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GAP FORUM ON

INFORMATICS IN BIOLOGY & MEDICINE

Report

4 & 5 December 2003

Melbourne, Australia

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INTRODUCTION

The GAP Forum on Informatics in Biology and Medicine 2003 brought together contributors from the highest levels of Australian Government and Industry.

Participants from **51 organisations** attended the Forum over the two days *(see App. 7, page 41)*, including Australian State and Australian Government Ministers and ministerial representatives, heads of Government departments, pro-vice chancellors of research from major Australian universities, directors of leading Australian biotechnology/bioinformatics companies, research directors from pharmaceutical companies and venture capitalists.

Unlike many events, which are introspective, the GAP Forum had a multi-disciplined approach to its planning, discussions and outcomes. Its objective was to encourage executive stakeholders from government, research, industry and the vendor community to develop a strategy to drive a sustainable and value creating life sciences business model in Australia. The focus was specifically on building an informatics capability for the biological science and health sectors that would support the four key stakeholder groups represented at the Forum – Public Research organisations, Pharmaceutical companies, Biotechnology firms and Government.

The following core issues formed the agenda of the Forum:

- **Global Positioning** - measures for increasing Australia's participation in and benefits from the global knowledge exchange;
- **Government and Policy** - coordination and a more focused approach in education, policy and investment in health and life sciences;
- **Research** - needs of the research sector for growth and development;
- **The Health Industry** - leveraging information management to drive better health outcomes;
- **Information Technology** - establishing a globally competitive IT infrastructure in health and biological informatics;
- **Legal** – obtaining a broader understanding of the legal and ethical issues facing Informatics in health and life sciences

Prior the Forum, desired outcomes were: for the Forum to feed into the National Bioinformatics Strategy being developed by the Australian Government Department of Industry, Tourism and Resources, in consultation with other Australian Government, State and Territory agencies (*for more information, see page 7*); to stimulate investment in the industry (including biotechnology, health and the environment); for this process to continue and for events to be held in the industry next year.

States involved within the GAP Forum on Informatics in Biology and Medicine directly benefited from the participation, by developing their position in the health and life sciences informatics industry in Australia, strengthening their relationships with other states, benchmarking our performance against that of the rest of the Asia-Pacific region as well as with Europe and the USA in health informatics and in generating commercial outcomes.

The main topics of discussion at the Forum were: The Industry, The Opportunity, Australia's Competitive Advantage, Access to Information, Big Projects, Funding, Government Commitment, and Networking.

Disclaimer

This report represents a wide range of views and interests of the participating individuals and organisations. Statements made during discussions are the personal opinions of the speakers/delegates and do not necessarily reflect the views of the Australian Government.

Definitions

HEALTH INFORMATICS: "the collection, storage, retrieval, communication and optimal use of health-related data, information and knowledge" (source - The Health Informatics Society of Australia)

BIOINFORMATICS: "the application of information technologies and sciences to the organisation, management, mining and use of life-science information" (source – "Bioinformatics: Issues and Opportunities for Australia" (Littlejohn Report))

EXECUTIVE SUMMARY

The medical- and life-sciences have been transformed in the past decade through the advent of revolutionising technologies in genomics and functional genomics. These technologies have resulted in the generation of biological data in digital format at a vast rate. In parallel, advances in information technologies have allowed us to convert this data into information and detailed knowledge of the innermost working of numerous living systems. This understanding has extended to human health; with the decoding of the human genome, we sit at the beginning of a new era in medicine, where information will be at the core of medicine.

We are therefore at a strategic point in time for government and industrial activities in the medical- and life-sciences. The health, environment, biotechnology and pharmaceutical industries are all undergoing shifts as the importance of information and its management become central, and intellectual property becomes the major business asset.

If Australia is to make the most of the opportunities these changes present, we need to understand our capabilities and strengths, as well as our competitive weaknesses and global threats. In recognition of this need, the first GAP forum on the role of Informatics in Medicine and biology was held in Melbourne on 4 & 5 of December 2003.

The major outcome of this meeting was the formation of an **Australian National Committee on Informatics in Medicine and Biology (ANCIMB)**, comprising members from industry, research and governments, and chaired by Dr Tim Littlejohn. The roles of the Committee are to:

- Interact with government and play a role in facilitating policy development and industry growth
- Gain an understanding of the needs of the health and biological informatics industry through mechanisms such as a feasibility study
- Play a role in developing and deploying standards in the industry to accelerate growth

The ANCIMB will consider the full range of business opportunities and will undertake a number of projects, managed by a series of subcommittees including the following:

- Establish links with key large industry players through:
  - Development of networks across industry, education and research sectors to pursue matters of mutual interest
  - Development of relationships with the pharmaceutical industry in the broader sense to enhance commercial and national health outcomes
  - Development of strategies for assisting the agriculture industries by engaging with industry players and State/Territory and Australian governments policy makers and legislators
  - Coordination of activity and connection of key public and private stakeholders

- Work with the bioinformatics community to develop standards for interoperability, integration and data exchange to accelerate industry development in informatics in medicine and biology
- Establish a process of delivering advanced health outcomes by utilising the already well established connectivity of health general practitioners in Australia[1]
- Investigate the feasibility of establishing a Centre of excellence[2] in information based medicine, focusing on computer technologies for health information
- Establish a National Clinical Trials Registry
- Develop strategies for using informatics to enhance the environmental protection of Australia's unique biota as well as development of industry growth around this valuable asset
- Encourage new venture creation by engaging with start-up firms in informatics in medicine and biology and with the innovators in industry and academia and with the finance, especially venture capital (VC) sector
- Raise the community's awareness through:
    - Development and deployment of a strategy for working with government and the education sector to ensure that biological and health informatics are recognised as a unique discipline and part of the education portfolio
    - Establishing approaches to simplifying and demystifying information technology for non experts in the health and life sciences
    - Fostering an entrepreneurial culture for informatics in medicine and the biological sciences
    - Creating strategies for skills development and training for informatics in medicine and biology
    - Establishing a WWW site and email list to keep community informed of developments in informatics in medicine and biology
- Develop relationships with international bioinformatics organisations; identify sources and discuss the potential use of funding from the USA, Europe and others
- Convene the next Forum by mid 2005

[1] *The Australian Government Department of Health and Ageing is implementing activities that aim to improve connectivity between general practitioners and other health care providers. These activities include significant support for the computerisation of GP practices, implementing* 'Health*Connect', the proposed national health information network to facilitate the safe collection, storage and exchange of consumer health information between authorised health care providers, and providing rural GPs with access to broadband technology.*

[2] *There are a number of Centres of Excellence in Health Informatics across Australia. However, it was noted that there is a need for further enhancing and developing Australia's capacity in the area of information based medicine, a new area of health-related informatics.*

INDUSTRY BACKGROUND

The life sciences have been transformed in the past decade through the advent of revolutionary technologies in genomics and functional genomics. These technologies have resulted in the generation of biological data in digital format at a vast rate. In parallel, advances in information technologies have allowed us to convert this data into information and detailed knowledge of the innermost working of living systems.

