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The critical role of the clinical research coordinator for clinical trials: a survey in oncology

Margherita Cinefra[1], Celeste Cagnazzo[2], Laura McMahon[3], Francesca Arizio[4], Sara Campora[5], Roberta Camisa[6], Giuliana Canzanella[7], Marianna Contu[8], Paola Frati[9], Roberta Sottile[10], Stefania Gor[11], Giuseppe Procopio[12], Oriana Nanni[13] on behalf of the AIOM Working Group Coordinatori di Ricerca Clinica

[1] Medical Oncology and Breast Unit, "A. Perrino" Hospital, Brindisi - Italy
[2] Clinical Research Office - Fondazione del Piemonte per l'Oncologia (FPO), Candiolo Cancer Institute (IRCCS), Candiolo (TO), Candiolo - Italy
[3] Istituto Oncologico Veneto IRCCS Padova, Padova - Italy
[4] Department of Oncology, University of Turin, AOU San Luigi, Orbassano, Italy
[5] SC Oncologia Medica, E.O. Ospedali Galliera, Genova - Italy
[6] UOC di Oncologia Medica, Azienda Ospedaliero-Universitaria di Parma, Parma - Italy
[7] Unità Sperimentazioni Cliniche, Istituto Nazionale Tumori – IRCCS – Fondazione G. Pascale, Napoli - Italy
[8] UOC di Oncologia Medica, Azienda Ospedaliero-Universitaria di Sassari, Sassari - Italy
[9] Unit of Immunotherapy of Human Tumors, Fondazione IRCCS, Istituto Nazionale dei Tumori, Milano - Italy
[10] Department of Oncology, Azienda Sanitaria Universitaria Integrata di Udine, Udine - Italy
[11] Oncologia Medica, Ospedale Don Calabria - Sacro Cuore, Verona - Italy
[12] Divisione di Oncologia Medica 1, Fondazione IRCCS, Istituto Nazionale dei Tumori, Milano - Italy
[13] Biostatistics and Clinical trial Unit - Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (I.R.S.T.) S.r.l. I.R.C.C.S. Meldola (FC) - Italy

ABSTRACT

Background: Access to innovative medicine requires proper evidence from clinical trials with the growing demand of qualified and experienced personnel. The clinical research coordinator (CRC) plays an important role in the conduction of research activities and provides a strong support to the research team. In Italy, this role is not recognized at any institutional level and its professional outline is still indefinite. Several national associations (Associazione Italiana di Oncologia Medica, Collegio Italiano dei Primari Oncologi Medici Ospedalieri, Gruppo Italiano Data Manager) are committed to promoting the enhancement and recognition of the professional status of CRCs, underlining their role as fundamental.

Methods: A web survey, proposed by the AIOM CRC Working Group, was submitted to 319 Italian oncology sites with items focusing on the organization of sites, the research activities, the staff composition, and the presence of coordinators and the multidisciplinary team.

Results: A total of 115 sites (35.9%) responded to the web survey. Clinical studies were carried out at 88.7% of the investigated sites, and coordinators were on staff at 75.5% of the active investigational sites. Interestingly, there was a direct association between the number of clinical studies and the number of coordinators, whose contribution to the research activities is believed to be essential for trial conduct in 82.4% of cases. Most sites retain that the quality of clinical research has absolutely improved (83.3%) after the implementation of a coordinator as member of the team.

Conclusions: Given the constant growth of the number of clinical trials performed at Italian oncology sites, the CRC proves to be an essential component of the research team. However, there is an urgent need to institute the professional role alongside the need to standardize the training of coordinators to establish the minimum requirements enhanced by qualifying courses.

Keywords: Clinical research, Clinical research coordinators, Clinical trials, Good clinical practice, Research team

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Corresponding author:
Dr. Celeste Cagnazzo
Clinical Research Office
Fondazione del Piemonte per l'Oncologia (FPO)
Candiolo Cancer Institute (IRCCS)
SP 142 Km 3,95
10060 Candiolo (TO), Italy
celeste.cagnazzo@ircc.it

Introduction

Access to innovative drugs requires proper evidence from clinical trials, which, over the past decade, have become more complex and diversified, involving not only pharmaceutical companies but also academic institutions, cooperative groups, and contract research organizations (CRO). This growth of clinical research (CR) has been accompanied by an increasing need to move from a "physician addicted" research to a multidisciplinary specialist approach (1-3).

