DNA Analysis for Human Health in the Post-Genomic Era

An APEC-Wide Foresight Study

Vol. I Summary Report

Asia-Pacific Economic Cooperation
APEC Industrial Science and Technology Working Group

The APEC Center for Technology Foresight
National Science and Technology Development Agency
Bangkok, Thailand
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Asia-Pacific Economic Cooperation (APEC) is a cooperative grouping of “member economies” located around the Pacific. Currently, it includes 21 countries: Australia; Brunei Darussalam; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; South Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; Philippines; Russia; Singapore; Chinese Taipei; Thailand; USA; and Vietnam.

Within APEC is the Industrial Science and Technology Working Group (ISTWG). ISTWG’s goals and objectives relate to the following statement of APEC Leaders:

Our vision for the 21st century is of a dynamic and prosperous Asia-Pacific region built on the development and application of industrial science and technology which improves quality of life while safeguarding the natural environment.

Osaka Action Agenda

Established as a project of the ISTWG in 1998, the APEC Center for Technology Foresight aims to develop and diffuse foresight capability across the APEC region. The Center is hosted by the National Science and Technology Development Agency of Thailand (NSTDA).

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Science and technology are vital to our society, economy and environment. They lead to wealth creation and improvement of the quality of life. Successful exploitation of technology has become critical to achieving economic competitiveness. However we live in a world which is changing rapidly and we must be able to respond to change with flexible strategies. The concept of Foresight is concerned with the development of a range of possible futures which emerge from alternative sets of assumptions about emerging trends and opportunities. It is not based on extrapolation of existing patterns; it explicitly recognizes that the future is uncertain and that seriously disruptive events can, and will happen. Most importantly the role of Foresight is not just to prepare well for the future but also to take every opportunity to shape and create the future.

The APEC Center for Technology Foresight (APEC CTF) was established in Bangkok in February 1998 by the Royal Thai Government under the National Science and Technology Development Agency and Ministry of Science, Technology and Environment, as a project of the APEC Industrial Science and Technology Working Group (ISTWG). The objective was to serve and involve all APEC economies in diffusing Foresight capability across the APEC region. However the aim was not just to assist member economies with their own Foresight activities through training, consulting and promotion of Foresight but also to conduct studies at multi-economy level to develop technology collaboration leading to partnerships and alliances. The present study is the sixth conducted by APEC CTF; these studies have involved up to 13 APEC economies.

Foresight is not a new technique; it has been developing over the past thirty years and the current definition used by APEC CTF reflects an approach of futures linked to society and driven by researchers, industry and stakeholders, namely:

“Foresight involves systematic attempts to look into the future of science, technology, society and the economy, and their interactions, in order to promote social, economic and environmental benefit.”

A simpler definition is: “Foresight is a systematic approach to understanding and engaging the future.” Thus Foresight addresses three major challenges posed by the future:

- **Complexity**: cause and effect relationships are not always obvious. Thus causal factors may interact, there may be long time delays between the cause and the effect or there may be inter-societal differences.
- **Uncertainty**: many relationships are too complex to unravel completely. Even simple relationships may be associated with high uncertainty if the knowledge base does not exist or if people are powerless to affect the outcome.
- **Ambiguity**: differing interpretations of identical information and data are possible because people have different interests and beliefs.
In this study Foresight is applied to the rapidly developing area of health sciences with particular emphasis on the links between genetic makeup of people and their susceptibility to diseases, and the potential for development of new cures.

Over recent years there has been intensive research on the understanding of genes and their link to diseases, and on the mapping of the human genome. Thus, important steps have been taken in the understanding of the molecular basis of many single-gene disorders based on inheritance e.g. congenital malformation and mental retardation. A start has been made on a better understanding of the genetic component of diseases such as strokes, diabetes and cancer. This is leading to the development of therapeutic agents to deal with these diseases.

The recent sequencing of the human genome as well as the genomes of other organisms such as pathogens, disease vectors, insects and animals points the way to a new approach to biology, a new way to consider human health, new avenues for drug development and drastic changes in health care systems. The implications for the next decades are enormous and there are many issues-scientific, industrial, social and ethical –which need to be addressed. Against this background APEC CTF proposed a Foresight study of DNA analysis for human health in the post-genomic era in the context of APEC.

The idea was discussed at the meeting of the APEC Industrial Science and Technology Working Group (ISTWG) in Hanoi in April 2001, a Concept Paper was presented to the ISTWG meeting in Penang in October 2001 and the study was approved with strong and unanimous support from the ISTWG meeting in Singapore in April 2002. Supplementary funding from the APEC Central Fund was approved and made available in late 2002. The study commenced in January 2003.

APEC CTF is grateful for the substantial contribution of Position Papers from four economies, namely, from Australia on micro-arrays and nanochips, and on gene diversity and health; from Canada on bioinformatics, and on gene therapy; from Japan on drug development; from Thailand on ethical, legal and social issues. In addition Thailand provided an Issues Paper drawing out the main issues as an input to the Experts’ Meeting in Bangkok. We are particularly grateful to the authors and their organizations that enabled them to devote considerable time and effort to the study.

APEC CTF would also like to thank the 37 Experts and 5 Observers from 13 APEC member economies who gave their time and experience to create a successful Meeting in Bangkok in August 2003 and the economies which supported their attendance. The lively discussion both in the Meeting and outside it led to a strong set of outcomes and possible policy thrusts. A wider group of 340 respondents from 9 economies answered a questionnaire which attempted to examine social and cultural differences in the use of the new approach to genes and diseases, and we are grateful to them for taking the time to make a valuable input to the study.

This Report (Volume 1) is aimed at policymakers and their advisors and sets out the essential steps of the process, the key issues in the development of DNA technology and the views of Experts on the direction of development of this area of the health sciences. A further Report (Volume 2) is aimed at increasing the awareness of the potential of DNA analysis for human health in the APEC
economies and contains an Overview Paper, all the Position Papers, the Issues Paper, the questionnaire and its responses, and the detailed scenarios created in the Meeting.

We are pleased to note that a major new initiative, the APEC Life Sciences Innovation Forum, has been launched by the APEC Committee for Trade and Investment on 14-15 August 2003 at Phuket, Thailand with the strong support of the Royal Thai Government. The Forum implements a decision by the APEC Leaders at their meeting in Los Cabos, Mexico in 2002 to place emphasis on life sciences and their application in the health sciences. The present study complements the activities of the Forum and APEC CTF made a presentation on the study at Phuket. Close contact will be maintained with the Forum organizers to ensure that the outcomes of the present study contribute to the development of the Life Sciences Strategic Plan to be developed by the Forum.

APEC CTF is pleased to acknowledge the continued financial support of the Royal Thai Government through the National Science and Technology Development Agency and the generous financial contribution to the study by the APEC Central Fund.

APEC Center for Technology Foresight
National Science and Technology Development Agency
This report describes a Foresight study of “DNA Analysis for Human Health in the Post-Genomic Era”, conducted by APEC Center for Technology Foresight (APEC CTF). The driving force for the study was the recognition by the International Advisory Board of APEC CTF that the life sciences are changing dramatically as a result of the convergence of information technology, small scale technologies as micro- and nanotechnology, and molecular biology and genetics leading to the sequencing of the human genome. The implications of this convergence for society in the 21st century are profound in terms of new ways to consider human diseases, new avenues for drug development and new approaches to healthcare.