As a consequence of this transformation, the life sciences have been transformed into information sciences. Living systems can be increasingly accurately modelled in the computer, and the scientific discovery is being dragged inexorably from *in vitro* (in glass, test tubes etc) to *in silico* (in silicon, in computers).

For these reasons, we are at a strategic point in time for government and industrial activities in the life sciences. The health, environment, biotechnology and pharmaceutical industries are all undergoing shifts as the importance of information and its management become paramount, and intellectual property becomes the major business asset.

If Australia is to make the most of the opportunities these changes present, we need to understand our capabilities and strengths, as well as our competitive weaknesses and global threats.

Key life science industries, in which information is now an economic driver, include Health (and pharmaceutical), Biotechnology and Environment.

The Australian Government has taken the initiative of developing the National Biotechnology Strategy to support the Government's vision for biotech.

The National Biotechnology Strategy (NBS) was launched in July 2000. The Strategy was boosted in January 2001 by the Innovation Statement, Backing Australia's Ability, with funding for the Biotechnology Centre of Excellence and additional funding for the Biotechnology Innovation Fund.

The key objective of the Strategy is to provide a framework for Government and key stakeholders to work together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection. The Strategy addresses six key themes with specific objectives and strategies to achieve them: Biotechnology in the community; Ensuring effective regulation; Biotechnology in the economy; Australian biotechnology in the global market; Resources for biotechnology; and Maintaining momentum and coordination.

The intersection of informatics/IT and the life sciences is often referred to as Bioinformatics.

The Australian Government Department of Industry, Tourism and Resources, in conjunction with other Australian Government, State and Territory agencies, is currently developing Australia's **National Bioinformatics Strategy**.

The Strategy is being developed in conjunction with the NBS and will address several key themes, including education and training, research and development, infrastructure, commercialisation and the public good. It aims to compare Australia with international best practice, identify niche areas for Australian bioinformatics development, and devise national objectives and means of achieving them.

A consultation process seeking input from individuals and key community, research and industry groups on the development of the Strategy has been undertaken. All submissions received during this process are now publicly available on the Biotechnology Australia website at www.biotechnology.gov.au.

The National Bioinformatics Strategy is currently being developed in consultation with key industry experts and Australian Government, State and Territory officials. Final approval and clearance will be sought from Government officials, and Australian Government, State and Territory Ministers, in 2004.

THE STEERING COMMITTEE

GAP convened a Steering Committee of stakeholders and experts from Government and Industry to ensure that business and policy outcomes flowed for participants and that discussions are focused and contribute in a significant way to the Australian bioinformatics landscape.

For their time, enthusiasm and dedication we thank:

Mr Philip Allnutt
General Manager
Industry Development Branch
Department of Communications, Information Technology & the Arts
Australian Government

Dr Amanda Caples
Director
Biotechnology
Department of Innovation Industry & Regional Development
Victoria

Dr Renée Dutton
Platform Technologies Coordinator
Office of Science and Technology
Department of Innovation, Industry & Regional Development, Victoria

Prof Peter Fritz AM
Group Managing Director
TCG Group, Chair GAP Forum

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Regional Manager
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Biotechnology Development
Pharmaceutical & Biotechnology Branch
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Australian Government

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Life Sciences ANZ
IBM Australia

Dr Ian Smart
Deputy Director
Information City Victoria Management

Dr David Swanton
Manager Biotechnology Development
Pharmaceutical & Biotechnology Branch
Innovation Division
Department of Industry, Tourism & Resources
Australian Government

Mr Krzysztof Zielinski
Marketing Manager
IBM Life Sciences Australia

SPONSORS

Government participation is essential to these discussions because the Government have the power to create and change policy and are customers of the industry.

The GAP Forum on Informatics in Biology & Medicine 2003 was co-sponsored by Industry and Government. Our thanks for their contribution and foresight go to:

- **Department of Industry, Tourism & Resources, Australian Government**

- **Department of Innovation, Industry & Regional Development Government of Victoria**

- **IBM Life Sciences**

- **Department of Communications, Information Technology & the Arts Australian Government**

- **Telstra Research Laboratories**

The role of partners and sponsors extends beyond the Forum through a continuity strategy, which encourages future events to build on the existing outcomes.

SPEAKERS

The GAP Forum on Informatics in Biology & Medicine was facilitated by **Dr James Edwards**, Executive Secretary of the Global Biodiversity Information Facility (GBIF) – an intergovernmental organisation, formed in 1999 following the OECD Megascience Forum on biological Information. GBIF is devoted to making biodiversity data freely and openly available via the Internet.

For almost two decades Dr Edwards has been involved with the Directorate for Biological Science at the US National Science Foundation (NSF), which funds the majority of non-medical biological research at US colleges and universities, with a yearly budget of approximately $500 million. Dr Edwards served on several Australian Government task forces and was the chair on an United States interagency steering committee on Biological and Ecological Informatics *(see Profile in App. 2, page 30)*.

In his presentation, "Biological Informatics: Essential Infrastructure for the 21st Century ", Dr Edwards talked about the current state of the global bioinformatics industry and future scenarios for Australia in that space. His presentation was followed by discussions between participants *(see Presentation Brief in App. 2)*.

An international perspective on what is required to drive commercial outcomes at a national level, and an overview of emerging trends in the life sciences industry landscape, were presented by **Dr Caroline Kovac**, General Manager, IBM Life Science, USA.

Dr Kovac oversees the development of cutting-edge information technology at IBM for the life sciences market, which includes the biotechnology, genomic, e-health, pharmaceutical, and agri-science industries. She is responsible for developing partnerships with other enterprises and directing IBM investments in this fast-growing area. During her tenure, IBM Life Sciences has become one of IBM's most successful new businesses, which provides innovative services and technologies for research, development and business *(see Profile in App. 3, page 33)*.

