

Population Surveys and Biobanking

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Foreword

Rapid developments in medical research produce a continuous stream of new knowledge about disease processes. However, the possibilities for early detection or, preferably, prevention of disease remain limited. Population-based prospective studies investigating the interaction between genetic predisposition to a disease and exposure to environmental factors are a prerequisite to gain knowledge for the development of disease-preventing strategies. Increasingly, it is being realised that population surveys and biobanking – systematically assembling collections of genetic material and other relevant information about individuals – will play a key role in achieving the medical paradigm shift from “cure” to “prevention”.

A multitude of national and regional population- and disease-oriented biobanks have been established in Europe. However, the exchange of data and materials within national legal frameworks is still difficult and European biobanking efforts are characterized by fragmentation.

The European Science Foundation's medical section, the European Medical Research Councils (EMRC), initiated this science policy activity because studies of complex diseases require population surveys directed at building a knowledge base to improve early detection techniques and ultimately develop primary preventive measures.

This report is the outcome of an ESF/EMRC Workshop on Population Surveys and Biobanking, involving an international high-level expert group, whose members made specific recommendations to stimulate co-ordinated activity in population surveys and biobanking across Europe. The recommendations, summarized at the end of this report, are intended to trigger targeted efforts by relevant stakeholders, including the ESF and its Member Organisations, governments, the European Commission, other international agencies, industry and academia.

To strengthen Europe's position in this scientific field, emphasis has to be put on increased collaboration to converge European biobanking activities, to address ethical issues and to prevent fragmentation by integrating parallel activities in this field. Sustained funding of biobanks is a prerequisite to fostering further development of this research area in Europe.

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Introduction

Many common diseases, including Alzheimer's, asthma, arthritis, cancer, cardiovascular diseases, diabetes, hypertension, obesity, Parkinson's, and psychiatric disorders, are complex conditions that not only cause major human suffering but also represent a burden to European society in terms of healthcare cost and loss of economic productivity. Successful treatment of these diseases remains elusive because they do not have roots in single defects but are caused by a large number of small, often additive effects arising from genetic predisposition, lifestyle and the environment.

The development of new treatments, prevention strategies and the promotion of health requires three steps: establishment of diagnostic patterns, elucidation of the molecular processes involved, and understanding of the causal pathways.

The study of complex diseases requires comparison of large numbers of affected and unaffected individuals ('cases' and 'controls'). Population based prospective health surveys and biobanks (repositories of genetic material from individuals, together with associated information about the individual) have thus become indispensable to elucidate molecular processes and causal pathways, be they genetic or environmental, and to translate biomedical research into real improvements in healthcare.

To this end, large and well-organised biobanks have been established, are underway or are planned in many European countries. Typically these contain data on health, nutrition, environmental risk factors, demographic, socioeconomic and lifestyle variables, combined with collections of well-preserved biological material from patients and healthy individuals. The integration of these resources with powerful 'omics' approaches (genomics, transcriptomics, proteomics and metabolomics and various combinations of these), integrated by bioinformatics, promises to greatly advance our understanding of disease development, thus leading to new ways to prevent and cure many chronic and life-threatening diseases.

With Europe's long tradition of excellence in education, research and medical care, the European biobanks represent a great asset and one of the few competitive advantages that Europe has compared with the US and Japanese research communities. However, despite this unique European strength, valuable and irreplaceable national collections typically suffer from underutilisation due to fragmentation of the European biobanking research community. Promising international initiatives are challenged by the heterogeneous legal, ethical and

societal landscape of Europe. For Europe to stay at the forefront, and to take full advantage of the huge research potential in its human biobanks, there is an urgent need for coordination and harmonisation of the biobanking and biomolecular resource infrastructure. A concerted effort is necessary to devise rational and practicable procedures for collecting, exchanging and linking samples and data. While this should be attempted within existing regulatory frameworks, in those cases where conflicting regulations might impede progress, the advantage of adapting regulations should be made clear.

