These reports will appear on a monthly schedule whenever available. They are based on information provided by individuals or clinical and research groups pertinent to cancer research. More detailed information if needed may be obtained by writing to

H.J. Tagnon, M.D.
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Boulevard de Waterloo, 125
1000 Brussels (Belgium)
Tel : (2)538.27.66 - Fax : (2)539.41.66

Guidelines for the preparation for publication of reports from EORTC Cooperative Groups

1. The chairman, convener or secretary of the Group is requested to mail the report to the office of the European Journal of Cancer & Clinical Oncology. The reports will be edited and published in the Journal within 6 to 8 weeks after reception in the office.
   Address : H.J. Tagnon, M.D.
   Editor, EUROPEAN JOURNAL OF CANCER & CLINICAL ONCOLOGY
   Institut Jules Bordet
   Rue Héger-Bordet, 1
   1000 Brussels (Belgium)

2. Please send the report typewritten on one side of page, double spaced with a 5 cm left margin. Brevity is essential. Tables and figures are difficult to print and should be replaced by an appropriate text.

3. Please consult the reports published in the March 1989 issue of the Journal and consider them as models to be adopted for all reports with possible exceptional adaptations.

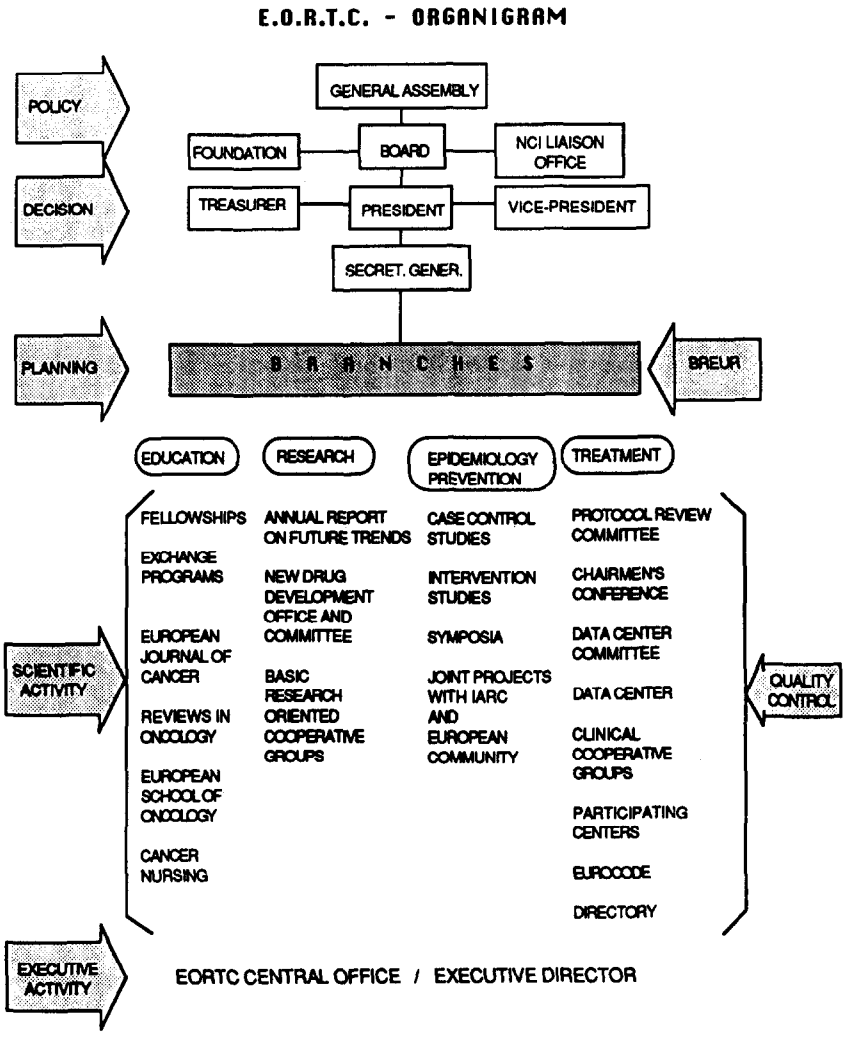
4. We request omission of list of names of attendants to the group meetings. Reports should be signed by either the chairman, convener, secretary of the group, or by all three ad libitum.

