FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Okayama Medical Center	Hospital or Medical Center	1711-1 Tamasu kita-ku, Okayama, Okayama, Japan, 701- 1192

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Karaki, Yumi	karaki.yumi.nz@mail.hosp.go.jp	Facility Profile Manager
No	Nishiyama, Atsuko	nishiyama.atsuko.vd@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)			
Therapeutic Area	Sub Therapeutic Area		
Bacterial Infections and Mycoses			
Cardiovascular Diseases			
Congenital, Hereditary, and Neonatal Diseases and Abnormalities			
Digestive System Diseases			
Endocrine System Diseases			
Hemic and Lymphatic Diseases			
Respiratory Tract Diseases	Bronchial Diseases		
Respiratory Tract Diseases	Laryngeal Diseases		
Respiratory Tract Diseases	Lung Diseases		
Respiratory Tract Diseases	Respiration Disorders		
Respiratory Tract Diseases	Respiratory Hypersensitivity		
Respiratory Tract Diseases	Respiratory System Abnormalities		
Respiratory Tract Diseases	Respiratory Tract Infections		
Respiratory Tract Diseases	Thoracic Diseases		
Respiratory Tract Diseases	Tracheal Diseases		
Other Areas of Expertise			
Study Phase Capabilities			
Phase I; Phase II; 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	No
clinical trial subjects, usually this is the same investigator who sees subjects at the primary site location.	
What study types does your Facility have experience with?	Industry; Investigator Initiated
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	

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	Clinical trial
Department Contact Phone Number	086-294-9519
Department Contact Email Address	504-chiken-crc@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?	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?	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

your Facility using a Local Lab?		
Local Lab: National Hospital Organization Okayama Medical Center Clinical Laboratory Department of		
Lab Name National Hospital Organization Oka Center Clinical Laboratory Departm		
Lab Contact First Name		
Lab Contact Last Name		
Address	1711-1,tamasu,kita-ku, Okayama, Okayama, Japan, 701-1192	
Phone Number	086-294-9911	
Fax Number		
Email Address		
Local Lab Accreditation	Others	
Other Local Lab Accreditation	Japanese Association of Medical Technologists,Okayama Prefecture Medical	
Additional Questions		
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?		

• • • • • • • • • • • • • • • • • • • •	rature bio-specimen storage requirements are known to respor	sible
staff to ensure compliance?		
What is the system or tool that the site currently has or utilizes	to document Bio-specimen (Sample) Processing Steps/ Chair	n of
Custody?		
Please indicate tissue collection and processing capabilities a	t your site?	
·	compliance with study-specific lab manual instructions for bio-	
specimen processing?		
What are your Facility's capabilities for tissue collection and/or	r 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
No Records		

CONSENT & TRAINING

Consent	
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	No
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?	No
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?	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?	No

FACILITY & EQUIPMENT

Facility Capabilities		
Can your Facility support patient visits on weekends?	No	
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?	No	
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; X-Radiation;	

No Records

cognizant shared investigator platform

Identify the Diagnostic Equipment available at or near the Fac	Magnetic Resonance Angiography; Magnetic Resonance Spectroscopy; Mammography; Nuclear Medicine (e.g.Bone scan,Thyroid scan,Thallium cardia stress test); Electrocardiogram		
General Equipment			
Does your Facility have an SOP or process that ensures routing general equipment include: scale, pulse oximeter, stadiometer	of No		
Equipment Capabilities: Refrigerator (2 to 8 Degrees C)			
Do you have the ability to generate a temperature monitoring		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.		
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 equipn	nent?	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	No		
How frequently can temperature measurement occur? Check	the most frequent measurement your equipment can support.		
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 res	earch studies?	Yes	
What type of computer operating system(s) does your institution	on 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)		o Yes	
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 processes will be performed during a crisis at your Facility?	otect essential business operations which describes how those	Yes	
Attach Your BCP or SOP			
Document Type	Document Name	Document Description	

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Preparation and Administration Of Investigational Product

