Future Needs for Research Infrastructures in Biomedical Sciences

Report based upon a Workshop held in Brussels, Belgium on 16 March 2005, and organized by the European Commission, Research Directorate General, Directorate B (unit B3 “Research Infrastructures”) in collaboration with Directorate F (Health)

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1. Summary

This workshop was intended to encourage discussions on the needs for biomedical Research Infrastructures (RI) in Europe. The discussions aimed at identifying these needs, understanding the appropriate size and nature of infrastructures for responding to these needs, and leading to some guidance on how to implement the 7th Framework Programme (FP7), i.e. help in identifying the most efficient ways for supporting the identified needs.

The workshop was structured with individual presentations around seven general types of research infrastructures relevant to Biomedical Sciences:

- Bio-banks, living organism resources, molecular tools and reagents
- Protein structure facilities
- High throughput genome, genotype and proteome phenotype, sequence and interaction measurement facilities
- Bioinformatics, databases, software, resources and Grid-linked services
- Imaging living systems capabilities
- Ion and radiation therapy research facilities
- Clinical research infrastructures

For each general type, presentations described the current status, identified needs for the future and expressed specific requirements in terms of support and funding. Three additional presentations covered the European Science Foundation and Commission Surveys on existing and/or needs for new research infrastructures, as well as the work of the European Strategy Forum for Research Infrastructures (ESFRI).

Further horizontal issues were discussed through two round-tables. The following points were identified as being critical issues in the biomedical sciences:

- Data acquisition and treatment are very important for all infrastructures. Data generated in this domain increases exponentially even, especially due to new imaging and computational and high throughput capabilities. The handling, curation and accessibility to the data on the long term need to be taken care of.
- Biomedical sciences are a diverse and very fast evolving domain, with a wide range of sizes of infrastructure. As a first consequence, it is difficult to clearly identify RI needed in 10 years from now. However, it is at the same time an advantage that many infrastructures can be upgraded rapidly by incremental purchases of medium cost equipment. As a second consequence, there is a strong interdependency between research and the corresponding up-to-date RI. Consistency of the approaches with the thematic priorities is therefore required, with a better interlinking of RI to the needs of their actions. As a third consequence, the domain lacks coordination in some areas, but is highly co-ordinated in others, such as bioinformatics, structural biology, etc.
- There is a need for more integration with industry in order to reinforce innovation, funding mechanisms and for preventing investments draining toward third countries (mainly USA).
- Funding on a longer term for a wide range of biomedical infrastructures is needed. Too many actions and infrastructures seem to have suffered from interruptions in funding and short-term projects, e.g. in bio-banks and resource areas. Business plans (in the sense of not just commercial aspects, but a long term plan for the organisation) should be associated to RI projects together with assessment of success/failure.
- Time invested in preparation of proposals for EU funding is too high. The Commission must simplify procedures and financial regulations and shorten time-to-contract scales, for example by some version of a two stage proposal submission. However, the “Integrated Infrastructure Initiatives” (I3) is a very welcome and valuable Commission instrument. It is flexible, and could be improved by allowing more possibilities of upgrading infrastructures and equipment during the project. Also, clear and concise criteria for infrastructures and the ways of funding them need to be developed by the scientific communities for the political process, in particular for the Commission, European Parliament and Council. The Commission is indeed pulled in many directions. It is hard to meet all requirements and we need consistency in policies. On the other hand, there is a common concern regarding ESFRI biomedical committee “visibility” in the scientific community. A better communication including conferences is suggested.

2. Individual presentations

The workshop was structured with presentations around seven general types of research infrastructures relevant to Biomedical Sciences. The choice of category of biomedical and life sciences research infrastructure corresponds closely with categories identified by the European Strategy Forum for Research Infrastructures (ESFRI) steering group on “Biology and Medical Sciences”, and also to an European Commission conducted "Survey of European Research Infrastructures". In the following sections, each type of infrastructure is discussed, with specific features and needs identified.

2.1. The need for improved coordination of bio-repositories at the EU level (Bio-banks, living organism resources, molecular tools and reagents)

Martin Hrabé de Angelis, Co-ordinator of the FP6 project "EMMAinf", Neuherberg, Germany
Sean May, Director of the Notthingham Arabidopsis Stock Centre Bio-bank, UK

Examples were presented for animal tissue (mouse) repositories and living plant organism (Arabidopsis) resource centres. Even at the major EMMA http://www.emma.rm.cnr.it facility, it was found that a single centre cannot meet the community needs, and that linked resources at widely separated geographical location are necessary. At EMMA, 1500 genetic mouse lines need to be put into the archive, and future needs are exploding. A major bottleneck also occurs is disseminating results and resources. Is a one-centre concept possible? No, it is much too large, and distributed centres have much better links to research community. The proposal for the future is that the resource centres must be linked to enlarge capacity, include all lines, add new types and partners, and link to phenotyping centres. Long term funding is a major problem, and the possibility of means for renewing EU grants is essential, especially since the linked centres function at the European level.

At the Arabidopsis resource centre http://arabidopsis.info/, there are 500,000 accessions, with 30-40,000 per year being added, based on mostly national UK funding. A big problem is gathering data and samples from the research community, of which there is an exponential increase. Part of our business model includes cost-recovery by selling seed, and also by exporting. The centre also offers an Affymetrix service, and also has an important bioinformatics component for expression data (Array Express). The centre also sponsors conferences and training courses. From the point of view of the presenters, it can be seen that one way of categorising resource centres is the commercial value of their resource. Commercial (cows, tomatoes) versus science (mice, Arabidopsis) resources can be separated very clearly. Intellectual property is often a key consideration.

2.2. Facilities for Protein Structure determination. Status and future needs (Protein structure facilities)

Manfred Weiss, Research Dir. of the FP6 project "Bioxhit", EMBL-Hamburg outstation, Germany
Lucia Banci, Forum in European Structural Proteomics, University of Florence, Italy

The genomic revolution has open the need and the challenge of characterizing the products of the genome of a continuously increasing number of organisms. The knowledge of their structure is a fundamental and necessary step for the understanding of their function and of the processes in which they are involved.

