Pharmacy Cancer Clinical Trial Initiation Checklist Template

**Verison 1**

**Approved: 06/12/2024 by NCCP Cancer Clinical Trials Pharmacist Subgroup**

* **This checklist in not intended to be used with Advanced Therapy Medicinal Products (ATMPs).**
* **To note, this template is intended to be a guide only; the fields included in this form are not mandatory or exhaustive. Some fields will not be relevant to all cancer clinical trials.**
* **This checklist may be adapted for use at each site as deemed applicable to local practice.**

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| **General Information (Refer to feasibility checklist for further general trial information)** | | | | | |
| Study Protocol Name: | ABC | | | | |
| Protocol Number at SIV: | 123 | SIV Date: | |  | |
| **Clinical Trial Documentation at SIV date** | | | **Version No.** | | **Date of Version** |
| Electronic site file | Yes No Received | | | | |
| Pharmacy Folder (s) incl. IB / SmPC etc. | Received | |  | |  |
| Pharmacy / Drug Preparation Manual | Received N/A | |  | |  |
| IXRS Manual | Received N/A | |  | |  |
| Current Protocol Version | Received | |  | |  |
| Sample IMP Labels | Received | |  | |  |
| HPRA approval | Received | |  | |  |
| NREC approval | Received | |  | |  |
| CRA Contact details |  | | | | |

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| **Investigational Medicinal Product (IMP) Details** | | | | | | |
|  | **Medications** | **Route of Admin** | **Dosage Form / strength** | **Storage Conditions**  **(Temp/light)** | **Quantity in Initial shipment** | **Supply route (Local / Central)** |
| A |  |  |  |  |  |  |
| B |  |  |  |  |  |  |
| C |  |  |  |  |  |  |

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| **Supply & Ordering** | |
| Initial shipment | Triggered by:  SIV Site Activation First patient screened |
| Documents to be received with IMP | Certificate of analysis QP cert/Batch release SPC  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Reordering process | Manual Form required Lead time\_\_\_\_\_\_\_\_\_\_\_\_  Online via IXRS  Automatic |
| Is temperature monitoring required in transit? | Yes No |
| Are temperature loggers to be retained? | Yes No |
| Are shipping cartons to be recovered by courier? | Yes No  Process for recovery: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Confirmation of receipt process | Manual  Online via IXRS Form required  Automatic |

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| **Accountability** | |
| Accountability of IMP | Paper log Electronic Both |
| Can in-house accountability logs be used? | Yes No |

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| **Temperature Monitoring** | | |
| Clarify minimum threshold / interval for alarms |  | |
| Can temperature results be rounded? | As per local policy As per clinical trial\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No | |
| Process for reporting a temperature excursion | Electronic form Online portal | |
| **Waste disposal** | | |
| Is there a requirement to retain outer boxes of any presentation of IMP?  e.g. vial outers / labels after prep in ACU, pre-filled syringes | | Yes No |
| Can local policy be followed with respect to waste disposal? | | Yes No |

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| **Clinical queries** | |
| Drug / kit allocation if trial uses individually numbered stock units | Pharmacy staff Research Nurse  Other staff\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A |
| Dose calculation information | Is there a maximum dose or weight specified for any agents in the trial? |
| Calculation of doses:  Weight should be rounded before dose calculation  Dose should be rounded after calculation based on unrounded weight |
| Timing and frequency of weight measurement:  As per local policy As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Recalculation of doses for weight changes during treatment:  As per local policy As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| BSA based dosing – Formula | CRA informed of local practice |
| Creatinine clearance - Formula | CRA informed of local practice |
| Can calculated doses be rounded to measureable volumes? | No  As per local policy  As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Can SOC treatments be dose banded as per local / national policy? | Yes No |
| Are there any particular supportive care requirements? Or non-routine test results which need to be reviewed? |  |

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| **Aseptic Compounding Unit Details - Table may need to be completed for each drug in clinical trial)** | |
| Stability / storage when reconstituted? |  |
| Can CSTD be used for prep / admin of IMP? | Yes No |
| Are any special consumables needed for preparation? | Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Supplied To be ordered locally Not required |
| Is any light protection required during preparation? | Yes No |
| New drug set up required? If Yes has the NCIS team been informed? | Yes No  NCIS Informed |
| Are specific new drug forms required by site ACU | Yes No |
| ACU Specific guide ( may be incorporated into local pharmacy dispensing guide) | Required Not required |

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| **Administration** | | |
| Is any filter required for administration? | | Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Supplied To be ordered locally  No |
| Is any specific giving set required for administration? | | Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Supplied To be ordered locally |
| Is light protection required for administration? | | Light protective giving set: YesNo  Line covering: YesNo |
| Is any specific patient monitoring during or post infusion required? | |  |
| **General** | | | |
| Pharmacy Budget | Drafted Agreed with sponsor N/A | | |
| Sample dispensing labels / worksheet if applicable | Not required Completed | | |
| Local Prescriptions | Not required Completed | | |
| IXRS Passwords | Not required Received | | |
| Material Safety Data Sheet | Not required Received | | |
| Documents required as per local site policies (if applicable) | In-house accountability logs  Local Pharmacy disp guide (May include ACU guide also)  ACU training log  Pharmacy training log  SIV training log  SIV delegation log | | |

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| **Items for follow up** |
| Documents sent to sponsor  **Calibration certificates  Waste disposal SOPs  IMP Management SOPs**  Note to file(s) sent to sponsor  **Temp monitoring  GCP/CVs  CSTDs Superseded protocols / IBs** |
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