The conduct of the study involved the preparation by APEC CTF of an Overview Paper which identified critical emerging technologies; the commissioning from four APEC economies of six Position Papers on these technologies including one non-technology paper:

1. Microarrays and nanochips
2. Genome diversity and health
3. Bioinformatics
4. Drug development
5. Gene therapy
6. Ethical, social and legal implications

It also includes the preparation of an Issues Paper by Thai experts; a questionnaire involving 340 experts across 9 APEC economies; and the identification of key issues and policy initiatives using scenario creation and analysis at an Experts’ Meeting in Bangkok in August 2003. The Meeting involved 37 Experts from 13 economies and included both researchers and clinicians.

The Position Papers provided a sound technical framework for the study while the Issues Paper provided a framework for discussions of broader matters. Ten key issues were identified namely:

1. Definition of Post-Genomics
2. Implications for Human Health
3. Scientific and Technological Inputs
4. The Integration of Post-Genomic Research into the Healthcare System
5. Funding, Infrastructure and Resources
6. Education and Training
7. Collaboration and Networking
8. Commercialization
9. Societal Implications of the Post-Genomic Era
10. Implications for Small and Less-Developed Economies.

The questionnaire was designed to draw out similarities and differences between economies in their approach to post-genomics and human health considering their cultural, social and economic diversity. However the differences were not brought out in the responses possibly because the responses were from experts who were linked in an international view of the topic or alternatively because distinctions between the diseases patterns of developed and developing
economies are now blurred due to economic development, migration and global travel. Detection and treatment of infectious diseases was seen as the major priority together with diseases associated with more affluent lifestyles such as diabetes, hypertension and arteriosclerosis.

The Experts’ Meeting identified eight critical policy initiatives as:
1. Restructuring the International Intellectual Property Regime
2. Education for a bio-Social Future
3. Harmonization of International Standards, Protocols and Access
4. Cooperation and collaboration between economics and regime
5. New Business Models for the Health and Pharmaceutical Industries
6. Increased Cost Effectiveness in the Health Products and Services Industries
7. Addressing ‘Translational Issues’
8. Need for ‘Honest Brokers’

Both the key issues and the policy initiatives map closely with the outcomes of the inaugural meeting of the newly created APEC Life Sciences Innovation Forum held in Phuket, Thailand just before the Experts’ Meeting for this study. The Forum provides an excellent opportunity to implement the findings of the present study since the Forum has the strong support of APEC leaders and thus APEC CTF plans to maintain close links to the Forum and its activities.
1. Introduction

1.1 The Basic Concepts of Genomics

With the exception of diseases that are intracellular parasites most living organisms are divided into two general classes\(^1\) - the single celled organisms with simple internal organization like bacteria and yeasts called prokaryotes, and those single cell and complex organisms with membrane-bound nucleus and compartmentalized subcellular structure like algae, fungi, plants and animals called eukaryotes. Living organisms contain genetic material which provides information for performing cellular tasks and for making new cells. This genetic information is transferred from one generation to the next by subcellular structures called chromosomes. Prokaryotes usually have a single chromosome while eukaryotes can have up to several hundred. For example, in humans there are 23 pairs, one of each pair is inherited from each parent.

Chromosomes consist of a tightly packaged length of a chemical structure called DNA (deoxyribonucleic acid) together with proteins that help to define its structure and level of activity. DNA consists of two strings of nucleotide bases wrapped around each in a double helix. There are four bases-adenine (A), guanine (G), cystocine (C) and thyamine (T). Genes are specific lengths of DNA that encode the information to make protein or a ribonucleic acid product. The different structures and functions of proteins depend on the order of the amino acids in the peptide chains and the way in which they are constructed and this, in turn, is controlled by the order of nucleotide bases in the genes. The sum total of this information for any organism is called its genome. The study of genomes is called genomics.

DNA has the remarkable property of self-replication. As cells divide, so do chromosomes, and each pair of DNA strands comes apart and acts as the template of a new strand. Because of the strict pairing of bases (A always pairs with T and C with G) the new pairs of DNA strands are therefore identical to those from which they were synthesized. But they are not always identical, sometimes mistakes or mutations occur resulting from the substitution of a different base. Many of the mutations have little or no effect on the function of a gene, but some can alter properties favourably leading to resistance to diseases while others can act in the opposite way leading to defective gene function and susceptibility to diseases. One challenge of genomics in human health is to discover the genetic variations that cause diseases so that genetic testing can be developed to forecast the risk of individuals having diseases at a future date.

The link between genetics and disease requires some discussion. Although many diseases can be traced through families because they result from a single defective gene, with few exceptions they are rare and are not a major health problem. On the other hand most common diseases are the result of infectious agents or other environmental factors and for many of them the cause is unknown. However there are two major influences of genetics in these latter situations. Firstly any disease process can be explained ultimately in biochemical terms which, in turn, reflect gene function. Secondly there is a remarkable degree of individual

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1 It is now accepted, though, that archaea or archaebacteria forms the third kingdom unto themselves since they differ biochemically in the arrangement of the bases in their ribosomal RNA and in the composition of their plasma membranes and cell walls. These organisms emerged at least 3.5 billion years ago and live in environments that resemble conditions existing when the earth was young.
variation to susceptibility to environmental factors which are linked to genetic variations.

Over the past 20 years important steps have been taken in the understanding of the molecular basis of many single-gene disorders based on inheritance e.g. congenital malformation and mental retardation. A start has been made on a better understanding of the genetic components of diseases such as strokes, diabetes and cancer. This is leading to the development of therapeutic agents to deal with these diseases.

The announcement of the success of the Human Genome Project has given an enormous thrust to this field. The project was carried out independently in the private and public sectors using different but related approaches. In June 2001 both Celera Genomics, a private company, and the International Genome Mapping Consortium, funded by governments and charities in several countries, announced the completion of “working drafts” of the human genome. Work has been continuing to complete the sequence analysis and to resolve ambiguities.

The human genome contains about 32,000 genes and it will take a long time to determine the function of all of them and how they interact. However it appears that human DNA sequences are 99.9 per cent identical to each other and it is the 0.1 per cent of variations that are of great practical value. Within genes it is possible to identify DNA markers which are sites (roughly 1 in 1,900) at which single nucleotide bases differ from person to person. These single nucleotide polymorphisms (SNPs) offer the possibility of linking genetic variations in populations to specific diseases. The result is that medical treatment could change to become comprehensive and highly integrated, highly individualized and focused on prevention rather than on treatment of established diseases.

1.2 The Role of Emerging Technologies

We can distinguish five areas where rapid advances in technology are likely to have major impacts on our understanding and application of genomics in human health. These are: diagnostics; proteomics; bioinformatics; drug development; gene therapy.