The clinical research coordinators (CRCs), also known as "study coordinators" or – rather improperly – "data Managers," are the focus of the modern CR enterprise.

CRCs are research professionals responsible for organizing, managing, and monitoring the conduction of clinical trials (CTs), in accordance with the principles of the "Declaration of Helsinki" (4), the International Conference of Harmonization (ICH) Guideline for Good Clinical Practice (GCP) (5, 6) and the Protocol Standard Operating Procedure – with consideration of patient privacy requirements, associated laws, and applicable government regulations. Under the supervision of the principal investigator, the legal responsible for the trial management, the CRC is the heart and soul of the trial (7, 8), supporting, assisting, facilitating, and coordinating the activities of the research team (RT).

Furthermore, the CRC is the reference point for the multidisciplinary RT, the contact for regulatory and administrative structures, department, sponsors, and institutions involved, such as the ethics committee (EC), health departments, competent authority, and CRO.

The CRC encourages the RT to be compliant with rules and regulations that are in force and applicable during the process of conducting CTs. CRCs' tasks usually also include: interaction with clinical research associates (site activation, study monitoring, site close-out visits); drawing up trial-related e-tools (i.e., case report forms or database); coordinating site activities (managing the supporting documents for EC, site monitoring, quality assurance of data processing); and grant office activities (feasibility analysis, drawing up of a preliminary budget, and verifying costs).

CRCs are skilled professionals with a solid academic background and specific qualifications, including a basic knowledge of medicine, pharmacy, and CTs methodology (9). Furthermore, literature reinforces the CRCs' role in CR, assuming that it has an important impact on patients enrolment and retention, and in influencing the scientific integrity of the entire research process (10).

Unfortunately, in Italy, this career profile is not included among the recognized professions, and there are no established guidelines for the CRCs' educational background.

As a result, Italian CRCs represent an uneven variegated picture of local realities with no access to permanent contracts or positions, and are confined to temporary – at time unsatisfactory – positions (11).

Nevertheless, the increasing complexity of CR and the recent implementation of a new regulatory system not only solicits the creation, but also the formal adoption of clinical trials units made up of highly trained professionals (12-14).

Associazione Italiana di Oncologia Medica (AIOM) and Collegio Italiano dei Primari Oncologi Medici Ospedalieri (CIPOMO), in partnership with the Gruppo Italiano Data Manager (GIDM), have drafted a document underlining the importance of including this new breed of professionals in the Italian National Health System. A recent bill proposal for the professional recognition of CRCs has been filed and it is presently before the House (15).

In the meantime (awaiting for ratification) CIPOMO has included the assignment of CRCs in its KAIROS project, which focuses on the 10 priorities in the field of oncology research for the decade 2012-2022.

Another positive indicator comes from AIOM, which, in 2015, established the CRC Working Group (WG) thus recognizing the inestimable added value of this professional role to the conduction of CTs. Interestingly, in the same year, the Italian Pharmaceutical Agency enacted a law (AIFA Determination 809/2015 for phase I CTs) ratifying the minimum requirements that sites must hold in order to perform phase I trials: among these, the requisite of the establishment of "connecting figures" with the aim of networking stakeholders and managing clinical data has been further stressed (16).

As evidenced in an official document drafted by Federazione delle Associazioni dei Dirigenti Ospedalieri Internisti (FADOI) in collaboration with 112 Italian preeminent scientific institutions in December 2016 (17), the presence of a CRC has become needful in order to conduct quality academic research, especially in light of the recent stand taken by the European Medicines Agency with regard to the qualitative standards that it must achieve.

More recently (March 2017) the GIDM drafted a position paper in which the need for official recognition of the CRC as an essential component of RT was stressed yet again (18).

In this context, AIOM CRC WG carried out a survey aimed at mapping the composition and the organization of RTs at Italian oncology sites.

