


Instruments	
Instrument	Form Name
Case report form	case_report_form

	#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)								
Instrument: Case report form (case_report_form)  Enabled as survey												
	1	[record_id]	Record ID	text (number)								
	2	[study_id]	Section Header: <i>General Information</i> Study ID <i>Unique Identifier assigned to each participant</i>	text (number, Min: 1, Max: 500), Required, Identifier Question number: 1								
	3	[site_id]	Site ID <i>Unique identifier for the study site</i>	text (number), Required, Identifier Question number: 2								
	4	[investigator_name]	Investigator Name <i>Name of the Principal Investigator</i>	text Question number: 3								
	5	[patient_id]	Patient ID <i>Unique anonymized Patient number</i>	text (number, Min: 1, Max: 500), Required, Identifier Question number: 4								
	6	[visit_detail]	Visit Detail <i>Corresponding visit</i>	dropdown, Required <table><tr><td>1</td><td>Screening</td></tr><tr><td>2</td><td>Baseline</td></tr><tr><td>3</td><td>Follow up</td></tr><tr><td>4</td><td>Final Visit</td></tr></table> Question number: 5	1	Screening	2	Baseline	3	Follow up	4	Final Visit
1	Screening											
2	Baseline											
3	Follow up											
4	Final Visit											
	7	[date_of_visit]	Date of Visit <i>DD/MM/YY</i>	text (date_dmy) Question number: 6								

	8	[age]	Section Header: <i>Demographic information</i> Age <i>Enter patient's age at enrollment</i>	text (number, Min: 18, Max: 65), Required Question number: 1									
	9	[gender]	Gender	radio, Identifier <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr><tr><td>3</td><td>Others</td></tr></table> Question number: 2	1	Male	2	Female	3	Others			
1	Male												
2	Female												
3	Others												
	10	[pregnancy_status] Show the field ONLY if: [gender] = '2'	Pregnancy Status <i>Exclusion criteria</i>	radio <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> Question number: 3	1	Yes	2	No					
1	Yes												
2	No												
	11	[weight]	Weight <i>Record weight to the nearest 0.1Kg</i>	text (integer) Question number: 4									
	12	[height]	Height (cms) <i>Record height in cms</i>	text (integer) Question number: 5									
	13	[bmi]	Section Header: <i>Baseline Information</i> BMI <i>Auto calculated from height and weight</i>	calc Calculation: $([weight]/([height]*[height]))*10000$ Question number: 1									
	14	[blood_pressure_mm_hg]	Blood Pressure (mm/Hg) <i>Systolic and Diastolic</i>	text Question number: 2									
	15	[hba1c]	HbA1c (%) <i>Baseline HbA1c level</i>	text (number) Question number: 3									
	16	[fasting_plasma_glucose_mg]	Fasting Plasma Glucose (mg/dL) <i>Measure and record at screening</i>	text (integer) Question number: 4									
	17	[medical_history]	Medical History	checkbox <table><tr><td>1</td><td>medical_history__1</td><td>Hypertension</td></tr><tr><td>2</td><td>medical_history__2</td><td>Cardiovascular disease</td></tr><tr><td>3</td><td>medical_history__3</td><td>Chronic Kidney disease</td></tr></table>	1	medical_history__1	Hypertension	2	medical_history__2	Cardiovascular disease	3	medical_history__3	Chronic Kidney disease
1	medical_history__1	Hypertension											
2	medical_history__2	Cardiovascular disease											
3	medical_history__3	Chronic Kidney disease											