Investigational Product Shipping Details					
IP Recipient Name	Address	Email Address	Phone Number	-	Fax Number
National Hospital Organization Okayama Medical Center	1711-1,Tamasu,Kita-ku, Pharmacy Department, Shinya Adachi, Okayama, Okayama, Japan, 701- 1192	adachis@okayamamc.jp	086-294-9911		086-294-9508
Investigational Product Storage Lo	cation				
IP Recipient Name	Address	Email Address	Phone Number	•	Fax Number
Pharmacy	1711-1,Tamasu,Kita-ku, Pharmacy Department, Okayama, Okayama, Japan, 701-1192	nishiyama.atsuko.vd@mail.hosp.go .jp	086-294-9911		086-294-9508
Investigational Product Storage Eq	uipment				
Identify the Investigational Product				Refrigerator (2 to Degrees C)	8 Degrees C); Freezer (-20 to -30
Equipment Capabilities: Refrigerate	or (2 to 8 Degrees C)			,	
Do you have the ability to generate	a temperature monitoring log for this e	quipment?		Yes	
Does this equipment provide Min/M	ax Temperature Monitoring?			Yes	
How frequently can temperature me	easurement occur? Check the most free	quent measurement your equipment c	an support.	By Minute	
Does this equipment have back-up	power?			Yes	
Does this equipment have a temper	rature alarm?			Yes	
Do you have an SOP which supports calibration of this equipment?			No		
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 me	easurement occur? Check the most free	quent measurement your equipment c	an support.	By Minute	
Does this equipment have back-up	power?			Yes	
Does this equipment have a temper	ature alarm?			Yes	
Do you have an SOP which support	ts calibration of this equipment?			No	
Investigational Product Storage An	d Handling				
Is the Investigational Product Storage	ge Room secured with controlled acces	ss?		Yes	
Do you have the ability to generate	a temperature monitoring log for this In	vestigational Product Storage Room?		Yes	
Does the Investigational Product St	orage Room provide Min/Max tempera	ture 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?			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 F	Product Storage And Handling Capabili	ities			

Identify the Investigational Product preparation capabilities at your Facility	Extemporaneous Preparation; Vertical laminar flow hood (chemo/hazardous drugs)
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?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Not Applicable

Attachments		
Document Type	Document Name	Document Description
No Records		

SOURCE DOCUMENTATION & REMOTE MONITORING

Source Documents	
What type of source documents will be used?	Paper
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)	
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.	ID、パスワード
Do you work with a vendor that can electronically exchange data for clinical research from the EHR/EMR?	
Are monitors able to access EHR/EMR while off site?	
Does your Facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose?	
Monitoring	
Check all equipment that will be available to Monitors:	Copy Machines; Internet Access
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Oracle Inform; Medidata Rave; Oracle RDC Remote
	Data Capture; Others : DATA TRAK,My
Describe Other EDC Systems	Trials,iMedidata DATA TRAK,My Trials,iMedidata
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote	DATA HAR,IVIY Hais,IIVIEUIUAIA
monitoring?	
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
Yamamoto,Nozomi	yamamoto.nozomi.wc@mail.hosp.g o.jp	03-Feb-2023		Pending

