cognizant
shared investigator platform

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
Beppu Medical Center	Hospital or Medical Center	1473 Uchikamado Ooaza, Beppu, Oita, Japan, 874-0011

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Fujimoto, Airi	fujimoto.airi.kc@mail.hosp.go.jp	Facility Profile Manager
No	Aso, Tomoe	aso.tomoe.gn@mail.hosp.go.jp	Facility Profile Manager
No	Sato, Akiko	sato.akiko.zw@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	**Sub Therapeutic Area**
Allergy	
Anesthesia	
Bone	
Chemically-induced Disorders	
Digestive System Diseases	
Endocrine System Diseases	
Eye Diseases	
Female Urogenital Diseases and Pregnancy Complications	
Fertility	
General Surgery	
Hemic and Lymphatic Diseases	
Immune System Diseases	
Infectious Diseases	
Internal Medicine	
Male Urogenital Diseases	
Mental disorders	
Musculoskeletal Diseases	
Neoplasms	
Nephrology	

cognizant
shared investigator platform

Therapeutic Area	Sub Therapeutic Area
Nutritional and Metabolic Diseases	
Oncology	
Orthopedics	
Otorhinolaryngologic Diseases	
Pain	
Parasitic Diseases	
Pathological Conditions, Signs and Symptoms	
Pediatrics	
Respiratory Tract Diseases	
Skin and Connective Tissue Diseases	
Stomatognathic Diseases	
Vaccines	
Virus Diseases	
Women's Health	
Wounds and Injuries	
Bacterial Infections and Mycoses	
Nervous System Diseases	
Cardiovascular Diseases	
Congenital, Hereditary, and Neonatal Diseases and Abnormalities	

Other Areas of Expertise

Study Phase Capabilities
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?	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

SIP Facility Profile Export generated on 10-Jun-2026 17:08:00

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	Department of Clinincal Trial Management
Department Contact Phone Number	+81-977-67-1111
Department Contact Email Address	618-chiken1@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?	Yes
Other Steps Explain	IRB documents should be submitted at least 2 week prior to the IRB.

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: National Hospital Organization Beppu Medical Center Institutional Review Board	
IRB/ERB/Ethics Committee Name	National Hospital Organization Beppu Medical Center Institutional Review Board
Address	1473 ooaza uchikamado, Beppu, Oita, Japan, 874-0011
Registration#	**Registering Body**
NA	NA
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Monthly
How long before IRB/ERB/Ethics review is the Submission Packet required?	2 weeks
Does the IRB/ERB/Ethics Committee require payment prior to release of final approval documents?	No
Does the IRB/ERB/Ethics Committee require contract/budget approval prior to release of final approval documents?	No

LOCAL IRB/ERB/ETHICS COMMITTEE ATTACHMENTS

Document Type	Document Name	Document Description
No Records		

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

cognizant
shared investigator platform

Local Lab: Department of Clinical Laboratory	
Lab Name	Department of Clinical Laboratory
Lab Contact First Name	
Lab Contact Last Name	
Address	1473 ooazauchikamado, Beppu, Oita, Japan, 874-0011
Phone Number	+81-977-67-1111
Fax Number	+81-977-67-6267
Email Address	618-chiken1@mail.hosp.go.jp
Local Lab Accreditation	Others
Other Local Lab Accreditation	Japanese Association of Medical TechnologistsJananese Committee for Clinical Laboratory Standard
Additional Questions	
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?	No
What is the system or tool that the site currently has or utilizes to document Bio-specimen (Sample) Processing Steps/ Chain of Custody?	Prefer to use Sponsor provided System/ Tools
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?	No
What are your Facility's capabilities for tissue collection and/or processing (embedding)?	Tissue biopsy is performed on-site. Pathological processing including embedding and sectioning is conducted by the in-house pathology department.
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?	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?	No
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)	NA
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?	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, Dual-Energy X-ray Absorptiometry or Bone Densitometry, Magnetic Resonance Imaging, Fluoroscopy, X-Radiation, Magnetic Resonance Angiography, 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 maintenance of 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
Identify the equipment available at the Facility to support Research studies?	Refrigerated Centrifuge, Centrifuge, 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.	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: 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.	Less than 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?	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?	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?	Yes
Does your Facility continuously update the anti-virus software to the most recent version?	Yes
Does your Facility have an SOP or process that documents both physical and firewall security measures that are used for electronic systems?	Yes
How is access to the electronic devices (e.g. computers, laptops, iPad/tablet) secured against unauthorized use?	Access to electronic devices is secured through password authentication and physical key locks on the research facility.
Does your Facility perform periodic system reviews to ensure they remain in a validated state?	Yes
Does your Facility have an SOP or process that documents user management processes that are used for electronic systems?	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
What type of internet browser(s) does your institution use to support studies? (Check all that apply)	Edge
Is access to the internet secured against unauthorized use?	Yes
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)	Yes
Does your institution allow the download of information from an external portal ?(e.g. eDC system)	Yes
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)?	Yes
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
Beppu Medical Center	1473 ooazauchikamado, Beppu, Oita, Japan, 874-0011	+81-977-67-1111	+81-977-67-6267	618-chiken1@mail.hosp.go.jp	

