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The EORTC Clinical Research Coordinators Group

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Abstract

The Clinical Research Coordinators Group (CRCG) is an umbrella organisation, compiled from four existing groups, namely the Oncology Nurses Group, the Data Management Group, the Radiation Technologists Group and the Early Clinical Studies Group Research Nurses. From the existing steering committees, a new board was formed and consists of two members per group. The CRCG will function as an independent group within the EORTC. The CRCG will create conditions and standards for implementing and conducting clinical protocols according to Good Clinical Practice. © 2002 Published by Elsevier Science Ltd.

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1. Aims of the EORTC CRC Group

a. To make a positive impact upon the quality of clinical trials by improving the involvement of the clinical research co-coordinator at the international, national and local levels.
b. To stimulate, improve and expand the collaboration of different skills, roles and knowledge of those working within the Clinical Research Coordinators Group (CRCG) and by doing so, to improve the conditions of patients who participate in cancer clinical trials. The CRCG will function as an independent group within the EORTC and will create conditions and standards for implementing and conducting clinical protocols according to Good Clinical Practice.

1.1. Recent achievements

The CRCG was formed in 2000. The group has defined and set out its statutes.

Work has begun on a project to develop a workload measurement instrument for cancer clinical trials, and an application for funding the study has been made. The aim of the study is to measure the workload of the clinical research personnel involved in clinical trials and to develop an instrument for measuring it.

1.2. Projects/strategies

1. Organisation of a course for clinical research coordinators
2. Organisation of a joint symposium open for all members
3. Initiation and implementation of a research project
4. Development of instruments to facilitate the conduct of clinical trials
5. Development of common standards for practical on-site modalities to conduct clinical trials

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1.3. Collaboration with other groups (EORTC and others)

The workload measurement instrument will be designed to accompany EORTC clinical trials in centres working on phase I, II and III studies. Thus, the group will be collaborating with the clinical groups running the various studies.

2. The Radiotherapy Technologists Group (RTT)

2.1. Background

The RTT has been a group within the EORTC since the early 1990s and it has grown significantly, particularly over the past 3 years. An important factor in this growth has been the strong links developed with the Radiotherapy Group and the regular attendance and participation of some of our members at all of the Radiotherapy Group meetings.

2.2. Aims and objectives

The EORTC, with its international reputation for the promotion of excellence, has been very supportive to the group with respect to the setting out of aims and objectives and in the striving to meet them. The Radiation Technologists have long realised that we have a very positive role to play in the conduct of clinical trials with a radiotherapy component. Historically, Radiation Technologists have not been directly involved in the management of clinical trials and to address this issue has been one of the main aims of the group. An essential aspect in enhancing the quality of future trials is considered to be that Radiation Technologists understand the specific needs and requirements of trial patients, trial co-ordinators and the EORTC Data Center personnel. This aim will be met by developing education programmes for Radiotherapy Technologists and by direct involvement in writing the technical guidelines section of protocols for new radiotherapy trials.

One of the biggest challenges faced by the group was to raise the awareness of the Radiation Technologists' role, both within the profession and in relation to other associated professionals, at both the national and international levels and to convince the groups within the EORTC of the potential value.

2.3. Achievements

The Radiotherapy Technologists Group received funding from the Europe Against Cancer Programme in 1999 and have now submitted the final project report to the European Commission. We have prepared a set of guidelines for Radiation Technologists involved in clinical trials which is currently at the final draft stage and have taken a proactive role in reviewing technique details on two new trials. The group have recently received the initial documentation on a third trial. Documentation will be prepared to accompany each trial protocol for completion by the Radiation Technologists involved in the treatment of the trial patients. Covering documentation will be available in all European languages. With respect to increasing awareness, all of our members have received reports on the activities of the Group and the database is currently being updated.

To meet the educational objectives set, the Radiotherapy Technologists Group, as part of the Clinical Trials Co-ordinator Group, in conjunction with the Data Managers and Oncology Nurses, have organised and will participate in a teaching course on the organisation and implementation of cancer clinical trials and will emphasise the role of the Radiation Technologist. The aim is to raise the level of understanding of the Radiation Technologists of the importance of implementing and accurately documenting the patient's progress through the trial, including details of the technique used and the side-effects experienced by the patient. The information will be returned to the Data Center and evaluated by members of the Radiotherapy Technologists Group. Following review, any necessary changes identified will be implemented.

A representative of the Group has been appointed to the Quality Assurance Committee and will attend future meetings of the Group to give feedback on the progress of this collaboration.

