Facility Details for National Hospital Organization Kyushu Medical Center

Cognizant Shared Investigator Platform

## FACILITY NAME & ADDRESS

| Facility Name | Facility Type | Facility Address |
|---|---|---|
| National Hospital Organization Kyushu Medical Center | Hospital or Medical Center | 1-8-1 Jigyohama Chuo-ku, Fukuoka, Fukuoka, Japan, 810-8563 |

## FACILITY CONTACTS

| Primary FPM? | Name | Email Address | Roles |
|---|---|---|---|
| Yes | Nagaosa, Naomi | nagaosa.naomi.ze@mail.hosp.go.jp | Facility Profile Manager |

## THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)

| Therapeutic Area | Sub-Therapeutic Area |
|---|---|
| Bacterial Infections and Mycoses | Bacterial Infections |
| Bacterial Infections and Mycoses | Central Nervous System Infections |
| Bacterial Infections and Mycoses | Infection |
| Bacterial Infections and Mycoses | Mycoses |
| Bacterial Infections and Mycoses | Zoonoses |
| Bone | |
| Cardiovascular Diseases | |
| Chemically-induced Disorders | |
| Congenital, Hereditary, and Neonatal Diseases and Abnormalities | |
| Digestive System Diseases | |
| Disorders of Environmental Origin | |
| Endocrine System Diseases | |
| Eye Diseases | |
| Female Urogenital Diseases and Pregnancy Complications | |
| Hemic and Lymphatic Diseases | |
| Immune System Diseases | |
| Male Urogenital Diseases | |
| Mental disorders | |
| Musculoskeletal Diseases | |
| Neoplasms | |
| Nephrology | |

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| Therapeutic Area | Sub-Therapeutic Area |
|---|---|
| Nervous System Diseases | |
| Nutritional and Metabolic Diseases | |
| Ob-Gyn | |
| Allergy | |
| Occupational Diseases | |
| Oncology | |
| Orthopedics | |
| Pain | |
| Parasitic Diseases | |
| Pathological Conditions, Signs and Symptoms | |
| Pediatrics | |
| Respiratory Tract Diseases | |
| Skin and Connective Tissue Diseases | |
| Stomatognathic Diseases | |
| Vaccines | |
| Women's Health | |
| Wounds and Injuries | |
| Virus 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. | 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 | Adults - Ages 18-64; Geriatrics - Greater than or equal to 65 |

| Patient Population Comments |
|---|
| Japanese 90% |

## IRB/ERB/ETHICS COMMITTEE

| General Questions | |
|---|---|
| What is the average time (in days) to start a study once you have received the regulatory package? | Less than 30 |
| Does your facility perform IRB/ERB/Ethics Committee submissions? | Yes |
| Does your facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions? | Yes |
| Department Contact Name | Clinical |
| Department Contact Phone Number | +81-92-852-0700 |
| Department Contact Email Address | 602-irb@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? | 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 | |

## LOCAL IRB/ERB/ETHICS COMMITTEE

| Local IRB/ERB/Ethics Committee: National Hospital Organization Kyushu Medical Center Institutional Review Board | |
|---|---|
| IRB/ERB/Ethics Committee Name | National Hospital Organization Kyushu Medical Center Institutional Review Board |
| Address | 1-1-1,Jigyouhama,Chuo-ku,Fukuoka, Fukuoka, Fukuoka, Japan, 810-8563 |
| What is the meeting frequency of the IRB/ERB/Ethics Committee? | Monthly |
| How long before IRB/ERB/Ethics review is the Submission Packet required? | Greater than 2 weeks |
| Does the IRB/ERB/Ethics Committee require payment prior to release of final approval documents? | |

| Registration# | Registering Body |
|---|---|
| NA | |

LOCAL IRB/ERB/ETHICS COMMITTEE ATTACHMENTS

| Document Type | Document Name | 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 |
| **Local Lab: National Hospital Organization Kyushu Medical Center** | |
| Lab Name | National Hospital Organization Kyushu Medical Center |
| Lab Contact First Name | |
| Lab Contact Last Name | |
| Address | 1-8-1 Jigyohama Chuo-ku, Fukuoka, Fukuoka, Japan, 810-8563 |
| Phone Number | +81-92-852-0700 |
| Fax Number | |
| Email Address | 602-irb@mail.hosp.go.jp |
| Local Lab Accreditation | ISO |

| 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 | 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. | 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 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? | 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; Positron Emission Tomography Scan; X-Radiation; Magnetic Resonance Angiography; Magnetic Resonance Spectroscopy; 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.? | Yes |
| Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)? | Yes |
| **Equipment Available At The Facility To Support Research Studies** | |
| 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? | Yes |
| **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. | 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? | |

Attachments

| Document Type | Document Name | Description |
|---|---|---|

## INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details

| IP Recipient Name | Address | Email Address | Phone Number | Fax Number |
|---|---|---|---|---|
| National Hospital Organization Kyushu Medical Center | 1-8-1 Jigyohama Chuo-ku, Fukuoka, Fukuoka, Japan, 810-8563 | | +81-92-852-0700 | |

Investigational Product Storage Location

| IP Recipient Name | Address | Email Address | Phone Number | Fax Number |
|---|---|---|---|---|
| Pharmaceutical department | 1-8-1 Jigyohama Chuo-ku, Fukuoka, Fukuoka, Japan, 810-8563 | | +81-92-852-0700 | |

| 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? | Yes |

| 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? | Yes |
| 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? | 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 Product Storage & Handling Capabilities | |
| Preparation and Administration Of Investigational Product | |
| Identify the Investigational Product preparation capabilities at your Facility | Vertical laminar flow hood (chemo/hazardous drugs); Horizontal laminar flow hood (non-hazardous drug preparation) |
| 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 | Description |
| Investigational Product Destruction Policy/SOP | SOP1_2013_07.doc | |

SOURCE DOCUMENTATION

| 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? | Each Satellite Site and Main Facility |
| 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 |
| 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? | |
| Which of the following capabilities are available to support remote source data verification? (Check all that apply) | |

## 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 Facility. Please reference the section name if applicable.

**Facility Attachments**

| Document Type | Document Name | Description |
|---|---|---|
| No Records | | |

## ORGANIZATION AFFILIATIONS

**Organization Affiliations**

The Organization (s) that requested Affiliation with your Facility/Department are listed below with Affiliation Status

| Organization Name and Address | Organization Affiliation Type | Organization Affiliation Status | Status Date |
|---|---|---|---|
| No Records | | | |

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