FACILITY NAME & ADDRESS

THOILIT I WINE WAS BILLED			
Facility Name	Facility Type	Facility Address	
National Hospital Organization Hiroshima West Medical	Hospital or Medical Center	4-1-1 Kuba, Otake, Hiroshima, Japan, 739-0651	
Center			

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Nakamura, Hiroko	nakamura.hiroko.fq@mail.hosp.go.jp	Facility Profile Manager; Head of Facility Delegate
No	mikami, makiko	mikami.makiko.yu@mail.hosp.go.jp	Facility Profile Manager; Delegation Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)		
Therapeutic Area	Sub Therapeutic Area	
Mental disorders		
Oncology		
Male Urogenital Diseases		
Hemic and Lymphatic Diseases		
Pediatrics		
Nutritional and Metabolic Diseases		
Orthopedics		
Infectious Diseases		
Pain		
Other Areas of Expertise		
Study Phase Capabilities		
Phase I; Phase III; Phase IV		
Other Facility Details		
Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondar clinical trial subjects, usually this is the same investigator who sees subjects at the primary site.	Yes	
What study types does your Facility have experience with?		Industry; Investigator Initiated; Academic; Government
Is your Facility affiliated with a government agency or part of a government funded health service?		Yes
Patient Population		
Patient Population Demographics		Pediatrics - Less than or equal to 17; Adults - Ages 18-64; Geriatrics - Greater than or equal to 65
Patient Population Comments		
Japanese96%, Asian2%, Caucasian2%		

IRB/ERB/ETHICS COMMITTEE

General Questions	
What is the average time (in days) to start a study once you have received the regulatory package?	30-60
Does your Facility perform IRB/ERB/Ethics Committee submissions?	Yes
Does your Facility have a Facility or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Hiroko
Department Contact Phone Number	81-827-57-0461
Department Contact Email Address	508-chiken@mail.hosp.go.jp
Is your Facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?	Yes
What types of IRB/ERB/Ethics Committee does your Facility use?	Local
Does your institution and/or local regulation mandate the distribution of safety reports [e.g., Development SafetyUpdate Report (DSUR), suspected unexpected serious adverse reaction (SUSAR)] to a local Review only IRB/ERB/Ethics Committee?	Yes
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No
Other Steps Explain	

OTHER REVIEW BOARDS

Does your Facility have Other Review Boards that need to approve the study prior to IRB/ ERB/Ethics Committee submission? For	No
example, scientific, radiation safety committees, or others.	

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Department of Clinical Laboratory	
Lab Name	Department of Clinical Laboratory
Lab Contact First Name	Yoshiro
Lab Contact Last Name	Tachiyama
Address	4-1-1, Hiroshima Nishi Medical Center, Kuba, Otake, Hiroshima, Japan, 739-0651
Phone Number	+81-827-57-0461
Fax Number	+81-827-57-0461
Email Address	tachiyama.yoshiro.cn@mail.hosp.go.jp
Local Lab Accreditation	Others
Other Local Lab Accreditation	Japanese Association of Medical Technologists
Additional Questions	
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?	
Do your written procedures ensures that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance?	
What is the system or tool that the site currently has or utilizes to document Bio-specimen (Sample) Processing Steps/ Chain of Custody?	
Please indicate tissue collection and processing capabilities at your site?	
Does your Facility has established processes to oversee staff compliance with study-specific lab manual instructions for bio- specimen processing?	
What are your Facility's capabilities for tissue collection and/or processing (embedding)?	
Are LOINC codes available for the Local Lab? (If Yes, you can upload the relevant LOINC list as an attachment in Lab	
Facility Profile Format accounted on Tay 200 Jun 2000 44 50 00 OMT 2000	1

Facility Profile Export generated on Tue, 06-Jun-2023 11:52:00 GMT+09:00

Facility Details for National Hospital Organization Hiroshima West Medical Center

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Documentation)		
Attachments		
Document Type	Document Name	Document Description
No Records		

