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FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Yamaguchi Ube Medical Center		685 Higashikiwa, Ube, Yamaguchi, Japan, 755-0241

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Takemura, Naoko	takemura.naoko.ty@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	**Sub Therapeutic Area**
Oncology	Carcinoma
Respiratory Tract Diseases	Bronchial Diseases
Respiratory Tract Diseases	Lung Diseases

Other Areas of Expertise

Study Phase Capabilities
Phase I; Phase II; Phase III; Phase IV

Other Facility Details	
Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects, usually this is the same investigator who sees subjects at the primary site location.	Yes
What study types does your Facility have experience with?	Investigator Initiated
Is your Facility affiliated with a government agency or part of a government funded health service?	No
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

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	Naoko
Department Contact Phone Number	81-836584017
Department Contact Email Address	takemura.naoko.ty@mail.hosp.go.jp
Is your Facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?	No
What types of IRB/ERB/Ethics Committee does your Facility use?	Central Acting as Local; 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?	No
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 example, scientific, radiation safety committees, or others.	

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: National Hospital Organization Yamaguchi-Ube Medical Center	
Lab Name	National Hospital Organization Yamaguchi-Ube Medical Center
Lab Contact First Name	Naoko
Lab Contact Last Name	Takemura
Address	1F, 685,Higashikiwa, Ube, Yamaguchi, Japan, 755-0241
Phone Number	81836582300
Fax Number	81836584017
Email Address	takemura.naoko.ty@mail.hosp.go.jp
Local Lab Accreditation	Others
Other Local Lab Accreditation	Japanese association of Medical TechnologistsJapan Medical Association
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 Documentation)	

Attachments		
Document Type	Document Name	Document Description
Lab Certification or Accreditation	日本医師会20220218_09-Jun-2023_02-08-56_GMT.pdf	
Lab Certification or Accreditation	日臨技20220825_09-Jun-2023_02-09-27_GMT.pdf	
Lab Normal Ranges	検査基準一覧20220301_09-Jun-2023_02-07-54_GMT.pdf	

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?	Yes
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?	Not Applicable
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?	Yes
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)?	Yes
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; Fluoroscopy; X-Radiation; Electrocardiogram

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
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	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.	By Minute
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?	No
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.	By Minute
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?	No
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; Wi-Fi
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?	I don't Know
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		
Document Type	Document Name	Document Description
No Records		

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
Naoko Takemura	685, pharmacy, Higashikiwa, Ube, Yamaguchi, Japan, 755-0241	takemura.naoko.ty@mail.hosp.go.jp	+81-836584017	+81-836584017

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Investigational Product Storage Location				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
pharmaceutical department	685,Higashikiwa, Ube, Yamaguchi, Japan, 755-0241	takemura.naoko.ty@mail.hosp.go.jp	81836582300	81836584017

Investigational Product Storage Equipment	
Identify the Investigational Product Storage Equipment at your Facility	Refrigerator (2 to 8 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.	Hourly
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?	No
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?	Yes
Do you have an SOP which supports calibration of this equipment?	No
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?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	No
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); Glove box (non-vented); Horizontal laminar flow hood (non-hazardous drug preparation); Glove box (vented to outside)
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
Investigational Product Destruction Policy/SOP	企業主導治験に係る標準業務手順書_09-Jun-2023_02-22-42_GMT.pdf	

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Document Type	Document Name	Document Description
Facility License for Controlled Substances	20220907155545_07-Sep-2022_07-00-38_GMT.pdf	

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)	Paper
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)	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system do you use?	In-house system
For Facilities with satellite sites, where is the monitor required to access source documents?	Main Facility Only
Please list any access limitations/requirements for the Electronic Medical Records.	
Do you work with a vendor that can electronically exchange data for clinical research from the EHR/EMR?	No
Do you have institutional approval to export data from the EHR/EMR for the clinical research?	No
Are monitors able to access EHR/EMR while off site?	No
Does your Facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose?	No
Monitoring	
Check all equipment that will be available to Monitors:	
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	
Describe Other EDC Systems	
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?	No
Which of the following capabilities are available to support remote source data verification? (Check all that apply)	

Attachments

Document Type	Document Name	Document Description

No Records

ADDITIONAL LOCATIONS

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 INFORMATION & ATTACHMENTS

Additional Information
Please provide additional information not captured in other sections of the Facility Profile that you feel is important for Sponsors to know about your site. Please reference the section name if applicable.

