Site Sponsor Green Light Checklist

Study Title:	
Reference No:	
Chief Investigator:	
Site Name:	
Principal Investigator:	
Site Type:	☐Research site ☐PIC site

Trial Wide Checks (include for all sites)	Date Completed / Comments
Date of MHRA Approval	
Date of REC Favourable Opinion	
Date of HRA Approval	
Other Approvals Required and Issued *(i.e., CAG, ARSAC; please list)*	<insert relevant details or mark N/A>
Overarching Trial Contracts Required and Fully Executed date *(i.e., Funder agreement, Safety data exchange agreements, Collaboration agreement)*	<insert relevant details or mark N/A>
Date Roles and Responsibilities of CI Agreement signed	
Protocol Version & Signature Page Received	Vx.x signed CI DD/MM/YYYY
IB/SmPC Version & Signature Page Received	Vx.x signed CI DD/MM/YYYY
Trial Master File Set-Up Confirmed	
Final CRFs Received	<insert name, version and date of final CRFs>
Date of IT Services Assurance for Database	
Go-Live Date for Database	
Go-Live Date for Randomisation System	

Go-Live Date for IWRS system	
Technical (QP) Release of IMP/Placebo Confirmed	\<insert date for all IMP/Placebo or mark N/A>
Stability Data for IMP/Placebo Received	\<insert relevant details or mark N/A>
Risk Assessment Finalised	\<insert version and date>
Monitoring Plan Finalised	\<insert version and date>
Study Registration Number	\<insert register and study ID number>

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Site-Specific Checks	Date Completed / Comments
Was site included in initial application?	☐ Yes ☐ No
If no, confirm amendment number which added site	\<insert amendment number>
Date Site Feasibility Assessment Completed	
Date Pharmacy Feasibility Assessment Completed	
Site Initiation Visit	Date Conducted: Date Report closed:
Pharmacy Initiation Visit	Date Conducted: Date Report closed:
Investigator Site File Set-Up Confirmed	
Protocol Version & Signature Page Received	Vx.x signed PI DD/MM/YYYY
IB/SmPC Version & Signature Page Received	Vx.x signed PI DD/MM/YYYY
Trial Documents Localised	\<insert date confirmed>
Signed Source Data Agreement Received	Vx.x signed PI DD/MM/YYYY
Site Delegation Log Received	\<insert initials & date reviewed>
PI CV & GCP Received	
Site Investigator Tracker Received & Checked	\<insert initials & date reviewed>
Date Site Agreements fully executed (*mNCA and OID*)	

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Pharmacy Green Light *(if site pharmacy issue or N/A if included in C & C)*	
Date of Confirmation of Capacity & Capability (C&C)	*<insert date C&C issued for all amendments relevant to this SGL>*
Date IMP received at site	
Date Randomisation System Access Granted to Site	
Date Database Access Granted to Site	
Pre-SGL Amendments Included	*<insert list of all pre-SGL amendments relevant to this SGL>*
Sponsor Green Light Date	
Sponsor Green Light Checked By (Name)	

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***Delete if not required ***

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PIC Site-Specific Checks	Date Completed / Comments
Was site included in initial application?	☐ Yes ☐ No
If no, confirm amendment number which added site	<insert amendment number>
Date Site Agreements Fully Executed (PIC *mNCA and OID*)	
Date of Confirmation of Capacity & Capability (C&C) or equivalent	*<insert date C&C issued for all amendments relevant to this SGL>*
Pre-SGL amendments included	*<insert list of all pre-SGL amendments relevant to this SGL>*
Sponsor Green Light Date	
Sponsor Green Light Checked By (Name)	

RGO Checks	Date Completed / Comments
Study Tracker Updated	<insert date or mark N/A>
EDGE Updated	<insert date or mark N/A>
Study documents moved on X:Drive	<insert date or mark N/A>