- **Diagnostics**

  The challenge is to develop cheap, fast techniques which will provide individuals with their own gene sequence. Current techniques are relatively slow and it appears that it will take about 5 years before sequencing technology reaches a point where it is fast enough and cheap enough to make personal genomics possible. Given that the variations between individuals are small, accuracy is essential.

  One approach is that of DNA microarrays or DNA chips. The surface of the array (about 1 sq.cm. overall) consists of a glass or silicon substrate on which fragments of DNA strands (the probe) from a known source are fixed by chemical reaction. To analyze a sample the target material, labeled with a fluorescent molecule, is then exposed to the chip to see whether it will react with any of the probe strands. By locating and quantifying the fluorescent signal in each DNA probe deposited on the chip the nature of the target material can be characterized in one step. It is possible to analyze tens of thousands of genes simultaneously on one chip and thus determine the gene sequence. Further, by comparing gene expression patterns from normal and diseased samples or treated
and non-treated samples, drug targets can be identified and potential toxicities of compounds can be examined.

• Proteomics

The coding information in genes causes the cells to produce proteins which determine biological functions. However although every cell contains roughly the same genes the proteins can vary widely due to the interaction between cells and their environment. Thus the relatively small number of human genes (around 32,000) can probably produce up to a million proteins.

The protein complement of a cell is called a proteome and the large scale analysis of proteomes is called proteomics. To this end the development of protein micro-arrays and protein chips has followed on the heels of DNA micro-arrays. The basic construction of such chips has similarities to DNA chips, such as the use of glass or plastic surfaces coated with an arrays of molecules such as antibodies, antigens and enzymes. Protein arrays are considered crucial to the characterization of multiple proteins and will lead to an understanding of molecular pathways that in turn will lead to useful information for drug discovery and diagnostic applications.

• Bioinformatics

The efforts of researchers have yielded thousands of genes and millions of SNPs as well as millions of proteins expressed by genes and the amount of data doubles each year. As a result of the need to process these data there has been a convergence of information technology and biological sciences into the new field of bioinformatics. We can define bioinformatics as the application of analytical theory and practical tools of mathematics and computer science to provide the computational management of biological information.

Bioinformatics takes in bioinformatic databases, genomic data analysis, proteomic data analysis, protein 3-D structure analysis, and clinical and pharmacological data analysis. The need to process extraordinarily large amounts of data is driving the development of larger and faster computer systems. The future growth of the information technology industry will be bioinformatics not in communications.

• Drug Development

All the drugs that have been invented up to now have come targeting the protein products of some 500 genes. While some 32,000 genes have been identified in the Human Genome Project it is considered that only 10 per cent of these are possible drug targets i.e. some 3,000 genes. However this is still a significant increase and to reap the rewards of genomics drug companies will need to increase the use of computer and automation in the process of drug discovery.

The ultimate aim is to develop new therapies, particularly in personalized medicine, based on personal genetic data. The promise of personalized medicine or pharmacogenomics is based on the fact that people react differently to different drugs depending on their SNPs variations. Thus adverse drug reactions could be prevented and more effective medications made available.

• Gene Therapy

More advanced knowledge of genes and their interactions offers the possibility for curing disease by altering the genetic make-up of cells, organs and individuals through gene therapy. Somatic gene therapy (altering the structure of body cells not involved in reproduction) involves the modification of the genome
of individual organs or tissues. Although somatic gene therapy is being widely researched there have been few successes.

The main problem is to deliver the “healthy” gene to the right cells and to insert it into the cell's genome in a stable and effective manner. There are prospects that diseases such as haemophilia and cystic fibrosis and certain cancers can be treated by gene therapy.

All of these clearly have a role to play in the future development of application of DNA analysis to human health in the post-genomic era.
An Overview Paper prepared by APEC CTF identified the emerging technologies noted in the Introduction. The Overview Paper is included in Volume 2. Based on this information APEC CTF then sought the assistance of APEC economies represented on its International Advisory Board in the preparation of Position Papers on these technologies. These were designed to give a snapshot of the current situation and to indicate future directions. Five position Papers were prepared: microarrays and nanochips (Australia); gene diversity and health (Australia); bioinformatics (Canada); drug development (Japan) and gene therapy (Canada). A further Position Paper was prepared on ethical, social and legal issues by Thailand.

On the basis of these and earlier discussions at a Core Group Meeting in Bangkok in April 2003, an Issues Paper was prepared by Thailand which identified ten general issues deemed to be important for the future of the widespread application of genomics in human health. These issues are discussed in Section 3. All of these materials were placed on the APEC CTF website² with a view to creating awareness of DNA technology and its application in the APEC region and to stimulating debate with stakeholders around the region.

The Core Group Meeting identified that there could be social and cultural differences between APEC economies in the use of the new approach to treating diseases. This arises from differences in genetic make-up, epidemiology, economic development, culture and values. To test this view a survey instrument was developed as a questionnaire and this was placed on the APEC CTF website. Nine economies with a range of backgrounds were approached to select a small number of experts to respond to the questionnaire. The results are summarized in Section 4.

An Experts’ Meeting was held in Bangkok from 26-28 August 2003. 37 Experts from 13 economies participated in the full meeting while an additional 5 Observers attended to listen to the presentations of the background papers on the first day. The Experts debated the issues identified in the Issues Papers. The scenario creation technique was then used to create three scenarios for human health in the region in 2015. This is described in Section 5. Finally, key policy outcomes and initiatives were identified as discussed in Section 6.

A chart describing the whole study process is summarised in Figure 1.

² http://www.nstda.or.th/apectf
Figure 1. The study process.

- **Overview Paper**
  - 28 May

- **Position Papers**
  1. Microarrays (Australia)
  2. Gene Diversity (Australia)
  3. Bioinformatics (Canada)
  4. Drug Development (Japan)
  5. Gene Therapy (Canada)
  6. Ethical Legal and Social Implication (Thailand)

- **Issues Paper**
  - 26 July

- **Report on Surveys**
  - 14 August

- **Report for APEC Life Sciences Innovation Forum**

- **Final Report**
  - Vol 1, 2
  - December

**APEC CTF Support and Organization**
- **Core group Meeting**
  - 3-4 April, Bangkok
- **Develop instrument**
- **Survey**
  - 9 Economies - Australia, Canada, Japan, Malaysia, Singapore, Taiwan, Thailand, USA, Vietnam
  - 24th ISTWG Meeting
  - 26-28 May, New Zealand
- **Life Sciences Innovation Forum, 14-15 August**
  - Phuket, Thailand
- **APEC-wide Expert Meeting**
  - 26-28 August, Bangkok
- **25th ISTWG Meeting**
  - 16-17 September, Singapore

**Timeline**
- **2002 November**
- **2003 April**
- **May**
- **June**
- **July**
- **August**
- **September**
- **December**
- **2004 January**
3. Key Issues in the Development of DNA Analysis for Human Health

These issues were identified through examination of the extensive literature and the material provided in the Position Papers. The full Issues Paper is in Volume 2.

3.1 Definition of Post-Genomics

A new paradigm is emerging with the availability of the entire sequence of the human genome and the development of new technologies to analyze this information. This has been termed the post-genomic era. While exciting new opportunities for genomics are opened up, it is important to recognize that they build on several decades of molecular biology research and the understanding of gene structure and the role of DNA developed during that period.

