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Proposal for a Council Regulation on a Community Action in the field of

Information Technology and Telecommunications applied to health care

AIM

(Advanced Informatics in Medicine in Europe)

- Pilot Phase -

(submitted by the Commission)

Contents

SUMMARY

European Heads of State and Government have agreed that medical care and work in related technological areas represents a priority area for European cooperation. This includes, as one specific line of action the exploitation of the advances in information technologies, telecommunications and broadcasting to improve medical care and support the underlying technological efforts in medicine and biotechnology.

Health is next to food and shelter one of the basic human needs. Conscious of the high priority of health care and of the growing possibilities, but also of the cost constraints, the Community needs to optimize its efforts towards this common objective. Leading experts have joined the Commission in identifying actions which are suited to exploit the technological advances in Medical and Bio-informatics so as to bring the maximum care to the patient while staying within reasonable limits of individual and collective expenditure.

The Community initiative in Medical and Bio-informatics (MBI) is to be seen as part of a concerted effort in related domains, both medical and technological, on which it builds and of which it forms a specific action to re-inforce progress and draw systematically on the benefits of collaboration on a European scale in the form of greater cost-effectiveness and a faster propagation of the best practices. (1). The conception and development of new health care technology and services calls for an optimal use of human resources, facilities as well as financial means and the participation of all the main sector actors. Broad consensus and participation is a key requirement for success and progress in this domain where social and human considerations are of outstanding importance.

Based on exploratory work in 1985/86 involving 150 leading experts (2) a programme of cooperation in MBI has been developed of which this proposal represents the Pilot Phase.

The global objective is to serve the concertation of European efforts towards

sustained improvement in health care in the Community for the 1990's within economically acceptable limits by exploiting the potential of Medical and Bio-informatics.

AIM is designed in such a way that it will contribute to the strengthening of the internal market and free competition for health care related equipment and services which depend on compatibility and interoperation of information processing and communication. It will do this by

- fostering work which will lead to the identification of common functional specifications, minimum standardization and conventions for Medical Bioinformatics for health care related telematics which is the pre-requisite for an open competition and the strengthening of the market for information and telecommunication assisted health care services;

- stimulating the standardization work in related areas and contributing to the specific work required for MBI equipment and services;

1) In particular the Medical Research Programme, ESPRIT, RACE and the work on standardization and certification

2) BICEPS Planning Exercise and Exploratory Investigations in 1985/6

- fostering Community-wide open competition of ideas and approaches to developing specific MBI-based health care concepts and services at the pre-normative and pre-competitive level;

- initiating reflection on the adaptation of the regulatory framework facilitating Community-wide collaboration in developing and using advanced medical and bio-informatics to improve the quality and cost-performance of health care.

The proposal consists both of 'precompetitive systems R&D' and of pre-normative measures concerning the establishment of synergy in developments in related applications (personal computing, consumer electronics, telecommunications and broadcasting) which will be beneficial for an open competition on a European market place.

AIM at the technological level situates itself at the 'pre-competitive' and 'pre-normative' stage, while being quite specific as to the objectives to be achieved. The present situation being one of extreme fragmentation and, for advanced work, subcritical effort, the suggested worksharing and cooperation can be expected to reduce duplication but not so extensively as to constrain competition. The allocation of contracts will be based on an open competition and in some cases it may be desirable to explore several competing concepts as a means to a stated objective.

AIM will help to establish the basis for a European market for Health Care Services. However, AIM designedly does not include development or production as such, but only the common tools and facilities this will require.

In its contribution to standardization and certification AIM will help to stimulate competition by early on defining principles and initial development conventions.

Within these general objectives AIM is expected

- to make major contributions towards improving quality, flexibility and accessibility of health care in the Community;

- to increase the effectiveness of patient care in order to bring about a reduction in the cost of health care;

- to make a major contribution towards increasing that part of the sector resources which directly benefits the patient and assists the medical profession in their mission;

- to contribute to the establishment of minimum standards and common functional specifications prerequisite for the emergence of a strong and competitive European industry providing medical informatics equipment and services;

- to contribute to the development of agreed codes of good practice, protection of privacy, and reliability for medical informatics as a prerequisite of appropriate regulation and protection of the patients privacy;

- to stimulate collaboration and concertation in the analysis of the requirements and opportunities in MBI and its application;

(1)

- to contribute to the common adaptation of the regulatory framework to advances in the nature of health care.

AIM will pursue these objectives through the more effective deployment in the Community of new MBI-techniques

- to support all branches of health care, including prevention, diagnosis, treatment, the medical record and its analysis; and
- to support the advance of research in related scientific and technological areas by using MBI to increase R&D-productivity.

AIM directly concerns

- the national authorities administering health care,
- staff providing health care,
- patients receiving health care,
- the medical equipment industry,
- the communications industry,
- medical and biotechnology researchers,

and strongly concerns the interests of :

- health insurance
- the pharmaceutical industry
- medical education and training institutions.

AIM is to be implemented in a phased approach starting with a Pilot Phase which is the subject of this proposal. Subject to a successful implementation of the Pilot Phase a Main Programme extending initially over 5 years may be proposed.

The nature of the work proposed includes

- analytical work towards the identification of common requirements and their functional characteristics;

- pre-normative work on MBI towards common functional specifications and the development of minimum standardization proposals;

- pre-competitive work as required to establish the techno-economic feasibility of common functional specifications and standardization proposals;

- verification of standards and their testing with respect to the functions and operations they are to support in medical care and biotechnological research;

- contributing to the rapid exploitation of the results by systematically familiarizing the health care professionals with the potential of MBI applications.

In order to carry out the Pilot Phase of the action described in this communication, it has been estimated that 300 Man Years of work will be required. Industry is expected to contribute at least 50% to this action. For non-profit making participants not receiving any related support from other sources the requests for support of up to 100% may be considered. Assuming that 2/3 of the projects can be supported at a level of 50% and 1/3 can only be carried out by higher funding levels, the amount of Community funding is estimated at 20 MECU over a period of 18 months.

1. INTRODUCTION "THE CHALLENGE IN MEDICAL CARE"

After a mainly evolutionary advance in health care, recent decades have seen a considerable acceleration driven by scientific and technological progress as well as a strong and lasting commitment of large resources to this objective. Some of the new means already available and the potential of the coming decades may well revolutionize health care. This is of obvious social consequence but it is also of considerable political and economic importance. Europe can pride itself on a leading role in some areas of health care and the related scientific domains. However, as the need increases for concentration of efforts, skills, facilities and financial resources for R&D in related domains such as biotechnology and medical informatics, so Europe is rapidly falling behind. Cooperation between scientists, research centres and increasingly with industries is becoming a necessity to engage and stay in this high-technology domain.

For a more cost-effective approach to the challenge in health care and related technological R&D, flexible and effective frameworks for concertation and cooperation are required which permit the sector actors to make their respective contributions within a consistent perception of objectives, thereby avoiding redundancy where it is wasteful and focussing resources on central objectives.

1.1 Growing opportunities in medical care and the implicit role of informatics

The last decade has seen

- the introduction of powerful diagnostic tools based on technological progress in the medical field as well as the systematic application of MBI, e.g. magnetic resonance (MR), computer tomography (CT), nuclear medicine (NM), ultrasound, digital subtraction angiography (DSA), etc.;

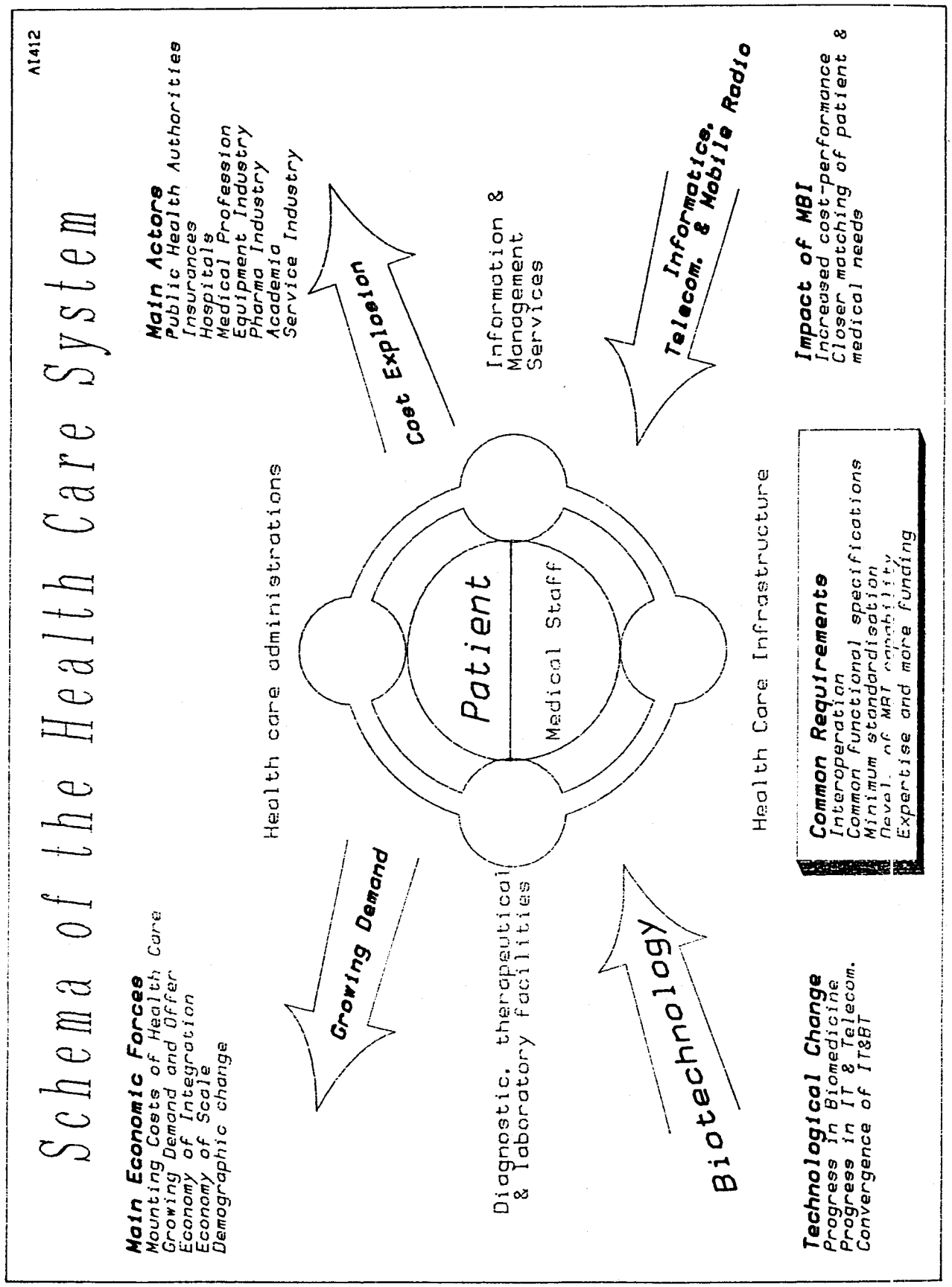
- the integration of these tools into department-wide systems;

- the introduction of more precise and less invasive therapy methods, such as laser angioplasty, endoscopic surgery, extracorporeal shock wave lithotripsy (ESWL), and precision radiotheraphy;

- the emergence of biotechnology, intimately linked with the progress in bioinformatics, as a new driving force of techno-economic change, with the bulk of expenditure in biotechnology effort being focused on health care in the areas of therapeutics, diagnostics, selective delivery systems, and immunology, bringing greater understanding, information intensity, screening possibilities, greater precision of diagnosis and therapy, rational drug design, genetic intervention;

- the penetration to the bio-molecular level of analyses, diagnostics, treatment and bio-engineering assisted by some of the most advanced products of information technology, eg gene-mapping, computer-assisted engineering of substances, computer simulation of biomolecular processes, etc;

Figure 1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Schema of the Health Care System
Main Economic Forces
Mounting Costs of Health Care
Growing Demand and Offer
Economy of Integration
Economy of Scale
Demographic change
Main Actors
Public Health Authorities
Insurances
Hospitals
Medical Profession
Equipment Industry
Pharma Industry
Academia
Service Industry
Cost Explosion
Information & Management Services
Telecom. & Mobile Radio
Impact of MBI
Increased cost-performance
Closer matching of patient & medical needs
Health care administrations
Growing Demand
Diagnostic, therapeutical & laboratory facilities
Patient
Medical Staff
Biotechnology
Health Care Infrastructure
Common Requirements
Interoperation
Common functional specifications
Minimum standardisation
Expertise and more funding
Technological Change
Progress in Biomedicine
Progress in IT & Telecom.
Convergence of IT&BT

Table 1:

SCOPE OF APPLICATIONS OF MBI IN BIOMEDICAL R&D

Medical Bio-Informatics is strongly embedded in all sectors of health care and the scientific/technological activities it is based on. The following listing gives examples where MBI is playing a particularly strong role.

PREVENTION

Efforts are increasing in preventing health problems from arising or from reaching a level where therapy becomes necessary. Examples where MBI is important include:

- screening of tissue samples for cancerous cells
- epidemiological screening of the population
- search and identification of new diseases and health problems
- information and education of the population (eg using the media in the case of AIDS)

DIAGNOSTICS

Computer assisted diagnostics

- Expert Systems
- Data Bases

Imaging

- Digital radiology and digital angiography
- Computer Tomography
- Nuclear Medicine
  . single photon emission computer tomography (SPECT)
  . positron emission tomography (PET)
- Magnetic Resonance
- Echography
- computer assisted diagnosis.

Laboratory equipment

- Molecular absorption spectrophotometer
- Liquid chromatography
- Electrophoresis
- Blood cells counter
- Electronic microscopes
- Cytofluorimeters
- Microscope image analyzers
- Doctor's office tests
- Microbiology analyzers
- Specific uses of MBI to achieve
  . reliability
  . speed
  . non-invasiveness
  . miniaturization and portability
  . autonomy
  . interoperation
  . remote control and monitoring.

THERAPY

High precision radiotherapy

- Brachytherapy
- Precise dynamic beam control

Fibroscopy

- Classical fibroscopes
  . plastic and silica fibres
  . bundles
- Video-endoscopy
  . CCD transducers miniaturization
- Infrared thermography
  . Infrared photodetection

New surgical techniques

- Electrotome
- Cryosurgery & coagulation by electromagnetic wave
- Therapeutic laser
- Lithotripsy & ultrasonic lancet
- Operating microscopy
- Life support systems

Sensors for in vivo diagnostics

MEDICAL COMMUNICATIONS

In Prevention/Early Detection/Self Care

- Use of telecommunications networks for epidemiology purposes and medical counselling
- Computer assisted systems providing health information, health education, training in elementary health care.

