
Electronic Case Report Form

PROTOCOL	2021년 7월 교육실습
STUDY TITLE	2021년 7월 교육실습 (이송영)

SITE	-
책임 연구자	-
CRF Version	1.00
CRF Effective	-
스크리닝 번호	-
배정 번호	-
이니셜	-

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습		

	Enrollme nt	V1	V2	V3	V4	V5	UV1	All
Enrollme nt	<input type="checkbox"/>							
Visit		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Demogra phics		<input type="checkbox"/>						
Medical History		<input type="checkbox"/>						
Vital Signs		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Local Laborato ry Test		<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	
Pregnanc y Test		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
Inclusion/ Exclusion Criteria		<input type="checkbox"/>						
Randomi zation			<input type="checkbox"/>					
IP Prescripti on		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Adverse Event								<input type="checkbox"/>
Prior and Concomi tant Medicati ons								<input type="checkbox"/>
Dispositi on								<input type="checkbox"/>
Principal Investigat or's Signature								<input type="checkbox"/>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Enrollment	Enrollment

Enrollment	
Date of informed consent	<div>EN.ICDTC (C10)</div> <div></div>
Screening No.	<div>EN.SUBJID (C6)</div> <div></div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Visit	V1, V2, V3, V4, V5, UV##

Visit	
Visit date	<div>SV.SVDTC (C10)</div> <div>_____</div>
Reason for unscheduled visit	<div>SV.SVUVREAS (N2)</div> <div>[1] <input type="radio"/> Adverse event</div> <div>[2] <input type="radio"/> Others → <u>Specify below</u></div>
Others, specify	<div>SV.SVUVRECO (C10)</div> <div>_____</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Visit	V1, V2, V3, V4, V5, UV##

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	SVUVR EAS		All	Exclude	All	Reason for unscheduled visit
QST	SVUVR EAS		UV##	Include	All	Reason for unscheduled visit
QST	SVUVR ECO		All	Exclude	All	Others, specify
QST	SVUVR ECO		UV##	Include	All	Others, specify

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Demographics	V1

Demographics	
Birth date	<div>DM.BRTHDTC (C10)</div> <div>_____</div>
Age	<div>DM.AGE (N2)</div> <div>만 _ Years</div>
Sex	<div>DM.SEX (N2)</div> <div>[1] <input type="radio"/> Male</div> <div>[2] <input type="radio"/> Female</div>
Alcohol	<div>DM.ALCOHOL (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Medical History	V1

Medical History				
No	Medical history term	Ongoing	End date	Administration of medication
<div>ND</div> <div> <div>MY.MHND (N1)</div> <div>[1] <input type="checkbox"/> ND</div> </div>				
<div>MH.SEQ (N2)</div> <div>1</div>	<div>MH.MHTERM (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>	<div>MH.MHONGO (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>	<div>MH.MHENDTC (C10)</div> <div>_____</div>	<div>MH.MHCONTRT (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Vital Signs	V1, V2, V3, V4, V5, UV##

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</div>
Height	<div>VS.HEIGHT (N3)</div> <div>— cm</div>
Weight	<div>VS.WEIGHT (N3.1)</div> <div>— kg</div>
Systolic blood pressure	<div>VS.SYSBP (N3)</div> <div>— mmHg</div>
Diastolic blood pressure	<div>VS.DIABP (N3)</div> <div>— mmHg</div>
Pulse rate	<div>VS.PULSE (N3)</div> <div>— beats/min</div>
Respiratory rate	<div>VS.RESP (N3)</div> <div>— breaths/min</div>
Temperature	<div>VS.TEMP (N2.1)</div> <div>— °C</div>
If there are any newly noted clinically significant abnormal result since the last Visit, please specify the details on the [Adverse Event] page	

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Vital Signs	V1, V2, V3, V4, V5, UV##

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	HEIGHT		All	Exclude	All	Height
QST	HEIGHT		V1	Include	All	Height

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Local Laboratory Test	V1, V2, UV##

Local Laboratory Test	
ND	<div>LY.LBND (N1)</div> <div>[1] <input type="checkbox"/> ND</div>
Collection date	<div>LY.LBDTC (C10)</div> <div>_____</div>
*If there are any newly noted abnormal result since the last Visit, please specify the details on the [Adverse Event] page	