5. Please add as a conclusion to your report : "Additional information may be obtained by writing to the secretary of the group".

6. Protocols will be published at the request of the groups.

This office will be glad to receive your comments, criticism and suggestions on the edition and publication of your reports.

The Editor.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REPORT ON THE EORTC LEUKEMIA COOPERATIVE GROUP MEETING
Paris, March 17-18, 1989

Chairman: R. Zittoun

Participants: Haanen C, Hayat M, Solbu G, Suciu S, Visani G, de Cataldo R, Jaksic B, Strijckmans P, Goudsmit R, Sandra M, Willemze R, Louwagie A, Peetermans M, Sizoo W, Haak H, Abels J, Sonneveld P, Ribeiro M, Gerhartz H, Knauf W, Ho A, Jehn U, Zwierzina H, Thijss A, DeWitte T, De Bock R, Fillet F, Jacobs A, Schmalzl F, Falconi E, Epetti M, Amadori S, Labar B, Fanin R, Cauchin C, Hagemeyer A, Haas R.

March 17, 1989

MDS:

Low risk: The study has recently started. Accrual is excellent: 24 patients in 3-4 months.

High risk: H. Gerhartz presented several individual cases. Probably more than 3 courses are necessary to induce CR. Several centers have entered patients in this study without being a member. This problem will be addressed by the study coordinator and the chairman/secretary of the group.

Intensive chemotherapy in bad risk MDS < 60 years: The protocol has not been accepted by the PRC, but the revised version was accepted after the meeting (March 31, 1989). Maintenance therapy will be given at low dose Ara-C 10 mg q 12 hours s.c. for 14 days with 4 weeks intervals. This study will be a pilot study to assess the feasibility of intensive chemotherapy in this group of patients and the accrual rate in the EORTC Leukemia Group.

Multiple myeloma: Debusscher has written a letter saying that she will not be able to coordinate development of myelogenous studies. Monconduit has informed C. Haanen about a French cooperative group with protocols for several stages of multiple myeloma. He will be asked to give more details. A questionnaire will be prepared by U. Jehn and C. Haanen about future trials in multiple myeloma.

CLL: B. Jaksic will coordinate a protocol writing committee on 2 phase II parallel studies in advanced untreated CLL: a high dose chlorambuclin; b fludarabine.

Phase II studies AML: R. Willemze presented a pilot study in AML first relapse treated with deoxy-azacytidine (DAC) and mAMSA. He will develop a phase II study comparing DAC/Idarubicine and DAC/mAMSA in first relapse AML patients. R. Willemze will develop a protocol on carboplatin in resistant AML patients after first relapse.
T. DeWitte will develop an addendum to the AML 8a/b protocols: rescue after remission induction failure with salvage treatment consisting of Idarubicin and intermediate dose Ara-C.
T. DeWitte presented a protocol on maintenance treatment of AML in second remission. Treatment will consist of 6 courses of low dose Ara-C for 14 days and GM-CSF during the first 7 days of Ara-C. This will be a joint study of the EORTC Leukemia Cooperative Group and an AML study group from Germany (coordinator Hoelzer).

March 18, 1989

Scientific presentations: A. Jacobs and A. Hagemeyer presented their data on epidemiology of MDS and molecular cytogenetics respectively.

Business meeting: The secretary presented an updated list of active members, probationary members and collaborative members. Several amendments to the statutes have been proposed and approved by the meeting.

Active members: Should also participate in phase III studies. The board of the group will annually examine and discuss quality of centers.

Probationary members: Should participate in 2 trials with 2 different drugs, preferably one phase III trial. After 2 years the PM will be evaluated by the board of the group. A representative of this center has to attend at least one meeting annually.