In Primary Care

- Professional medical information system
- Management of referral
- Medical record data collection and analysis
- administration of health check-ups

In Secondary Care

- Hospital communications
- Resource scheduling
- Patient record data bases
- Clinical research

- Data processing for ancillary services
- Integrated hospital information systems

* In Administration of health care systems
- Medical records management
- Decision support for medical resource management
- Health statistics
- Epidemiology
- Surveillance functions
- Medical information management
  . laser cards and disks
  . large data base management techniques
  . advanced decision support
  . advanced presentation aids

BIOMEDICAL RESEARCH

- Supercomputing in bio-molecular research
- X-ray crystallography and analysis of structures in solution
- Dynamic modelling of biological systems
- Gene mapping and sequencing
- Protein engineering
- Artificial intelligence as a research support tool.

MEDICAL TRAINING
- Computer-based simulation in diagnosis
- Expert systems as diagnostic check and in tutoring
- Computer assisted special skill training

etc.

- an unprecedented growth in medical and related scientific knowledge, e.g.
  . the number of researchers in life sciences represents about 25% of the total number of scientists;
  . the number of distinct diseases recorded in medical literature has increased more than tenfold since 1900;
  . the number of pharmaceutical products, which presently exceeds 10 000, increases by about 250 each year;
  . in recent years biotechnology has resulted in dramatic progress in the quality and production economics of pharmaceutical products;

Throughout MBI has been instrumental and an essential ingredient of progress.

Figure 1 and Table 1 illustrate the role of medical and bioinformatics in Health Care.

1.2 Medical care is a major socio-economic sector with great potential for the future

- with roughly 8% of the GDP of Member States going into medical care, this sector is comparable to spending on Defence and bigger than Telecommunications;

- within the European Community there are roughly 800 thousand doctors and 15 thousand hospitals with more than 3 million hospital beds for a population of about 320 million. This makes it the biggest service sector;

- with a growth rate of 8% per annum, health care services are one of the most rapidly expanding markets in Europe. Within this the growth-rate of MBI is about 15% per annum and is expected to increase its importance over the next decade until it represents 5% of the equipment and service expenditure. Due to the continued rise in expectations of improving the quality of life medical care can be expected to remain a crucial sector in future societal developments;

- non-pharmaceutical medical products represent today a market of about ECU 25 billion market worldwide, growing at a compound rate of 10% per annum. Europe's part of this market is only 20%, despite the size of its population and the growing demand.

1.3 Characteristics of future developments

Future trends will be shaped by growing demand for health services (world wide and in developed countries reinforced by demographic factors) and rapid advances in science and technology constrained primarily by the cost of providing health care.

Technology will be instrumental in
- offering more cost-effective means of diagnosis and therapy
- contributing to the further improvement of existing techniques of health care
- offering better adaptation to the needs of patients, doctors and health care services,

but will at the same time, in order to improve the delivery, organization and management of health care
- permit improvements in providing health care in hospitals as well as in ambulant services (eg home health care)
- offer new and enhanced possibilities in supporting training and specialization of medical staff, and

- facilitate the administration of medical data and accounting.

This can be expected to occur as a rapid evolution. However, some of the changes are likely to affect strongly the organizations involved in health care and the division of labour between different branches of health care. Implicit in this evolution are major structural changes involving all parts of health services including the supporting services and extending to the regulatory and legal environment as well as training and qualification of health care staff.

The exact evolutionary paths are difficult to assess at this stage, but some of the main features can be identified and attention be focused on them. The following section outlines a scenario of the kind of health service which might emerge in the late 1990's.

1.4 Medical care by the year 2000

The technological developments of the coming decades will extend the possibilities of health care and at the same time remove traditional constraints to providing care. Health care will have been much more adapted to the needs of the patients, ie offered when, where and in the way the patient wishes, rather than according to the location and organization of health care infrastructures and services.

Some examples can serve as illustration of the kind of changes one may see:

1) "Telemedicine" : Certain health care services, in particular of a diagnostic kind, could be offered by the use of advanced telecommunication services, combined with new techniques of diagnostic packs, which permit the patient to provide the doctor with the essential information. The benefit would be to reduce the necessity of moving patients and improving the access to the doctor;

2) "Open Hospital Care": With the advance in medical equipment technology, their interworking with telemetry and remote control, it becomes possible to provide hospital-type care outside the constraints of hospital complexes;

3) "Integrated Hospital Care": An Integrated Hospital approach would bring the therapy and diagnostics to the patient instead of moving the patient to the facilities as is today largely the practice. This becomes possible only as a result of a systematic development of health care technology and their interoperation;

4) "Customized pharmaceuticals": As part of an integrated approach to health care and supporting services it will become possible to interpret the diagnostic data and treatment strategy in terms of designing patient-specific prescriptions. This will include drugs themselves, the mode of administration and the rate of administration. The drugs can be expected to include conventional pharmaceutics as well bioengineered products. The advantages of tailoring drugs and their delivery to the specific needs of the patient are considerable. The side effects could be reduced and thereby the speed of recovery could be expected to improve and the need for further treatment minimized.

Many other features and changes in the way health care is offered can be expected to emerge. When and how they will be seen depends on several factors, BUT one of them is common to all scenarios, the dependence on functional integration and interoperation of equipment and services as offered by MBI.

2. OPPORTUNITIES AND ISSUES IN MEDICAL- AND BIO-INFORMATICS

2.1 Socio-political dimension

Health care and the use of technology to support it must, more than other domains take into account the social dimension. The use of technology, the organization of health care, the way it is offered need to be governed by and centred on human relations. This implies that the consideration of all use of technology in medical care directly relating to the patient or the patient's relationship with medical staff needs to be conceived and developed in accordance with the medical and psychological needs of patients and medical staff. Human Factor Engineering needs therefore, to play a central role in developing MBI where it relates to the patient and the patient relationship with medical staff.

The proper understanding of the human element and its relationship to technology is a crucial element for acceptance and therefore utility. Furthermore the economic success of the related equipment, products and services is largely affected by the success in addressing this issue.

In the MBI domains not relating directly to the patient-doctor relationship but to the utilisation of MBI within the professional medical services, good adaptation to meet user needs is also very important and needs to be addressed, but is not of the same paramount importance as in the patient-doctor context, where it is crucial.

The reason for stressing this point in the context of pre-competitive and pre-normative work is that more and more of the features of the ultimate application are conceived at the early research stages, ie the social dimension needs to be included as a research objective and design criterion already at this stage.

2.2 Convergence of health care and information services

Health care is the result of the systematic use and integration of many approaches and techniques. But all of them depend to a very large degree on communications between the patient and medical staff on the one hand and between medical specialists and associated services on the other hand. It is, therefore, to be expected that health care will increasingly exploit the enhanced possibilities of telecommunications. Now already medical advice is being offered via the telephone. With the emergence of broad band services one can expect that this kind of medical service will expand progressively. Videoconferences between specialists in different parts of the world on a particularly difficult case, may become standard practice in the 1990's, to mention just one example relating to the work of doctors. Biochemists supporting health care already rely on protein data bases developed and maintained by experts world-wide. This kind of development can be expected to expand rapidly offering progressively more powerful research tools.

In technical terms this means that health care is a leading-edge user of information services ranging from broad-band services to very sophisticated data base management systems making use of the latest in artificial intelligence. While the basic techniques will be in common between biomedical information services and many others, there are additional specific requirements which need to be taken into account, eg relating to the development of common functional specifications and minimum standards so that the uninhibited use of these services becomes possible.

2.3 Convergence of Biotechnology and Information technology (Mastering the complexity)

Biological systems are the most complex known and investigated by man. Progress in understanding has, therefore, at all times to be closely related with the ability to gather information, analyze and interpret it. The scientific basis of future health care is to be found largly in the understanding of the molecular basis of biological processes. This may include the analysis and interpretation of millions of atoms making up the biomolecular functions. One refers, therefore, in this context to 'Megacomplexity' which needs to be dealt with. It is for this reason that progress in biotechnology is intrinsically linked with progress in information technology. Inversely, the biological processes are increasingly serving as model for advanced work in information technology. For this reason it is expected that in the long term information and bio-technology will converge to a significant extent.

2.4 Speed of evolution

The scientific basis of medical care is evolving so rapidly that some refer to mankind facing a revolution. The reason for this lies in the fact that biotechnology has reached a level of maturity where its application has come within reach. The application potential and the associated economic potential have resulted in a major change in approach and scale of efforts. Increasingly large resources in terms of money, equipment and human resources are focused on specific objectives. Those countries who wish to maintain strength in this domain will need to reflect not only on the financial resources but in particular on the organization and orientation of their efforts. Providing a highly dispersed scientific and technological community with a common framework for collaboration is one of the necessities implicit in this trend to more concentration and requirement for scale.

2.5 Mastering economics and shortages in technological resources

Health care and all associated disciplines are major sectors of activity to which very considerable financial and human resources are dedicated as well as extensive facilities. Already this domain is highly capital intensive in the research stage, development, trial and application. This trend can be expected to continue and with the emerging biotechnology the requirements for scale of R&D efforts needed to participate in advanced work may reach the dimensions known to govern other high-technology fields such as aerospace and information technology. Cooperation is then not only an advantage but becomes a necessity in term of financial as well as expert human resources. The interdisciplinary nature of health care re-enforces the need to cooperate between different domains.

Success in meeting this challenge in economics (financial as well as in human resources) depends on setting up effective frameworks supporting the various sector actors in making their respective contribution. The action under consideration is to assist the sector actors in domains where the European dimension offers the most advantageous framework of action.

2.6 Conclusions

- Health Care is of central socio-political as well as economic importance for the Community. The demand for further improvements are increasingly being met by advances in science and technology.

- All European countries (and most others in the world) face serious problems in the growth of their health delivery systems. For some the percentage of GNP spent on health care has reached at least 6 %, depending on what is seen as part of the health budget; it easily can be also seen as already surpassing the 10 % limit in some EC-member nations. Though most experts consider this level of expenditure the maximum economically acceptable one, still most countries are conscious of deficiencies in their health system which they try to overcome by setting up new institutions and programmes.

- in spite of the differences in the socio-economic structure of the health care systems in the EC-member nations, these developmental areas provide a high degree of commonalty, ie a chance, if not the need, for joint efforts at Community level specifically in the area of advanced informatics.

- The field of medical informatics itself provides several excellent test beds and leading edge development areas for informatics in general.

- Medical information technology is a world market, as can be seen by the strong and still growing role that non-EC-based companies play in Europe and EC-based companies play outside Europe in areas like Hospital Information Systems, Medical Laboratory technique, and dedicated Systems in Image and Signal Processing.

- The future role of medical informatics will include:

  . the support of well understood routine tasks in broad application areas, efficient, cheap and robust enough to serve throughout the Member countries;
  . the provision of knowledge and expertise in situations and localities where these will not be routinely present, thus enhancing the quality of local problem handling;
  . the provision of local and regional communication facilities to provide pertinent patient data wherever and whenever needed, while observing privacy and security, thus reducing unnecessary replications of check-ups and delay of action;
  . the provision of aggregated data for more efficient health care resources planning. These and other effects which can be expected from a strategic implementation of medical informatics can be generalized to play a role in quality assurance, cost containment and equality of social service as well.

- The initiative is timely since:

  . several Member States of the EC are now at the point of starting or developing pilot projects and R&D programs to promote their information technology in medicine on the national level, e.g. in areas such as informatics for primary health care, regional health information services, hospital information services;

. with the advent of personal computing and powerful mini computers, computing now becomes affordable on a broad scale to hospitals, general practitioners and other health care providers;
. advances in telecommunications and radio open up new possibilities for health care, eg mobile integrated services.

- The functional integration of health care equipment and services made possible by the advances in MBI permits the realization of major advances in the quality and economics of health care (economies of integration and economies of flexibility).

- The realization of advances building on the new possibilities offered by MBI to improve quality and cost-performance depends on the collaboration of several sectors (Medical Profession, Molecular Biotechnology, Laboratory Instrumentation, Research Equipment, Telecommunications, Information Technology as well as of the standardization bodies working on the related domains).

- Progress in MBI opens up new possibilities with the potential for making health care more flexible and adapting it better to individual patient and needs of medical staff.

- Progress depends on the cooperation of independent actors making their respective contribution in a coherent framework of action.

- Shortage of human resources is in addition to lack of appropriate facilities and finance the most important argument in favour of cooperation on a European scale.

- The exploratory work which has preceded this proposal has confirmed the readiness of the sector actors to work together in this domain and identified areas of opportunities for cooperation.

- USA and Japan are investing large amounts of money in advanced informatics in medicine (e.g. in expert systems, communication, image processing) whereas at the same time dedicated US software companies are getting a growing share of the existing medical computing market in Europe.

- The existing R&D resources in Europe in certain areas like hospital information systems, image processing, expert systems and others are sufficiently strong to be able to capture relevant market shares in Europe and worldwide, provided that sufficient scale is achieved by joint efforts and harmonization.

- AIM can build on the cooperative efforts, in particular, ESPRIT and RACE as well as other advanced work realized in other frameworks and thereby contribute to the exploitation of generic work done in these programmes.

AIM will combine tangible progress in the mid-term with work requiring longer term efforts towards more ambitious objectives.

3. OUTLINE OF AN ACTION PLAN

The central function of AIM is to improve the use of limited resources for the advance of health care and its constituent sectors. This includes human resources, facilities, and finance but also the time element, so as to achieve accelerated progress in quality as well as cost-performance.

This implies the purposeful cooperation of the sector actors within a consistent framework of action. To this end, in order to make cooperation in such a complex domain manageable and effective, the action should be structured by reference to the main contribution each group of actors can make. The following Action Lines represent an approximate structure of the envisaged efforts. During the Pilot Phase these will be explored further and precise objectives as well as the optimal approach defined.

3.1 Action Line I

Improvement of the effectiveness of public and private actions

by means of

the development of a common conceptual framework for cooperation at the planning and management level in Europe.

This would be undertaken by the construction of a reference model (Annex, page 4). This model would embody the consensus of the main actors as to the common patterns which underlie the activities of the sector, including the economic aspects. The model would be composed of several sub-models, each representing one of the environments which can be recognised within the sector.

In health care very considerable private and public efforts are being undertaken in Europe. Their impact could be considerably strengthened by an enhanced concertation in the stage of the definition of objectives, the derivation of requirements, the participation in the evaluation as well as in the translation into applications

This Action Line would enable regular reports to be rendered, identifying objectives, achievements, recommendations, approaches to economic evaluation, requirements and indicating the orientation for future efforts in the domain of MBI. These reports would provide an integral view of the European situation and prospects in the world context.

