**Study Start-Up Checklist**

|  |  |
| --- | --- |
| **Protocol Number** |  |
| **Protocol Name** |  |
| **Sponsor** |  |
| **Principal Investigator** |  |
| **Trial Team** |  |

**Feasibility received**

|  |  |  |
| --- | --- | --- |
| **Action** | **Staff responsible** | **Complete** |
| Unit approached for expression of interest in study | Sponsor, PI, Feasibility Co-ordinator |  |
| Confidentiality agreement (CDA) institutionally reviewed and signed off | PI, Institution counsel, Sponsor,  Trial Unit, Satellite Sites,  Feasibility Co-ordinator |  |
| Protocol or synopsis received and distributed to PI and Trial Unit, Satellite Sites for review | Feasibility Co-ordinator |  |
| Feasibility questionnaire completed and sent to sponsor | PI, PS Trial Co-ordinator,  SS Trial Co-ordinator,  Feasibility Co-ordinator |  |
| Complete New Trial Assessment Form, including budget considerations | PI, PS Trial Co-ordinator,  SS Trial Co-ordinator,  Feasibility Co-ordinator |  |

**Site Selection Visit (SSV) Preparation**

|  |  |  |
| --- | --- | --- |
| **Action** | **Staff responsible** | **Complete** |
| Co-ordinate meeting date and time for SSV | Feasibility Co-ordinator, Sponsor |  |
| Provide SiteDocs access and manual to sponsor for access to reference ranges and SOPs from all sites | Feasibility Co-ordinator,  SS Co-ordinator, |  |
| Provide site qualification documents to sponsor (Site Profile, PI CV & GCP, EMR qualification form) | Feasibility Co-ordinator,  SS Co-ordinator, |  |
| Provide SOPs for sponsor to review and acknowledge | Feasibility Co-ordinator,  SS Co-ordinator, |  |
| Review protocol and prepare SSV questions for sponsor. | PI, Trial Co-ordinator, SS Co-ordinator, Feasibility Co-ordinator, Sponsor |  |

**SSV**

|  |  |  |
| --- | --- | --- |
| **Action** | **Staff responsible** | **Complete** |
| Facilities site qualification tour | Feasibility Co-ordinator, Sponsor |  |
| 30 min discussion with PI | PI, Trial Co-ordinator, SS Co-ordinator, Feasibility Co-ordinator, Sponsor |  |
| 30 min logistics review with Trial team | Trial Co-ordinator, SS Co-ordinator, Feasibility Co-ordinator, Sponsor |  |
| Write to sponsor after SSV to communicate timelines for site endorsement | Feasibility Co-ordinator |  |

**Internal submission presentation**

|  |  |  |
| --- | --- | --- |
| **Action** | **Staff responsible** | **Complete** |
| Arrange for trial to be presented to disease group | PI |  |
| Complete Trial Presentation Form | PI, PS and SS Trial Unit, Feasibility Co-ordinator |  |
| Disease group endorsement | PI, PS and SS Trial Unit, Disease group members |  |
| Accept / decline trial and set timelines | PI, PS and SS Trial Unit, Feasibility Co-ordinator |  |
| Written acknowledgement of outcome – whether to accept or decline | PI, Feasibility Co-ordinator |  |

**Site selection**

|  |  |  |
| --- | --- | --- |
| **Action** | **Staff responsible** | **Complete** |
| Sponsor to formally accept site for trial and satellite sites for teletrial participation | Sponsor |  |
| Obtain documents from sponsor: final protocol, customized PICFs, pharmacy manual, lab manual | PI, PS and SS Trial Unit, Feasibility Co-ordinator, Sponsor |  |
| Review and finalise NTAF and above standard of care budget assessment | PI, PS and SS Trial Unit, Feasibility Co-ordinator |  |
| Prepare Supervision Plan | PI, PS and SS Trial Unit, Sponsor |  |