Carol talked to the audience via a 20-minute video presentation followed by a live telephone hook up to New York, where participants had the opportunity to ask her questions *(see App. 3, page 34)*.

Dr David Swanton, Manager of Biotechnology Development in the Australian Government Department of Industry, Tourism and Resources, addressed the Forum on the National Bioinformatics Strategy *(see App. 4, page 36)*. David has policy responsibility for the National Stem Cell Centre (Australia's Biotechnology Centre of Excellence) and the $40m Biotechnology Innovation Fund. In previous roles David has managed the Prime Minister's Science and Engineering Council and has been heavily involved in the development of the Australian Government's legislation on gene technology and research involving embryos *(see Presentation Brief in App. 4)*.

KEY OBJECTIVES

The long and short-term objectives of the Forum were discussed with the Steering Committee and supporting organisations. Key objectives were related to:

1. **The current structure of Informatics in Biology and Medicine in Australia:**
   - Identification of areas on which Australia may need to concentrate for its own unique purposes
   - Identification and discussion of niche areas of Australian expertise
   - Consideration of information gathered at the Forum for inclusion in the National Bioinformatics Strategy

2. **Issues for users of data and IT:**
   - Understanding the different types of bioinformatics requirements for different applications (eg simple database construction for health records vs analysis of genetic material vs complex systems analysis vs environmental bioinformatics etc) –

3. **A coordinated national approach:**
   - What is needed to progress Australia's national vision for bioinformatics (as provided in the National Bioinformatics Strategy)
   - Gaining a commitment to strategy development for a greater degree of coordination amongst Australian stakeholders
   - Identification of ways in which national and international stakeholders can be engaged with the Australian Bioinformatics Community

4. **Business outcomes:**
   - How Australian expertise translates into products/outcomes for economic and social gain

5. **Policy outcomes:**
   - Identification of the short, medium and long term needs for bioinformatics in Australia, including understanding Australia's education and training needs
   - Recognition and clarification of the role for the Australian, State and Territory Governments
   - Consideration of ethical issues with the use of different types of bioinformatics

6. **Education and research:**
   - How education and research strategies Australia-wide will assist in the development of a strong skills base

(For a full list of topics and lead questions submitted prior to the Forum, please see App. 5, page 38)

PARTICIPANTS

Organisations involved in the GAP Forum on Informatics in Biology & Medicine 2003:

- AusBiotech
- Australian Genome Research Facility
- Australian Government Department of Communications, Information Technology & the Arts
- Australian Government Department of Education, Science & Training
- Australian Government Department of Health and Ageing
- Australian Government Department of Industry, Tourism & Resources
- Australian National University
- Australian Research Council
- BioComm Services
- BioConnection
- Centre for Health Informatics, UNSW
- Cerner Corporation
- Clinical Trials Victoria
- Corporate & Clinical Support Services, Melbourne Health
- CSIRO Mathematical & Information Sciences
- CSIRO Molecular Science
- Forsight Associates Pty Ltd
- Genomic Disorders Research Centre
- Global Access Partners
- Global Biodiversity Information Facility (GBIF), Denmark
- Howard Florey Institute
- IBM Life Science Solutions Australia
- IBM Life Sciences, USA
- Information City Victoria Management
- Intelligent Island Tasmania
- ISSC
- Merck Australia Pty Limited
- Ministry of Science & Medical Research (former BioUnit NSW Government)
- Monash University
- Morphepius
- Multimedia Victoria, Victorian Department of Infrastructure
- Murdoch Children's Research Institute
- National Health and Medical Research Council (NHMRC)
- National Office for the Information Economy (NOIE)
- National Stem Cell Centre (NSCC)
- Northern Health
- Peter MacCallum Cancer Centre
- Primary Healthcare Monash University
- Proteome Systems
- School of Information Technologies, Sydney University
- SGI
- South Australian Department of Human Services
- TCG Group of Companies
- Telstra Research Laboratories
- University of Wollongong
- Victorian Bioinformatics Consortium
- Victorian Department of Human Services
- Victorian Department of Innovation, Industry and Regional Development
- Victorian Department of Premier & Cabinet
- Victorian Partnership for Advanced Computing (VPAC)

INFORMATICS IN BIOLOGY AND MEDICINE 2003

The GAP Forum on Informatics in Biology and Medicine was held at the Department of Innovation, Industry and Regional Development in Melbourne, Victoria, over two days on 4 and 5 December.

GAP forums are unique both in concept and format. A GAP forum operates as a "Think Tank", with participants contributing to debate during a round table discussion facilitated by a key speaker. The structure of GAP forums allows each participant to drive their own agenda, speak freely and share their experience, and get a reality check from the related parties' response to the personal views. The level of participants - a selected group of decision makers, who are open to new ideas and have the power to bring about real change in both business and government – makes this a landmark opportunity to discuss Australia's future in a "closed-doors" environment.

Two similar sessions were held on **Day One (Boardroom Day**) with a different audience at each session, examining the issues of informatics in biology and medicine from a decision makers' point of view (Government representatives were attending), while **Day Two (Workshop)**, with a wider audience, had a more in-depth look on the subjects.

Each session was opened by a Government representative. Those who addressed the Forum were:

The Hon. Matt Viney
Parliamentary Secretary
Innovation and Industry, Victoria

The Hon. Bronwyn Pike
Minister for Health, Victoria

Mr Randall Straw
Executive Director, Multimedia Victoria
Department of Infrastructure, Victoria

Dr Edwards presented on both days, which was followed by discussions between participants and question and answer time.

BOARDROOM DAY - SUMMARY OF ISSUES

The suggested format for discussion was to look from participants' own personal point of view and to move towards concrete outcomes that they then could progress into the future.

The following summary of issues was based directly on what was said during discussion.

Australia's capability

- Australia leads the world in linking together biodiversity resources. It was agreed that government support was critical for the development and maintenance of publicly accessible databases because these types of databases will not be self-funded.
- Australia leads the world in a number of agricultural and environment industry projects. Uniqueness of flora and fauna is an advantage for Australia.