Methods

During the second and third quarters of 2015, an online survey aimed at mapping the presence and organization of multidisciplinary RT engaged in the management of CTs was submitted to 319 Italian oncology sites. The reproducibility of this survey was not analyzed and a pretest phase was not performed: simple and objective questions were developed and the chance of misunderstanding was very limited.

The survey, preceded by a brief description of the aims, consisting in 20 structured items as follows:

- Questions 1-4 aimed to characterize the oncology sites: public/private institution, teaching hospital/Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS)/country hospital, Italian region, most frequent types of tumor
- Questions 5-8 focused on the research activity: presence or not of active CTs, the nature of sponsorship (profit/academic), the phase of CTs, the number of ongoing CTs
- Questions 9-12 concerned the presence or not of an RT and the multidisciplinary composition of the team
- Questions 13-20 focused on the presence or not of CRCs, their number, working experience, academic background, working position (ended contract/fixed contract), and detailed description of CRCs jobs/tasks.

All the medical oncology directors were contacted by email thorough AIOM and invited to complete the web survey; a reminder was sent to all members 2 weeks later. A statistical analysis on the representativeness of the responders (observed frequencies) was performed according to the available data on geographic area (northern, central, southern) of all clinical centers (expected frequencies), using a chi-square test. Study results were summarized using absolute

frequencies and a percentages chi-square test for independence was performed. Data were analyzed using MS Excel for Windows and SAS 9.4 (SAS Institute). The results of the survey were discussed during a closed meeting within AIOM CRC WG and presented at the XVII AIOM National Congress in Rome, October 23-25, 2015.

Results

Of the 319 oncology sites accounted for in Italy in 2015 (*Libro Bianco AIOM 2015*), 115 sites (35.9%) completed the survey: 54.8% of the respondents were located in northern Italy, 19.1% in the central region, and 26.1% in southern region, as shown in Table I. The distribution of responder centers and population centers in Italy were not different (p = 0.404). As a consequence, we can consider the samples of the responder centers – regarding the area of distribution – as representative of the population of oncological centers in Italy. Characteristics of the responder centers are reported in Table II.

About half of the respondents (50.4%) worked at public hospitals, 14.8% in teaching hospitals and the remaining were equally distributed among research dedicated centers (IRCCS) (17.4%) and other types of sites (17.4%) as nursing homes or private institutes. The types of cancer treated at the oncology sites are shown in Figure 1: specifically, most sites managed breast cancer (39.1%), gastrointestinal tract tumors (29.6%), and lung cancer (13.0%).

Clinical studies were carried out in 88.7% of the investigated sites: in 9.8% of cases, only academic (nonprofit studies) were run, and in 2.0% only for-profit studies were performed. However, while in 88.2% of sites, both for-profit and nonprofit trials were implemented, thus corroborating the assumption that CR is an essential part of clinical activities at Italian oncology units. As shown in Figure 2, most respondents (93.1%) were involved in phase III studies, and prospective and retrospective observational studies were also carried out in 83.3% and 84.3% of sites, respectively. In 75.5% of sites, both phase II and phase III studies were ongoing.

The analysis of study distributions showed that more than 80% of sites were involved in ≥5 trials. In most cases, from 20 to 50 CTs were active, and in approximately 15% of the investigated sites, more than 50 studies were carried out. In addition, in 63.7% of the clinical sites, sponsorship for nonprofit, investigator-driven, and academic trials was also provided. To support such research activities managed as "direct sponsor," an enhanced RT was available in 71.6% of the sites. This optimization included the presence of a multi-professional staff as research nurses (at least 1 in 67% of the sites with an RT),

TABLE I - Geographical representatives of oncological responders sites

	Overall (n = 319) No. (%)	Responder centers (n = 115) No. (%)
Northern	165 (51.7)	63 (54.8)
Central	78 (24.5)	22 (19.1)
Southern	76 (23.8)	30 (26.1)