Associated/Confirmed Site Users				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
takahashi,chiho	takahashi.chiho315@eps.co.jp	09-Dec-2022		Confirmed
Okada,Hirofumi	agocanon@gmail.com	05-Dec-2022		Confirmed
Yokohama,Fumi	kagawakenntakamatusimiyawakich o@yahoo.co.jp	05-Dec-2022		Confirmed
Kobashi,Miki	kobashi.miki222@eps.co.jp	09-Dec-2022		Confirmed
Hayashi,Kazuna	orangefamily.38@gmail.com	13-Dec-2022		Confirmed
Sogabe,Rie	sogabe.rie142@eps.co.jp	09-Dec-2022		Confirmed
Yamamoto,Sayaka	yamamoto.sayaka153@eps.co.jp	09-Dec-2022		Confirmed
Kanezawa,Misaki	me422030@s.okayama-u.ac.jp	13-Dec-2022		Confirmed
SURUGA,KAZUKI	suru1541@yahoo.co.jp	01-Dec-2022		Confirmed
shimokawahara,hiroto	hiroto.shimokk@gmail.com	01-Dec-2022		Confirmed
Ogawa,Aiko	ogawa.aiko.nv@mail.hosp.go.jp	05-Dec-2022		Confirmed
Yamamoto,Nozomi	yamamoto.nozomi.wc@mail.hosp.g o.jp	03-Feb-2023		Confirmed
Yamaguchi,Mao	yamaguchi.mao712@eps.co.jp	21-Feb-2023		Confirmed
katsube,Sho	katsube.sho.nf@mail.hosp.go.jp	10-Apr-2023	10-Apr-2023	Confirmed
Nishiyama,Midori	nishiyama.midori.ac@mail.hosp.go.j	07-Apr-2023		Confirmed
yamaguchi,yuta	yamaguchi.yuta.bj@mail.hosp.go.jp	11-Apr-2023		Confirmed
Nishizaki,Mari	nishizaki.mari.wr@mail.hosp.go.jp	13-Apr-2023		Confirmed
Kimura,Tomonari	tomonari_ver21@yahoo.co.jp	27-Apr-2023		Confirmed
Sato,Kimi	skimi926@gmail.com	28-Apr-2023		Confirmed
Honda,Akira	puab0nul@gmail.com	27-Apr-2023		Confirmed
Karaki,Yumi	karaki.yumi.nz@mail.hosp.go.jp	26-Apr-2023	27-Oct-2023	Confirmed
kawara,yuko	kawara.yuko.yq@mail.hosp.go.jp	01-May-2023		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Yamaguchi,Tomoko	tyamaguchi@okayamamc.jp	15-Jan-2019	12-Aug-2020	Confirmed
Sunami,Kazutaka	kazusuna@pop12.odn.ne.jp	17-Mar-2020	18-Apr-2024	Confirmed
Akaishi,Makiko	akaishi.makiko.vd@mail.hosp.go.jp	21-Apr-2020		Confirmed
Korai,Mutsuko	korai.mutsuko.at@mail.hosp.go.jp	11-Aug-2020	02-May-2023	Confirmed
Okada,Rieko	okada.rieko.nt@mail.hosp.go.jp	18-Feb-2021		Confirmed
Fujii,Yumi	fujii.yumi.gn@mail.hosp.go.jp	27-Dec-2021		Confirmed
Makita,Masanori	makita.masanori.uw@mail.hosp.go.j	27-Dec-2021		Confirmed
yoshioka,takanori	takanori.yoshi@gmail.com	17-Dec-2021		Confirmed
Sando,YASUHISA	yasuhisa.sando@gmail.com	21-Dec-2021		Confirmed
Nishiyama,Atsuko	nishiyama.atsuko.vd@mail.hosp.go.	06-Apr-2022	21-Jun-2024	Confirmed
Kaneko,Tamami	kaneko.tamami.pe@mail.hosp.go.jp	06-May-2022		Confirmed
Ueno,Anna	ueno.anna.cp@mail.hosp.go.jp	11-May-2022		Confirmed
Masumoto,Fumi	masumoto.fumi.eu@mail.hosp.go.jp	07-Jun-2022		Confirmed
Tsuno,Saeko	tsuno.saeko974@eps.co.jp	11-Nov-2022		Confirmed
tabuchi,isao	edrc3560as@gmail.com	29-Nov-2022		Confirmed
Fukuda,Yoshitake	fukuda.y9303@gmail.com	26-Nov-2022		Confirmed
