



أجندة

ورشة عمل عن الإشراف علي تنظيم التجارب الإكلينيكية في مصر

Clinical Trial Regulatory Oversight in Egypt Workshop

Topic	Lecturer	Date	Duration
DAY I			
Registration			09:30-10:00 a.m.
Welcome address	Prof. Dr. Ayman El Khatieb Dr. Engy Mohamed Elhosary	19/07/2022	10:00 – 10:15 a.m.
Introduction of Regulatory Framework and legal provisions of Clinical Trial Oversight in Egypt	Dr. Engy Mohamed Elhosary Dr. Rania Ibrahim Hassan		10:15 - 11:00 a.m.
Ethics Committee legal provisions	Dr. Amr Youssef		11:00 - 12:00 p.m.
Break			12:00-12:30 p.m.
Reliance of Clinical Trials	Dr. Rania Shosha	19/07/2022	12:30– 1:15 p.m.
Technical support in preclinical results submission and clinical trial protocols	Dr. Aya El Abd & Dr. Rehab Saied		
Required documents to submit a phase I clinical trial in Egypt	Dr. Nesma Gamal		2:00 - 2:45 p.m.
Pathway to Innovation in Egypt	Dr. Marwa Ali		2:45 – 3:15 p.m.
Open Discussion (Q & A)	All Trainers		3:15 - 4:00 p.m.
DAY II			
Registration			09:30-10:00 a.m.
Work flow of the submission of a clinical trial protocol to EDA	Dr. Rania Shosha	20/07/2022	10:00 -11:00 a.m.
Required documents from PI/CRO/ Sponsor for conducting clinical trial in Egypt	Dr. Dalia Kamal		11:00 -11:45 a.m.
Safety reporting to EDA of clinical trials adverse Events	Dr. Mona Essam		11:45 -12:30 p.m.
Break			12:30-1:00 p.m.
Submission of amendment of clinical trial	Dr. Salma Salah	20/07/2022	1:00 -1:45 p.m.
Inspection of clinical trial site	Dr. Rania Ibrahim & Dr. Rania shosha		1:45 – 2:45 p.m.
Open Discussion (Q&A)	All Trainers		2:45 – 3:15 p.m.