

## SOP: Adding / Checking chemotherapy trials on Aria (as regimens)

### **OBJECTIVE AND SCOPE**

How to add and check the master template(s) of a prescription(s) for trials to Aria (the chemotherapy electronic prescribing system) in the form of regimens. Allow 1 month from sending the request to the network pharmacists before the trial will be approved for use on Aria (assuming clinician check sheet completed in a timely fashion), Allow 2 weeks for second pharmacy check

### **RESPONSIBILITIES**

Master regimen(s) are to be added and 1<sup>st</sup> checked by an Aria trained Pharmacist in planner following the attached paperwork (checklist) (for trials entered by OUH pharmacists, this is two different Aria planner trained pharmacists). The regimen is then put into 'testing' and prescribed in manager for a dummy patient. The PI for the study, prescribes and clinician checks (using clinician checking form) the regimen in manager and records amendments as required. It is 2<sup>nd</sup> checked by an Aria trained pharmacist and approved for use in the live system. At each of the 3 checks the regimen is prescribed for a dummy patient– the same dummy patient should be reused for each check by discontinuing the regimen. The Thames Valley electronic prescribing pharmacist can then check the trial for consistency with other network regimens.

### **This SOP is set out as follows;**

- Section 1- planning the regimen(s)
- Section 2- adding the regimen(s)
- Section 3- adding the study drugs to aria
- Section 4- adding a dummy patient
- Section 5- pharmacy checking list
- Section 6- PI checking list

### **SECTION 1 – planning the regimens**

You cannot delete a regimen on ARIA once it has been added. You may however amend something. Therefore prior to adding anything into planner you need to be clear what needs to be added in terms of regimens and agents. It is recommended to **sketch out the trial plan before putting anything into aria**. If in doubt about setting it up get your draft plan checked by the Thames Valley electronic prescribing pharmacist

**Regimens** - contains the agent(s) and dose(s) that occur on specific days for a set number of cycles. A regimen specifies the dosage for scheduled and unscheduled agents with administration notes. Appropriate toxicities must be added and so they are available in Manager if doctors /nurses wish to grade them. Tests must be attached to a regimen as required by the trial protocol. The system has the capability to calculate the appropriate doses based on BSA, GFR (AUC–CrCl or AUC -EDTA), mg/kg, flat doses, zero doses, age-based dosing and dose banding. It has cycle/day events associated which will appear in the patient's schedule window and the medications window in the Treatment Tab in Manager.

#### **EXAMPLE**

If all the cycles in a given arm have the same cycle length that arm can be added to aria as 1 regimen with cyclical or non-cyclical drugs. If an arm starts with a 30 day cycle and then has 10 x 28 day cycles it would need to be added as 2 different regimens.

#### Trial test has 3 arms.

**Arm A**– control, 6 cycles of 21 days, cycle 1-3 of FEC, cycle 4-6 of docetaxel. This can be put on aria as 1 regimen of cycle length 21 days number of cycles 6 with non-cyclical drugs scheduled.

**Arm B**- investigation, 6 cycles of 21days, cycle 1-3 of FEC, cycle 4-6 of docetaxel + wonder drug cycle 1, 3, 5 and wonder drug alone cycle 7 onwards every 3 weeks until progression. This can be put on as 1 regimen of cycle length 21 days number of cycles 12 (as we don't know how long patients would receive the wonder drug for using 12 cycles would mean that extra cycles may be added from cycle 7

**Arm C**- research, 2 cycles of 28 days wonder drug followed by 6 cycles of 21days, cycle 1-3 of FEC, cycle 4-6 of docetaxel + 'wonder drug' every cycle continuing to progression. This can be put on as 2 regimens the first regimen of cycle length 28 days number of cycles 2. The second regimen of cycle length 21 days number of cycles 12 (as we don't know how long patients would receive the wonder drug for using 12 cycles would mean that extra cycles may be added from cycle 7 when wonder drug continues alone)

**Agents** – in aria agent = drug. All licensed drugs should be selected from the First DataBank (FDB) drug data base that is incorporated into aria. This allows all drug interactions to be checked within the system. Licensed drugs that are being used in trials should also be selected from this database. **Investigational agents** in pilot phase I and phase II studies will need to be added to the system as customised drugs. These WILL NOT be included in the drug interactions checking within aria. See Section 3 for detailed information.

In the above example the agents in FEC and docetaxel will all be selected from the FDB drug data base. The only drug that needs adding to the aria system would be 'wonder drug.' As the same wonder drug is used in all 3 arms it only needs to be added to the system once.

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## Section 2– Adding the regimen(s) to Planner

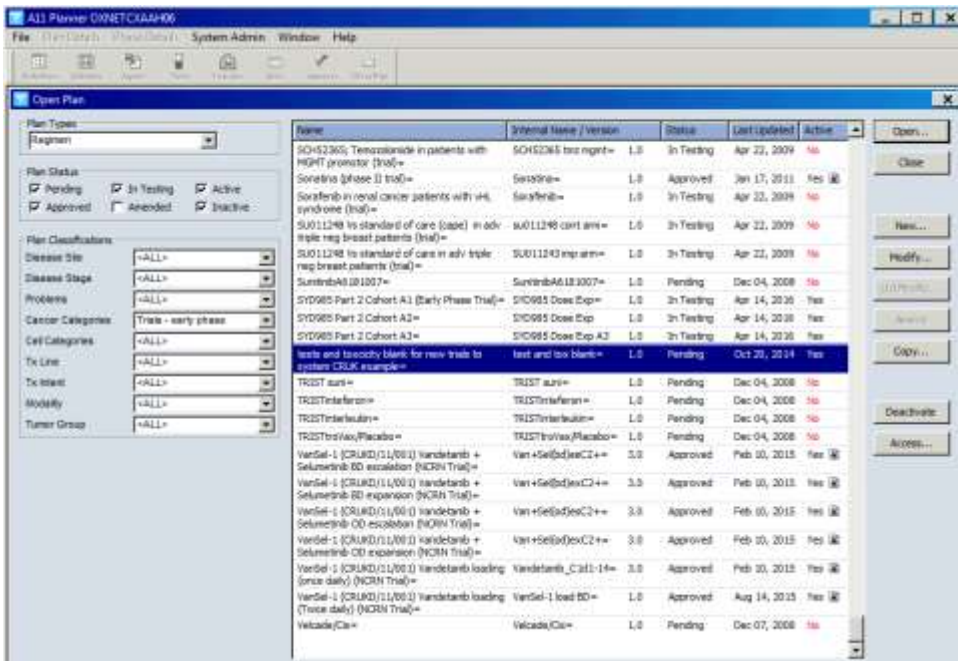
**Log into Planner** – in citrix open the TVCN folder, click on the live planner icon NOT the test or training version. Ensure you are logged in using your admin user ID, from the TVCN, using your password and login to TVCN as the institution.