Conceptually, the legal framework in Europe is broadly homogeneous and based on the common principles of safeguarding privacy, advancing freedom, allowing informed decision-making and preventing coercion. However, the practical regulatory formats have become unnecessarily diverse due to the multitude of independent national legislative processes in the member states. This seriously hampers progress in a major field where Europe is otherwise poised to take a leading role.

Impact of Population Surveys and Biobanking

Biomedically relevant, quality-assessed samples and data as well as associated biomolecular resources are essential for clinical, academic and commercial research to treat and prevent common and rare human diseases. Population surveys and biobanking are the driving force of technological development, proactive health programmes and preventive medicine. It is now widely accepted that understanding the etiology of complex diseases critically depends on international coordination and collaboration of biobanked data and samples. Networking and harmonisation of biobanking initiatives across Europe will increase the success of coordinated large-scale biomarker¹ discovery and validation, facilitate the identification of susceptibility genes and environmental and lifestyle factors and etiological pathways for multifactorial diseases, and aid the design of drugs and treatments and accelerate personalised medicine. Clearly, then, the economic potential and value to society of such knowledge is immense. Furthermore, activities aimed at achieving such integration and collaboration will play a critical role in building and maintaining cutting-edge competencies in the relevant scientific areas across Europe. Major benefit can be expected in all the areas discussed below.

¹ A biomarker is an indicator for a particular physiological or pharmacological state. A biomarker can be a substance, an image, a molecule, a protein or any measurable parameter that serves as an indicator. Definition taken from the Innovative Medicines Initiative (IMI) joint undertaking (IMIJU) www.imi-europe.org.

Health potential

Complex diseases are responsible for 77% of the disease burden and 86% of premature deaths across Europe. Population surveys and biobanking research are essential tools in the elucidation of the etiology of complex diseases and the molecular basis of disease subtypes. A more precise, biology-based classification of disease will speed up the development of more effective – and cost-effective – treatment, reduce the incidence of undesired side effects of medicines, improve success in clinical trial design, and lead to new concepts of disease prevention and health promotion.

Socio-economic potential

Chronic and slowly progressive complex diseases cause a large direct and indirect economic burden across Europe. Because research based on population surveys and biobanking is expected to lead directly to improvements in disease prevention and treatment, there will be important economic impacts in terms of reducing the need for healthcare resources and increasing productivity through a healthier workforce. Such benefits more than justify the large investment that will be required to establish and maintain a pan-European biobanking infrastructure.

Industry potential

Life sciences and biotechnology are widely regarded as being among the most promising 'frontier' technologies for the coming decades. A strong European focus on population surveys and biobanking will stimulate research activity across European countries, foster new synergies between the industrial and academic sectors, and strengthen the competitiveness of European biotech and health-related industries and businesses. In addition to the final goal of prevention and therapy, the short-term benefit will be improved disease classification and the development of new and more powerful diagnostic tools. Molecular diagnostics, a new discipline exploiting the 'omics' technologies to classify and understand diseases and to assist individuals at particularly high risk, is currently one of the fastest growing segments in the healthcare industry.

Legal, political and social potential

Given the challenges of optimizing resources and sustaining a high level of healthcare in Europe in the changing economic and environmental landscape of the 21st century, communication between different disciplines within society urgently needs to be improved. Recent debates within society on areas such as food safety, cloning and the patenting of genes have shown that poor communication can result in misunderstanding and a damaged public image for science. It is likely that the life sciences and biotechnology will play an increasingly important role in technological advance in the future. The process of aligning pan-European regulatory frameworks in the field of population surveys and biobanking offers a unique opportunity to improve communication and foster better understanding between the scientific, medical, legislative and social disciplines, as well as between professionals, patient communities and the public at large.

European Strengths

In several European countries biological samples have been systematically collected for decades through the national healthcare systems. These collections now comprise hundreds of millions of samples that can potentially be used for medical research and represent an enormously rich resource.

