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PROPOSAL FOR A COUNCIL DECISION

adopting a second R&D programme

of the European Economic Community

in the sector of

MEDICAL AND PUBLIC HEALTH RESEARCH

consisting of

five multiannual concerted projects

(submitted to the Council by the Commission)

SECOND PROGRAMME OF RESEARCH ACTIONS
in the sector of
MEDICAL AND PUBLIC HEALTH RESEARCH

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1. SUMMARY

The proposed second research and development programme of the EEC in the sector of medical and public health research consists of five multiannual concerted projects in the fields of :

1. Attempted suicide as public health problem (4 years);
2. Detection of tendency to thrombosis (4 years);
3. Evaluation, understanding and substitution of impaired hearing (3 years);
4. Criteria for perinatal monitoring (4 years), and
5. Common standards for quantitative electrocardiography (4 years).

The legal basis for this programme is Article 235 of the Treaty establishing the European Economic Community, and the Council Decision of 13 February 1978 adopting three multiannual concerted projects as a first programme of Community research actions in the sector of medical and public health research.

Its principal objectives are :

- to enlarge the current Community medical research programme towards further fields which are meeting the medico-social and economic needs of all Member States;
- to acquire more effectively scientific and technical knowledge in the selected five fields of common interest by collaborative Community research efforts;
- to bring under Community R & D policy an increasing proportion of national research activities in the sector relating to health policy which should be linked to various Community policies, in the mutual interest of the Community and the Member States.

Interested third countries participating in European Cooperation in the field of Scientific and Technical Research (COST) will be associated to the programme.

The maximum financial contribution of the Community for expenditure commitments and for staff necessary for the implementation is estimated at 2,70 million EUA and 4 staff for the duration of the programme.

The programme is foreseen to start on 1 January 1979.

2. INTRODUCTION

The role of medical and public health research is to maintain or restore living conditions conducive to the optimal individual health and to the society. The wide-spread diseases of modern civilization and the steady increase in the costs of maintaining public health are among the most important problems confronting health policy in all Member States. Research and development represent the essential components of a successful policy and they can highly contribute to progress in medicine and public health.

Considering the complexity of the problems involved in medical research as well as the urgency of tackling the latter, on the one hand, and the available national research possibilities and facilities, on the other hand, efficient research execution **often requires a joint European** effort, a repartition of research tasks and work, and coordination of national activities. Such collaboration would optimize its efficacy, would greatly facilitate research progress in particular fields and would save time and money.

In this view, the "first" programme of research actions in the sector of medical and public health research, of which the three concerted projects have been adopted by the Council on 13 February 1978, has to be seen as bearing the first elements to meet these requirements of all Member States, and the present "second" programme as the next logical step of its enlargement.

This proposal for a Council Decision adopting a second R & D programme of the EEC in the sector of medical and public health research has been elaborated by the Commission, adviced by the Committee on Medical and Public Health Research (CRM/CREST), in the spirit of the Council Resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology, and of the one relating in particular to the coordination of national policies in the field of science and technology.

Moreover, this programme proposal corresponds to the Resolution of the European Parliament embodying its opinion on the first programme, in which "the Commission is expected, in accordance with the traditionally universal nature of medical knowledge, to continue to promote such research at European level and to ensure that it is coordinated and, where possible, integrated with similar research being carried out in other parts of the world".

3. CHOICE OF THE CONCERTED PROJECTS

After identification and critical evaluation of particular research fields of Community interest, several proposals for possible concerted projects have been elaborated by CRM's Working Groups in compliance with the following **principles :**

(a) The main objectives of European cooperation in the medical field should be **the prevention, the early detection of disease and the rehabilitation.**

(b) Implementation of common actions should be performed by or in association with the research organizations of the Member States.

(c) The following important criteria should be applied to the choice of common actions :

- the topic should be of importance to the Community as a whole;
- the topic should have practical importance in particular from the social and economic point of view;
- on scientific grounds : either the project should **be implemented jointly or at least could be carried out much more effectively on Community level than separately in each Member State;**

- the project should be expected to give clear and reasonably early results.

From these proposals, CRM has suggested as components of the second programme the following five concerted projects which are related to the particular fields of :

1. Attempted suicide as public health problem;
2. Detection of tendency to thrombosis;
3. Evaluation, understanding and substitution of impaired hearing;
4. Criteria for perinatal monitoring;
5. Common standards for quantitative electrocardiography.

This choice is formally accepted by the national research organizations; it has been achieved following the comparative evaluation of all available proposals and the establishment of priorities by :

- commenting on their scientific, medico-social and economic importances;
- considering the feasibility of their implementation and coordination;
- taking into account the relevant activities in progress in other countries, as well as those of appropriate International Organizations such as WHO, OECD, Council of Europe, European Medical Research Councils, European Science Foundation, etc.

4. DESCRIPTION OF THE CONCERTED PROJECTS

4.1. Multiannual concerted project No 1 (4 years) relating to

ATTEMPTED SUICIDE AS PUBLIC HEALTH PROBLEM

4.1.1. Elaboration

In compliance with its mandate, the Committee on Medical and Public Health Research (CRM), assisted by its Specialized Working Group : Epidemiological, Statistics and Clinical Trials, has recommended as a project of interest to the Community a joint action in the field of "Attempted suicide as public health problem" and advised the Commission in elaborating this proposal for a multiannual concerted project.

In accordance with this opinion the Commission has chosen this specific research field :

- on the basis of the exploratory work carried out by the Specialized Working Group;
- considering the agreed objectives of European cooperation in the medical and public health domain;
- applying the mentioned criteria for the selection of research priorities, and
- having regard to the conclusions elaborated by international experts in this specific field during a workshop, held on 22-24 September, 1976 in Dublin under the sponsorship of CRM and the Commission, where according to the present state of the art the most significant research problems were identified, and where the needs for the most efficient handling of the problem, from the point of view of R & D requirements, were evaluated.

Relevant activities in progress in non-Member States, particularly in European countries, as well as those of appropriate International Organizations, and in particular of WHO, have been taken into account.

4.1.2. Motivation

2.1. Scientific importance

Attempted suicide represents a growing public health problem in all western European countries placing and increasing burden on primary health care, hospitals and specialized psychiatric services.

Although official mortality statistics suggest that completed suicide is declining in the EC, mainly due to a drastic decrease of the number of elderly persons committing suicide and to a faster and improved therapeutic intervention, all countries report in recent years a disturbing increase in both attempted and completed suicide of young persons. Besides a current so-called "epidemic of self-poisoning", of which one factor is the growing

abuse and over-prescribing of psychotropic and other drugs encouraging suicide, the roots and determinants of attempted suicide are poorly understood.

Moreover, despite the apparent similarity of the problem throughout western Europe, there are still differences from country to country in the frequency and the circumstances of suicide attempts due to a complicated intermeshing network of social and cultural factors.

The burden this phenomenon is placing, both on society in social terms and on health services in administrative and financial terms, is so considerable that most European countries are urgently seeking some alleviation of the problem.

National research efforts in performing epidemiological studies in geographical areas, social settings such as preventive services and leisure activity facilities etc., as well as local controls to discourage indiscriminate usage of potentially dangerous drugs, they all can be considered still insufficient to tackle efficiently the complexity, the urgency and the magnitude of the problem.

Because of the considerable cultural contribution to the problem, greater insights into its phenomenology can better and faster be achieved through a collaborative research project based on a number of different cultural and social settings than could be obtained through a study based on one geographical location only. This indicates that a community research programme, involving a standardized methodological approach, may yield a much richer harvest of information concerning frequency, characteristics, determinants and outcome of attempted suicide than can emanate from research confined to one country alone. Similarly, a variation of very different preventive and treatment approaches in different countries will also be more productive of information helpful in providing guidelines for a future action than a strictly uninational approach.

The results of this proposed concerted research project will greatly facilitate an elaboration of appropriate means to reduce efficiently the incidence of attempted suicide of young people in Europe.

2.2. Socio-economic importance

National budgets devoted to health and social welfare within the countries of the Community are now reaching 7 per cent of the gross national product. General hospital services make a very substantial contribution to this budget; many of their expensive resources such as beds and the precious time of their medical personnel are now being taken up both in in-patient wards and in casualty departments by the flood of persons having attempted suicide who are brought to these hospitals. Any reduction of their number will significantly decrease the cost of general hospital services. Likewise, expenditure on general practitioner services, social work services and ambulance services has been increased by the ever-growing use of these services by persons who have attempted suicide. These are examples of the direct economic gain through ability to prevent or at least reduce the incidence of attempted suicide, in the countries of Europe. However, many more

detailed indirect benefits will also accrue, such as increased knowledge of the needs of young persons in leisure-time activities. Furthermore, knowledge of more effective usage of preventive services should be a further socio-economic gain from a project such as that proposed here.

4.1.3. Aim and objectives

The aim of the proposed research programme is to arrive at knowledge of the means of reducing attempts of suicide of young people by understanding the social factors and cultural conditions involved in attempted suicide, and particularly affecting young people, and by elaborating proposals for appropriate preventive actions meeting the needs of suicide attempters.

The proposal is directed towards promoting and coordinating a joint collaborative research effort with the following main objectives :

3.1. To assemble data on the extent and characteristics of the problem and its social concomitants or determinants in defined areas of the Member States;

3.2. To develop scales and rating devices for the identification of the recidivist suicide attempter and the suicide attempter particularly at the risk of completed suicide;

3.3. To evaluate the effectiveness of different forms of services for the suicide attempter;

3.4. To devise, implement and evaluate control policies in relation to attempted suicide and in particular to self-poisoning by drugs;

3.5. To establish and develop methodologies and instruments on a collaborative basis to enable a standardized research approach to the above four objectives, and

3.6. To analyse the results of such research findings to enable recommendations to the Member States concerning the incidence of attempted suicide and intentional self-poisoning, and the treatment of its consequences.

4.1.4. Requirements and timing

Besides the general requirements for coordination purposes (project leader, secretariat, meetings of Concerted Action Committee), this concerted project will need the facilities of workshops, visits and short exchange of research workers for the dissemination of knowledge and the discussion of results.

It is envisaged that the project will last four years and the approximate phasing of work during these years would be as follows :

First year	Collating of information and developing of tools and training;
Second year	Field work including examination of study area and selection of cohorts for follow-up;
Third year	Continuation of field work and follow-up;
Fourth year	Data analysis, elaboration of conclusions and preparation of final report.

4.2. Multiannual concerted project No 2 (4 years) relating to

DETECTION OF TENDENCY TO THROMBOSIS

4.2.1. Elaboration

In compliance with its mandate, the Committee on Medical and Public Health Research (CRM), assisted by its Specialized Working Group : Research in the field of Medical Biology, has recommended as a project of interest to the Community the joint implementation of research in the field of "Detection of tendency to thrombosis" and advised the Commission in elaborating a corresponding proposal for a multiannual concerted project.

In accordance with this opinion the Commission has chosen this specific research field :

- on the basis of the exploratory work carried out by the Specialized Working Group;
- considering the agreed objectives of European cooperation in the medical and public health domain;
- applying the mentioned criteria for the selection of research priorities, and
- having regard to the conclusions elaborated by the European experts in this specific field during two workshops held in 1974 and 1976 under the sponsorship of CRM and the Commission, where according to the present state of the art the most significant research problems were identified, and where the needs for the most efficient handling of the problem, from the point of view of R & D requirements, were evaluated.

Relevant activities in progress in non-Member States, particularly in European countries, as well as those of appropriate International Organizations have been taken into account.

As modality of research execution preference is given to a "Concerted project".

4.2.2. Motivation

2.1. Scientific importance

Thromboembolic processes are frequent and are known to be involved in most serious diseases and in most causes of death. Alone the fact that in most instances thrombosis and its often severe consequences can be prevented, if clearly diagnosed in time, not only elucidates the existing scientific problem with which biomedical research is faced today, but also justifies the urgent demand for the possibility of early diagnosis of a tendency to thrombosis in order to detect any corresponding risk situation.

Recognized as a major health hazard, any approach to tackle the problem of thrombosis is doubtless of considerable interest to all Member States.

Considering the three main objectives of European cooperation in the medical field it can be stated that this proposed research project is clearly directed towards two of them, namely to prevention and to early diagnosis of diseases.

On scientific grounds, the project can be carried out much more effectively on an international basis than separately in each Member State mainly for the following reason : due to the magnitude and to the complexity of the problem of thrombosis its efficient tackling necessitates a close multidisciplinary collaboration between clinicians, physiologists, biochemists, enzymologists, immunologists, pharmacologists, etc... as well as the availability of adequate research facilities. Therefore, only a restricted number of institutes succeeded to dispose of these requirements and to gain a reputation of competence which is covering at least a part of the various aspects involved in the problem; their cooperation and coordination within the frame of a common European project would greatly facilitate the achievement of clear and reasonably early results.

The expected results of such multiannual cooperation would be the following :

- better insight in the complex mechanisms involved in the process of thrombosis;
- improvement of available methods and/or development of new ones capable to detect a tendency to thrombosis;
- assessment of their clinical value through pilot studies in well-defined populations, and
- elaboration of an extended action programme aiming at population screening.

2.2. Socio-economic importance

Thromboembolism represents a leading cause of morbidity and mortality in the Western industrialized countries. Unfortunately its importance, which is likely to grow with the increasing longevity, is often inadequately appraised, partly because it is related to pre-existing disease, surgery, or trauma which obviously results in placing major emphasis on these conditions. Nevertheless, thromboembolism is a hazardous factor in the health state of a patient and survivors remain often crippled and disabled.