Publications: see new studies

Data manager: The number of protocols has increased, but financial support has decreased. 200 ECU per patient from studies with investigational drugs should go to P. Strijckmans. 0.5 data manager in Brussels will be provided by the EORTC Leukemia Cooperative Group for one year. The situation will be evaluated after one year.

Cytologic committee: Three panels will be established for 3 different categories of diseases:
a: AML/ALL: Paris
b: MDS/CML: Innsbruck
c: Lymphoproliferative diseases: Brussels
The panels will be responsible for review of slides, immunological and cytogenetic data. Each panel should consist of a clinician, morphologist and immunohematologist.

Cytogenetics: Hagemeyer will send an inquest form to all centers. Cytogenetic evaluation in the ongoing studies is insufficient. Coordinators are needed for each study and regional coordinators for the larger study. Funding is needed.
The business meeting will be restricted to active members and the board only and it will take place on Friday after the general meeting.

Ongoing studies:

AML8a: Accrual is progressing quite well: 379 patients have been entered. Randomization seems to improve a bit.

AML8b: Accrual depends mainly on the GIMEMA contribution. 200 patients have been entered and 93 randomized.

TNF in refractory AML: Accrual is slow. Standard forms will be made for phase II studies in AML by R. Willemze, P. Strijckmans and G. Solbu.

Pentostatin in lymphoid neoplasma: Pentostatin is more available now. Negociations with the NCI about our previous proposals will be resumed.

AML 9: Quality control of registration and exclusion criteria is needed. R. Zittoun will contact Löwenberg about this.

CML HU vesrus IFa: Patient entry has just started. All patients should be entered before or at start of treatment with HU.

ALL: Forms will be available before July 1st, 1989. Good risk protocol should be started as soon as possible.

Next meeting: October 6-7, 1989, Paris, France.

REPORT ON THE EORTC RADIOTHERAPY COOPERATIVE GROUP
Leuven, April 14-15, 1989.

Present: Bartelink (Amsterdam), Bernier (Bellinzona), Bolla (Grenoble), Bosset (Besançon), Budach (Essen), Calais (Tours), Cartei (Pisa), Crabeels (Brussels), Elsby (Göteborg), Garavaglia (Bellinzona), Gardani (Milan), Glanzmann (Zürich), Hamers (Tilburg), Hansson (Göteborg), Hoogenraad (Nijmegen), Horiot (Dijon), Hager (Heerlen), Johansson (Göterborg), Karim (Amsterdam), Kobeyssi (Paris), Laddaga (Pisa), Le Floch (Tours), Lenz (Brussels), Lopez Torrecilla (Valencia), Mak (Deventer), Meerwaldt (Rotterdam), Monpetit (Vannes), Morgan (Nottingham), Nguyen (Reims), Pierquin (Créteil), Regnier (Brussels), Renaud (La Louvière), Roth (Düsseldorf), Scallier (Brussels), Schipper (Arnhem), Schulz (Krefeld), Sernbo (Göteborg), Spits (Amsterdam), Trovo (Pordenone), Van Daal (Nijmegen), Van den Bogaert (Leuven), Van den Weyngert (Antwerp), Van der Schueren (Leuven), Van Dijk (Arnhem), Van Glabbeke (Brussels), Van Limbergen (Leuven), Van Rijn (Enschede), Vantongelen (Leuven), Vijgen (Tilburg).
Absent with notification: Ciambellotti (Biella), Chenal (Rennes), De Vilhena (Lisbon), Gerbaulet (Villejuif), Littbrand (Umea), Maners (Little Rock), Sealey (Liverpool), Tobias (London).

1. Data Centre reports on on-going studies

22844: randomized trial on dose response in radiation therapy of cerebral gliomas.
Accrual: 250 patients to date. Of these 45 are off study, mostly due to recurrence/progression. Three hundred patients are needed and the trial should be complete by 1990. The results of the pathology review will be sent to each local pathologist through the responsible radiotherapist. Participants are asked not to send any more CT scans for the time being.