Genomic research involves not only the human gene; thus the genes of more than 200 species have been completely sequenced. Comprehensive and comparative analysis of these sequences are providing insights into diseases affecting humans. Thus in the case of malaria the complete genome sequences of the three species involved in this disease, namely humans, malarial parasites and mosquitoes harboring the parasites, have been determined. Detailed analysis of the interaction of these genomes will provide a unique opportunity to understand the mechanism of infection.

The new paradigm offers the opportunity to move from the established base of single-gene disorders based on inheritance to many common human diseases having a more complex genetic background. Possible genomic studies may involve areas outside traditional genetics such as anesthesiology where genetic makeup may influence a patient’s response to general anesthesia and thus the outcome of surgery.

Clearly the term post-genomic era needs to be used carefully in raising awareness of these developments.

3.2 Implications for Human Health

Some examples of implications for human health are:

- **Expanding the basic knowledge of health and diseases**
  
  Genomic research will lead to the understanding of detailed mechanisms of diseases and of their development, progression and severity. It may also provide insights into the basis of good health which, in addition to ‘not being sick’ may also involve physical characteristics, emotions, mental state and intelligence.

- **Disease diagnosis and risk prediction**
  
  Genomic-based screening to predict future health status and risk for diseases is now possible. This may include prediction for disease susceptibility, disease severity, disease progression, as well as response to therapeutic drugs and other forms of treatment. Disease may be diagnosed at a much earlier stage and progression of disease can be monitored.

  By screening early in life it will be possible to develop a plan to prevent or lower identified risks with a medication or gene therapy before the disease
symptoms appear. Lifelong prevention may involve avoiding risk factors, changing diet intake and modifying lifestyle.

- **Personalized treatment**

  Appropriate treatment for an individual can be customized based on the knowledge of the person's genetic make-up and the understanding of the genomic basis of drug response and toxicity. Drugs can be chosen to maximize efficiency and safety.

- **New medicines**

  New genomic approaches will reduce the time and cost of development of new drugs. Further the targets for drug treatment of currently untreatable or difficult diseases may be identified, leading to new drugs that specifically and effectively interact with those targets.

- **New industries**

  In addition to changes in the manufacturing components of the pharmaceutical, biotechnology and diagnostic industries there are opportunities for new service industries centered on genomic-based health care.

  These possibilities will develop during the next decade and clearly it is necessary to develop strategies and policy options now to deal with the implications.

### 3.3 Scientific and Technological Inputs

Research in the post-genomic era depends on the emerging technologies discussed in Section 1.2. Each of these involves sophisticated and expensive facilities which require both high installation and maintenance costs. Post-genomic era research is highly technology-dependent and the technology is evolving rapidly. This means that it is essential to monitor the emerging areas and make the most appropriate choice for particular applications.

An example of the rapidly changing research scene is the solution of protein structures which is difficult. Until recently a typical pharmaceutical firm could only solve 5-10 structures a year. However the need to deal with the increasing number of proteins deemed to be relevant has led to the development of high throughput X-ray crystallography equipment which will produce protein structures for one-tenth of the present price with a consequent speeding up in output. Once the structure is stored in a database specially developed software enables rapid screening to sort out promising compounds.

As noted in Section 1.2 the ever increasing amount of data on genome sequences and protein expressions is leading to a revolution in data handling and the need for larger and faster computer systems. This needs to be coupled with increasingly sophisticated software development. However at the same time since most researchers are not trained programmers the challenge is produce 'tool kits' which can be used to archive and handle data produced from DNA arrays or protein arrays in laboratories. The input of bioinformatics will be critical to the future development and application of genomic data.

Every economy will need to make choices on the extent to which it will be able to participate in the post-genomic era based on its scientific, technological and economic resources.
3.4 The Integration of Post-Genomic Research into the Healthcare System

Progress in post-genomic research may transform the future of clinical medicine as noted above. However there is still a gap between basic research and its applications. It is still unclear how it will be applied in the healthcare system. The integration/implementation of developments in post-genomic research requires public policy with careful planning, translational research and an appropriate health care system with active participation from the private sector. The success will depend on social, community and economic constraints in different societies.

Post-genomics medicine will shape the future of the healthcare system but correspondingly the extent of adoption by the healthcare system will shape the directions of research. Figure 1 illustrates the complex net of interacting elements involved in the integration of post-genomics into healthcare systems. Thus important factors include efficient and robust clinical trial regulation, mechanisms providing benefit to the individual and to society, and the accessibility and cost-effectiveness of implementing the research findings.

There must be a continuous dialogue between the researchers and the healthcare professionals to ensure that appropriate genomics research is implemented in the healthcare system.

Figure 2. Integration of Post-Genomics into Healthcare Systems.
3.5 Funding, Infrastructure and Resources

The issue of expensive infrastructures has already been noted above and this raises the issue of sharing, both of infrastructure and resources. This is of particular concern to smaller economies and also less-developed economies. There is a need for an audit of research capabilities in the APEC region with a view to developing mechanisms for making facilities in developed economies available to researchers from developing economies. Conversely, developing economies may be able to make contributions through access to cohorts of populations for clinical studies of diseases which cross national boundaries or niche areas where they have comparative advantages.

The European experience in developing the European Molecular Biology Laboratory is a possible model for APEC economies. This has a core permanent staff to maintain equipment and facilities funded by all European countries and has a large number of visiting researchers working in multi-economy teams.

Already there is sharing of gene sequences among all researchers through agencies such as the US National Center for Biotechnology Information, DNA Databank of Japan and the European Bioinformatics Institute that have missions to ensure accessibility of data to all researchers. In future these may have to extend their mission to cover data on clinical trials linked to genome studies.

The sharing of facilities and resources for genomic research in the APEC region needs to be explored as a matter of urgency.

3.6 Education and Training

The current developments in genomics have arisen from a fusion of molecular biology, small scale technologies and information technology. These are challenging the conventional concepts of education and training which tend to operate in disciplines. Each area has developed its own language and culture and the most significant problem is inadequacies of human understanding and communication. There is a need to develop new approaches, e.g. the use of cognitive science, to effectively use the three technologies and to achieve the breadth and depth of people to enable them to create new concepts in genomics and its application.

Using bioinformatics as an example currently there are few formal university bioinformatics courses and even fewer degrees in bioinformatics. Given the importance of the area it is imperative that undergraduate life science courses should include bioinformatics courses directed at providing instruction in the basics of informatics and informatics techniques. Universities need to restructure their current degree courses to develop new ones based around molecular biology, computational biology, bioinformatics and computer science.

In the application of genomics it is clear that education and training is needed for all levels of health professionals to enable them to understand the underlying science and technology and its interpretation. In ten to fifteen years one will not recognize how physicians engage in diagnosis and treatment. New professions may emerge such as genetic counselors who advise patients on the results and accuracy of tests for genome sequences, the implications of the tests and future treatment.

In the wider community, information and opportunities for learning about genomics and its implications must be made available to policy makers, opinion leaders and legislators to ensure fair, open and knowledgeable discussions.
The issue of education and training for the post-genomic era is a critical one for all APEC economies but especially the developing economies which are short of both human and physical resources.