				<table><tr><td>4</td><td>medical_history__4</td><td>Other</td></tr></table> Question number: 5	4	medical_history__4	Other			
4	medical_history__4	Other								
	18	<div>[others]</div> <div>Show the field ONLY if: [medical_history(4)] = '1'</div>	<div>Others</div> <div>Specify others</div>	notes						
	19	<div>[concomitant_medications]</div>	<div>Concomitant Medications</div> <div>List ongoing medications</div>	<div>text</div> <div>Question number: 6</div>						
	20	<div>[randomization_group]</div>	<div>Section Header: Study Drug Administration</div> <div>Randomization Group</div>	<div>radio, Required</div> <table><tr><td>1</td><td>Active drug</td></tr><tr><td>2</td><td>Placebo</td></tr></table> <div>Question number: 1</div>	1	Active drug	2	Placebo		
1	Active drug									
2	Placebo									
	21	<div>[study_drug_dose]</div>	<div>Study Drug Dose (mg/day)</div> <div>Specify dosage as per randomization</div>	<div>text (number, Min: 1, Max: 300), Required</div> <div>Question number: 2</div>						
	22	<div>[date_of_first_dose]</div>	<div>Date of first dose</div> <div>DD/MM/YY</div>	<div>text (date_dmy)</div> <div>Question number: 3</div>						
	23	<div>[compliance]</div>	<div>Compliance</div>	<div>radio</div> <table><tr><td>1</td><td>< 50%</td></tr><tr><td>2</td><td>50%-75%</td></tr><tr><td>3</td><td>>75%</td></tr></table> <div>Question number: 4</div>	1	< 50%	2	50%-75%	3	>75%
1	< 50%									
2	50%-75%									
3	>75%									
	24	<div>[adverse_event_reported]</div>	<div>Section Header: Safety and Adverse Event Monitoring</div> <div>Adverse Event Reported?</div>	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Question number: 1</div>	1	Yes	2	No		
1	Yes									
2	No									
	25	<div>[adverse_event_description]</div>	<div>Adverse Event Description</div> <div>Specify symptoms and Severity</div>	<div>notes</div> <div>Question number: 2</div>						

	26	[onset_date]	Onset Date <i>DD/MM/YY</i>	text (date_dmy) Question number: 3						
	27	[resolution_date]	Resolution Date <i>DD/MM/YY</i>	text (date_dmy) Question number: 4						
	28	[serious_adverse_event]	Serious Adverse Event?	radio <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> Question number: 5	1	Yes	2	No		
1	Yes									
2	No									
	29	[relation_to_drug_study]	Relation to Drug Study	radio <table><tr><td>1</td><td>Related</td></tr><tr><td>2</td><td>Not Related</td></tr><tr><td>3</td><td>Unknown</td></tr></table> Question number: 6	1	Related	2	Not Related	3	Unknown
1	Related									
2	Not Related									
3	Unknown									
	30	[action_taken]	Action Taken	radio <table><tr><td>1</td><td>Dose Reduced</td></tr><tr><td>2</td><td>Treatment Discontinued</td></tr><tr><td>3</td><td>Other</td></tr></table> Question number: 7	1	Dose Reduced	2	Treatment Discontinued	3	Other
1	Dose Reduced									
2	Treatment Discontinued									
3	Other									
	31	[other] Show the field ONLY if: [action_taken] = '3'	other <i>Specify</i>	notes						
	32	[date_of_last_visit]	Section Header: <i>Study Completion and Final assessment</i> Date of Last Visit <i>DD/MM/YY</i>	text (date_dmy) Question number: 1						
	33	[final_hba1c]	Final HbA1c (%) <i>Measured value at study end</i>	text Question number: 2						

	34	[final_weight]	Final Weight <i>Measured value at study end</i>	text (integer) Question number: 3										
	35	[final_bp_mmhg]	Final BP (mmHg) <i>Measured value at study end</i>	text Question number: 4										
	36	[reason_for_discontinuation]	Reason for discontinuation	radio <table><tr><td>1</td><td>Completed Study</td></tr><tr><td>2</td><td>Lost to Follow-up</td></tr><tr><td>3</td><td>Withdrawn</td></tr><tr><td>4</td><td>AE</td></tr><tr><td>5</td><td>Other</td></tr></table> Question number: 5	1	Completed Study	2	Lost to Follow-up	3	Withdrawn	4	AE	5	Other
1	Completed Study													
2	Lost to Follow-up													
3	Withdrawn													
4	AE													
5	Other													
	37	[case_report_form_complete]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete				
0	Incomplete													
1	Unverified													
2	Complete													