22845: randomized trial on the efficacy of radiation therapy of the cerebral gliomas. Accrual (below the desired amount): 57 patients. Since the Brain Tumour Group has entered most of these patients, Karim will raise to the members of this group the question of continuing the trial.

22861: randomized phase II trial of radiotherapy alone and radiotherapy with concomitant chemotherapy in treatment of anal carcinoma.
Accrual: 28 patients. The aim is 60 patients and it is hoped to combine the groups from the UK and US after 2 years.

22863: controlled clinical trial in high metastatic risk carcinoma of the prostate comparing pelvic radiotherapy alone to pelvic radiotherapy plus LHRH analogue.
Accrual (decreasing slightly): 51 patients.

08844: randomized phase III study in inoperable non-small cell bronchogenic carcinoma.
This study will probably be closed fairly soon. Accrual: 322 patients, with 10 centres from the Radiotherapy Group with 137 patients (43%), Lung Group participation: 24% and joint Lung Group/Radiotherapy Group participation: 33%.

08861: phase III study of adjuvant therapy in completely resected non-small cell lung cancer.
Radiotherapy Group participation in this study is minimal and accrual is low.

10863: phase III trial of external irradiation versus no treatment for in-situ ductal carcinoma of the breast treated by wide excision.
Accrual: 162 patients.

22831: controlled clinical trial for resectable rectal cancer using postoperative pelvic radiotherapy with or without elective irradiation of para-aortic nodes and the liver (Data Centre, J.C. Horiot)
Accrual: 367 patients since January 1984. The trial will remain open for another year (460 patients). Acute side effects: nausea and vomiting and severe haematological side effects: significantly more frequent in the extended field arm. Follow-up available for 269 patients, 4 years disease-free survival: 54%. Survival at 4 years: 63%. Local recurrences are almost all within the irradiated field.

Liver metastases survey (D. Gonzalez)
Questionnaires have been sent for data on patients in whom liver metastases have developed. Information is available for 38 patients.

Protocol 22851: randomized trial on accelerated fractionation of radiotherapy in advanced head and neck cancer (Data Centre, J.C. Horiot)
Accrual: 240 patients. Off study: 76 patients, mostly due to progression or recurrence. Of 29 patients a total of 25 are fully evaluable. Encouraging results have been obtained in the annex study on cell kinetics (contact person: A. Begg, Netherlands Cancer Institute, Amsterdam). More patients are needed. Svoboda reported on his own work on fractionated radiotherapy and cell proliferation testing with a group of 41 patients with rectosigmoid carcinoma.

New protocols

22881/10882: joint Radiotherapy/Breast Group study in conservative treatment of breast cancer (H. Bartelink)
This study can start as from May 15, 1989. Some remaining problems were discussed.
1. Adjuvant therapy: each centre has to define its policy and adhere to it throughout the trial.
2. Quality Control: a pilot study on in-vivo dosimetry is proposed.
3. Each centre makes its choice known on how the boost will be carried out, before patients are randomized.
The final protocol which will be presented to the Breast Group, will be sent to all active members of the group.

Proposal for a new study in rectum carcinoma (J.F. Bosset)
Three treatment options were proposed for unresectable cases: radiotherapy in combination with 5FU and low dose Leucovorin (as a sensitizer); radiotherapy with continuous 5FU infusion; accelerated radiotherapy schedule.
The second choice was preferred but resectable patients should also be included. A phase II feasibility study will be designed with 2 levels of chemotherapy doses, up to the maximum tolerability. Centres interested: Grenoble, Dijon, Tours, Pisa, Valencia, Amsterdam VU, Reims, Milan and Besançon. Bosset will write the protocol and submit it to the Steering Committee.

Pilot study in external irradiation with etanidazole radiosensitizer in advanced bladder cancer (T.D. Nguyen)
The implementation of this protocol is dependent on the provision of etanidazole. As soon as the drug is available in all the participating countries, a start can be made. Nguyen will adapt the protocol slightly (regarding follow up of patients). Centres interested: Valencia, Tours, Amsterdam AMC, Dijon, Pisa and Grenoble.

