FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization - Osaka National Hospital - Institute For Clinical Research	Hospital or Medical Center	2-1-14,Hoenzaka,Chuo-ku, Osaka, Osaka, Japan, 540-0006

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Hada, Kaoru	hada.kaoru.yx@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
Cardiovascular Diseases	Kidney Diseases
Cardiovascular Diseases	Metabolic
Cardiovascular Diseases	Cardiovascular Abnormalities
Cardiovascular Diseases	Cardiovascular Infections
Cardiovascular Diseases	Heart Diseases
Cardiovascular Diseases	Pregnancy Complications, Cardiovascular
Cardiovascular Diseases	Vascular Diseases
Chemically-induced Disorders	Drug-Related Side Effects and Adverse Reactions
Chemically-induced Disorders	Poisoning
Chemically-induced Disorders	Substance-Related Disorders
Digestive System Diseases	Inflammatory Bowel Disease
Digestive System Diseases	Biliary Tract Diseases
Digestive System Diseases	Digestive System Abnormalities
Digestive System Diseases	Digestive System Fistula
Digestive System Diseases	Digestive System Neoplasms
Digestive System Diseases	Gastrointestinal Diseases
Digestive System Diseases	Liver Diseases

Therapeutic Area	Sub Therapeutic Area
Digestive System Diseases	Pancreatic Diseases
Digestive System Diseases	Peritoneal Diseases
Disorders of Environmental Origin	Environmental Illness
Endocrine System Diseases	Adrenal Gland Diseases
Endocrine System Diseases	Bone Diseases, Endocrine
Endocrine System Diseases	Diabetes Mellitus
Endocrine System Diseases	Dwarfism
Endocrine System Diseases	Endocrine Gland Neoplasms
Endocrine System Diseases	Female Athlete Triad Syndrome
Endocrine System Diseases	Gonadal Disorders
Endocrine System Diseases	Parathyroid Diseases
Endocrine System Diseases	Pituitary Diseases
Endocrine System Diseases	Polyendocrinopathies, Autoimmune
Endocrine System Diseases	Thyroid Diseases
Endocrine System Diseases	Tuberculosis, Endocrine
Eye Diseases	Asthenopia
Eye Diseases	Cogan Syndrome
Eye Diseases	Conjunctival Diseases
Eye Diseases	Corneal Diseases
Eye Diseases	Eye Abnormalities
Eye Diseases	Eye Diseases, Hereditary
Eye Diseases	Eye Hemorrhage
Eye Diseases	Eye Infections
Eye Diseases	Eye Injuries
Eye Diseases	Eye Manifestations
Eye Diseases	Eye Neoplasms
Eye Diseases	Eyelid Diseases
Eye Diseases	Lacrimal Apparatus Diseases
Eye Diseases	Lens Diseases

Therapeutic Area	Sub Therapeutic Area
Eye Diseases	Ocular Hypertension
Eye Diseases	Ocular Hypotension
Eye Diseases	Ocular Motility Disorders
Eye Diseases	Optic Nerve Diseases
Eye Diseases	Orbital Diseases
Eye Diseases	Pupil Disorders
Eye Diseases	Refractive Errors
Eye Diseases	Retinal Diseases
Eye Diseases	Scleral Diseases
Eye Diseases	Uveal Diseases
Eye Diseases	Vision Disorders
Eye Diseases	Vitreous Detachment
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases
Female Urogenital Diseases and Pregnancy Complications	Pregnancy Complications
Hemic and Lymphatic Diseases	Anemia
Hemic and Lymphatic Diseases	Hemophilia
Hemic and Lymphatic Diseases	Hematologic Diseases
Hemic and Lymphatic Diseases	Lymphatic Diseases
Hemic and Lymphatic Diseases	
Immune System Diseases	
Male Urogenital Diseases	Genital Diseases, Male
Male Urogenital Diseases	Pelvic Floor Disorders
Male Urogenital Diseases	Tuberculosis, Urogenital
Male Urogenital Diseases	Urogenital Abnormalities
Male Urogenital Diseases	Urogenital Neoplasms
Male Urogenital Diseases	Urologic Diseases
Musculoskeletal Diseases	Arthritis
Musculoskeletal Diseases	Bone Diseases
Musculoskeletal Diseases	Cartilage Diseases