Two main techniques are essentially used for protein structure determination, X-ray crystallography and NMR spectroscopy (Electron microscopy is also becoming important). X-ray crystallography, that was the first to be developed and applied, is the most extensively used. EMBL Hamburg http://www.embl.org/sites/hhsite.html is located on the site of DESY (German Synchrotron Research Centre) that provides synchrotron radiation (SR) through its DORIS positron storage ring. This radiation is used to study the structure and function of proteins using state-of-

the-art equipment and methods. It is important to note that DESY was built for high energy physics studies, and the synchrotron radiation is basically a by-product that we use for biological structures research. The EMBL Outstation operates seven SR beam lines, five of which are dedicated to bio crystallography, one to small angle scattering of biological samples and one to X-ray absorption spectroscopy (EXAFS). The research developments are paralleled by an integrated approach to carry out scientifically demanding projects in structural biology, with facilities in molecular biology, heterologous expression in prokaryotic and eukaryotic hosts, protein purification, biophysical characterisation and crystallisation, complementing X-ray data acquisition and processing infrastructure. Structure determination and interpretation is carried out on high performance computers and state-of-the-art graphics facilities. In biology, a major principle is that protein function is directly dependent on its structure. Currently 30,000 structures are available in worldwide databases, of which there are just 3-4,000 without redundancy. Of these, 80% have been determined by crystallography, and 90% using synchrotron radiation. There are 1000 times more protein sequences than protein structures. In the future we need a more integrated approach to determining structure, and need all facets done together. For example, in Hamburg, Petra III is an integrated life sciences centre. Upgrading of existing facilities is very important and cost effective. In the future, we need an assessment of status and needs (FESP, EuroSync), Networking of synchrotrons, Access, Investments into hard- and software, Continuous upgrade of experimental stations, Operation of facilities, Fedex data collection (needs staff support), and Additional facilities, e.g. Sample preparation, Sample characterization, HTP crystallization, Automated structure determination.

Nuclear Magnetic Resonance (NMR) is the other main technique to determine macromolecule structure. NMR spectroscopy allows us to study macromolecules of biological interest at atomic resolution in conditions similar to physiological ones. NMR allows us “to speak with nuclei” (with those having spin different from zero!) of specific atoms of the molecule and to achieve information, in addition to their position, i.e. the structure, also on how they move and on what surrounds them. Such information is used for the characterization of a protein. The study of the relationship between the three-dimensional structure and biological function of proteins, in physiological conditions, represents a field of primary importance. Furthermore, NMR is the most suitable technique to study protein-protein, protein-DNA/RNA and protein-small molecules interactions. Its power in this respect resides in the fact that most of the physiologically relevant interactions and weak and the various partners exchange with the free ones on fast time scales, thus preventing co-crystallization. NMR is the key technique in this respect as it is performed in solution and can detect even very weak interactions. On this respect it has also a tremendous importance and role in pharma industry in various steps for drug design and screening. The potential of the NMR technique in this field is great! NMR has allowed us to study and unravel structure-function relationships of metal coordinating proteins that are important for charge transfer processes, radical degradation processes and metal ion transport. CERM http://www.cerm.unifi.it is involved in post-genomic research in order to study proteins involved in important cellular processes. Calculation programs and mathematic algorithms (Bioinformatics) are also used in CERM to study several biological systems. This type of research is important for life sciences, for human health, for industrial development in the field of biotechnologies, giving, for example, a contribution to the development of new drugs (Drug design). A centre such as CERM has nine NMR machines, with field up to 22 Tesla. There are multiple centres around Europe, with access now provided on voluntary basis. The future needs are especially for funds to keep instrumentation updated (EC could support depreciation), acquire new advanced equipment, and to re-establish access. There is a continuous need for technology upgrades and advancements to follow up and promote the methodological developments in the field as well as the requests of genomic and proteomic projects. Future challenges include the full integration of structural biology with other disciplines, especially other areas of bioinformatics. A priority is characterising molecules linked to clinical information.

2.3. Infrastructures in Genomics and Proteomics (High throughput genome and proteome phenotype, sequence and interaction measurement facilities)

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Patrick Boisseau, Co-ordinator of the FP6 project “Nano2life”, CEA, Grenoble, France

Proteomics is a broad and rapidly growing field http://www.sdu.dk/Nat/CPA/. After the sequencing of the human genome, it is now clear that much of the complexity of the human body resides at the level of proteins rather than the DNA sequences. This view is supported by the unexpectedly low number of human genes, and the high estimated number of proteins (which is currently about 300,000 - 450,000 and steadily rising) generated from these genes. For example, it is estimated that on average human proteins exist as ten to fifteen different post-transitionally modified forms all of which presumably have different functions. Much of the information processing in healthy and diseased human cells can only be studied at the protein level, and there is increasing evidence to link minor changes in expression of some of these modifications with specific diseases. Together with rapidly improving technology for characterising the proteome, there is now a unique chance to make an impact in this area. Using cutting edge technology, the Centre for Proteome Analysis (CPA) can separate cell or tissue samples into more than 17,000 proteins. The resulting gel images are then quantitated accurately using image analysis software (written and developed in-house) to detect the subtle changes in levels of expression related for example to the development of a disease. This high resolution provides excellent separation of post-translational modifications, which is of critical importance since particular modifications often play decisive roles in disease development. These highly purified proteins (or particular post-translational modifications) can then be recovered from the gels, in amounts although small, sufficient for their identification by mass spectrometry, or to raise antibodies. The application of proteome analysis using 2DGE has allowed CPA to make discoveries with great potential relevance for treatment of a number of the major diseases, which afflict humanity, including diabetes, cardiovascular disorders (ischaemia, hypertension, heart transplantation), cancer (cervical, breast and colon), cancer metastasis, rheumatoid arthritis and neurological diseases (Parkinson's and epilepsy) and ageing.

Despite these encouraging advances, we also learn that 90% of cancer research might be considered a waste of time, since based on lab cultures, whereas proteins are modified everywhere in living systems. Moreover, little is happening in Europe to update equipment and facilities, leaving nothing to build on. We need a wide variety of new equipment, which becomes out of date quickly. To start a facility, 10-20 million euros are needed for equipment, and running the sources. The related equipment industry is all moving to the USA. In Europe, universities, industry and research teams must work together. We need 10-15 centres linked through Europe. More stable funding is especially needed, to develop the lab without walls concept. We should do basic equipment at national levels, since needs evolve so quickly. At EU level, we could fund new tools, new samples, new reagents. We have had huge initial developments in Europe (e.g. Lehrach at MPIMG invented expression chips), but these developments were entirely commercialised in the USA.

