Momentum Clinical Research-Taringa

Local Services Offered: Early Phase, Clinical trials site, GP trials, Trial Patient Recruitment, Treatment of patients, Completion of study documentation as per ICH GCP and contract
Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Please provide your Facility Website.	https://momentumclinicalresearch.com/
Is your Facility affiliated with a government agency or part of a government funded health	No
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
Please provide other facility details.	Other Momentum Clinical Research Sites
Please list any sub-therapeutic areas.	Sexual Health
Does your Clinical Trial site or Service undertake any recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	95%
Has your Clinical Trial Site or Service been accredited?	Yes
If your Clinical Trial Site or Service has been accredited, please select all relevant types	ISO, NATA
IRB/ERB/Ethics Committee:	
HREC Committee Name	Bellberry HREC
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others	Yes

Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission.	Only sponsor approval
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission?	2 weeks
Does the HREC Committee require payment prior to the release of final approval documents?	No
Does the HREC require contract/budget approval prior to release of final approval documents?	Yes
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 paediatric populations?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	No
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	Syneos Health GCP and IATA training
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 And Equipment:	

Facility Capabilities:	
Can your Facility support in-patient admissions for research studies?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Can your Facility support patient visits on weekends?	No
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 the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
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
IT Capabilities:	
Does your Facility have computers that 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 10, etc)
What browser does your facility use?	Internet Explorer/Edge, Chrome
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Phone, Fax, Copy Machines, Internet Access
Labs:	
Local Lab Usage	No
Does your Facility use private laboratory services?	No
IP Storage Details:	
IP Recipient Name	Momentum-Taringa

Is the Investigational Product Storage Room secured with controlled access?	Yes
Does the Investigational Product Storage Room have back-up power?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes
Source Documents:	
Does your Facility have patient record archiving on-site?	No
Provide Location name and address of any offsite archives.	
Please describe Other EDC Systems:	All
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
Please list any access limitations/requirements for the Electronic Medical Records.	N/A