Therapeutic Area	Sub Therapeutic Area
Musculoskeletal Diseases	Fasciitis
Musculoskeletal Diseases	Foot Deformities
Musculoskeletal Diseases	Foot Diseases
Musculoskeletal Diseases	Hand Deformities
Musculoskeletal Diseases	Jaw Diseases
Musculoskeletal Diseases	Joint Diseases
Musculoskeletal Diseases	Muscular Diseases
Musculoskeletal Diseases	Musculoskeletal Abnormalities
Musculoskeletal Diseases	Rheumatic Diseases
Neoplasms	Cysts
Neoplasms	Hamartoma
Neoplasms	Neoplasms by Histologic Type
Neoplasms	Neoplasms by Site
Neoplasms	Neoplasms, Experimental
Neoplasms	Neoplasms, Hormone-Dependent
Neoplasms	Neoplasms, Multiple Primary
Neoplasms	Neoplasms, Post-Traumatic
Neoplasms	Neoplasms, Radiation-Induced
Neoplasms	Neoplasms, Second Primary
Neoplasms	Neoplastic Processes
Neoplasms	Neoplastic Syndromes, Hereditary
Neoplasms	Paraneoplastic Syndromes
Neoplasms	Precancerous Conditions
Neoplasms	Pregnancy Complications, Neoplastic
Nervous System Diseases	Autoimmune Diseases of the Nervous System
Nervous System Diseases	Autonomic Nervous System Diseases
Nervous System Diseases	Central Nervous System Diseases
Nervous System Diseases	Chronobiology Disorders
Nervous System Diseases	Cranial Nerve Diseases

Therapeutic Area	Sub Therapeutic Area
Nervous System Diseases	Demyelinating Diseases
Nervous System Diseases	Nervous System Malformations
Nervous System Diseases	Nervous System Neoplasms
Nervous System Diseases	Neurocutaneous Syndromes
Nervous System Diseases	Neurodegenerative Diseases
Nervous System Diseases	Neurologic Manifestations
Nervous System Diseases	Neuromuscular Diseases
Nervous System Diseases	Neurotoxicity Syndromes
Nutritional and Metabolic Diseases	Metabolic Diseases
Nutritional and Metabolic Diseases	Nutrition Disorders
Otorhinolaryngologic Diseases	Ciliary Motility Disorders
Otorhinolaryngologic Diseases	Ear Diseases
Otorhinolaryngologic Diseases	Laryngeal Diseases
Otorhinolaryngologic Diseases	Nose Diseases
Otorhinolaryngologic Diseases	Otorhinolaryngologic Neoplasms
Otorhinolaryngologic Diseases	Pharyngeal Diseases
Skin and Connective Tissue Diseases	Connective Tissue Diseases
Skin and Connective Tissue Diseases	Skin Diseases
Stomatognathic Diseases	Ankyloglossia
Stomatognathic Diseases	Jaw Diseases
Stomatognathic Diseases	Mouth Diseases
Stomatognathic Diseases	Pharyngeal Diseases
Stomatognathic Diseases	Stomatognathic System Abnormalities
Stomatognathic Diseases	Temporomandibular Joint Disorders
Stomatognathic Diseases	Tooth Diseases
Virus Diseases	Viremia
Virus Diseases	Arbovirus Infections
Virus Diseases	Bronchiolitis, Viral
Virus Diseases	Central Nervous System Viral Diseases