This new situation must be taken into account when considering the creation of new EU-level infrastructures for biological research. Many genome-related technologies have rapidly become commodities, and it is not necessarily worthwhile to create EU-level high-throughput genome sequencing centres or central facilities for expression analyses at the level of mRNA etc. These are services that should be supported at country or university levels, or by commercial organizations. Instead, there is a need for EU-level coordination for principally three kinds of genome-related infrastructures, namely ones aimed at ensuring widespread access to advanced tools, reagents, and to biological samples.

The need for research tools. A number of fundamental (and economically substantial) techniques for molecular biological analysis originated in Europe. Examples include monoclonal antibodies, Sanger DNA sequencing, and micro array technology. However, so far Europe has largely failed to capitalize on these developments as this initiative has been rapidly transferred to USA, with important consequences both for scientific and commercial applications of these technologies. Efforts to join groups working on next-generation molecular tools therefore could be valuable by providing the breadth of expertise required to create new techniques for biological investigations. Such infrastructures will also play a crucial role in the early and general dissemination in Europe of advanced molecular tools for biological analysis to academic scientists, to the biotech and pharma industries, and for applications in healthcare, forestry, agriculture, husbandry, and environmental monitoring. An example of such a project is the MolTools FP6 IP (www.moltools.org).

The need for reagents. Despite theoretical knowledge of the molecular composition of organisms, these factors remain largely inaccessible because of lack of appropriate research strategies – tools - as discussed above, and because specific reagents are needed. The need for appropriate reagents is particularly striking for the study of proteins. An infrastructure aimed at creating a precompetitive, that is generally available, resource of specific binders against all protein in e.g. humans therefore

could prove critical to enable a very wide range of biomedical research. Because of the strong European tradition in this research field preconditions for such an initiative must be viewed as excellent.

The need for samples. The accumulation of research tools and reagents for specific analysis of genes, transcripts, proteins and other cellular components will enable extensive analyses in large numbers of samples. What was done once with great difficulty for decoding the human genome, will be repeated for parts or whole genomes in patient and other samples. The ongoing characterization of basic mechanism for transcription control will be repeated for individual patients, and individual tissue samples, and following time-courses to study mechanisms of disease and find diagnostic and therapeutic targets. The same applies to studies of other organisms, and it is important now to organize the collection of samples, to ensure harmonized good practices that optimally preserve biological information along with high-quality information about clinical history etc. Ethical questions concerning the collection and use of patient samples also must be considered. The value of creating European-level bio-banks of collected samples lies in the potential to identify for any given disease sufficient numbers of samples across Europe to reach sufficient numbers for statistically sound analyses, upon mutual agreement between collaborating scientists and with the approval of sample donors.

Concerning the needs for nanobiotechnology:

- For developing European nanobiotech not only in academia but more important, for supporting their industrial development, we need research infrastructures open to a large number of scientists from public and private partners to support their experiment, and also to train them on these new technologies
- Because there is no unique costly equipment needed for nanobiotech but rather a range of complementary equipment, no large central facility like ESRF is needed but more distributed specialised platforms like for instance analytics in Münster, integration in Grenoble-Lausanne, Bio-interface in Barcelona. They should be specialised to prevent again duplicates and fragmentation we are fighting hard.
- In coherence with the on-going preparation of EIN (European Institute of Nanobiotech), we believe that besides their European objectives, these platforms should have a regional policy for supporting regional research and training of scientists to support the regional development of nanobiotech clusters.
- The detailed definition of the objectives and the content of these platforms should be tightly associated with the on-going preparation of EIN and of the European Technology Platform “Nanomedicine” (http://www.nanoforum.org/events/workshop/Boisseau.pdf). The definition of the strategic research agenda should include the definition of these infrastructures to prevent dispersed efforts.
- The FP6 Nano2Life project http://www.nano2life.org/ already experienced what kind of mobility is really needed by scientists from public and private sector to develop their research. That is why task "resources & mobility" has set up a database on equipment available among our 23 partners as well as a mobility scheme to ease access to the equipment.

2.4. Bioinformatics Infrastructures for Molecular Biology and Genome Research (Bioinformatics, databases, software, resources and Grid-linked services)

Janet Thornton, Director of the European Bioinformatics Institute, Cambridge, UK
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The new biology, with its move from molecular to systems biology, depends on the ability to exploit large and diverse data collections from high-throughput science. Bioinformatics involves the collection, organisation and dissemination of such data and the development and application of the tools to exploit them. The bioinformatics data and tools are an indispensable part of the infrastructure for all biologists, including medics, life scientists, agriculturists and environmentalists. Public resources are heavily used, not only by academia, but also by industry, for example in drug discovery, diagnostics and biotechnology in large and small companies (the EBI’s website http://www.ebi.ac.uk sees upwards of 1.3 million hits per day). Key areas are: Data resources; Annotation; Software tools; Search and retrieval; Standards.

"Core" and "specialist" data resources collect, curate and distribute essential data.

Core data resources typically build a comprehensive, public-domain collection of experimental data (now often HTP) at a designated site in Europe, as agreed by journals and the community. They curate the data for posterity and exchange them with the rest of the world. Their services are available 24/7, mature, relatively stable and highly used. Such core resources in Europe include those for nucleotide sequences and genomes, protein sequences, protein structures, protein-protein interactions and expression data. These core resources need stable infrastructure funding through regularly-evaluated rolling 5-year grants. The I3 mechanism, appropriately adjusted to reflect the needs of databases and electronic services for all science, would be an appropriate instrument. This is the TOP priority.

Core data resources also include the model organism data resources, which are compiled by expert annotators and heavily used by specific groups of biologists, working on a model organism. In contrast to the generic databases, these resources include information of all types for a given organism. There are about 5 such major resources (fly, mouse, yeast, worm, Arabidopsis), which are almost exclusively supported by the US, but serve their communities worldwide. In the coming years an equivalent human resource will be needed and Europe should be involved.

