Case Report Form (CRF)

Definitions:

Case Report Forms are the research instruments or tools designed to collect the data that are necessary to answer the research questions of a specific protocol.

• The Good Clinical Practice (GCP) standard developed by the International Conference on Harmonization, defines CRF as "the printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject."

• Generally, data recorded on a CRF include basic subject-specific sociodemographic information such as birth date, ethnicity, race, education level; data from study specific examinations, measurements or specialty tests, data abstracted from the subject's medical record or other source

documents such as ambulatory and in-patient records, laboratory results, other tests and special procedures. Design of research surveys and questionnaires require special considerations that are addressed in the "CRC Research Practice Guideline for Developing Surveys".

□ Purpose of CRFs:

i- Capturing all protocol-required information

ii- Facilitates data collection and entry

iii- Benefits data management

iv- Benefits statistical analysis

v. Simplifies database design and data validation processes as well as manipulation of data during statistical analysis.

CRFs Development Process:

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. Because of the significance of the CRF in the

successful completion of the clinical trail, and the importance of its design to the different contributors to that endeavour, a team-based approach to CRF design and review is highly recommended.

Ideally, this team would, as a minimum include:

- CRF designer
- Medical advisor
- Clinical monitor
- Data entry leader
- Data manager
- Statistician

. Prior to designing the CRF, the investigator and study team should carefully review the study protocol and do the following:

1. Develop the list of variables that need to

be collected. Use the research questions specified in the IRB-approved protocol to guide development of the variable list. For each research question, make a list of the specific, measurable variables that are needed to answer that question.

2. Identify the best source for the data to be collected. For each variable listed, identify where the data will come from, i.e. the data source.

3. Determine the timing and availability of the data to be collected. Data points that will be collected at the same time (e.g. same study visit) or from the same location (e.g. lab results from Power Chart), or available at the same time (e.g. lab results from batched runs from central labs) should be grouped together

(e.g one CRF for local lab data available within 24 hours of the visits and another CRF for central lab data available twice per year)

4. Determine the data management system. Early in the planning stage, the Principal Investigator should determine the data management system that will be employed for the study. CRF design may be significantly affected by the functionality of the data management application used.

5. Determine the regulatory requirements for the study. There are CRF content and formatting conventions that will support compliance with FDA regulations if the research study is FDA regulated.

•Well designed CRFs will support the goal of accuracy and completeness in data collection and compliance with human Subject's protection regulations. Whenever possible, Investigators should use already existing CRFs as templates and modify as needed to create study specific CRFs.

1. Content Standards:

• Include a data field for the unique, confidential subject identification (ID) number on each page of every form.

•NEVER use the Subject's name, medical record number, or social security number as a study identifier, and never include such identifiers on the same CRF that includes other research data.

• Include a standard section at the beginning

of each form and include key variables that identify the subject and the research event. The CRC (cyclic Redundancy Check) routinely labels this as "Section A. General Information" and includes the subject's unique study ID number, date of study visit or event, an event or visit code, and ID/initials of person completing the form.

• Dated signatures by a PI or their IRB approved designee on the study are necessary on some CRFs according to FDA regulations and to support best practices.

• Include a header on the first page and include the name of the study, the form name, the assigned form number and version date of every approved CRF that was used to collect data.

• Include a standard footer on every page

and include the form name, form number and page number in the footer.

- Provide variable definitions and abbreviated instructions on the CRF for proper form completion wherever applicable.

- When possible, use closed-ended questions and assign numeric codes to each of the response categories. Avoid open-ended open text questions.

- List all parts of a question series on the same page.

2. Formating Standards:

- To minimize data recording and data entry errors, consider who the end users will be when deciding about design issues such as formatting and font size.

- For paper CRFs, use adequate font size for readability. The CRC routinely uses 11-point font as a default font size.
- Use adequate line spacing for easy readability to minimize data recording and data entry errors. The CRC commonly uses 1.5 line spacing.
- Assign a number to each question and sub-question to provide a clear reference to every item on paper.
- Use subsections to divide the form and organize it by topic. For example, Section A: General information; Section B: Demographic data etc.
- Document "dates" consistently following a standard format: MM/DD/YYYY.
- Use a table format when there is a series of questions that have the same response categories, and organize the questions in rows and responses

in columns.