TABLE II - Characteristics of responder sites

	Responder centers (n = 115) No. (%)
A) Type of institution	
Public hospital	58 (50.4)
Teaching hospital	17 (14.8)
Research dedicated center (IRCCS)	20 (17.4)
Other type of center	20 (17.4)
B) Type of treated cancer*	
Breast	45 (39.1)
Gastrointestinal tract	34 (29.6)
Lung	15 (13.0)
Genitourinary	5 (4.4)
Gynecological	4 (3.5)
All solid tumors	3 (2.6)
Sarcoma/GIST	2 (1.7)
Cerebral	2 (1.7)
Lymphoma/Leukemia	1 (0.9)
Other (only phase I, only melanoma, etc.)	4 (3.5)
C) Involvement in clinical studies	
No	13 (11.3)
Only academic	10 (9.8)
Only profit	2 (2.0)
Both academic and profit	90 (88.2)
D) Type of clinical studies*	
Phase I studies	23 (22.5)
Phase II	80 (78.4)
Phase III	95 (93.1)
Phase IV	54 (52.9)
Retrospective studies	86 (84.3)
Prospective studies	85 (83.3)
At least phase II and III	77 (75.5)
E) Number of studies	
<5	19 (18.6)
5-9	20 (19.6)
10-19	21 (20.6)
20-49	27 (26.5)
50-99	9 (8.8)
≥100	6 (5.9)
F) No. of studies promoted by clinical center	
None	37 (36.3)
At least one	65 (63.7)
G) RT presence in center/institute	
No	29 (28.4)
Yes	73 (71.6)
H) If RT present, number of CRC involved	
None	4 (5.5)
One	32 (43.8)
Two	14 (19.2)
Three or more	21 (28.7)
I) If RT present, research professions involved*	
A research nurse	43 (67.2)
A pharmacist	53 (70.8)
A CRC	67 (94.4)
A biologist	33 (61.1)
A lab technician	20 (40.0)
A statistician	29 (56.9)

* Each center can be counted more than once.
CRC = clinical research coordinator; GIST = gastro intestinal stromal tumor. IRCCS = Istituto di Ricovero e Cura a Carattere Scientifico; RT = research team.

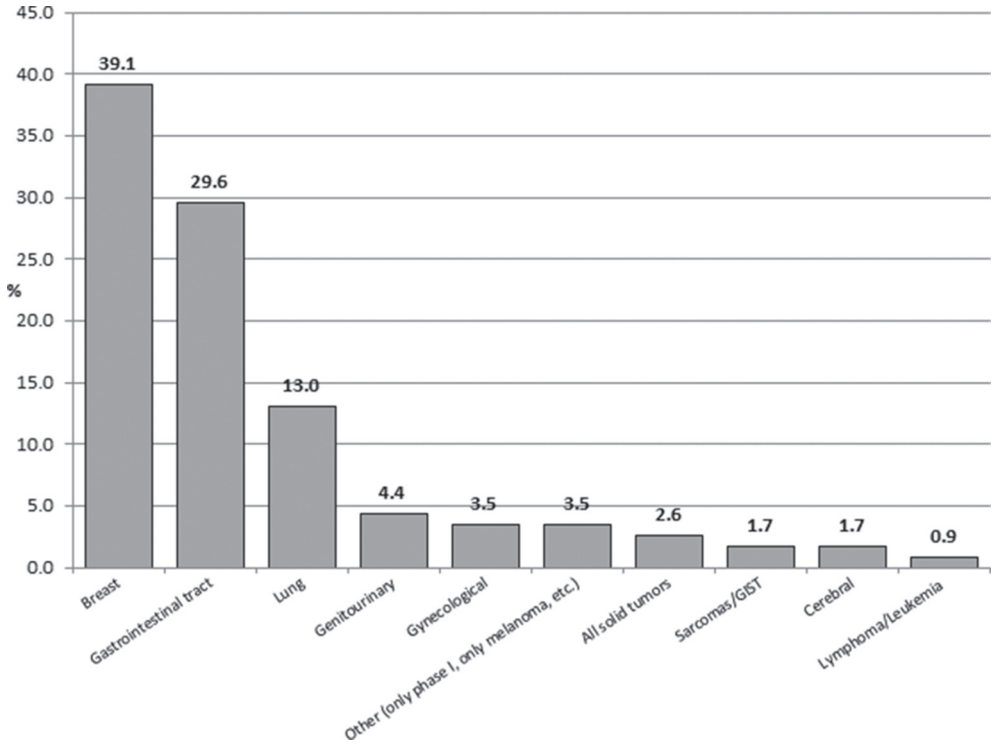

Fig. 1 - Types of cancer treated by survey participating sites.