3.7 Collaboration and Networking

This has been noted above in the context of infrastructure but also applies to education and training. An assessment needs to be carried out of capabilities in genomics research and training in the APEC region and the potential for collaboration. As an initial step to promoting collaboration the current state of interaction through networks needs to be established. Such networks have been actively developed in specific areas of genomics research in both Europe and North America and these can serve as models for a wider development in the APEC region.

An area of concern in collaboration in genomics is that of large scale clinical studies which are essential for linking genomics to diseases and human health. In many diseases diverse groups of populations are needed to obtain sufficiently large samples to validate the results while in some economies there may be unique groups with specific diseases. The context of clinical studies may be significantly different between developed and less-developed economies and even between less-developed economies themselves. There have already been cases of exploitation of vulnerable populations by research and commercial groups from developed countries and there is an urgent need to ensure that regulatory procedures are in place to protect vulnerable groups. This is an area where APEC can play a significant role and promote collaboration on an equitable basis.

Collaboration and networking among APEC economies needs to be addressed to ensure more equitable development and application of genomics to improve the quality of life of all people in the APEC region.

3.8 Commercialization

A significant link in Figure 2 is the translation of research results into products and services. This involves pharmaceutical firms, diagnostic tool manufacturers, biotechnology firms, information technology firms among others. Significant issues of intellectual property rights, regulation, international standards and risk capital are involved in commercialization.

Increasingly there will be collaborations between commercial firms, universities, government research agencies, and foundations as has already occurred in the Human Genome Program and intellectual property rights of participants need to be safeguarded. This is particularly so when less-developed economies are involved.

The framework of international agreements exists such as TRIPS (Trade-Related Aspects of Intellectual Property Rights Agreement). Laws and regulations in most APEC economies are TRIPS-compliant although the detailed interpretation of TRIPS may vary from one economy to another. There is a need to maintain open dialogue on intellectual property issues in commercialization of genomics among APEC economies.

The APEC Life Sciences Innovation Forum provides an ideal opportunity to explore the issues of commercialization of genomics in the APEC region.
3.9 Societal Implications of the Post-Genomic Era

Post-genomics has the potential to transform healthcare and, through that, society as a whole. While some feel that the change will occur rapidly—the Genomics Revolution—experience shows that it will occur through the confluence of old and new technologies in a context of evolving economic needs. For example, the recent advances in diagnostic technology and interpretation have led to a renewed thrust to traditional Asian herbal medicines.

The ability to provide individual genome sequences raises many social, ethical and legal questions. Thus if the genetic information indicates a person is at risk from a disease in later life how should he or she be encouraged to take preventative measures to avoid problems particularly if economic circumstances are adverse? How much should governments intervene in the public good? What are the rights of children in terms of possible intervention through gene therapy? How confidential is an individual’s genomic data? What if it used to stigmatize a person or used as a basis for discrimination by insurance companies?

The Position Paper on ethical, social and legal issues in Volume 2 canvasses many of these issues. Equity issues in application of genomics to healthcare are of particular concern both between economies and within economies. The availability of adequate healthcare to ensure an improved quality of life in APEC economies is clearly a priority of APEC Leaders as evidenced by their statement at Los Cabos, Mexico in 2002.

Open and transparent debate on ethical, legal and social issues of the applications of genomics in the post-genomic era needs to be actively encouraged at all levels of society to ensure that there is no adverse backlash as occurred with genetically manipulated plants in the food chain.

3.10 Implications for Small and Less Developed Economies

Many of the issues for small and less developed economies have been raised in the previous issues namely availability of expensive equipment, changes in education systems, protection of population rights in clinical trials, identification of niche advantages etc. The limitations of human, economic and physical resources will limit their abilities to gain adequate benefit for their societies from the post-genomic era.

As an example it is estimated that it will take about 5 years before sequencing technology reaches a point where it is fast enough and cheap enough to make personal genomics feasible. In this context cheap enough means US$ 1 000—a figure that will be affordable for wide use in developed economies but is not affordable for most people in developed economies. Clearly a major priority is to develop cheaper and cost-effective technology to ensure equity across APEC economies.

The APEC Life Sciences Innovation Forum provides an opportunity to identify those priority areas for research and development in genomics with particular benefits for small and less developed economies and to establish cooperative mechanisms to tackle them.
In developing this study, considerable evidence emphasised that issues of human health in the post-genomic era would be, and should be considered, very different, in different member economies. This is a consequence of differences in genetic make-up, epidemiology, level of economic development, culture and values.

Hence, as part of this project, a single-round survey instrument was designed, with the purpose of identifying the views of a small group of experts in genomic research in different member economies about likely genome-based technological developments, the time of their realisation and their impact on human health.

The instrument was developed from a number of earlier surveys and refined by testing with a group of Thai experts. It included 24 developments; (the detailed instrument is available in Volume 2). The experts were asked to assess, for each development, on a 1-5 scale:

- Significance - the extent to which it will address the most pressing health needs of their economy
- Impact on improving health in their economy
- Feasibility, by 2015
- Appropriateness to their economy- affordable, appropriate, acceptable (socially, culturally, and politically).

They were also asked to identify the relative importance of the development, ranked in terms of the ten most important developments for human health in their economy and to estimate the likely year of realisation. Finally, they were given the opportunity to suggest extra key developments.

The survey instrument was mounted on the APEC CTF website. Nine APEC member economies agreed to participate: Australia, Canada, Chinese Taipei, Japan, Malaysia, Singapore, Thailand, USA and Vietnam. 340 responses were received with an extremely strong input from Japan with 267 responses.

Analysis of the responses showed that, on average, all 24 developments were rated as very significant, having a very important impact, feasible to very feasible, and very appropriate. These results confirm that these selected developments will be highly influential in the application of genomics to human health across APEC member economies. However, they may also indicate that possible but less certain developments about which there is a wide range of opinion were not included in the survey.

With regard to specific developments, six stood out as having uniformly high significance, impact and appropriateness:

Development No.:

12. Cheap, simple, and quick identification/diagnosis of infectious diseases;
13. Vaccines available to treat the full range of common infectious diseases;

3 Specifically Bio-Express – Pre-normative research requirements for European biotechnology (an EC funded initiative to assess the requirements for pre-normative research in agri-food, environmental and medical biotechnology) http://www.npl.co.uk/biotech/bioexpress/questionnaire1.html, and relevant sections of the Japanese Seventh technology Foresight produced by NISTEP http://www.nistep.go.jp, and the article Top ten biotechnologies for improving health in developing countries, Nature Genetics volume 32, October 2002.
14. Capacity to identify new infectious diseases and develop effective treatment within 4 weeks;
17. Identification of genes for diabetes, hypertension and arteriosclerosis;
19. Stem cell technology in practical use for repair and replacement treatments;
22. Procedures established to ensure individual ownership and confidentially of their genetic information.

The results also show only minor variation between the views of experts from the various member economies. In general, those from the more industrially advanced group regard developments as being more feasible than those from the industrializing group, and place more emphasis on education.

