cognizant
shared investigator platform

SIP Facility Profile Form

***Note**: Invalid phone numbers and email address if entered in text fields in the form shall not be populated in SIP.*

Facility Name

Therapeutic Areas And Patient Population

Therapeutic Area(s): Provide the list of Therapeutic Areas for your Facility

Sub-Therapeutic Areas:

***Note:** Sub-Therapeutic Areas can be selected online from the Facility Profile in SIP.*

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. Yes No

What study types does your Facility have experience with?

Academic Industry Investigator Initiated Government Other

Is your Facility affiliated with a government agency or part of a government funded health service? Yes No Not Applicable

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 Form

IRB/ERB/Ethics Committee

What is the average time (in days) to start a study once you have received the regulatory package? Less than 30 | 30-60 | 90 | 91-120 | 61-Greater than 120

Does your Facility perform IRB/ERB/Ethics Committee submissions? Yes | No

Does your Facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions? Yes | No

Department Contact Name

Department Contact Phone Number

Department Contact Email Address

Is your Facility able to initiate study activities prior to IRB/ERB/ Ethics Committee protocol approval? Yes | No

What types of IRB/ERB/Ethics Committee does your Facility use? (Select all that apply.) Local | Central Acting as Local Sponsor Provided Central

Does your institution and/or local regulation mandate the distribution of safety reports [e.g., development Safety Update report (DSUR), suspected unexpected serious adverse reaction (SUSAR) to a local Review Only IRB/ERB/Ethics Committee? Yes | No

Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission? Yes | No

If Yes, provide details about the role various committees play in your site's review and submission process. If you have multiple local IRBs, explain what drives the decision on which IRB to use.

SIP Facility Profile Form

Local IRB/ERB/Ethics Committee

IRB/ERB/Ethics Committee Name

Street Name and Number

Building/Floor/Room/Suite

Additional Address Info

Country

State/Province/Region

City

Zip/Postal Code

Registration No. Registering Body

What is the meeting frequency of your Local IRB/ERB/Ethics Committee? Weekly Twice a Month Monthly Quarterly Other

How long before IRB/ERB/Ethics Committee review is the Submission Packet required? 1 week 2 weeks Greater than 2 weeks

Does the IRB/ERB/Ethics Committee require payment prior to release of final approval documents? Yes No

Does the IRB/ERB/Ethics Committee require contract/budget approval prior to release of final approval documents? Yes No

Note: *Attachments can be uploaded online from the Facility Profile in SIP.*

Note: *Additional Local IRB/ERB/Ethics Committees can be added online from the Facility Profile in SIP.*

Central Acting as Local IRB/ERB/Ethics Committee

Note: *Central Acting as Local IRB/ERB/Ethics Committee can be selected online from the Facility Profile in SIP.*

SIP Facility Profile Form

Review Only IRB/ERB/Ethics Committee

IRB/ERB/Ethics Committee Name

Street Name and Number

Building/Floor/Room/Suite

Additional Address Info

Country

State/Province/Region

City

Zip/Postal Code

Registration No. Registering Body

Note: *Additional Review Only IRB/ERB/Ethics Committees can be added online from the Facility Profile in SIP.*

Other Review Boards

Does your Facility have other review boards that need to approve the study prior to IRB/ERB/Ethics Committee submission? Yes No

For example, scientific, radiation safety committees, or others.

Review Board Name Meeting Frequency

Weekly Twice a Month Monthly

Quarterly Other

Weekly Twice a Month Monthly

Quarterly Other

SIP Facility Profile Form

Local Lab

Is your Facility using a local lab? Yes No

Lab Name

Lab Contact First Name

Lab Contact Last Name

Street Name and Number

Building/Floor/Room/Suite

Additional Address Info

Country

State/Province/Region

City

Zip/Postal Code

Phone Number

Fax Number

Email Address

Local Lab Accreditation (Select all that apply)

None GLP CLIA CAP ISO Others

***Note**: Attachments can be uploaded online from the Facility Profile in SIP.*
***Note:** Additional Local Labs can be added online from the Facility Profile in SIP.*

Does your Facility have a SOP/written procedure for documenting bio-specimen (sample) processing steps/chain of custody? Yes No

Do your written procedures ensure that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance? Yes No

What is the system or tool that the Site currently has or utilizes to document Biospecimen (Sample) Processing Steps/Chain of Custody?