Many EU states operate a system of personal/national identification numbers for their citizens and this provides the opportunity to link information derived from a particular sample, held for example in a pathological biobank, to clinical data, data on exposure or data derived from a second biological sample that was collected earlier as part of a prospective population-based health survey. This unique situation makes data available that can lead to a better understanding of the mechanisms behind the development of disease. When this type of data is taken together with national registries on healthcare information and mortality and genealogical data, these European countries are among the few in the world where it is genuinely possible to perform conclusive population-based genetic studies of complex diseases.

A long tradition of epidemiological research in Europe together with a willingness of the population to participate in health surveys, broad access to large-scale technologies, and a high level of expertise in genetics, epidemiology, clinical medicine, mathematics and information technology, creates a European niche with unprecedented possibilities for healthcare and genomic research. If individual nation states can work together at an integrated European level, this would result in a significant advantage and would help to ensure that the EU develops and maintains a leading global position in medicine, genetic epidemiology and population genetics.

European Population Surveys and Biobanking: Rationale, Current Status and International Context

Rationale

A range of study designs can be used to investigate various aspects of the relationships between different exposures to environmental factors, the presence of predisposing genetic factors and the risk of disease. Longitudinal population-based cohorts are followed prospectively and are valuable for assessing the natural occurrence and progression of common diseases and for classifying disease subcategories. Clinical case/control studies focus on defined diseases and may be used to discover or validate genetic and non-genetic risk factors. These may or may not have an added longitudinal perspective.

The combination of longitudinal cohorts with information (from biological material and questionnaires, interviews and/or clinical measurements) on exposure to environmental factors collected prior to the development of disease and clinical data with information on disease, provides a unique opportunity for studies of multiple end points influenced by a single exposure, or single end points influenced by multiple exposures. Such studies also allow for investigations of diseases with high mortality and for flexible diagnostic criteria.

So-called population isolate studies are undertaken on populations isolated from other populations, sometimes by geography. This type of investigation can be useful because the population is typically more homogeneous genetically and environ-

mentally than other populations, which can make it easier to pinpoint genetic factors that might predispose someone to a disease. Many collections of genetic and medical data on individual families in different European countries also represent a resource comparable to population isolates. Twin registries containing details of monozygotic (MZ) and dizygotic (DZ) twins allow the parallel dissection of the effect of genetic variation in a homogeneous environment (DZ twins) and of environmental effects against an identical genetic background (MZ twins). These data also permit the estimation of age- and sex-specific genetic and environmental effects. Recent methodologies applying genome-wide epigenetic analyses to data from MZ twins have provided one of the most powerful natural designs for investigating how exposure to environmental factors may affect gene expression.



Figure 1: The Netherlands Twin Register contains samples and phenotypic assessments of 20,000 adults and 60,000 children, here depicted in historic paintings (Courtesy of Dr. Boomsma).

Current status of biobanking in European countries

For the above reasons, a broad spectrum of population-based biobanks for biomedical research has been established or is being planned in European Member or Associated States. In the United Kingdom the ongoing UK Biobank project alone aims to collect data and biological samples from half a million UK citizens aged 40–69. Large population-based biobanks also exist in the Nordic countries as well as in Austria, Estonia, France, Germany, Italy, The Netherlands, Portugal and Spain. Several other countries have studies in the preparatory phase. The existing European biobanks are quite diverse with respect to the populations included, the nature and size of the biological specimens held and the clinical and anthropomorphic data available. National coordination and funding programmes on biobanking activities have been launched in Denmark, France, The Netherlands, Norway, Sweden and the UK. These initiatives reflect the growing realisation of the value that these biobank resources bring to the national and international health research community.

European networking and funding consolidation

The European Commission has funded a number of networking activities and collaborative research projects related to population surveys and biobanking, such as EUROBIOBANK² and GenomeEUtwin³ under the 5th Framework Research Programme (FP5); ENGAGE, EUHEALTHGEN⁴, COGENE and PHOEBE⁵ under FP6; and the topic is also implemented in FP7's Cooperation Work Programme. Moreover, the roadmap of the European Strategy for Research Infrastructures (ESFRI) foresees a 'European Infrastructure for Biobanking and BioMolecular Repositories' (BBMRI). The decision to fund the preparatory phase of this project has been made; the developments are ongoing⁶.

