**Standard Operating Procedure**

# Production of Chemotherapy Protocols

**(SOP:CH001)**

## 1. Objective

1.1 The purpose of this standard operating procedure (SOP) is to describe the procedure to be followed when writing, checking and maintaining the library of chemotherapy protocols that are used by the former Central South Coast Cancer Network acute Trusts (Trusts who are part of the ARIA electronic prescribing system project).

## 2. Scope

2.1 This SOP refers to non-trial chemotherapy protocol production and validation.

2.2 This SOP also describes the identification of clinical trial protocols for entry onto the ARIA electronic prescribing system.

## 3. Chemotherapy Protocols

### 3.1 Responsibility

3.1.1 The lead ARIA pharmacist will be responsible for co-ordinating the production of the chemotherapy protocols.

3.1.2 The lead ARIA pharmacist will be responsible for maintaining the library of approved chemotherapy protocols.

3.1.3 It is the responsibility of each individual to ensure that they are referring to the most recent version of the protocol.

3.1.4 Protocols will be written and approved by an oncology pharmacist and consultants from any one of the participating Trusts. It is the responsibility of each Trust to ensure the documents are appropriate for use in their organisation. No liability can be held by those writing and approving the documents for any errors that are contained in the documents.

3.1.5 The protocols are only one source of information. They must be used in conjunction with the relevant Summary of Product Characteristics and published information.

### 3.2. Method

3.2.1 All requests for a chemotherapy protocol must be made to the lead ARIA pharmacist.

3.2.2 All protocols will be written by an oncology pharmacist / pharmacy technician from one of the participating hospitals using the standard template. Where this individual is not a pharmacist, the protocol must be checked by such a professional before the consultation begins.

3.2.3 Once written and checked the protocol must be sent for consultation. This document will be sent by the lead ARIA pharmacist or system manager to the ARIA user group who are responsible for ensuring it is sent to relevant colleagues in their organisation. The consultation must last for a minimum of two weeks and a maximum of four weeks. All comments received after the end date may not be acted upon unless this would pose a serious clinical risk.

3.2.4 All comments received must be documented and kept by the ARIA pharmacist / system manager.

3.2.5 At the end of the consultation all protocols will be updated in line with the comments received. The comments and updated protocols will be approved by a consultant oncologist / haematologist with an interest in the disease area.

3.2.6 All chemotherapy protocols will be password protected and stored electronically by the ARIA pharmacist. Copies will be available on a designated website.

**4. Clinical Trials**

**4.1 Responsibility**

4.1.1 Each acute Trust is responsible for informing the ARIA electronic prescribing system manager of trials they wish to be placed on the system and must provide up to date copies of the protocol. It is the continuing responsibility of the acute Trusts to inform the ARIA electronic prescribing system manager of updates to these protocols.

4.1.2 The Principal Investigator for each Trust is responsible for ensuring the regimen on ARIA is suitable for use at their site. This applies irrespective of who has approved (released) the protocol on ARIA.

**4.2 Method**

4.2.1 The most recent version of the clinical trial protocol, approved for use at the Trust, will be used to build the chemotherapy regimen on the ARIA electronic prescribing system.

4.2.1 The regimen on ARIA will be built by a suitably trained pharmacy technician or pharmacist. The build will be checked by a pharmacist with GCP training. A PI will validate the test prescriptions before the regimen is released.

## DOCUMENT CONTROL

| Version Number | Description of Change | Amended By | Date |
|---|---|---|---|
| 1.3 | References to CSCCN removed<br>Responsibilities updated<br>Time frames clarified | Dr Deborah Wright<br>Principal Pharmacist | 16/05/18 |
| 1.2 | Document control added | Dr Deborah Wright<br>CSCCN Lead Pharmacist | 09/09/10 |
| 1.1 | Section 4 added on clinical trials | Dr Deborah Wright<br>CSCCN Lead Pharmacist | 29/07/10 |