Shigetoshi,Masataka	masataka.shigetoshi@gmail.com	15-Nov-2022		Confirmed
Kobashi,Soichiro	soichiro.kobashi@gmail.com	18-Nov-2022		Confirmed
Watanabe,Atsuyuki	watanabe.atsuyuki.ct@mail.hosp.go	14-Sep-2022		Confirmed
Matsubara,Hiromi	matsubara.hiromi@gmail.com	20-Oct-2022		Confirmed
Wakabayashi,Aiko	wakabayashi.aiko.qg@mail.hosp.go	07-Nov-2023		Confirmed
Iwamoto,Keiko	iwamoto.keiko.kf@mail.hosp.go.jp	31-Aug-2023		Confirmed
Furujo,Mahoko	furujo.mahoko.ra@mail.hosp.go.jp	19-Sep-2023		Confirmed
Murakami,Michiko	michiko.kishi.831@gmail.com	18-Jan-2024		Confirmed
Shimizu,JUNYA	shimizu.junya.sb@mail.hosp.go.jp	19-Jan-2024		Confirmed
Kageyama,Misao	misao0330@me.com	14-Feb-2024		Confirmed
Tamai,Kei	tamaikei0821@gmail.com	18-Jan-2024		Confirmed
takao,miyabi	miyabi-takao.gh@cmicgroup.com	29-Feb-2024		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Otsuki,Minako	ootsuki.minako@neues.co.jp	17-Jan-2024		Confirmed
Maitani,Sachiko	maitani.sachiko@neues.co.jp	17-Jan-2024		Confirmed
Fujiwara,Shintaro	fujiwara.shintaro.jq@mail.hosp.go.jp	03-Feb-2024		Confirmed
Honda,Momo	momo-honda.yc@cmicgroup.com	04-Mar-2024		Confirmed
Igarashi,Jun	jun-igarashi@cmicgroup.com	04-Mar-2024		Confirmed
KAMIYA,YUSAKU	chopan0707@hotmail.co.jp	14-Feb-2024		Confirmed
Nakamura,Makoto	nakamura.makoto.nt@mail.hosp.go.	06-Feb-2024		Confirmed
Sano,Nagako	sano.nagako363@eps.co.jp	01-Mar-2024		Confirmed
Saito,Takashi	saito.takashi.tb@mail.hosp.go.jp	05-Feb-2024		Confirmed
Higuchi,Yousuke	higuchi.yosuke.cx@mail.hosp.go.jp	18-Jan-2024		Confirmed
Watanabe,Keiko	keiko-watanabe@cmicgroup.com	04-Mar-2024	04-Mar-2024	Confirmed
Yasutake,Miyu	yasutake.miyu@neues.co.jp	28-Nov-2023		Confirmed
UENO,MASAYA	ueno.masaya.gh@mail.hosp.go.jp	22-Dec-2023		Confirmed
Takeuchi,Akihito	gmd18025@s.okayama-u.ac.jp	09-Jan-2024		Confirmed
Kondo,Akira	kondo.akira.rh@mail.hosp.go.jp	27-Dec-2023		Confirmed
Uenaga,Noriko	uenaga.noriko@neues.co.jp	28-Dec-2023		Confirmed
matsuda,masayuki	matsuda.masayuki.by@mail.hosp.g o.jp	05-Jan-2024		Confirmed
Tanita,Noriko	tanita.noriko@neues.co.jp	29-Dec-2023		Confirmed
Eda,Mutsumi	eda.mutsumi@neues.co.jp	05-Dec-2023		Confirmed
Ota,Kosuke	oota.kosuke.vn@mail.hosp.go.jp	29-Mar-2024		Confirmed
Mariko,Hattori	hattori.mariko.yb@mail.hosp.go.jp	15-Apr-2024		Confirmed
Fujiwara,Keiichi	fujiwara.keiichi.ng@mail.hosp.go.jp	23-Apr-2024		Confirmed
Nakamura,Makoto	mattari.n.makoto@gmail.com	28-Apr-2024		Confirmed
Ikeda,Misa	ikeda.misa@neues.co.jp	15-Apr-2024		Confirmed
Chikama,Shunsuke	fuel_0245@yahoo.co.jp	30-Apr-2024		Confirmed
Ando,Tsubasa	tsubasaando1103@gmail.com	04-May-2024		Confirmed
Hamaguchi,Yasuhito	yhamaguchist0206@gmail.com	28-May-2024		Confirmed
Fujiwara,Masumi	fujiwara.masumi995@eps.co.jp	25-May-2024		Confirmed