OPTIONAL COURSE 1 CREDIT PROF. LUIGI GODI CRO (CONTRACT RESEARCH ORGANIZATION) DEVELOPMENT AND MANAGEMENT

The Contract Research Organization (CRO) is a company, institution or private organization with which the Sponsor of the investigation has stipulated a contract assigning all or part of its functions on the subject of clinical investigation.

The objective of "CRO Business Management" is to introduce the Students to the CRO environment, at national and international levels, including concepts on planning, organizing, staffing, leading and directing, controlling and reporting business to Sponsor.

The fundamental concepts of the relationship between Sponsor and CRO will be presented, i.e. transparency, timelines respect, quality standard compliance, budget adherence.

The Italian CRO Decree will be introduced with main focus on minimal requirements for organizational and structural considerations, quality and staff training.

Main concepts of Business Development, marketing, and quoting will be presented to the Students offering them some Team Workshop too.

Finance and Accountability will be shortly introduce with special reference to their management during a clinical trial.

Main concepts of Human Resources in the CRO will be introduced too: training (initial, periodical and on demand) and its documentation (paper and electronic), different types of performance review and carrier development in the CRO (mainly in the Operations) will be also faced.