3. CRF version control:

- When drafting CRFs, always save the most recent version of the document with a unique version date added as an extension to the MS Word document name. Then update the version in the header and standard footer on each page of the CRF.

- For example, to revise a CRF in development, open the document named, "Form 1-version 10-01-15.doc" and save it.

4. Quality control review for programmability:

A CRC Project Manager/ Research Coordinator should complete a critical review of the CRFs prior to pre-testing to evaluate the form for

programmability. The Project Manager/ Research Coordinator will evaluate variables and coding schemes for compatibility with the selected database application.

5. Pre-Testing:

CRFs should be pre-tested prior to study start up to evaluate the logic, wording and general construction of the CRFs as well as the overall feasibility of the data collection plan and procedures. A pre-test should be completed by experienced study staff with a small number of subjects or volunteers. Ideally, those responsible for data collection will assist with pre-testing data forms.

6. Review and approval of final CRFs:

- The last step in the CRF development process is to incorporate all the changes that resulted from the pre-test and obtain official "Sign-off" from the Principal Investigator and the Study Biostatistician prior to sending CRF for database programming.
- The Study Principal Investigator and Biostatistician should provide an official "Sign-off" of each CRF to certify each is final and includes all variables required to answer the protocol research questions. This sign off should be provided in writing via a hard copy or electronic method. The official "Sign-off" should be maintained in the study research files.

Frequently, the PI will ask all co-Investigators, Biostatistician, the Study Project Director and/or Study Coordinator to review and "Sign-off" on all or a Sub-set of the CRFs

prior to providing his/her own final "sign-off".

7. Convert CRFs to PDF document for use in the field.

- If the study uses hard copy CRFs, always convert the study CRF documents to PDF documents prior to distribution to data collectors.

Do not distribute the final approved CRFs as Word documents to data collectors to avoid inadvertent or intentional alterations to the approved master CRFs.

- Changes to CRFs should be made only by authorized persons with PI approval.

□ Paper Case Report Form V.S. Electronic CRF:

- There are two types of CRFs used in clinical research, that is, traditional paper CRF and

improvised electronic CRF (eCRF). Paper CRF is the traditional way of data capture and a better option if studies are small or vary in design, whereas eCRFs are considered if studies are large with similar designs.

• In the current global scenario, eCRFs are preferred over paper CRFs as they are less time consuming, and also encourage the sponsor/ pharmaceutical company to carry out large multicentric studies at the same time due to the ease of administration. It is designed in such a way that data entry can be done with zero/ minimal errors.

Moreover, the regulatory authorities are readily accepting submissions in which validated electronic data capture (EDC) systems are used.

.While designing an eCRF, repetitive data such as protocol ID, site code, subject ID, and patient initials will be generated by the system automatically from the first page to all others, thus ensuring no duplication of CRF pages. In eCRF, linking the data between two related pages of CRFs becomes easy and quick.

.Designing a paper CRF is a tedious job that could result in data errors and wrong conclusions, requiring more attention to minimize duplication of CRF pages. Chances of error during data transfer from the source document to paper CRF are common. However, this method may not require user training and system validation as in the case of EDC systems.

.Despite their many advantages, eCRFs have not

been accepted widely. Main reasons behind this are lack of available on-site technology, investigators' lack of motivation, complexity of installation, and maintenance of the software and high investment cost.

