NAMSA

Project Kick-Off Meeting for Limacorporate
UK000442 Multigen CCK & H and Delta revision cup

Version: 1 dated 07Jan2020

PROJECT DETAILS

CLIENT	Limacorporate S.p.A
PROJECT MANAGER	Irfan Din
PROJECT MRM	Aissa Benyattou
TYPE OF PRODUCT	Medical Devices
SCOPE OF PROJECT	Review of study protocol, site management and monitoring
DATE OF MEETING	09Jan2020

CLIENT ATTENDEES	Chiara Lenarduzzi - Clinical Research Associate Gloria Viti – Clinical Trial Lead
NAMSA ATTENDEES	Irfan Din – NAMSA Project Manager (PM) Aissa Benyattou – Clinical Study Manager (CSM)

PROJECT KICK-OFF MEETING MINUTES

Discussion Topics	Comments Identify any relevant documents including revision level, or state if not applicable or not discussed.
Introductions • Who is in the meeting and what their role is on the project	**LimaCorporate** Chiara Lenarduzzi - Clinical Research Associate Gloria Viti – Clinical Trial Lead **NAMSA** Irfan Din – NAMSA Project Manager Aissa Benyattou – Clinical Study Manager
Signed proposal • Key Dates, Financials, and Deliverables • Factors at risk to making schedule or budget	• The project will be invoiced on a monthly basis. The deliverables include review of study protocol, site management and monitoring. • No factors of risk have been identified. • Lima in contact with the site since Aug2019 and have not received confirmation regarding a visit for CCK and H. • Timelines • Multigen CCK & H - Protocol review – advise in coming month - EC submission – 30 Apr 2020 - Sample size calculation may require updating for NAMSA to create the calculations. - CRA for France will be Aissa Benyattou • Delta Revision cup - Gloria to advise on timelines - Submission end of Mar 2020. - CRA for Poland will be Adam Kogut
Governing SOPs • Obtain signed approval • Define in the Project Management Plan, SOP tracker or Training Completion document	• As the projects are running the Lima SOPs will be used for this project. The CSM and CRA will be trained on the Lima SOPs. • NAMSA forms and templates can be used as per UK000333 and 405.
Communication • Discuss communication (email, conference calls and frequency, C&C project inbox)	• Communication mainly via e-mail however regular calls are required during the startup of the projects to ensure smooth transition. • Ad hoc calls when required.
Escalation Plan for Site Compliance Issues	• NAMSA template can be used.

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Project Risk and Mitigation • Discuss risks and potential mitigation as action items for the project team, complete.CSOP-002-T23 Risk/Issue/Change Log	• NAMSA can create a risk log.
Documentation of Informed Consent Issues – Protocol Deviations/Monitoring Action Items	• The informed consent should be documented by the site. The CRA can review the patient's informed consent during site visits. • Lima require assistance with Informed consent forms, Lima to provide template. Possibly for all studies. ID to reach out to Fabiana and Federica.
Training Needs (if applicable) • GCP/QSR/IDE/SOPs etc. • Sponsor's requirement for frequency of current GCP/CV document collection (NAMSA requires GCP training and CV at the start-up of the trial)	• CRA and CSM will be trained on the Lima SOPs, EDC and also eCRF. • eCRF training will be billed as adhoc clinical support • GCP training and CVs for investigators should be documented on site and can be reviewed by the CRA during monitoring visits, as per LIMA's requirements. • Device training to be provided by LIMA.
Administrative Topics • NAMSA/Sponsor travel billing policy • Monitors in training may shadow NAMSA monitor at no cost to client • Invoice format • Budget tracking to Phase instead of Activity • Project metrics to keep project on schedule and on budget • Specific project questions	• NAMSA travel billing policy is billed as a pass through cost with a 5% admin fee. • The invoices will be billed per line item on the proposal. • Budgets for the project will be tracked by overall phase and not each individual activity.
Plans • Clinical Project Plan • Escalation Plan • Communication Plan • Safety Plan • Other required plans per sponsor	• As Lima SOPs will be used, Lima should provide the Clinical Project Plan, Escalation Plan and Safety Plan however Lima have confirmed no plans are in place. All information included within the protocol specific plans are not in place. • LIMA will provide the monitoring plan for the CCK & H study as well as the revision cup.

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• Monitoring Plan (Risk-based monitoring/traditional)	
Location of Project Files • If sponsor to hold original files, frequency of sending • eTMF	• Sponsor to hold original files. Documents to be returned to sponsor along with paper copy CRF, frequency is to be confirmed by LIMA. • Lima confirmed TMF is paper based.
Project Start Date	Jan 2020
Internal project meetings • Frequency • Does client want to attend?	Communication mainly via e-mail and monthly internal calls when required.

ORGANIZATION	
Main Client Contact and contact information	Multigen CCK & H – Chiara Lenarduzzi Delta Revision Cup – Gloria Viti
Other Client Contacts and contact information	

PROJECT MANAGER	**Signature**	**Date**
Irfan Din		
CSM	**Signature**	**Date**
Aissa Benyattou		
CLINICAL TRIAL LEAD	**Signature**	**Date**
Gloria Viti	Gloria Viti	13-JAN-2020
CLINICAL RESEARCH ASSOCIATE	**Signature**	**Date**
Chiara Lenarduzzi	Chiara Lenarduzzi	13-Jan-2020