

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Nagoya Medical Center		4-1-1 Sannomaru, Nagoya, Aichi, Japan, 460-0001

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Sato, Natsuki	sato.natsuki.vs@mail.hosp.go.jp	Facility Profile Manager; Delegation Manager; Facility Clinical Trial Contact
No	Hirashima, Manabu	hirashima.manabu.rp@mail.hosp.go.jp	Facility Profile Manager; Delegation Manager; Facility Clinical Trial Contact
No	Yamada, Sayumi	yamada.sayumi.pf@mail.hosp.go.jp	Facility Profile Manager; Delegation Manager; Facility Clinical Trial Contact

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub Therapeutic Area
Allergy	
Bacterial Infections and Mycoses	
Bone	
Cardiovascular Diseases	
Digestive System Diseases	
Endocrine System Diseases	
Eye Diseases	
Hemic and Lymphatic Diseases	
Immune System Diseases	
Male Urogenital Diseases	
Mental disorders	
Musculoskeletal Diseases	
Neoplasms	
Nervous System Diseases	
Nutritional and Metabolic Diseases	
Oncology	
Otorhinolaryngologic Diseases	
Respiratory Tract Diseases	
Skin and Connective Tissue 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
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?	Less than 30
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 Administration
Department Contact Phone Number	+81529511111
Department Contact Email Address	311-chicken@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?	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?	No
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No

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 Nagoya Medical Center	
Lab Name	National Hospital Organization Nagoya Medical Center
Lab Contact First Name	Division
Lab Contact Last Name	Administration
Address	4-1-1, Sannomaru, Nagoya-shi, Aichi, Japan, 46000001
Phone Number	+81529511111
Fax Number	
Email Address	311-chicken@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?		
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?	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?	
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.	eaAPRIN
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?	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?	
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; 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
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?	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
Equipment Capabilities: Freezer (-20 to -30 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
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
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; Wi-Fi
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
National Hospital Organization Nagoya Medical Center	4-1-1, Sannomaru, Naka-ku, Pharmaceutical department, Nagoya-shi, Aichi, Japan, 46000001	311-chicken@mail.hosp.go.jp	+81529511111	

Investigational Product Storage Location				
IP Storage Location Name	Address	Email Address	Phone Number	Fax Number
Pharmaceutical department	4-1-1, Sannomaru, Naka-ku, 1, Nagoya-shi, Aichi, Japan, 46000001	311-chicken@mail.hosp.go.jp	+81529511111	

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.	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: 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
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