Postoperative radiotherapy in carcinoma of the caecum and ascending colon (A.B.M.F. Karim)
This protocol has been circulated to all active members of the group. Some members present are willing to enter approximately 30 patients per year. Centres interested: Grenoble, Reims, Pisa, Deventer, Krefeld and Amsterdam. Karim will prepare the protocol for presentation to the Protocol Review Committee.

Bile duct cancer (D. Gonzalez) Questionnaires have been sent for the registry of exta-hepatic bile duct carcinoma cases. Centres responding: Arnhem, Reims, Tenon Paris, Besançon, Arkansas, Rotterdam, Lyon, Biella and AMC. Information on 276 patients, concerning the location of cholangiocarcinoma, sex of patients, type of surgery performed, radiotherapy and intraluminal treatment, has been gathered.

Pilot study in escalating radiation dose in astrocytoma grade IV (D. Gonzalez and E. van der Schueren)
Pilot study which is being carried out both in Amsterdam AMC and in Leuven to be finished by the end of the year. Four radiation schedules are being studied: 3 daily fractions of 2 Gy up to a total dose of
a) 42 Gy in 9 days
b) 48 Gy in 10 days
c) 54 Gy in 11 days
d) 60 Gy in 12 days
No toxicity problems have been encountered. Future work: either a phase III study or another phase II study with other fractionation schedules.

Proposal for a study in advanced endometrial carcinoma (M. Bolla)
After a review of the literature in stage I grade III endometrial carcinoma Bolla proposed a protocol in radiotherapy and sequential hormone therapy. The Steering Committee was not in favour due to the fact that accrual would be too low. Bolla will make a new proposal for presentation to the Steering Committee.

Quality Control Program (U. Hansson, J.C. Horiot, K.A. Johansson)
Johansson and Hansson (Göteborg) presented details of the program concerning the site visits in the second half of 1989 and the mailed TLD program extended to include electron beams. In vivo dosimetry will also be extended to include work on the new breast protocol.
Bartelink gave details of the development of a system for real time imaging and quality control in radiation therapy in which are involved: Amsterdam, Leuven, Dijon, and Florence. This proposal was submitted to the EC for financial support: situation looks favourable. Within 12 months, it must be shown that the plan can work whereafter a full grant application must be submitted.

Other Business
- R.E. Leake (Department of Biochemistry at Glasgow University) proposes the setting up of a central bank of tumour material for the EORTC. Further information is available from the Chairman.
- MRC study to define the optimum field size in adjuvant treatment of clinical stage I testicular seminoma: (presented to the Radiotherapy Group during a previous meeting). Study coordinators A. Horwich, Royal Marsden Hospital, London or S. Fossa, Norwegian Radium Hospital, Oslo.
- Dirk Crabeels, Data Manager in Brussels Data Centre will be leaving and was thanked for all his work and for the good collaboration.

- Next meeting: Palace Hotel, Viareggio (Italy), October 6 and 7, 1989.

REPORT-JOINT MEETING OF THE EDUCATION BRANCH AND CANCER NURSES
Paris, June 2, 1989

Present delegates: Celestina Arrigo, Rita Bodenmüller, Alberto Costa, Agnes Delogne, Jerzy Einhorn, Helen Gall, Bernhard Kornhuber, Clementine Molin, Robert Zittoun, Yvonne Willems and Per Hall.

1-The meeting was opened by the chairman.

2-The agenda of the meeting was approved upon.

3-Per Hall was approved as Acting Secretary in the absence of Karl-Henrik Robert.

4-Jerzy Einhorn presented the Education Branch of EORTC and indicated that this was a joint meeting to initiate the feasibility of the study group of cancer nurses within the EORTC. Views of the president of the EORTC, Denis, and chairman of chairmen's conference, Newling were presented. Each of the participants expressed their view the study group.

5-Following separate meetings for the nurses and EB a decision was made to propose to the president of EORTC and PAC to initiate a group of cancer nurses to perform a feasibility study. The nurses elected Clementine Molin as interim chairman and Helen Gall as secretary. The nurses expressed the wish to act within the EB in the feasibility study.