**Creating the regimen** – The best method is to find a regimen that is similar to the trial regimen you plan to set up and copy it or use 'tests and toxicity blank for new trials to system, by clicking on the copy button on the right hand side once the regimen you wish to copy is highlighted (under plan types (top left) select from the drop down list – regimen. This is quicker than starting each trial and will lead to some consistency with the trials for associated tests and toxicities and standard TV chemotherapy regimens.

When a regimen is copied the following must be completed in the **view plan window – definition tab**

- **Plan Name** (20 character limit should always have an "=" after name) NOTE Unable to have 2 plans / regimens with the same name.
- **Display Name** (80 character limit should always have an "=" after name) will appear in Manager. Use the standard format of '**protocol name and arm choice (Trial)=**'
- **Plan Type** Check Regimen is selected
- **Authorised Users Tab** ensure your admin username appears in this window or you CANNOT modify the regimen. Authorised users should always include. You, the Thames Valley Electronic Prescribing pharmacists and VMS CS, VMS CA, VMS KS from Varian.. Then press OK to copy

Do not use apostrophe ('), quotes (" "), semi-colons (;) or tildes (~) or tabs in the Plan Name or Display Name fields. Avoid using these characters in any fields in Planner.



Other General info on this screen; Left side

**1) Plan Status** (mid left) allows viewing any of the plan types by Active versus Inactive Status.

Active and approved for use are the ones that are seen in Manager for live patients. Pending protocols cannot be seen in manager, 'in testing' regimens can only be prescribed in test patients.

Inactive status - the plans are not seen in Manager. This allows plans to be 'turned off' if they are no longer required in Manager i.e. trials that have finished.

**2) Plan classifications** can be selected to limit where regimens are seen in manager

Trials should only have disease site and the cancer category NCRN / early phase trial to ensure they are in the correct folders in manager. OPCS codes and NRN names should be added as a cancer category

**(Do NOT add any cell types (eg mesothelioma, sarcoma) or cancer categories (eg adjuvant) to trials)**

Right side

**Amend-**The Amend button will be disabled if you do not have Access to the plan type or if it still in pending or in testing. If updates are required for a specific regimen, this allows an approved the regimen to be updated.

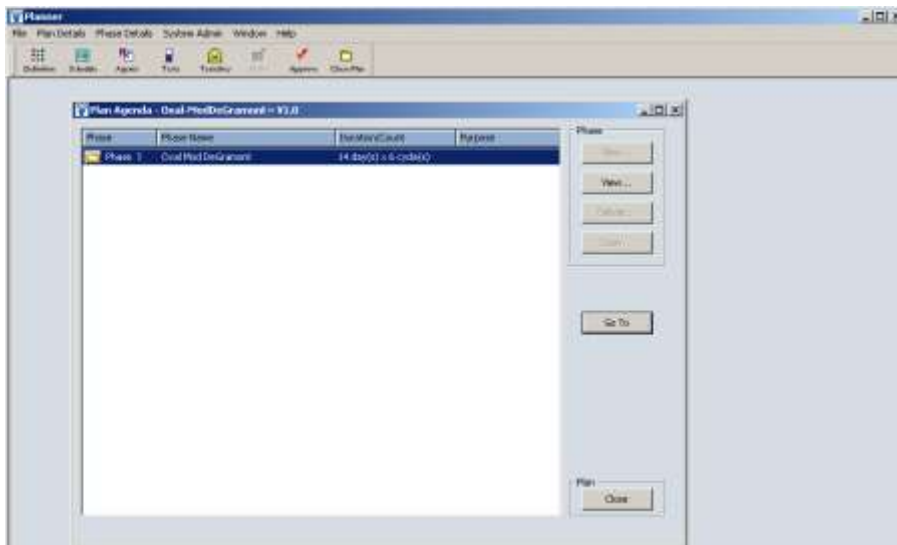
**Access Button-**This allows you to give access to specific institutions or remove access for specific users. If there is no institution assigned to a plan in Planner, it will not be visible in Manager. TVCN institution must be given access to all regimens.

**Ltd Modify** – Allows the External Name and Plan Group in an approved regimen to be amended without changing version.

## Amending the regimen

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Once you have copied an appropriate regimen you need to populate all the following fields with information specific to the trial. To modify the regimen highlight the regimen you wish to change and press the 'open' button. This opens the plan agenda window and will activate the lower icon bar



**NOTE:** information can be copied and pasted into aria from pdfs and ntepad but not word documents. The aria windows work like word documents. The best source to copy from is notepadk.

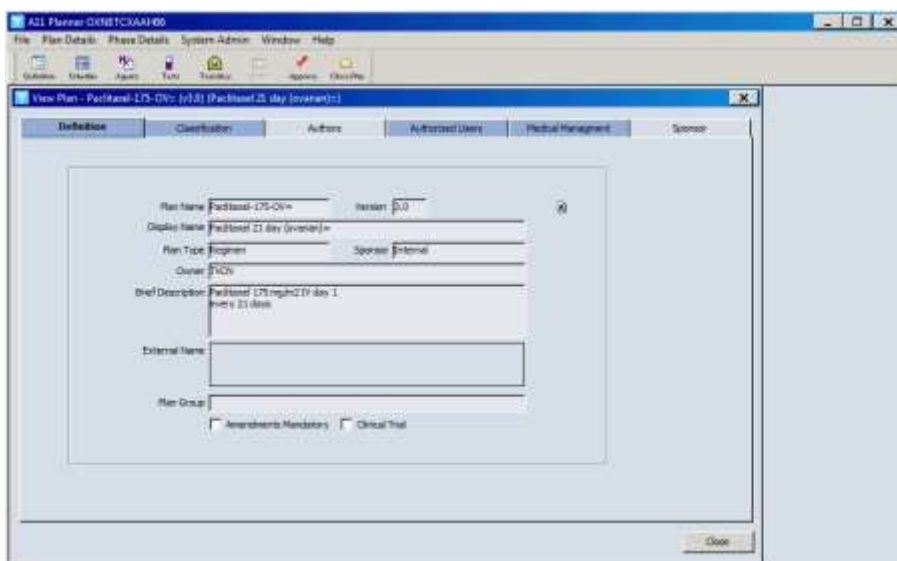
**Populate the Plan Details – Access.** This gives access of regimens to specific users and institutions. Select Plan Details and Access from the upper toolbar this default opens the Institutions tab.

- **Institutions tab** ensure only the relevant institutions, only the wards where this regimen will be administered (not parent institutions ie hospital / Trust name), have been selected but must include TVCN. Until a trial is open to recruitment only TVCN should be ticked. Access must be granted in Planner to a location otherwise the regimen cannot be seen in Manager at that location.
- **Users tab** all regimens will be available to all Drs [this is the Ability to EXCLUDE a user access to a Regimen. If a checkbox is selected beside a user, the user will not see the Regimen in Manager.]
- Then press OK to save

**Check the Plan Details- Consent** no consent required. Each trial / trust has a different consent form and must keep several copies of it. Also this function is NOT an electronically signed consent and would need to be printed off.