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CASE REPORT FORM

Trial Title

Short Title/Acronym

Chief Investigator:
Sponsor Number: XX/XXXX
EudraCT Number: XXXX-XXXXXX-XXX
Name of site:
CRF Version Number: X, XX/XXX/XXXX

Patient Initials	☐☐☐	Subject No.	☐☐☐
Screening No.	☐☐☐	Centre No.	☐☐☐

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VISIT 1 (SCREENING) DEMOGRAPHIC DATA

Date of Assessment: ___/___/_____
(DD / MMM / YYYY)

Informed Consent:	
Date participant/relative signed written consent form: ___/___/_____ (DD / MMM / YYYY)	**Date of first trial-related procedure:** ___/___/_____ (DD / MMM / YYYY)
Name of person taking informed consent: _____	

Demographic Data:							
Date of Birth: ___/___/_____ (DD / MMM / YYYY)							
Ethinicity:							
White	White British ☐		White Irish ☐		White Other ☐		
Mixed race	White & Black Caribbean ☐		White & Black African ☐		White & Asian ☐	Other mixed background ☐	
Asian or Asian British	Indian ☐		Bangladeshi ☐		Pakistani ☐	Other Asian background ☐	
Black or Black British	Caribbean ☐		African ☐		Black Other ☐		
Chinese or other ethnicity	Chinese ☐		Other ☐ (please specify)				
Sex: ☐ Male ☐ Female							

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

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VISIT 1 (SCREENING) MEDICAL HISTORY

Date of Assessment: ___/___/_____

(DD / MMM / YYYY)

Has the patient had any relevant medical history?	☐ No ☐ Yes, Complete below		
Condition / illness /surgical procedure	**Start date** (DD/MMM/YYYY)	**Stop date** (DD/MMM/YYYY)	Or tick if ongoing at Screening Visit?
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject/Screening No. ___ ___ ___

Patient Initials ___ ___ ___

Site Name

VISIT 1 (SCREENING) PHYSICAL EXAM

Date of Assessment: ___/___/_____

(DD / MMM / YYYY)

Was Physical Examination performed?			☐ No ☐ Yes, Complete below	
System	*Abnormal	Normal	Not done	*If noted ABNORMAL, please provide brief description and comment if clinically significant or not (CS/NCS)
General Appearance	☐	☐	☐	
Skin	☐	☐	☐	
Eyes, Ears, Nose & Throat	☐	☐	☐	
Head, Neck & Thyroid	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Respiratory	☐	☐	☐	
Abdomen	☐	☐	☐	
Extremities	☐	☐	☐	
Genitalia	☐	☐	☐	
Anorectal	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Muscular-Skeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Others (please specify)	☐	☐	☐	

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject/Screening No. ☐☐☐ Patient Initials ☐☐☐ Site Name

VISIT 1 (SCREENING) VITAL SIGNS & ECG

Were Vital Signs performed?	☐ No (comment below) ☐ Yes, Complete below Comment*:
Date of Vital Signs:	___/___/_____ (DD / MMM / YYYY)
Time of Vital Signs:	_____:_____ HH:MM
Blood Pressure supine/standing/seating :	___ ___ ___ / ___ ___ ___ mmHg
Pulse:	___ ___ ___ beats/min
Weight: ___ ___ ___ . ___ kg	Height: ___ . ___ ___ m
Oral/ Tympanic Temperature:	___ ___ . ___ °C

Was an ECG performed?	☐ No (comment below) ☐ Yes, Complete below Comment*:
Date & Time of ECG:	___/___/_____ _____:_____ (DD / MMM / YYYY) HH:MM
The ECG is:	☐ Within normal limits ☐ Abnormal, NOT clinically significant ☐ Abnormal, clinically significant, please specify: _____

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

VISIT 1 (SCREENING) HAEMATOLOGY

Clinical Haematology Laboratory tests performed?	☐ No (comment below) ☐ Yes, Complete below Comment: _____
Date of Sample:	___/___/_____ (DD / MMM / YYYY)
Time of Sample	____:____ HH:MM
Was laboratory sample taken at different hospital to <insert investigator's site lab name>?	☐ No ☐ Yes, Complete below Laboratory name / Location: _____

HAEMATOLOGY Laboratory Parameter	Value	Unit (site to pre-complete prior to the finalization of the template)	If parameter indicated as out of normal range on report, please check if clinically significant:
WBC			☐ No ☐ Yes
RBC			☐ No ☐ Yes
Hb			☐ No ☐ Yes
HCT			☐ No ☐ Yes
MCV			☐ No ☐ Yes
MCH			☐ No ☐ Yes
PLT			☐ No ☐ Yes
NEUTROPHILS			☐ No ☐ Yes
LYMPHOCYTES			☐ No ☐ Yes