The possibility of an early detection of tendency to thrombosis and thus of taking prophylactic measures in time would reduce significantly not only the frequency of deaths but also the number of crippled and disabled persons suffering under the severe sequela of embolic organ damage. In addition, prevention of thrombosis would often shorten the duration of hospital care, too. All that on its part would certainly eliminate an important part of the present burden to national health care systems.

On the other hand, a coordinated research action in this particular field would avoid unnecessary duplication of efforts, would accelerate the possibility to perform population screening, and would thus save time and money.

4.2.3. Aim and objectives

The aim of the proposed programme is to acquire the scientific and technical knowledge, necessary to understand better the pathogenesis of thrombosis and the complexity of the mechanism involved, and to develop reliable tests capable to detect a tendency to thrombosis at an early state. Such tests would enable the clinician to start prophylactic measures in time, would help to identify persons in a high risk state, and would contribute to further development of antithrombotic drugs.

The research work is expected to cover the following objectives :

3.1. Detection of activated clotting factors and of their reaction products :

- Qualitative and quantitative analysis of the activated components of the intrinsic and extrinsic pathways of the prothrombin activation sequence by applying functional, biochemical, and immunological criteria;

- Interlaboratory comparison, improvement and/or elaboration of methods for the detection of fribrinogen which is altered by the clotting and fibrinolytic systems.

3.2. Quantitative analysis of the inhibitors of the clotting system, in particular of the antithrombins, by immunological and enzymatical methods; interlaboratory comparison of existing methods and development of new ones.

3.3. Studies of the active and inhibitory components of the fibrinolytic system :

- Study of the mechanisms involved in the activation process and identification of its active components; quantification of the response of the body to stimuli apt to increase fibrinolytic activity;

- Elaboration of methods for the qualitative and quantitative analysis of fibrinolytic inhibitors.

3.4. Studies on blood platelets :

- Qualitative and quantitative analysis in the plasma of in particular high molecular weight substances released from the platelets; interlaboratory comparison and improvement of existing methods;

- Studies of the surface properties, of the procoagulant activity as well as of the changes in physical and biochemical parameters of altered platelets.

- Detection of the mechanisms involved in spontaneous platelet aggregation, and in particular, when stored in anticoagulated plasma.

3.5. Pilot studies in well-defined populations following standardization of materials and methodology :

- Definition of suitable patients for a chosen test procedure; elaboration of corresponding guidelines.

- Performance of "in vivo" studies and evaluation of the clinical value of the chosen test procedures.

3.6. Elaboration of an extended action programme aiming at the detection of high risk groups with tendency to thrombosis by means of population screening.

4.2.4. Requirements and timing

In order to facilitate the execution of the proposed European research action, following possibilities should be foreseen : a plenary meeting once a year to obtain an interdisciplinary view of the related research and to discuss own results as well as future trends and plans; interlaboratory meetings for exchanges of ideas, methods and results either by sub-group meetings or by visits of the scien ists engaged; short term exchange of research workers between collaborating laboratories for training in special methods or to perform investigations on the spot using available facilities; a coordination centre, acting also as secretariat and being responsible for the handling of common funds, and a project leader.

Considering the complexity of the problem and the magnitude of the research work to be carried out by the various collaborating institutes, this joint research effort should be planned for a period of 4 years with reconsideration after the first 2 years.

Following the establishment of a precise working plan, which foresees an optimal sharing of tasks as well as a complementary working method between the participants, all methodological work and all basic studies will start simultaneously. Only the "in vivo" pilot studies will follow at a later time but with gradual increase in their implementation.

The elaboration of a new proposal for an extended programme is planned for the last year in order to ensure also a desirable continuity of work aside of its main task.

4.3. Multiannual concerted project No 3 (3 years) relating to

EVALUATION, UNDERSTANDING AND SUBSTITUTION OF IMPAIRED HEARING

4.3.1. Elaboration

In compliance with its mandate, the Committee on Medical and Public Health Research (CRM), assisted by its Ad-hoc Working Group : Congenital and Environmental Factors in Deafness, has recommended as a project of interest to the Community the joint implementation of research in the field of "Evaluation, understanding and substitution of impaired hearing" and advised the Commission in elaborating a corresponding proposal for a multiannual concerted action.

In accordance with this opinion the Commission has chosen this particular research field :

- on the basis of the exploratory work carried out by the Ad-hoc Working Group;
- by considering the agreed objectives of European cooperation in the medical and public health domain;
- by applying the mentioned criteria for the selection of research priorities, and
- having regard to the conclusions elaborated by the European experts in this particular field during a workshop on "Neurophysiology of Hearing" (publication of 180 pages), held on 20-22 May 1976 under the sponsorship of CRM and the Commission, where according to the present state of the art the most significant research problems were identified, and where the needs for the most efficient handling of the problem, from the point of view of R & D requirements, were evaluated.

Relevant activities in progress in non-Member States, particularly in European countries, as well as those of appropriate International Organizations have been taken into account.

4.3.2. Motivation

2.1. Scientific importance

In the Member States of the EC, a steadily increasing number of more than 250 000 inhabitants are handicaped by perceptive (sensory - neural) hearing losses in which the inner ear or more central pathways are affected due to a variety of causes like inborn disorders, diseases, ageing, tumours, trauma and/or environmental factors.

Etiology and pathogenesis of these disorders of the inner ear remain often obscure and methods for early diagnosis, therapy and substitution procedures are still inadequate or lacking despite the scientific and technological progresses achieved.

Great research efforts have been made during the last decennia to tackle the multiple aspects of the complex problem of perceptive hearing losses. A survey of the present state of the art, of current activities and of available facilities revealed the following situation :

- Although knowledge on the morphology and physiology of the auditory system has markedly increased, we still insufficiently understand the basic principles involved in hearing and in particular the pathophysiological processes and mechanisms involved in the multiple disorders of the inner ear.

- Within the EC, there are excellent laboratories specialized in morphological and neurophysiological research on the auditory system. Unfortunately, those capable to carry out modern histological studies are mainly involved in projects on experimental animals and are not cooperating with the laboratories specialized in human neurophysiology, whereas many of the existing neurophysiological laboratories are neither collaborating among themselves nor familiar with the use of histological preparations for their own investigations.

- Electrophysiological studies have in the past contributed both to a better diagnosis of auditory disorders and to a rehabilitation of hearing impaired individuals. Single laboratories have reached a high level of their own individual research and have provided for instance new diagnostic tools such as Electrocochleography and Evoked Response Audiometry; the proper use of latter tools however and their further improvement still remains restricted to a relative small number of institutes because of their requirements for competent scientists and adequate facilities.

- Similarly, research on artificial auditory stimulation remains the domain of few highly specialized institutes since this new concept is still faced with numerous scientific and technological R & D problems; its first applicable results to patients suffering from complete perceptive deafness are encouraging greater research efforts which in turn demand closer collaboration at both multidisciplinary and international level.

