

Profile

An interview with Laura McMahon on the role of clinical research coordinators in Italy

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Clinical research coordinators (CRCs) – a CRC is not a clinical research associate but one is frequently mistaken for the other – have a fundamental role in clinical research. Their work involves a wide range of activities and responsibilities in conducting clinical trials according to good clinical practice under the immediate supervision of the principal investigator.

Laura McMahon has a long experience in this field in Italy. After obtaining a CRC certificate from the Association of Clinical Research Professionals in London, she immediately started working as a CRC in the oncology and haematology departments of different hospitals in Venice and Treviso. Since 2010, she is the president of a unique association in the Italian scene, the Italian Data Managers Group (Gruppo Italiano Data Manager; GIDM) which despite its name, is devoted to the CRC profession and dates back to 1998. GIDM lists among the many responsibilities of a CRC some activities which are very much linked to medical writing. We turned to Laura to find out how clinical research coordination and medical writing are interlinked in Italy.

Medical Writing (MEW): At the conference 'Evolution of clinical research in Italy' held in Chieti on the 26 January 2004, it was stated that the responsibilities of a CRC include writing the documentation for the Independent Ethics Committee (IEC), preparing mid-term study reports, collaborating in the writing of the study protocol – activities that are typical to medical writers. In your opinion are these two professions seen as two distinct roles in Italy or do they often overlap?

Laura McMahon (LM): Besides the clinical hypothesis to be investigated, the linguistic quality of study protocols is paramount in making sure that concepts are unequivocally clear and understandable. Not only a 'sloppy' protocol may dim the clinical significance of the research, but ambiguity may lead to personal interpretation, with potential adverse effect on patients' safety and data accuracy. The right balance between exhaustive clinical information and readable materials is at times difficult to achieve. It is the case, for instance, of informed

consent forms for study participants which need to comply with normative requirements on completeness and, at the same time, be comprehensible to the lay reader.

CRCs in Italy are required to draw up all study documents before submission to the IECs and I do not think medical writers in Italy are usually involved in the drafting process. I do not think they are perceived as two different professions, as medical writing is not that widely known in Italy. I believe there is a need to promote the field of medical writing in the country.

MEW: Has this scenario changed in the last few years?

LM: I believe awareness is increasing, and despite professional medical writing's inconspicuous status in Italy, emphasis on robust background in the linguistic setting and specific training is arising. Globalisation of research and of readership requires papers to be clear, concise, and understandable and medical writers are highly knowledgeable on the quality standards required for publication. On the other hand, CRCs have the organisational and managerial skills to manage the practical aspects of protocols—such as case report form design, pharmacovigilance reporting, and adherence to normative and local regulations.

The reduction of resources in recent years has brought on an increased pressure on CRCs who are required to be skilled not only in theoretical and practical aspects of protocol development but also in English, information technology, and medical writing. Funds for research, especially for investigator initiated trials are limited and integration of professional expertise is required in order to optimise budgets.

MEW: Would CRCs benefit from specific medical writing training?

LM: Absolutely! I would be the first to avail of such an opportunity! Perfecting a harmonious overall view of the whole project would result in a better

written and understandable protocol. I think we would immensely benefit from writing tools and strategies, such as abstract writing, for instance. We are sometimes asked to revise the contents of manuscripts for editorial submission and although we perceive some sort of linguistic awkwardness, we feel unqualified to convey ideas that may have an impact on scientific content.

MEW: How can medical writers help CRCs?

LM: Collaboration is the key word in this world. The competence of medical writers can complement the proficiency of CRCs and the merging of both expertise would result in a successful cooperation. It would definitely be a great asset to have a medical writer go over the proofs or, even better, have a medical writer involved right from the very beginning of an editorial process or in the early phases of the study protocol development.

MEW: Do you think the role of medical writers will change in the next 10 years? If yes, how?

LM: I think there is a 'cultural' void with regards to the relevance of medical writing in clinical research which definitely needs to be promoted and

encouraged. Physicians should be more aware of the role of medical writers and their contribution to overall quality of scientific documents. I hope this awareness will increase in the next 10 years.

I would like to see in the next 10 years an increase in courses and educational initiatives focused on written communication. Every year, there are a number of educational activities on the elaboration of clinical protocols that take place in Italy but they are mostly focused on methodology and statistical issues. I do not think there have been many training opportunities on medical writing to date. The Italian contribution to the scientific community has always been excellent, but summing up the contents of a whole publication in a 250-word abstract is a huge challenge, even for accomplished clinicians.

The EMWA autumn conference in Florence will definitely be a great opportunity for Italian medical writers and related professions to take part in an international event devoted to training and networking. As Laura McMahon says in this interview, we need to speak out loud and promote the role of medical writers.

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