

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 Takemura
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 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 Organization Yamaguchi-Ube Medical Center		
Lab Name		National Organization Yamaguchi-Ube Medical Center
Lab Contact First Name		Naoko
Lab Contact Last Name		Takemura
Address		685,Higashikiwa,Ube,Yamaguchi-pref, 1F, Ube, Yamaguchi, Japan, 755-0241
Phone Number		620836582300
Fax Number		
Email Address		takemura.naoko.ty@mail.hosp.go.jp
Local Lab Accreditation		Others
Other Local Lab Accreditation		JAMT JMA
Additional Questions		
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?		Yes
Do your written procedures ensures that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance?		Yes
What is the system or tool that the site currently has or utilizes to document Bio-specimen (Sample) Processing Steps/ Chain of Custody?		Other
Please indicate tissue collection and processing capabilities at your site?		On site collection and Processing
Does your Facility has established processes to oversee staff compliance with study-specific lab manual instructions for bio-specimen processing?		Yes
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)		No
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?	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
What types of eConsent platforms does your Facility use? (Select all that apply)	

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 study conduct (e.g. consent, study 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 maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanomer, etc.?	Yes
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes
Identify the equipment available at the Facility to support Research studies?	Refrigerated Centrifuge, Centrifuge, Refrigerator (2 to 8 Degrees C), Freezer (-70 to -80 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.	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

Does your Facility have antivirus software on all these electronic devices?		
Does your Facility have an SOP or process that documents both physical and firewall security measures that are used for electronic systems?		
Does your Facility perform periodic system reviews to ensure they remain in a validated state?		
Does your Facility have an SOP or process that documents user management processes that are used for electronic systems?		
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
What type of internet browser(s) does your institution use to support studies? (Check all that apply)		
Is access to the internet secured against unauthorized use?		
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 your institution allow the download of information from an external portal ?(e.g. eDC system)		
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	Phone Number	Fax Number	Email Address	Site Specific Requirements
Naoko Takemura	685, pharmacy, Higashikiwa, Ube, Yamaguchi, Japan, 755-0241	+81-836584017	+81-836584017	takemura.naoko.ty@mail.hosp.go.jp	

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

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 the temperature monitoring 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
Facility License for Controlled Substances	20220907155545_07-Sep-2022_07-00-38_GMT.pdf	
Investigational Product Destruction Policy/SOP	2024.4改訂_ IRB標準業務手順書(企業主導治験)_09-Jul-2024_07-33-07_GMT.pdf	

SOURCE DOCUMENTATION & REMOTE MONITORING

Source Documents

What type of source documents will be used?	Paper, Electronic
Do all of the Facility's systems/technology used to store and manage source data conform with international system standards (e.g. ICH/GCP/EU)?	
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
Does your Facility have an SOP or process that documents how to limit access and prevent the premature destruction of the Facility's files?	
What type of investigator site file/regulatory binder used (select all that apply)	Paper
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 the EHR/EMR systems conform with international system standards (e.g. ICH/GCP/EU)?	
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
Does your Facility utilize any additional electronic systems to capture source data outside of the EMR/EHR?	
Does your Facility utilize any additional electronic systems or paper-based systems to access patient medical history?	
Do the systems used for clinical trial data entry and management have audit trail functionality?	

Bring Your Own Device		
Can your Facility support the use of bring your own device (BYOD) technologies to conduct Clinical Trials?		
Monitoring		
Check all equipment that will be available to Monitors:		None
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?		Oracle Inform, Medidata Rave, Oracle RDC Remote Data Capture
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?		No
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.					
SIP Registered Locations					
Location Name			Address		
No Records					
SIP Non-Registered Locations					
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	User Role	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Takemura,Naoko	Clinical Research User	07-Dec-2018	07-Dec-2018	Confirmed
Aoe,Keisuke	Investigator	28-Jun-2019	28-Jun-2019	Confirmed
Sasaki,Fumiko	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Inoue,Junko	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Saiki,Megumi	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Gyoubu,Fumihiro	Clinical Research User	18-Jun-2020	18-Jun-2020	Confirmed
Miyakawa,Takayuki	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Kinoshita,Hiroki	Investigator	23-Jun-2020	23-Jun-2020	Confirmed
Furuya,Sachiko	Investigator	18-Jun-2020	18-Jun-2020	Confirmed
Mizuguchi,Atsuko	Investigator	19-Jun-2020	19-Jun-2020	Confirmed
Hayashi,Rika	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Kajii,Takahiro	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Izutsu,Noriko	Investigator	16-Jun-2020	16-Jun-2020	Confirmed
Izutu,Noriko	Investigator	24-Jul-2020	24-Jul-2020	Confirmed
Okada,Yumiko	Clinical Research User	06-Oct-2020	06-Oct-2020	Confirmed
Watanabe,Ayano	Clinical Research User	07-Oct-2020	07-Oct-2020	Confirmed
Okamoto,Ritsuko	Clinical Research User	06-Oct-2020	06-Oct-2020	Confirmed
TAKESHITA,MOMOE	Clinical Research User	07-Oct-2020	07-Oct-2020	Confirmed
Chikamori,Kenichi	Investigator	02-Dec-2020	02-Dec-2020	Confirmed
Ito,Kosuke	Investigator	06-Jul-2021	06-Jul-2021	Confirmed
Taguchi,Kotaro	Investigator	06-Jul-2021	06-Jul-2021	Confirmed
Osoreda,Hisayuki	Investigator	06-Jul-2021	06-Jul-2021	Confirmed
matsuda,kazuki	Investigator	09-Jul-2021	09-Jul-2021	Confirmed
Maeda,Tadashi	Investigator	28-Jun-2021	28-Jun-2021	Confirmed
Suetake,Ryo	Investigator	07-Jul-2021	07-Jul-2021	Confirmed
Utsunomiya,Toshiaki	Investigator	30-Jul-2021	30-Jul-2021	Confirmed
Harada,Misa	Investigator	16-Aug-2021	16-Aug-2021	Confirmed
Murakawa,Keita	Investigator	15-Jul-2021	15-Jul-2021	Confirmed

Name	User Role	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Fujii,Tetsuya	Investigator	28-Dec-2021	28-Dec-2021	Confirmed
Suizu,Junki	Investigator	19-Apr-2022	19-Apr-2022	Confirmed
Uehara,Sho	Investigator	20-Apr-2022	20-Apr-2022	Confirmed
Okimura,Masatoshi	Investigator	29-Oct-2024	29-Oct-2024	Confirmed
Yanagi,Taiki	Investigator	30-Apr-2025	30-Apr-2025	Confirmed
Fujii,Tomoe	Clinical Research User	17-Jan-2024	17-Jan-2024	Confirmed
Watanabe,Michiya	Investigator	17-Mar-2024	17-Mar-2024	Confirmed
Kanesada,Haruka	Investigator	22-Apr-2024	22-Apr-2024	Confirmed
Hisamoto,Yukari	Investigator	17-Apr-2024	17-Apr-2024	Confirmed
Yonezawa,Kosei	Investigator	16-Apr-2024	16-Apr-2024	Confirmed
Sakamoto,Kenji	Investigator	18-Mar-2024	18-Mar-2024	Confirmed