- Moreover, recent development of computer technology would allow to progress in the modelling of both auditory systems and auditory disorders. Such steps, although deemed indispensable for a better understanding of auditory function and dysfunction, are still fragmentary mainly because of the lack of cooperation between the appropriate institutes or laboratories.

This actual research situation in the EC clearly states the particular need for a closer collaboration between existing institutes of different disciplines and underlines the scientific importance of creating a concerted research project at European level.

Such an undertaking would not only allow to tackle more efficiently the multiple aspects of the complex research problem and thus facilitate the execution of the highly specialized work, but it would also promise clear and reasonably early results concerning prevention, early diagnosis and rehabilitation of perceptive hearing losses.

Furthermore, a progressive coordination of the related national activities would contribute :

- to avoid unnecessary duplication of research efforts;
- to raise the level of existing research in the different countries to a European standard, and
- to compete scientifically with the research performed in other continents.

2.2. Socio-economic importance

With children, deafness due to perceptive hearing loss results in poor speech acquisition, psychoaffective and intellectual disturbances and thus handicaps greatly their mental development. With adults, even moderate hearing impairment influences considerably their self-confidence and in particular their social relations for which auditory- and speech-communication is of greatest importance; severe impairment may also change for the worse their social situation.

The number of deaf persons which cannot be helped efficiently is considerable since available therapies of sensory-neural disorders are very disappointing and corrections through hearing aids are still difficult and in some cases impossible. Moreover, this number is expected to increase mainly due to acoustic trauma (high level environmental noise) and to presbyacousis (which appears with age and spares nobody).

The socio-economic importance of the proposed concerted research action is evident when taking into account the total number of persons affected by perceptive hearing losses in the EC (estimated at more than 250 000) as well as the resulting burden to the national health care systems, and when considering the impact such disorders have on the social community and in particular on the suffering persons themselves.
In addition, any improvement of possibilities for prevention, early diagnosis and rehabilitation will safe money spent from national social budgets, and any avoidance of duplication of unnecessary research efforts that spent from public research resources.

4.3.3. Aim et objectives

The overall aim of this concerted research action is to help deaf people to overcome their impaired hearing by substitution of the affected sensory-neural parts of their inner ear and thus to provide them with adequate speech intelligibility, as well as to improve the possibilities of prevention, of early diagnosis and of therapy of perceptive hearing losses by tackling the following aspects of the complex problem :

a. What is the structure and function of the normal hearing system ?

b. What are the histo-morphological alterations in an impaired system?

c. What causes and what is its neurophysiological dysfunction ?

d. How can both diagnosis and prevention of such impairments be improved ?

e. How can a dysfunction be restaured or a functional loss be substituted ?

The research work, to be carried out in close collaboration between the appropriate institutes or laboratories of different disciplines, is expected to cover the following objectives :

3.1. Comparative studies along common guidelines of the relationships between histopathological, functional and clinical data in the following particular cases of sensory-neural hearing losses : hereditary deafness, congenital deafness (Rubella, etc...), neonatal deafness (kernicterus, anoxia ...),and deafness acquired through : acoustic trauma, drugs, ageing, viral diseases,Meniere's disease, neurinoma, etc...

For this purpose the organization of a European bone bank is proposed which should consist of surface preparations of temporal bones from patients who previously have been examined by advanced electrophysiological and audiological methods.

Animal models of such pathological entities will be of course, when possible, carefully considered.

3.2. Development and/or improvement of electrophysiological tests of auditory function; special attention should be given to : early diagnosis of neurinoma, precise diagnosis of Meniere's disease, brainstem-, central- and neural disorders, testing of eventual low frequency residue, and development of objective tests of neural function when the sensory structures are totally impaired.

3.3. Improvement of artificial auditory stimulation. Here, preliminary studies of multidisciplinary character should include : electrode performances, tolerance of chronic cochlear implants, effects of long lasting current flow through the cochlea, comparison of electrode sites (multichannel systems), and coding of sound into impulses on the electrodes.

3.4. Elaboration of adequate mathematical models for peripheral and central physiological information processing; development of hard- and software for the modelling of normal and impaired auditory systems.

4.3.4. Requirements and timing

Besides the general requirements for coordination purposes such as project leader, administration, meetings of Concerted Action Committee, etc., this concerted project needs in particular the availability of adequate means for subgroup meetings, short exchange of research workers, interlaboratory visits, organization of workshops, etc., in order to disseminate rapidly knowledge and thus ensure an efficient collaboration.

A duration of three years is proposed for this concerted action, but due to the complexity of the problem to be tackled, this 3-year period should be considered as an initial phase.

It is expected that a 2-year period will be necessary to establish an effective collaboration between the appropriate institutes by using common guidelines and standardized methods.

First results should be obtained within this period; continuation is foreseen by the submission of a new programme proposal in due time.

4.4. Multiannual concerted project No 4 (4 years) relating to

CRITERIA FOR PERINATAL MONITORING

4.4.1. Elaboration

In compliance with its mandate, the Committee on Medical and Public Health Research (CRM), assisted by its Specialized Working Group : Research in the field of Biomedical Engineering, has recommended as a project of interest to the Community the joint implementation of research in the field of "Criteria for Perinatal Monitoring" and advised the Commission in elaborating a corresponding proposal for a multiannual concerted project.

In accordance with this opinion the Commission has chosen this specific research field :

- on the basis of the explorative work carried out by the Specialized Working Group;
- considering the conclusions reached by international experts in this field during a number of meetings on "Standardization of perinatal monitoring equipment" held in Amsterdam, March 1972, and amended since then;
- having regard to the conclusions reached by international experts in this field during a workshop on "Perinatal Intensive Care", held in La Spezia, December 1975 under the sponsorship of the CRM and of the Commission, where the most urgent research problems in this field have been identified;

- taking cognizance of the relevant activities in progress in several institutes in the Member States, as well as in other States, particularly in Europe and in North-America;

- considering the agreed objectives of European cooperation in the medical and public health domain, and

- applying the mentioned criteria for the selection of research priorities.

4.4.2. Motivation

2.1. Scientific importance

The most frequent causes of neonatal mortality are prematurity and dysmaturity. In the Member States perinatal mortality varies from 10 % to > 20 %, whereas e.g. in Sweden in 1976 there has been reached a perinatal mortality of 9 %. Increasing life standard and quality of health care will result in only a minor further decrease of perinatal mortality.

Although in some Member States perinatal mortality is amongst the lowest in the world, the research for the causes of perinatal morbidity still is an area of utmost importance. It has been established that a great part of the mentally and/or physically handicapped children owe their handicap to pathological conditions during pregnancy and labour.

