

Amendment Sponsor Green Light Checklist

Study Title:	
Reference No:	
Chief Investigator:	
Amendment Ref:	
Category	<input type="checkbox"/> Category A <input type="checkbox"/> Category B <input type="checkbox"/> Category C (C & C not required)
Site Name:	<specify all if implementing amendment on 35-day rule>
Principal Investigator:	<specify all if implementing amendment on 35-day rule>

*****Delete for NSA-NSWR Amendments*****

Substantial & Non-Substantial Amendments	
Trial Wide Checks	Date Completed / Comments
<u>Overarching Trial</u> Contracts (relevant to this amendment) and Fully Executed <u>date</u> (i.e., <u>Funder agreement</u> , <u>Safety data exchange agreements</u> , <u>Collaboration agreement</u> , <u>Transcription Company Agreements</u>)	<insert relevant details or mark N/A>
Date of MHRA Approval	<insert date or mark N/A>
Date of REC Favourable Opinion	<insert date or mark N/A>
Date of HRA Approval	
Date of Other Approvals (i.e., CAG, ARSAC; please list)	<insert relevant details or mark N/A>
Protocol Version & Signature Page Received	< insert Vx.x signed CI DD/MM/YYYY or mark N/A>
IB/SmPC Version & Signature Page Received	< insert Vx.x signed CI DD/MM/YYYY or mark N/A>
Updated CRFs Received	<insert name, version and date of updated CRFs>
Go-Live Date for Updated Database	<insert version, date or mark N/A>
Risk Assessment Updated	<insert version and date or mark N/A>

Monitoring Plan Updated	<insert version and date or mark N/A>
Site-Specific Checks	Date Completed / Comments
Date Site Notified of Amendment	
Date Site Agreements Fully Executed (<i>mNCA and/or OID</i>)	<insert date or mark N/A>
Date of Pharmacy Green Light	<insert date or mark N/A if included in site C & C, Cat C or 35-day rule applies >
Date of Confirmation of Capacity & Capability (C & C)	<where issued or mark N/A if Cat C or 35-day rule applies>
Implementation on 35-day rule	<insert +35-day date and confirm no objections/requests for additional time or mark N/A>
Protocol Version & Signature Page Received	<insert Vx.x signed CI DD/MM/YYYY mark N/A>
IB/SmPC Version & Signature Page Received	<insert Vx.x signed CI DD/MM/YYYY mark N/A>
Updated CRFs Sent to Site	<insert date or mark N/A>
Date Site Granted Access to Update Database	<insert date or mark N/A>
Sponsor Green Light Date	
Sponsor Green Light Checked By (Name)	

*****Delete for SA and NSA Amendments*****

NSA No Study-Wide Review (NSA-NSWR) Amendments Checks	
Trial Wide Checks	Date Completed / Comments
<u>Overarching Trial</u> Contracts (relevant to this amendment) and Fully Executed <u>date</u> (<i>i.e., <u>Funder agreement</u>, <u>Safety data exchange agreements</u>, <u>Collaboration agreement</u>, <u>Transcription Company Agreements</u></i>)	<insert relevant details or mark N/A>
Date of HRA acknowledgement	
Site-Specific Checks	Date Completed / Comments
Date Site Notified of Amendment	
Date Site Agreements Fully Executed (<i>mNCA and/or OID</i>)	<insert date or mark N/A>
Date of Confirmation of Capacity & Capability	<where issued or mark N/A if 35-day rule applies>

Implementation on 35-day rule	<insert +35-day date and confirm no objections/requests for additional time or mark N/A>
Protocol Version & Signature Page Received	Vx.x signed PI DD/MM/YYYY
IB/SmPC Version & Signature Page Received (if applicable)	<insert Vx.x signed CI DD/MM/YYYY mark N/A>
Updated CRFs Sent to Site	<insert date or mark N/A>
Date Site Granted Access to Update Database	<insert date or mark N/A>
Sponsor Green Light Date	
Sponsor Green Light Checked By (Name)	

All Amendments	
RGO Checks	Date Completed / Comments
Study Tracker Updated	<insert date or mark N/A>
EDGE End Date Updated	<insert date or mark N/A>
Study Documents Moved on X:Drive	<insert date or mark N/A>