6-The interim chairman of the cancer nurses feasibility study group accepted to prepare the next meeting of cancer nurses.

7-The EB agreed that the two initial aims of the study group of nurses should be to create a net-work for communication between nurses working with clinical trials within the EORTC. The first step could be a course for nurses that will motivate, educate and back up bed-side nurses. The course should, if possible, be inside the European School of Oncology. Alberto Costa informed the meeting that 25 scholarships for a suitable course for cancer nurses were available. It was decided that the EB and the nurses should work for additional scholarships through national cancer societies and other channels if necessary. The second aim was to create a channel for nurses to influence clinical protocols within the EORTC. As the first step the nurses will propose a suitable oncology nurse to be included in the Protocol Review Committee.

8-It was decided that Bernhard Kornhuber should help the nurses create a budget for 1990. BK should also apply for additional funds for the EB during the rest of 1989.

9-The feasibility study group will meet in Frankfurt, October 2, and there will be a joint meeting with the EB the day after.

10-The study group decided that one further nurse, preferably with educational experience, should be invited to the next meeting.

11-The meeting was closed.

REPORT-EDUCATION BRANCH
Paris, June 2, 1989

Present members: Alberto Costa, Jerzy Einhorn, Bernhard Kornhuber, Robert Zittoun and Per Hall

1-The meeting was opened by the chairman.

2-The agenda of the meeting was approved.

3-The minutes of the last meeting in Paris were approved.

4-Per Hall was approved as Acting Secretary in the absence of Karl-Henrik Robert.

5-Cancer Nursing Study Group: The EB acknowledged the need for additional representation in the Cancer Nursing Study Group.

6-Reviews in Oncology: It was decided that the aim for Reviews in Oncology should either be a commercial journal with enough subscriptions to carry the costs, which needs marketing. If this doesn't succeed in three years time the journal should be offered to the EORTC Newsletter.

7-Since Michael Peckham was not present the discussion about the Bonn documents was postponed to the next meeting.

8-Other topics: It was decided that Bernhard Kornhuber should make a draft statement on specializing oncology nurses and send it to the Acting Secretary for circulation.
The EB felt that the statement should be forwarded as soon as possible to the EB. J. Einhorn will discuss the route and method to do it with Louis Denis.

9-It was decided that H. Tagnon should be invited to the next EB meeting in Frankfurt.

10-The next meeting of the EB will be October 3, at Frankfurt airport in the Sheraton Hotel. The meeting will start at 10:00 and finish at 17:00. The morning will be devoted to EB activities and the afternoon to the cancer nurses study group.

11-The meeting was closed.

REPORT EORTC NEW DRUG DEVELOPMENT AND COORDINATING COMMITTEE MEETING
Amsterdam, April 6th, 1989

Present: Workman, Harrap, Armand, Pinedo, Yoder, Van Oosteroom, Stevens, Staquet, Cavalli, Hansen, Winograd (ex officio).

1-Minutes of previous meeting, September 14th, 1988 were approved.

2-Information from the Chairman:

a. A report on the special meeting held immediately before the present meeting was given, focussing on the future structure for a New Drug Development programme within EORTC. A detailed report will be forwarded to the members.

b. **NCI-EORTC Symposium: Pinedo gave a report on the very successful symposium on March 7th-10th, 1989 with more than a thousand participants. The chairman congratulated Pinedo and his staff on the very excellent arrangements.**

c. **Next symposium** is planned for **November 1991** in either USA or Europe (Amsterdam). Bruce Chabner, NCI will be contacted in order to see whether or not NCI might be interested in arranging this symposium.

d. **Joint EORTC meeting June 27th-29th, 1990, Glasgow.** Stan Kaye will be in charge of the arrangement and he will be invited to the next NDDCC meeting in order to discuss the detailed programme (a preliminary programme has been received).