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

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MONOCYTES			☐ No ☐ Yes
EOSINOPHILS			☐ No ☐ Yes
BASOPHILS			☐ No ☐ Yes
RETICULOCYTES			☐ No ☐ Yes

VISIT 1 (SCREENING) BIOCHEMISTRY

Clinical Biochemistry Laboratory tests performed?	☐ No (comment below) ☐ Yes, Complete below Comment: _____
Date of Sample:	___/___/_____ (DD / MMM / YYYY)
Time of Sample	____:____ HH:MM
Were laboratory samples taken at different hospital other than <insert investigator's site lab name>?	☐ No ☐ Yes, Complete below Laboratory name / Location: _____

BIOCHEMISTRY Laboratory Parameter	Value	Unit (site to pre-complete prior to the finalization of the template)	If parameter indicated as out of normal range on report, please check if clinically significant:
SODIUM			☐ No ☐ Yes
POTASSIUM			☐ No ☐ Yes
CHLORIDE			☐ No ☐ Yes
BICARBONATE			☐ No ☐ Yes

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

Sponsor No. | X | X | / | X | X | X | X |

Subject/Screening No. | | | |

Patient Initials | | | |

Site | Name |

UREA			☐ No ☐ Yes
CREATININE			☐ No ☐ Yes
TOTAL PROTEIN			☐ No ☐ Yes
TOTAL BILIRUBIN			☐ No ☐ Yes
ALBUMIN			☐ No ☐ Yes
ALK PHOS			☐ No ☐ Yes
ALT			☐ No ☐ Yes
AST			☐ No ☐ Yes
CALCIUM			☐ No ☐ Yes

VISIT 1 (SCREENING) < INSERT ASSESSMENT>

Clinical <insert assessment> Laboratory tests performed?	☐ No (comment below) ☐ Yes, Complete below Comment *: _____
Date of Sample:	___/___/_____ (DD / MMM / YYYY)
Time of Sample	____:____ HH:MM
Was laboratory sample taken at different hospital to <insert investigator's site lab name>?	☐ No ☐ Yes, Complete below Laboratory name / Location: _____

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

Sponsor No. X X / X X X X

Subject/Screening No. | | |

Patient Initials | | |

Site Name

<INSERT ASSESSMENT> Laboratory Parameter	Value	Unit (site to pre-complete prior to the finalization of the template)	If parameter indicated as out of normal range on report, please check if clinically significant:
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

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< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject/Screening No. | | | | Patient Initials | | | | Site Name

VISIT 1 (SCREENING) SCREENING CONCOMITANT MEDICATIONS

Date of Assessment: ___/___/_____

(DD / MMM /YYYY)

Is the participant taken any concomitant medications at screening or <insert time frame as specified in protocol>					☐ No ☐ Yes, Complete below		
Medication (Record Generic or trade name)	Reason for use (Medical History diagnosis or other reason, e.g. Prophylaxis)	Dose and units	Frequency	Route	Start Date (DD/MMM/YYYY)	Stop Date (DD//MMM/YYY)	Or tick if ongoing at Screening Visit
1.					___/___/___	___/___/___	☐
2.					___/___/___	___/___/___	☐
3.					___/___/___	___/___/___	☐
4.					___/___/___	___/___/___	☐
5.					___/___/___	___/___/___	☐
6.					___/___/___	___/___/___	☐
7.					___/___/___	___/___/___	☐
8.					___/___/___	___/___/___	☐
9.					___/___/___	___/___/___	☐
10.					___/___/___	___/___/___	☐

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject/Screening No. | | | |

Patient Initials | | | |

Site: Name

VISIT 1 (SCREENING) SMOKING / ALCOHOL STATUS

Date of Assessment: ___/___/_____

(DD / MMM / YYYY)

