Arab Republic of Egypt
Egyptian Drug Authority
CA of Biological and Innovative products and clinical studies.
GA of Clinical Trials

جمهورية مصر العربية
هيئة الدواء المصرية
الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الاكلينيكية
الإدارة العامة للدراسات الإكلينيكية

Follow Up Report Template

From:

Protocol Title:

Protocol ID:

Follow up report no.:

Covering period:…… to ……

Study status: Pending ☐ Recruiting ☐ Completed ☐

Site Name	PI	Site activation date	Total number of screening subjects	Screening failure	Number of Enrolled subjects	Number of subjects completed study	Number of doses given to date	SAE	AEs	Causality

العنـــــــــــوان: 51 شارع وزارة الزراعة، العجوزة - الجيزة
البـريد الإلـكـتـرونـي: المكتب الفني / bio.tech@edaegypt.gov.eg، المكتبالإداري /bio.admin@edaegypt.gov.eg
التـــلـيـــفـــــون: 0237484988

Changes to trial Personnel	
Changes regarding clinical trial package data	
Monitoring & Audit Reports	

Notes:

- Applicant should be reported to administration of Protocols and Studies follow up at GA of CT at Bio Inn-EDA by serious adverse events within 24 hours of the PI becoming aware of them and submit the case report(s) with 7 days.
- Applicant should be reported to administration of Protocols and Studies follow up at GA of CT at Bio Inn-EDA by adverse events within 7days of the PI becoming aware of them with the case report(s).
- Interim follow-up report to administration of Protocols and studies follow up at GA of CT:

-Interim follow-up report of clinical trials are expectally to be received at three monthly intervals for trials of less than one year duration.
-Interim follow-up report of clinical trials are expectally to be received at six monthly intervals for trials of more than one year duration.
-An interim report at about half way through the trial should be provided.