FILL THE VOID

The invisible hand of Clinical Research Coordinators in supporting oncology clinical research in Italy

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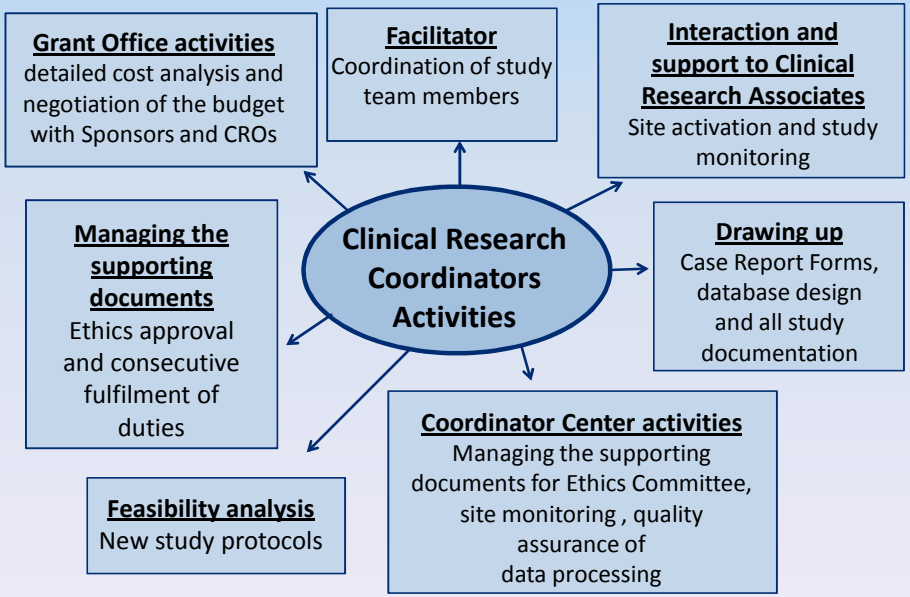
Background

Italy plays a leading role in the international clinical research scene, both for participation to industry sponsored trials and in investigator initiated or driven research protocols.
Contribution of Italian researchers to the international community has been outstanding and ranked as third in number of submissions at the ASCO 2013 Meeting, preceded only by the USA and Japan.
This growing and challenging involvement in the world clinical research scenario, which requires hard-and-fast methodology, in depth knowledge and expertise, and the support of highly skilled personnel, has highlighted the want for expert professionals who manage and run the multifaceted aspects of clinical trials, thus ensuring high scientific and ethical standards.

Where are we now?

The legislative and normative void has led to the present heterogeneous system of data and trial management which relies on Clinical Research Coordinators (CRC) to support the research team, promoting data integrity, adherence to protocols and dispositions, harmonization of information and flows, ethicality of procedures, and respect with local regulations.
Specifically, besides the mere data management tasks, Clinical Research Coordinators play a key role in acting as *trait d'union* between the Investigator and the several stakeholders involved in the process.



Conclusions

Clinical Research Coordinators fill the void in clinical research in Italy, supporting and aiding investigators in promoting independent non profit trials, networking with institutions and partners in order to assure flawless study conduct and good quality data.
The other –bigger- void, in the legislative legal framework, ought to be filled soon

The 2014 GIDM survey

A G.I.D.M survey carried out in May 2014 has spotlighted the many activities necessary to trial conduct which are carried out by CRCs in Italy. A sample population of CRCs operating in the country, has shown variability about the working structure: Public Hospital and Institutional Research in predominance with 81%, followed to ASL, Private Hospitals, ONLUS, CROs. Moreover, the integration of this figure in the context of organized units "Clinical Trial Unit" (54%) in which the CRC can operate in synergy with the other members of the research team, is on the increase. According to the request, the CRC activities are so distributed: