

Checklist Trial Start up

Trial name:

	Date done / received
Patient recruitment docs <ul style="list-style-type: none"> ○ Patient telephone script ○ Patient questionnaire in/excl ○ Patient email script 	
Source <ul style="list-style-type: none"> ○ Work-sheets ○ Visitplanner ○ Trial filing cabinet 	
General <ul style="list-style-type: none"> ○ Verification letter for GP ○ Log – lists (internal use) ○ Trial added to time sheet ○ Prescreening lists ○ Screening and Randomisation list ○ Timelines ○ Monitoring schedule 	
Lab <ul style="list-style-type: none"> ○ Lab manual available ○ Airwaybill + courier information ○ Dry ice order and shipment information ○ Ambient shipment information ○ Lab kits (check use by date) ○ Shipment material ○ Pregnancy tests 	
Trial material <ul style="list-style-type: none"> ○ Final Protocol ○ Patient documents (diary/trial contact card /...) ○ IRB approval ○ Sponsor contact details ○ IP ○ ICF ○ Trial specific website ○ Recruitment material ○ SAE reporting procedure 	

Vendors <ul style="list-style-type: none">○ eDC log in details○ IVRS log in details○ Trial portal log in details○ eDiary / manual / portal / log in○ eTool manual / portal / log in○ core lab information / log in○ External equipment (i.e. ECG)	