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Original Article

Data managers and clinical research coordinators: a tool to collect the hourly activity

Data manager e coordinatori di ricerca: uno strumento per il monitoraggio dell'attività oraria

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Key words: clinical trial center, clinical research coordinator, data manager, clinical research, job description.

ABSTRACT

Background and Aims: the main purpose of this paper is analyzing the hourly activities performed by Data Managers (DMs) and Clinical Research Coordinators (CRCs) in a Clinical Trial Center (CTC) of an Italian Public Hospital in order to define and monitor the relevant job descriptions of these professionals

Materials and Methods: the CTC of the Research and Innovation Departments (DAIRI) has created a tool to collect the hourly activity of DMs and CRCs. In the period between January 1 and December 31, 2022; the activities were collected and grouped in 24 macro areas.

Results: the main activities conducted by staff are found in the macro areas «Study Management» (15.78%); «Briefing/Planning» (12.86%) and "Data Management/Data Entry" (12.42%). A difference was found between the activities carried out by CRCs and those conducted by DMs.

Conclusions: the results of this monitoring, compared with data obtained at the national level, confirm the heterogeneity of the tasks performed by these professional figures. These differences increasingly underscore the need to obtain recognition of the figure by the National Health System (NHS) with the definition of a precise "job description".

Obiettivi: lo scopo principale di questo lavoro è analizzare le attività orarie svolte dai Data Manager (DM) e dai Coordinatori della Ricerca Clinica (CRC) in un Centro di Sperimentazione Clinica (CTC) di un ospedale pubblico italiano, al fine di definire e monitorare le relative job description di questi professionisti.

Materiali e Metodi: il CTC del Dipartimento Attività Integrate Ricerca e Innovazione (DAIRI) ha creato uno strumento per monitorare l'attività oraria dei DM e dei CRC. Nel periodo compreso tra il 1° gennaio 2022 e il 31 dicembre 2022, le attività sono state raccolte e raggruppate in 24 macroaree.

Risultati: le principali attività svolte dal personale si trovano nelle macroaree "*Gestione dello studio*" (15,78%); "*Briefing/pianificazione* del lavoro" (12,86%) e "*Gestione dei dati/inserimento dei dati*" (12,42%). È stata riscontrata una differenza tra le attività svolte dai CRC e quelle svolte dai DM.

Conclusioni: i risultati di questo monitoraggio, confrontati con i dati ottenuti a livello nazionale, confermano l'eterogeneità dei compiti svolti da queste figure professionali. Queste differenze sottolineano sempre più la necessità di ottenere il riconoscimento della figura da parte del Sistema Sanitario Nazionale (SSN) con la definizione di una precisa "job description".

Introduction

The increasing complexity of clinical research has made it essential for hospital centres wishing to conduct clinical trials to have adequate infrastructures and, especially, a dedicated multidisciplinary team.[1]

The main figures involved in the clinical centre are the Principal investigators, the Data Managers (DMs) or Clinical Research Coordinators (CRCs), the research nurses, and all the various technical support figures such as pharmacists, biostatisticians, biologists, *etc.*[2]

These figures, over the years, have always played a more important role in clinical research and, to date, are recognized as a key element in coordinating and conducting clinical trials in accordance with the required quality and ethical standards.[3]

CRCs or DMs, in particular, are involved in the activation, organization, management, and monitoring of clinical trials and play a very important role in the data collection process,[4] always ensuring that studies are conducted in accordance with the International Conference of Harmonization - Good Clinical Practice (ICH-GCP).[5]

However, despite the centrality and the importance of the work of the CRC or DM, in Italy, this professional figure has not yet been recognized at the institutional level by the National Health Service (NHS) causing over the years the lack of job stability and, especially, the absence of standardization of the work performed.

The lack of recognition of these figures makes the tasks assigned to CRC or DM differ from one clinical center to another and are assigned according to their own internal organization, creating further labor and contractual instability.[3]

In this context, the lack of a well-defined identity also leads to a lack of clarity in the naming of these professional figures.