This may reflect commonly held views among the international community of genomic researchers – views which may not be the same as other members of their economy. An alternative explanation that emerged during the Experts’ Meeting is that it is no longer possible to make a clear distinction between the diseases of the industrialised and developing worlds: “all diseases are international”.
Scenario creation is a way of envisaging what the future might hold for a particular economy, industry sector or organization. Rather than using projections from past trends, scenario creation attempts to develop internally consistent stories about possible futures. The technique has been used in Europe in two recent studies on genomics and human health—one from the viewpoint of identifying social research issues and the other from the viewpoint of standards and measurement and testing requirements. These are discussed in the Overview Paper in Volume 2. The present study was aimed at a broader view of post-genomics and human health in the multi-economy context of APEC.

In the present study the first stage in the development of scenarios of human health in the post-genomic era was to identify the major drivers of this future. This was done against the five STEEP categories: social, technological, economic, environmental and political. Participants identified, on 'Post-it' notes, the specific drivers they considered most important. These were subsequently clustered into common groupings.

On this basis the drivers described in Table 1 were developed:

**Table 1. Drivers of Human Health Treatment in the Post-Genomic Era.**

<table>
<thead>
<tr>
<th><strong>Social</strong></th>
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| • ageing population, including expectation of a longer life  
| • accessibility and equity in health care  
| • human/individual rights and protection of these rights  
| • education  
| • mobility, leading to faster and greater disease transmission  
| **Technological** |  
| • generic technology advances in bio- and information technology  
| • specific technological advances  
| - fast broadband telecommunications  
| - safe and effective nucleic acid transfer  
| - transfer of genes from animals and plants to make human proteins  
| - bio-sensors  
| - efficient, functional genomic technology platform  
| - home-based diagnostics  
| **Economic** |  
| • demand for a cheaper healthcare system  
| • affordable drugs  
| • wealth and profit generation  
| **Environmental** |  
| • environment-based emerging diseases  
| • environmental awareness  
| • impact of poor environment directly on health  
| • impact of global warming directly on health  
| **Political** |  
| • educating and influencing government decision-makers  
| • internationalisation and harmonisation of genome-based healthcare  
| • sharing of equity across APEC |
The second stage in the development of the scenarios involved the identification of the major uncertainties which could change the pattern of development of human health treatment in the post-genomic era to 2015. These are shown below in Table 2:

Table 2. Uncertainties in Human Health Treatment in the Post-Genomic Era.

<table>
<thead>
<tr>
<th>Uncertainty</th>
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<tr>
<td>1. Peace, war, terrorism</td>
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<td>2. Asteroid strike</td>
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<td>3. Efficacy of preventative measures</td>
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<td>4. Acceptance of minor illness as natural/acceptable occurrence</td>
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<td>5. Inclusion versus exclusion (rich VS poor- with respect to access to health care)</td>
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<td>6. Impact of global population shifts (domino effect)</td>
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<td>7. Economic downturn</td>
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<td>8. New high impact diseases</td>
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<td>9. Super Asian medicines</td>
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<tr>
<td>10. Long term downside of health technologies</td>
</tr>
<tr>
<td>11. Public acceptance of international cooperation</td>
</tr>
<tr>
<td>12. Community responses to new health sciences</td>
</tr>
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<td>13. Environmental changes e.g. global warming</td>
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These uncertainties, ranked according to the extent of their impact and uncertainty (ie lack of basis to predict their occurrence) were used to develop the parameters for three highly distinct scenarios of human health treatment in the post-genomic era to 2015:

Scenario 1: ‘Should Grandma Die’ or ‘Bio Beware’
- continuing and growing economic disparity between the developed and developing countries, and within these countries, between the rich and poor;
- genomic technology is predominantly owned by a small number of global companies;
- a few highly specific genomic-based health treatments, targeted at the ills of the rich, are strongly promoted and taken up;
- unexpected and fatal side-effects emerge after a few years, leading to a very high level of litigation;
- a significant economic downturn occurs.

Scenario 2: ‘Disneyland can be fun ’ or ‘Universal Genomic health’
- strong national and international commitment to universal health care;
- agreed international regulations and effective cooperation mechanisms;
- major pharmaceutical companies cooperate with UN agencies to deliver affordable drugs to all countries;
- genomic technology rolls out at a slow but steady rate;
- genomic technology is generally regarded in a positive light by the community;
- new high-impact infectious diseases are emerging at regular intervals.

Scenario 3: ‘Happy Birthday Somsak’ or ‘The Real Genomic Future’
- spectacular breakthroughs in genomic technology for health care;
• a significant number of these emerged from traditional Asian herbal medicines, derived from genome mapping initiated in China;
• some of these advances provide the weapons for an international wave of bio-terrorism;
• global warming is proceeding at a faster rate than predicted, leading to major population shifts around the world.

Three scenarios were developed by three sub-groups of experts. In each case, the scenario took the form of a family story, reflecting the operation of the various features of their future to 2015. Summaries are presented below. The full scenarios are presented in Volume 2.

Scenario 1: ‘Should Grandma Die’ or ‘Bio Beware’

In 2012 there was a worldwide epidemic of SARS2, with much greater impact than the 2003 version. Many die and the global economy is tripped into severe recession. There is widespread resentment toward the biotechnology industry, because they had focussed so strongly on the diseases of the rich – diabetes, obesity and cancer, and put very little research effort into infectious diseases, like SARS. With significant levels of poverty, many families move to form small self-sufficient communities, relying on extended family or the community for support, and turn to their spiritual faith for comfort, and natural remedies for health problems. There is widespread social unrest, but the rich remain relatively secure in their walled compounds. The richest of all, of course, are the lawyers leading the litigation against the ‘bio-killers’.

Note: ‘Grandma’ is the main actress has to be present in this scenario. She lives with her family. There are five members: mother, father, two small sons and grandma. Grandma was taken to the public clinic in the city and the results have shown that she has cervical cancer. The public clinic did not offer the treatments which are DNA vaccine-based, and that they could not afford the cost in private clinics.

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Scenario 2: ‘Disneyland Can be Fun’ or ‘Universal Genomic Health’

Biotechnology has developed at a moderate pace over the 12 years to 2015, but such that technologies that were pushing the frontier in 2003 are now commonplace. The key structural feature was the establishment of a cooperative United Health Care Systems across the Asia-Pacific to which countries and companies contribute, and draw from, to provide an excellent healthcare system underpinned by leading science. There have been four epidemics of ebolafluenza since 2003, and this has lead to strong international cooperation in diagnosis, rapid sequencing and therapeutic vaccine development. Through all these trials,
there has emerged a greater acceptance of human diversity, and in particular, genetic disability.

Note: ‘Disneyland can be fun’ is the story about a family with 4 members: father, mother who has adopted 2 children, a 10-year-old daughter and a 6-year-old son. Their daughter is healthy but the son is an AIDS orphan who is HIV positive. Later the mother became pregnant gave birth to a son who has Thalassemia major. After the suffering the couple planned an IVF PGD pregnancy in Singapore to use stem cell transplant from ex cord blood to help their foreborn son. The plan worked and United Healthcare Systems funded the family to Disneyland, Hong Kong for a holiday but the mother contracted Ebolaflenza on the way. Nevertheless, the well-coordinated international collaboration helped solved the crisis and provided an excellent healthcare system to the family and the rest.

