cognizant
shared investigator platform

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Hokkaido Cancer Center		2-3-54 Kikusui 4-jo, Sapporo, Hokkaido, Japan, 003-0804

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Miura, Kiyofumi	miura.kiyofumi.kf@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)

Therapeutic Area	Sub Therapeutic Area
Oncology	Bladder
Oncology	Breast
Oncology	Carcinoma
Oncology	Cervical
Oncology	Colorectal
Oncology	Esophagael
Oncology	Gastric
Oncology	Gastrointestinal
Oncology	Genitourinary
Oncology	Head and Neck
Oncology	Hematologic Malignancies
Oncology	Hepatocellular Carcinoma
Oncology	Leukemia
Oncology	Lung
Oncology	Lymphoma
Oncology	Multiple Myeloma
Oncology	Ovarian
Oncology	Prostate
Oncology	Radiation Oncology
Oncology	Renal
Oncology	Sarcoma

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Therapeutic Area	Sub Therapeutic Area
Oncology	Uterine

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.	No
What study types does your Facility have experience with?	Investigator Initiated; Academic
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes

Patient Population	
Patient Population Demographics	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	National
Department Contact Phone Number	+81118119111
Department Contact Email Address	100-ml080100c@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?	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 example, scientific, radiation safety committees, or others.	No

Local Lab

Is your Facility using a Local Lab?	Yes

Local Lab: Clinical Laboratory	
Lab Name	Clinical Laboratory
Lab Contact First Name	hidenori
Lab Contact Last Name	kato
Address	4-2-3-54 kikusui shiroishi-ku, 2F, sapporo, Hokkaido, Japan, 003-0804
Phone Number	+81118119111
Fax Number	+81118119232
Email Address	100-ml080100c@mail.hosp.go.jp
Local Lab Accreditation	Others
Other Local Lab Accreditation	Japanese Medical AssociationJapanese 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 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?	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.	APRIN e-learning program (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; Dual-Energy X-ray Absorptiometry or Bone Densitometry; Magnetic Resonance Imaging; Positron Emission Tomography Scan; X-Radiation; Mammography; Nuclear Medicine (e.g.Bone scan,Thyroid scan,Thallium cardiac stress test); 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.?	No

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?	No
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?	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.	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

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)?	
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?	

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
clinical trial management office	4-2-3-54 kikusui shiroishi-ku, 3F, sapporo, Hokkaido, Japan, 003-0804	100-ml080100c@hosp.go.jp	+81118119111	+81118119232

Investigational Product Storage Location

IP Recipient Name	Address	Email Address	Phone Number	Fax Number
clinical trial management office	4-2-3-54 kikusui shiroishi-ku, 3F, sapporo, Hokkaido, Japan, 003-0804	100-ml080100c@hosp.go.jp	+81118119111	+81118119232

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); 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: 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.	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?	No
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?	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?	No
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?	Not Applicable
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)
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?	Not Applicable
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?	Not Applicable
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		

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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)	
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?	
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?	
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:	Phone; Fax; 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 : Apices viedocmacro
Describe Other EDC Systems	Apices viedocmacro
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote 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
No Records				