A representative has also been appointed to The New Treatment Techniques Working Group, recently established by the Radiotherapy Group. This underlines the increasing level of co-operation between these two related EORTC Groups.

2.4. Current activities

The Radiotherapy Technologists Group has identified new members through the Radiotherapy Group and involvement by as many members as possible in our various activities is encouraged. An update of activities is presented at each meeting of the Radiotherapy Group and a summary is then circulated to all members. It has been decided to restructure the Group to reflect the different levels of knowledge, interest and involvement and to develop a more interactive focus in the future.

In collaboration with the New Techniques Group, issues specific to Radiation Technologists, such as patient position, immobilisation and verification methods, will be examined and guidelines prepared as appropriate.

The Steering Group will continue to develop the area of protocol appendices for Radiation Technologists, to

carefully monitor responses and to liaise with the lead clinicians and Data Center personnel to ensure that all needs are being met.

2.5. Conclusions

The Radiotherapy Technologists Group is very excited about the progress made over the past year and looks forward to real achievements in the coming years. We very much appreciate the role of the EORTC in supporting us in this development.

3. The ECSG Research Nurses Group

The ECSG Research Nurses Group consists of Research Nurses who work on ECSG clinical trials and whose Principal Investigator is a member of the ECSG. The group was founded in 1984 to give nurses involved in ECSG phase I and II trials a forum to share their experiences and problems related to patient care in the development of new drugs. From just a handful of members, the Group has grown steadily over the years and, at present, has about 60 members with representatives from most Western European countries, as well as Israel. Not all ECSG centres have a Research Nurse, but some centres have two or more.

The Group meets annually to coincide with the ECSG Investigators' June meeting. Issues concerning the functions and action plans of the Group are discussed in the general business meeting, and the members are encouraged and invited to participate actively by giving presentations regarding clinical trials that they are involved in, or to stimulate discussion on points with regard to the practical issues of research nursing or other topics that may be of interest and importance to the Group. Work done by the Group in the past includes surveys on the use of elastomeric and electronic pumps for chemotherapy administration, and the job description of research nursing in the various centres.

3.1. Aims and objectives

The *aims* of the Research Nurses coincide directly with those of the ECSG itself, namely:

1. *To provide the highest standards of clinical research:* We aim to provide the best possible care to patients who participate in phase I and II clinical trials, thereby contributing to the generation of high-quality scientific data. Our active involvement in patient selection, eligibility screening, patient registration, practical issues of treatment administration, informed consent, and providing information for patients all ensure high standards of clinical research.
2. *The preliminary assessment of the activity of new anticancer drugs from a clinical, pharmacokinetic and pharmacodynamic point of view*: Our work includes toxicity recording, data collection and Serious Adverse Event reporting, as well as the management of practical aspects of pharmacokinetics, such as sample collection, handling, storage and transport to the analytical laboratory.
3. *To provide guidelines for further detailed study of specific tumour types:* our contribution lies mainly in symptom management. Nursing studies have helped to increase knowledge about the effects of treatment on the patient or the effects of the disease itself.
4. *To conduct Phase I and II studies according to two main criteria: quality and speed:* GCP requirements and industry standards increasingly demand that Standard Operating Procedures and the ICH-GCP guidelines be followed. The Research Nurse is a key figure in implementation of GCP in daily practice to promote quality assurance.

3.2. The objectives of the ECSG Research Nurses

i. to provide a platform for the exchange of information, experiences and ideas with multi-disciplinary colleagues involved in new drug development;
ii. to create links with other special interest groups, thereby improving communication and knowledge about oncology nursing. Examples include the Oncology Nursing Societies of Europe, USA and Canada, as well as the various components of the EORTC-Clinical Research Coordinators Group (CRCG).

3.3. Achievements of the Group

In October 2001, *The Manual for Research Nurses,* written by various members of the Group, was published. This Manual contains information on clinical trials: how to perform them, as well as the role of the Research Nurse. Its aim is to be a reference book and guideline for novice or experienced Research Nurses, as well as other professionals involved in clinical trials. The contents cover both theoretical and practical aspects of clinical trials.

The group has been involved, together with the ONG, in the organisation of interactive symposiums at ECCO 8 (Paris), ECCO 10 (Vienna) and ECCO 11 (Lisbon).

