This form should be completed as fully as possible by the Sponsor at the point of initial contact with Pharmacy regarding the trial. If Imperial College Healthcare NHS Trust (ICHNT) is the Sponsor, Pharmacy should liaise with the Investigator, Study Nurse or Coordinator to complete this form.

**Trial Information**

|  |  |
| --- | --- |
| Date |       |
| Full Trial Title |       |
| Short Title/Acronym |       |
| Protocol Number |       |
| EudraCT Number |       |
| Sponsor |       |
| Protocol Version Number Provided |       |
| Does the study have NIHR-badging?(**YES / NO / APPLICATION PENDING**)Please inform Pharmacy if at any time you gain NIHR-badging |       |
| IF YES: CRN Number |       |
| National Research Ethics Service Number (if available) |       |
| ICHT R&D (JRCO) Reference (if available) |       |
| Trial Monitor Details | Organisation |       |
| Contact Name |       |
| Telephone Number |       |
| Email Address |       |
| ICHT Principal Investigator |       |
| ICHT Trial Nurse/Coordinator |       |
| ICHT Site(s) to be opened(mark **Y** or **Recruitment Only** where applicable) | Charing Cross |       |
| Hammersmith |       |
| St Marys |       |
| Western Eye |       |
| Predicted number of patients at each ICHT Site | Charing Cross |       |
| Hammersmith |       |
| St Marys |       |
| Western Eye |       |
| Recruitment period |       |
| Post-trial arrangements (**e.g., no post-trial arrangement, compassionate use program, extension study, etc.**) |       |
| Expected ‘First Patient First Visit’ |       |
| **PHARMACY USE ONLY** | Confirmed with PI / Amended FPFV       |

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| Product name(s), strength(s) and formulation(s) (specify whether oral, injection, etc)  |       |
| IF INJECTION: Does Pharmacy need to prepare the product(s) aseptically? (**Y / N / UNKNOWN**) |       |
| IF YES: Explain why this is necessary (e.g., safety, to maintain the blind, etc.) |       |
| Is the product(s) an **IMP**(s) or **nIMP**(s)? |       |
| Source of product supply (e.g., **free of charge from Sponsor, local hospital supply**, etc,) |       |
| Is the product(s) hazardous? (**Y/N**) |       |
| IF YES: Describe (e.g., **cytotoxic, teratogenic, mutagenic, gene therapy etc**.)  |       |
| Method of reconstitution (if product is not in a form ready for administration, provide details of diluents, container, equipment to be used and MSDS information) |       |
| Stability of product(s) after reconstitution/preparation |       |
| Source of supply of Pharmacy consumables/equipment (e.g., **provided by Sponsor, local hospital supply, etc**.) |       |
| Pharmacy involvement in blinding/unblinding process |       |
| Will IXRS be used for dispensing by Pharmacy Staff? (**Y/N**) |       |
| Process for product receipt and ordering (include details of how initial shipment is triggered) |       |

**Product Information**

**Dosing Information**

|  |  |
| --- | --- |
| Dose-banding criteria (**oncology trials only** – specify whether dose-banding can be applied. If so, give details) |       |
| Equations for calculating specific parameters, such as BSA or CrCl (**eg, calculate in-line with local practice, or use a specific equation**) |       |

|  |  |
| --- | --- |
| Product storage requirements (temperature conditions, etc.) |       |
| How much stock is Pharmacy expected to hold? |       |
| Product dimensions |       |
| Will dispensing be required outside normal working hours (0900-1700 Mon-Fri)? (**YES / NO**) |       |
| Intended destruction of Product? (mark **Y** where applicable) | Collected from ICHT by Sponsor (Pharmacy preference) |       |
| Destroyed on site by ICHT staff(charge applies to this service) |       |
| State the Standard of Care (SOC) for the intended study population |       |

**Ordering, Storage and Destruction**

Once completed this form should be emailed to the Pharmacy Trials Teams at the relevant sites.

Pharmacy may require up to **2 weeks** set-up period following the site initiation visit and receipt of necessary documentation.

|  |  |  |  |
| --- | --- | --- | --- |
| **Charing Cross Hospital** | Gareth Barker | Gareth.Barker@imperial.nhs.uk | 020 331 30382 |
| Andrea Davis-Cook | Andrea.Davis-Cook@imperial.nhs.uk | 020 331 11834 |
| **Hammersmith Hospital** | Regina Storch | Regina.Storch@imperial.nhs.uk | 020 331 34333 |
| Sharon Rennie | Sharon.Rennie@imperial.nhs.uk | 020 331 32685 |
| Ilyas Ali | Ilyas.Ali2@imperial.nhs.uk | 020 331 34333 |
| **St Marys Hospital /****Western Eye Hospital** | Severine Rey | Severine.Rey@imperial.nhs.uk | 020 331 27643 |
| Chi-Man Wong | Chi-Man.Wong@imperial.nhs.uk  | 020 331 25165 |

**Please note: For all oncology and haematology studies, this form must also be sent to the Onc/Haem Clinical Trials Pharmacist:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Oncology and Haematology**  | Annette Musallam | Annette.Musallam@imperial.nhs.uk | 020 331 34711 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Clinical Trials Lead Pharmacist**  | Victoria Latham | Victoria.Latham@imperial.nhs.uk  | 020 331 34350 |
| **Deputy Chief Pharmacist** | David Leonard | David.Leonard@imperial.nhs.uk |  |