Hematology			
Test Name	Result	Normality	Clinically Significant
<div>LB.LBTEST (C50)</div> <div>Erythrocytes</div>	<div>LB.LBORRES (N4.3)</div> <div>_____</div>	<div>LB.LBNOR (N2)</div> <div>[1] <input type="radio"/> Normal</div> <div>[2] <input type="radio"/> Abnormal</div>	<div>LB.LBCLSIG (N2)</div> <div>[1] <input type="radio"/> NCS</div> <div>[2] <input type="radio"/> CS</div>
<div>LB.LBTEST (C50)</div> <div>Hemoglobin</div>	<div>LB.LBORRES (N4.3)</div> <div>_____</div>	<div>LB.LBNOR (N2)</div> <div>[1] <input type="radio"/> Normal</div> <div>[2] <input type="radio"/> Abnormal</div>	<div>LB.LBCLSIG (N2)</div> <div>[1] <input type="radio"/> NCS</div> <div>[2] <input type="radio"/> CS</div>
<div>LB.LBTEST (C50)</div> <div>Hematocrit</div>	<div>LB.LBORRES (N4.3)</div> <div>_____</div>	<div>LB.LBNOR (N2)</div> <div>[1] <input type="radio"/> Normal</div> <div>[2] <input type="radio"/> Abnormal</div>	<div>LB.LBCLSIG (N2)</div> <div>[1] <input type="radio"/> NCS</div> <div>[2] <input type="radio"/> CS</div>
<div>LB.LBTEST (C50)</div> <div>Platelets</div>	<div>LB.LBORRES (N4.3)</div> <div>_____</div>	<div>LB.LBNOR (N2)</div> <div>[1] <input type="radio"/> Normal</div> <div>[2] <input type="radio"/> Abnormal</div>	<div>LB.LBCLSIG (N2)</div> <div>[1] <input type="radio"/> NCS</div> <div>[2] <input type="radio"/> CS</div>
<div>LB.LBTEST (C50)</div> <div>Leukocytes</div>	<div>LB.LBORRES (N4.3)</div> <div>_____</div>	<div>LB.LBNOR (N2)</div> <div>[1] <input type="radio"/> Normal</div> <div>[2] <input type="radio"/> Abnormal</div>	<div>LB.LBCLSIG (N2)</div> <div>[1] <input type="radio"/> NCS</div> <div>[2] <input type="radio"/> CS</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Local Laboratory Test	V1, V2, UV##

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	LBND		All	Include	All	ND
QST	LBDTC	COMMENT_ APPEND	V1	Include	All	*If there are any clinically significant abnormal result, please specify the details on the [Adverse Event] page.

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Pregnancy Test	V1, V2, V3

Pregnancy Test	
Was the pregnancy test performed?	<div>PG.PGYN (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>
Collection date	<div>PG.PGDTC (C10)</div> <div>_____</div>
Result	<div>PG.PGORRES (N2)</div> <div>[1] <input type="radio"/> Positive</div> <div>[2] <input type="radio"/> Negative</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Inclusion/Exclusion Criteria	V1

Inclusion/Exclusion Criteria	
Is the Subject eligible to participate in this clinical trial due to having satisfied all eligibility criteria?	<div style="text-align: right;">IE.IEYN (N2)</div> <div> <input type="radio"/> Yes <input type="radio"/> No </div>
Date of screening failure	<div style="text-align: right;">IE.IEDTC (C10)</div> <div>_____</div>
Reason of screening failure	<div style="text-align: right;">IE.IEREAS (N2)</div> <div> <input type="radio"/> Inclusion/Exclusion criteria not met → Specify below <input type="radio"/> Subject's consent withdrawal <input type="radio"/> Other → Specify below </div>
Specify the reason of screening failure	<div style="text-align: right;">IE.IEREASCO (C255)</div> <div> <div>_____</div> <div>_____</div> <div>_____</div> </div>

Inclusion Criteria
1. Subject who is outpatient, either male or female, aged between 19 and 74 years old, inclusive.
2. Subject who has a Hemoglobin A1c (HbA1c) value between 7.0% and 9.0% at Visit 1.
3. Subject who has estimated glomerular filtration rate (eGFR) $\geq 45\text{mL/min/1.73m}^2$.
4. Subject who has systolic blood pressure value at Visit 1. a) Treated with antihypertensive drugs: systolic blood pressure $< 180\text{ mmHg}$ b) non-treated: $140\text{mmHg} \leq \text{systolic blood pressure} < 180\text{mmHg}$

Exclusion Criteria
1. Subject who has been diagnosed with type 1 diabetes mellitus.
2. Subject has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) value exceeding 3 times of upper limit of the normal range, or bilirubin value exceeding 3 times of upper limit of the normal range at Visit 1.
3. Female subject of childbearing potential, who is not at least one year post-menopausal or is not surgically sterile, has positive for the pregnancy test (urine or serum) at Visit 1 or is not willing to use appropriate contraception during the study. Female subject is hoping to become pregnant or is currently pregnant or breast-feeding.

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4. Subject who has a history of clinically significant acute artery disease(s) within 3 months prior to date of Visit 1.