International context

It is important that European biobanking should not be developed in isolation. Pioneering steps towards global biobank networking have already been taken by the Public Population Project in Genomics (P3G)⁷, whose goals include providing a worldwide overview of biobanking resources and making harmonised tools available to the scientific community. Notably, two of the three founder parties of P3G are European biobank research activities: the FP5 Integrated Project GenomEUtwin and the Estonian Population Biobank. Other agencies have also entered the biobanking arena: the OECD working party on biotechnology is in the process of developing best practice guidelines for human genetic research databases, and the International Society for Biological and Environmental Repositories (ISBER) also has best practice guidelines for the collection, storage and retrieval of human biological samples. Other parties, including UNESCO and WHO, are equally interested, as are national governments.

To balance this high-level worldwide interest with the relatively small number of researchers in the field, a key priority in addition to coordinating the research field – where the main players are typically well-connected – may be to consolidate the diverse political and funding interests. The pursuit of this challenge, avoiding inter-agency rivalry as much as possible, would make a vital contribution towards optimising harmonisation, integration and global progress.

Key Challenges of European Biobanking

While population surveys and biobanking present unique opportunities for Europe, a number of barriers need to be overcome. At present, there is little collaboration between European biobanks. This is largely because of ethical, legal, practical and financial difficulties in sharing or exchanging material and/or information. The lack of standardized and quality-controlled protocols for data and sample collection, storage, retrieval, analysis, and access, also presents problems for collaboration, as does a lack of knowledge about where collections exist and what they contain. Many population surveys lack detailed and accurately measured phenotypic data, and few studies obtain information on prospective clinical outcomes. These problems cut across a range of policy and scientific fields and many agencies are involved. To make real progress in developing a more coordinated and integrated strategy towards population surveys and biobanking, these legal and regulatory issues must be addressed.

Ethical, Legal and Social Issues (ELSI)

The collection, storage and use of samples and data from individual citizens raises serious issues surrounding legality, ownership, privacy and ethics. These issues are under continuous scrutiny and are the subject of ongoing debate. As science advances and new methodologies emerge, the nature of these issues evolves and changes. Ethics has a special relevance in population surveys and biobanking as the activities involve the use of personal health information and human biological material.⁸

Many EU member states have launched efforts to harmonise the collection and storage of human biological material and its use for research purposes within their borders. However, while the underlying regulatory concepts are common in Europe (and nearly common worldwide) and centred around concepts of privacy and free, informed choice on the part of the citizen, the translation of these concepts into laws and regulations regarding consent forms, ownership of samples, and secondary use of samples and data, is often incompatible between countries. Consequently, researchers cannot easily or freely transport samples or information pertaining to samples between all EU member states. In particular, the lack of uniform international statements and guidelines for secondary use of data and samples represents a major impediment to the utilisation of population biobanks and longitudinal studies.

² www.eurobiobank.org

³ www.genomeutwin.org

⁴ www.wellcome.ac.uk/doc_WTX026759.html

⁵ www.phoebe-eu.org

⁶ www.biobanks.eu

⁷ www.p3gobservatory.org

⁸ The Council of Europe (www.coe.int) has elaborated recommendations aimed at the harmonisation of ethical issues relevant to biobanking; see Recommendations Rec 4 (2006) of the Committee of Ministers to member states on research on biological materials of human origin.

In view of rapid scientific developments in the field and the need for international collaboration it is essential to establish a minimum regulatory and administrative foundation that will facilitate the exchange of human bio-specimens and associated information throughout Europe.

Notably, an important distinction exists between the “analysis” of specimens in the course of observational studies, for example in epidemiological or genetic epidemiological research, and the “testing” of subjects in clinical practice with the aim of providing clinically useful diagnostic or prognostic information. This distinction is often not clear to politicians and the public – not even amongst patients and professionals. A key aim of the biobanking community should be that this fundamental difference is better explained and encapsulated within a proper, practicable, legal and ethical framework.

