## **Shared Care Centre (POSCU) Activation Process**

The R&D department should The local CLRN will then grant The Lead CLRN will then issue a letter of access to the RDMIS CSP Module distribute this approval for the trial to take to the R&D departments at each documentation to POSCU. They will then be able to place at the POSCU. A copy local CLRN for all of this should to be sent to access all relevant trial POSCUs involved. the PTC. documentation including SSIF. The Trial Sponsor will send a Each pharmacy at a POSCU will receive a Pharmacy Shared Care Centre Site File (mini File from the Trial Sponsor and this will be followed up ISF) to the Clinical Collaborator at with a full initiation from the Trial Sponsor in the form of each POSCU. a meeting or telephone conference. Once this has taken place the Trial Sponsor will notify the PTC that Pharmacy initiation is complete. The PTC must then confirm that the following are in place: written agreement between PTC and POSCU, copy of R&D approval letter from POSCU. site signature and delegation log from POSCU and is signed off by the PI at the PTC, CV and evidence of GCP training form Clinical Collaborator at the POSCU, pharmacy initiation at the POSCU has been performed by the Trial Sponsor confirmation that Mini ISF and Pharmacy File has been received at the POSCU. Copies of all of these documents will be held in the POSCU file at the PTC. Once all of the documentation is in place the PTC are required to notify the POSCU that they are now 'active' and may participate in the trial as per their delegated duties. The PTC is then required to fax completed 'Shared Care Centre Activation Form' to the Trial Sponsor. The PTC must retain a copy of the 'Shared Care Centre Activation Form' and acknowledgement of receipt of this form in the ISF. TRIAL OPEN TO RECRUITMENT AT POSCU

A Trust to Trust contract is drawn up between the PTC and the POSCU agreeing roles and responsibilities for conducting clinical trial activity within the POSCU. This needs to be signed by both the Clinical Collaborator at the POSCU and the R&D departments at both the PTC and the POSCU.

The Trial Co-ordinator at the Trial Sponsor will upload the signed SSIF for each POSCU cluster to RDMIS CSP Module with the other trial documentation. This will then be available to the lead CLRN for the PTC.

The Trial Sponsor will generate a SSIF which will be sent to the PI at the PTC for signature