Necessity of a big life- science project

- Internet has given everyone a fantastic opportunity to make connections. People should recognise the value in making their data freely available, and the mechanisms to break down the closed-minded approach that exists within people are still to be identified. The real challenge is the human challenge.
- Information-based medicine requires collaboration and the multidisciplinary approach. Fostering cooperation between Departments of health, hospitals, mathematicians and bioinformaticians was seen as essential to reinforce the interest of small and large IT and life-science firms in contributing to projects.[3]
- It was proposed to build a Centre of Excellence in information-based medicine focusing on digital technologies for health information, that could attract large IT and/or life-science firms as major investors (possibly in the order of $10-20 million to set this up). In addition, the project has in-principal support from the State/Territory governments that have so far been approached. The aim of the project is as follows - improvements in integration of health data resulting in huge savings to help their systems (e.g. handling order entry better, not using inappropriate medicine). There are a number of highly autonomous health services that use different protocols, IT etc. There is a huge opportunity to develop software (e.g. a business-to-business (B2B) problem).

[3] *A national health IM&ICT governance structure is in place that manages health information related activities across jurisdictions. Health Ministers agreed to these arrangements in July 2003, and the Australian Government Department of Health and Ageing works within this structure on all national health information activities and projects. Under the Australian Government's* National Strategic Framework for the Information Economy*, a national strategic plan for health information management and technology has existed since 1999, entitled* Health Online*:* A Health Information Action Plan for Australia. *This plan was revised in September 2001 and has been endorsed by Health Ministers. A further review of the plan is currently underway, which is being done jointly by the National Health Information Group and the Australian Health Information Council. Under the* Health Online *national plan, there has been significant national health information activities progressed, including in the areas of health privacy, health data and health IT standards, electronic health records, telehealth, electronic decision support and supply chain reform in hospitals. More information is available at* www.health.gov.au/healthonline.

- By taking a systems approach as a fundamental approach for delivering better health care, Australia can look to innovative IT technology.[4] Winning areas will be: a) Decision support systems; b) Resource management systems.
- Risk management is relevant, it is encompassed under decision support systems.
- Australia's innovations in health informatics need to be in-step with global efforts and initiatives. This is important to ensure that, down the road, health information exchange is possible not just within but between nations, and that national and global health and economic benefits that come compatible systems are maximised.
- Most importantly, there is a need to overcome current problems with access to senior management in pharmaceutical companies, through the development of personal relationships with CEOs of the top 10 pharmaceutical companies. It was suggested to form a club of friends with the CEOs of big pharma at head office. This could extend to include agribusiness and IT companies.[5]
- Why should pharmaceutical companies do their drug development in Australia? Australia should have another niche – population providing health records is a huge product to be able to offer to research.[6]
- Astra Zeneca Research Centre at Griffith University's case study – a success story in attracting investment into research, but also an example of what Australia is doing wrong (no value add to … IP). Issue is that once a lot of the early identification work has been done, the follow up work can be done elsewhere.
- Regarding infrastructure –it is a matter of selling spades to miners. The Global reach of Australia will be to provide tools.
- Australia needs to create the fastest bio search engine. Gene mining is like resource mining.

[4] It was noted that there is already considerable work underway in the areas of health IT standards development to achieve interoperability of health systems and clinical decision support but that further research and investment is needed, particularly in the area of integration of health information with broader but related life-science information.

[5] It was later noted that such collaboration of course is not restricted to pharmaceutical industry executives but would include the relevant biotechnology industry executives and other key stakeholders. In addition it was later noted that existing relationships with the pharmaceutical industry's peak body, Medicines Australia, might be useful as a starting point for building such collaborations.

[6] It was later noted that any proposal to use medical records for research must be approached with caution. The collection, use and disclosure of personal information is regulated by the Privacy Act 1988 (Cth) as well as regulation at the state and territory level and that under the Privacy Act 1988 (Cth), health information is regarded as sensitive information and is therefore subject to higher privacy standards. For this reason it is highly unlikely that the use of individuals' medical records (in order to create a competitive advantage for Australia as a research base for pharmaceutical companies) would meet the requirements of the Privacy Act 1988 (Cth).

- Health informatics and immediacy of benefits that can be delivered to the lowest common denominator through Telstra's broadband is incredible. Telstra has a number of projects, they are prepared to invest in other states.
- The Victorian Government has put $1.5M on the table for the Wallaby Genome project. In terms of flora – developments in salt tolerance, frost resistance, drought resilience can be used in progressing Australia's agricultural industry.

  Victorian Government commitment to innovation (in a broad sense):
  - over $900million of investments in this area
  - substantial investment in universities, Bio21, promoting biotechnology industry in Victoria;
  - one third of top 200 ICT businesses are housed in Melbourne

OPPORTUNITY

The average Australian sees their GP 5 times a year. 90% of GPs have a computer on their desk. These systems work independently, but have the capacity to work together. [7]

National approach

- Creation of a national Committee. It is very important to have a national approach, and the Committee will seek endorsement from the Australian Government to operate under the banner of the Australian National Committee on Informatics in Biology and Medicine (ANCIMB).
- The composition of the Committee of 7-8 members will include industry, research and government. Sub-committees will be established to undertake specific tasks or projects.
- The feasibility study is in the making and the Committee will be looking at having that funded.

Entrepreneurial culture

- Australia needs to build an entrepreneurial culture for the people who work in the bioinformatics world. [8]
- Where are the resources going to make the most difference?
- In relation to middleware and information databases for the health field – where is there market failure?

[7] *Connectivity between medical professionals is currently being addressed through the development of the '*Health*Connect' network.*

[8] *It was later noted that the needs for entrepreneurs in bionformatics, while essential, is not sufficient to meeting all the needs of the Australian community in this area.*

- The people that can "make things happen" – e.g. the entrepreneurs - are not routinely invited to the committees. If centres are established, then the nimble individuals, who can find a need and match it with something in the centre, should be included in the process and information should be available to them.

Experience of Tasmanian Intelligent Island initiative

- In Jan 2002 Tasmania decided to focus on bioinformatics, with an aim to develop the Tasmanian ICT sector. It proved difficult to find effective commercial application in the bionformatics area. It has focused on Health and Biological Informatics.
- Key challenge will be working out the exact details of the research and activity programme. Government will insist that the research and activity plan is very commercially focused. The Issue will be in recruiting an effective director to take this forward.
- Intelligent Island has commercialisation as its prime objective. Tasmanian enterprises are by and large small SMEs. This brings a need for real commercial relationships - now, immediately.
- A willingness to share data is much easier in biodiversity than health, but is equally important to derive knowledge.