In some centres, DM and CRC are considered similar while in other centers are distinct figures. The lack of a specific job description for these professionals complicates the management of human resources and the division of the workload among the available staff, raising the need to develop tools to measure the impact of the management of a clinical trial on these professionals.[6]

The report of clinical trials, published by AIFA (*Agenzia Italiana del Farmaco*) in 2023, provided an accurate qualitative and quantitative description of clinical research in Italy, showing an increase in the number of authorized trials, in comparison with previous years and in comparison with the rest of Europe (equal to 30.6%).[7] This has increased the demand to have, within its structure, a qualified team to design and conduct clinical trials, organized into a proper unit called precisely Clinical Trial Unit (CTU).

The establishment of these CTUs has facilitated the development and accessibility of experimental treatments to patients who had few therapeutic options so far and has enabled the development of further knowledge on disease management.

At the international level, a testimony from Switzerland evaluated the development of a network linking CTUs. This model underpinned its success by centralized coordination of research activities carried out in the different CTUs and led to the application of such structuring within the same clinical center, leading to the definition of modern Clinical Trial Centers (CTCs), organizational structures that operate as a center for coordinating clinical research activities within a healthcare centre.[8]

The Alessandria Hospital (AO AL) in 2013 established the CTC, nowadays a centralized facility of the Research and Innovation Departments (DAIRI), with a dual location, one at AO AL and one at the «S. Spirito» Hospital in Casale Monferrato of the Alessandria Local Health Authority (ASL AL).[9]

The goal of the CTC-DAIRI is to ensure better efficiency in the activation and conduct of clinical trials, ensure compliance with GCP, and support the design, collection, analysis, and publication of data from independent studies sponsored by AO AL and ASL AL.

The CTC-DAIRI staff, available at both locations, is qualified and adequately trained through a package of training courses dedicated to clinical research and a Level I Master's course «Data Management and Coordination of Clinical Trials» activated by the University of Eastern Piedmont in collaboration with AO AL, starting from a.y. 2019/2020.

To date, CTC-DAIRI research activity is carried out by a multidisciplinary team consisting of: i) CRCs, hired on a permanent basis following the first region-wide open competition held by AO AL in 2021 for professional technical collaborator cat. D (the category in which Clinical Research Coordinators fall at the regulatory level), who are mainly involved in protocol design and drafting, project management, and scientific production; ii) DM fellows, who are primarily responsible for clinical trial management and data entry (in accordance with the job description reported by FADOI, 2016).[10]

This study analyzed the hourly activities performed by DMs and CRCs in a CTC of an Italian Public Hospital during 2022 with the aim of helping to define and monitor the relevant job descriptions of these professionals, which do not yet appear to be recognized by the NHS (*Appendix 1*).

Materials and Methods

The CTC-DAIRI has created a tool to collect the hourly activity of DMs and CRCs afferent to the facility.[1] There are 24 macro areas reported in the tool, which include all activities carried out by DMs or CRCs (Table 1).

In the period between January 1 and December 31, 2022, CTC-DAIRI staff recorded daily the time spent (according to multiples of 15 minutes) on each of the above macro areas reported in Table 1. The data collected by 6 CRCs and 9 DMs in January and 6 CRCs and 12 DMs in December, are then percentualized in tables for each month. Subsequently, the activities are grouped into a single annual timetable.

A total of 141 clinical trials were activated in 2022, 114 at AO AL (101 no-profit and 13 profit which 87 were observational studies and 27 interventional studies) and 25 (23 no-profit and 2 profit which 22 were observational studies and 3 interventional studies) at ASL AL. For all, the CTC-DAIRI staff was involved in the evaluation phase of technical-economic-scientific aspects and submission to the local Ethics Committee (EC). For 36 clinical trials, both observational and non-pharmacological interventional studies sponsored by the AO AL or ASL AL, the CTC-DAIRI also provided support in the design phase which also includes the actual writing activities of the study protocol. A total of 448 studies were found to be active at AO AL and 59 at ASL AL, including 289 in which CTC-DAIRI staff performed study management and data management activities.