Has the participant ever smoked? ☐ No ☐ Yes, Complete below

☐ **Current Smoker**

Participant's average daily use:
- Number of cigarettes : ___
- Number of cigars : ___
- Number of pipes : ___

Smoked for ___ months/years

☐ **Former smoker**

Smoked for ___ months/years

Date when smoking ceased: ___/___/_____
(DD / MMM / YYYY)

When smoking, participant's average daily use:
- Number of cigarettes : ___
- Number of cigars : ___
- Number of pipes : ___

Participant's alcohol consumption

Participant's average consumption per <insert time frame stated in protocol>:
- Number of units of wine : ___
- Number of units of beer : ___
- Number of units of spirits : ___

(see protocol for definition of units)

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

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< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject/Screening No. | | | |

Patient Initials | | | |

Site: Name

VISIT 1 (SCREENING) INCLUSION CRITERIA

Date of Assessment: ___/_____/_____

(DD / MMM / YYYY)

The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):		Yes	No	N/A
1.		☐	☐	☐
2.		☐	☐	☐
3.		☐	☐	☐
4.		☐	☐	☐
5.		☐	☐	☐
6.		☐	☐	☐
7.		☐	☐	☐
8.		☐	☐	☐
9.		☐	☐	☐
10.		☐	☐	☐
If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.				

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject/Screening No. | | |

Patient Initials | | |

Site Name

VISIT 1 (SCREENING) EXCLUSION CRITERIA

Date of Assessment: ___/___/_____

(DD / MMM / YYYY)

The following criteria MUST be answered NO for the participant to be included in the trial:		Yes	No
1.		☐	☐
2.		☐	☐
3.		☐	☐
4.		☐	☐
5.		☐	☐
6.		☐	☐
7.		☐	☐
8.		☐	☐
9.		☐	☐
10.		☐	☐

If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject/Screening No. | | | |

Patient Initials | | | |

Site | Name |

VISIT 1 (SCREENING) PARTICIPANT ELIGIBILITY REVIEW

End of Screening Visit Checklist:			
		Yes	No
1.	Does the participant satisfy the inclusion and exclusion criteria to date?	☐	☐
2.	Have all Screening Visit procedures been completed?	☐	☐
3.	Have the Medical History and Concomitant Medication pages been completed?	☐	☐
4.	Is the participant still willing to proceed in the trial?	☐	☐

Participant's eligibility Investigator Sign-Off:	
Is the participant eligible to take part in the Clinical Trial?	☐ Yes ☐ No, Please give reason for screen failure below
Investigator's Signature: _____ Date : ___/___/_____ (DD / MMM / YYYY)	
Investigator's Name: _____	
Reason(s) for screen failure:	
1.	
2.	
3.	

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

VISIT <INSERT VISIT No.> / NAME>

Participant Randomisation/Enrolment	
Participant study Number allocated:	___ ___ ___
Date of Randomisation/Enrolment:	___/___ ___/___ ___ ___ (DD / MMM / YYYY)

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject No. | | | |

Patient Initials | | | |

Site: Name

VISIT X <INSERT VISIT NAME> CHECKLIST

Date of Visit: __/___/_____
(DD / MMM / YYYY)

Visit Checklist:

		Yes	No
1.	**Have there been any new Adverse Events?** (If yes, please record in Adverse Events page)	☐	☐
2.	**Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	☐	☐
3.	**Add further assessments required at each visit, amend the following pages to fit your requirements**	☐	☐
4.		☐	☐

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. | | |

Patient Initials | | |

Site Name

VISIT X <INSERT VISIT NAME> PHYSICAL EXAM

Date of Assessment: ___/____/_____

(DD / MMM / YYYY)