e. Yoder reported on the **NCI-EORTC-CRC Steering Committee, April 5th, 1989.** At that meeting the question of the second joint CRC-EORTC-NCI workshop to be held in Bethesda was discussed. It was agreed that the workshop last year was successful and a similar meeting should be arranged around the ASCO-AACR meeting scheduled in Washington, DC, May 1990. Yoder will explore further on this in a report due in the fall. One of the primary objectives will be for members of the CRC-EORTC directly participating in the joint agreement to update the NCI Drug Development and Treatment staff on progress to date.
The report on the meeting of the Joint Formulation Working Party (JFWP) on March 11th, 1989 was also given. The JFWP under leadership of John Slack has been progressing well with more than 15 drugs now at various stages of formulation development. The question of funding for that working party was discussed. It was noted that the CRC and the NCI already have made a substantial financial contribution and it was suggested that the EORTC leadership should be informed of this and be encouraged to make a more or less equivalent contribution. It was emphasized that any joint drug development efforts will depend heavily on JFWP to ensure the availability of acceptable dosage forms for clinical use. R. Lobezzo has resigned from the JFWP and will be replaced by Benjamin Winograd.

f. Armand informed about the work being performed within the EEC which is preparing guidelines for the evaluation of anticancer drugs in man. A draft of these guidelines has been circulated. The draft is very close to the EORTC recommendations.
Staquet informed that EORTC has not been formally requested to be active in the elaboration of the guidelines, but that the EEC committee to a certain degree has been aware of the guidelines developed by the EORTC.
It was agreed that the NDDCC should invite representatives from the EEC to one of the upcoming meetings in order to inform them about the activities within the EORTC concerning new drug development.

3-Information from the Director, NDDO: Pinedo gave an update of the status at the office, including the fact that Lobezzo has left the office. A replacement has not yet been found.
The chairman regrets that Lobezzo has left the programme. Lobezzo has for the past years been very instrumental in the rapid expansion of the programme of the NDDO and it will be difficult to replace him.

4-Guidelines for preclinical toxicology
Two sets of guidelines exist. One from the CRC and one from the EORTC. It was agreed that it was expediant to have one joint set of guidelines. Fox and Winograd will be responsible for preparing a joint set and these will be circulated before the next meeting.

5-Other items
Staquet informed that he is withdrawing as member of the NDDCC. Hansen expressed appreciation for the work performed by Staquet, especially at the time when the NDDCC was established.

6-Next meeting
Amsterdam, October 12th, 1989
Preliminary programme:
08:30-10:00 Planning of the joint meeting in Glasgow
10:00-16:00 General meeting

HEMATOLOGY/ONCOLOGY FELLOWSHIP

A Research and Clinical Trainee position is available for MD training in pediatric hematology/oncology. Applicants should submit resume to:

Dr. Paul Benoit
Division of Hematology/Oncology
Ste. Justine Hospital
3175 Ste. Catherine Street
Montreal, Quebec
Canada, H3T 1C5

XIVTH INTERNATIONAL SYMPOSIUM FOR COMPARATIVE RESEARCH ON LEUKEMIA AND RELATED DISEASES

Vail, Colorado, USA, October 8-12, 1989

Information:
International Association for Comparative Research on Leukemia and Related Diseases (IACRLRD)
410 W. 12th Avenue, Suite 302
Columbus, Ohio 43210
U.S.A.
tel: (614) 292-5602
fax: (614) 292-1544

ERRATUM

This is a correction to the last issue-The following date is accurate.

INTERNATIONAL CONFERENCE ON BLOOD CELL GROWTH FACTORS: THEIR BIOLOGY AND CLINICAL APPLICATIONS

Capri, Italy, October 8-12, 1989

Information:
Ann Murphy
Conference Coordinator
4100 South Kettering Boulevard
Dayton, Ohio 4539-2092
U.S.A.
tel: (513)-293-8508
fax: (513)-293-7652

CONFERENCE ON COMPLICATIONS OF TREATMENT OF CHILDREN AND ADOLESCENTS FOR CANCER

Buffalo, New York, June 22-24, 1990

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