3.2 Action Line II

Strengthening Europe's position in MBI and health care

by means of

cooperation in pre-normative and precompetitive technology exploration concentrating selectively on re-inforcing and complementing the technology base of MBI and its services.

This is to provide the reinforcement and minimum organizational framework necessary for multidisciplinary cooperation drawing on Europe's assets in this domain.

This part of the action will need to involve medical practioners, researchers, the related equipment and services industries as well as the related standardization bodies.

Scope

The ground to be covered under this Action Line would be the following headings of the Workplan

- Medical Informatics Environment
- Data Structures and Medical Records
- Communication and Functional Integration
- Biomedical Expert Support Systems
- Biomedical Instrumentation and Research Tools

Information technology and telecommunications brings flexibility and helps to overcome distance and access constraints to information. For this to benefit health care, application-specific functional specifications and minimum standardization need to be agreed upon by the health care sector. This is a pre-requisite for the improvement in speed and accuracy of all information related processes in health care. Furthermore, it is a prerequisite for the sharing of medical resources and equipment.

Therefore, one of the horizontal aspects of these activities to be explored early in the action would be towards reinforcing the efforts in standardisation of medical classifications as related to MBI, including diagnosis and data structures relating to records, taking full account of data protection requirements.

Full advantage can be taken of the advances realized in information technology and telecommunications generally only if a complementary effort is undertaken addressing the aspects which are health care specific or specific to the needs of the related biomedical and biotechnological research.

Therefore, other more technology-intensive collaborative, research activities would relate to specialist fields such as expert systems for use in knowledge-base construction and access as well as in more 'intelligent' human-machine interfaces, and to the exploitation of MBI in medical laboratories and in research. This work would lead the way, via the development of common functional specifications and minimum requirements of standardisation referred to above, towards the exploration and development of advanced MBI techniques by means of cooperation in pre-normative and pre-competitive R&D in specific domains of MBI particularly relevant to progress in health care or related research domains and suited for a transnational approach.

3.3 Action Line III

The creation of an environment favourable to rapid progress in the introduction and appropriate application of MBI in health care

by means of

the development of specific proposals addressing the policy, regulatory, legal, organizational framework of MBI applications including the training and manpower related factors.

Scope

The work relating to this Action Line is identified in the Workplan under the heading:

- Non-technological factors.

4. PHASING OF THE IMPLEMENTATION

Progress in this domain requires the purposeful cooperation of several actors within their respective responsibilities. The challenge is as much in the motivation of the collaboration as it is in the subject itself. However, motivation and a cooperative attitude cannot be planned or decided but must grow and prove itself. A phased approach is therefore suggested, permitting the progressive reinforcement of the effort as the definition of the objectives improves, the cooperation proves its value and the commitment of the actors increases the credibility of the approach.

4.1 Pilot Phase

Following the completion of the exploratory work which has led to the formulation of the proposal the full-scale implementation is to be preceded by a Pilot Phase. The Pilot Phase will serve to explore the scope and options to be included in the Main Phase, as well as to develop and test the framework of cooperation. The work during the Pilot Phase is to be exploratory in nature and self-contained, though representing the basis for later work under the Main Phase.

The initial Workplan for the AIM Pilot Phase is annexed to this document. It will be subject to revision by the Management Committee to be set up under the Decision adopting the action.

4.2 Main Phase

The Main Phase will be proposed based on the success of the launching and implementation of the Pilot Phase. Its objective will be to carry out the pre-normative and where necessary pre-competitive R&D required to achieve measurable progress with respect to the objectives identified for this programme and will be complemented by the specific technical objectives in the Workplan which is to accompany the proposal for the Main Phase.

5. ORGANIZATION AND MANAGEMENT OF THE COOPERATION

Cooperation in MBI, even at the level of exploratory work and advanced work, is very demanding in terms of management and organization. There are several important factors which already need to be taken into account in the Pilot Phase

- there should be for each component of the work a clearly defined objective in terms of functional characteristics and cost-performance together with the fixing of milestones marking progress towards the objective. The verification of progress by this means is the ultimate measure of the technology investment and the standard by which the results can be evaluated. It is not the technical feasibility as such which matters but the techno-economic feasibility and the benefit for health care;

- the health care system and its merger with research, information services including mobile communications creates a high degree of complexity and interdependence of future investments and applications;

- there are numerous actors with their own respective responsibilities who need to work together in a purposeful manner (the medical profession, service providers, hospital and medical service operators, industry and on regulatory issues also the respective administrative and political authorities).

This makes organization and management of cooperation in this domain a challenge in itself. Developing a sound approach to these questions will be decisive for reaching the objectives and minimizing the overheads inevitably associated with cooperation.

5.1 Evaluation

The evaluation is an ongoing process designed into the workplan including verifiable objectives and assured in the execution by progress monitoring and milestone reviews. The evaluation of the project proposals and of the results will be carried out with the assistance of independent experts. The overall evaluation of the Pilot Phase will be carried out by the Management Committee itself.

5.2 Relationship with International Projects and National Efforts

An estimated overall investment of the order of 100 billion ECU in R&D for health care will be made in developed countries over the next ten years. The work envisaged for AIM serves to minimize risks and uncertainties as well as the optimal use of limited human resources and finance. AIM relates to the initial R&D stage of very much larger efforts required later on for product development. AIM is focused towards infrastructure technologies where these are specific to health care and supporting scientific services and relate to predominantly common requirements requiring large scale cooperation or the establishment of a critical size of effort by cooperation. Where international or national projects are engaged with related objectives close coordination and collaboration between the efforts is proposed and will be essential.

5.3 Participation of public and private organizations established in Non-Community European countries

During the AIM Pilot Phase it is proposed to work closely together with existing bodies and administrations working in this domain. This should where possible extend to include public or private organizations established in non-Community European countries.

The Community has a strategic as well as an operational and economic interest to come to a European solution for health care questions which also includes non-Member States. Therefore, the Commission, intends to allow for the interest expressed by industry, hospital operators, health care service providers, and health administrations in the COST countries by extending the criteria for participation in AIM.

It is suggested that private or public organizations established in COST countries be permitted to submit proposals and to be signatories to AIM projects where a Framework Agreement on R&D Cooperation has been concluded with the corresponding country.

The select organizations would, however, have to cover their own costs (plus, as appropriate, a participation in the operational expenses).

Projects with participants from these countries would have to comply with the same selection criteria, contract conditions and management procedures.

5.4 Secondment Scheme

In order to mobilize the human resources and make optimal use of research facilities it would be of great advantage if experts from one organization could be associated with a AIM project carried out by another organization where this is wished by both parties.

This mechanism would aid the organizations responsible for the respective AIM project by providing additional skilled manpower and it would assist the seconding organization in participating in the form of one of its experts in leading-edge work.

5.5 Participation of SMEs, Research Organizations and Universities

The importance of SMEs, Research Organizations and Universities as a strong inventive and innovative element is well recognized and therefore their appropriate participation will be an important consideration in the implementation of AIM.

High technology SME's, Research Organizations and Universities will in general stand to gain from AIM in that it creates a framework in which the specific strength of SME's can express themselves and create market opportunities by fostering a symbiotic relationship with large companies and service providers.

50% or more of the employees in the Community telecommunications industry are in firms with 20-99 employees. This is an index for the variety of activities comprised within this industry, the different effects of scale between activities, and the extend of sub-contracting. There is little doubt that this high degree of involvement of SME's, Research Organizations and Universities will also characterize the future work in MBI and AIM.

5.6 Overview of actions in MBI

In order to situate the objectives of AIM in the context of existing national and international actions this section contains a strongly condensed overview of some of the major activities which have been taken into account in the definition and orientation of the proposal for the AIM Pilot Phase.

Belgium

Good level of R&D in medical informatics. Some research teams are outstanding in the following fields : medical terminology, medical record administration, integrated hospital systems, intensive care monitoring, data banks in cardiology, etc.
No national programme in bio-informatics, but some funding has been allocated to this area through various channels (public bodies, BAP framework, etc.).

Denmark

Denmark cooperates with Finland, Norway and Sweden in two major medical informatics R&D programmes : CART (Computer-Aided Radiotherapy) and KUSIN-MED (Knowledge-Based Systems in Medicine).

Public funding for basic research in the general area of biotechnology comes from general purpose appropriations channelled through the Research Council in Science, Medicine, Agriculture and Technology. There are presently two specialized programmes relevant in the context of bio-informatics : the Biomolecular Technology Programme (Dkr 33 million over 5 years starting 1984), and a 5 year programme of basic research underlying industrially related developments in biotechnology (start 1985 with a total budget of Dkr 60 million). The Danish government is considering a major effort in biotechnology.

France

Medical informatics has received in the past significant support from government, public institutions (Agence de l'Informatique, Centre Mondial Informatique et Resources Humaines) and national institutions (INSERM, CNRS). In addition, a number of scientific associations are engaged in developing medical informatics, in particular MEDIA, which groups 5 pilot teams selected by the Ministry of Health. In 1985, Agence de l'Informatique helped establish a new association called Ophis, intended for participating in the organization of the medical informatics market.
In biotechnology and bio-informatics, public funding of research operates at two levels. First, there are a number of research bodies, including CNRS, Institut Pasteur, INRA and INSERM, each with its own funding, laboratories, staff, etc. Secondly, France has a specific programme, the "Programme Mobilisateur: Essor des Biotechnologies", originally set up in 1982 and administered by the Ministry of Industry. This programme has a subprogramme in bio-informatics whose objective is to encourage and support the utilization of computational tools in the development of biotechnological research and industry.

CGR, a subsidiary of Thomson, is internationally active in the MBI sector.

Germany

In biotechnology, a major effort was launched in 1984, in the form of a programme administered by the Bundesministerium für Forschung und Technologie (BMFT). This programme, which has a total budget of DM 1140 million, should be seen in the context of local initiatives in the individual Länder. Although the programme does not specifically identify bio-informatics as a research priority, research in this area is supported under this scheme. Between the Länder the percentage of computerisation in hospitals varies from about 80-100%. The in-hospital usage of computers consists mainly of mini-computers with the exception of large hospital sites (eg in München, Hannover, Göttingen, Aachen and Kiel) which have hospital computer centres. The main usage is in administration and financial applications based on the use of software harmonised with the support of governement.

Hessen has recently given a contract for a demonstration project for a state-wide Hospital Information System.

In biomedical instrumentation, the FRG is the principal European manufacturer. Siemens is the world leader in Imaging and, on its domestic market, stands well ahead of C.H.F. Müller (a subsidiary of Philips), Hellige (a subsidiary of PPG Industries) and CGR Koch & Sterzel (a subsidiary of Thomson).
Many developments in medical informatics, especially expert systems.

Greece

Funding of research in biotechnology and bio-informatics is the responsibility of the Ministries of Industry, Agriculture, and Health and Welfare. There is work on basic research in biology at universities and research centres. There is at present no national research programme relating specifically to bio-informatics.
Two companies, Vioryl and Bio-Hellas, are known for their work in biotechnology.

Ireland

Basic and applied research in Ireland is supported by the National Board for Science and Technology (NBST), the Industrial Development Authority, the Irish Medical Research Council, a number of private foundations, and directly by the government Departments. The NBST, which has the responsibility for advising government on general matters of science policy, has identified biotechnology as one of three areas in which research is to be funded under a Strategic Research Programme. Bio-informatics has been identified by the NBST as an important element in biotechnology and advanced molecular biology.

Italy

A National Research Programme, to be completed in 1989, has been launched in the biomedical field. For its execution a service company called Tecnobiomedica S.p.A. was founded in December 1980 to identify, set up and develop applied research projects in the biomedical field. At present it is managing 16 research projects for an approximate total amount of ITL 85 billion. In this framework 16 manufacturers are working together with more than 20 research centres (Universities, Hospitals, Units of the National Research Council).
Specifically relating to the field of Medical Informatics, there are several major activities working on the use of artificial intelligence in medicine : Roma, Pisa, Pavia, Torino, Milano, Padova, Genova, etc. However, the level of government support (National Council of Research, Department of Public Education) for this work is comparatively low.

The Netherlands

Medical informatics is developed at Universities (Free University of Amsterdam, University of Leiden, State University of Maastricht, State University of Groningen...) and by industry (Philips and local subsidiaries of US companies such as Unisys, Datapoint, SMS, Honeywell, Hewlett-Packard...).

Philips, which has in 1987 formed a joint venture with GEC, has a strong position on the world market in specific sectors, eg imaging.

Portugal

Research is funded by the Research Council of the Ministry of Planning, which has declared biotechnology and bio-informatics priority areas.

Spain

Some projects are currently being developed in application of the National Informatics and Electronic Plan.
Spain participates jointly with Denmark and France in a Eureka development programme for non-invasive medical measuring methods ("Galeno/2000").

United Kingdom

There have been two major initiatives in advanced computing : the Alvey Initiative - the British 5th Generation programme - and the three-phase programme initiated by the Forty Report on Future Facilities for Advanced Research Computing. Within the Alvey programme there were some projects directly related to medical informatics.

The IT 86 Report, which addresses the follow-up to be given to the Alvey Programme, recommends a three-pronged programme: applications (ECU 700 million), research (ECU 770 million) and end-user education. Health has been considered as one of eight priority application projects, with emphasis put on clinical data and process models.

Several UK centres are involved in advanced software developments for protein and nucleic acid studies. The Cambridge Structure Databank (CSD) is one of Europe's most important data bases for biological research.

The UK has strong activities in medical expert systems in research institutions (ICRF, Imperial College, Manchester University, Sheffield U., St-Thomas' Hospital, Sussex U., ...) and industry (ICL, Logica, Oxford University Press, Hewlett-Packard...).

Funding for research in biotechnology and bio-informatics is provided by the Department of Education and Science (DES) and the Department of Trade and Industry. DES funding is mostly done via Research Councils: the Agricultural and Food Research Council (AFRC), the Medical Research Council (MRC), the Natural Environment Research Council (NERC), and the Science and Engineering Research Council (SERC).

British biomedical industry is relatively strong with a number of companies which are competitive on strategic segments (imaging, monitoring, superconductive magnets for MRI...). General Electric Company (GEC) is a major company in the imaging through its subsidiary Picker International.

United States

The US was among the first countries seriously to address the application of computers to the health care area, starting in the early 1960s. Most recently in 1983, the implementation of Medicare's Prospective Payment System (PPS) for hospital inpatient services has had a major effect on health care administration, resulting in a significant boost for the computer industry as hospitals found their old systems unable to cope with the new scheme. Presently 90% of all hospitals with more than 100 beds have some degree of automation in the patient admission/handling areas.