Was Physical Examination performed? ☐ No (comment Below) ☐ Yes, Complete below

Comment*:_____

System	*Changed	Not Changed	Not done	*If CHANGED from previous examination or new abnormality noted, please provide brief description and comment if clinically significant or not (CS/NCS). IF CS consider if it is an AE and add to log (if appropriate)
General Appearance	☐	☐	☐	
Skin	☐	☐	☐	
Eyes, Ears, Nose & Throat	☐	☐	☐	
Head, Neck & Thyroid	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Respiratory	☐	☐	☐	
Abdomen	☐	☐	☐	
Extremities	☐	☐	☐	
Genitalia	☐	☐	☐	
Anorectal	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Muscular-Skeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Others (please specify)	☐	☐	☐	

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. ☐☐☐ Patient Initials ☐☐☐ Site Name

VISIT X <INSERT VISIT NAME> BIOCHEMISTRY

Clinical Biochemistry Laboratory tests performed?	☐ No (Comment Below) ☐ Yes, Complete below Comment*:_____
Date & Time of Sample:	__/___/____ (DD / MMM / YYYY) _____:_____ HH:MM
Was laboratory sample taken at different hospital to <insert investigator's site lab name>?	☐ No ☐ Yes, Complete below Laboratory name / Location: _____

BIOCHEMISTRY Laboratory Parameter	Value	Unit (site to pre-complete prior to the finalization of the template)	If parameter indicated as out of normal range on report, please check if clinically significant if CS consider if it is an AE and add to log (if appropriate)::
SODIUM			☐ No ☐ Yes
POTASSIUM			☐ No ☐ Yes
CHLORIDE			☐ No ☐ Yes
BICARBONATE			☐ No ☐ Yes
UREA			☐ No ☐ Yes
CREATININE			☐ No ☐ Yes
TOTAL PROTEIN			☐ No ☐ Yes
TOTAL BILIRUBIN			☐ No ☐ Yes
ALBUMIN			☐ No ☐ Yes
ALK PHOS			☐ No ☐ Yes
ALT			☐ No ☐ Yes
AST			☐ No ☐ Yes
CALCIUM			☐ No ☐ Yes

Completed by:_____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject No. | | | |

Patient Initials | | | |

Site: Name

VISIT X <INSERT VISIT NAME> <INSERT ASSESSMENT>

Clinical <insert assessment> Laboratory tests performed?	☐ No (Comment Below) ☐ Yes, Complete below Comment*:_____
Date & Time of Sample:	___/___/_____ (DD / MMM / YYYY) _____:_____ HH:MM
Was laboratory sample taken at different hospital to <insert investigator's site lab name>?	☐ No ☐ Yes, Complete below Laboratory name / Location: _____

<INSERT ASSESSMENT> Laboratory Parameter	Value	Unit	If parameter indicated as out of normal range on report, please check if clinically significant IF CS consider if it is an AE and add to log (if appropriate)::
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes
			☐ No ☐ Yes

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. | | | Patient Initials | | | Site Name

VISIT X <INSERT VISIT NAME> TRIAL MEDICATION ADIMINSTRATION

<Insert name of trial medication> Administration

CHOOSE APPROPRIATE DOSING/DISPENSING TABLE FOR YOUR PROTOCOL AND MODIFY AS REQUIRED

Date of Dosing (DD/MMM/YYYY)	Time of Dosing (24 hr)	Dose (including units)	Comment ONLY if dose delayed, interrupted, reduced or altered
/ /	:		
/ /	:		

Start date of dosing (DD/MMM/YYYY)	Stop date of dosing (DD/MMM/YYYY)	Dose (including units)	Comment ONLY if dose delayed, interrupted, reduced or altered
/ /	/ /		
/ /	/ /		

INFUSION

Date of Infusion (DD/MMM/YYYY)	Start time of infusion	Stop time of infusion	Dose (including units)	Comment ONLY if dose delayed, interrupted, reduced or altered
/ /	:	:		
/ /	:	:		

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject No. | | | |

Patient Initials | | | |

Site | Name |

VISIT X <INSERT VISIT NAME> TRIAL MEDICATION DISPENSING

DISPENSING

Date of Dispensing IMP (DD/MMM/YYYY)	Quantity Dispensed (no. tablets/ pens/patches)	<Daily> Dose (including units)	Comment ONLY if dose delayed, reduced or altered
___/___/___			

