

---

# 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	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
SCHEDULE	2021년 7월 교육실 습				

	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"/>

Enrollment	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Enrollment	2021년 7월 교육실 습				
전자서명					

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

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

Visit	
Visit date	<div>SV.SVDTC (C10)</div>

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Demographics	2021년 7월 교육실 습				
전자서명					

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>

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Medical History	2021년 7월 교육실 습				
전자서명					

Medical History

ND

MY.MHND (N1)

[1] ☐ ND

No	Medical history term	Ongoing	End date	Administration of medication
<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>

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

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	

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Local Laboratory Test	2021년 7월 교육실습				
전자서명					

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 clinically significant abnormal result, please specify the details on the [Adverse Event] page.	

Hematology			
Test Name	Result	Normality	Clinically Significant
<div>LB.LBTEST (C50)</div> Erythrocytes	<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> Hemoglobin	<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> Hematocrit	<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> Platelets	<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> Leukocytes	<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>



V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Pregnancy Test	2021년 7월 교육실 습				
전자서명					

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>

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Inclusion/Exclusion Criteria	2021년 7월 교육실습				
전자서명					

Inclusion/Exclusion Criteria	
Is the Subject eligible to participate in this clinical trial due to having satisfied all eligibility criteria?	<div>IE.IEYN (N2)</div> <div>[1] <input type="radio"/> Yes</div> <div>[2] <input type="radio"/> No</div>
Date of screening failure	<div>IE.IEDTC (C10)</div> <div>_____</div>
Reason of screening failure	<div>IE.IEREAS (N2)</div> <div>[1] <input type="radio"/> Inclusion/Exclusion criteria not met → <a href="#">Specify below</a></div> <div>[2] <input type="radio"/> Subject's consent withdrawal</div> <div>[3] <input type="radio"/> Other → <a href="#">Specify below</a></div>
Specify the reason of screening failure	<div>IE.IEREASCO (C255)</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.

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Inclusion/Exclusion Criteria	2021년 7월 교육실습				
전자서명					

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

V1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
IP Prescription	2021년 7월 교육실 습				
전자서명					

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>

V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

Visit	
Visit date	<div>SV.SVDTC (C10)</div>

V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</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	

V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Local Laboratory Test	2021년 7월 교육실습				
전자서명					

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>

V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Pregnancy Test	2021년 7월 교육실 습				
전자서명					

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>



V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Randomization	2021년 7월 교육실 습				
전자서명					

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

V2	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
IP Prescription	2021년 7월 교육실 습				
전자서명					

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>

V3	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

Visit

Visit date

SV.SVDTC (C10)

V3	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</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	

V3	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Pregnancy Test	2021년 7월 교육실 습				
전자서명					

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>

V3	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
IP Prescription	2021년 7월 교육실 습				
전자서명					

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>

V4	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

Visit	
Visit date	<div>SV.SVDTC (C10)</div>

V4	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</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	



V4	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
IP Prescription	2021년 7월 교육실 습				
전자서명					

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>

V5	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

Visit	
Visit date	<div>SV.SVDTC (C10)</div>

V5	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</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	

V5	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
IP Prescription	2021년 7월 교육실 습				
전자서명					

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>

UV1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Visit	2021년 7월 교육실 습				
전자서명					

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

UV1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Vital Signs	2021년 7월 교육실 습				
전자서명					

Vital Signs	
ND	<div>VS.VSND (N1)</div> <div>[1] <input type="checkbox"/> ND</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	

UV1	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Local Laboratory Test	2021년 7월 교육실습				
전자서명					

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> Erythrocytes	<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> Hemoglobin	<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> Hematocrit	<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> Platelets	<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> Leukocytes	<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>





Prior and Concomitant Medications	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Prior and Concomitant Medications	2021년 7월 교육실 습				
전자서명					

Prior and Concomitant Medications				
ND	<div>CY.CMND (N1)</div> <div>[1] <input type="checkbox"/> ND</div>			
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
<div>CM.SEQ (N2)</div> <div>1</div>	<div>CM.CMTRT (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>	<div>CM.CMDOSTOT (N5.3)</div> <div>_____</div>	<div>CM.CMDOSU (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>	<div>CM.CMROUTE (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>
	<div>CM.CMSTDTC (C10)</div> <div>_____</div>	<div>CM.CMONGO (N1)</div> <div>[1] <input type="checkbox"/></div>	<div>CM.CMENDTC (C10)</div> <div>_____</div>	<div>CM.CMINDC (N1)</div> <div>_____▼</div> <div>CM.CMINDCMH (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div> <div>CM.CMINDCAE (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div> <div>CM.CMINDCO (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>
<div>CM.CMINDC (N1)</div> <div>Indication</div>		<div>[1] Medical history , [2] Adverse event , [3] Other</div>		
<div>CM.CMINDCMH (C255)</div> <div>Medical history</div>		<div>_____</div> <div>_____</div> <div>_____</div>		
<div>CM.CMINDCAE (C255)</div> <div>Adverse event</div>		<div>_____</div> <div>_____</div> <div>_____</div>		

Prior and Concomitant Medications	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Prior and Concomitant Medications	2021년 7월 교육실 습				
전자서명					

<div>Other</div> <div>CM.CMINDCO (C255)</div>	<div></div> <div></div> <div></div>
---	-------------------------------------

Disposition	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Disposition	2021년 7월 교육실 습				
전자서명					

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 → <a href="#">Specify below</a></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 → <a href="#">Specify below</a></div>
Comment	<div>DS.DSREASO (C255)</div> <div>_____</div> <div>_____</div> <div>_____</div>

Principal Investigator's Signature	PROTOCOL	SITE	SCREENING NO.	ENROLLMENT NO.	INITIAL
Principal Investigator's Signature	2021년 7월 교육실 습				
전자서명					
Principal Investigator's Signature					
Investigator's Signature	<div>SN.SNNAME (C10)</div> <div></div>				
Signature Date	<div>SN.SNDTC (C30)</div> <div></div>				