Federal funding is directed mainly to universities and colleges, and federally funded R&D centres, through agencies such as the National Science Foundation (NSF) which is the primary agency responsible for funding basic research at universities. The NSF's budget will be ECU 3.2 billion by 1992, three times that in 1980. The Department of Energy (DOE) plans to spend ECU 20 million to ECU 40 million a year on the "Genome Initiative" for the next four to seven years after 1988. The objective of this project is to map and sequence the entire human genome, thus accomplishing the tremendous task of reading the exact sequence of the more than 3.5 billion chemical units.

Biomedical research instrumentation is mainly supported by the NIH (National Institute of Health). In the fiscal year 1985 the Division of Research Resources (DRR) of the NIH awarded 1103 research grants. The appropriations for the DDR amounted to 300 Million ECU.

The research division of the National Library of Medicine (MIH) was created to address specifically the application of information technology and telecommunications to problems in health care and to improve the system for collecting, processing and disseminating biomedical information. In 1987 its activities included electronic image processing, electronic document storage and retrieval, video imaging systems, knowledge based information systems to name just some of the more ambitious projects.

Federal funding has also begun to flow into the private sector. Two kinds of federal support concern MBI : SBIR (small business innovation research programme) and SBICs (small business investment companies). Small high technology companies also receive state and local support through various mechanisms (Corporations for Innovative Development, State Pension Funds, venture capital) aimed at spurring innovation and growth. As concerns local support, there are some very interesting examples, such as the NBS-University of Maryland partnership on biotechnology (GARB), or the Chicago Technology Park which, together with nearby University of Illinois and medical centres, is reportedly the largest medical training centre in the world. US suppliers have become world leaders in the provision of health care-related software products. Major suppliers include IBM, Shared Medical Systems (SMS), McDonnell Douglas, DEC, Unysis, Technicon Data Systems, which represent just a few of the 160 leading suppliers active today in this market.

This results in a very strong position in the world medical equipment market and an outstanding position in medical and bio-informatics.

Japan

Public funding of research in MBI lies under the auspices of the Agency of Industrial Science and Technology (AIST), the Ministry of International Trade and Industry (MITI), the Ministry of Education, Science and Culture, and the Ministry of Health. Exchange between public research and private research are very dense. On the basis of the fundamental technology about system control and filing information obtained through past trial tests, and on the basis of adopting the newest picture processing and storage technologies, NTT has developed a new interactive video information system called Video Response System (VRS). An experimental service for "Medical VRS" was started on April 23, 1986. In 1976 the Technology Research Association of Medical and Welfare Apparatus was established to meet the need for products which are difficult and financially risky to develop and have low selling price. In 1974, the Ministry of Health and MITI set up the Medical Information System Development Centre (MEDIS DC). A significant feature of the growth of hospital information systems has been the increased market share held by the native companies from 20% in 1960 to 80% today, mainly through the strategically directed production of small and medium-sized computers.
Key players in medical informatics include Fujitsu, NEC, IBM Japan, Hitachi, and DEC Japan. Biotechnology-related market may reach Yen 6 trillion by the year 2000 (Yen 25 million in 1986), with the market growth being mainly attributable to the accelerating commercialization of pharmaceuticals. Medical equipment is in Japan a fast-growing industry which comprises close to 20 important makers. Three leading companies : Toshiba, Hitachi and Shimadzu. Medical informatics develops rapidly, especially local area networks for hospitals and medical IC card systems.

On the research side, Japan's Science and Technology Agency will begin in 1988 a study to carry out exploratory work to fund a project to develop advanced equipment for decoding DNA. Sequencing the whole genome with a totally automated, rapid DNA sequencing system, would take 30 years instead of 250 years and ECU 1.1 billion if done by hand. MITI has proposed in 1986 the Human Frontier Programme with the intention to promote basic research on a world scale which includes medical and bio-informatics.

EUREKA Projects

- Galeno 2000: Development of non-invasive medical measuring methods
- Expert System for incorporation in medical instruments
- Biomedical Image Processing
- Ultrasonic Signal Capture Systems
- Oncology Therapy Advisor
- Protein Design
- Operating room 2000
- Medical disposable sensors
- Automated diagnosis of blood

COST Actions

Cost 13 : Artificial Intelligence and Pattern Recognition.
Among the collaborative research projects is "Artificial Intelligence in Medical Science". The objective is to study and critically evaluate:

- communication between the clinical staff and a decision support system;
- knowledge acquisition by apprenticeship, literature and learning from example;
- knowledge representation techniques for medical data;
- handling of uncertain medical data;
- decision support systems with clinically acceptable response times.

Community

Research and development co-ordination programme of the EEC in the field of medical and health research:
Three coordination programmes of medical and health research have been adopted by the Council between 1978 and 1986. A fourth coordination programme encompassing more than 70 concerted actions is expected to become operational until 1989. Ref.: COM (86) 549 final
"Europe against cancer" programme: proposal for a plan of action 1987-1989. Ref.: COM (86) 717 final

The Community has specific programmes both on information technology and biotechnology. The ESPRIT and RACE programmes address the information and telecommunication technologies respectively. The Biotechnology Action Programme (BAP) does include some aspects of the applications of information technology. AIM is conceived as a well focused specific effort to complement these programmes with respect to developing specific advanced and new capabilities.

6. GLOSSARY

AIM	Advanced Informatics in Medicine
Ambulatory care	Care rendered without hospitalisation - ie primary care, outpatients hospital care, emergency visits and one-day care surgery
Angiography	Techniques for depicting blood vessels
Angioplasty	Ways of dealing with obstacles to the flow of blood - eg by laser
APACHE	Acute Physiology and Chronic Health Evaluation, a classification system developed at the George Washington University Intensive Care Research Unit
Architecture	The selection, design, and interconnection of the physical components of a large scale computer system
Artificial Intelligence (AI)	The concept that computers can be programmed to assume some capabilities normally thought to be like human intelligence, such as learning, adaptation, and self-correction. Applications also known as Intelligent Knowledge Based Systems (IKBS)
Automatic encoding	Transformation of each medical term in natural language into a code inside the computer, without human intervention
AVG's	Ambulatory Visit Groups. Methodology used in the United States to define the product of health care in ambulatory setting
Bio-Informatics	The various topics at the interface between information technology and biotechnology. One important attribute is that bio-informatics covers not only the present use of computers for information processing in biotechnology, but also the potentials for computerization within this area
Biomolecular modelling	A scientific field at the interface between advanced computing and biotechnology. Main areas include databases of nucleic acid structures, protein sequences, macromolecular crystal structures and organic crystal structures, sequence modelling for laboratory sequence and cloning studies and for detection of sequence homologies between different molecules, prediction of protein structure from amino acid sequence to model both secondary and tertiary structure, macromolecular energy calculations, and molecular graphics to display and manipulate representations on calligraphic and raster screens
Biosensor	A device which recognises an analyte in an appropriate sample and converts its concentration into an electrical signal via a suitable combination of a biological recognition system and an electrochemical transducer
Biotechnology	Application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services

Bus	An interconnected system path over which information is transferred, from any one of many sources to any one of many destinations, the devices involved being connected in parallel
CART	The Nordic Radiographic planning project involving industry, R&D institutes and users for the development of new radiographic systems and communications
CCD	Charge-Coupled Device, a new and compact image sensor technology
CIM	Computer Integrated Manufacturing
Classification	A distribution by classes or categories, following preexisting criteria. The International Classification of Diseases (ICD) has been designed for statistical purposes and for the indexing of hospital records by diseases and operations, for data storage and retrieval
Coding	The coding of diseases or medical terms is the process of attributing a code to each notion which is to be separately identified. This notion can then be found in a classification or a nomenclature
COM(86) 549	Proposal for a research and development co-ordination programme in the field of medical and health research (1987-1989)
COM(86) 717	Proposal for a plan of action against cancer (1987-1989)
COMAC-BME	Concerted Action Committee-Biomedical Engineering
Computer graphics	The use of computers to process graphics. Unlike image processing, the images are not from life but are man- or machine-made. Graphics are easier to manipulate than images because they are defined to a computer's "mind" as geometric figures - a set of points and a few other bits of information regarding shading or coloring
Compatibility	Refers generally to the ability of two (hardware/software) devices to work in conjunction
Computer language	A set of characters, conventions, and rules that is used for conveying information
COST	Committee of European Cooperation in the field of Science and Technology
CREST	The Scientific and Technical Research Committee. Set up in 1974, it is composed of senior officials of the member states and gives advice to both the Commission and the Council
Data Integrity	Data must be received as sent and not be changeable by a false author or by "noise" in the system, at any point en route or at either sender or receiver's station without being detectable by the sender or receiver
Data modelling	Procedure according which the data are seen within a model that defines their relationships and meaning in order to meet information requirements. Data models extracted from information needs form the baseline from which to approach the question of information technology systems

DNA	Deoxyribonucleicacid
DRG's	Diagnosis Related Groups. DRG's are a subclassification of the ICD-9-CM code that groups patients by diagnostic categories with homogeneous costs based on length of stay and medical activity analysis
DSA	Digital Subtraction Angiography (see also angiography)
ECG	Electrocardiography
Economies of integration	Economic advantages arising from multiple use and therefore higher utility of facilities
Economies of scale	Advantages arising out of scale of production or service
Economies of scope	Advantages arising out of commonality and synergy between different products or services
Electronic Image Processing	The use of electronic imaging technology in the capture, storage, processing, online retrieval, transmission and display of biomedical documents and medical imagery
Electrophoresis	Separation of macromolecules according to their size and electrical charge by passing through a gel under the influence of an electric field
Endoscopy	The use of flexible tubes for in vivo examination, diagnosis and treatment
ESPRIT	European Strategic Programme for Research and Development in Information Technology
ESWL	Extracorporeal Shock Wave Lithotripsy, an apparatus which permits the fragmentation of lithiases (stones) in urology, by transferring accross the tissues towards the lithiases shock waves produced outside the body
Eureka	Industrial cooperation scheme in high technology commercial development
Expert System	A computer program that simulates or mimics the judgement and reasoning of human experts, allowing it to address problems normally thought to require human specialists for their solution
Fibroscope	A long, flexible endoscope using optical fibres to transmit the image
Functional specification	Definition of what a device/system is designed to do but not how it is done
Genome	All human genes taken together. More than 3.5 billion chemical units make up the human genome, and only 1% to 2% of the genome has been sequenced
Harmonisation	An increase in consistency of approaches rather than a strict conformity of measurement systems. Harmonisation can also be obtained through a learning process by a transparency of results and more systematic international exchange of comparable informations
Laser Card	A data recording technique similar to an optical disk but in a card form

Lithotriptor	Apparatus which allows the fragmentation of lithiases in urology. Extracorporeal shock wave lithotripsy (ESWL) allows fragmentation of a "stone" by transfer across the tissues towards the lithiasis of a mechanical wave produced outside the body
Man-Machine Interface	Interaction of the user with a computer or communication system
MBDS	The Minimum Basic Data Set, recommended by the EEC in 1982
MBI	Medical- and Bio-Informatics
MEDIA	A French association grouping five pilot teams in medical informatics
Medical Record	Information acquired in the process of medical consultation, examination, investigation, and treatment
Medicare	A US. government programme of medical care especially for the aged
MIB	The medical information bus, a standard communications protocol for instrumentation used in hospitals, and particularly for intensive care
MITI	The Japanese Ministry of Industry and Foreign Trade
Molecular Biotechnology	A research field which plays a key role for health care, eg in the form of diagnostic tests, drugs, hormones, proteins, vaccines and so on
MRI	Magnetic Resonance Imaging
NHS	the UK National Health Service
NM	Nuclear Medicine
OSI	Open systems integration standards
PACS	Picture Archiving and Communication Systems
PET	Positron Emission Tomography
Portability	The ability of an application to be physically moved with ease or used on a variety of different types of computer
PPS	The Prospective Payment System of the U.S. Medicare programme
Pre-competitive R&D	Mid- to long-term R&D preceeding commercial product development
Pre-normative R&D	R&D required to prepare the definition of standardisation proposals
Primary Health Care	Essential health care made universally accessible to individuals and families in the community by means acceptable to them, through their full participation and at a cost that the community and country can afford

Procedures in health care	Medical treatment and in particular surgical interventions follow specific rules of conduct involving the patient, highly trained specialists and special facilities in a hospital setting (e.g. cardiac catheterization, laparoscopy, liver biopsy, endoscopy with biopsy)
RACE	R&D in Advanced Communications Technologies in Europe
R&D	Research and Development
Secondary Care	Care provided (a) in a clinic or office located at a hospital, by a consultant specialist, (b) in acute or general hospitals
Smart card	One portable storage and processing device used for authentication, payment and storage of personal data. Small microprocessor or memory chips are encapsulated in a plastic card meeting ISO standards. With existing technologies up to 64 Kbits can be at present be stored.
SMEs	Small- and Medium-sized enterprises
SPECT	Single Photon Emission Computer Tomography
Standardisation	Standardisation of medical data is international harmonisation of medical terminologies with classifications and nomenclatures allowing to encode medical terms
Telemedicine	The use of telematics to offer medical services
Tertiary care	Long-term care provided through long-stay in special hospitals, nursing homes, and similar residential facilities
Voice processing	Voice processing technology gives a computer the ability to hear and speak. These capabilities are provided by two distinct aspects of the technology: voice recognition, which allows a computer to understand spoken words and execute the appropriate commands or actions; and voice output, which endows the computer with speech

Proposal for a Council Regulation on a Community action in the field of information technology and telecommunications applied to health care — Advanced informatics in medicine in Europe (AIM) — Pilot phase

COM(87) 352 final

(Submitted by the Commission to the Council on 13 August 1987)

(87/C 355/02)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130Q (2) thereof,

Having regard to the proposal from the Commission,

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

In cooperation with the European Parliament,

Whereas the Community has as its task, by establishing a common market and progressively approximating the economic policies of Member States, to promote throughout the Community a harmonious development of economic activity and closer relations between the States belonging to it;

Whereas the Heads of State and Government emphasized the importance of health care as a major factor for economic growth and social development;

Whereas the European Parliament, in its assessment of the situation and development, stressed the role of cooperation in health care and related areas for the future political, social and economic development of the Community;

Whereas the European Parliament, in its assessment of biotechnology in Europe, has stressed the importance of medical biotechnology and bioinformatics [1];

Whereas the Economic and Social Committee supports initiatives in this domain;

Whereas, with the emergence of advanced and mobile communication services and the progressive introduction of computing in health care and services, the conditions for major improvements for health care and possibilities for reduction of cost increases are emerging;

Whereas developments in health care will benefit the general public and the international competitiveness of the European industry and health services in particular;

Whereas advances in health care will contribute to resolving pressing social needs associated with changing age structures;

Whereas the concerted efforts in this domain will contribute to the creation of the internal market and prevent the formation of new internal frontiers to health care;

Whereas the development of common functional specifications for equipment and services will permit the less-developed regions to benefit fully from the efforts of Member States piloting the improvements of health care, management and infrastructure developments in the Community;

Whereas the development of the health care infrastructure technology and services offers a wide range of opportunities for small and medium-sized companies in the manufacture of equipment and in the provision of specialized services within the Community;

Whereas cooperation in pre-normative and pre-competitive research and development towards the development of standards can make a major contribution, notably by facilitating the evolution towards future more effective health care also at regional and local levels;

Whereas the framework programme for Community actions in respect of research and technological development (1987 to 1991) [2] envisages the utilization of the technologies of information, telecommunications and broadcasting in the interests of new services of common interest under its second heading 'Towards a large market and a society based on information and communication'; whereas the framework programme contains special provision for a Community action in the field of medical and bio-informatics;

Whereas the constitution or consolidation of a specifically European industrial potential in the technologies concerned is an urgent necessity; whereas its beneficiaries must be industry, health care service providers, research establishments, undertakings, including small and medium-sized enterprises and other bodies established in the Community which are best suited to attain these objectives;

[1] OJ No C 76, 23. 3. 1987, p. 25.