Facility Attachments		
Document Type	Document Name	Document Description
No Records		

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
Takemura,Naoko	takemura.naoko.ty@mail.hosp.go.jp	07-Dec-2018	24-Sep-2020	Confirmed
Aoe,Keisuke	Yamaguchi.Ube.AOE@gmail.com	28-Jun-2019		Confirmed
Sasaki,Fumiko	sasaki.fumiko.wg@mail.hosp.go.jp	16-Jun-2020		Confirmed
Inoue,Junko	inoue.junko.tx@mail.hosp.go.jp	16-Jun-2020		Confirmed
Saiki,Megumi	saiki.megumi.gj@mail.hosp.go.jp	16-Jun-2020		Confirmed
Gyoubu,Fumihiro	gyobu.fumihiro.fq@mail.hosp.go.jp	18-Jun-2020	18-Jun-2020	Confirmed
Miyakawa,Takayuki	miyakawa.takayuki.vz@mail.hosp.go.jp	16-Jun-2020		Confirmed
Kinoshita,Hiroki	kinoshita.hiroki.zp@mail.hosp.go.jp	23-Jun-2020		Confirmed

Facility Profile Export generated on Thu, 08-Jun-2023 21:32:00 GMT-05:00

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Furuya,Sachiko	furuya.sachiko.cr@mail.hosp.go.jp	18-Jun-2020		Confirmed
Mizuguchi,Atsuko	mizuguchi.atsuko.th@mail.hosp.go.jp	19-Jun-2020		Confirmed
Hayashi,Rika	karimine.rika.yd@mail.hosp.go.jp	16-Jun-2020		Confirmed
Kajii,Takahiro	kajii.takahiro.kz@mail.hosp.go.jp	16-Jun-2020		Confirmed
Izutsu,Noriko	izutsu.noriko.tg@mail.hosp.go.jp	16-Jun-2020		Confirmed
Izutu,Noriko	izutsun@yamaguchi-hosp.jp	24-Jul-2020		Confirmed
Okada,Yumiko	okada.yumiko.kd@mail.hosp.go.jp	06-Oct-2020		Confirmed
Watanabe,Ayano	watanabe.ayano.jw@mail.hosp.go.jp	07-Oct-2020		Confirmed
Okamoto,Ritsuko	okamoto.ritsuko.ur@mail.hosp.go.jp	06-Oct-2020	06-Oct-2020	Confirmed
TAKESHITA,MOMOE	takeshita.momoe.zb@mail.hosp.go.jp	07-Oct-2020	07-Oct-2020	Confirmed
Chikamori,Kenichi	ken-chi@xa2.so-net.ne.jp	02-Dec-2020		Confirmed
Ito,Kosuke	shoji_dayo_ito_chigauyo@yahoo.co.jp	06-Jul-2021	06-Jul-2021	Confirmed
Taguchi,Kotaro	k.tag.755.0241@gmail.com	06-Jul-2021	06-Jul-2021	Confirmed
Osoreda,Hisayuki	osore@isis.ocn.ne.jp	06-Jul-2021	06-Jul-2021	Confirmed
matsuda,kazuki	k0m1a2t8s1u1d2a1@gmail.com	09-Jul-2021	09-Jul-2021	Confirmed
Maeda,Tadashi	maeda.tadashi.jy@mail.hosp.go.jp	28-Jun-2021	28-Jun-2021	Confirmed
Suetake,Ryo	suechi64@gmail.com	07-Jul-2021	22-Nov-2021	Confirmed
Utsunomiya,Toshiaki	t_utsunomiya0316@yahoo.co.jp	30-Jul-2021		Confirmed
Harada,Misa	harada.1993.misa@gmail.com	16-Aug-2021		Confirmed
Murakawa,Keita	murakawakeita124@gmail.com	15-Jul-2021	15-Jul-2021	Confirmed
Fujii,Tetsuya	gk.bxbx.q.q@gmail.com	28-Dec-2021		Confirmed
Suizu,Junki	relativity.theory135@gmail.com	19-Apr-2022		Confirmed
Uehara,Sho	okiyamamie@yahoo.co.jp	20-Apr-2022		Confirmed