After the introduction of perinatal monitoring techniques several parameters and criteria for perinatal monitoring have been developed, but most of these are not evaluated and therefore recognized and accepted. Reasons for this lack of evaluation are :

- only a few obstetric centres in the EC have simultaneously available data concerning both the monitoring period and the neonatal condition, such as hemodynamic and metabolic parameters, the Agpar score, a neurological examination yielding a neurological score, a monitoring of potential adverse effects of drugs, etc. This implies that so far it is hardly possible to correlate the above data with relevant perinatal data;

- systematic information differs in its completeness from one country to another due to variations in patient populations and to differences in terminology and definitions, in setting up records, and in running registers;

- the number of cases in high risk groups as well as in a non-manifest abnormal group is insufficient for an effective study at local level alone;

- the recorded data are of various types because the criteria applied vary to a great extent;

- recently introduced techniques and methods to derive additional information, such as PEP, (L)VET, and continuous measurement of pH and po_2, give promising preliminary results and hence deserve to be evaluated systematically.

Better knowledge of methods and techniques to detect the risks of neonatal deprivation during labour, the set up of criteria for perinatal monitoring, neurological condition, drug monitoring, etc., a cooperative approach for exchange of information and a pooling of resources are, therefore, necessary to make statistically valid studies feasible.

In order to obtain sufficient significant data on patient populations to be selected, on methods and techniques used, and on therapeutic treatments to be applied, institutions of the Member States should combine their efforts in a cooperative action at Community level.

2.2. Socio-economic importance

It is the population of neonates that will profit of the results of this concerted action.

The mental load on a handicapped child and its environment is heavy, but cannot be expressed quantitatively. However, the costs of special care to be given to these children can be determined. Precise figures are still to be acquired.

4.4.3. Aim and objectives

The aim of the proposed concerted project is to detect and decrease high-risk for neonatal morbidity by evaluating and even developing new perinatal monitoring techniques, by acquiring data on the neonatal condition, by correlating these with perinatal data, obtained especially during labour, and by developing common criteria for perinatal monitoring. Successful completion will result in a considerable benefit to all participating countries by raising the standard of both medical research and medical care.

The research work is expected to cover the following objectives :

3.1. Definition of specific high-risk groups : definition of patient populations of several recognized high-risk groups of neonatal morbidity like dysmaturity, prematurity, and maternal hypertension; common protocols will be established to gather this information; studies on the underlying mechanisms will be carried out in a task-sharing way.

3.2. Processing techniques : evaluation and improvement of locally used and newly developed processing techniques as well as methods for monitoring; aspects like averaging, trigger accuracy, pattern recognition and data reduction without loss of information will be covered; technical aspects, such as patient safety, handling comfort and reliability, may be investigated, too.

3.3. Neonatal condition : elaboration of a common protocol for the quantitative definition of the neonatal condition; evaluation, comparison and improvement of available methods, such as the Apgare score, neurological score, and the use of haemodynamic and metabolic parameters.

3.4. Studies of the correlations between neonatal conditions and relevant perinatal parameters obtained during labour; establishment of common criteria for perinatal monitoring : locally used and newly developed methods, such as the classification schemes of e.g. Caldeyro-Barcia, Hammacher, Hon and Wood, as well as methods like PEP, (L)VET, and continuous measurement of pH and pO_2 will be evaluated; additional information will be obtained by performing experiments on pregnant animals and by simulating pathological conditions during labour with computer models.

It is obvious that, in order to be able to draw commonly valid conclusions from the parameters of the patient populations, definition of homologized terminology, techniques, methods, parameters and criteria to be applied by the centres involved in the programme, is a prerequisite. This may have a spin-off to other obstetric centres, for the benefit of patient care.

4.4.4. Requirements and timing

In order to ensure an efficient collaboration, this common research project will need the availability of adequate means for subgroup meetings, short exchange of research workers, interlaboratory visits, workshops and rapid dissemination of knowledge, aside from the requirements for the coordinating action.

The duration of the programme will be 4 years, i.e. 1 year for the preparatory work and 3 years for the mentioned research work. Due to the complexity of the study involved, this period should be considered as an initial phase. Continuation is foreseen by the submission of a new programme proposal in due time.

4.5. Multiannual concerted project No 5 (4 years) relating to

COMMON STANDARDS FOR QUANTITATIVE ELECTROCARDIOGRAPHY

4.5.1. Elaboration

In compliance with its mandate, the Committee on Medical and Public Health Research (CRM), assisted by its Ad-hoc Working Group : Monitoring the Seriously Ill, has recommended as a project of interest to the Community the joint implementation of research in the field of "Common standards for quantitative electrocardiography" and advised the Commission in elaborating a corresponding proposal for a multiannual concerted project.

In accordance with this opinion the Commission has chosen this particular field of research :

- on the basis of the exploratory work carried out by the Ad-hoc Working Group, and of a contractual review on the present state of computer assisted electrocardiographic research in the EC (P.W. MacFarlane, 180 pages, 1976);

- having regard to the conclusions reached by international experts in this particular field during the workshop, "Trends in Computer-Processed Electrocardiograms" (Nort-Holland Publ. Co., 437 pages, 1977), held on 3-5 November 1976 under the sponsorship of CRM and the Commission, where according to the present state of the art the most significant research problems were identified, and where the needs for their most efficient handling, from the point of view of R & D requirements, were evaluated;

- by considering the agreed objectives of European cooperation in the medical and public health domain, and

- by applying the mentioned criteria for the selection of research priorities.

Relevant activities in progress in non-Member States, particularly in European countries, as well as those of appropriate International Organizations have been taken into account.

4.5.2. Motivation

2.1. Scientific importance

Electrocardiography has been used for many years as a key, non-invasive method in the diagnosis and early detection of coronary heart diseases. It is estimated that more than 50 million ECGs were recorded 1975 in the EC Member States, for routine diagnostic purposes in and outside hospitals, by general practitioners, for screening purposes etc. Since it is likely that only a small percentage of all these routine or monitoring ECGs was reported by trained cardiologists, whose interobserver variation is well known, misleading interpretations are inevitable.

For these reasons and in view of the heavy workload in reading all ECGs, several groups in the U.S. and Europe are in the process of developing computer programmes for the automatic interpretation of ECGs. As its outcome more than 15 proprietary or public ECG programmes are already in limited use in the Member States of the EC but not a single one is presently accepted as giving scientific satisfaction mainly due to deficiencies of measurement and diagnostic parts of the programme.

An existing lack e.g. of common measurements criteria, of agreed definition of waves, of standardized terminology for classification and reporting, as well as of exchange of knowledge and experience is basically responsible for the confusing situation of incomparability of data and is thus hampering collaboration, evaluation of the results, as well as a judgement on utility and validity of a programme.