[2] COM(86) 430 final.

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Whereas exploratory investigations have confirmed the need and the advantages of Community cooperation in this field;

Whereas it is in the Community's interest to consolidate the scientific and financial basis of European research by means of the involvement to a greater extent of participants from European third countries in certain Community programmes and particularly in programmes involving cooperation in medical bio-informatics;

Whereas the AIM pilot phase will benefit from the results of ESPRIT and RACE as well as the on-going efforts in standardization;

Whereas the Community's programme in biotechnology (1985 to 1989) will include the application of medical bio-informatics and draw on the results of the work to be undertaken under AIM;

Whereas there exists a need for close coordination with actions on the national level and periodic reviews; whereas it is therefore necessary for the execution of the pilot phase that the Commission be assisted by a Committee;

Whereas the implementation of concerted actions in the COST framework is an essential element to complement industrially-oriented research and development projects;

Whereas the Scientific and Technical Research Committee (Crest) has expressed its opinion,

HAS ADOPTED THIS REGULATION:

Article 1

1. A pilot phase of a Community action in the field of medical and bio-informatics, hereinafter referred to as 'AIM', is adopted for an initial period of 18 months commencing 1 January 1988.

2. The action is designed, in concertation with public and private actions in the field of medical and bio-informatics (MBI) undertaken at national and international level, to promote the competitiveness of the Community's industries, health service providers in order to make available to the citizens and health services, at minimum cost and with minimum delay, the improvements in health care, thereby contributing to social as well as economic objectives.

Article 2

The action shall consist of the development of a common conceptual framework for cooperation, pre-normative work and technology exploration and the investigation of the non-technological factors as required for the objective of concerting European efforts in improving health care by means of MBI.

The scope of the AIM pilot phase is described in the Annex and in the draft workplan.

Article 3

1. The detailed objectives of the action to be undertaken are defined in a work plan to be adopted under the procedures set out in Article 7.

2. The evaluation of projects is carried out by the Commission having regard to the objectives defined in the Annex and in the work plan. The eligibility of projects involving a research and development effort exceeding 50 man-years is to be decided under the procedure set out in Article 7. For other projects the results of the evaluation will be brought to the notice of the Committee referred to in Article 6.

3. Projects relating to the action shall be executed by means of shared cost contracts to be concluded by the Commission with industrial enterprises, service providers, universities, research institutes and other organizations established in the Community. Contractors shall be expected to bear a substantial proportion of the costs, which should normally be at least 50 % of the total expenditure.

4. The proposals for projects shall, as a general rule, be submitted in reply to an invitation to tender published in the *Official Journal of the European Communities* and involve the participation of at least two independent partners, not all established in the same Member State. One of the partners shall be a commercial undertaking.

5. In exceptional cases, where the call for tenders has not resulted in a satisfactory response, in case of urgency or in cases where the call for tenders is not the right procedure in point of cost-effectiveness, the decision may be taken, in accordance with the procedure set out in Article 7, to derogate from the principles set out in paragraphs 3 and 4.

Article 4

Where Framework Agreements for scientific and technical cooperation between non-Community European countries and the European Community have been concluded, organizations and enterprises established in these countries may become partners to a project undertaken within this action.

Article 5

1. The funds estimated as necessary for the Community contribution to the execution of the pilot phase

amount to 20 million ECU over 18 months, including expenditure on staff (nine A, two B and four C temporary officials).

2. The indicative allocation of these funds is set out in the Annex.

Article 6

1. The Commission shall ensure that the action is properly performed and shall take the measures necessary to this end, without prejudice to the procedures provided for in Article 3.

2. The Commission shall be assisted in the execution of its tasks by a Committee, composed of two representatives from each Member State, chaired by a representative of the Commission and hereinafter referred to as 'the Committee'.

The members of the Committee can call on the assistance of experts or advisors according to the nature of the problems under study.

The proceedings of the Committee shall be confidential. The Committee shall adopt its own internal procedures. The Commission shall provide the secretariat of the Committee.

3. The Commission may consult the Committee on any matter within the field of application of this Regulation.

Article 7

Where the procedure laid down in this Article is to be followed, the chairman shall refer to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on this draft within a time limit set by the chairman in relation to the urgency of the matter. This shall normally be one month and in no case shall be longer than two months. The opinion is delivered by the majority specified in Article 148 (2) of the Treaty for decisions which the Council is required to adopt on a proposal from the Commission. In the Committee the votes of the representatives of the Member States are weighted as indicated in that Article. The chairman does not vote.

The Commission shall adopt the measures under consideration when they are in accordance with the opinion of the Committee. When the measures under consideration are not in accordance with the opinion of the Committee, or in the absence of an opinion, the Commission shall submit to the Council without delay a proposal relating to the measures to be taken. The Council shall decide by a qualified majority.

If, after the expiry of a period of one month following the Council's consideration of the matter, the Council has not taken a decision, the proposed measures shall be adopted by the Commission.

Article 8

The result of the action shall be reviewed by the Commission after 12 months. The Commission shall report to the Council and the European Parliament on the results of this review, together with any proposals for modification or prolongation of the action which the Commission deems appropriate.

Article 9

1. With regard to the coordination activities provided for in Article 1 (2), the Member States and the Commission shall exchange all appropriate information to which they have access and which they are free to disclose concerning activities in the areas covered by this Regulation, whether or not planned or carried out under their authority.

2. Information shall be exchanged according to a procedure to be defined by the Commission after consulting the Committee, and shall be treated as confidential at the supplier's request.

Article 10

This Regulation shall enter into force on 1 January 1988.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX

INTRODUCTION

The *rationale* developed in the main document illustrates the opportunities for cooperation but also the difficulties and complexities their inter-sectoral nature will pose to a concerted effort on a European scale. Besides the need to refine objectives one will need to analyze alternative approaches as well as test the ability to manage successfully the numerous inter-dependencies. Success of this action will ultimately depend on the ability to complement and reinforce efforts undertaken by the sector actors on a national level. Developing and reinforcing the mechanisms of concertation between the sector actors on a European scale is as much a challenge as the technical content of this initiative. Success in this respect will be decisive for realizing the advantages of concertation and cooperation and thereby a better use of the scarce human, institutional, technical and financial assets of the Community in this domain.

For this reason a pilot phase has been conceived with the sector actors which has the following aims:

— analyze and assess future requirements in health care and biotechnology for medical and bio-informatics (MBI),

— explore and assess technological developments and options with respect to their contribution to progress in MBI,

— define precise objectives and the optimal approach for concertation and collaboration in the field of MBI at European level complementing and re-enforcing efforts of private and public organizations working in this and closely related areas,

— test and validate the organization and management support for concerted efforts in MBI,

— develop an action plan for MBI based on analyses of future requirements and opportunities,

— identify legal, regulatory, economic and other non-technological factors which may play a key role in using MBI for the stated objectives.

The following section describes the scope of the work proposed for the pilot phase. The areas of investigation and exploration have been chosen in accordance with the above objectives of the pilot phase so as to provide significant results without prejudice to the follow-up.

1. DEVELOPMENT OF A COMMON CONCEPTUAL FRAMEWORK FOR COOPERATION

Health care is in a process of continuous evolution and so is the technology supporting it. Central to the assessment of the role and contribution of MBI is the accurate understanding of the present and future role of information and the way it is used.

The types of data a doctor generally needs to handle, review, merge in a report, are:

— text (e.g. reports from colleagues in the referral system),

— numeric laboratory results,

— graphical presentations (of both numeric data and body sites),

— signals (e.g. electro-cardiograms),

— images (e.g. X-ray, sonograms, etc.).

These data have three main origins: data they generate themselves about patients, data others generate about their patients, and general medical knowledge.

The data handling requirements of researchers working on the molecular basis of biological systems are:

— automatic collection of experimental data from different sources,

— comparison of experimental data with those stored in data banks and data bases,

— tertiary structure prediction from sequence data,

— molecular modelling,

— quantum mechanical calculations for structure refinement.

This suggests three directions for the development of medical informatics:

a) medical records;

b) communications; and

c) information retrieval/decision-support systems.

Formulating a strategy about information technology for health care requires to identify the information needs and how they can best be met. This implies the analysis, understanding and agreement between the main actors concerned as to the approach best suited to meet user needs in a way which is consistent with economic and technological constraints.

1.1. **Development of a reference model for MBI**

Objective

The developments in MBI will build wherever possible on the developments in information technology, telecommunications, broadcasting and value-added services. In addition, and relating to the application specific aspects MBI will develop specific features and capabilities. For example, remote patient monitoring may feed into cellular radio, but will require the development of data capture and broadcasting techniques specific to health care. Similarly protein and nucleic acid data bases will use standard data base management systems, but will need special tools, e.g. expert systems, to assist in the efficient use of the data.

To permit MBI to build on synergy with other domains and to help identify the requirements in common functional specifications and minimum standardization, it is proposed to start, as part of the pilot phase, with the conception and development of a reference model for MBI. As far as the telecommunications and broadcasting is concerned, this work can build on the reference model developed as part of the RACE programme.

The specific objectives of this work are:

— to create and maintain transparency for the requirements and their functional characteristics,

— to come to a common understanding of the evolution in MBI,

— between the main sector actors to come to a common definition and understanding of the functional and minimum standardization requirements,

— to support the work of common functional specifications and of standardization by the appropriate bodies to facilitate progress in MBI for health care and research in related domains.

Scope

The work will comprise three major elements, namely those relating to the informatics environment of the doctor, the scientist/technologist working in related domains, and the general requirements for the development of the reference model.

1.1.1. *Reference model for the doctor information environment*

This will include all the functional descriptions relating to the information processes involving the doctor in his relationship to the patient and the supporting infrastructures (e.g. hospitals, etc.) and services (e.g. laboratories, etc.). In identifying and describing the functional requirements both technical as well as cost considerations will be taken into account.

1.1.2. *Reference model for the scientist/technologist information environment*

This covers the functional description relating to the work of scientists and technologists working in health care related domains, e.g. laboratories engaged in diagnostics, but more generally those engaged in biotechnology. Though the scope of biotechnology goes beyond health care, the bio-informatics requirements are to a large extent common to all domains of biotechnology.

1.1.3. *Integration and interoperation concepts*

This work would concentrate on analyzing and extending the OSI concepts for open interconnection for the field of MBI. As far as equipment is concerned, it will build on OSI work but extend the concept 'open interconnection' to the sector specific upper layers of the OSI model. Main issues include access control and user identity; electronic signature and time stamping; confidentiality; data integrity.

1.2. **Data requirements analyses for MBI**

Objective

In order to develop information systems which are open and flexible in meeting the needs of health care by building on the evolution of the underlying sciences and technologies, it is necessary systematically to analyse information requirements. The understanding of information requirements is the pre-requisite for the conception and definition of common information processing functions and the development of information exchange and portability. This in turn is a pre-requisite for common functional specifications and minimum standardization.

Scope

The scope of the work needs to include the analyses of health care related information requirements and the specification of the associated specific features relating to data capture, processing, verification, protection, authentication, storage, transmission, recall, and presentation for the following relationships:

— patient-health care services,

— doctor-patient (correspondence, information, advice, etc.),

— doctor-reference information (case history, diagnosis of symptoms, prognosis, treatments options, prescriptions, recent experiences in treatments, etc.),

— doctor-diagnostic services (laboratories),

— doctor-therapy (surgery, dispensaries, special therapies of various kinds),

— doctor-administrations (hospital, insurance, public administrations, accounting, etc.).

With respect to the laboratories and research infrastructure for health care, the corresponding analyses will need to be carried out including the following relationships:

— scientist/technologist-reference information (e.g. DNA and protein sequence and structure data bases, literature, etc.),

— scientist/technologist-experimental data (e.g. X-ray and neutron diffraction); two-dimensional high-resolution nuclear magnetic resonance, electron microscopy),

— scientist/technologist-experimental equipment (e.g. molecular dynamics simulation, X-ray crystallography, advanced 3-D graphic system, etc.),

— scientist/technologist-administrations (hospitals or other service demander, insurance, public administrations, accounting, etc.).

The result should identify the options and the approach for the development of application-specific coding structures, allowing for technology expansion and refinement for data transmission

in processable form. Within the scope of the pilot phase this could already be expected to make a significant contribution to the urgently needed harmonization of future developments as well as prepare the ground for further detailed work.

1.3. Assessment of the cost-performance potential of MBI

Objective

Informatics can be used in health care and biomedical research both to increase performance and to achieve better economies. The objective of this work in the context of the reference model is to investigate the cost-performance potential of MBI.

Scope

The work in this domain will consist of the identification of the various levels of the health care system where information technology provides opportunities to develop methods for containing costs yet improving care. Specifically the following areas will be scrupulously investigated:

— prescribing,

— radiology-image processing,

— laboratory equipment,

— benefit of sensor techniques,

— population screening,

— cancer therapy,

— primary care,

— biomolecular research.

Prescribing

With the development of expert system- and communications-based approaches to primary care prescribing the administrative overheads can be reduced and the accuracy of matching patient needs improved.

Radiology

The use of digital techniques and optical disk storage, by generating a much more advantageous data acquisition, storage and retrieval system, can significantly reduce the annual cost of radiology today in comparison with X-ray film, chemicals, current equipment maintenance and film storage [1].