## MODIFY PLAN WINDOW-

**Populate the regimen definition.** In the lower icon bar click on definition. Taking you to the 'modify plan' window.



#### Definition tab

- Check **Plan Name** (20 character limit should always have an “=” after name). Cannot be amended.
- **Check / Complete Display Name** (80 character limit should always have an “=” after name). Standard format of **protocol name and arm choice (Trial)=**. This can be amended
- **Version number** starts at 1.0 and changes automatically if a regimen is amended.
- **Plan Type** check Regimen is select
- **Sponsor** set as Internal
- **Owner** set as TVCN. [If owner is the parent (TVCN), you will be able to view the regimens at all child institutions]
- **Brief Description** textbox. (200 character limit) check the brief description of what the regimen entails. [This appears on the prescription.]
- **Clinical Trial** checkbox is selected, this will display the Trial Phase dropdown list select the correct trial phase.
- **External Name** Type in the short name on the national OPCS list, or ‘No national regimen name’ if not included on list
- **Plan Group** – leave blank
- **Amendments Mandatory** check box should not be selected

#### Classification tab

- **Sex, and age** are *not applicable* for regimens, they should both be blank
- Check the relevant **disease site(s)** for the Regimen appear in the list. Add, modify or remove as appropriate. Major sites only e.g. breast lung.
- Check the ONLY **Cancer Category(s)** added are
  - NCRN / early phase trials / commercial trial
  - appropriate NRN name
  - OPCS codes.
 (Do **NOT** include adjuvant etc). Add, modify or remove as appropriate.
- **Cell categories** NONE should not be added

NB If Sarcoma is the diagnosis required for the regimen use disease site bone, soft tissue or other disease site depending on trial (but do not add cell categories).

#### Authors tab

Ensure that the principal investigator for the study is listed. There may be more than one if the trial is run on various sites. This is visible on the prescription. Use the standard format surname, first name and the hospital abbreviation (BHT, GWH, HWP, MKG, OUH, RBFT). Add, modify or remove as appropriate

#### Authorised Users Tab

If your name does not appear in this window you CAN NOT modify the regimen. Authorised users should always include. You, the Thames Valley Electronic Prescribing pharmacists and VMS CS, VMS CA, VMS KS from Varian.

#### Medical Mgmt Tab –

The only addition on this page should be under ‘Classification’; where Toxicity Grading NCI CTCAE (SI units) should be selected and appropriate BSA, GFR calculation as specified in the trial protocol [The default for Aria is Wright so if protocol specifies a specific calculation it must be added here, even it is the same as the default to ensure that the regimen remains correct even if the default for network is altered.]

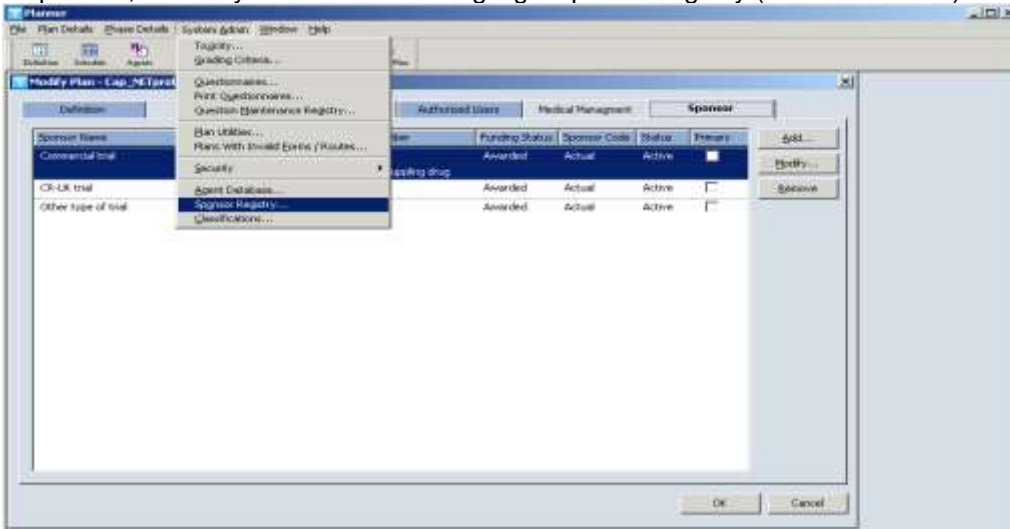
**Sponsors tab** (Only visible in Planner). Check all applicable entries have been selected. Add, modify or remove as appropriate from the drop down list. Use the table in appendix 2 when reading the protocol to confirm which sponsors (PI and phase information) are being added but should include

- EudraCT number and NIHR / TSC number (will need adding to the sponsor registry for each trial so it appears on the dropdown list as EudraCT no:)
- NCRN flag / BMRC flag / ECMC flag / CRUK flag (need selecting from the drop down)
- commercial / non-commercial (need selecting from the drop down)
- proof of concept / new technologies / gene therapy & vaccine / other (need selecting from the drop down)

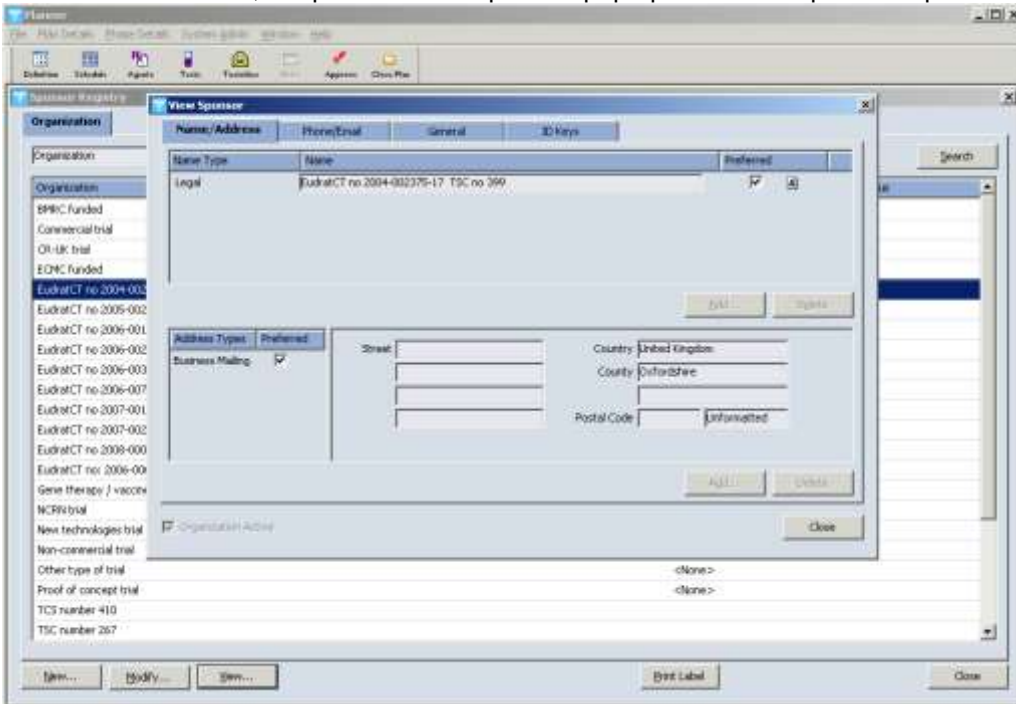
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## How to add information on the sponsor registry