The consequences of this situation, with which R & D is faced today, are the following :

- further initiative for ECG development and diffusion will be more and more in the hands of commercial companies (like : IBM, TELEMED, HP, Marquette from the U.S.A., Siemens, etc...) who are offering their own proprietary programmes as software to accompany their hardware;

- the use of many public programmes in Europe (like the following systems : Glasgow, Hannover, Lyon, Cimhub (Brussels), TNO-modular (Utrecht), etc...), developed by excellent research groups mainly in university medical centres, will be limited to the parent institute and a few friendly neighbours;

- future research, supported by public funds, will mainly be directed towards improvement of existing local programmes,will be painfully slow and costly, and will obtain modest scientific results.

On the other hand, the building up of EURONET, the European "on-line" information network, as well as CRM's own activity in the field of medical data transmission by public telephone systems will both offer in near future an ideal possibility for better, sheap, and easily practicable diagnosis of coronary heart diseases through quantitative (in opposition to "qualitative and subjective") electrocardiography.

Therefore, the here proposed establishment of guidelines for the urgently needed common standards in quantitative electrocardiography has to be seen as the first indispensable step to overcome the existing difficulties and to create an effective European collaboration offering the benefit of mutual experience and expertise.

The expected scientific results of such multiannual (4 years) cooperation would be the following :

- availability of common standards for ECG measurements,

- comparability of data reported by the participating institutes,

- progressive availability of harmonized diagnostic criteria,

- pooling of resources and building up of a small ECG library for an evaluation of existing ECG interpretation systems and their further improvement, and

- a great step towards a common interpretation system with the possibility of using EURONET.

Execution in form of a concerted project is deemed important if work on the inherent research problems is to be carried out efficiently. Because none of the national efforts alone is likely to ensure adequate and reasonably early results, the chances of success can be significantly improved by their integration into a coordinated action.

2.2. Socio-economic importance

Cardiovascular diseases represent a challenging problem in Western countries because of their increasing frequency in morbidity and mortality. Circulatory and heart diseases, indeed, account for about 50 % of all deaths, and nearly 60 % of their mortality is due to coronary heart disease. The morbidity due to myocardial infarction and angina pectoris plays an important role in the incapacity for work and early invalidism and has a very high socio-economic and financial impact on each of the Member States.

Primary prevention measures aimed at the population at large will ultimately produce the most rewarding results in the combat of coronary heart diseases; nevertheless, reliable and early diagnosis of this disease, through computer-aided ECG interpretation, easily practicable also by the general practitioner, is of utmost importance.

As already mentioned, more than 50 millions ECGs were 1975 recorded in the EC and this number is steadily increasing. Here, misleading interpretations are inevitable and estimated to vary between 20 - 50 % (!!!) dependent on local facilities and other circumstances. If calculating the sum yearly spent without utility for health care, it becomes evident that each and even a modest improvement will certainly save a considerable amount of money.

Furthermore, it is generally argued that computer-aided interpretation has so far increased the cost of health care everywhere. The automation of the interpretation however, even partially, in selected categories, could radically reduce the cost of ECG service.

4.5.3. Aim and objectives

The aim of the proposed concerted project is to establish guidelines for common standards in quantitative electrocardiography including routine diagnostic electrocardiography and patient monitoring. In addition, initial steps will be taken towards the creation of a library of ECGs to improve diagnostic criteria and to provide the means of testing newly developed techniques, which conform with proposed standards. Successful completion will allow the elaboration of a feasible and extended second programme in this particular research field aiming at early diagnosis of coronary heart diseases by improved diagnosis performance, which will be of considerable benefit to all participating countries both for scientific and socio-economic reasons.

This aim can be subdivided into the following three objectives :

3.1. Standardization of ECG measuring procedures in quantitative (computer) terms; comparative studies of measurements performed by different programmes; elaboration of guidelines and definition of common standards for measurement;

3.2. Pilot studies to standardize the diagnostic criteria and the algorhythmic documentation of their operation, and

3.3. Establishment of a modest pilot library of ECGs mainly for the standardization purposes.

4.5.4. Requirements and timing

In addition to the general requirements of a concerted project, like project leader, meetings, exchange of personnel, etc., the implementation of this proposed action necessitates the following particular possibilities of which the costs should be charged on a common budget :

- exchange of software between the participating centres, and

- a central facility for data handling, comparison and programmation.

A duration of 4 years is proposed for this concerted project.

Following a preparative phase (agreement on working schedule and methods) the standardization of ECG measurements will start as soon as possible and gradually proceed over the years; only their results will allow to start the setting up of a pilot library (2nd - 4th year); the first steps towards standardization of criteria for diagnostic interpretations are not expected to be taken before the 3rd year.

A new proposal for an extended programme will be submitted in due time.

5. IMPLEMENTATION

The second R & D programme in the sector of medical and public health research will be implemented likewise by carrying out its five multi-annual concerted projects. Because of its scientific, social and economic importance, it will be of interest to all Member States, even to those not involved in a particular line of research or lacking the required facilities to participate actively.

In principle, the competent national authorities intend, as part of the rules and procedures applicable to their national programmes, to carry out their contributions to the respective projects, and are prepared to integrate such research into a process of coordination at Community level.

A Concerted Action Committee will be established for each project, in which the Member States are represented by the persons responsible for co-ordinating the national contributions to the programme.

The coordination of the concerted project will be carried out under the responsibility of the Commission, assisted by a project leader to be appointed by the Commission in agreement with the respective Concerted Action Committee.

After the Council Decision, third countries involved in European cooperation in the field of scientific and technical research (COST) will be invited to participate in this programme.

The competence of the Committee for Medical and Public Health Research (CRM) covers also the implementation of this programme; this Committee is, in particular, duly qualified to give this research its proper place within the sectorial policy of the European Communities as well as to ensure its success.

6. FINANCIAL VOLUME AND STAFF

The financial volume of the national research contributions to the respective concerted projects is estimated at 37 million EUA (European Units of Account) for the duration of the programme.
Its partition is as follows :

Conc. project	Duration in years	EUA in million
1	4	3,4
2	4	10,0
3	3	9,0
4	4	7,6
5	4	7,0
	Total	**37,0**

The cost of coordination, charged to the Community budget, is estimated at 2,70 million EUA for the duration of the programme.