Internal Electronic System (LIMS)

Manual Log (e.g. Excel based tool)

Prefer to use Sponsor-provided system/tool

Other

Please indicate tissue collection and processing capabilities at your Site?

On-site collection and processing

Site utilizes a sub-contractor for collection and/or processing

Other

SIP Facility Profile Form

Local Lab

Does your Facility have established processes to oversee staff compliance with study-specific lab manual instructions for bio-specimen processing? Yes No

What are your Facility's capabilities for tissue collection and/or processing (embedding)?

Are LOINC codes available for the lab? Yes No

Consent And Training

Consent

Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	Yes	No
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for pediatric populations?	Yes	No
Does your Facility have a written SOP/Policy/Procedure for: Other vulnerable populations?	Yes	No
Will your Facility require language translations for consents? ***Note**: Languages can be selected online from the Facility Profile in SIP.*	Yes	No
If located in the US, has your Facility used or are you able to use the informed consent short form?	Yes Don't Know Not Applicable	No

Training

Does your Facility have a training program for the research staff?	Yes	No
Does the course content include GCP?	Yes	No
Does your Facility use an external program to conduct research training?	Yes	No
Please provide program course name:		
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes	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?	Yes	No

SIP Facility Profile Form

Facility And Equipment

Facility Capabilities

Can your Facility support patient visits on weekends?	Yes	No
Can your Facility support in-patient admissions for research studies?	Yes	No
Does your study staff have sufficient English knowledge to understand communications in English?	Yes	No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study specific instruction)?	Yes Not Applicable	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes	No
Is the lab kit storage space able to support early phase studies which may require an increased number of kits?	Yes	No
Does your Facility have the ability to collect and store PK/PD specimens?	Yes	No
Does your Facility have the ability to collect PK/PD samples beyond normalbusiness hours?	Yes	No
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes	No

Equipment

Identify the Diagnostic Equipment available at or near the Facility to support Research studies? (Check all that apply.)

NA	Not Applicable
CT Scan	Computerized Tomography Scan
DXA	Dual-Energy X-ray Absorptiometry or Bone Densitometry
ECG/EKG	Electrocardiogram
FLRO	Fluoroscopy
MRI	Magnetic Resonance Imaging
MRA	Magnetic Resonance Angiography
MRS	Magnetic Resonance Spectroscopy
MAMMO	Mammography
NMED	Nuclear medicine (e.g. Bone scan, Thyroid scan, Thallium cardiac stress test)
PET	Positron Emission Tomography Scan
X-ray	X-Radiation
Other	Other

Describe any additional equipment relevant to Clinical Trials:

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	No
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes	No

Identify the equipment available at the Facility to support Research studies

Centrifuge

Refrigerated Centrifuge

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	Yes	No
equipment? Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (-20 to -30 Degrees C)

Equipment Capabilities: Freezer (-20 to -30 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (-70 to -80 Degrees C)

Equipment Capabilities: Freezer (-70 to -80 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (Liquid Nitrogen -135 Degrees C)

Equipment Capabilities: Freezer (Liquid Nitrogen -135 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

SIP Facility Profile Form

Computer Capabilities

Does your Facility have computers which are dedicated to research studies? Yes No

What type of computer operating system(s) does your institution use to support studies?

- Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc.)
- I don't know
- Other
- Unix/Linux (Solaris, Ubuntu, Redhat, etc.)
- Windows (Windows XP, Windows 7, Windows 8, etc.)

What type of internet access does your Facility have?

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)?

Does the Facility have access to local IT support?

Does your facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)? Yes No I don't know

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? Yes No

SIP Facility Profile Form

Investigational Product & Controlled Substances

Investigational Product Shipping Details

IP Recipient Name

Street Name and Number

Building/Floor/Room/Suite

Additional Address Info

Country

State/Province/Region

City

Zip/Postal Code

Phone Number

Fax Number

Email Address

Note: Additional Investigational Product Shipping Details can be added online from the Facility Profile in SIP.