Specialist data resources, often based on Core Data Resources, are usually developed by a single laboratory or group of individuals, to address their specialist needs. Typically they are not major collectors of primary data from the community, and often they attach computationally derived inferences to core data. Their services and content continually adjust to the research interests of their developers with limited commitment to stability, comprehensivity, or standardisation. Often they emerge as the output of research funded under small national or EU grants. Those which turn out to be of generic and enduring use may mature into stable, well-used, essential services, requiring a continuity meriting consideration for infrastructure funding. Some could form consortia of related data resources (e.g. protein family resources) requiring central coordination of standardised data access.

Annotations are assertions about the scientific "meaning" of underlying data. Annotation comes from three sources: the original provider of the data, the group curating the data, or third parties who add information after the data have been made available. The basis of the annotation can be either experimental evidence or computer analysis (or a mixture). The provision of such annotation is by inclusion in the underlying database, or as ancillary resources designed to be used with the database (Distributed Annotation, e.g., via DAS). The Commission-funded Network of Excellence for Distributed Genome Annotation, BioSapiens, creates a virtual institute of 26 laboratories in 14 countries. It develops annotation tools and provides computed annotations for sequences, structures, interactions and pathways. NoEs provide a good instrument to fund such efforts.

Search and Retrieval Systems. Many laboratories, including the Core Resources, develop search and retrieval tools for sequences and structures. The EU has funded the EMBRACE Network of Excellence to develop tools for Data Integration, programming interfaces to exploit the information and to exploit novel IT/GRID developments. This distributed effort is best funded through the NoE mechanism.

Standards are central to optimising the exploitation of the interlinked composite of data resources and tools. New and evolving scientific techniques (e.g., currently in proteomic) create a constant need for the development and enhancement of standards. Design Studies funded under infrastructures could be a good instrument to support this.

2.5. The future of imaging facilities in Europe (Imaging living systems capabilities)

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Andreas Engel, Biozentrum, University of Basel, Switzerland
Werner Hax, Life Science Product Manager, FEI Electron Optics B.V., The Netherlands

This is a field in which Europe leads and investment is needed to maintain this leadership and to exploit it for understanding disease mechanisms, development of methods of non-invasive disease monitoring, drug discovery and assessment of therapeutic efficacy. Research is performed at these facilities at the microscopic, cellular, systems – functional and structural levels. There are important levels, and are all important for European industries. The clinical neurosciences are dealing with diseases of increasing relevance to our societies of the future: dementia, stroke, movement disorders, psychiatric disease and behavioural disorders of the elderly. Their cost to society is huge and increasing with prolongation of the average age at death. One approach to the investigation of these disorders that has become influential and increasingly useful is brain imaging; both functional and structural. There is already good evidence that certain neurodegenerative diseases can be detected with accuracy and sensitivity in the pre-clinical phase when degeneration is already considerable but clinical symptoms are not yet manifest because of cerebral compensation mechanisms. The opportunities for preventive or effective delaying treatments and measurement of their efficacy then becomes a very interesting proposition. The hardware needed for optimal imaging is very expensive and improved performance (for example by higher power magnets for MRI scanning) demands continuing research & development funded by large investments in money and expertise.

The breadth of funding streams is impressive: over 40 are listed. The world leaders in some areas in this field are European. For example, the functional imaging laboratory of the Institute of Neurology, University College London http://www.fil.ion.ucl.ac.uk undertakes research into the functional anatomy of the human brain in health and disease, using Positron Emission Tomographic (PET) and Functional Magnetic Resonance Imaging (fMRI) techniques. In 2002 the existing MRI was replaced with 2 new machines. 1.5T Siemens Sonata and 3T Siemens Allegra. PET was discontinued in 2004 and a order placed for a CTF Omega 275 MEG. The research programme divides into groupings by subject matter, but is essentially multi-disciplinary. Thus, imaging is a key methodology for medical research, and is important to society; industry, medicine, and brain research. New technologies are coming on board, as are new methods, analytical tools, principled methods of data interpretation and applications. The field is hugely diverse and is growing very quickly. What do we need? For example, we need new neuroimaging facilities – 7-9T (humans) - 11.7T (primates), 17T (rodents). Since the field is very multidisciplinary, there are advantages in a single centre model, if the funding is available. The European neuroscience community would benefit immensely from a technological research platform (for example: CEA sponsored Neurospin and Imagene projects in Saclay, France) dealing with directed instrumental development and biological exploration/validation of the acquired data, surrounded by a network of associated imaging research laboratories of excellence.

Electron microscopy (EM) has an outstanding track-record in visualizing living matter and has made substantial contributions to our understanding of biology. The capacity to image structures from atoms to cells is what makes EM so powerful. While traditional methods to prepare samples for observation by EM introduce some artefacts, modern vitrification techniques warrant perfect preservation of the native biological structure. In addition, damage introduced by the electron beam is minimized by state-of-the-art low dose image recording procedures. Therefore, EM is a unique technique to assess the three-dimensional (3D) structure of cells, their crowded interior with supra-molecular assemblies, isolated macromolecular complexes and membrane proteins. The wealth of structural information thus acquired is an essential prerequisite to understand the complex networks that constitute living organisms. It is therefore not unexpected that EM is strongly supported in the research communities of the US and Japan. The aim of the "3D-EM" Network of Excellence http://www.3dem-noe.org/about/index.html is to make Europe the leader in three-dimensional electron microscopy analysis. The integration of the leading European laboratories in electron microscopy is suggested as a fundamental tool to develop standardized procedures and innovative equipments for comprehensive structural analysis based on advances in electron microscopy. These will be made accessible to the Biological and Medical communities via the creation of state-of-the-art centres with adequate regional distribution to provide access to instrumentation and protocols developed within the Network. The inclusion of the internationally leading manufacturer for high performance instrumentation for life sciences, FEI Electron Optics, in the 3D-EM NoE will guarantee a close interaction of academic and applied research within the network and an immediate transfer of knowledge from basic science to industrial application. In the future, we need a structure for studying protein signalling, involving multi-million euro costs for equipment. We also need automatised screening, which is needed for systems biology, requiring a joint effort from several regions, needing continuous development.