Genome-based knowledge derived from population surveys and biobanking should be responsibly and effectively integrated into public health decisions. This could be facilitated through collaborative efforts with other networks established by the European Commission (EC), including the Public Health Genomics European Network (PHGEN), EuroGentest (which addresses questions about the clinical validity and utility of genetic tests), EUnetHTA (which works on health technology assessment), Orphanet (European network on rare diseases), and NuGo (European network on nutrigenomics).

Standardizing sample handling and storage protocols

The lack of high-quality clinically annotated bio-specimens is seen as a major bottleneck in medical research and a barrier to the development of new treatments. Sample collection, processing, storage and retrieval have a major impact on sample quality and utility for future analyses.

There are very few standardized and quality-controlled protocols for pre-analytical procedures, which makes it difficult to compare and share samples from different studies, particularly as the sample sizes needed are likely to be very large. There is a need for international efforts to agree on standardized – in some cases at least harmonized or cross-convertible – protocols, infrastructure and sample formats to ensure that these valuable resources can be utilised to their fullest extent. To reach this goal pan-European quality assurance schemes and guidelines for pre-analytical procedures for sample collection, handling, transport, processing and storage need to be worked out. In this regard, the ISBER⁹ protocol on best practice for repositories might serve as a useful guide.

Sample storage and retrieval systems

Safe and efficient storage and retrieval systems are an absolute prerequisite for biobanks storing millions of samples in multiple tube and vial formats. Whereas flexible automated solutions have been developed for some storage formats (for example for DNA archives), the technology is still immature for ultra-low temperatures, which may be necessary for longer-term storage of fluids and tissue samples. The lack of automation becomes a significant practical challenge when large sample sets are to be retrieved and an obstacle to the effective delivery of high-quality samples to the scientific community. Thus, emphasis needs to be placed on developing technologies for modern, effective storage and retrieval.

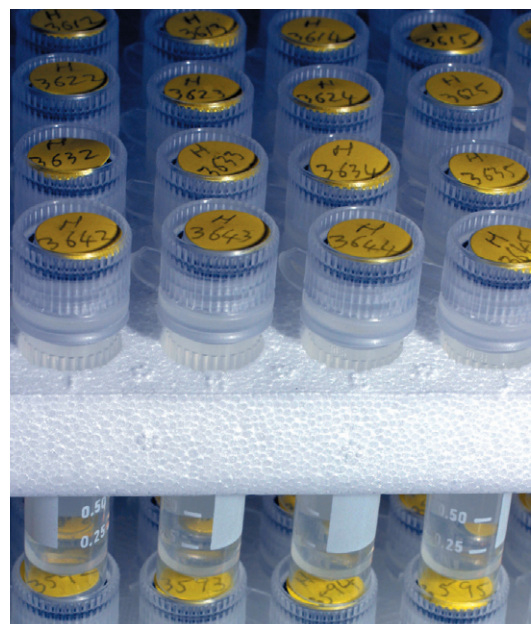


Figure 2: Example of sample storage for automatic retrieval systems (© Istock photos).

⁹ International Society for Biological and Environmental Repositories, 9650 Rockville Pike, Bethesda, MD 20814-3993 (USA), www.isber.org

The need for large sample size

Recent findings arising from genome-wide association (GWA) scans have provided novel insights into the pathological etiology of complex diseases and revealed new therapeutic targets. It has become clear that risk factors come in different forms. The more common ones often have modest relative risk, but may be widespread and thus affect a significant fraction of the population, while others are rare but present substantial relative risk to their carriers. There is a growing realisation among scientists that, for most complex traits, the power of genetic approaches to detect the first category, which is important from a preventive point of view, relies on the availability of very large sample sets, extending far beyond the reach of any single initiative or nation. Therefore, there is an urgent need for European if not world-wide collaborative research.