3.4. Future strategies

3.4.1. Coordinating Research Nurse (CRN)

Translational Research has become an important part of clinical research and is now incorporated into most of the new clinical trials. In order to achieve and maintain the highest possible quality in cancer clinical trials, it is essential that a CRN position be re-established at the EORTC. The main role of this figure lies in the coordination of all nursing and practical aspects related to clinical trials, from the draft protocol writing stage and through all the phases of trial implementation. The CRN would be a central point of reference for Study Coordinators, Principal Investigators, Research Nurses, basic scientists and data managers in the various ECSG centres in Europe, thus helping to create uniformity in the practical issues regarding clinical trials.

3.4.2. Nursing studies

The group would like to initiate some *companion nursing studies* in conjunction with ECSG medical trials to study important issues regarding symptom management, e.g. fatigue in the elderly cancer patient and oral mucositis. This project would incur a tight collaboration with the Oncology Nurses Group, as well as the support of the Data Manager's Group.

4. Data Management Group (DMG)

On 23–24 September 1985, the EORTC Data Center organised, for the first time in Europe, a meeting that gathered together 'data managers' responsible for the day-to-day collection and management of data related to clinical cancer research. The EORTC/SGDM was born. From the beginning, the aims of the Group were directed to provide and stimulate education and training of data managers involved in EORTC trials, to improve the quality of data management in EORTC studies, but also to increase contacts between European data managers and maintain direct links with other international groups involved in clinical trial monitoring.

Full members —

- Should be *actively involved* in data management and work in an institution which *participates in EORTC trials*
- Are prepared to attend the group meeting at least *every 2 years*
- Should *actively respond* to the mailings and Group meeting invitations

Corresponding members —

- Not fulfilling the criteria of Full Member, but interested in the Group's activities
- Will be invited for the Group meetings and can receive proceedings upon request.

In 1989, the Group edited a book on Data Management and Clinical Trials, and has published several articles in peer review journals on quality control aspects, training of data managers, grading scales, data acquisition, etc. In addition, the current Guide to EORTC Studies was an initiative launched by and still edited with the collaboration of the Group.

Through the initiative of the DMG, quite a lot of the Clinical Groups have annually implemented the Data Managers meeting linked to the Group meeting. Data managers of the Data Center do contribute to the organisation of these meetings. The most active Groups are: GI–GU–GY–Lymphoma–Radio Therapy.

4.1. Projects/strategies for the next year

It is hoped that data managers will continue to be encouraged to accompany investigators and attend the Clinical Group meetings in 2001.

4.1.1. Training programme

The DMG was actively involved in the development of a three-level training programme. The first course was organised in 1991 in collaboration with the ESO. From 1993 onwards, the three levels were completed.

Level 1: One-day introduction to EORTC trials, an annual event, free of charge for our collaborators.

Level 2: Data Management in Cancer Clinical Trails. A 1-week residential course organised since 1994 on a bi-annual basis and since November 2001 replaced with the new EORTC–CRC Group collaborative effort 'Organisation and Implementation of Cancer Clinical Trials'. We have broadened the areas covered and encompassed other aspects of clinical trials, thus encouraging participation from a wider audience.

Level 3: 'Methodology in Cancer Clinical Trial. This was initially a bi-annual course but, due to its success, it will be run annually. Both level 1 and level 3 are currently coordinated at the EORTC Data Center level; level 2 has become the collaborative event of the EORTC CRC Group.

4.1.2. Quality control

From the creation of the EORTC Quality Assurance Committee in 1987, the EORTC Study Group on Data Management was involved in the conduct of the QA programme in medical oncology funded by the European Commission. The SGDM participated in the site visits performed in the frame of this project and the experience gained which led to the development within the EORTC of the Systemic Therapy Checklist and the first edition of the Guide to Clinical Trials (March

1994). Several articles in collaboration with the SGDM were published in peer review journals [1,2]. With the current increase of quality control in clinical trials, the Data Management Group continues to support and maintain the quality control procedures within the EORTC Groups by inviting data managers involved in specific Cooperative Groups to the Group meetings.

5. Oncology Nurses Group

5.1. Main achievements and future plans

The Oncology Nurses Group (ONG) is mainly focused on promoting the quality of care for patients with cancer, who participate in clinical studies. This aim can be reached by improving the nurses' participation–collaboration in clinical trials and providing them with educational opportunities and instruments aimed at improving their participation.

5.1.1. Education of nurses involved in clinical trials

Nurses are rarely offered specific educational opportunities related to research. The number of nurses involved in clinical trials is increasingly growing across Europe and no common educational courses specifically related to clinical trials are available. The ONG has developed a core curriculum for nurses involved in clinical trials, endorsed by the European Oncology Nursing Society and ECSG Research Nurses. After its implementation, the core curriculum will be updated and revised.