Results

In the period January 1, 2022, and December 31, 2022, the CRCs and the DMs recorded the hourly activity for 114 different activities carried out, combined in their respective 24 macro areas. The collected data showed that the main activities carried out by staff are found in the macro area of «Study Management» (15.78%); secondarily, the macro area of «Briefing/Planning (12.86%)», which is work planning and preparation for the "meeting" activities and planning of various short- and long-term activities, is found (Table 2). The third most widely practiced macro area turns out to be "Data Management/Data Entry" (12.42%) followed by"Education/Training" (9,03%) and "Meeting" (8,80%).

As shown in Table 3, the most tasks performed during the year by CRCs are grouped in the «Briefing/ Planning» macro area (27.51%), followed by the «Meeting» macro area (14.70%), while in third place we find the macro area "Study design" (10.24%).

The activities gathered in the fourth most developed macro area, namely «Reading» (mainly bibliographic research) which occupies 8.32% of the time spent by CRCs, are also crucial for the purpose of scientific production, as critical reading of scientific articles is preparatory to the development of the activities grouped in «Study design» and the «Writing» macro area, that is the work/preparation for the future publication of the study results (in the form of scientific papers and/or scientific articles).

The fifth macro area found, on the other hand, is that related to "Study Management" (7,05%).

Table 4 shows the main macro areas that DMs deal with. In the first place was the macro area of «Study Management» (21.05%); the second and third were the activities of «Data Management/Data Entry» (19.25%) and «Education/Training» (10.63%), respectively. In fourth place, we found the macro area "Study Doc Evaluation"

(7,30%). In fifth place, we had the macro area "Meeting" (5,24%).

Table 5 shows the percentage changes in CRC and DM activities between January and December 2022.

Regarding the comparison between activities of the CRCs in Table 5, a reduction in the macro areas "Briefing/Planning" (from 31,36% in January to 12,99% in December) and "Data Management/Data Entry" (2,37% in January to 0,72% in December) and a slight decrease in the macro area "Reading" (from 11,24% to 9,77%) was found. On the other hand, an increase was identified in the «Grant» (from unavailable data in January to 1,83% in December), «Event Organization and Training» (from unavailable data to 4,61%), «Writing» (from 3,35% to 8,58%), «Meeting» (from 12,82% in January to 15,69% in December), and «Study Start-up phase» macro areas (from 0,39% to 2,62%).

Regarding the DMs' activities, a decrease in the macro areas of «Biological Sample Processing» (from 7,35% to 2,69%), «KPIs Reporting» (from 4,30% to 2,67%), «Study Management» activities (from 29,26% to 22,46%) and a slight decrease in «eCRF/CRF design» activities (from 3,33% to 1,40%) represented the biggest change found. On the other hand, there was a percentage increase in the «Education/Training» (from 0,69% to 15,64%), «Reading» (from 2,36% to 5,37%), «Statistics» (from 1,25% to 4,10%), «Writing» (from 2,64% to 7,99%) macro areas.

Discussion

In comparison with the activities carried out by the CTC-DAIRI staff in 2021,[1] the overall analysis of the data monitored in this paper shows that the macro areas increased from 7 to 24 and the activities performed from 26 to 114. This is a result of a further organization

Table 1. The activities of the Clinical Trial Center of the Research and Innovation Departments (CTC-DAIRI).