Therapeutic Area	Sub Therapeutic Area
Virus Diseases	Coinfection
Virus Diseases	DNA Virus Infections
Virus Diseases	Encephalitis, Viral
Virus Diseases	Eye Infections, Viral
Virus Diseases	Fatigue Syndrome, Chronic
Virus Diseases	Hepatitis, Viral, Animal
Virus Diseases	Hepatitis, Viral, Human
Virus Diseases	Opportunistic Infections
Virus Diseases	Pneumonia, Viral
Virus Diseases	RNA Virus Infections
Virus Diseases	Sexually Transmitted Diseases
Virus Diseases	Skin Diseases, Viral
Virus Diseases	Slow Virus Diseases
Virus Diseases	Tumor Virus Infections
Virus Diseases	Zoonoses
Bone	Bone
Bone	Osteoporosis
Fertility	Fertility
Infectious Diseases	Infectious Diseases
Inflammation	Inflammation
Internal Medicine	Internal Medicine
Nephrology	Nephrology
Neuroscience	Neuroscience
Ob-Gyn	Ob-Gyn
Oncology	Brain
Oncology	Breast
Oncology	Central Nervous System
Oncology	Cervical
Oncology	Esophagael

Therapeutic Area	Sub Therapeutic Area
Oncology	Gastric
Oncology	Bladder
Oncology	Colorectal
Oncology	Gastrointestinal
Oncology	Genitourinary
Oncology	Head and Neck
Oncology	Hematologic Malignancies
Oncology	Hepatocellular Carcinoma
Oncology	Leukemia
Oncology	Lung
Oncology	Lymphoma
Oncology	Melanoma
Oncology	Multiple Myeloma
Oncology	Ovarian
Oncology	Pediatrics
Oncology	Prostate
Oncology	Radiation Oncology
Oncology	Renal
Oncology	Skin
Oncology	Uterine
Oncology	Carcinoma
Oncology	Sarcoma
Orthopedics	Orthopedics
Vaccines	Vaccines
Women's Health	Women's Health
Device	Device
Other Areas of Expertise	
Study Phase Capabilities	
Phase I; Phase II; Phase III; Phase IV	

Facility Profile Export generated on Mon, 19-Jun-2023 01:02:38 GMT-05:00

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?	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	
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?	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	Division of Clinical research Promotion
Department Contact Phone Number	81-6-6946-3581
Department Contact Email Address	408-chiken@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	General notes

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: National Hospital Organization Osaka National Hospital Institutional Review Board Ⅰ	
IRB/ERB/Ethics Committee Name	National Hospital Organization Osaka National Hospital Institutional Review Board Ⅰ

Registration#	Registering Body
NA	NA

What is the meeting frequency of the IRB/ERB/Ethics Committee?	Monthly
Other	
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

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

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
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?	Yes
Does your Facility have access to translators and translation support for trial conduct (e.g. consent, trial specific instruction)?	NA
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 maintenancof general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphymomanomer, etc.?	Yes

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.); Apple/Mac (OS X Snow Leopard, Mountain Lion, El Capitan, etc.)
What type of internet access does your Facility have?	Cable or DSL

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
National Hospital Organization Osaka National Hospital	2-1-14 Hoenzaka, osaka, Osaka, Japan, 5400006	408-chiken@mail.hosp.go.jp	+81-6-6946-3581	+81-6-6946-3582

Investigational Product Storage Location

No Records

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)

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?	Yes
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.	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?	No
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 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); 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	Document Description
No Records		

Facility Profile Export generated on Mon, 19-Jun-2023 01:02:38 GMT-05:00

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)	Paper; Electronic
What investigator site file (eISF) / eRegulatory system do you use?	DD works Trial Site
Are monitors able to access eISF/eReg while off-site?	Yes
Please list any access limitations/ requirements for eISF/eReg	Only DDworks while off-site
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.	Personnel ID and password required.
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
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 etc.
Describe Other EDC Systems	etc.
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?	No
Which of the following capabilities are available to support remote source data verification? (Check all that apply)	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.

Location Name	Contact Name	Address	Phone Number	Fax Number	E-mail Address
No Records					

Facility Profile Export generated on Mon, 19-Jun-2023 01:02:38 GMT-05:00

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

No Records