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?		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		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?		
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?		
Does the Facility have the ability to handle radio-labelled Investigational Product?		
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?		
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
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
What type of investigator site file/regulatory binder used (select all that apply)	
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?	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.	ID and password
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
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?		
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
Nishimura, Yuka	nishimura.yuka672@eps.co.jp	08-Dec-2022	08-Dec-2022	Confirmed
Iida, Hiroatsu	iida.hiroatsu.kr@mail.hosp.go.jp	08-Dec-2022	08-Dec-2022	Confirmed
Miyakawa, Keiko	miyakawa.keiko.kr@mail.hosp.go.jp	04-Jul-2022		Confirmed
Yamada, Sayumi	yamada.sayumi.pf@mail.hosp.go.jp	08-Jul-2022	21-Apr-2025	Confirmed
Morozaki, Yuki	yuki-morozaki.gr@cmicgroup.com	16-Jun-2023		Confirmed
Adachi, Tatsuya	adachi.tatsuya.gk@mail.hosp.go.jp	02-Jul-2023		Confirmed
Imahashi, Nobuhiko	nimahashi@med.nagoya-u.ac.jp	03-Jul-2023		Confirmed
Hirashima, Manabu	hirashima.manabu.rp@mail.hosp.go.jp	29-Mar-2023	01-May-2025	Confirmed
Shiroto, Miki	miki-shiroto.af@cmicgroup.com	02-May-2023		Confirmed
sato, seiko	sato.seiko.tq@mail.hosp.go.jp	30-May-2023		Confirmed
Shiiba, Ritsuya	ritsuya_shiiba@med.miyazaki-u.ac.jp	15-May-2023		Confirmed
Adachi, Naoya	adachi.naoya.hr@mail.hosp.go.jp	30-Aug-2019	28-Jul-2020	Confirmed
Tanabe, Kazue	tanabe.kazue.nc@mail.hosp.go.jp	04-Sep-2019		Confirmed
Saka, Hideo	saka@med.nagoya-u.ac.jp	10-Oct-2019		Confirmed
Hashimoto, Mizuho	hashimoto.mizuho.nr@mail.hosp.go.jp	30-Aug-2019	11-Mar-2020	Confirmed
Niwa, Hideyuki	nmc.niwahide@gmail.com	04-Nov-2019	04-Nov-2019	Confirmed
Nagata, Shoko	nagata.shoko.yj@mail.hosp.go.jp	29-Nov-2019	21-Apr-2025	Confirmed
Oki, Masahide	masahideo@gmail.com	18-Feb-2020		Confirmed
Yokomaku, Yoshiyuki	yoshiyukiyokomaku@gmail.com	15-Apr-2020		Confirmed
Yonejima, Tadashi	yonejima.tadashi.ab@mail.hosp.go.jp	01-Jun-2020	22-Mar-2022	Confirmed
Inoue, Hirotaka	inoue.hirotaka.mj@mail.hosp.go.jp	26-May-2020	21-Apr-2025	Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Murata,Saeko	murata.saeko.mv@mail.hosp.go.jp	21-Jul-2020		Confirmed
Tsuruta,Yuko	tsuruta.yuko.kg@mail.hosp.go.jp	09-Jul-2020		Confirmed
Suzuki,Masami	suzuki.masami.yv@mail.hosp.go.jp	07-Jul-2020		Confirmed
Igarashi,Nami	igarashi.nami.yf@mail.hosp.go.jp	08-Jul-2020	08-Jul-2020	Confirmed
Misawa,Kana	misawa.kana.dy@mail.hosp.go.jp	10-Jul-2020		Confirmed
Torii,Atsushi	a51009068@gmail.com	16-Jul-2020		Confirmed
Kodaka,Chihiro	inoue.chihiro.uc@mail.hosp.go.jp	17-Jul-2020	11-Aug-2021	Confirmed
KITAGAWA,CHIYOE	ckitag@kd6.so-net.ne.jp	24-Jul-2020		Confirmed