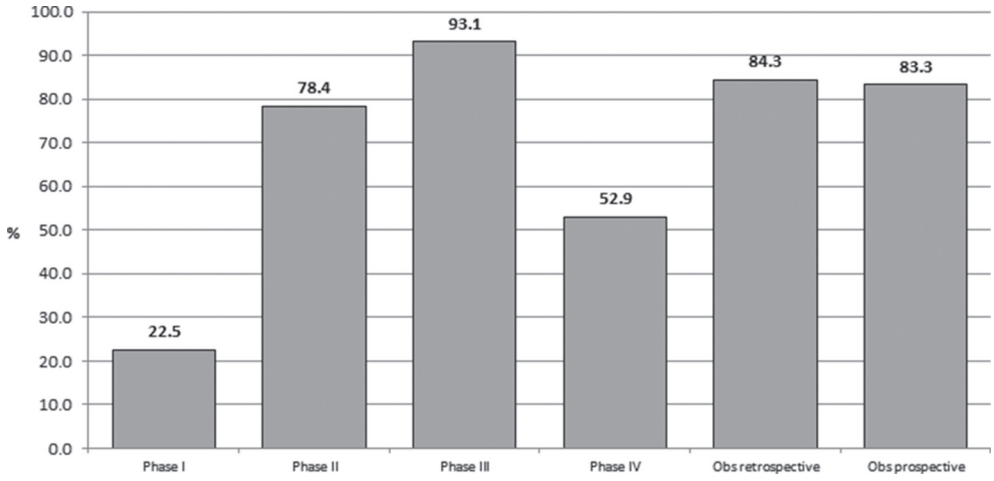

Fig. 2 - Type of studies active in survey participating sites.

pharmacists (70.8%), CRCs (94.4%), biologists (61.1%), lab technicians (40.0%), and statisticians (56.9%). In 75.5% of the sites that carried out CR, at least 1 CRC was present on staff: most of them (67.5%) had a 6-year working experience at the same site. Notably, 31% of CRCs had been working in the field for over 10 years. As shown in Table III, there was a direct association between the number of clinical studies and the number of CRCs ($p = 0.0016$): in all the sites with >50 active trials, at least 3 CRCs were present.

CRCs were more frequently employed at IRCCS: 72.2% of IRCCS employed 3 or more CRCs, compared to 21.4% and 17.2% of public and teaching hospitals, respectively ($p = 0.0023$). None of the other structures had 3 or more CRCs.

About 200 CRCs were present at 77 of the respondent sites involved in CR: of these, only 14.9% had an open-ended contract and 10.1% had a fixed-term contract, while the remaining CRCs were involved – irrespective of seniority – with precarious contracts. Interestingly, 74.2% of the surveyed CRCs had a Master's degree in CR or other pertinent fields.

CRCs' duties include attending investigator's meetings (97.4%), receiving monitoring visits (96.1%), managing administrative tasks (e.g., setting up the documentation for EC [94.8%]) and completion of the case report forms (89.6%). The presence of CRCs was considered to be essential for trial conduct in 82.4% of cases, and in 83.3% of the oncology sites, the quality of CR was perceived to be absolutely improved after the implementation of a CRC within the RT.

