

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 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:

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 91-120	30-60 Greater than 120	61-90
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 Sponsor Provided	Central	Acting as Local 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.

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

Every 6 months

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.

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

Yes

No

Review Board Name

Meeting Frequency

Weekly

Twice a Month

Monthly

Quarterly

Other

Weekly

Twice a Month

Monthly

Quarterly

Other

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.

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: Other vulnerable populations?	Yes	No
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for pediatric populations?	Yes	No
Will your Facility require language translations for consents?	Yes	No

Note: Languages can be selected online from the Facility Profile in SIP.

If located in the US, has your Facility used or are you able to use the informed consent short form?	Yes	No
	Don't Know	
	Not Applicable	

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

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
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 normal business 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 (MRA) |
| MRS | Magnetic Resonance Spectroscopy (MRS) |
| 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, sphygmomanometer, etc.?	Yes	No
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Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes	No
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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 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

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?

Windows (Windows XP, Windows 7, Windows 8, etc)

Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc)

Unix/Linux (Solaris, Ubuntu, Redhat, etc)

I don't know

Other

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?

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

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 .

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

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.

SOURCE DOCUMENTATION

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.		

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:

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:

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.