CONSENT & TRAINING

Consent	
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for Pediatric Populations?	No
Does your Facility have a written SOP/Policy/Procedure for: Other Vulnerable Populations?	Yes
Will your Facility require language translations for consents?	Yes
Select the required languages	Japanese
If located in the US, has your Facility used or are you able to use the informed consent short form?	
Training	
Does your Facility have a training program for the research staff?	Yes
Does the course content include GCP?	Yes
Does your Facility use an external program to conduct research training?	Yes
Please provide program course name.	eAPRIN
Do you have a process or program in place to retrain research staff when a protocol is amended?	No
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	Yes

FACILITY & EQUIPMENT

Facility Capabilities	
Can your Facility support patient visits on weekends?	Yes
Can your Facility support in-patient admissions for research studies?	Yes
Does your study staff have sufficient English knowledge to understand communications in English?	No
Does your Facility have access to translators and translation support for trial conduct (e.g. consent, trial specific instruction)?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Is the lab kit storage space able to support early phase studies which may require an increased number of kits?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Equipment	
Identify the Diagnostic Equipment available at or near the Facility to support Research studies?	Computerized Tomography Scan; Dual-Energy X-ray Absorptiometry or Bone Densitometry; Magnetic Resonance Imaging; Fluoroscopy; Positron Emission Tomography Scan; X-Radiation; Magnetic Resonance Angiography; Mammography; Nuclear Medicine (e.g.Bone scan,Thyroid scan,Thallium cardiac stress test); Electrocardiogram

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Document Description

General Equipment	
Does your Facility have an SOP or process that ensures routine calibration and maintenancof general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphymomanomer, etc.?	Yes
Equipment Capabilities: Refrigerator (2 to 8 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Equipment Capabilities: Refrigerator (-70 to -80 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	No
Do you have an SOP which supports calibration of this equipment?	Yes
Computer Capabilities	
Does your Facility have computers which are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP, Windows 7, Windows 8, etc.)
What type of internet access does your Facility have?	Cable or DSL
Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research? (e.g. web portals to submit documents to sponsors or CROs)	No
Does the Facility have access to local IT support?	Yes
Does your Facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)?	No
Business Continuity Plan	
Does your Facility have Business Continuity Plan (BCP) to protect essential business operations which describes how those processes will be performed during a crisis at your Facility?	No
Attach Your BCP or SOP	

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Document Type

No Records

Investigational Product Shipping Details				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
Hiroko Nakamura	4-1-1 Kuba, Otake, Hiroshima, Japan, 739-0651	nakamura.hiroko.fq@mail.hosp.go.j	+81-827-57-0461	

Document Name

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Investigational Product Storage Location				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
National Hospital Organization Hiroshimanishi Medical Center	Kuba4-1-1, Otake, Hiroshima, Japan, 739-0651		+81-827-57-0461	

Investigational Product Storage Equipment				
Identify the Investigational Product Storage Equipment at your Facility	Refrigerator (2 to 8 Degrees C); Freezer (-20 to -30 Degrees C)			
Equipment Capabilities: Refrigerator (2 to 8 Degrees C)				
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes			
Does this equipment provide Min/Max Temperature Monitoring?	Yes			
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily			
Does this equipment have back-up power?	Yes			
Does this equipment have a temperature alarm?	No			
Do you have an SOP which supports calibration of this equipment?	Yes			
Equipment Capabilities: Freezer (-20 to -30 Degrees C)				
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes			
Does this equipment provide Min/Max Temperature Monitoring?	Yes			
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily			
Does this equipment have back-up power?	Yes			
Does this equipment have a temperature alarm?	No			
Do you have an SOP which supports calibration of this equipment?	Yes			

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Investigational Product Storage And Handling	
Is the Investigational Product Storage Room secured with controlled access?	Yes
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	Yes
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?	Yes
Does the Investigational Product Storage Room have back-up power?	Yes
Does the Investigational Product Storage Room have a temperature alarm?	No
Do you have an SOP which supports calibration of this equipment?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?	Yes
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Not Applicable
Describe additional Investigational Product Storage And Handling Capabilities	
Preparation and Administration Of Investigational Product	
Identify the Investigational Product preparation capabilities at your Facility	Extemporaneous Preparation; Vertical laminar flow hood (chemo/hazardous drugs); Horizontal laminar flow hood (non-hazardous drug preparation)
Is your Facility capable of administering infusions?	Yes
Is your Facility adequately staffed to support studies with both blinded and un-blinded Investigational Product?	Yes
Controlled Substances	
Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?	Yes
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes

Attachments		
Document Type	Document Name	Document Description
No Records		

SOURCE DOCUMENTATION & REMOTE MONITORING

Source Documents	
What type of source documents will be used?	Paper; Electronic
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives	
What type of investigator site file/regulatory binder used (select all that apply)	
What investigator site file (eISF) / eRegulatory system do you use?	
Are monitors able to access eISF/eReg while off-site?	
Please list any access limitations/ requirements for eISF/eReg	

Electronic Medical Records (EMR) / Electronic Health Records (EHR)

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Do you have Electronic Health	n Records (EHR)/ Electronic Me	Yes	Yes			
What EMR/EHR system do yo	ou use?	In-house system	In-house system			
For Facilities with satellite sites, where is the monitor required to access source documents?				Main Facility Only	Main Facility Only	
Please list any access limitations/requirements for the Electronic Medical Records.					The electronic medical system is capable of restricting the CRA's access to only the patient records of clinical trial participants.	
Do you work with a vendor that	at can electronically exchange d	ata for clinical research from th	ne EHR/EMR?			
Are monitors able to access E	HR/EMR while off site?					
Does your Facility require Spo	onsor representative to sign any	local form (paper or electronic) for access, or any other purpos	e?		
Monitoring						
Check all equipment that will I	be available to Monitors:			Phone; Copy Machines	; Internet Access	
What Electronic Data Capture	e (EDC) systems has your staff ι	used for clinical trials?		Oracle Inform; Medidat Data Capture; Others	a Rave; Oracle RDC Remote	
Describe Other EDC Systems	S					
Does your site/institution and/ monitoring?	or local regulations allow remote	e source data verification of stu	udy participant data to support re	mote		
Which of the following capabil	ities are available to support rer	note source data verification?	(Check all that apply)			
				<u>'</u>		
Attachments						
Document Type		Document Name		Document Description	ument Description	
No Records						
ADDITIONAL LOCATION	IS					
Additional Locations						
Add any addresses you wish to be available in the Study Site Profile. These addresses will be available for selection in the following sections of the Study Site Profile -Additional Study Locations - These addresses can be added to your FDA Form 1572, if applicable.						
Location Name	Contact Name	Address	Phone Number	Fax Number	E-mail Address	
No Records						
ADDITIONAL INFORMAT	TION & ATTACHMENTS					
Additional Information						
Please provide additional info if applicable.	rmation not captured in other se	ctions of the Facility Profile tha	at you feel is important for Sponso	ors to know about your site. Ple	ase reference the section name	
Facility Attachments						
·			Document Description			
No Records				-		

Facility Details for National Hospital Organization Hiroshima West Medical Center

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ORGANIZATION AFFILIATIONS

Organization Affiliations				
The Organization (s) that requested Affiliation with your Facility are listed below with Affiliation Status				
Organization Name and Address	Organization Affiliation Type	Organization Affiliation Status	Status Date	
No Records				

ASSOCIATED SITE USERS

Associated Site Users

Once checked, this checkbox will enable the Approval/Rejection workflow for this Facility. Any site user requesting to associate with this Facility would require to send the affiliation requests and only once Approved, this Facility will be shown on User's Profile.

Site User Association Requests				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
No Records				,

Associated/Confirmed Site Users				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Nakamura,Hiroko	nakamura.hiroko.fq@mail.hosp.go.j p	03-Aug-2022	03-Aug-2022	Confirmed
mikami,makiko	mikami.makiko.yu@mail.hosp.go.jp	06-Jun-2023	06-Jun-2023	Confirmed
Watanabe,Chigusa	watanabe.chigusa.qx@mail.hosp.go .jp	31-Aug-2020		Confirmed
Chihara,Kumiko	chihara.kumiko.wv@mail.hosp.go.jp	27-May-2021		Confirmed
MORINAGA,MUTSUMI	morinaga.mutsumi.hc@mail.hosp.g o.jp	10-Mar-2022		Confirmed