Conclusions

The results of this survey point out once again that CTs are increasingly becoming part of the clinical activity performed

TABLE III - Number of clinical research coordinators (CRCs) involved (if research team are present n = 73) according to type and number of studies

	Number of CRC N (%)					
	Unknown	**None**	**1**	**2**	**3 or more**	**Total**
Type of institution						
Public hospital	1 (3.3)	1 (3.3)	16 (53.3)	7 (23.3)	5 (16.7)	30
Teaching hospital	-	2 (13.3)	6 (40.0)	4 (26.7)	3 (20.0)	15
Research dedicated center (IRCCS)	-	1 (5.3)	3 (15.8)	2 (10.5)	13 (68.4)	19
Other type of center	1 (11.1)	0 (0.0)	7 (77.8)	1 (11.1)	0 (0.0)	9
Type of studies*						
Phase I studies	-	2 (8.7)	4 (17.4)	3 (13.0)	14 (60.9)	23
Phase II	2 (3.0)	3 (4.5)	28 (41.8)	13 (19.4)	21 (31.3)	67
Phase III	1 (1.4)	4 (5.6)	32 (44.4)	14 (19.4)	21 (29.2)	72
Phase IV	-	1 (2.2)	21 (45.7)	10 (21.7)	14 (30.4)	46
Retrospective studies	1 (1.5)	4 (6.2)	28 (43.1)	12 (18.5)	20 (30.8)	65
Prospective	1 (1.5)	4 (6.2)	30 (46.2)	11 (16.9)	19 (29.2)	65
At least phase II and III	1 (1.5)	3 (4.5)	28 (42.4)	13 (19.7)	21 (31.8)	66
Number of studies						
<5	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	4
5-9	1 (9.1)	1 (9.1)	9 (81.8)	0 (0.0)	0 (0.0)	11
10-19	-	2 (11.1)	9 (50.0)	4 (22.2)	3 (16.7)	18
20-49	-	1 (4.0)	9 (36.0)	9 (36.0)	6 (24.0)	25
50-99	-	0 (0.0)	2 (22.2)	0 (0.0)	7 (77.8)	9
≥100	-	0 (0.0)	0 (0.0)	1 (7.1)	5 (23.8)	6

* Each center can be counted more than once.
IRCCS = Istituto di Ricovero e Cura a Carattere Scientifico.

in Italian Oncology Departments. Given the greater complexity of study protocols and the stricter application of GCP and regulatory guidelines, CT management claims for increased competence and the presence of trained professionals. CRC is, indeed, the professional figure that could best respond to these requirements and whose presence is perceived as essential to trial conduction for most of the Italian oncology sites (82.4% of responders of our survey).

Furthermore, this issue is stressed by the high percentage of sites that validated the presence of CRCs in their RT (94.4%) and the direct relationship between number of CTs conducted and the number of CRCs as staff members ($p = 0.0016$).

Thirty-one percent of CRCs have been working in the field for over 10 years, remarking that their presence in RT has been felt as an urgent need by oncologists long before the new regulation was enacted.

Unfortunately, this strongly established reality has not been translated into corresponding enhancement by Italian laws with regard to the formal institutionalization of a CRC as a figure dedicated to the management of CTs. This is demonstrated by the low percentage (10%) of CRCs employed with a permanent staff position compared to the high number of temporary contract positions, irrespective of seniority.

As there is no defined academic background for CRCs and their *alma mater* is uneven, there is a growing need to standardize the training of CRCs, defining minimum requirements, such as a Bachelor's degree in scientific disciplines, fortified by a Master's degree in CR.

A moratorium for experienced CRCs with a diverse academic background should be accounted for (5 years of experience could be considered an adequate subrogation of a BSc.). An influential contribution in this regard could be implemented with the set-up of a qualifying and professionalizing course formally recognized by national scientific societies, which can lead to the acquisition of a certificate of qualification.

Proper training should come from ad hoc educational courses (GIDM, AIOM and regional courses) as well as the scientific training provided by major national conferences.

It is now extremely urgent for the Italian Regulatory Affairs and Health Institutions to acknowledge that CRCs are not only an added value but a real need of RTs, especially in oncology departments where CR is an essential component of clinical practice.

Abbreviations list

AIOM	Associazione Italiana di Oncologia Medica
CIPOMO	Collegio Italiano dei Primari Oncologi Medici Ospedalieri
CR	Clinical research
CRC	Clinical research coordinator
CRO	Contract research organizations
CTs	Clinical trials

EC	Ethics committee
FADOI	Federazione delle Associazioni dei Dirigenti Ospedalieri Internisti
GCP	Good Clinical Practice
GIDM	Gruppo Italiano Data Manager
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico
RT	Research team
WG	Working group

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