OPTIONAL COURSE 2 CREDITS

PROF. PAOLO PRIMIERO M.D

Clinical Monitoring in Clinical Trials

“The purposes of trial monitoring are to verify that:
(a) The rights and well-being of human subjects are protected.
(b) The reported trial data are accurate, complete, and verifiable from source documents.
(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).”
ICH HARMONISED TRIPARTITE GUIDELINE - Guideline for Good Clinical Practice - E6(R1) - Current Step 4 version
The course will introduce the main topics related to clinical trials monitoring of drugs, through a general part concerning definition of operating environment, relations between the actors of the sector, tasks, activities and responsibilities of Clinical Monitor.
A specific part will be dedicated to the different types of visits on trial site (site selection visit, site initiation visit , periodic monitoring visit, close –out visit) and related activities as pre-study site assessment, SDV (source data verification), data collection, check of informed consents, management of essential documents of Clinical Trials Files, safety information (AE, SAE, SUSAR) and study drug management.
Finally new risk - based approach to monitoring (centralized/remote monitoring) will be illustrated.