In planner, select system admin then highlight sponsor registry (see screen shot)



Press the new button; to open the 'view sponsor' pop up box to set up a new sponsor



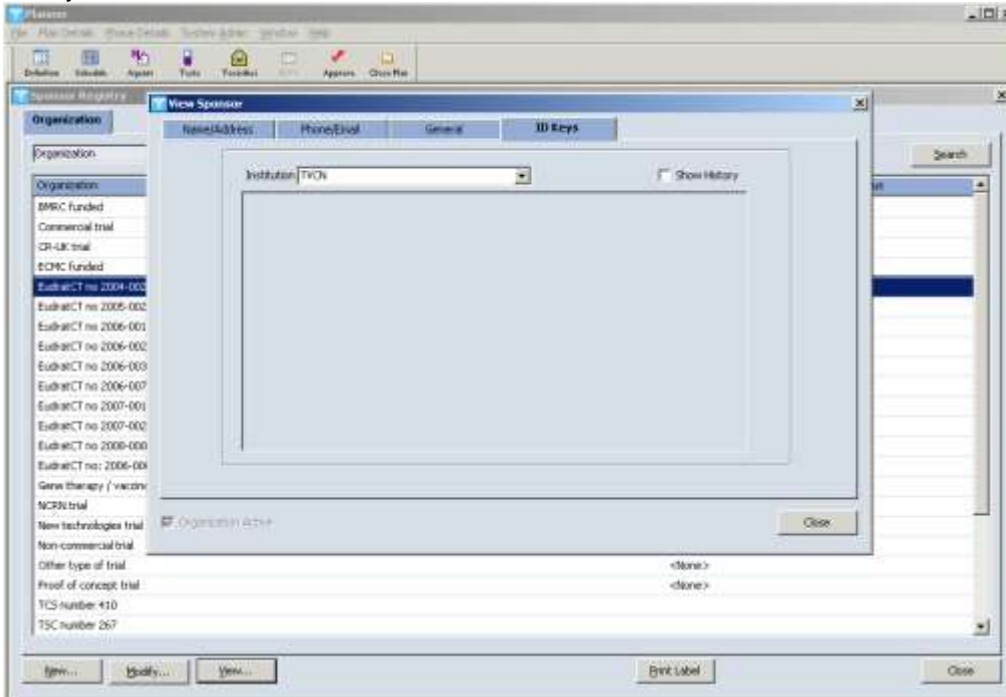
Type the name of the sponsor i.e EudraCT no: xxxx-xxxxxxx-xx NIHR / TSC no xxxx  
Leave the phone and mail page as per default settings



In the pop up leave the general tab as per default

The screenshot shows the 'View Sponsor' dialog box in the Clinical Trials.gov system. The dialog box is titled 'View Sponsor' and has tabs for 'Name/Address', 'Phone/Email', 'General', and 'Eligible'. The 'General' tab is selected. The main area shows a 'Classification' field with a dropdown menu. Below the field, there is a checkbox labeled 'Organization follows' and a 'Close' button. The background shows the 'Sponsor Registry' window with a list of organizations, including 'EudratCT no 2004-001' which is highlighted.

ID keys tab ensure default is TVCN



And click Close in the 'view sponsor' pop up window to save the information and then close to take you back to the sponsor tab in the modify plan window.

Click 'modify' to open the plan 'agenda Window' to the 'modify phase' window.

## MODIFY PHASE WINDOW

Populate the following

- **Phase** – leave as default - phase 1
- **Phase Name** – 20 character limit.
- **Purpose**- N/A leave blank
- **Service Type**, Inpatient, inpatient/outpatient or outpatient etc should be selected as relevant to the script
- **Modality**, select chemotherapy if straight chemo if chemo-radiation or other leave the box blank.
- **Toxicity Causes Required** this box should be left unchecked. [Checking the box means when grading a toxicity  $\geq 1$  in Manager, the user must enter the 'Toxicity Cause', prior to approving the toxicity assessment. The 'Cause Certainty' does not have to be completed, but is available if the client chooses to enter it the default setting will be to leave the box blank i.e. toxicity causes optional.]
- **Closed to Accrual** – Leave unchecked (Checking the box will stop the regimen being prescribed in Manager)
- **Schedule Type** – Cyclical is the one typically used for most chemotherapy. This indicates that treatment will occur repeatedly on a regular schedule. Linear – Negative Days is for BMT regimens ONLY. This allows the regimen to start on a negative day and work up to and past day 0 which is the day the BMT would take place on. (This is strictly for a one cycle event)
- **Cycle length** will set up the appropriate schedule in the Treatment Tab and in the Schedule Window in Manager as defined in the protocol
- **Number of Cycles** will set up the appropriate number of cycles in the Treatment Tab and in the Schedule Window in Manager as defined in the protocol
- **Max Drift (days)** leave as default 0 days
- **Description** – leave blank. Then **press OK** to save the information

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### Section 3- adding the study drugs to aria

New drugs are added to the system in the security module. Access to this module is limited to Cancer ICT at the IM&T and, the Thames Valley electronic prescribing pharmacists.

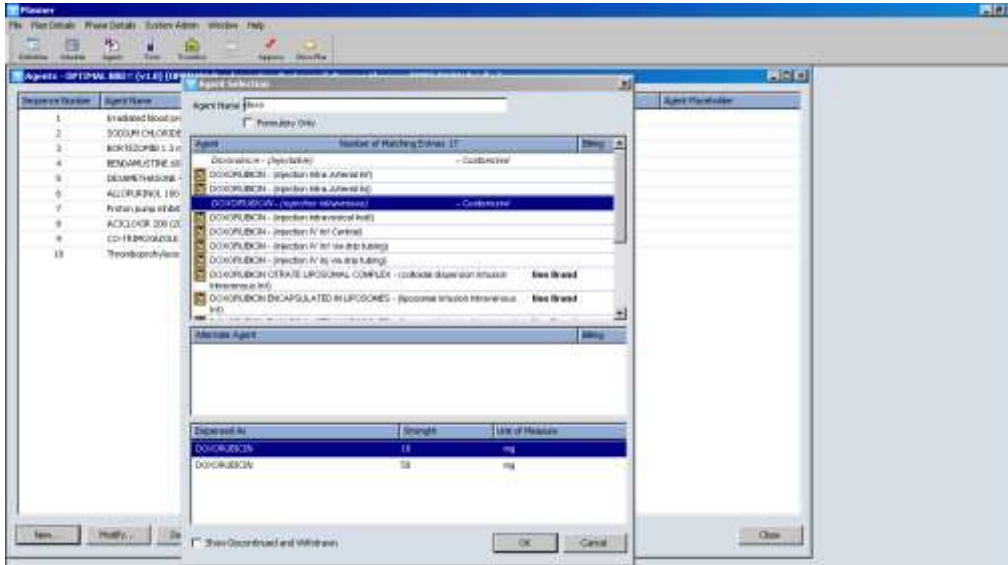
Once the drugs have been added in security they will be selectable **In PLANNER** as below (check formulary only box is ticked), ensure a strength is picked, this ensures the dose rounding or dose banding pulls through:

Fluorouracil bolus up to 750mg/m<sup>2</sup> pick 500mg strength and for infusions pick 1000mg strength

Cytarabine doses <400mg/m<sup>2</sup> pick 100mg strength doses >400mg/m<sup>2</sup> pick 1000mg strength

Methotrexate doses <300mg pick 5mg strength, 300-900mg pick 500mg strength, 900mg pick 5000mg strength

### AGENT WINDOW



**Add, removing or amending agents** In the lower tool bar click on agents. Taking you to the agent window. Add all the agents required.

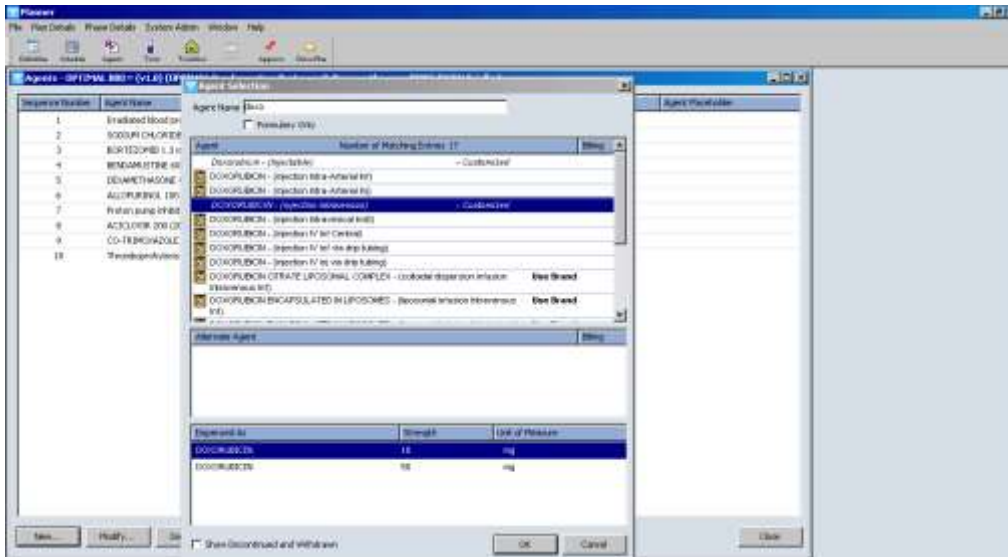
- Ensure that all of the regimen's drugs specified as per the Trial protocol are listed in the "Agents" window.
- Ensure that all of pre-meds, supportive care drugs and pre- and post- hydration are included. If you are unsure which supportive drugs to add to the regimen, please contact the PI and/or a senior pharmacist
- No anti-emetics should be attached to the regimen as they can be added from the support list in Manager.
- Ensure that all drugs are listed in the correct administration order and amend the sequence number if needed.
- If the regimen only contains drugs which do not contain an agent with a mg/m<sup>2</sup> or there are cycles that do not have a mg/m<sup>2</sup> agent scheduled dose add the agent BSA calculation and renal calculations for SACT 1mg/m<sup>2</sup> and schedule day 1 and tick the cyclical box (this will ensure height and weight are submitted to SACT each cycle).

NOTE; add agents where possible from the FDB database of agents (these are licensed agents shown on UPPER CASE) all categories with specific forms, routes and strengths. This ensures drug interaction checking occurs in Manager. Any new agents added via security to the formulary (lower case) drugs will NOT be included in interaction checking.

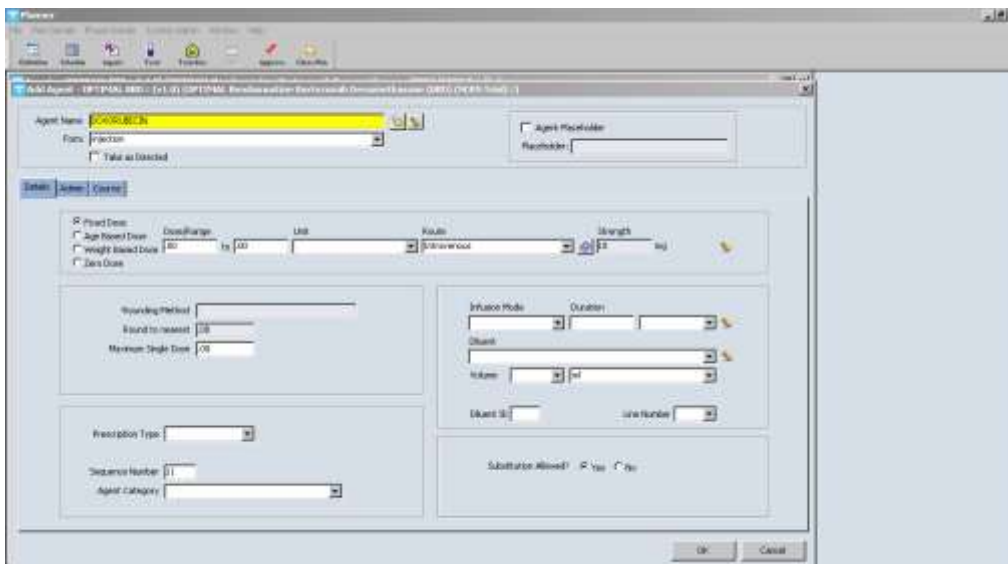
Select **new** on the 'agents window'. On the 'agent selection' window put the 1<sup>st</sup> few letters of a drug and then select from the available drug options. Select the agent which has strength and unit of measurement in the bottom section and select an appropriate agent, this ensures the appropriate dose banding or rounding is pulled through from security. For IMPs dose rounding / banding can only be used if it is stated in the trial protocol or has been confirmed with the trial office.

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Click **OK** to select that drug. This takes you back to the new / modify agent window and populates the top portion of the page.



**Details tab** fill out all relevant fields

Ensure the appropriate dose is in the **Dose/Range** field.