Laboratory equipment

While the cost of maintenance of laboratory equipment, computers excluded, is considerable, adoption of a policy of having expert system diagnostics in even the most simple laboratory equipment would permit economies and improvement in service.

Sensor techniques

Advanced sensorics offer considerable potential for remote and unattended sensing. This can be used to greatly improve monitoring, accuracy and overcome time and distance constraints.

Population screening

Information technology can improve population screening for a curable but otherwise fatal disease, by enabling much of the preliminary detailed screening to be automatic.

Cancer therapy

The quality of life of a cancer patient can be significantly improved by the use of computer models aid decision-making allowing for better treatment, e.g. optimizing the use of surgery, chemotherapy and radiotherapy. The challenge is to link the information base with the developing models to optimize therapy for each patient.

Primary care

A combination of new measurement technology and information processing enables better primary care to be provided, showing how technology convergence operates to the advantage of health care. In particular, development of 'alternate-site' medicine requires convergence of film technology, chemistry, molecular biology and information processing.

Bio-molecular research

Bio-molecular research has the potential of revolutionizing the economics of pharmaceutical production and the related research and development. There are already examples where bio-molecular engineering techniques have been able to produce directly highly pure substances at greatly better economics than traditional techniques permitted.

2. MEDICAL INFORMATICS ENVIRONMENT

Description

In context of the rapid development of technology and automated information systems, standards are required to enable comparisons and exchange of health information at international level. Medical data availability and comparability in Europe should allow better understanding of the patterns of evolution of chronic diseases, optimize resources with the result that the quality of care and the quality of life will improve and contribute to management and research to the benefit of patients.

The growth of information technology in medicine is now leading to a proliferation of independent systems in Europe. Thus, there is a danger of an increasing lack of comparability between medical information systems that will limit the possibility of large-scale, national or international studies, as well as the possibility of evaluating the efficiency and quality of care at the European level.

The first priority is therefore to produce the required commonalty of medical languages as the fundamental basis for transferable systems through design and development of a European medical lexicon of syntax and semantics. This lexicon will form a focus for most of the medical functions, thus allowing for the development of the concepts of integration and convergence in health care.

[1] Purchase of X-ray films accounts for 2% of the overall budget of a hospital and 60% of its radiology department.

Objective

The main objective of the work under this heading is to achieve the development of improved classification systems for the coding of medical terminology as a prerequisite for the solution of transboborder health care problems.

At a scientific level, the adoption of comparable classification systems is particularly important to obtain a better understanding of the differences in the spread of diseases as well as of differences in health care delivery systems and their cost in Europe.

At a political level, accurate and reliable data bases are vital for the monitoring of the efficiency and the quality of care, as well as for the development of strategies and of international standards.

Scope

To meet this objective, four major areas of activity are required:

— international comparison of diagnostic criteria and procedures related to costs (hospital in-patients),

— definition of a minimum basic data set (MBDS) for ambulatory care in Europe,

— semi-automatic encoding of standardized medical data classification systems in Europe,

— development of European criteria to define severity of cases.

2.1. International comparison of diagnoses and procedures related to costs

Objectives

— Harmonization of medical data classification systems through comparisons and common results, using the European MBDS defined for hospitals.

— Evaluation of the diagnosis related group (DRG) methodology in Europe, to understand differences and explore ways of comparisons.

This work has an exceptional importance in order to coordinate actions generated independently in each European country in the field of MBDS and diagnosis related groups, and to understand better differences in health services activities, productivity and quality of hospital care in Europe.

Scope

The work in this part will consist of seven strongly interrelated areas:

Development of standards for data input

The two major aspects of this work concern the definition of standards for the collection and interpretation of medical data, taking into account that manual procedures are more and more being replaced by computerized data entry and processing.

Differences in diagnostic classification systems among European hospitals

Whenever MBDS are available and comparable within and between countries, pilot studies will be designed to obtain data exchange and comparisons in Europe, and between Europe and the United States.

Differences in classification of procedures among European hospitals

Unlike diagnoses, which tend to be uniformly classified according to the international classification of diseases, operations and other procedures are coded by national classifications or nomenclatures which have been elaborated following different requirements of clinicians, health care managers, financing bodies and social insurance funds, for various purposes, mainly administrative in nature. The task is to upgrade any classification systems of medical data in order to cope with evolution of medical techniques, new diagnoses and management changes, taking into account that the original classification schemes of procedures in each country might include some better organizations than the ICD-9-CM code. The study of a combination of a minimum set of medical data from each European classification scheme will eventually be developed internationally.

Differences in case-mix among European hospitals

As a first step it is recommended to carry out a comparison of the international classification systems measuring the costs for specific case-mixes for European hospitals, e.g. ICD-9, ICD-9-CM and DRG's, and to develop an approach to harmonizing their use.

Influence of case-mix on length of stay and cost factors in European hospitals

As resources tend to be allocated according to past requirements, new indicators are needed to measure the productivity of health care delivery systems. The most widely available source of medical indicators of productivity indicating why certain care has been delivered to patients appears to be the medical record summary that includes the hospital MBDS with all diagnoses and procedures performed for each in-patient. The work will be aimed at obtaining a better description of the health care delivery systems in Europe by linking MBDS levels, abstracted from medical record summaries with financial data as well as knowledge data bases.

Definition of proposals to harmonize medical data classification systems in European hospitals

Programs will be developed in Europe to harmonize medical data classification systems. They must be as universal as possible — taking into account needs of all countries, including underdeveloped countries — and flexible in order to allow for changes in the future. The approach will be multi-disciplinary, to enable dialogue between health professionals and managers.

Definition of research and development requirements in software and hardware to allow competitiveness with the US industry

Harmonization of medical data is a prerequisite for a large-scale European market in medical informatics. In order to have the capacity to compete against strong American companies, the European industry will be supported to design and further provide well adapted packages that include MBDS and DRG's.

2.2. **Definition of a minimum basic data set for ambulatory care in Europe**

Objectives

— Harmonization of medical data classification systems by defining a MBDS for ambulatory care, e.g. the core of knowledge that should be available everywhere in a comparable way for the maximum number of usages in ambulatory care.

— Evaluation of the ambulatory visit groups (AVG) methodology in Europe to explore its feasibility, advantages and disadvantages.

Scope

The scope includes the following tasks:

Definition of an MBDS for ambulatory care

So far in Europe only a small number of general practitioners (between 1 and 5% in different countries) use computers to process medical information. Standardization of classifications is therefore a prime concern. The task is aimed at the validation of standardization concepts and pre-normative work for the coding in ambulatory care and the definition of a MBDS for family and out-patient care.

Use of the MBDS defined and of the AVG methodology in pilot centers in Europe

Once a MBDS has been defined at European level, there is a strong need for assessing the ambulatory visit groups methodology which has been developed in the USA in 1986, in order to compare medical data linked with financial data in ambulatory care.

Definition of proposals to harmonize medical data and patient classification systems for ambulatory care in Europe

The definition of a MBDS in ambulatory care which is of paramount importance in the frame of health care delivery systems will allow the requisite preparations for the harmonization of medical data classification systems.

Definition of research and development requirements in software and hardware to allow competitiveness with the US and Japan

Building on the advanced professional know-how in ambulatory care in Europe and the considerable experience in the field of financial data on ambulatory care, the work will define software and hardware specifications for medical data classification systems in ambulatory care.

2.3. **Semi-automatic encoding of standardized medical data classification systems in Europe**

Objectives

— Encoding and decoding from natural medical language to international classification systems.

— Automatic grouping of these classifications into sub-classifications related to costs (DRG's for in-patients and AVG's for out-patients).

— Harmonization of rules for medical data classification systems in Europe.

This work has a strategic importance for the development of coherent health indicators and thereby health services standards, as well as the development of harmonized medical information systems that could generate a large industrial market for medicine in Europe.

Scope

Specifically the work is to concentrate on two major areas of activity:

Development of standards for diagnoses in European languages

This work aims at meeting the need for standards in extensions of the ICD-9 coding scheme for diagnoses in Europe. Semi-automatic programs for encoding medical diagnoses will be designed and then made available on a European scale. Coding could be part of an expert system front-end which, apart from coding transparently from free-text input will incorporate context-specific coding and automatic error detection and corrections.

Development of standards for procedures in each European language

Comparisons will be made between national procedures for coding schemes and between extensions of international classifications and nomenclatures that are currently being generated in several European countries. The appropriateness of those classification schemes will be examined in relation to their use for different purposes: epidemiology, cost control, severity of cases, quality of care, clinical research and management at all levels. Application specific coding structures will be investigated, allowing for terminology expansion and refinement for data transmission in processable form.

These procedures must be compatible with DRG's and AVG's, which requires the development of editing programs and grouping programs.

2.4. **Development of European criteria to define severity of cases**

Objective

The objective of this part is to obtain a simple set of criteria to determine the severity of cases in hospital and in ambulatory care, allowing the better assessment of the productivity of health services in all European countries. Work in this domain will provide a better understanding of the cause of health care costs, a better control of costs adjusted to the need of the population, and a large potential for the market of hospital information services and ambulatory care systems.

The strategic importance of this work is summarized hereunder:

— variations in costs have been shown in the USA as well as in some European studies to be largely dependent on the severity of cases, but criteria to define 'severity' are not yet standardized, even in the USA,

— criteria of severity should be easily available countrywide. They can be based either on an analysis of the content of the

MBDS or on physiological signs (like the Apache system in intensive care).

Scope

Physiological indicators

The task is to select physiological indicators in relation to intensity of care and severity of cases, with linkage to financial data.

Complications and procedures in DRG's

The work in this domain is aimed at refining the definition of DRG's in relation to intensity of care and severity of cases, with linkage to financial data.

3. DATA STRUCTURES AND MEDICAL RECORDS

Description

As information requirements are identified, the data to meet those requirements must be carefully defined if they are to be consistent, aggregated, manipulated for a variety of purposes, exchanged and shared. As the data will be processed and stored in computers of different types at different locations, they must be seen within a model which defines their structure. This is a prerequisite for the computerization of medical records. Regarding the broad medical market with abundant varieties of initiatives in hardware and software developments mostly without conceptual links to each other, only major breakthroughs in the conceptualization and development of the medical record can dramatically enhance the quality of medical care and at the same time really open the market as the doctor is the major actor in the field and provides the main market target. The potential growth of the demand is therefore very strong, but first requires standardization and harmonization work to be achieved at European level.

Objective

The objective of this part is to stimulate work at a European level in the development of medical data and process models as a key to progress with information technology in health care, and to foster concertation on the common functional specifications and minimum standardization required for the computerization of medical records and progress in portable storage techniques.

Scope

To meet these objectives, this part would comprise three major areas of activity:

— clinical data and process modelling, the development of which is essential not only for information transfer across boundaries, but also as dynamic reference models for voice input, image processing and so on,

— specification of the functional requirements for a general distributed medical record,

— common functional specifications and harmonization proposals for patient data cards to be used for storage of a single patient's relevant data.

3.1. Clinical data and process modelling

Description

The lack of transferable understanding of a set of facts is often a serious impediment to the solution of day-to-day problems and to long-term progress. This is particularly true in medicine, pharmacy, therapeutics, and biotechnology, where there is a data set which needs to be understood by a non-specialist in that particular data. Clinical data modelling needs to be developed for ensuring transferability of data and processes. In principle, the clinical process (a patient's entry to, passage through, and exit from clinical care) can be expressed as a series of related data and process statements. These can be formally encoded to provide a scheme describing the care of the patient. Since the scheme is based on the patient and the disease, there is minimal dependence on style of practice.

Objective

The objective is to design standard clinical data models acceptable across Europe. This will enable the reference model to operate in any required direction at any required level of care.

Scope

Specifically the work is to concentrate on:

Development of a common coding set

The task is to develop a common coding set integrating the requirements of medicine and data protection. Medical codes are necessary as they provide a satisfactory compressed base for truly transportable systems, independent of the user language and the host system; they satisfy an increasing need to produce statistical analyses of reliable demographic data on an international scale; they are required to provide common links for medical expert systems; data protection can be built into codes in fulfillment of national obligations, yet the embedded code is still transportable between different systems and different users.

Development of common data formats

Common formats are required to represent diseases and therapeutic processes. They optimize transfer of data and process information which thereby become independent of communications and of host systems. Transferred data can immediately be reconstructed, whether it is read from an input communications line, a magnetic tape or a smart card.

Correctness, validation and verification

At present there are no formal rules of medical correctness for validating medical expert systems. One of the great applications for expert systems in medicine is their role in defining 'normality', thereby saving staff appreciable time and effort which can be more efficiently directed to solving the problems of abnormality. Correctness of medical expert systems is therefore central to the development of biomedical informatics, especially as prac-

titioners thereby know that a particular system for clinical use has been formally validated as correct.

3.2. General distributed medical record

Objective

The objective is to design a record system that should provide easy, flexible structuring and summarizing of complex patient records and be integrated with the decision support functions. The record system must both aid in the care of individual patients and support studies of populations for research and 'anticipatory care'. Above all, doctors must find that its usefulness repays the effort of entering data and the maintaining system.

Scope

Conceptual studies will be undertaken to clarify the potential of a harmonized approach to a medical distributed data base/ transaction model. Major interest will be focussed on the approach of distributed transaction processing.

Identification of common functional requirements

Main activities will be directed to clarifying the requirements for developing model hospital information systems and model regional systems using the new techniques of distributed transaction processing based on medical standards of data exchange.

Development of standardization proposals

Standardization developed in this context may finally lead to data exchange protocols on the medical application layer conform to the OSI concepts.

3.3. Medical record system/data cards

Description

As the central source of information for all forms of clinical practice, the medical record is a key issue in the computerization of medicine. The choices made in the design of computerized medical record systems, which determine not only how medicine can be practiced, but also how changes can be made in practice or in computerized activities, are vast and affect many aspects of medical communications. There are several issues relevant to an efficient medical record system. The ability to develop systems on a European basis requires answers to the following questions: what should be stored in a record? How should information be stored? Where should data be stored? What medium should it be stored on?

Objective

There are several issues relevant to an efficient medical record system. Any strategy in information technology for health care will depend on projects incorporating studies on the design and use of medical records. In this section reference is made to patient data cards to be used for storage of a single patient's relevant data. The conceptualization and harmonization of this developing technology has to be thoroughly prepared in order to develop standards efficiently.

Scope

Specifically the work in the following areas is envisaged:

Card technologies

The task is to stimulate collaboration and concertation in the analysis of the requirements and opportunities in card technologies, e.g. improved storage capacity for smart cards, mixed smart-optical cards, readers, writer-readers.

Pointers

Adequate addressing is required for use of pointers which, stored on the card, would allow retrieval of certain information, such as X-ray pictures, if necessary.