2.6. New developments for Ion and X-Ray radiation therapy research facilities (Ion and radiation therapy facilities)

Daniela Schulz-Ertner, University of Heidelberg, Germany

In the past it has been shown that new technical developments in the field of x-ray radiation therapy can fast be transferred into clinical application at few specialized centers. Preclinically, radiobiologic research and research in the field of medical physics and dosimetry are important. They need to be intensified. However, the current FP instruments do not sufficiently support clinical research aiming in proving the superiority of new radiation therapy modalities in comparison to standard techniques and thus distribution of new techniques is still a problem. The indications for carbon ion RT and proton RT are not yet clear as clinical phase III trials are completely missing and the number of treatment facilities needed in Europe can only be estimated very roughly. Controlled multicenter clinical phase I-III trials need to be carried out at a European level in order to reach the necessary large patient numbers and to enable the transfer of knowledge which is still concentrated in few centers.

While the implementation of central reference centers for radiobiologic and physics research might be a good strategy to support preclinical research in the field of ion and x-ray RT, several facilities in different European countries are needed for translational and clinical research because of the limited mobility of the patients. In this connection a close connection between the new ion therapy facilities and the existing modern radiation facilities of the universities is crucial to allow for clinical phase III trials and for integration of the new modalities in multidisciplinary oncological treatment concepts at a national level. On the other hand, a close cooperation between the different European heavy ion centres on a European scale is necessary to design and coordinate international multicenter trials (clinical research network, regulatory support and quality assurance for clinical trials)

Currently, trained personnel is limited and knowledge is concentrated in a few centres. As several new heavy ion facilities are planned to be built in different European countries within the next 10 years, collaboration between the centres becomes more and more important. Transfer and exchange of experience and knowledge is necessary in all subfields of heavy ion research. Education and teaching of personnel is another important issue. Support for networking activities and exchange of personnel for teaching / training purposes is still needed.

2.7. Clinical research: A need for constructing a new European infrastructure

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Clinical research, the only way to find prevention strategies and/or treatments for human diseases, is the ultimate goal of health research. Therefore, translation from basic to clinical field should be placed at the top priority of any research aiming at improving Human health, and disease prevention/cure. Although clinical research is quite expensive and offers only few immediately visible outputs and/or technics and/or infrastructure, reinforcing clinical research, in a Public Health policy perspective, is an urgent need for construction a new European Clinical Research Area. Until now, this field of Research was under-estimated at the EU level, and we can only regret that it has never been put forward, through instrument such as Framework Programme.

Clinical research emcompasses research with human participation, research with access to personal data, research which involves clinical samples, and research with technology development for clinical use. The Creation of a European clinical research area, within the European Research Area will support European Harmonization in the health sector, maintain a High quality level of this research area, anywhere in Europe, allow Europe to gain competitive advantage in compliance with international guidelines, and can have a strong structural effect on the achievement of this European Research Area. There is an increasing gap between Europe and the US, South Africa and South-America countries: trials are increasingly conducted there, instead of in Europe. European pharma

industries spent 73% (in 1990) but only 59% (in 1999) of their world-wide R&D expenses on EU territory, which can become a real threat for:

- The European pharma sector
- The European Health strategy, as Europe can and is loosing leadership (and thus leading role in defining the priorities)
- The European clinical sector, which, if it cannot find support at the European level to support a high-quality and safety exigencies, will continue to see its R&D expenses decreasing, hence a threat also for the safety and quality guarantees.

Actions have already been done at the EU level (EMEA, European Directive (2001/20/EC), GCPs, Pediatric clinical trials initiative). European Clinical Research Infrastructure Network (ECRIN) is a consortium of 8 networks in 6 countries (Denmark, France, Germany, Italy, Spain, Sweden) proposing hospital-based facilities, dedicated personnel and dedicated beds and focusing on proof of concept studies, biotherapy trials, medical devices trials and pathophysiological studies.

Acting at the EU level is highly relevant, as we can then benefit from high-skilled trained scientists and medical investigators, EU ethnic diversity, access to rare conditions, possibility to test hypothesis requiring a high number of subjects, opportunities to built project in cross-cutting domains, selecting only excellence centres in Europe, etc. However acting at the EU level can also have disadvantages, for example, health and social insurance systems in differing between members and organisation of clinical research make a common action more difficult.

Examples of Clinical Research Infrastructures might include:

- Clinical Research Information and Statistical Analysis Centre (single sited) and a Distributed European Clinical Research Training centres network (multi sited) by up-grading the ECRIN project and building patient's and investigators European networks (private and public practice). The bottlenecks for EU clinical research are patient recruitment, Quality, Common standards and Statistics. In order to improve patient recruitment, EU needs to develop access to investigators networks, implication and participation of consumers through patient's associations, to reinforce credibility, safety and patients' trust, via, e.g. a European list of voluntary patients, organised and centralised at the European levels, to take the full advantage of the ethnic diversity of Europe. In order to improve Quality, EU needs better trained and skilled professionals, Coordination, Quality assurance, Regulatory and Logistic support. Evaluation is also essential (from academics and private). Possible actions are: new training programs relevant to clinical research (European PhD programs, European training centre), etc. E-clinical research, remote data entry/capture, harmonisation of e-tools and procedures, data management, common standards and best-practices guidelines, statistics, etc. should be monitored at an EU level. Since there are different separate fields in both academic and pharmaceutical research, such networks should focus on specific populations (Populations at risk, Rare and Orphan diseases, Pediatrics, Cancer, Psychiatry, Neurodegenerative diseases, Diabetes and metabolism, Cardio-vascular). Risks of health (non-)intervention should also be addressed in order to compare therapeutic strategies, detect and avoid serious adverse events. Therefore, there is an urgent need for a European pharmaco-epidemiology network.
- European Bio-manufacturing platform (single sited). Production of GMP clinical trials therapeutic units for Biotechnology (recombinant antibodies), Clinical grade vectors for gene and cellular therapy, Genetically modified agents, is a Strategic issue with High competition issues with the U.S.A. (Possible examples: LFB-Pierre Fabre, Toulouse).
- European Health and Road Safety platforms in link with the DG Tren. Road safety is a major problem over Europe (> 40 000 deaths a year, 200 000 families implied) with mortality varying from 1 to 4 fold according EU member states. There is a need for few integrated centres allowing behavioural and sociological studies, Simulation assisted by virtual reality tools, studying Drug influence on driving performance, Age and physiological conditions influence, Adaptation to disability.
- Up-graded Medes clinic (Space Clinic). Already settled in Toulouse (France), this clinic is an opportunity for the EU; a well-advanced centre with experience of isolation, sleep deprivation. More recent applications are the space surveillance of epidemics by deployment of ground Health Information Systems, use of bio-mathematical modelling of epidemic phenomena dynamics and remote sensing approach (environmental approach).