5. Subject who has a history of heart failure or arrhythmia within 6 months prior to date of Visit 1.

6. Subject with secondary dyslipidemia or iatrogenic dyslipidemia at Visit 1.

7. Subject who has a history of malignant tumor

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Randomization	V2

Randomization	
Is patient randomized?	<div>RN.RNYN (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>
Strata	<div>RN.RNSRATA (N2)</div> <div>[1] <input type="radio"/> 1</div> <div>[2] <input type="radio"/> 2</div>
Randomization No.	<div>RN.RNNO (C10)</div> <div>_____</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	IP Prescription	V1, V2, V3, V4, V5

IP Prescription	
Is the IP prescribed?	<div>IP.IPYN (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>
Date of prescription [Click SAVE the bottom of the page to allocate IP]	<div>IP.IPDTC (C10)</div> <div>_____</div>
IP_CODE [Click SAVE the bottom of the page to allocate IP]	<div>IP.IPCODE (C10)</div> <div>_____</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Adverse Event	Adverse Event

Adverse Event					
ND		AY.AEND (N1)			
		[1] <input type="checkbox"/> ND			
Record all adverse events noted from Visit 1 to study completion.					
Line Number	Adverse Event	Start date	Outcome	End date	SAE
		Severity	Relationship to study treatment	Action taken with study treatment	Other action taken
AESEQ (N2) 1	AE.AETERM (C255)	AE.AESTDTC (C10)	AE.AEOUT (N2)	AE.AEENDTC (C10)	AE.AESER (N2)
		AE.AESEV (N2)	AE.AEREL (N2)	AE.AEACN (N2)	AE.AEACNOTH (N2)
Outcome		[1] Fatal , [2] Not recovered , [3] Recovered/Resolved , [4] Recovered/Resolved with sequelae , [5] Recovering/Resolving , [6] Unknown			
SAE		[1] No , [2] Death , [3] Hospitalization , [4] Life threatening , [5] Congenital anomaly or birth defect , [6] Significant disability , [7] Other medically important event			
Severity		[1] Mild , [2] Moderate , [3] Severe			
Relationship to study treatment		[1] Not related , [2] Unlikely related , [3] Possibly related , [4] Related			
Action taken with study treatment		[1] Dose increased , [2] Dose not changed , [3] Dose reduced , [4] Drug interrupted , [5] Drug withdrawn , [6] Not applicable , [7] Unknown			
Other action taken		[1] None , [2] Drug treatment , [3] Non-drug treatment , [4] Drug and non-drug treatment			

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Prior and Concomitant Medications	Prior and Concomitant Medications

Prior and Concomitant Medications				
ND		CY.CMND (N1) [1] <input type="checkbox"/> ND		
Please record all medications within 4 weeks prior to Visit 1 except for IP.				
Line Number	Medication or therapy	Total daily dose	Dose Unit	Route
	Start date	Ongoing	End date	Indication
CM.SEQ (N2) 1	CM.CMTRT (C255) _____ _____ _____	CM.CMDOSTOT (N5.3) _____	CM.CMDOSU (C255) _____ _____ _____	CM.CMROUTE (C255) _____ _____ _____
	CM.CMSTDTC (C10) _____	CM.CMONGO (N1) [1] <input type="checkbox"/>	CM.CMENDTC (C10) _____	CM.CMINDC (N1) _____▼ CM.CMINDCMH (C255) _____ _____ _____ CM.CMINDCAE (C255) _____ _____ CM.CMINDCO (C255) _____ _____ _____
Indication		CM.CMINDC (N1) [1] Medical history , [2] Adverse event , [3] Other		
Medical history		CM.CMINDCMH (C255) _____ _____ _____		
Adverse event		CM.CMINDCAE (C255) _____ _____ _____		

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Prior and Concomitant Medications	Prior and Concomitant Medications

<div>CM.CMINDCO (C255)</div> <div>Other</div>	<div></div> <div></div> <div></div>
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PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Disposition	Disposition

Disposition	
What was the subject's status?	<div>DS.DSDECOD (N2)</div> <div>[1] <input type="radio"/> Completed</div> <div>[2] <input type="radio"/> Withdrawal</div>
What was the date of study completed/withdrawal ?	<div>DS.DSDTC (C10)</div> <div>_____</div>
Reason for withdrawal	<div>DS.DSREAS (N2)</div> <div>[1] <input type="radio"/> Failure to meet randomization criteria → Specify below</div> <div>[2] <input type="radio"/> Withdrawal by subject</div> <div>[3] <input type="radio"/> Lost to follow-up</div> <div>[4] <input type="radio"/> Adverse event</div> <div>[5] <input type="radio"/> Others → Specify below</div>
Comment	<div>DS.DSREASO (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Principal Investigator's Signature	Principal Investigator's Signature

Principal Investigator's Signature	
Investigator's Signature	<div>SN.SNNAME (C10)</div> <div></div>
Signature Date	<div>SN.SNDTC (C30)</div> <div></div>