Archival storage

New techniques for adequate archival storage have to be investigated.

Picture storage

Compression techniques for picture storage require further developments.

Medical records storage

The task is to define methods for storing medical records in a hierarchical fashion, from a brief description of episodes, information used to reach a diagnosis, and related data.

4. COMMUNICATION AND FUNCTIONAL INTEGRATION

Description

Medical informatics still relies to a large degree on isolated solutions implying costly and wasteful procedures of transferring information between the different processes occurring in the health care system. Establishing communications between the range of equipment and systems in use and under development offers considerable saving in terms of cost, but even more importantly in terms of time and flexibility. Beyond establishing the ability to transfer and access information there is the potential of removing some of the inherent redundancy in stand-alone equipment and facilities. This is referred to as 'economies of integration' and means simply that as a result of functional integration resources can be shared between equipment and facilities giving a considerable improvement in cost-performance and flexibility.

However, the benefits of 'economies of integration' require the realization of functional integration and inter-operability going beyond the simple exchange of information.

Objective

The work in this part is to investigate requirements and technology options in the domain of medical communications by

concentrating on some specific aspects of particular importance for future developments.

Scope

The scope includes the consideration of the information flow and communication functions specific to the health care system. The proposed work is structured in distinct work areas described below.

4.1. Hospital information services

Description

The functioning of a hospital is highly information-intensive and has very stringent requirements. The information needs to be available when and where needed often with no advance notice or even real-time; the system needs to function in a reliable manner; the services it offers must be well adapted to both the medical personnel and, in parts, to the patients, placing considerable demands on the human factor engineering of such systems in order to make them user-friendly.

These and other requirements specific to the hospital environment make hospital information services an issue requiring special attention.

Local area network techniques as developed for office automation will provide the basis for the development of information services in hospitals, but additional efforts will be required to meet the specific needs of health care.

Hospital information services require an interactive computer based system which will progressively integrate and automate the entire flow of information in a hospital. Although there are still discussions about the choice between hierarchical and relational data bases for information systems in hospitals, the trend is towards integration of patients' information at the data level. Hospital information services in the 1990s will be provided from a central data base where diagnoses and procedures will be part of the long term patient abstract. The data base will be analyzed through a query language and accessed through a central communication system. The collection of data will be done from peripheral units or personal computers at admission and discharge points. Encoding will be facilitated by a data dictionary, a knowledge base editor, a data interpreter and a knowledge base.

Objective

As there should be no formation of internal frontiers to health care it is of great importance to start the reflection on the requirements and functional specifications of hospital information services early enough to permit a coherent development in this sector facilitating the collaboration between hospitals, of hospitals with insurance and administrations, and also to make the hospital administrative procedures easier and more transparent to patients.

Harmonizing present efforts and at the same time preparing actions for the future require focussing on the definition of a hospital information network. Within this initiative the objective would be to obtain a close collaboration of European industry and health care experts in the investigation, conception, designing and development. A major advantage of such a development would lie in the further foundation of a European-wide standard in medical local area networks which could be used in connection with other efforts in harmonization to develop an attractive market and to contain health care costs.

Scope

Further developments in technology, notably in the areas of communications, local area networks, distributed processing and data-base systems/techniques as well as in the progress made on the agreement to international technical communication standards, mean that the present emphasis in the area of hospital information services is on the integration of the different functional systems within a hospital into one unified information planning and management system.

The scope consists therefore in bringing together the relevant European companies, the health care specialists and health economists to develop the basic design and prerequisites for a common standard in hospital information networks.

Specifically, this work will have to include the consistent investigation of all the main aspects of integral information processing, i.e. medical standards for data exchange, medical bus, interconnection to medical instrumentation, and so on.

The medical information bus

The task is to define a standard communication protocol for instrumentation used in hospitals, particularly for intensive care. A wide range of instruments used in hospitals lack a common means for data acquisition, and often lack computer-addressable interfaces. Furthermore the development of closed-loop control for drug infusion or ventilation has accentuated the need for a simple means of computer control. The medical information bus is explicitly designed to meet these deficiencies and needs.

Picture archiving and communication systems (PACS)

The object in developing PACS is to assist the tasks of storage, archiving and transmission of images in diagnostic radiology departments. Ultimately techniques developed for this purpose may also be extended for other medical communication purposes and even for other functions. The specific task here is to support the work carried out by European actors in the identification of the common functional requirements of PACS.

4.2. Wide area biomedical information services

Description

Within modern health systems there is a growing need for wide area communication services. This is due to several reasons, the major ones being the promotion of primary health care (including home care), the propagation of real-time information regarding transplants, drug security, nutrition, environment, etc. Other aspects of health care also require wide area services, e.g. the linking of laboratories in quality assurance programmes, etc.

Typical user requirements of wide area biomedical information services include the provisions of general clinical data, the transfer

of laboratory analytical data. This implies the exchange of data files of several megabytes concerning structural analyses or digitized images.

In the related research areas there is a need for unrestricted access to the large data-bases and collections which form the basis for modern biotechnology. Among these are:

— nucleic acid and protein sequences,

— structural data on proteins and biopolymeres,

— genetic maps,

— vectors for nucleic acid sequencing.

A start has been made under the BAP which provides for improved access for researchers to nucleic acid and protein sequence data-bases, to a monoclonal antibody data bank and to strain collections. However, this access needs to be extended to encompass structural data, genetic mapping libraries, cloning vectors and bibliographic data-bases, etc. and to take in industry as well as academia.

AIM is in this context to develop new tools to address these objectives.

Objective

The objective is to offer a universal solution to the need for a common biomedical network which takes account of such aspects as time zone differences and holiday periods in Member States, and also the need to deal with functional aspects such as unread messages.

Scope

It can be expected that most wide-area communication needs for health care applications will be met by the general development of telecommunication services, i.e. requiring no specific actions to be taken. However, the use of these techniques for health care may raise a number of operational, regulatory and political issues which need to be identified in time and for which appropriate answers need to be found. These may well impact the technical and operational features to be developed. For these reasons this limited analytical work is included as part of the pilot phase.

The scope will include preparative work on electronically- or optically-linked terminals, and on link by a portable medium such as a compact disk.

4.3. Data protection/authentication/fail safe

Description

In the context of health care some of the most sensitive data-protection issues arise. Data protection is a fundamental aspect of data handling which will gain in importance as health care networks grow, as information networks grow, as the community becomes more litigation conscious, and as information gains in commercial value in response to the world-wide competitive position of Member States. As a consequence, consideration of data protection becomes enmeshed with details of international standards, network developments, computer architectures and the means by which data transferable systems will work independently of system and network architectures. The issue is complex, for data protection has to be very high for the individual, yet the mechanism of data protection has to be sufficiently transparent, so that it does not impede the legitimate and authorized use of the data.

Objective

Positive identification of authorized users of data is an important issue which needs to follow the organization and management of health care. Fail-safe considerations are also application specific. The standards developed, e.g. for office automation, are not necessarily adequate for health care. The objective of this work is therefore the identification of the functional and technical requirements as derived from the needs in health care.

Scope

The scope of the work will include all generic information handling operations in health care and the supporting services. It is to include the concerns of the individual, whether as patient, doctor, researcher, economist or legal specialist.

4.3.1. *Assessment of the data protection, authentication and fail-safe requirements in MBI*

Objective

With the participation of the main actors concerned with the development and use of MBI systems, the issues of data protection, authentication and fail-safe requirements are to be investigated for the health care applications. This will be done based on a critical assessment of the state-of-the-art with respect to the requirements. The result will be to identify measures and actions to provide adequate solutions.

Scope

Data-protection aspects involve all areas of data acquisition, transmission, filing, interpretation. The scope involves therefore several aspects such as, e.g., in-house systems, regional systems, data cards, etc. It also includes related aspects such as data interpreting.

4.3.2. *Development of international medical data-protection protocols*

Objective

The objective is to specify the requirements for protection-based information handling tools in order to ensure user confidence in high-efficiency information handling systems.

Scope

The scope of the work is to:

— develop a coherent set of good practice rules from which data-protection principles can easily be adopted as part of the national legislation for medical information handling,

— meet the need to link data protection in computer networks and individual host machines to systems of patient-portable data such as data cards,

— devise data-protection rules for development of intelligent-knowledge based systems, building on the satisfactory map-

ping of certain questions concerning the data and process aspects of disease into open systems interconnection protocols,

— foster further research on design of large scale data-protected networks. These aspects include encryption, addressing, authentication of sender, authentication of recipient, notification of dispatch, notification of arrival, freedom from error, indelible audit of information trails,

— define the most effective algorithms for solving the abovementioned issues,

— contribute to the further development of existing open systems protocols in order to satisfy the medical data-protection requirement.

5. BIOMEDICAL EXPERT SUPPORT SYSTEMS

Description

Expert support systems — the marriage between computers and management science — are a promising development as expert systems and decision support systems are merging to create the software support required for a new type of computer system.

Decision support systems were developed within the data-processing world because of the practical limitations of data processing for helping people solve complex problems in actual organizations such as hospitals or national health organizations. Expert system technology reflects a largely independent evolution that took place in computer science research laboratories in answer to the limits of traditional computer science techniques for solving the complex problems that people can solve. These two separate progressions can now be united to help solve a broad range of important practical problems.

Objective

The objective of this part is to explore the opportunities of expert support systems in the field of health care and to identify the common functional specifications prerequisite for the emergence and development of a competitive European market for this very promising area.

Scope

To meet the objective stated above, this part would comprise the following tasks:

5.1. Biomedical expert and knowledge-based systems

Description

Whatever the speed and success of expert systems developments in medicine, the already observable impact in standard products of medical informatics reaching from dedicated systems to full size hospital information systems are remarkable and could even be more important in a broader sens of quality assurance in medical care. The same holds for the impact on biomedical training.

Expert systems can improve the quality of medical actions by increasing the accuracy of diagnoses and more specific and individualized recommendations for medical treatment.

Expert systems can also contribute to control cost of care:

— mistakes are reduced thus allowing for a more efficient problem handling,

— the diagnostic process can be shortened or logistically simplified (in the sense that less referral from institutions to others is required),

— patient-oriented expert systems will enable more patients with chronic diseases to navigate their disease effectively.

Objective

The objective of the work here is to identify requirements and opportunities for expert and knowledge based tools in medical care and related research domains.

Scope

The task is to investigate and demonstrate the feasibility of European cooperation in the development of artificial intelligence tools for health care and related research. In order to limit the scope it is suggested that the task be restricted initially to a specific medical problem area, e.g. diabetes. On-going collaborations could form the basis for such an initiative. This experiment would help to develop the empirical background on which to judge future work towards sharing of diagnostic tools and other health care features. Specifically it would be expected to show the impact that these developments could have on quality and cost containment in health care. Main tasks would include:

— definition of a framework for expert systems in medicine,

— analysis of knowledge representation,

— analysis of medical reasoning,

— analysis of the interfaces,

— interaction between expert systems and other types of systems.

The framework for expert systems in medicine

The areas of medicine and health care in which it is possible to apply expert systems are to be identified and the possible conditions for their effective use are to be analyzed.

Knowledge representation

The types of knowledge used in health care are to be analyzed and the way in which the usual techniques of artificial intelligence can exhaustively capture that knowledge is to be studied.

Medical reasoning

The various types of expert systems usable in health care (diagnosis, description of possible scenarios, planning with their

respective architectures are to be analyzed, focussing attention on the procedural aspects and those that are supposed to be meta-knowledge.

Interfaces

Starting from an analysis of the existing interfaces used in expert systems, the characteristics that the interfaces for the next generation of expert systems should have are to be studied, focussing attention on both natural language and graphics.

Interaction

The types of systems already existing in an information system (decision support systems, mathematical models and statistical package) that will have to interact with expert systems will be analyzed as well as the type of interaction. Data bases, especially those that have a universal relation interface, will be also considered.

5.2. Dedicated computer language tools

Description

It is proposed to investigate the feasibility of a 'macro language for health care', i.e. a language building on general purpose languages but having special features facilitating their use in health care and related research.

Objective

Usefulness, developmental speed and acceptance of applications on medical communication systems would be greatly increased if a computer language existed that would support applied nomenclatures and classification schemes as well as their further development: meta-information as a tool of integration. The objective of the work is to explore the options for a computer language that could support the design and usage of application software in terms of medical and health organization meta-data and their contextual (semantic) and syntactical relations (semantic data models).

Scope

This work could build on the work in ESPRIT and on progress made in other countries relating to this objective. The pilot phase could help clarify the chances of success and the timeliness of such an initiative. The work could also include some exploration of semantic data models for medical data-base developments.

5.3. Special information processing requirements

Description

Health care and related research very often require the processing of images or other problems entailing extremely high computing power. Although there are a number of European ventures in novel processors or super-computers, further research and development is needed before they can find an application to the problems in health care and the related research areas particularly biotechnology.

Real-time high-speed processing of medical information is required in several areas including:

— image processing [1],

— voice processing,

— real-time and greater-than-real-time modelling,

— development of neuromuscular prostheses,

— network management.

Among improvements which real-time high-speed processing could bring to biotechnological research are:

— a substantial increase in the quality of information displays on the screen,

— the spreading up of multiple iterative calculations for the validation of computer modelling of proteins.

Objective

It is proposed to examine the options and the comparative advantages of special purpose super-computers for the domain of health care and biotechnological research (this does not mean that other application areas may not have similar special purpose requirements). Specifically this work would investigate concurrent high order integration computers for biomedicine.

Scope

The scope would include the design and the requirements for its development, as well as the assessment of the potential field of application in MBI and other domains of similar needs.

This work can build on the work carried out in the framework of ESPRIT and national programmes in this domain as well as the experience in other countries working in this area.

5.4. Human-computer interface

Description

As information processing systems require data input from medical and other staff, great weight needs to be given to the development of the user interface. In particular, there is a strong need for a clear demonstration that these systems will be of benefit to the user who has to input the data.

Objective

The definition of European standards and their feasibility requires a specific effort which is the objective of the work defined here.

Scope

The general usability requires as much harmonization as possible in the human interface, regardless of the special medical application. It has to be developed to serve under the special working conditions of doctors taking into account also the requirements for efficient data protection.

[1] Medical scanning accounts for 11% of the US image-processing market. Fast-developing applications range from dynamic cardiac imaging to fracture analysis and use of biosensor-derived information.

5.5. Flexible open-architecture inference systems

Description

Use of information technology by physicians will largely be affected by the future developments in artificial intelligence which will require the ability to offer high-speed graphics and inferential processing in a form accessible to a large market of practitioners. In practical terms though, present developments are of limited usefulness as they neither provide integration with every day system aspects, as e.g. the patient data-base, nor provide for interconnections or transferability. To realize its potential usefulness, artificial intelligence has to be part of an integrated concept, where it plays the role of the assistant in every day work.