Macro areas	Description
Archiving	Paper or digital archiving activities of clinical trial documentation
Biological sample processing	Biological sample processing activities specific to clinical trials
Briefing/planning	Organization and planning activities for short/medium/long-term goals
Clinical trial feasibility/evaluation process	Completion of feasibility questionnaires, sent by a CRO or Promoter for evaluation and possible participation of the Clinical Center in a «profit» trial
Data management/data entry	The entry into study-specific databases of patient data collected during the study (clinical data, master data, questionnaires, instrumental examinations) and the resolution of queries sent by the CRO or the sponsor
eCRF/CRFdesign	Creation, review, and editing of case report forms (paper or digital questionnaires used specifically in clinical research for data collection) and corporate databases
Education/training	Participation in shadowing courses, trainings and webinars
Fundraising	Fundraising activities to be dedicated to research
Grant	Selection of calls for proposals and submission of projects to research calls provided by different entities
KPI's reporting	Monitoring of scientific activity carried out by collecting specific indicators (number of activated clinical trials, number of active clinical trials, number of patients enrolled, number of publications)
Meeting	The time for discussion aimed at planning the strategy for achieving the objectives through the resolution of any critical issues encountered in study management and the proposal of new projects. They also include departmental, facility and sector-specific meetings
Multicenter clinical study coordination	Communication and coordination activities of satellite centers participating in clinical trials promoted by AO AL or ASL AL
Event organization and training	Organization and management of training courses, events or the master's program
Public relation CRO/pharma	Managing communications with CROs and pharmaceutical companies
Reading	Critical reading of scientific articles
Scouting	Research and evaluation of funding calls issued by different types of Institution (local, national, European, public and private)
Statistics	Statistical analysis and interpretation of the data collected during the trial
Study close out	Study closure activities following the conclusion of the clinical trial
Study design	Writing up the protocol and related documentation
Study docs evaluation	Technical-scientific evaluation and compilation of center-specific documents, checking the completeness of documentation to be submitted to the Ethics Committee (EC), including budget analysis for sponsored trials
Study management	Activities related to the management and conduct of clinical trials
Study monitoring and audit	Activities carried out during monitoring, on site or remotely, conducted by the clinical research associate (monitor) sent by the CRO or the sponsor
Start-up phase	Actions conducted in the activation process of new studies once they have been approved by the relevant EC and authorized by the institute (Site Initiation Visit, SIV), delegation logs completion, study staff GCP certificates collection, etc.)
Writing	Content writing and activities aimed at scientific communication (publication, paper, abstract, case report)

implemented in 2022 by the facility, which led to a reallocation of the tasks performed through the creation of new macro areas with the aim of increasingly categorizing the specific activities handled.

In 2022, a differentiation in roles between CRC and DM became evident at CTC-DAIRI, due primarily to contract type.

Although the activity most performed overall by the two professionals is still inherent to the area of "Study Management", as in 2021, the analysis conducted in 2022 identifies that the CRCs are mainly concerned with the planning and design of studies and coordination of the activities conducted by the DMs; the latter, on the other hand, are mainly concerned with the collection and management of clinical data (data entry activities) and the performance of all clinical trial-related activities according to good clinical practice. Comparing the activities carried out and recorded by CRCs and DMs in January and December the decrease observed in the «Briefing/Planning» macro area for CRCs is mainly due to the inclusion of additional activities in the «Grant» and «Event Organization and Training» macro areas, which thus allowed for a greater classification of the activities carried out by CRCs.

The decrease in the data inherent in the macro area «Data Management/Data Entry» under the CRCs, is mainly due to the inclusion of 3 new units of DMs, who took charge of this activity. On the other hand, there is no significant change in the percentage of activities carried out in this macro area as far as DMs are concerned, as these are spread over a larger number of staff, rising from 9 units in January to 12 in December.

Table 2. Activities carried out at the Clinical Trial Center of the Research and Innovation Departments (CTC-DAIRI) by afferent staff.