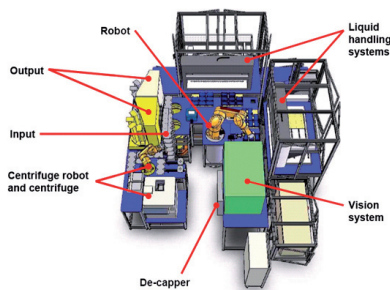


Figure 3: Fully automated sample handling robot (Courtesy of Professor Frank Skorpen).

Integrating local and national biobank resources into a coherent research infrastructure will significantly improve access to large sample sets, and thus increase the research value of any biobank in the network. Such a global movement across international boundaries has taken off with the establishment of P3G (see above). In addition, because risks related to genetic and environmental factors may vary across different populations, a full understanding of disease risk, gene–environment interactions and treatment options will require replication and study in large sample collections from different populations.

Assessment of phenotypes and lifestyle exposures

A main factor limiting high-quality molecular genetic epidemiology concerns the resources required to obtain detailed, accurately measured phenotypic data. The phenotypic data¹⁰ in existing biobanks are often variable in content, format, depth and vocabulary. In several cases, following critical appraisal, this shortcoming can be remedied by collection of additional data, or by retrospective harmonisation of phenotypes that have already been collected in the various biobanks. There is also a need for improved assessment and classification of multivariate phenotypes associated with complex disease. The lack of a common language and standardized vocabulary to describe phenotypic characteristics in sufficient detail represents a major barrier to both national and trans-national research collaboration.

To gain insights into the causal pathways for both normal development and disease processes, it is important to acknowledge that late-onset diseases are often influenced by earlier life events. For this reason studies may sometimes have to incorporate a developmental perspective, considering the effects of expressed genes and intermediary phenotypes (endophenotypes) across the life course. This requires access to longitudinal medical records, or follow-up assessment and repeated sample collection from individuals over time.

Accessibility to health registries

Population-based health registries are essential tools in disease control, healthcare planning and research. Many areas of the world have national or regional health registries, for example cancer registries. However, marked differences in practice exist between registries with respect to data sources, definitions and processing methods, and in many cases registries are not accessible to researchers. There is a need to bring together researchers with an interest in health surveys and biobanking, experts in legal and ethical issues, and national and international agencies responsible for health registries, to increase the availability and accessibility of these important sources of healthcare information to researchers under certain conditions.

¹⁰ A phenotype is any observable characteristic of an organism, such as its morphology, development, biochemical or physiological properties, or behaviour. Phenotypes are influenced by a combination of genetic and environmental factors (<http://en.wikipedia.org/wiki/Phenotype>).

Informatics and bioinformatics

Large-scale population survey and biobanking projects generate extremely large quantities of data, ranging from health-related information, sample storage data, documentation and exchange, to storage, retrieval and processing of analytical results. Good, inter-operable Information Technology (IT) systems are required so that information contained in the different datasets can be adequately mined by integration or, at least, interfacing, and efficiently linked to relevant information from other sources. The fact that many biobanks or biobanking networks use different IT platforms and different message formats and terminologies represents a significant obstacle to communication with, within, and between biobanks.

To allow efficient exchange of information between biobanks, it will be necessary to develop IT systems capable of providing comprehensive and accessible information on the data (with, for example, specific formats and definitions) and samples (such as storage conditions) collected. Such information is critical to evaluate (1) the consistency of information between different biobanks, (2) the quality of data and samples collected and (3) the potential of integrated use of the information to investigate a specific research question. For example information may need to have been collected according to a specific standard operating procedure, or alternatively be robustly convertible to this, to perform some specific analysis.

Bioinformatics systems need to be based on common language and developed to allow information to be accessed rapidly and securely.

Funding

Lack of sustained funding is typically identified as a major bottleneck in the long-term maintenance and operation of central resources in the life sciences. This applies even more to biobanks: they are both expensive to set up and maintain, and they need long-term financial stability to fulfil their mission and ensure access by researchers. Nowadays, patient organisations and national and international private foundations, often established to finance research into disease, play an increasing role in supporting this kind of key research infrastructure. However, to acknowledge the overarching value of these assets to public healthcare, in the next decade we need to develop a consolidated long-term funding framework for these invaluable resources, a framework that includes national and European funding schemes, healthcare systems, academic users and industrial parties and other private funding sources.

