list arranged alphabetically. Medical Management Tab: NCI CTCAE v3.0 changed to v4.0, Estimated GFR changed to “only selected if a formula other than Cockcroft and Gault is required” Modify Phase – sub-window: Title merged into section above. Phase name – “for a regimen or a description of symptom management plan” added, “Closed to accrual” added, “Toxicity risk” added, “Chemo order instructions” added Agents: Title amended. Table page numbers changed from 4 and 5 to 5 and 6. Tests/Toxicities: title amended, wording changed to reflect new format in V10. Schedule: Title amended. Starting on field – supplementary information added. Cyclical/Non cyclical lists -wording updated. Plan summary: changed to include reference to CSCCN website or trial protocol. | Rebecca Wills CSCCN Electronic Prescribing Pharmacist | 20 th January 2013 |

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| | Access: user tab – wording amended – all users to have access. Testing the regimen in ARIA: The last three statements removed and incorporated into the pharmacist checklist. Instructions on how to approve for use added Tables 1 and 2 – “Central South Coast Cancer Network” title removed (already in header) Table 2: Extra line added, Maximum Variation column removed, Agent placeholder, Fixed dose, Form, dose/range and units, Record dose and Refill columns added “(√) (X)” from columns moved to title with “(N/A)” option added | | |
| 1.8 | Documentation changed so that only the large prescription need be printed. Testing the regimen changed to state that each cycle must be checked if doses change between cycles | Dr Deborah Wright CSCCN Lead Pharmacist | 13 th June 2012 |
| 1.7 | Nanda Basker added to approved list of users and Sara Brown removed | Dr Deborah Wright CSCCN Lead Pharmacist | 31 st May 2012 |
| 1.6 | Summary section changed to reflect the removal of the protocol and it’s replacement with the link to the website | Dr Deborah Wright CSCCN Lead Pharmacist | 18/11/10 |
| 1.5 | Section on not including antiemetics removed Document control added | Dr Deborah Wright CSCCN Lead Pharmacist | 09/09/10 |
| 1.4 | Coding added as a check under classification | Dr Deborah Wright CSCCN Lead Pharmacist | 05/08/10 |
| 1.3 | Section added describing documentation | Dr Deborah Wright CSCCN Lead Pharmacist | 29/07/10 |
| 1.2 | Approval table re-formatted | Dr Deborah Wright CSCCN Lead Pharmacist | May 10 |
| 1.1 | Authorised users amended | Dr Deborah Wright CSCCN Lead Pharmacist | Feb 10 |

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