Associated/Confirmed Site Users				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Watanabe,Kenichi	hcc@watanabekenichi.com	10-Jul-2022		Confirmed
Mizugaki,Hidenori	hidenori.mizugaki@jfcr.or.jp	01-Mar-2023		Confirmed
Fujimoto,Katsuya	kfujimo@med.hokudai.ac.jp	08-Mar-2023		Confirmed
Kobayashi,Shinya	shinya-kobayashi@iromgroup.co.jp	08-Mar-2023		Confirmed
Kamada,Miku	miku-kamada.fr@cmicgroup.com	12-May-2023		Confirmed
Ito,Kazuyoshi	ito.kazuyoshi.fk@mail.hosp.go.jp	09-May-2023		Confirmed
Ishihara,Chie	ishihara.chie.gy@mail.hosp.go.jp	09-May-2023		Confirmed
Seino,Madoka	madoka-seino@cmicgroup.com	18-May-2023	18-May-2023	Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Tashiro,Mayumi	mayumi-tashiro@cmicgroup.com	12-May-2023		Confirmed
Kadomasu,Shiori	kadomasu.shiori.mn@mail.hosp.go.jp	10-May-2023		Confirmed
Asahina,Hajime	asahina.hajime.vc@mail.hosp.go.jp	08-May-2023		Confirmed
Hatakeyama,Yuki	yukihatake.0418@gmail.com	12-May-2023		Confirmed
Takada,Shinya	takada.shinya.fa@mail.hosp.go.jp	08-May-2019	29-Jul-2020	Confirmed
Souma,Mikiko	souma.mikiko.er@mail.hosp.go.jp	12-Nov-2019		Confirmed
Miura,Kiyofumi	miura.kiyofumi.kf@mail.hosp.go.jp	12-Nov-2019	04-Apr-2023	Confirmed
Takamichi,Yuka	takamichi.yuka.ty@mail.hosp.go.jp	12-Nov-2019		Confirmed
Todo,Yukiharu	yukiharu961026t@yahoo.co.jp	07-Jan-2020	07-Jan-2020	Confirmed
Echizen,Ayana	echizen.ayana.wb@mail.hosp.go.jp	25-Nov-2019		Confirmed
Uno,Asami	uno.asami.ye@mail.hosp.go.jp	25-Nov-2019		Confirmed
Kato,Hidenori	kato.hidenori.cy@mail.hosp.go.jp	12-Dec-2019		Confirmed
Minobe,Shinichiro	minobe.shinichiro.hb@mail.hosp.go.jp	20-Dec-2019		Confirmed
Tajima,Hiroe	tajima.hiroe.wz@mail.hosp.go.jp	25-Nov-2019		Confirmed
Yamagishi,Kayo	yamagishi.kayo.uw@mail.hosp.go.jp	13-Nov-2019		Confirmed
Nitta,Masayo	nitta.masayo.re@mail.hosp.go.jp	25-Nov-2019		Confirmed
Shirooka,Yukari	shirooka.yukari.rw@mail.hosp.go.jp	25-Nov-2019		Confirmed
Nishiwaki,Satoko	nishiwaki.satoko.ws@mail.hosp.go.jp	18-Nov-2019		Confirmed
Itagaki,Yoriko	itagaki.yoriko.qu@mail.hosp.go.jp	12-Nov-2019	04-Apr-2021	Confirmed
Nakagawa,Yuko	nakagawa.yuko.ny@mail.hosp.go.jp	12-Nov-2019		Confirmed
Takahashi,Masato	masato.takahashi0725@gmail.com	12-Dec-2019	02-Feb-2021	Confirmed
Minowa,Kaoru	minowa.kaoru.gt@mail.hosp.go.jp	26-Dec-2019	26-Dec-2019	Confirmed
Fukai,Yuta	fukai.yuta.ax@mail.hosp.go.jp	25-Jun-2020	04-Apr-2023	Confirmed
Sato,Yoshimi	sato.yoshimi.yd@mail.hosp.go.jp	24-Jul-2020		Confirmed
Tsuruta,Tomohiko	tsuruta27@hotmail.co.jp	18-Sep-2020		Confirmed
Yamada,Ryutaro	yamada.ryutaro.dg@mail.hosp.go.jp	18-Sep-2020		Confirmed
Harada,Masao	harada.masao.py@mail.hosp.go.jp	15-Oct-2020		Confirmed
Oizumi,Satoshi	soizumi@hokkaido.med.or.jp	15-Oct-2020		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Saito,Chiharu	saito.chiharu.sd@mail.hosp.go.jp	10-Nov-2020		Confirmed
Iguchi,Aki	iguchi.aki.ab@mail.hosp.go.jp	10-Nov-2020		Confirmed
YAMADA,NORIYUKI	yamada.noriyuki.qw@mail.hosp.go.jp	05-Nov-2020		Confirmed
Yokouchi,Hiroshi	hyokouch@gmail.com	05-Nov-2020		Confirmed
Kudo,Risa	kudo.risa.sk@mail.hosp.go.jp	24-Nov-2020		Confirmed
Morioka,Yuuki	morioka.yuuki.rj@mail.hosp.go.jp	10-Nov-2020		Confirmed
Nishikawa,Noboru	nishikawa.noboru.kr@mail.hosp.go.jp	15-Dec-2020	15-Dec-2020	Confirmed
Nishiyama,Noriaki	nishiyama.noriaki.vr@mail.hosp.go.jp	04-Dec-2020		Confirmed
nishikawa,yukiko	nishikawa.yukiko.kj@mail.hosp.go.jp	01-Dec-2020		Confirmed
Fukumoto,Shin-ichi	fukumoto.shinichi.ad@mail.hosp.go.jp	11-Dec-2020		Confirmed
Harabayashi,Toru	harabayashi-jua@umin.ac.jp	18-Jan-2021	14-Jun-2021	Confirmed
Maruyama,Satoru	maruyama_satoru@yahoo.co.jp	18-Feb-2021		Confirmed
Kikuchi,Minoru	kikuchi.minoru.ft@mail.hosp.go.jp	05-Apr-2021		Confirmed
SUZUKI,YUTARO	suzuki.yu.1989@gmail.com	29-Apr-2021	29-Apr-2021	Confirmed
Minatogawa,Hideki	minatogawa.hideki.wb@mail.hosp.go.jp	25-Jun-2021		Confirmed
Shiroshita,Takashi	shiroshita.takashi.zu@mail.hosp.go.jp	21-Sep-2021		Confirmed
Sakakibara,Jun	konishj@med.hokudai.ac.jp	01-Sep-2021	01-Sep-2021	Confirmed
Yamamoto,Mitsugu	phei@sh.rim.or.jp	03-Dec-2021		Confirmed
Tomioka,Nobumoto	nmhtomsfhcc@yahoo.co.jp	21-Dec-2021		Confirmed
Maeda,Hideki	chiken.maeda@gmail.com	14-Dec-2021		Confirmed
Sato,Keiichi	sato.keiichi.ky@mail.hosp.go.jp	24-Mar-2022		Confirmed
Sato,Yuma	sato.yuma.wd@mail.hosp.go.jp	18-Apr-2022		Confirmed
Kawamura,Nanami	kawamura.nanami.bj@mail.hosp.go.jp	11-Oct-2022		Confirmed