Note: add more rows depending on how IMP is dispensed and Returned

RETURNS (add to subsequent visit)

Date of Returning IMP (DD/MMM/YYYY)	Quantity Returned (no. tablets/ pens/patches)	Comment on compliance
___/___/___		

Completed by: _____

Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. ☐☐☐ Patient Initials ☐☐☐ Site Name

TRIAL COMPLETION

Did participant complete the trial?	☐ **Yes,** Please provide date of last visit: ___/_____/20___ (DD / MMM / YYYY) ☐ **No,** Please provide date of withdrawal and complete below: ___/_____/20___ (DD / MMM / YYYY)

Early Withdrawal: please tick most appropriate reason for participant not completing the trial:

- ☐ **Adverse Events related:** please state related AE: _____ (add details to AE page)
- ☐ **Participant's decision, specify:** _____
- ☐ **Investigator's decision, specify:** _____
- ☐ **Sponsor's decision**
- ☐ **Lost to follow up**
- ☐ **Patient deceased**
- ☐ **Other, specify:** _____

Completed by: _____
Name Signature Date

* Record the comment on the protocol deviation/violation log.

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. ☐☐☐ Patient Initials ☐☐☐ Site Name

ADVERSE EVENTS PAGE

AE No	Event Name (Please give Diagnosis if known)	Start date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Serious? If serious, please complete a JRO SAE form	Con-comitant Medication given	Severity 0 - Mild 1- Mode-rate 2 - Severe	Study Drug Action 0 - None 1 - Temporarily interrupted 2 - permanently withdrawn	Outcome 0 - Resolved 1- Resolved with sequelae 2 - Not resolved	Relationship to Study Drug 0 - Definitely 1 - Probably 2 - Possibly 3 - Unlikely 4 - Not related 5 - Not assessable
1		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
2		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
3		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
4		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
5		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
6		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				

I have reviewed the AEs on this page and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature _____ **Date:** _____ ☐ **Please check box if this is the last page used**

Completed by: _____

Name Signature Date

< Short Title/Acronym>

Sponsor No. | X | X | / | X | X | X | X |

Subject No. | | | |

Patient Initials | | | |

Site: Name

ADVERSE EVENTS PAGE (CONTINUATION PAGE)

AE No	Event Name (Please give Diagnosis if known)	Start date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Serious? If serious, please complete a JRO SAE form	Concomitant Medication given	Severity 0 - Mild 1- Moderate 2 - Severe	Study Drug Action 0 - None 1 - Temporarily interrupted 2 - permanently withdrawn	Outcome 0 - Resolved 1- Resolved with sequelea 2 - Not resolved	Relationship to Study Drug 0 - Definitely 1 - Probably 2 - Possibly 3 - Unlikely 4 - Not related 5 - Not assessable
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				
		__/__/__	__/__/__	☐ No ☐ Yes	☐ No ☐ Yes				

I have reviewed the AEs on this page and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature_____ Date:_____

☐ Please check box if this is the last page used

Completed by: _____ _____

Name Signature Date

< Short Title/Acronym>

Sponsor No. X X / X X X X

Subject No. ___ ___ ___ Patient Initials ___ ___ ___ Site Name

CONCOMITANT MEDICATIONS LOG

Has the participant used any Concomitant Medications? ☐ No ☐ Yes, Complete below

CM No.	Medication name (Record <specify Generic or Brand> name)	Start date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Or tick if ongoing at end of study?	Reason for use (Enter related AE diagnosis, or other reasons for use, e.g. Prophylaxis)	Dose (Units)	Route	Frequency
1.		__/__/__	__/__/__	☐				
2.		__/__/__	__/__/__	☐				
3.		__/__/__	__/__/__	☐				
4.		__/__/__	__/__/__	☐				
5.		__/__/__	__/__/__	☐				
6.		__/__/__	__/__/__	☐				
7.		__/__/__	__/__/__	☐				

☐ Please check box if this is the last page used

Note: Use the Concomittent log to record Non-IMPs

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Completed by: _____ _____ _____

Name Signature Date