- The dose range boxes are for agents that are given at a flat dose i.e. trial drug in cohorts from 10-100mg. The second box is not functional for agents that require dose calculation.
- If AUC dosing for Carboplatin administration is required for calculating a dose, ensure that AUC is the unit of measure. Need to specify AUC CrCl or AUC EDTA, if either can be used you will need two regimens, a CrCl and an EDTA version.
- Age based dose is used for those regimens which use different doses for different age groups. Add the age range in months and dose for each age group. (Try to avoid using this as there are currently issues)
- Weight based dose is used for those regimens which use different doses for different weights. Add the weight range in kg and dose for each weight range.
- Zero dose allows a zero dose to be added with a unit, which allows the prescriber to set the dose. Useful for cohort studies.

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Ensure the appropriate rounding is selected from the **Rounding Method** drop-down list. If the strength box is completed it will default to **Network dose rounding / dose banding**. For IMPs dose rounding /banding can only be used if it is stated in the trial protocol or has been confirmed with the trial office. Use or if not applicable limit to;

- **None** – You can leave the field blank, will default to TV dose banding
- **Up if halfway** - if a dose is to be rounded to the nearest 10 mg and the dose is calculated in the system to 225 the system would automatically round up to 230.
- **Dose Banded** –dose bands can be specified. Instead of rounding to a specified number, a user can define a specific dose to be administered for a defined dose range which would be calculated based upon BSA, mg/kg or AUC (use dose banding tables as per protocols.) Ensure the Minimum Dose range is larger than the previous Maximum Dose range. This value needs to be entered to the 4th decimal place (.0001) larger, rather than to the nearest 1.0. Based upon the number of decimals calculated within the computer there may be a missed dose if there is no decimal place indicated in the dose banding.

**Network level Dose rounding / dose banding** – has been set up in security for each drug as agreed in the Network. This is linked by ensuring the form route and strength in the agent (planner) are the same as they are set up in the agent formulary (security). To apply this click on the book icon at the end of the dose range field and pick the appropriate strength – this will automatically link the dose rounding /banding to security for this regimen. The advantage of this is that standardised dose rounding / banding is used for all standard drugs and can be amended if necessary without having to amend each regimen.

However if for specific regimens the standard dose rounding or banding is not appropriate e.g. capecitabine in some trial protocols is different from the network standard this can be inserted directly into the agent in the regimen and overrides the standard from security.

- Check the **Max. Single Dose** is filled in as applicable. A way of capping or limiting the amount of a dose for a specific agent per day. This is applied for calculated doses ONLY.

Ensure the correct **Prescription Type** is selected - (two main sorts for the TV)

- **Internal**- The agent will be administered within the clinic and dose recordings will be associated with the agent in Manager in the Daily Administration tab in the Drug Administration window. ie something ordered from the aseptic unit.
- **Pickup - Internal**- The intention is to have the prescription picked up within the clinic or hospital. This could be through either the chemo pharmacy or at an internal retail pharmacy dependent on where the local printing is set up.
- **Pick up – external** - is only used for Intrathecal injections.

Ensure the **sequence number** is filled in, organizes the sort order of the agents that displays and prints in the Prescription and the Drug Admin – Daily Administration tab, in Manager.

- The agents should be listed based on the order in which medications are to be administered.
- When an agent is added the seq# defaults to the next consecutive number.
- No two drugs should have the same sequence number unless they need to be added to the same diluent e.g. for IFOSFAMIDE /mesna in the same bag they can have the same diluent ID (see below). This will also add the same admin instructions to both agents.

Ensure the correct **Infusion mode** is selected, Displays in Manager as part of the course description. You are not required to complete the infusion mode, if the drop-down list does not match what is required by the regimen. The information can be put in the admin notes. **Limit choices to** - none, bolus or continuous

Ensure the appropriate **Diluent** is selected from the diluent drop-down list and appropriate volume and unit of measure (as per national dose specifications unless not allowed in trial protocol).

- Diluent ID field- If the same Diluent ID number is entered for another agent, both agents are considered mixed in the same diluent fluid or bag.
- Indicate appropriate Line # if required (maybe used in haem protocols to specify lines for cyclosporin) If there are multiple infusion lines for treatment, the Line # will indicate a specific agent to be administered through the identified line.
- Default Leave the Substitutions Allowed default as Yes. (Substitution is usually used for clinical trials if a specific brand is required. If No is selected this does not stop the user in Manager changing it, but it does flag the agent as NO SUBSTITUTIONS ALLOWED on the prescription)

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**General things in the agents list;**

All prescriptions with IV agents need a fluid bag for flushing added eg: 500ml sodium chloride 0.9% iv infusion added with the corresponding admin note. 0.9% sodium chloride infusion. To be used as a fast running drip with chemotherapy or a flush between infusion chemotherapy where needed. Volume as required. And scheduled accordingly on all days

All prescriptions with continuous infusors need the following added 5-10ml sodium chloride 0.9% iv injection and 5-10ml hepsal iv injection added with the corresponding note and scheduled accordingly As a disconnection flush

All infusors need the admin notes adding to state for aseptics that an infusor device is to be used, and how long the device should deliver the drug over Eg To be administered in an elastomeric pump over 46 hours

Carboplatin doses carboplatin regimens need to be set up as EDTA or CrCl versions in the title.

**Admin Tab-** add the admin instructions needed for the drug you are adding eg 10mins after eating, The admin instructions will appear in Manager in a notepad icon with the agent and will be printed on the Rx from Manager if selected to print Admin Instructions. Note - Keep as short possible..

The following standard instructions should be used for IMPs

For Intravenous IMP medications

This is a clinical trial drug to be manufactured as an Investigational Medicinal Product (IMP)

For oral IMP medications

Use Clinical trial Investigational Medicinal Product (IMP) stock.

**Course tab** Default this will usually be blank as the supportive medicines are added as support regimens. [allows agents to be listed with a specific frequency and duration. These agents are not required by the regimen but may be used as support medications.] However unscheduled agents which may be required by some groups of patients may be added here.

- Click ok to save the drug
- Repeat for each agent required.

**Populate the schedule** - In the lower icon tool bar click on schedule.

- **Starting On** - this field should always be blank, unless drugs are required on specific days eg co-trimoxazole M, W, F
- **View** 'cycle day' should always be selected
- **Maintain** 'schedule' should always be selected

To schedule each drug highlight the drug line and day box you want to schedule press '**add**' in the new window fill out the relevant details. You can schedule a drug as '**Cyclical**' to appear in the same way every cycle or '**Non-Cyclical**' to happen only on specified cycle numbers. Select the correct frequency and duration.

For agents that require some cyclical and some noncyclical scheduling eg day 1 every cycle, day 8 cycle 3 only add the dose that is required cyclically (day 1) as non-cyclical but for every cycle and the day 8 as non-cyclical cycle 3 only.

Each day a drug is needed from the aseptic unit needs to go in as a separate day on the schedule e.g.