2.8. Surveys on European Research Infrastructures

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European Science Foundation Action on Research Infrastructures ("RI"): RI weigh heavily in the budgetary and policy scale. Transnational/European coordination and "collaboration in competition" is therefore imperative in Europe, to serve science and research with advanced RI while making the best use of available resources. How to proceed at the European level (as regards support of networks & collaborative RTD on RI, access to RI, and scientific-strategic activities on RI)? In its 2004 advice to the European Commissioner, the European Advisory Board (EURAB) identified a set of "RI surveys" which should be set in place and pursued in Europe in a systematic and periodic manner: European Surveys on current RI needs versus current provision of RI; European Surveys on future RI needs based on bottom-up visions on future directions of science and research; European Surveys on new RI opportunities. In the same context, 2 years ago the ESF set in place two 'Priority Action Lines':

(i) its action line on "RI", to "explore core issues of RI and provide independent science-driven European advice, committed to the best use of human and financial resources available in Europe";

(ii) its action line on "Scientific Forward Looks (FLOOKs)" including future RI needs. The action line on "RI" was started in response also to the recommendations of the "EU 2000 Strasbourg Conference on RI".

Simultaneously the European Strategy Forum for Research Infrastructures was founded, to pursue in a rolling process "European Roadmaps for RI" and to facilitate inter-governmental information and coordination on RI. Also, last year, the ESF and the Dutch research council organised the 'Conference for Inter-Council Cooperation' (i.e. European cooperation between national research councils) which identified "medium-scale RI" (i.e. "RI below governmental but within national research councils' responsibility") as a priority area for future inter-council cooperation.

ESF applies as its mainstream instrument the "ESF Scientific Forward Looks (FLOOKs)" and related "Long-Range Plans" (e.g. from ESF-NuPECC and ESF-EMB on nuclear and marine sciences RI). In single cases ESF undertakes "Surveys" (at present: on "biomedical RI" and on "high-capacity research airplanes") and "evaluations on RI / large research facilities" (such as on "Synchrotron beamlines for Life Sciences"). From these engagements, ESF has gained in-depth experience in the intrinsic issues of RI at large, and of "large research facilities (LRF)" in particular. A crucial issue of scientific-strategic forward looks and RI-roadmaps is "the right input", i.e. the right balance of pulling and pushing input from the relevant actors on RI: young & senior scientists from fundamental basic & applied research, actual & potential RI users, science associations, RI developers & operators, funding agencies, governmental governing bodies. The particular intrinsic problem of LRF is their immense time dimension which, for a specific RI, usually covers several decades, from the first idea till its shut-down. Predicting a scientific-strategic case of a LRF over 20 years is a "difficult probability problem" or in other words a "high-risk gamble". From dedicated "backward looks" on long-existing LRF, ESF found out that e.g. one-quarter of the predictions of the original "science case (forward look)" of a successful LRF may materialise while three-quarters of its usage (including e.g. a Nobel Prize discovery) are unpredicted. In other words: generally every LRF gets out of phase with its original science case. As time passes, "research runs away its own RI". Therefore it is imperative that a LRF must follow research & researchers (otherwise it should be shut-down). In addition, very LRF have a "momentum of inertia" which affects the research & user community, research & funding organisations, and eventually opposes emerging new competitive LRF projects. Also, one has to recognise that - despite the high value and fruitful impact of the Framework Programme support line for RI (in particular the "I3 scheme") - it is the national agencies (ministries and research funding councils) which have the bulk responsibility on RI and LRF in terms of development, operation, and funding. This may remain so at least in the medium–term.

As regards the current "ESF Survey on bio-medical RI", this activity should be finished within the next months, resulting in a draft survey report on the features of existing RI in Europe for bio-med. sciences research and on longer-term visions and demands for future/new RI. The relevant

ESF Standing Committees will then decide whether the Survey will be followed-up with a fully-fledged Forward Look in this sector of science and research.

European Commission Survey on existing Research Infrastructures: The European Commission services have invited Research Infrastructure stakeholders to participate in a Survey of European Research Infrastructures. The objective of the Survey is to identify existing capacity of major Research Infrastructures in Europe and respective trends and developments. The up-to-date picture about the current pattern of Research Infrastructures in Europe that will be obtained will be made public (via the CORDIS website). It will help understanding the needs for future Research Infrastructures and thus developing a strategic approach at the European level.

The whole range of scientific and technological fields is covered by the survey, including the Life Sciences and Biotechnology. The Survey addresses existing Research Infrastructures as well as Research Infrastructures under construction within the next two years. It covers facilities and resources that provide essential services to the scientific community for basic or applied research, with a clear European dimension. In addition, each infrastructure should represent a total cumulative investment (for construction) of normally above € 20 million (today's equivalent). One of the core features of the survey is a questionnaire circulated to the European scientific community. A first round was launched in December 2004, with further iterations foreseen in the coming years, depending on the outcome of the first round and the evolution of the Research Infrastructures Action in general. The further iterations should allow to add further information and/or resolution to the obtained "picture".

In the first round of the survey, the main categories for Biomedical Sciences were found to be: imaging, synchrotrons, competence (training) centres, clinical research, animal repositories, genomics, structural biology. The main conclusions are that: (a) Most infrastructures are interdisciplinary, (b) The main categories covered by this workshop are the same as the survey, (c) However, some infrastructures are competence centres, and not really covered by this workshop.

2.9. The European Strategy Forum for Research Infrasructures process

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Tim Hall, Head of Unit F1, Strategy and Policy, European Commission, Brussels, Belgium

The European Strategy Forum on Research Infrastructures (ESFRI) was launched in April 2002 (http://www.cordis.lu/era/esfri_home.htm). ESFRI brings together representatives of the EU Member States, appointed by Ministers in charge of Research, and a representative of the European Commission. The role of ESFRI is to support a coherent approach to policy-making on research infrastructures in Europe, and to act as an incubator about concrete initiatives.