5.1.2. Network of nurses involved in clinical trials

The group started to recruit members 3 years ago and the actual number of members exceeds 70 research and staff nurses. Members are updated on the group's activities and their suggestions are elicited. They are also invited to the ECCO special interest sessions.

The main Cancer Conferences represent a unique opportunity to meet nurses and who are involved in cancer patient research and care and to obtain first-hand information on the problems encountered and nurses' needs. At each ECCO Conference, the ONG organises a special interest session where problems and challenges related to nurses' participation in clinical trials are discussed. The topic of ECCO 11 session was "How can nurses support the patients in clinical trials: education and practice" and it was organised in collaboration with the ECSG Research Nurses.

5.1.3. Network of collaboration with other Groups

Collaboration with other nursing groups (ECSG Nurses, European Oncology Nursing Society) and other EORTC groups (Quality of Life Unit) were activated in order to collaborate with common projects.

5.1.4. Publication of articles

The Group produced and published abstracts and articles in peer reviewed journals in order to render the group more visible and to share information on the 'state of the art' and problems and challenges related to nurses' participation in cancer clinical trials.

The ONG has collaborated to form an umbrella group, the Clinical Research Co-ordinating Group (CRC) consisting of the Data Management Group, the Radiotechnicians Group, the Early Clinical Study Group, and the Oncology Nurses Group. The CRC will stimulate a platform for collaborative work between the different groups, to combine resources and expertise in joint ventures.

5.1.5. The nurses' role and participation in clinical trials

Many changes are occurring across Europe. Nurses' educational level is increasing and clinical trials are now considered the only reliable way to evaluate new drugs and produce evidences on the effectiveness of new treatments. The EORTC-ONG published the first survey in 1994 [3], where the involvement of the nurses in clinical trials across Europe was assessed. The survey has been the first attempt ever in Europe to describe the nurses' role and tasks in clinical trials. Two articles with the data produced were also published in peer-reviewed cancer journals. These developments further elucidated the necessity of research nurses in clinical trials.

5.1.6. The research nurse in clinical trials

The research nurse plays many roles and functions at the same time, complementary and overlapping with those of the staff nurse. The role analysis proposed by Ocker and colleagues [4] differentiated the research nurse from the oncology nurse clinician, not on the basis of the activities performed, but on the focus and function of the role: while the main focus of the staff nurse is to provide patient care in order to meet the psychosocial, physical and emotional needs of the patient, the main focus of the research nurse's role is the implementation of the protocol. This includes the co-ordination of the care of the patients included in the protocol and the effective performance of the clinical trial. The research nurse acts as the consultant for the staff nurse and all others in the clinical trial team in dealing with problems related to conducting the clinical trials and the care of the patients involved. She may even have an active role in the direct care. The research nurse informs staff nurses about the protocol treatment, participates in patient education, collaborates in the selection of eligible patients, performs patient assessment and also renders the staff nurses more competent, able and active participants in clinical trials [4].

5.2. Nursing Summaries of cancer clinical trials

Nursing Summaries were proposed by the ONSG in 1995 and a publication was produced [5] and circulated in 1996 with guidelines for the preparation of a nursing summary. A Nursing Summary is a document where a selection of the more relevant and practical aspects of the clinical trial protocol is provided for the staff nurses in particular to facilitate their understanding of and participation in the clinical trial. A follow-up of the implementation of the Nursing Summaries across Europe has been planned in order to assess the main problems and adaptation necessary in different contexts for the implementation of the clinical trial protocols.

References

1. van der Schueren E, Horiot JC, Leunens G, *et al*. Quality Assurance in Cancer treatment. *Eur J Cancer* 1993, **29A**, 172–181.
2. Steward WP, Vantongelen K, Verweij J, *et al*. Chemotherapy administration and data collections in an EORTC Collaborative Group—can we trust the results? *Eur J Cancer* 1993, **29A**, 943–947.
3. Arrigo C, Gall H, Delogne A, *et al*. The involvement of nurses in clinical trials. Results of the EORTC Oncology Nurses Study Group. *Cancer Nurs* 1994, **17**, 429–433.
4. Ocker B, Plank DM. The research nurse role in a clinic-based oncology research setting. *Cancer Nurs* 2000, **23**, 286–289.
5. Di Giulio P, Arrigo C, Gall H, *et al*. Expanding the role of nurses in clinical trials: the nursing summaries. *Cancer Nurs* 1996, **19**, 343–347.