1. A four day infusion that needs 4 x 24 hour bags dispensing needs to be scheduled as once only for one day on days 1, 2, 3 and 4.
2. A four day infusion that needs 1 x infusor only needs to be scheduled as once only for 1 dose. The admin instruction and information on the agent's page will state the infusor details. This will also make the event appear once only in the scheduler in manager and not every day for the duration of the infusor.
3. Tablets that are given bd for x days at a time as a single dispensing would be scheduled to start on day 1 bd for x days i.e. dispense all days on day 1.

To amend a scheduled event / drug highlight the scheduled event and click the modify button. This allows the agent to appear in Manager on the appropriate cycle/day and for the appropriate duration for the regimen. NB the List button on the right hand side will show all agents that have been scheduled and how they have been scheduled (press All at the top)

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Checking adding, removing or amending tests - for information only

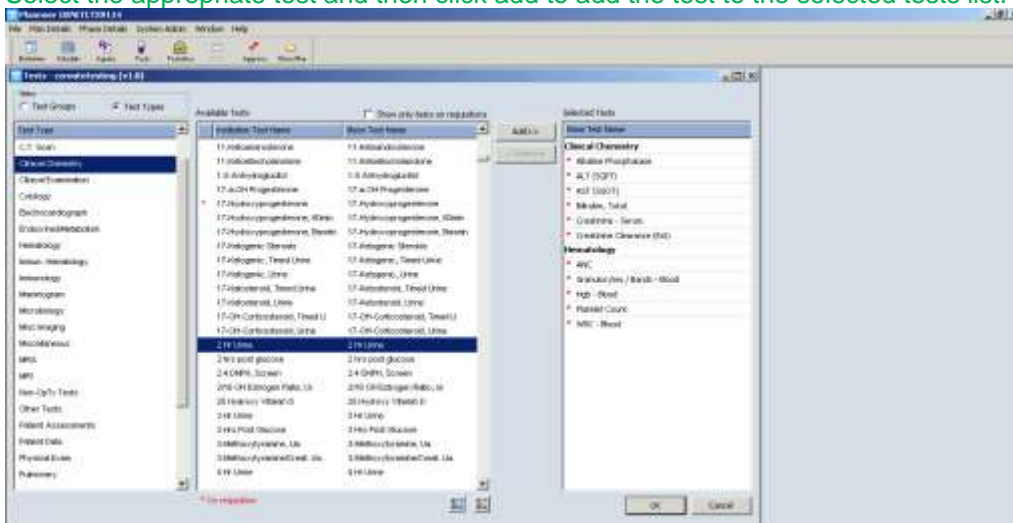
### TESTS DO NOT NEED TO BE ADDED, AMENDED OR CHECKED

Select the Tests icon in the toolbar to add, modify or remove these as necessary. DO NOT schedule the tests leave attached, but unscheduled. The list of tests in 'tests and toxicity blank' are the minimum as put in for all network protocols. Support regimens will need BSA, Height and Weight test added.

See below for screen shots

Open up the tests window

Click ok or the X close icon twice





### Checking Adding, removing or amending toxicities

Select the Toxicities icon in the toolbar to add, modify or remove these as necessary. DO NOT schedule the tests leave attached, but unscheduled. The list of toxicities in 'tests and toxicity blank' are the minimum as put in for all network protocols. Do not list every toxicity as specified in the protocol if there are a few major toxicities these can be added i.e. those toxicities you would want recorded when the patient is seen.

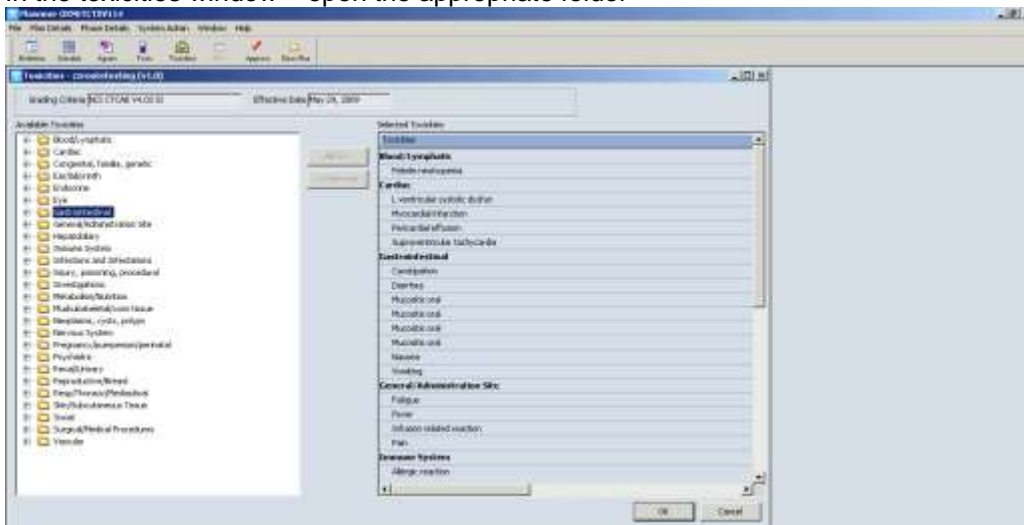
- In manager this creates a subset of toxicities from the standard main grading scheme that was attached to the regimen in the Med Management window. This allows the user to grade the appropriate toxicities without having to review all the toxicities associated with the selected grading scheme
- Ensures consistent outcomes since users would be grading the same toxicities for the same regimens.