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Scenario 3: ‘Happy Birthday Somsak’ or ‘The Real Genomic Future’

The new complex therapeutic formulae based on traditional medicines appeared to offer the prospect for huge advances in human healthcare. And they did. But at the same time, they led to major bio-terrorist attacks in 2005 and 2012 which killed hundreds of thousands. This inevitably lead to a surge in investment in protective measures, including national DNA information systems (carried on personal genome cards), portable typing devices and DNA-based immigration controls. But the headlines were all about the first hosting of the ‘Really Open and Genetically Modified Olympic Games’.

Note: ‘Somsak’ is the main actor in this scenario writing. He was 73 years old and the scene open on his birthday. From then on he was a President of Herbalomics, Mitsubishi Health Science Institute. The scenario described how his company and others grow on applying technologies to effectively protect intellectual property, specifically, based on understanding of traditional medicines.
The three scenarios all present futures where intensive R&D in genomics enables significant advances in healthcare to 2015, albeit somewhat selective and at differing rates. Commercialisation is envisaged within 10-15 years. However in the first scenario lack of equity of access to adequate healthcare for all leads to underutilization by the bulk of society. By contrast in the second scenario there is a strong acceptance by society because of the wise linkage of excellent genomics research to healthcare systems for the benefit of society as a whole. In the third there is ambivalence in society about the benefits in improving healthcare as opposed to the disbenefits when used for bio-terrorism. These alternative views of the future support the need to address social and ethical concerns about post-genomics and human health at an early stage.

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6. Policy Initiatives for the Future of Post-Genomics in the APEC Region

This study has identified a set of issues critical to the future of post-genomics and its applications to healthcare in the APEC region and policymakers must take account of these in considering the strategic planning and management of their S&T resources, both people and facilities. The discussions in the Experts’ Meeting on these issues, particularly those during the interactive group activities of scenario creation, highlighted a number of policy initiatives as set out below:

- **Restructuring the international Intellectual Property Regime**

  Advances in the biological sciences, particularly those flowing from the mapping of the human genome, are opening up a wide range of issues about claims to, the basis of, and jurisdictions for intellectual property. These include ownership of information based on individual human genes, intellectual property with respect to traditional and indigenous therapies, ownership and transfer of human genetic material, regulation of bio-prospecting, etc. At a time when, following on from the WTO TRIPS Agreement, the present national basis of intellectual property law is under consideration, it is appropriate to consider the far broader issues raised by applications of intellectual property to the human genome.

- **Education for a bio-social future**

  There is a strong requirement for effective multi-level educational programs. Targets include life scientists who are not keeping up with advances in post-genomic advances, health professionals who are not aware of the potential of post-genomic –based diagnosis and therapies, health policy-makers and regulators, the general community, including politicians, and school children. Acceptance of rapidly emerging technologies will require a much higher level of discourse between all involved, including careful consideration and working through of ethical, legal and social issues.

- **Harmonization of international standards, protocols and access**

  The advances in post-genomic diagnostics and therapeutics are occurring so rapidly, their potential for application to human health issues so great and the necessity for providing access to those in need so powerful, that development based on national boundaries is inappropriate. There is a need to establish international agreements about the development, application and availability of genome-based human health care, and to develop new international institutions, codes of practice and legal frameworks to shape these developments most effectively. One important boost to this approach might be the recognition that ‘all diseases are international’ and that the considerations of equity are as much about efficacy as they are about altruism.

- **Cooperation and Collaboration**

  In addition to harmonization of the international environment for genomic-based human health care, there will be a need for high levels of cooperation and collaboration between economies and regions. In general, (with some specific exceptions) genotypes do not align well with national boundaries, and with mass migration, that becomes less so. Major population-based genomic studies will require high levels of collaboration and regulation.
• **New business models for the health and pharmaceutical industries**

The health and pharmaceutical industries are substantially based on industrial and market models that may be increasingly inappropriate in a post-genomic era. The huge levels of investment and the long time to market have required the extraction of very high profits from successful therapeutics. However, the pressure to provide access to life-saving drugs according to need rather than revenue, and the potentially revolutionary impacts of post-genomic human health care, may require new business models to be examined, based perhaps on very high volume, low margin, products and services, or private/public/non-profit foundation partnerships such as that recently developed to produce a malaria vaccine.

• **Increased cost effectiveness in the health products and services industries**

There are currently many high-cost, long-delay components in the health product development system, which may be capable of substantial reduction. While much emphasis is placed on the generation of new knowledge, there may be substantial opportunities for dramatically increasing the productivity of the manufacture of molecular therapeutics, and for reducing the costs of clinical trials and government approval. Another avenue for increased cost effectiveness is through a greater focus on prevention rather than treatment.

• **Addressing ‘translational issues’**

There are a range of issues concerned with the rapid and effective translation of genomic knowledge into action. This is more than the traditional ‘technology transfer’. It includes the design and operation of health care systems, administration processes, the incorporation of genome-based knowledge into everyday preventative measures (e.g. diet) and the storage, ownership and access to key personal genomic and pharmacogenomic data and history of significant health events. A logical development but one with major social and ethical issues is a universal health card or an embedded microchip containing these data.

• **Need for ‘Honest Broker(s)’**

Pursuit of a range of these initiatives will need to build from existing appropriate international organisations eg WHO, WTO. The creation of the APEC Life Sciences Innovation Forum offers the opportunity to explore new multi-economy mechanisms with sufficient influence and appropriate objectives. One such mechanism might take the form of a multi-economy or APEC-wide funding scheme for both research and clinical studies in genomic-based human health, funded by governments, the major health companies, and international benefactors. This might also provide the basis for the examination of the establishment of international collaborative ‘biobanks’.
7. Conclusions and Further Thoughts

The life sciences are changing rapidly as a result of the convergence of information technology, nanotechnology and molecular biology leading to the sequencing of the human genome. The rapid increase in the understanding of the role of genes and the proteins expressed by them has far-reaching implications for the future of healthcare systems, the pharmaceutical industry, the education and training systems, and the legal and decision-making systems in APEC economies.

The Foresight approach has been effective in providing a mechanism for grasping the complexity of these issues and for reconciling the many different perspectives and areas of expertise involved in life sciences. The study has provided strategic intelligence for inputs to APEC decision-makers and has highlighted a number of important areas for their attention as:

• The new paradigm offers the opportunity to move from the established base of single-gene disorders to many common human diseases having a genetic background. Thus, for example, in the case of malaria which is endemic in much of the APEC region, knowledge of the gene sequences of humans, malarial parasites and mosquitoes will lead to development of drugs for prevention and treatment of the disease. A similar approach should be possible with dengue fever. The critical issue is the role of the pharmaceutical companies in the development and manufacture of such drugs in an unattractive cost structure for them.