Data manager and clinical research coordinator Macro areas	Sum of time in hours (%)
Study management	15,78
Briefing/planning	12,86
Data management/data entry	12,42
Education/training	9,03
Meeting	8,80
Study docs evaluation	6,06
Reading	5,87
Writing	5,04
KPIs reporting	4,80
Study design	4,52
Statistics	3,49
Biological samples processing	2,43
eCRF/CRF design	2,04
Study monitoring/audit	1,30
Archiving	1,29
Study start-up phase	0,87
Fundraising	0,72
Event organization and training	0,67
Grant	0,59
Clinical trial feasibility/evaluation process	0,51
Multicenter clinical studies coordination	0,39
Public relation CRO/Pharma	0,24
Scouting	0,16
Study close out	0,11
Overall total	**100,00**

Table 3. Annual hourly activities carried out by Clinical Research Coordinators (CRCs).

Clinical Research Coordinator Macro areas	Sum of time in hours (%)
Study management	27,51
Briefing/planning	14,70
Data management/data entry	10,24
Education/training	8,32
Meeting	7,05
Study docs evaluation	7,03
Reading	6,39
Writing	4,39
KPIs reporting	4,01
Study design	1,46
Statistics	1,31
Biological samples processing	1,11
eCRF/CRF design	1,08
Study monitoring/audit	1,08
Archiving	0,80
Study start-up phase	0,76
Fundraising	0,57
Event organization and training	0,53
Grant	0,49
Clinical trial feasibility/evaluation process	0,48
Multicenter clinical studies coordination	0,40
Public relation CRO/pharma	0,25
Scouting	0,02
Overall total	**100,00**

Table 4. Annual hourly activity carried out by Data Managers (DMs).

Data Manager Macro areas	Sum of time in hours (%)
Study management	21,05
Briefing/planning	19,25
Data management/data entry	10,63
Education/training	7,30
Meeting	5,24
Study docs evaluation	5,04
Reading	4,95
Writing	4,39
KPIs reporting	4,01
Study design	3,90
Statistics	3,84
Biological samples processing	2,79
eCRF/CRF design	1,92
Study monitoring/audit	1,80
Archiving	1,07
Study start-up phase	1,04
Fundraising	0,51
Event organization and training	0,37
Grant	0,30
Clinical trial feasibility/evaluation process	0,19
Multicenter clinical studies coordination	0,16
Public Relation CRO/pharma	0,16
Scouting	0,09
Study close out	0,02
Overall total	**100,00**

In light of the change in duties, staff have been more involved in specific training courses present in the ECM training package («Research & Training») sponsored by DAIRI. This increased involvement was seen in the percentage increase in the data for the macro area «Education/Training,» which increased between January and December for both DMs and CRCs. Particularly for DMs, there has been a high increase in this activity following the start of the Level I Master's program «Data Management and Coordination of Clinical Trials».

During 2022, the specific macro area «Event Organization and Training» was also created because of the involvement of CRCs as lecturers, lesson organizers, and scheduling of Master's exams.

Compared to the beginning of the year, «Fundraising» activities tangentially involved both DMs and CRCs during 2022, going to underscore the importance that fundraising takes on for research.

Percentage data for the «Grant» macro area are not available in January because it is a variable entered during the year due to the increased involvement of CRCs in the design and submission of projects to funded calls.

Regarding the macro area «Study Management,» the percentage decreased slightly for the figure of DMs since the data is related to the number of studies that DMs are pursuing in that specific time frame (in this case in the current month).

The data for the macro area «Writing» increased for both figures, as one of the most closely monitored parameters in clinical research is scientific articles published in impacted and/or indexed journals.

Comparing the data with those collected at the national level[4] shows that the activities carried out in clinical centres by research staff are the same, even if grouped differently.

Although the activities of CTC-DAIRI are aligned with those of other Italian centers, some differences emerge mainly among the activities carried out by CRCs.

«Handling of study material» in the other centers turns out to be one of the main tasks performed by CRCs, while at CTC-DAIRI these tasks are assimilated into the macro area of «Biological sample processing», an area that DMs are exclusively responsible for.