The Informal Competitiveness Council of 1-3 July 2004 "welcomed the Commission's proposal to develop a strategic roadmap for Europe in the field of Research Infrastructures for the next 10 to 20 years", and recognized that "in this context, ESFRI could play a role of increasing importance". At its meeting of 3 Sept. 2004 in Amsterdam, ESFRI decided to give immediate priority to this request. The objective of ESFRI will be to provide an overview of the needs for research infrastructures of pan-European interest in different fields of science and technology. The roadmap will be used to facilitate decision-making by Member States and by the European Commission. ESFRI will not prioritise or decide on funding and location for future infrastructures. In the context of the ESFRI roadmap, the term "research infrastructures" refers to facilities that provide essential services to the scientific community for basic or applied research. They may concern the whole range of scientific and technological fields, from social sciences to astronomy, going through genomics or nanotechnologies. They may be "single-sited", "distributed", or "virtual".

Following a request from the European Commission, ESFRI also decided to compile a List of Opportunities in order to assist the Commission in the preparation of its proposal for the Seventh Framework programme (FP7). The List of Opportunities is a balanced set of examples of projects for new Research Infrastructures of pan-European interest. This list (published on March 22, 2005;

ftp://ftp.cordis.lu/pub/era/docs/esfri_list_opportunities_290305.pdf) includes examples of projects needed in the field of Biology, again very similar to the areas considered in this workshop:

- Advanced infrastructure for brain and whole body scanning
- Bio-informatics infrastructure for Europe
- European infrastructure for research and protection of biodiversity
- European network of advanced clinical research centres
- European network for biobanks & genomic resources
- High security laboratories for emerging diseases and threats to public health
- Infrastructure for functional analysis of a whole mammalian genome
- Model animal facilities for biomedical research

3. Key horizontal issues discussed

3.1. Data acquisition and treatment

A high level of agreement was reached on the following points. All areas of biomedical research need their own bioinformatics and data analysis support. The lack of good bioinformatics support for research and infrastructures is in particular a bottleneck for a lot of Genomics and Proteomics research. The volume of data is a huge challenge, along with organizing/managing the data, holding the data on a long term and having inter-operability of databases. A more appropriate funding mechanism is needed for a better and continuous support for bioinformatics, funding the core data resources and links to more specialised databases, together with web services, grids, and standards.

3.2. Diversity and flexibility

The field of Biomedical Sciences is however very diverse ranging from studies on molecular interactions to physiology experiments, from in vitro experiments and in vivo observations to in silico modelling. Correspondingly, there exists a great diversity of infrastructures with vastly different sizes and different needs. Some are networks of rapidly implemented and flexible centres (e.g. in genomics). Some others are central facilities (e.g. in structural biology). The equipment aspect itself is also diverse ranging from single or multiple medium sized instruments in multi-purpose buildings with rapid upgrading or expansion, up to very large scale instruments. A first step for planning the future of research infrastructures in Biomedical Sciences is therefore to decide on what needs to be centralised or not. Biomedical Sciences are also a very fast evolving domain. As a first consequence, strategic choices for research infrastructures i.e. “20 years” organisations, are particularly difficult, and just setting technologies at the start of an infrastructure design is inefficient, since these are evolving all the time very rapidly. New ideas must be captured as they come, and very direct and strong links with research priorities must be established. As a second consequence, the limits between the construction of new infrastructures and the upgrading of existing ones might be looser than in other scientific fields. There is a need for a dynamic upgrading of the infrastructures and the “new" and "upgraded" as defined under the ESFRI process was felt to be too tight. For many life sciences infrastructures, the most appropriate approach is to concentrate on existing infrastructures, by maintaining them, upgrading and linking them, constructing some new modules, and shutting down some parts. For that purpose, periodic evaluation is always needed. As a third consequence, several participants to the workshop were concerned that the biomedical community would be disadvantaged in the ESFRI process of establishing priority lists for RIs, since most biomedical equipment being used now did not even exist 10-15 years ago (and is evolving at an ever increasing pace), in contrast to large physics projects that sometimes have been in design phase for many years. Hence ESFRI biomedical projects sometimes do not have the same level of readiness, giving the impression that the scientific communities are not well organized whereas some like bioinformatics are already well structured (although not yet appropriately funded). Another difference is the low construction costs and high maintenance cost in the Life Sciences when compared to Physics for example. The constantly changing and exponentially expanding Life Sciences data and experimental landscape demand different funding structures and special care about the continuity of support.

It is therefore recommended that support for research infrastructures in the domain of Biomedical Sciences is adapted to the high level of diversity by applying different criteria within this field, and provides responsive tools to allow for flexibility and rapid implementation.

3.3. Links with the industry

There is a need for more cooperation between industry and basic science. Infrastructures should act as glue between industry and academia. The main outcome from research infrastructures

is to make the best services available to the community. Structures to develop intellectual property can be part of this service and intellectual property rights developed in the projects hosted at the infrastructures should be exploited in a more systematic way. Exploiting more what research infrastructures produced already is indeed needed, with public and private partners, to be able to compete with massive investments being made in the USA. Also, very importantly, it must be made sure that developments in infrastructures have actual or potential links to clinical research.

Participants also outlined that it will be important to explore possible links between the technology platforms and research infrastructures.

3.4. Long term perspectives

A critical problem in Life Sciences, is that infrastructures are created in terms of databases, equipments and teams, on the basis of fixed, short-term research grants. At the end of the grant, it happens that the infrastructures are lost, whereas they often represent key resources that could be used/upgraded to serve the entire community. Thus, there is a need for long term perspectives.

All infrastructure managers need to define criteria for success and failure of their infrastructure, with measurable goals that are not only publication targets, from its beginning, and to develop a "business plan". Such plan should detail the long term plan for sustainability of the infrastructure, and should keep commercial aspects in mind, even when major funding is available from the public domain, considering the whole value chain, from basic to commercial. This is in particular essential for decision makers to decide on funding priorities and defend them, and to reach long term perspectives.