• There are large differences between, and within, APEC economies in their capabilities to understand and use, let alone develop, DNA technology. Thus, while costs of equipment for sequencing human genes are falling as technology improves, they are still expected to be too expensive for widespread use in developing countries in the short-term. A major challenge is to accelerate the development of cheaper and cost-effective sequencing technology to ensure broad equity across APEC economies.

• As standards of living rise in developing economies and a greater proportion of the population changes its living and dietary habits it is no longer possible to make a clear distinction between diseases of the developed and developing economies. This is exacerbated by the increasing flow of people across borders both as tourists, as migrant workers and as refugees so that “all diseases are now international”. Thus, in the study, identification of genes for diabetes, hypertension and arteriosclerosis was seen as a priority across all APEC economies.

• A significant area is the coordination of collaboration and sharing of information, facilities and training across APEC to redress the imbalances between economies. Harmonization of standards and the safeguarding of intellectual property rights are major issues that need to be addressed to ensure the orderly development of gene technology in APEC. Another significant issue is that of large-scale clinical trials which are essential for linking genomics to diseases and human health; vulnerable populations across APEC need protection.

The exponential growth of the knowledge base both in the three converging technologies of information technology, nanotechnology and molecular biology, and in life science itself, poses enormous challenges in ensuring efficient
communication between researchers in these fields. It has been suggested elsewhere that cognitive science will become an increasingly important field for research in order to use effectively this rapidly growing knowledge base. In turn this knowledge base will enable major advances in the study and application of cognition by allowing the construction of physical models of brain function. A schematic diagram illustrating the interaction of these converging technologies to produce a so-called ‘twenty first century architecture’ for life sciences is shown in Figure 3.

Figure 3. The convergence of information technology, biotechnology, nanotechnology and cognitive sciences in 21st century architecture for life sciences.

The Experts’ Meeting of this study followed closely on the launch of a major new initiative by the APEC Committee on Trade and Investment, namely the APEC Life Sciences Innovation Forum which has the stated goal of developing a Life Sciences Strategic Plan for APEC. Given the strong support from APEC Leaders to the creation of the Forum it should provide the means to implement identified initiatives. It is therefore pleasing to see that there is considerable coincidence between the ten key issues of Section 3 and the thirteen key themes arising from the Forum meeting (see Appendix 2).

The concluding discussions of the Forum suggested that substantial outcomes could be achieved through the Forum in five general areas:

- **Capacity building**: capacity building in areas of science and technology, education and training in the life sciences, including the capabilities required to make effective use of advanced drugs;
- **Regulation, Clinical Trials and Access**: programs to make regulatory and related processes more transparent and more efficient, to coordinate and rationalize clinical trials and to improve access for innovative drugs;
- **Diseases Prevalent in Developing Economies**: initiatives to encourage the creation and marketing of medicines for illnesses prevalent in the developing economies but which do not currently provide a sufficient
market to encourage drug development (such as tuberculosis, malaria, dengue fever, and e coli–related diseases);

- **Integration of Advanced Electronics into Biomedicine**: mechanisms for the cooperative integration of the leading edge expertise of East Asian economies in electronics and information technology into biomedical products; and

- **Commercialization and Venture Capital**: strengthening the processes for commercialization of intellectual property in APEC member economies, perhaps including initiatives to strengthen the venture capital market outside North America.

Since these map closely with the important areas that emerged from the present study as noted above, APEC CTF plans to maintain close links to the Forum and its activities as part of the follow-up through a post-Foresight program. Further, opportunities will be sought to make presentations to decision-makers in APEC economies and to regional conferences, and to write articles in appropriate journals. The active support of the APEC Industrial Science and Technology Working Group and of the participants in the study will be important in the post-Foresight phase to ensure the implementation of the outcomes of the study.
Appendix 1: List of Contributors

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26-28 August 2003 at the Siam City Hotel, Bangkok, Thailand

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Life Sciences innovation was recognized as a critical area of growth and socio-economic development – healthy people produce healthy economies. Productivity gains far outweigh the costs of developing innovative products. New product development adds significantly to longevity, wellness and economic potential.

Generating a successful life sciences industry requires political leadership and commitment from the top and depends on the proper policy environment, public-private partnership, human capacity, and efficient and effective delivery of patient-focused products and services.

1. Building research capability in a systems science/medicine world

There was great stress on the need to build research capability in a systems science world. This must have regards to

- The long term and very competitive nature of life sciences innovation
- The need for both a variety of disciplines and for specialization
- Research capability needs to be directed both at unmet needs and at high value products

2. Importance of public/private partnerships, in many countries and areas

The importance of public/private partnership at all level e.g. between and within economies, between academia and governments, between business and governments, and between academia and business, was emphasized with reference to research, commercialization and funding, manufacturing and regulation.

3. Policy Environment

A general consensus emerged concerning the importance of establishing the right policy environment to stimulate and promote life sciences innovation. This included Intellectual Property Rights protection, regulatory framework and commercialization and investment policies.

4. Incentives for products with great health benefits but limited market potential

There are important issues about incentives for private firms to pursue innovation in respect of products that offer major health benefits but little scope for appropriating market revenues. Some programs in the USA have been effective, and the issue is very important for some diseases prevalent in developing countries.

5. Gains, in terms of drug development, costs and time, from rationalizing and coordinating human trails

Important gains can be made by coordinating and rationalising clinical trials, and successes in Japan in this area were described. This could help other countries to participate more actively in global drug development programs.

6. The importance of building human capacities within economies

There is a clear need to build human capacities in APEC economies, in research and technical areas, management, education and regulatory affairs.
7. Harmonization of R&D and registration regulations

There is a scope for further programs to harmonise R&D and registrations programs in APEC economies.

8. Need for realism in the intensely competitive world of life science innovation

The need for realistic audit in assessing country capability, and devising future plans was highlighted. There was a general recognition that individual economies were more likely to succeed by focusing on niches or cluster industries and specific aspects of the value chain. Global pharmaceutical companies adopt rigorous processes in investment decisions, and local policies matter.

9. Central role of best practices in all aspects of the life sciences industries

Emphasis was placed on the central importance of achieving international best practice in the various aspects of the life sciences innovation value chain, from research, development, manufacturing and market regulation to delivery of health products and services.

10. Supply chains, from research to final consumer, as an integrated public/private process

A useful concept of the supply chain is that of an integrated public/private process from research and the creation of drugs to the final consumer. In all APEC economies there are undoubtedly ways in which life sciences innovation can make this supply chain more efficient and effective, and safer.

11. Results on the impact of new chemical entities sharpen the innovation challenge

Analysis of the impact of new drugs on human health and longevity and on other health costs show that, while new technologies are complex, expensive and require much infrastructure and support, improved innovation offers great social and economic benefits.

12. The opportunities for East Asia and other economies in terms of the integration of expertise in electronics and information technology into biomedicine

There are opportunities for East Asian countries, and others, to benefit from the integration of existing technological and industrial expertise into biomedicine. This will become more important as information technology and biotechnology converge with nanotechnology.

13. The underlying reality of the very real differences between APEC economies in terms of health needs, health system challenges, technology level and commercialization capabilities

This remains a key underlying issue, to be understood further and considered as the Forum proceeds with its work.