Investigational Product Storage Location

IP Storage Location Name
Street Name and Number
Building/Floor/Room/Suite
Additional Address Info
Country
State/Province/Region
City
Zip/Postal Code
Phone Number
Fax Number
Email Address

Note: *Additional Investigational Product Storage Locations can be added online from the Facility Profile in SIP .*

SIP Facility Profile Form

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	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (-20 to -30 Degrees C)

Equipment Capabilities: Freezer (-20 to -30 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (-70 to -80 Degrees C)

Equipment Capabilities: Freezer (-70 to -80 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

Freezer (Liquid Nitrogen -135 Degrees C)

Equipment Capabilities: Freezer (Liquid Nitrogen -135 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	Yes	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.		
Does this equipment have back-up power?	Yes	No
Does this equipment have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of this equipment?	Yes	No

SIP Facility Profile Form

Investigational Product Storage & Handling

Is the Investigational Product Storage Room secured with controlled access?	Yes	No
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	Yes	No
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?	Yes	No
Does the Investigational Product Storage Room have back-up power?	Yes	No
Does the Investigational Product Storage Room have a temperature alarm?	Yes	No
Do you have an SOP which supports calibration of the temperature monitoring equipment?	Yes	No
Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?	Yes	No
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?	Yes	No Not Applicable
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes	No 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)?	Yes	No Not Applicable

Describe additional Investigational Product Storage & 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)

Glove box (non-vented)

Horizontal laminar flow hood (non-hazardous drug preparation)

Glove box (vented to outside)

Preparation and Administration of Investigational Product

Is your Facility capable of administering infusions?	Yes	No
Is your Facility adequately staffed to support studies with both blinded and un-blinded Investigational Product?	Yes	No

Controlled Substances

Controlled Substances are defined as: A drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a Controlled Drug.

Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?	Yes	No	Not Applicable
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?	Yes	No	Not Applicable
Does the Facility have the ability to handle radio-labelled Investigational Product?	Yes	No	
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes	No	Not Applicable

Attachments

Upload relevant Investigational Product & Controlled Substances documentation including: relevant SOPs for managing or storing Investigational Product(s), IP storage equipment, or licenses/ registrations to receive, store, dispense and return controlled substances.

Note: *Attachments can be uploaded online from the Facility Profile in SIP.*

SIP Facility Profile Form

Source Documentation & Remote Monitoring

Source Documents

What type of source documents will be used? (select all that apply)	Paper	Electronic
Does your Facility have secure storage for patient records?	Yes	No
Does your Facility have patient record archiving on-site?	Yes	No
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? Please specify.		
Are monitors able to access eISF/eReg while off-site?	Yes	No
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	No
What EMR/EHR system do you use?	In-house system	Others

Note: *Please select other options for EMR/ EHR used at your Facility online.*

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? Please indicate the vendor used.	Yes	No

SIP Facility Profile Form

Please provide the name and e-mail for contact at Site who works with the vendor and sponsors

Do you have institutional approval to export data from the EHR/ EMR for the clinical research?	Yes	No
Are monitors able to access EHR/EMR while off-site?	Yes	No
Does your facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose? Provide details of information requested.	Yes	No

Monitoring

Check all equipment that will be available to Monitors:

None Phone Fax Copy Machines Internet Access

What Electronic Data Capture (EDC) systems has your staff used for clinical trials?

None Oracle Inform Medidata Rave Oracle Remote Data Capture (RDC) Others

Describe Other EDC Systems:

Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring? Yes No

Which of the following capabilities are available to support remote source data verification? (check all that apply)

- Video Conferencing
- Screen Sharing
- Systems or platforms for source document upload
- EHR/EMR access by monitor
- Can send pseudo anonymized certified source documents via secure transfer

Additional Information And 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

Upload any non-study specific Facility documents that have not been included in other sections of the profile. Lab, IRB/ERB/Ethics Committee, Investigational Product and Controlled Substance documentation should be included in those sections. The document type drop-down list provides examples of the type of documentation to be included in this section.

Note: *Attachments can be uploaded online from the Facility Profile in SIP.*