Knowledge Economy

- Australia will capitalise on tacit knowledge i.e. primary knowledge. This does not mean securing knowledge for Australia only but means freeing it up for global use.

Ethics

- Privacy legislation does not prohibit identifying data.[9] However, it generally requires that patients consent to the proposed use of their medical information.

[9] *It was later noted, that in discussions of the use of identified data in research, the following points need to be taken into consideration:*

- *Under the Privacy Act 1988 (Cth), health information is regarded as sensitive information and is therefore subject to higher privacy standards than other personal information.*
- *Under the Act, use and disclosure of personal information is not permitted without consent except in specific situations – eg, if subject to a subpoena.*
- *There are also strict rules about the collection, use and disclosure of identified health information for research purposes (see guidelines under section 95 and 95A of the Privacy Act 1988 (Cth)) which include approval by a Human Research Ethics Committee. Even if approved, an organisation may still decline to provide the information.*
- *To be valid, consent must be voluntary, fully-informed and capable of being withdrawn at any point. A person must be able to understand, provide and communicate their consent. There are also ethical and legal issues around the age at which individuals are capable of providing informed consent.*
- *There is also regulation at the State and Territory level.*

- People can take their medical records to whatever research, medical institute etc they want. The sense of ownership is the key.[10]
- It was suggested that individuals be given more ownership than they have, but health practitioners are not keen to give out the information.
- At the moment there is a lot of litigation regarding medical negligence, and therefore they are not keen to hand over the records. [11]
- It was suggested that health insurers offer a benefit for all individuals who hand over their health information.[12]

Educating decision makers

- It was suggested that Australia look at setting up an educative programme for decision makers[13]. Politicians will come up against very conservative people with larger powers.
- There is a vision that the question of people's willingness to allow their medical data to be used for research and development should be addressed at a federal referendum, where the views of the Federal Privacy Commissioner on all privacy related issues would be represented.

Multidisciplinary approaches

- One of the items for discussion was the creation of a career structure for health informaticians. It was suggested that there be an immediate engagement between the Australian Mathematical Science Institute (AMSI) and the ANCIMB.
- Australia needs 20 PhD students who can really capitalise on this initiative. A professorial chair in mathematics and statistics, and also teaching for the professorial chair in mathematics and statistics was suggested.
- The Public Relations aspect of this is very important.
- Need the customer, the supplier and the right policy.

[10] It was later noted that individuals do not own their medical records (as found by the Australian High Court in Breen v Williams (1996) 186 CLR 71 (HCA)). Furthermore, even if individuals had ownership of their medical records and were prepared to give access to researchers, consent to use the records would need to be voluntary, fully informed and able to be withdrawn. It was also noted that the individual must have the capacity to understand, provide and communicate their consent. Further, there are also ethical and legal issues around the age at which individuals are capable of providing informed consent, and that there is also the broader issue of the use of individuals' medical records for research purposes, including the need for research to be approved by a human research ethics committee, for instance.

[11] It was later noted that the provision of medical records in the case of litigation regarding medical negligence is a separate issue to the provision of medical records for research purposes.

[12] It was later noted that the Australian system of health insurance is community rated which means that it is not permissible to discriminate on the basis of a person's health status, and hence health insurers do not use individual health information to assess individual risk.

[13] It was later noted that improving general awareness of the importance of informatics in medicine in biology is a worthwhile activity that should include a broad spectrum of decision makers in the community.

- GBIF in a small way is also developing the issue of Chairs. It has just started a process to name 6 chairs in biodiversity informatics, 4 in developing countries and 2 in developed countries. GBIF is asking for pre proposals for March 2004.
- There is a possibility to have an Asia-Pacific office of GBIF, and the Chair establishment in Australia (through the ANCIMB) could be the perfect launch event for it. Another idea is to develop a GBIF centre in Australia.

Simplification of the technology

- Australia needs to have a compendium of capabilities that this technology requires. Colleagues that have biology as a first degree and IT as a second degree, still do not know how to operate the technology.
- What capabilities are needed in order to use the tools?
- If possible, is there a way to simplify the technology?

Effective and appropriate business models

- Australia should look at the cooperative research model as a good model.
- Small seed commercialisation is also very important.

Development of standards[14]

- Main issue is developing standards for the health industry. Australia needs to train people to do this.
- It was suggested to take an early contact with Standards Australia, they are keen to work.

Market drivers[15]

- The health system should have a natural demand for the kind of things that research is developing.
- Often it is Government led projects that lead to demand for products and in turn develop industry.
- Industry stakeholders need to look at platforms in which Government is involved. Health is one, but market opportunities will not come from just one platform.

[14] It was later noted that, under the national governance arrangements for health information management and information technology, the Information and Communications Technology Standards Committee is responsible for managing the development and adoption of health IT standards nationally, so this Committee will be key in implementing any new standards that will be needed (eg in information based medicine).

[15] It should be noted that research leading to health outcomes that show real innovation, in the sense that they objectively demonstrate a significant clinical improvement, should be the objective of research for the health sector.

Health opportunities. Clinical Trials Registry

- All over the world people want to build bridges between research/science and big pharma.
- The Victorian Government has funded an organisation that was built by academics. This organisation approached government for help.
- Clinical researchers feel they do not get the reward or funding they deserve. Australia only contributes 2% of total $ of sales. Clinical researchers in Australia have day jobs.
- Clinical Trials Victoria supplies an infrastructure to gifted researchers who are the partners. It is a contract research place. Researchers have said they want to be contracted to big pharma. Problem: getting human ethics committee approval.

Electronic Health Records[16]

- In relation to the electronic health record, it would be necessary to define what success would look like. There have been a proliferation of B2B exchanges, many of these failed and their objective in many cases was not made known. What should the initiative as a whole look like?
- Electronic health record project with a certain proportion of people contributing their details etc. is the success.
- The single most determinant of success or failure is the governance model. The democracy model does not work, there needs to be key stakeholders for it to work.
- Another key to success would be engagement of local subsidiaries and have local champions of a project.
- There seems to be a lot of little clusters of people doing their own thing in biotechnology. People are not aware of what others are doing. This issue is being addressed by the National Biotechnology Strategy and the National Bioinformatics Strategy.
- How can Australia get the connectivity better? GBIF started with getting OECD's support. The rationale was that having the information Australia is providing would help decision makers. People who need to figure out what to do about saving a particular species, would find this facility useful.
- Personal health record portability – if it is personalised, you need the info to characterise your person. Australia could forward a proposal to establish a centre to make this happen.
- Victorian Bioinformatics Consortium has a group of people including CSIRO, plant Biotech and Monash researchers. There are many projects currently underway via students and grander projects, which are to be advanced.