Other differences concern "Study Management" activities, which are very common throughout the country, but which at the CTC-DAIRI are mainly carried out by DMs and not by CRCs.

One finding from the CTC-DAIRI's annual hourly activity that is not reflected in the survey is definitely the percentage of activities grouped in the «Briefing/Planning» macro area, since CTC-DAIRI CRCs carry out activities to coordinate DMs' tasks and are responsible for projects that involve work on planning activities and managing participating teams.

This comparison confirms that in all Italian clinical centers, including the CTC-DAIRI, DMs' activities are focused on clinical

Table 5. Comparison of percentage changes in macro areas during the year between Clinical Research Coordinators (CRCs) and Data Managers (DMs).

	CRC		DM	
Macro areas	**January (%)**	**December (%)**	**January (%)**	**December (%)**
Archiving	0,99	0,00	1,66	0,99
Biological sample processing	0,00	0,00	7,35	2,69
Briefing/planning	31,36	12,99	7,63	6,73
Clinical trial feasibility/evaluation process	0,79	1,59	0,42	0,30
Data management/data entry	2,37	0,72	17,89	16,45
eCRF/CRF design	0,39	1,19	3,33	1,40
Education/training	2,37	7,95	0,69	15,64
Fundraising	0,99	1,43	0,00	0,51
Grant	ND	1,83	ND	0,00
KPIs reporting	6,11	8,38	4,30	2,67
Meeting	12,82	15,69	5,55	4,13
Multicenter clinical study coordination	2,56	0,00	0,00	0,63
Event organization and training	ND	4,61	ND	0,42
Public relation CRO/pharma	0,59	1,19	0,00	0,10
Reading	11,24	9,77	2,36	5,37
Scouting	1,58	0,00	0,00	0,00
Statistic	0,39	1,03	1,25	4,10
Study close out	0,00	0,00	0,00	0,00
Study design	10,06	9,06	0,55	1,08
Study docs evaluation	4,73	3,46	5,83	4,92
Study management	6,71	7,67	29,26	22,46
Study monitoring/audit	0,20	0,24	1,25	1,05
Study start-up phase	0,39	2,62	8,04	0,38
Writing	3,35	8,58	2,64	7,99

trial activation and management, with a prevalence of activities concerned with data collection and management.

In contrast, in the CTC-DAIRI, the tasks performed by the CRCs appear to be different from the activities found at the national level. This is mainly due to the fact that each clinical center assumes its own precise internal organization, going on to define the tasks carried out by each professional figure belonging to the center independently.

CTC-DAIRI CRCs play a role more similar to that of a project manager, with functions in project planning and development, acquisition of funding, and evaluation and enhancement of scientific results.

Conclusions

The lack of a well-defined «job description» for CRC and DM figures in Italy and the lack of recognition within the NHS are elements of professional destabilization, leading each clinical research center to have its own internal organization, as well as a nationally heterogeneous job description.

Given the lack of homologation of the job description of these professionals, a monitoring system of the activities carried out by DMs and CRCs was adopted at the CTC-DAIRI, which was essential to analyze and equitably distribute the workloads, going to define a possible need for personnel, in relation to the number and complexity of the studies in progress.

Monitoring at the center revealed a differentiation of roles between CRCs and DMs, which occurred mainly during 2022 and was due to the internal reorganization implemented in the sector.

In the current national panorama, we think that sharing a similar analysis can highlight the different activities carried out by CRCs and DMs in order to realize a precise job description. The hope is that these specific professional figures involved in clinical research activities will finally be recognized and regulated at the national level going to conform as much as possible to the rest of Europe and the world. This standardization would make national research centers more attractive to any private companies or any other sponsor that wants to invest in the research sector within our country.

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Online supplementary material

Appendix 1. The 114 different activities carried out by Data Managers (DMs) and Clinical Research Coordinators (CRCs), combined in their respective 24 macro areas.