Objective

The objective of the work in this domain is to design a 'flexible open-architecture inference system' as well as investigate its potential with respect to the technical features needed for efficiency and adaptation to user needs.

Scope

The scope is aimed at the definition of a high-level operating system which, using in-built expertise, can speedily and unambiguously interface with quite different system functions from different positions within the system. Specifically the task is to analyze and assess the requirements for the design of a net of interacting experts, in which every expert gets the same initial data and during the consultation process the output of the others. Further realization may be in a system of local distributed experts connected by a local area network or one computer with parallel processing facilities.

6. BIOMEDICAL INSTRUMENTATION AND RESEARCH TOOLS

Description

Biomedical instrumentation is one of the key factors of progress in MBI and is crucial for its future development. Information technology embedded in biomedical instrumentation represents the single most important factor in the explosive advance achieved in biomedical research. The crucial importance of integrating advances in all technological domains including, in particular advances in information technology, telecommunications and broadcasting is expected to persist for the coming decades.

While European scientists rank high in the international comparison, the productivity of their work is lower, i.e. the time spent for a given research result is very much higher. In other words the productivity of European research and development, not the quality, is lacking compared with other developed regions. This is to a large extent due to inadequate progress realized in biomedical instrumentation and the integration of information technology.

The performance of the Community in the timely adaptation of concepts and objectives to the technological advances will be decisive for the cost-performance of health care and also for the international competitiveness in offering health-care products, equipment and services.

6.1. Integrated biomedical laboratory

Objective

The objective is to investigate the options for realizing major improvements in research and development productivity in health care and related technological work by a concerted effort in biomedical instrumentation with particular reference to the role of MBI. The specific concept to be explored is that of an integrated biomedical laboratory.

The systematic development of the MBI as applied to biomedical laboratory activities could lead to the realization of integrated biomedical laboratories bringing a considerable improvement in the cost-performance, quality, flexibility, reliability and speed of biomedical research, i.e. have a major impact on the research and development productivity in this domain.

Scope

The scope of investigation of an integrated biomedical laboratory should include:

— integrated measurement of biomedical variables in vitro and their interpretation,

— in-vivo sensors for diagnostics and therapy,

— image and data interpretation,

— computerized scanning,

— magnetic resonance imaging (MRI),

— endoscopy, particularly video-endoscopy,

— picture archiving and communication systems (PACS),

— biochemical analyses,

— gene mapping,

— protein characterization,

— cell screening.

The result is to give clear indications as to the comparative advantages of the concept of integrated biomedical laboratories compared with other options of advanced approaches to instrumentation. Furthermore this work is to result in the definition of implementation concepts and the specification of the related technological work and indicate the key factors which would need to be taken into account.

6.2. Biomedical knowledge bases

Description

The complexity and volume of medical and biotechnological information is considerable and growing at a rapid rate. Tens of thousands of genes control specific life processes, three billion units of DNA form the human genome. With current techniques, sequencing these three billion units could consume 3 000 man-years. However, automated DNA sequencing machines are under development which may cut costs of sequencing a gene to a fraction of an ECU within the next decade.

Similar progress is being made in the analysis of other biological materials and in work on the molecular basis of medicine and therapy. However, much of this progress depends on the effective management of the information acquired. Here the design and development of biomedical knowledge bases is a central issue.

Objective

The objective is to identify and assess alternative approaches to manage biomedical information systems and avoid overloading. This requires the rapid storing and sharing of information from medical, pharmaceutical and genetic research.

Scope

The information system and therefore the related knowledge bases need to support biotechnological and genetic research as well as the development of pharmaceutics, medical research and medical care. The reason for this need derives from the increasing use of diagnostics and therapy based on the understanding of genetic and biomolecular processes.

The scope of the work would initially include the issues of effective information acquisition, organization, maintenance, retrieval, access, for biotechnological, pharmaceutical and medical uses.

The result of the exploratory work would serve to identify and assess the options for effective and economic management of genetic and biomolecular information.

6.3. Automated DNA sequencing

Description

Progress in biotechnology has led to new techniques for diagnosis, treatment and prevention of disease. Most of these — from new vaccines based on recombinant DNA to the creation of therapeutic proteins for the treatment of cancer or heart disease — depend on rapid and economic sequencing of DNA.

Over the past decade the rate at which DNA can be sequenced has increased to several thousand nucleotides per day. US and Japanese teams are developing automated DNA sequencers which will increase this by several orders and also reduce the cost.

Objective

The objective during the pilot phase would be the examination of the options for European cooperation in the development of automated DNA sequencing. The special emphasis would be on the application of advanced CIM techniques to achieve high productivity and reliability of the results. This would be pursued in close collaboration with biological researchers who are already involved in the BAP programme in improving sequencing techniques.

Scope

The work is to include the systematic assessment of requirements and technology options for automated DNA sequencing.

6.4. Automated protein analyzer/synthesizer

Description

Besides DNA there is a whole range of biomolecules playing a key role in medicine and biology. The problems of analyzing structures and synthesizing them in a controlled manner is of paramount importance for therapy on the molecular level.

Objective

The objective is the development of an approach to automated protein analysis and its linking to protein synthesis.

Scope

The scope of the exploratory work to be included here extends to medical, pharmaceutical and biotechnological requirements for protein analysis and synthesis. The work is to address primarily the potential of MBI and CIM.

7. NON-TECHNOLOGICAL FACTORS

The orientation of technological efforts towards meeting socio-economic needs implies taking into consideration the context in which the technology is to be used. The optimal use of resources implies furthermore that the organization and management issues are equally taken into account. The political nature of high technology requires that even at the stage of pre-competitive research and development these aspects are assessed and the implications brought to the forefront.

This part of the pilot phase is dedicated to analyzing and assessing some of the non-technical factors embedding this initiative in the wider context of related activities.

7.1. Investigation of the opportunities of closer collaboration between national actions

There is already a large effort under way within Europe and excellent work is being done. However, due to the predominantly national orientation of these activities, there is a significant amount of redundancy in the work being undertaken and the possibilities for synergy often remain unexploited.

The investigation proposed as part of the pilot phase is to develop measures to assist existing actors in identifying related activities and establishing collaboration where appropriate. The investigation and consultation will also include the formulation of recommendations to facilitate the common exploitation of results and transfer of technology.

7.2. Review of the functional specification, standardization and certification practices

The problem of coming to agreed functional specifications and minimum standardization for the use of information technology and telecommunications in health care and related research is complicated by the need to combine the efforts of these organizations focussed on health care and of others oriented towards information technology and telecommunications. In addressing the issues of MBI one will wish to build on existing standardization bodies. In order to achieve an effective approach and in view of the national differences and the multitude of organizations already involved in one way or the other it is proposed to carry out a survey of standardization, specification and certification practices in Europe and internationally. This work is to result in a recommandation as to the optimal approach to addressing future requirements in standardization, specification and certification in Europe.

7.3. Review of the legal and regulatory framework applying to MBI

The use of information technology and telecommunications for health care needs to include appropriate regulatory and legal

measures to assure the protection of patient interests as well as the commercial interest of service providers and operators.

In order to avoid the formation of new internal frontiers in the Community there is a need to engage in an effort aiming at the definition of common rules and conditions for the introduction of MBI.

As a starting point for so doing it is proposed to analyze the present regulations and legislations governing the use and introduction of MBI. The work is to result in the identification of the options and measures which could be developed in order to support a harmonious development of the regulatory environment for MBI applications in Europe.

7.4. Economic assessment of the MBI potential for health care and biomedical research

Besides the qualitative advances MBI offers for health care the potential of cost-containment is the most important contribution to be looked for. However, the relationship between the performance of a technology or a service and the impact on improvements in cost-performance are not straightforward. They depend on numerous other factors and conditions which need to be understood and taken into account. It is, therefore, proposed to investigate the economic impact of MBI on health care and on the supporting services, in particular biomedical research. The result of this work is expected to provide an understanding of the economics of information in health care and indicate the way MBI can make the best contribution to improvements in cost-performance of the overall system.

7.5. Assessment of special skill training requirements and options to meet them

For the exploitation of opportunities created by technological advance special training plays a key role. Typically the professional staff in place have received their education some 10 years back and even at that stage the education may not have been up to date. Of course there is a considerable investment in adult education and training, but in areas which are evolving very rapidly, as in the case in MBI, special efforts will be needed to overcome the difficulties of technology and knowledge transfer.

The work proposed as part of the pilot phase is the assessment of requirements and the development of a scheme for special skill training directed at familiarizing researchers and practitioners with the potential of advanced MBI.

FINANCIAL STATEMENT

1. Budget Heading: 7345

Advanced Informatics in Medicine in Europe (AIM)
- Pilot Phase -

2. Legal Base: Article 130

3. Description of project

The global objective is to serve the concertation of European efforts towards

sustained improvement in health care in the Community for the 1990's within economically acceptable limits by exploiting the potential of Medical and Bio-informatics.

AIM is an action of which the present proposal is a Pilot Phase, which seeks to concert the development, on a European scale, of the Medical- and Bioinformatics (MBI) services, equipment, systems, tools, standards, functional specifications and conventions for health care, by building, incrementally, on equipment, systems and services devised for other uses, and on complementary actions to realize in the shortest possible delay the advantages of technological progress for improving the quality and cost-performance in medical care and its supporting services. The Pilot Phase has 3 Lines of Action.

Action line I:
Improvement of the effectiveness of public and private actions
by means of
the development of a common conceptual framework for cooperation at the planning and management level

Action Line II:
Strengthening Europe's posture in MBI and health care
by means of
cooperation in pre-normative and pre-competitive technology exploration concentrating selectively on re-inforcing and complementing teh technology base of MBI and its services

Action Line III:
The creation of an environment favourable to rapid progress in the introduction and appropriate application of MBI in health care
by means of
the development of specific proposals addressing the policy, regulatory, legal, organizational framework of MBI applications including the training and manpower related factors.

4. Justification of the project

Health is next to food and shelter one of the basic human needs. Conscious of the high priority of health care and of the growing possibilities, but also of the cost constraints, the Community needs to optimize its efforts towards this common objective. Sector actors have joined the Commission in identifying actions which are suited to make best use of limited financial, human and technological resources to exploit the technological advances in Medical and Bio-informatics so as to bring the maximum care to the patient while staying within reasonable limits of expenditure.

AIM seeks, therefore, to take advantage of the progress made in information technology, telecommunications and mobile communications to contribute to qualitative advances in medical care and improvements in the cost-performance by means of actions suited to accelerate progress and to establish synergy between different streams of development and actors.

MBI equipment and services represent also a major future market opportunity for Community industry, but it will require quick and determined steps to increase the efforts in this direction and to make better use of existing human, industrial and financial resources, so as to match the increasing commitment to this domain in other parts of the world.

5. Financial implications for the intervention appropriations [1)]

5.0 Implications for expenditure (Million ECU)

5.0.0 Total cost over the whole of the expected duration:

From the Budget of the Communities:	20.00
From other sectors at the national level:	17.75
TOTAL:	37.75

5.0.1 Multiannual schedule

Commitment Appropriations	1987	1988	1989	1990	1991 and later	Total
Contracts	-.-	0.85	13.59	3.31	-.-	17.75
Personnel Costs	-.-	0.10	1.10	0.49	-.-	1.69
Administrative Costs	-.-	0.05	0.31	0.20	-.-	0.56
Total	-.-	1.0	15.0	4.0	-.-	20.00

Payment Appropriations	1987	1988	1989	1990	1991 and later	Total
Contracts	-.-	0.35	6.09	7.31	4.0	17.75
Personnel Costs	-.-	0.10	1.10	0.49	-.-	1.69
Administrative Costs	-.-	0.05	0.31	0.2	-.-	0.56
Total	-.-	0.5	7.5	8.0	4.0	20.00

1) The Proposal for a Council Regulation concerning the Framework Programme of Community Activities in the Field of Research and Technological Development (1987-1991) COM(86) 430 final includes the provisions for this action under Action Line III.

5.0.2 Method of calculation

a) Expenditure by contract

This expenditure covers the Community's financial contribution to analytical work, pre-normative and pre-competitive R&D as required for identifying functional specifications, standardization and technology requirements, carried out normally under shared-cost contracts (research and development for a total of about 300 Man Years) to be concluded with health care equipment industry, service providers, research establishments, undertakings, including small and medium sized enterprises and other bodies established in the Community (average Community financial contribution - about 50% of total costs).

b) Operational expenditure

Administrative costs (management committee and working party meetings, consultation of experts, missions, document distribution or dissemination of techniques, use of data processing, telecommunication and broadcasting equipment).

c) Management staff expenses

The requirements of this project have been estimated on the basis of a staff of :

[9] temporary officials - category A
[2] temporary officials - category B
[4] temporary officials - category C.

This staff is requested under the Budgets 87 to 89.

6. Financial implications for staff and current administrative appropriations

(See sub-point 5 above - included in the general budget of the Commission)

7. Financing of expenditure

The appropriations required to cover the Community's contribution to this project are to be entered in the Community's future budgets.

8. Implications for revenue

- Community tax on salaries of officials
- Officials' pension contributions.

9. Type of Control

- administrative control by the Director General for Financial Control as regards budget implementation;
- Scientific Control:
  - Management Committee
  - scientific control by officials of the Commission
  - audit by the Court of Auditors in accordance with provisions of the Treaty.

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AIM and the SME's

AIM is relevant for SMEs since

- **it provides opportunities for start ups and other innovative companies to enter a high-technology application at a formative stage,**
- **it reduces the development and innovation risks by defining common functional specifications, minimum standards and concepts, thereby reducing the entry-barriers for SMEs, and**
- **creates opportunities for the direct involvement in pre-normative and pre-competitive work on a European scale.**

The object of AIM, as a complement to Medical and Biotechnological Research Programmes, is to stimulate and support the development of Medical and Bioinformatics which is a crucial infrastructure for progress both in health care as well as the development and application of Biotechnology.. The supply side is at the moment largely in the hands of a few specialist IT and telecom equipment manufacturers with the services relying largely on techniques developed primarily for other uses. However, in order to exploit the potential of MBI the practitioners, hospitals and innovative specialized service providers have a major contribution to make. Within the consistent framework for action in MBI to be created by AIM these innovative SMEs will be able to engage with a calculable risk and perspective.

Part of the development of MBI depends on the creation of a European market-place - ie a means whereby buyers know where to seek information on what is available and suppliers can let it be known what they have to offer. The market-place is thoroughly imperfect at the moment, even nationally, and AIM will help to make it function, via communications links and contacts, at the Community level.