In addition, there is no mechanism for continued funding, especially but not only in EU funded research projects. It was felt that there should be co-ordination between EU and national and charity funding agencies to develop a policy so that funding for infrastructures has the possibility of continuing if appropriate. Some national governments do not have mechanisms for supporting or even upgrading infrastructure. Such support should never be automatic, but should require continuing scientific assessments. Outcome from the infrastructures should be evaluated and means for making results at the facilities available should be better developed.

3.5. Organization of the EU actions and Commission instruments

EU projects were felt to be of good quality and the scientific community should publicly support this view. However, many of the participants stressed that the EU funding process is too "heavy" and too bureaucratic. First the submission of proposal is very time consuming and applications should be simplified. Two stage calls for proposals might be an efficient way to deal with this problem, based on responding with a simplified first stage proposals. Second, the process between the selection of the project and the contract signature (“time to contract”) is considered as generally too long. Third, the monitoring is considered as a too heavy process, although mid-term review is particularly useful. The importance of simplification of all the steps, going quickly, easing the management requirements and teamwork between proposers and Commission was emphasised.

Continuity of funding after the end of the contract is considered to be a major problem. Linked to that, it is suggested to extend the timeframe of the grants to even more than 5 years. Also, many aspects of the funding process seem to not be acceptable for companies (again long time to contract, slow payment, financial requirements, no exemption from shared liability as for academic partners). Views and opinions were more divergent regarding top-down (specified topics) versus bottom-up approaches (completely open areas). Several participants favoured bottom-up calls with relatively general topics. On the other hand the need for a wide-open procedure for new ideas was expressed, as well as concerns about who would prioritize topics.

It was recognized that biology scientific communities are in general not enough organized, one consequence being that the Commission is being pulled in sometime divergent directions, whereas developing roadmaps for the future of Research Infrastructures requires joint efforts. Initiatives such as surveys or investigations on future needs should not be multiplied, to allow for a

better understanding on who does what among the main stakeholders of the domain. It was also outlined that more consistency should be reached between EU actions. This is even more needed that Biomedical Sciences is a field where research and infrastructures are very much interlinked.

Not only organization and consistency of the actions should be better taken care of, but also visibility and communication. Participants strongly supported the idea of establishing more direct and transparent links between the ESFRI process and the scientific communities, possibly through the organization of a conference targeted to the scientists. Also communication on agreed needs should be taken care of in a short and concise way, in particular to the Council. Lobbying and targeted information needs to be done outside the Commission.

Several EU funding "instruments" are available, both for projects primarily research-based and for those primarily infrastructure based (for details see http://www.cordis.lu/fp6/stepbystep/instruments.htm). It was pointed out that EU instruments are constrained by the need to act at the European level, and also by the fact that the total member states' infrastructure budget greatly exceeds that of the EU budget.

The choice of funding instrument depends on the type of infrastructure, the project, and the stage in the infrastructure life cycle. The participants familiar with Integrated Projects were satisfied with them, but this instrument does not fulfil all the requirements for research infrastructures in its present form. On top of access there should be funds to improve the effectiveness of the infrastructures. Networks of Excellence seem to face resource limits, as they are often implemented in a research context, with a large number of participants, but with little funds available for each.

The infrastructure instruments for funding design studies were found to be very suitable. I3 was considered by the participants as a very good instrument. Networking and improving existing infrastructures is indeed considered to be very necessary. It was outlined that, in I3s, research should always be present, and the possibility of purchasing and upgrading equipment should be added. There is indeed a need to make provisions for renovating and upgrading buildings and equipment on regular basis.

4. List of participants

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5. Agenda of the meeting

Introductory session

9:20-9:50 Welcome, Introduction, Round table presentation.
Research Infrastructures in FP6, FP7 and beyond (Hervé Pero)

First session: Needs for supporting existing research infrastructures at the EU-level

9:50-10:10 A need for improved coordination at EU level: the case of bio-repositories.
(Martin Hrabé de Angelis, Sean May)

10:10-10:30 The support to facilities for Protein Structure determination. Status and future needs.
(Manfred Weiss, Lucia Banci)

10:30-10:50 Infrastructures in Genomics and Proteomics
(Stephen Fey, Ulf Landegren, Patrick Boisseau)

10:50-11:20 Mapping existing infrastructures in Biomedical Sciences.
(Hans Karow, Hui Wang, Jean-Emmanuel Faure, Frederick Marcus)

11:20-12:00 Round table discussion

Second session: Needs for new research infrastructures at EU-level

13:00-13:30 Needs for new infrastructures as analyzed by the ESFRI steering group "Biology and Medical Sciences" (Tim Hall, Eckhart Curtius, Jerzy Duszynski)

13:30-13:50 The access to information from molecular biology and genome research
(Janet Thornton, Vaclav Paces)

13:50-14:10 The future of imaging facilities in Europe
(Richard Frackowiak, Andreas Engel, Werner Hax)

14:10-14:30 New developments for Ion and X-Ray radiation therapy research facilities
(Daniela Schulz-Ertner)

14:30-14:50 Clinical research: A need for constructing a new European infrastructure
(Olivier Blin)

Round table discussion and conclusions

14:50-16:30 Round table discussion
Recommendations for near-term research infrastructures within FP7
Identification of further work needed
Conclusions
(Moderator: Hervé Pero)

6. Relevant web-links

European Commission - Research Infrastructures Action
http://www.cordis.lu/infrastructures/home.html (Home page)
http://www.cordis.lu/infrastructures/documents.htm#wp (Work Programme)
http://www.cordis.lu/ist/rn/home.html (Communication Network Development)
http://www.cordis.lu/infrastructures/projects.htm (Projects funded under FP6)

European Commission - Life Sciences, Genomics, and Biotechnology for Health - Thematic Priority
http://www.cordis.lu/lifescihealth/thematic.htm (Home page)
http://www.cordis.lu/lifescihealth/workprogramme.htm (Work Programme)
ftp://ftp.cordis.lu/pub/lifescihealth/docs/book_abstract_priority1_merge_en.pdf (Projects funded FP6)

European Strategy Forum for Research Infrastructures (ESFRI)
http://www.cordis.lu/era/esfri_home.htm (Home page)
http://www.cordis.lu/era/esfri_steering_groups.htm (Steering Groups membership)

European Science Foundation - Research Infrastructures Programme
http://www.esf.org/esf_activity_home.php?language=0&domain=0&activity=9