[16] *The Australian, State and Territory governments are already moving towards implementing the national electronic health record network,* Health*Connect*.

The National Bioinformatics Strategy*

- Pathologists are trying to manage genes and environmental interaction.[17] Australia will only take a major leap forward if visualises where it wants to go in medicine. 2 institutes – firstly genes – How do Australia map all the genes of all the individuals in clinical trials? And then match drugs to genes? and then the efficacy of the drugs.
- There is a lot of complexity with health industry IT. Understanding the information technology that is really needed to build scaleable solutions is difficult.

**NB: These points are suggestions only, and the National Bioinformatics Strategy is yet to be finalised.*

Australia has a rich resource of biodata and the challenge is how to convert that into commercial reality.

WORKSHOP DAY. SUMMARY OF ISSUES
Audience: relevant nominees from participating organisations

Each group was to develop a one-page business plan for a national project in the informatics in biology and medicine area, with an aim to engage a big international investor *(for the details of workshop group projects, please see App. 9, page 46)*

David Swanton presented the National Bioinformatics Strategy to the workshop participants. Following is a summary of questions and answers arising after Dr D. Swanton's presentation.

A Vision for Australian Bioinformatics
Australia should aim to develop internationally competitive firms and research capability to capture global opportunities in health, pharmaceuticals, agriculture and environment arising from Bioinformatics applications.

To meet that vision would require enormous resources. If those resources are not provided then Australia might fall short of its target. Despite this, it was agreed by all stakeholders that Australia should be aiming high.

At the same time, people said that there was no pressing need for additional computing resources. There are many individual researchers with their own research projects, saying that they are content to continue as they are "we just want to do our research" There are researchers who feel that they have enough information on IT capacity and that computer software is not something they feel is needed.

[17] *It was later noted that there are serious privacy issues associated with this area.*

But in the case that one did want to relate genomic data to clinical outcomes, and decided to do that across hospitals and other organizations, Australia does not have the IT that enables integration of all the diverse sources of data or the ability to bring them together.

There is sufficient capacity now to do the things Australia is currently doing, but no capacity to do anything else. The issue here is **high performance computational capability**.

To build up the informatics side of the bioinformatics industry, Australia needs to engage biotechnologists from computer science departments and departments of mathematics try to work on the industry problems. It would be foolhardy trying to retrain biologists and chemists in mathematics and computer science and create biomathematicians out of those people. In the US, for example, massive investment by many computer science schools can be seen in places like Cornell, MIT, Stanford, Harvard. They are investing in people and hiring people in those areas, trying to generate the next generation of PhDs who have bioinformatics from the side of the bioinformatics - computer science and mathematics.

The skills sector, especially across disciplines, and coordination of linkages are the two big problem areas in Australia.

There is a Bachelor of Bioinformatics at one of the Victorian Universities at the moment, at the undergraduate level. The Bioinformatics Expert Taskforce and others have actually recommended that there be some provision for Bioinformatics teaching in Secondary Schools. The Australian Government has a schools kit in biotechnology available online. There is capacity to put in a little bit of information on bioinformatics in a useful project kit that school students would use, and this skills kit is provided to teachers.

Yet, the skills need further development, and raising interest across disciplines remains a challenge.

Australia needs an Australian center (such as the Victorian Bioinformatics Consortium VBC) to aim high at the very beginning, looking to get to some sort of commercialisation say in 10 years down the track.

Discussions of Day One revealed that participants see a pressing need to co-ordinate databases and exchange information.

Following Dr Swanton's presentation was a panel discussion to summarise the day's findings. A summary of this discussion follows:

Agenda: how to interface with everyone and, given that the focus is narrow (creating economic outcomes), how to facilitate business activity in this space?

The Australian Government, through Biotechnology Australia, is looking for continued input from the community in setting the agenda. During the Forum there was constant recognition of the value of focusing on outcomes in the health

industry (as seen in the majority of the 5 business plans) and the need for computing and computing solutions right across the health sector. It is very exciting to build a platform for better public health, but it is also a fantastic platform for drug discovery, for example.[18] The Industry needs to build a platform from health first.[19]

What are the economic outcomes that stakeholders believe will give credibility? Health funds, life science health informatics. How do Australian stakeholders drive that, where are the key demand generators and how does it interact with the more established views or emerging views of bioinformatics that the Expert Taskforce has? Some cooperation between the Bioinformatics Expert Taskforce and the ANCIMB may prove beneficial.

In terms of proportion of GDP and potential gain for the public good and for commercial enterprises, the health sector presents a lot of opportunities. There is a lot of potential there, discovery data manipulation in health is almost infinite, which creates some questions about computing capacity as well as skills of graduates and the like.

The Industry needs to be able to bring the results of science and discovery to the patient and to a business solution, and those two are of course interrelated. There is actually a lot of activity in this area. Stakeholders have visions of what they will do next, but they also need to look at the pieces that already exist, the strategies and initiatives that are already in place, and how they fit together with something new.

To work out a business model to commercialise on bioinformatics is difficult.

There are different security and privacy laws in every State. How can SA records be put with QLD records and then with NSW records and the data custodians?

A focus on the environment and agriculture
Some participants expressed the following views:

Treasuries see health as a black hole, and no matter how much you tell them you can save money by investing money, they won't do it. Whereas agriculture, particularly in Australia, is a very major bonus. It employs people, it is one of our largest exports and it is a good thing to do, according to Treasury. River Murray is Victoria's great water source and it is being destroyed. There are 30 or 40 other things that would come to mind in the environmental/agricultural arena. It could be easier to sell into government.

The argument is incontrovertibly correct. Whether that will influence government is another question. Governments and Health Ministers will certainly support this, and Health departments will support this, but the big dilemma is Treasury. It

[18] It was later noted that a platform for drug discovery would be an important component of a platform for better public health.

[19] It was later noted that the Australian Department of Health and Ageing has no plans to build a health IT platform.

certainly is something in which Australia could see huge commercial and intellectual advantage over the next decade. If any of the health models that the Workshops discussed were up and running in 5 years time, Australia would have world leadership.

Bioinformatics can help us develop potential drugs and identify their targets for the pharmaceutical industry to commercialise, with the aim of improving health outcomes.