### See below for screen shots

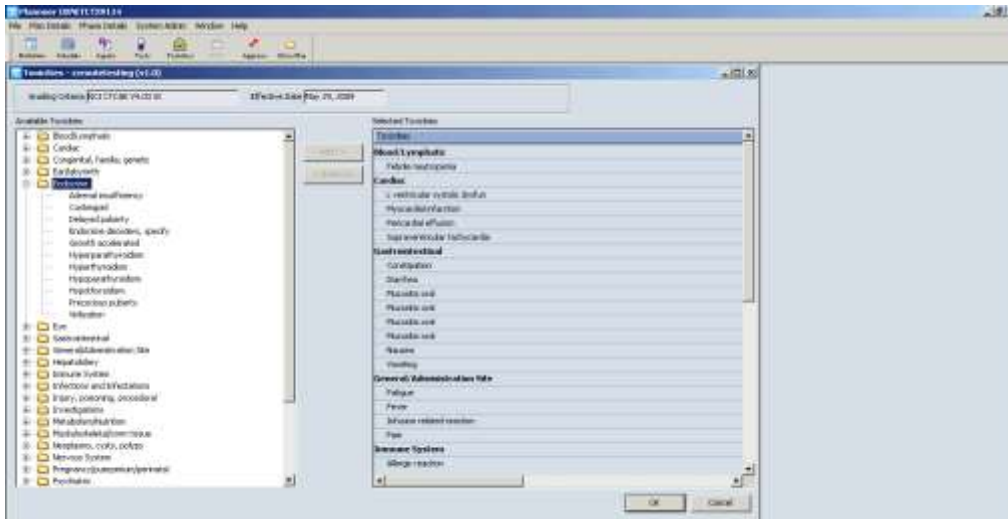
Open up the toxicity window



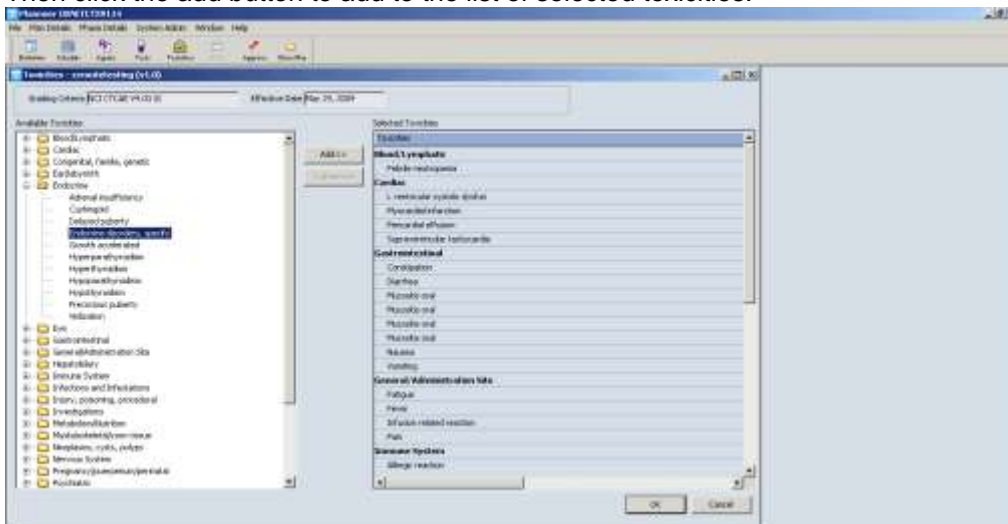
In the toxicities window – open the appropriate folder



Highlight the appropriate toxicity



Then click the add button to add to the list of selected toxicities.



## PLAN SUMMARY WINDOW

**Populate the Plan Details-Summary** Select Plan Details and Summary from the upper tool bar to open the Plan Summary window. The “Plan Summary” window shows information about the trial in 2 of the drop down fields under “Overview” and “Chemo Order Instructions” all other drop downs should be blank. In manager it will show as an Information Notepad after you select the Regimen and before you click the ADD button to actually apply the regimen to a patient.

## OVERVIEW

Under ‘**overview**’ ensure the following are present as required for your trial e.g.

- Trial name and version, EudraCT number
- **Indication:**
- **Brief drug regimen** ie accurate information on this arm, Dose to be entered as per cohort randomisation Cycle length and number of cycles.
- **NOTES;** brief information on which regimen to pick next or alternative arms / regimen e.g. chose regimen name ABCD4 –arm 1 or ABCD4- arm 2. If ABCD4-arm 2 is chosen use ABCD4-arm2 for 2 cycles then ABCD- arm2a for 3 cycles then ABCD4-arm b2 for 3 cycles and stop. Discontinuous dosing 7 and 21 days see separate regimens etc

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## CHEMO ORDER INSTRUCTIONS

Under '**Chemo Order instructions**' ensure the following are present as required for your trial e.g.

- ANTIEMETIC POLICY: XXXXXX emetic
- CONCURRENT MEDICATION – refer to the trial protocol section. ....
- INVESTIGATIONS – refer to the trial protocol. See Inclusion Criteria and Section .....
- DOSE MODIFICATIONS – refer to the trial protocol section.....

Then press OK to save

### Approve for testing-

This allows the user to test the regimen on an 'Error/Test Patient' in Manager. The regimen can either be approved through a) the Plan Details drop-down list or b) using the Approve Check box on the icon toolbar. Using either of these routes click **Analyze** if any messages come up once the analyze button is selected, read and adjust as necessary. Click on '**approve for testing**' the regimen will appear with a red asterisk beside the name in Manager under the appropriate disease site folder and can be used on Error/Test patients and further amended as necessary.

### Section 4- adding a dummy patient

You need to add a dummy patient in the manager module on which to prescribe the regimens you have added to see how it appears in manager and for the PI to do their check.

Why do we need the dummy patients?

- To ensure that agents are displayed correctly for every treatment day and for each cycle and check EACH cycle if the regimen contains non-cyclically scheduled drugs.
- To ensure that drugs are listed in the correct administration order for each treatment day and the administration instructions attached to each drug are accurate and relevant.
- To check the information in the "Plan Summary" notepad is correct and any amendments made in Planner are implemented

Follow the instructions in dummy script writing SOP for adding dummy patients to the live manager in aria. Ensure you are logged in to live manager using your user admin ID, from the TVCN using your password and login to TVCN.

### Section 5- pharmacy checking a trial

Once the above steps have been carried out, use the checklist for trial regimens to sign off the 1<sup>st</sup> pharmacist check.

Each arm needs a new form completing.

The 2<sup>nd</sup> pharmacist check should be done (carried out using a new blank checklist for each trial regimen arm) AFTER the PI has completed and returned their check.

### Section 6- PI check list

Once the 1<sup>st</sup> pharmacist check has been completed, and the dummy patient prescribed, and the regimen discontinued. Send the PI for the trial a word copy of the form 'Clinician Check List for chemotherapy regimens in Aria Med Onc', one for each regimen / arm in Aria, with the details in the top section completed by the pharmacists, for the PI to sign off each arm of the trial regimen as appropriate according to the trial protocol, and request each checklist is returned to pharmacy.

### Section 7- Trial Updates

When there is an update to a regimen protocol,, if there is no change to drugs set up in Aria amend the information on the regimen version in the regimen summary – overview. The can be done without clicking the amend button and therefore creating a new Aria version of the regimen- check that the section numbers have not altered also. Once this has been altered click ok and complete the AMENDMENTS section of the summary by adding a note of amendments made, with name and date in the amendments section.

If there are changes that require changes to the drugs then choose the regimen you wish to update and click amend. This creates a pending copy Aria regimen with the Aria version number increased by 1. Make the alterations that are required, you will need to re-enter the PI details in author. Once amendments are completed approve the regimen for testing, and then prescribe the updated regimen in manager using the dummy patient that was set up for the original version. Once this has been checked and 2<sup>nd</sup> pharmacist checked, approve the regimen for use.

#### NOTE:

Any changes you make in the regimen summary (overview and chemo order instructions) will automatically be seen in manager – even if you have amended the regimen and the new version is still in pending or in testing

### STORAGE

This SOP is to be stored electronically by the Thames Valley Electronic Prescribing pharmacists

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