Recommendations for European Biobanking and Population Surveying

Goal

This Science Policy Briefing aims to stimulate multidisciplinary and trans-national research, to maintain European excellence in molecular epidemiology, and to boost the innovative capacity and competitiveness of European health-related industries and businesses, by developing the following:

- A pan-European biobanking infrastructure as an integrated effort of multiple scientific disciplines, biobanking resources and interdisciplinary research centres.
- A sustainable funding system, based on cooperation between national and international research ministries, industry, and EC-related organisations.
- A social, legal and regulatory framework that facilitates and stimulates trans-national research and data exchange.

The following recommendations arose from discussions during the Amsterdam workshop and should be taken into account when establishing and/or optimizing a pan-European biobanking infrastructure obtained from a population survey.

Scope

- Inclusion of risk factors relating to both common and rare diseases, as well as environmental sensitivities.
- Integration of retrospective/existing and emerging population-based biobanks and prospective hospital-based populations.
- Development of a population-based, prospective, pan-European cohort.
- Inclusion of a study of the healthy ageing population parallel to studying disease to obtain a positive reference for disease.
- Application of new technologies with existing activities: linking of high-throughput genotyping and 'omics' research facilities and biological resource centres with population/cohort studies, disease/tissue biobanks, survey studies, and biological data collections.
- Development of cellular phenotyping, including live measurements for future refined studies.

Practical approach

- Initiate actions by a strategic working group small enough to efficiently move these forward.
- Hold regular user group meetings (every six months for example) to agree on practical issues of quality control and quality assurance and other technical aspects.
- First map current initiatives and organisations, utilising existing systems (e.g. P3G observatory).
- Coordinate activities by one or more pan-European conferences on biobanking.
- Pragmatically involve existing biobanks and ongoing high-throughput research while standardisation and harmonisation are mid-term goals.
- Harmonise standards and procedures at a global level, so the efforts of P3G and PHOEBE should not be duplicated but built upon.
- Integrate existing workshops for analysing data from international biobank projects (parallel to ongoing genetic analysis, e.g. GenomEUtwin and GAIN workshops).

Data integration and sample sharing

- Develop non-destructive data processing, for example quality control, allowing access to raw data.
- Enable transparent, integrated access across biobanks, while maintaining the integrity of the underlying existing biobank infrastructure, which can be achieved by a virtual data warehouse model (eg GenomEUtwin).
- Define a unique permanent identifier for every biobank to enable unambiguous referencing.
- Stimulate facilities for data and statistical analysis, computational capacity and database development, and stimulate of access to such facilities.
- Strengthen training in statistical genetic analysis of complex conditions and improve the user interface of state-of-the-art software.

Ethical, legal, social and political aspects

- Integrate research into implementation, clinical benefit and public perception as part of the biobanking research.
- Initiate the legal/social platform, an international grassroots movement of legal expertise that should be developed adopting an open user-amendable based model.

- Clear scientific, ethical and legal definitions should be formulated and widely disseminated that emphasize the difference between “analysis” of specimens in the course of epidemiological research and “testing” of subjects in diagnostic and prognostic clinical practice.
- Coordinate diverse activities, perceptions and approaches of national and international agencies and consolidate them into an inter-agency biobanking action.

Deliverables

- An advisory platform, integrated with the P3G observatory but with a European emphasis, easily accessible to national decision makers, regulators and the public, to address legal, ethical and public engagement issues as well as technical and managerial aspects.
- Standard operating procedures (including lexicon and data standards) for biobanking research and future integration of electronic health records (including prescription data if possible) complying with privacy legislation.
- Clear arguments, illustrated by examples, of the value to society of investment in biobanking both in the short term (e.g. diagnostic harmonisation, better standards of care; importance to research, including better rates of discovery, more and better clinical trial opportunities) and long term (targeted drug development, reduction of drug-related toxicity, personalised medicine and prevention).

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