One thing which Australia identified in previous discussions in the Steering Committee was the lack of connection between Australia and CEO's of large pharmaceutical and agricultural companies globally.

The consumer is at the heart of it as a beneficiary. In the interim phase of the research and discovery and sharing, there is also the other component of the telecommunications, along with the computing power, the exchange of information, the storage of information and the communication between the various components. There seems to be an assumption that Australians are all operating in a distributed environment.

Biotechnology and bioinformatics is crucial to agriculture at least as much as it is to health. To get success on getting a National Bioinformatics Strategy drawn on the health area (for its importance to human health in this country), but also to agriculture because it is such a strong portfolio within Australia's economy and is so important to our food supply anyway. Then you move on into the areas of gene technology regulation, for example, and Genetically Modified Organisms (GMOs) being released etc.

Bioinformatics is much broader than health. Plant biotech is a core partner in the Victorian Bioinformatics Consortium. Unfortunately there was no one taking part in the workshop that was able to put forward an idea for plant biotech.

The opportunity of creating a new way of accessing power directly and not in a democracy was discussed.

There is one thing that often frustrates the industrial side, and that is that a lot of these discussions on strategy and direction often preclude commerce because somehow businesspeople are seen as having dirty intentions.

This Forum tried to steer clear from the term "Bioinformatics". The Committee was very much clearer on the fact that this is a facilitation, it is a revolution in the way that medicine and biology is being done, because the industry is now information driven. These are information driven activities. But they are still the same activities. They are still agriculture, they are still biotechnology, they are still health. What's changing is the means by which they are done, and the impact that IT has on it, and its very difficult for the community to get away from some of the phraseology and some of the thinking.

The difficulties that were raised during the workshops, about business models, for example, are very hard in pure bioinformatics, they are not so hard in health in many ways. How can industry stakeholders do something collectively, or by way of

mechanism to carry on with some of the ideas that have come out of the workshop; raising some capital, getting some collaborative or co-operative agreements going, getting some expertise, getting the partnerships built. The Workshop created five very good presentations, five ideas. The next steps though have to be the formation the of the Committee to carry that charge forward and maybe then help to catalyse the creation of at least one of these projects.

OUTCOMES. FORMATION OF THE ANCIMB

The Australian National Committee on Informatics in Medicine and Biology (ANCIMB) was formed as a result of The GAP Forum on Informatics in Biology and Medicine 2003. The Committee's purpose is to drive commercial outcomes in medicine, health and biotechnology through the use of information and information technologies.

The first GAP forum on the role of Informatics in Medicine and biology identified a number of areas for exploration by the ANCIMB and its working groups:

- Officially establish the ANCIMB and identify the Federal, State and Territory Government representatives that will work with the Committee Establish links with key large industry players including those in pharmaceuticals
- Develop networks across industry, education and research sectors to pursue matters of mutual interest
- Work with the Australian bioinformatics community to develop relationships with international bioinformatics organisations
- Establish an awareness and education program in the importance of informatics in medicine and biology targeted at decision makers
- Convene the next forum by mid 2005
- Consider the full range of business opportunities, which could include clinical trials and data mining
- Work with the bioinformatics community to develop standards for interoperability, integration and data exchange to accelerate industry development in informatics in medicine and biology
- Identify sources and discuss the potential use of funding from the USA (eg NSF, NIH), Europe (the VIth framework) and others
- Establish a WWW site and email list to keep community informed of developments in informatics in medicine and biology

(For a full list of proposed activities and responsibilities of the ANCIMB, please see Executive Summary, pages 5-6)

CONCLUSION

The GAP Forum on Informatics in Biology and Medicine 2003 was an outstanding success. It is the beginning of a process, not the end, and provides initial direction to the formation of the Australian National Committee on Informatics in Medicine and Biology (ANCIMB).

Feedback from attendees confirmed that the Forum achieved its objectives on a number of levels and performed above expectations. The strong focus on commercialisation helped to identify ways for raising the profile of the bioinformatics sector within the business community. Discussions encouraged the sharing of ideas and individual views on how to increase Australian bioinformatics industry growth, building on its existing strengths and achievements.

The variety and the level of attendees gave those involved a perspective outside or their own and an insight into the best practices of others at both national and international levels. The States and Australian Government Departments involved expressed their desire to engage in continuing discussions, and to working with the ANCIMB on Informatics in Medicine and Biology.

Appendix 1 – Global Access Partners Pty Ltd

GAP is a proactive and influential network which initiates high-level discussions at the cutting edge of the most pressing commercial, social and global issues of today. Through forums, conferences, missions and advisory boards, we facilitate real and lasting change for our partners and participants, sharing knowledge, forging progress and creating input for Government policy.

GAP promotes Australia's capacity to find novel solutions to the challenges facing the global community, and translates these innovative solutions into business opportunities. We focus on practical economic outcomes for Government and Business, and offer a landmark opportunity for those involved in the GAP process to discuss Australia's future in a high-powered environment.

GAP is an agent of change turning rhetoric into action.

GAP Initiatives 2003-2005

GAP's reputation for excellence is founded on its strong track record of successful high-level national and global initiatives covering a wide range of industries and issues:

- Virtual Opportunity Congress III on Security and Risk - December 2003
  With the support of the Australian Government and NSW Government, and the representation from the OECD, UN and EU, discussions promoted understanding of opportunities presented by the information age. This year's Congress focused specifically on issues of security and risk as engines of global economic activity.
- GAP Forum on Ecological Sustainability - June 2004
  This Forum will move "beyond the rhetoric" to find practical outcomes for business & Government in building sustainability. Discussions, led by Bjorn Stigson, President of the World Business Council on Sustainable Development, will focus on water, energy and waste management to find sustainable solutions with lasting economic benefit for all.
- OECD Ministerial and Business Symposium, Istanbul, Turkey - June 2004
- Virtual Opportunity Congress IV on Knowledge Capital – 2005
- GAP Forum on Nanotechnology - 2005
- Australian Mission to European Union and Central Europe – 2005

Each GAP project, be it a national round table or an international symposium, constitutes the beginning of a process. One of the main objectives is the formation of Consultative Committees of stakeholders who work to ensure the recommendations flowing from each GAP initiative become reality and deliver commercial outcomes.