These costs include salaries for scientific and secretarial staff involved in the coordinating action, (the allocation of 2 A and 2 C is requested for this programme), administrative costs (expenses for experts, meetings and publications) and expenditures by contracts (project leader, exchange of personnel, subgroup meetings, computer, etc.), subdivided as follows :

Personnel	766,400	EUA
Administration	294,700	EUA
Contracts	1.638,900	EUA
Total	2,700,000	EUA

ANNEX I

PROPOSAL FOR A COUNCIL DECISION

adopting a second R & D programme
of the European Economic Community
in the sector of

MEDICAL AND PUBLIC HEALTH RESEARCH

consisting of
five multiannual concerted projects

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the Economic and Social Committee,

Whereas by virtue of Article 2 of the Treaty establishing the European Economic Community, the Community has been assigned the task of promoting throughout the Community a harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standards of living;

Whereas by Decisions 78/167/EEC, 78/168/EEC and 78/169/EEC of 13 February 1978 (1) the Council has adopted three multiannual concerted projects as a first programme of community research actions in the sector of medical and public health research;

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(1) OJ No L 52, 23.2.1978,

Whereas in its Resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (1) the Council stressed that an appropriate approach should be adopted towards the whole range of available ways and means, including concerted projects and that whenever it proves desirable that third countries, particularly European ones, should be associated in these projects, steps should be taken to make this possible;

Whereas, in its Resolution of 14 January 1974 relating in particular to the coordination of national policies in the field of science and technology (2), the Council entrusted the Community institutions with the task of gradually ensuring such coordination, aided by the Scientific and Technical Research Committee (CREST);

Whereas the five concerted Community research actions in the sector of medical and public health research, forming the second R & D programme of the Community, are likely to contribute effectively to the achievement of the abovementioned aims;

Whereas the Member States intend, as part of the rules and procedures applicable to their national programmes, to carry out the research described in Annexes A.1 to A.5 to ANNEX I, and are prepared to integrate such research into a process of coordination at Community level over periods of three and four years respectively;

Whereas the execution of such research as described in Annexes A.1 to A.5 to ANNEX I will require a financial contribution of about 37 million European units of account from the Member States;

Whereas the Community is empowered to conclude Agreements with third countries in the fields covered by this Decision; whereas it may prove advisable to extend the coordination established by this Decision to third countries participating in European cooperation in the field of Scientific and Technical Research (COST); whereas, on the one hand, procedural conditions should be determined so as to lead a rapid conclusion of these Agreements, and on the other hand, negotiations should be opened with the countries referred to as soon as this Decision is adopted;

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(1) OJ No C 7, 29.1.1974, p. 6.

(2) OJ No C 7, 29.1.1974, p. 2.

Whereas the Treaty has not provided the specific powers for this purpose;

Whereas the Scientific and Technical Research Committee (CREST) has given its opinion on the Commission proposal,

HAS DECIDED AS FOLLOWS :

Article 1

In the sector of medical and public health research, the Community shall implement for a period of three or four years respectively five concerted projects, hereinafter referred to as "the projects", in the fields of :

1. Attempted suicide as a public health problem (4 years)
2. Detection of tendency to thrombosis (4 years)
3. Evaluation, understanding and substitution of impaired hearing (3 years)
4. Criteria for perinatal monitoring (4 years)
5. Common standards for quantitative electrocardiography (4 years)

The projects shall consist in coordination at Community level of the research described in Annexes A.1 - A.5 to ANNEX I, which form parts of the research programmes of the Member States.

Article 2

The Commission shall be responsible for such coordination.

Article 3

The financial contribution of the Community for the duration of the programme is estimated at 2,70 million European units of account and the staff allocation at 4 servants. The European unit of account is defined by the relevant Financial Regulation.

Article 4

To facilitate the execution of the five projects, a concerted action Committee, hereinafter referred to as "the Committee", shall be established for each project.

For each project, a project leader shall be appointed by the Commission in agreement with the respective Committee. He shall, in particular, assist the Commission in its coordinating action.

The terms of reference and the composition of these Committees are defined in Annex B to ANNEX I.

Each Committee shall draw up its rules of procedure. Its secretariat shall be provided by the Commission.

Article 5

In accordance with a procedure to be adopted by the Commission in agreement with the Committee, the Member State participating in the projects shall exchange regularly all useful information concerning the execution of the research covered by each project and forward to the Commission all information that may be useful for coordination purposes. They shall also endeavour to provide the Commission with information on similar research planned or carried out by bodies for which they are not responsible. This information shall be treated as confidential if so requested by the Member State which provides it.

The Commission shall prepare yearly progress reports on the basis of the information supplied, and shall forward them to the Member States and to the European Parliament.

At the end of the coordination period, the Commission shall, in agreement with each Committee, forward to the Member States and to the European Parliament a general report on the execution and results of each concerted project. The Commission shall publish this report six months after it has been forwarded to the Member States unless a Member State objects. In this case the report shall be distributed, at their request,

solely to institutions and undertakings, whose research and production activities justify access to the results of the research carried out under each project. The Commission may make provision that the reports remain confidential and are not disclosed to third parties.

Article 6

1. In accordance with the provisions laid down in Article 228 of the Treaty establishing the EEC, the Community may conclude Agreements with other States involved in European Cooperation in the field of Scientific and Technical Research (COST) with a view to extending the coordination which is the subject of this Decision to research undertaken in these States.

2. The Commission is hereby authorized to open negotiations for the conclusion of agreements of the type referred in the preceding paragraph.

Article 7

This Decision shall come into force on 1 January 1979.

Done at

For the Council

The President

Annex A to ANNEX I

IMPLEMENTATION AND COORDINATION OF THE NATIONAL CONTRIBUTIONS TO THE RESPECTIVE CONCERTED PROJECTS

The following competent medical research authorities of the participating Member States will ensure the implementation of the national contributions to the respective research programmes, indicated in the subsequent Annexes A.1 to A.5, as well as their coordination at national level :

Belgium : FNRM - Fonds national de la recherche médicale, Bruxelles

Denmark : Danish Medical Research Council, Copenhagen

France : INSERM - Institut national de la santé et de la recherche médicale, Paris

Germany :

Ireland : Medical Research Council of Ireland, Dublin

Italy : CNR - Consiglio Nazionale della Ricerca, Roma and Istituto Superiore di Sanità, Roma

Luxembourg :

Netherlands :

United Kingdom : MRC - Medical Research Council, London

Annex A.1 to ANNEX I

RESEARCH PROGRAMME RELATING TO ATTEMPTED SUICIDE AS PUBLIC HEALTH PROBLEM

(Concerted project No 1, 4 years)

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics :

1. Survey of extent and characteristics of the problem and of its social concomitants or determinants in defined areas of the Member States.

2. Elaboration of comparable scales and rating devices to identify the recidivist suicide attempter and the suicide attempter particularly at risk for completed suicide.

3. Evaluation of the effectiveness of different forms of services for the suicide attempter.

4. Establishment, implementation and evaluation of harmonized control policies in relation to attempted suicide and in particular to self-poisoning by drugs.

Belgium, Denmark, France, Germany, Ireland, Italy, The Netherlands and the United Kingdom will contribute research under the topics mentioned above.

Annex A.2 to ANNEX I

RESEARCH PROGRAMME RELATING TO THE DETECTION OF TENDENCY TO THROMBOSIS

(Concerted project No 2, 4 years)

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics :

1. Detection of activated clotting factors and of their reaction products.

2. Quantitative analysis of the inhibitors of the clotting system.

3. Studies of the active and inhibitory components of the fibrinolytic system.

4. Studies on blood platelets.

5. Pilot studies in well-defined populations following standardization of materials and methodology.

Belgium, Denmark, France, Germany, Ireland, Italy, The Netherlands and the United Kingdom will contribute research under the topics mentioned above.