Investigational Product Storage Location

IP Storage Location Name	Address	Phone Number	Fax Number	Email Address
Department of pharmacy	1473 ooazauchikamado, Beppu, Oita, Japan, 874-0011	+81-977-67-1111	+81-977-67-6267	618-chiken1@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.	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 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?	No
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?	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?	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
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)?	Yes

SIP Facility Profile Export generated on 10-Jun-2026 17:08:00

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?	Yes
What type of investigator site file/regulatory binder used (select all that apply)	Paper, Electronic
What investigator site file (eISF) / eRegulatory system do you use?	Others: Agatha eTMF
Are monitors able to access eISF/eReg while off-site?	Yes
Do the eISF/eReg systems conform with international system standards (e.g. ICH/GCP/EU)?	Yes
Please list any access limitations/ requirements for eISF/eReg	Access requires individual user authentication (username and password). Accounts are granted by the site upon request and managed by the system administrator. Access is limited to authorized personnel only.
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?	Other
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.	The Electronic Medical System permits to create a “read-only” user account for CRA which limit to review only study subject’s data.
Do the EHR/EMR systems conform with international system standards (e.g. ICH/GCP/EU)?	Yes
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?	No
Does your Facility utilize any additional electronic systems or paper-based systems to access patient medical history?	No
Do the systems used for clinical trial data entry and management have audit trail functionality?	Yes
Bring Your Own Device	
Can your Facility support the use of bring your own device (BYOD) technologies to conduct Clinical Trials?	Yes
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
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**
Shuto,Mayumi	Clinical Research User	21-Oct-2025	21-Oct-2025	Confirmed
Yamamura,Mitsuyo	Clinical Research User	17-Oct-2025	17-Oct-2025	Confirmed
uemura,tamami	Clinical Research User	17-Oct-2025	17-Oct-2025	Confirmed
Tanaka,Minori	Investigator	12-Jun-2023	12-Jun-2023	Confirmed
Fukuizumi,Satoko	Clinical Research User	04-Aug-2025	04-Aug-2025	Confirmed
Fujimoto,Airi	Clinical Research User	04-Aug-2025	04-Aug-2025	Confirmed
Yamamoto,Keisuke	Clinical Research User	04-Apr-2023	04-Apr-2023	Confirmed
Taniguchi,Noritaka	Clinical Research User	04-Apr-2023	04-Apr-2023	Confirmed
Yamashita,Manato	Clinical Research User	20-Aug-2019	20-Aug-2019	Confirmed
Abe,Akiko	Clinical Research User	08-Nov-2019	08-Nov-2019	Confirmed
Koga,Hiroshi	Investigator	19-Dec-2019	19-Dec-2019	Confirmed
Akai,Mayuko	Clinical Research User	05-Nov-2019	05-Nov-2019	Confirmed
Ashikari,Mao	Clinical Research User	03-Dec-2019	03-Dec-2019	Confirmed
Itonaga,Tomomi	Clinical Research User	23-Jan-2020	23-Jan-2020	Confirmed
Inoue,Daisuke	Clinical Research User	30-Mar-2021	30-Mar-2021	Confirmed
Nakashima,Yu	Investigator	27-Apr-2021	27-Apr-2021	Confirmed
Ishikura,Toshiya	Investigator	27-Apr-2021	27-Apr-2021	Confirmed
Sasaki,Madoka	Clinical Research User	02-Apr-2021	02-Apr-2021	Confirmed
Sato,Akiko	Clinical Research User	30-Mar-2021	30-Mar-2021	Confirmed
Korematsu,Tatsuya	Investigator	30-Mar-2021	30-Mar-2021	Confirmed
Matsui,Nodoka	Clinical Research User	07-Jun-2021	07-Jun-2021	Confirmed
Itai,Masako	Clinical Research User	30-Aug-2021	30-Aug-2021	Confirmed
Kajiwara,Kenta	Clinical Research User	01-Oct-2021	01-Oct-2021	Confirmed
Yamakita,Yuichi	Investigator	01-Oct-2021	01-Oct-2021	Confirmed
Watanuki,Keisuke	Investigator	01-Apr-2022	01-Apr-2022	Confirmed
Suzuki,Tomoya	Investigator	04-Apr-2022	04-Apr-2022	Confirmed
Higuchi,Ryunosuke	Investigator	04-Apr-2022	04-Apr-2022	Confirmed
Takazaki,Hiroomi	Clinical Research User	26-Apr-2022	26-Apr-2022	Confirmed

Name	User Role	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Anami,Ai	Investigator	08-Nov-2023	08-Nov-2023	Confirmed
Masui,Ryosuke	Clinical Research User	13-Aug-2025	13-Aug-2025	Confirmed
Okamoto,Tatsuro	Investigator	19-Sep-2025	19-Sep-2025	Confirmed
Tanaka,Ai	Investigator	23-Sep-2025	23-Sep-2025	Confirmed
Aso,Tomoe	Clinical Research User	19-Nov-2025	19-Nov-2025	Confirmed