Nishikawa,Natsuki	nishikawa.natsuki.cg@mail.hosp.go.jp	10-Jul-2020		Confirmed
Hasegawa,Manami	hasegawa.manami.fr@mail.hosp.go.jp	24-Jul-2020		Confirmed
Hayashi,Misato	hayashi.misato.vr@mail.hosp.go.jp	08-Jul-2020		Confirmed
Kaneno,Yoko	yoko-kaneno@cmicgroup.com	27-Jun-2020	08-Jul-2020	Confirmed
Koshiba,Tomomi	tomomi-koshiba.yc@cmicgroup.com	08-Jul-2020	19-Apr-2021	Confirmed
Hida,Naoki	naoki-hida@cmicgroup.com	24-Jul-2020		Confirmed
Kashiwagi,Kanako	kanako-kashiwagi@cmicgroup.com	24-Jul-2020		Confirmed
Sugiyama,Keiji	keiji.sugi@gmail.com	19-Oct-2020	19-Oct-2020	Confirmed
Yamada,Arisa	ariyama0524@gmail.com	16-Oct-2020	16-Oct-2020	Confirmed
Hayashi,Maiko	ma-hayashi@epsogo.co.jp	29-Nov-2020	29-Nov-2020	Confirmed
Wakita,Yukiko	y-wakita@epsogo.co.jp	24-Nov-2020	24-Nov-2020	Confirmed
Lee,YoungSook	ri.yonsuku140@eps.co.jp	05-Nov-2020		Confirmed
Sato,Hitomi	sato.hitomi818@eps.co.jp	18-Nov-2020	18-Nov-2020	Confirmed
Kogure,Yoshihito	yo-kogure@umin.ac.jp	18-Feb-2021		Confirmed
Otomo,Midori	ootomo.midori.fy@mail.hosp.go.jp	12-Feb-2021		Confirmed
Suenaga,Masaya	suenaga.masaya.tk@mail.hosp.go.jp	16-Mar-2021	16-Mar-2021	Confirmed
Kasahara,Takaaki	takaaki.kasahara@nnh.go.jp	26-Mar-2021		Confirmed
Muto,Akiko	muto-akiko@iromgp.com	19-Apr-2021		Confirmed
Chikaoka,Mayuko	chikaoka.mayuko.kb@mail.hosp.go.jp	28-May-2021	28-May-2021	Confirmed
yamamoto,ai	yamamoto.ai.tp@mail.hosp.go.jp	04-Aug-2021		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Mori,Yu	mori.yu.an@mail.hosp.go.jp	03-Aug-2021		Confirmed
Takeda,Shin	takeda.shin.ut@mail.hosp.go.jp	18-Aug-2021		Confirmed
Shinohara,Yuka	shinoyuka0107@gmail.com	22-Aug-2021		Confirmed
Nishibori,Riko	n.riko.0928@gmail.com	24-Aug-2021		Confirmed
Sato,Mariko	peter.roos.strase20@gmail.com	05-Oct-2021	05-Oct-2021	Confirmed
Kuroda,Kanako	kanako-kuroda@cmicgroup.com	02-Nov-2021		Confirmed
Sekimizu,Masahiro	masahiro.sekimizu@nnh.go.jp	12-Nov-2021	12-Nov-2021	Confirmed
Imahashi,Mayumi	mayumi.imahashi@nnh.go.jp	31-Jan-2022		Confirmed
Kato,Kyoko	kyoko.imamura213@gmail.com	18-Jan-2022		Confirmed
Kogure,Ayumi	kogure.ayumi.wq@mail.hosp.go.jp	17-Feb-2022		Confirmed
Nagai,Hirokazu	hirokazu.nagai@nnh.go.jp	04-Mar-2022	04-Mar-2022	Confirmed
Shiraishi,Kazuhiro	yuzushiraishi@gmail.com	05-Apr-2022		Confirmed
Numano,Yukari	yukari-numano.hp@cmicgroup.com	24-Nov-2022		Confirmed
Sano,Masahiro	masahilo@med.nagoya-u.ac.jp	31-Aug-2022		Confirmed
Takigawa,Yuki	tacky1024@gmail.com	12-Sep-2022	12-Sep-2022	Confirmed
Sato,Natsuki	sato.natsuki.vs@mail.hosp.go.jp	17-Apr-2025	01-May-2025	Confirmed
hiramatsu,Miho	miho-hiramatsu.yf@cmicgroup.com	12-Oct-2023		Confirmed
hasegawa,fujiko	hasegawa.fujiko787@eps.co.jp	24-Oct-2023		Confirmed
hayashido,emiko	hayashido.emiko.gd@mail.hosp.go.jp	25-Jan-2024		Confirmed
Sasaki,Nobuaki	nobuaki-sasaki@cmicgroup.com	26-Feb-2024	26-Feb-2024	Confirmed
Hattori,Hiroshi	hattori.hiroshi937@eps.co.jp	15-Apr-2024		Confirmed
ono,megumi	megumi-ono.eh@cmicgroup.com	09-Apr-2024		Confirmed
Asanuma,Chisato	chisato-asanuma@cmicgroup.com	11-Jul-2024		Confirmed