Annex A.3 to ANNEX I

RESEARCH PROGRAMME RELATING TO UNDERSTANDING
EVALUATION AND SUBSTITUTION OF IMPAIRED HEARING

(Concerted project No 3, 3 years)

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics :

1. Comparative studies of the relationships between histopathological, functional and clinical data in cases of perceptive hearing losses.

2. Development and/or improvement of electrophysiological tests of auditory function.

3. Improvement of artificial auditory stimulation.

4. Mathematical modelling of normal and impaired auditory systems.

Belgium, Denmark, France, Germany, Ireland, Italy, The Netherlands and the United kingdom will contribute research under the topics mentioned above.

Annex A.4 to ANNEX I

RESEARCH PROGRAMME RELATING TO CRITERIA FOR PERINATAL MONITORING

Concerted project No 4, 4 years)

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics :

1. Definition of specific high-risk groups for perinatal monitoring.

2. Evaluation and improvement of existing processing techniques and methods for monitoring.

3. Elaboration of common quantitative methods to define the neonatal condition.

4. Studies of the correlations between neonatal conditions and relevant perinatal parameters obtained during labour; establishment of common criteria for perinatal monitoring.

Belgium, Denmark, France, Germany, Ireland, Italy, The Netherlands and the United Kingdom will contribute research under the topics mentioned above.

Annex A.5 to ANNEX I

RESEARCH PROGRAMME RELATING TO COMMON STANDARDS FOR QUANTITATIVE ELECTROCARDIOGRAPHY

(Concerted project No 5, 4 years)

The research will be carried out with the purpose of acquiring scientific and technical knowledge in this field, selected for its importance at Community level.

The research is expected to cover the following topics :

1. Standardization of ECG measuring procedures in quantitative (computer) terms; comparative studies of measurements performed by different programmes; elaboration of guidelines and definition of common standards for measurement.

2. Standardization of the diagnostic criteria and of the algorhythmic documentation of their operation.

3. Establishment of a modest pilot library of ECG's.

Belgium, Denmark, France, Germany, Ireland, Italy, The Netherlands and the United Kingdom will contribute research under the topics mentioned above.

Annex B to ANNEX I

TERMS OF REFERENCE AND COMPOSITION
OF THE CONCERTED ACTION COMMITTE

1. The Committee shall :

   1.1. contribute to the optimum execution of the programme by giving its opinion on all of its aspects;

   1.2. evaluate the results and draw conclusions as regards their application;

   1.3. be responsible for the exchange of information referred to in the first subparagraph of Article 5;

   1.4. keep abreast of national research being done in the fields covered by the concerted project, and more especially of scientific and technical developments likely to affect the execution of the project;

   1.5. suggest guidelines to the project leader.

2. The Committee's reports and opinions shall be forwarded to the Commission and to the Member States participating in the project. The Commission shall forward these opinions to the CREST.

3. The Committee shall be composed of persons responsible for coordinating the national contributions to the programme, and the project leader. Each member may be accompanied by experts.

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(78) 377 final/2

Brussels, 21 August 1978

ADDENDUM: FINANCIAL DATA

PROPOSAL FOR A COUNCIL DECISION

adopting a second R&D programme

of the European Economic Community

in the sector of

MEDICAL AND PUBLIC HEALTH RESEARCH

consisting of

five multiannual concerted projects

(submitted to the Council by the Commission)

FINANCIAL DATA

1. BUDGET CHAPTER : 3371

2. HEADING OF THE BUDGET TITLE : Medical Research
   2nd programme

3. JURIDICAL BASIS : Art. 235 of EEC Treaty
   Council Decision of .....

4. DESCRIPTION, OBJECTIVES AND JUSTIFICATION OF ACTION :

4.1. Description :

Enlargement of the first medical research programme by a second one consisting of five multiannual concerted projects in particular fields of common interest and constituting the frame of a progressive coordination of the national activities in the sector of medical and public health research.

4.2. Objectives :

Joint European research effort by implementing five concerted projects in the fields of :

1. Attempted suicide as public health problem (4 years)
2. Detection of tendency to thrombosis (4 years)
3. Evaluation, understanding and substitution of impaired hearing (3 years)
4. Criteria for perinatal monitoring (4 years)
5. Common standards for quantitative electrocardiography (4 years)

4.3. Justification :

The second programme of research actions in the sector of medical and public health research meets the concern of all Member States; each of its parts, unanimously recognized and approved by the CRM/CREST, represents a valuable approach to tackle the problems in common; their execution as concerted projects ensures both efficacy and sharing of tasks between the Community and the competent national authorities of the Member States.

2

5. TOTAL FINANCIAL INCIDENCE OF ACTION IN EUA

5.0. Incidence on expenditures

5.0.0. Total costs, during the term envisaged, funded

- on Community budget	2,700,000	
- by national administrations - by other sectors at national level	37,000,000	
Total	39,700,000	EUA

5.0.1. Multiannual term :

COMMITMENT

in EUA

	1979	1980	1981	1982	Total
Staff	174,200	186,400	196,800	209,000	766,400
Manag.	74,000	71,000	75,300	74,400	294,700
Contracts	901,800	342,600	377,900	16,600	1,638,900
Total	1,150,000	600,000	650,000	300,000	2,700,000

PAYMENT

	1979	1980	1981	1982	Total
Staff	174,200	186,400	196,800	209,000	766,400
Manag.	74,000	71,000	75,300	74,400	294,700
Contracts	400,000	425,000	450,000	363,900	1,638,900
Total	648,200	682,400	722,100	647,300	2,700,000

5.0.2. Evaluation method

a. Staff expenditures

The staff needs for this programme are estimated at :

2 category A staff

2 category C staff

In addition to staff number estimates, the evaluation takes into account the parameters adopted for the establishment of the proposal for the budget forecast 1979. Only a variation of the correction coefficients is considered to meet possible needs originating from the general evolution of prices in the Community.

b. Administrative expenditures

They cover the costs of missions, organization of meetings (5 concerted action committees), convocation of experts, as well as those necessary for particular coordination purposes (e.g. computer costs for project 5, etc.).

c. Contracts expenditures

They cover all expenditures arising from service-contracts and providing the means for : project leader, his secretariat, workshops of participating research workers, short-term exchange of personnel, exchange of material, software, etc.

d. Multiannual forecasts

The indices applied to calculate the forecasts are as follows : 1980 - 1,07; 1981 - 1,13; 1982 - 1,20.

5.1. Incidence on the funds

- Community income tax on staff
- Functionaries contribution for retirement fund

6. CONTROL MEASURES FORESEEN

Scientific control : each concerted project is controlled by its Concerted Action Committee.

Administrative controls :

- Budget execution : Financial Control
- Regularity of expenditures : Financial Control

7. FUNDING ACTION

7.0.

7.1.