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Appendix 2 - Dr J. Edwards: Profile. Presentation Brief

Dr James L. Edwards
Executive Secretary
Global Biodiversity Information Facility (GBIF)
Universitetsparken
15 Copenhagen 2100
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Dr James Edwards is the Director and Executive Secretary of the Global Biodiversity Information Facility (GBIF), an intergovernmental organisation devoted to making biodiversity data freely and openly available via the Internet. He received his B.S. (1967) and Ph.D. (1976) degrees from the University of California at Berkeley. His research interests are the systematics and functional morphology of amphibians and fishes, and biodiversity informatics.

From 1974-1976, Dr Edwards was an Instructor in the Biology Department at Queens College of the City University of New York, and from 1976-1982 he was an Assistant and Associate Professor in the Zoology Department at Michigan State University.

In 1982, he took a position of Deputy Assistant Director for Biological Sciences (second in command for biology) at the US National Science Foundation (NSF), which funds the vast majority of non-health academic research in biology. While at the NSF, he served successively as Program Director for several programs (Systematic Biology, Biological Research Resources, Field Stations and Marine Laboratories, and Biotic Surveys and Inventories), as Deputy Division Director for Biotic Systems and Resources, and as Deputy Assistant Director for Biological Sciences. In the latter capacity, he was the second-in-command of a yearly budget of approximately $500 million.

Dr Edwards served on several Federal task forces, and was the chair of an interagency steering committee on Biological and Ecological Informatics. He also chaired a working group on Biological Informatics of the Megascience Forum of the Organisation for Economic Cooperation and Development (OECD), which in 1999 recommended the formation of the GBIF. Dr Edwards then chaired the Interim Steering Committee which developed the Memorandum of Understanding for the organization and recruited the requisite number of governmental members and funding to allow it to come into existence in March, 2001.

Currently, he is on a five-year leave of absence from NSF in order to serve as the Director and Executive Secretary of GBIF.

”BIOLOGICAL INFORMATICS: ESSENTIAL INFRASTRUCTURE FOR THE 21ST CENTURY ”

GBIF and Its Programs
The OECD Working Group started in 1996, focusing on Biodiversity Informatics and Neuroinformatics. Its final report was submitted in January 1999, and half a year later, OECD Science Ministers endorsed the formation of the Global Biodiversity Information Facility (GBIF) - an independent international organisation to make the world’s biodiversity data freely available to all over the Internet.

Started in March 2001, with a budget of approximately USD 3.5 million per year, GBIF currently encompasses 38 countries, 1 economy and 22 international organisations (Australia is a charter member of GBIF; it submitted an outstanding bid to host the GBIF Secretariat, but the country was seen as ”too far away from the rest of the world”, and Denmark won the bid). GBIF sees its goal in interoperably linking data sets, while databases remain with data providers.

Eventually GBIF intends to link all kinds of biodiversity data, from molecules to ecosystems, starting with species, specimen and observational data. Current programs include Data Access and Database Interoperability standards; Digitisation of content; Electronic Catalogue of Names of Known Organisms (authority file); Outreach and Capacity Building etc.

What is "Biological Informatics"?

- Informatics is the application of computers to information management;
- Biological Informatics (sometimes called Bioinformatics) is the use of informatics in the life sciences;
- Bioinformatics (in *sensu stricto*) is the informatics of molecular biology and includes genomics, proteomics, metabolomics etc.;
- Biodiversity Informatics is the application of informatics to the rest of biodiversity;
- Health Informatics is the application of informatics to health records, patient care etc.

To summarise, biological informatics is a set of computer-based tools and technologies to gather, store, share, manipulate, integrate, model, analyse and visualise biological data.

Biology in the 21st Century

We are living in the "Age of Biology". There is a vast array of new tools and approaches to tackle the immense complexity of life, and foremost among these are genomic and informatics tools - the tools that have enabled the "New Biology".

The New Biology is characterised as:

- Multidimensional: There are many collaborative projects, often in virtual centres or networks. The New Biology integrates across several levels of analysis, ranging from molecules to ecosystems; the concept of a "systems biology" was born (not single genes, but whole pathways; not single species, but whole ecosystems)
- Multidisciplinary: Many kinds of biologists, working with their colleagues from other sciences, are necessary to answer the major questions. Biology is fast becoming the *lingua franca,* by which numbers of scientists trained in other disciplines are able to work together.
- Information-driven: Information is a fundamental commodity of the New Biology; much of biology is becoming a data-driven science, and new informatics tools are at its core. Analysis of previously gathered information can lead to ground breaking new discoveries.

In 1998, at a US National Science Foundation Panel Meeting, Michael Levitt remarked that *"Computers have changed biology forever, even if most biologists don't yet realise it."*

Five years later, biologists (and everybody else) do realise it: *"The real paradigm shift is that some time over the last decade or so, computing has become so integral in biomedical research that you just can't do modern research without it." (*Eric Jakobsson, Director of the Center for Bioinformatics and Computational Biology, US National Institutes of Health, quoted in *The Scientist*, 11 November 2003)

*"Two months in the lab can easily save an afternoon on the computer." (*Alan Bleasby, *The Biochemist*, Oct. 1997).

Why is Informatics so Important to the New Biology?

Biological entities are more complex than all other physical and chemical entities in several ways. Each biological entity is unique at all levels of organisation. Phylogenetic (genealogical) and developmental history matters a great deal. Every biological entity has an important contingent relation to all other entities. For example, the same stem cell in your body could become any of several very different types (hair follicle, brain cell, bone cell) depending on where and when it matures.

Therefore, the law of large numbers does not hold in biology, since every living thing is genuinely unique. Physics needs calculus - the method for manipulating information about statistically large numbers of small, independent, equivalent things. Biology needs informatics, the method for manipulating information about large numbers of dependent, historically contingent, individual things. Thus, the New Biology couldn't develop until fast, cheap computers and search algorithms were invented.
There is lots of biological information to manipulate:

- 1.8 million known species on Earth (the total number range from 10 to 100 million);
- 2 billion specimens in the world's museums (if typed in 10-pitch font, the 3 billion base pairs of the human genome would stretch > 8000 km!)

- Duplicating the information storage capacity of all the DNA in the biosphere would need 10^{27} 10GB hard disks, which would fill a volume of 3.9 x 10^{13} cubic miles (though the volume of the Earth itself is only 1.8 x 10^{11} cubic miles (facts from Bob Robbins, Fred Hutchinson Cancer Institute)

What Makes a Successful Biological Informatics Infrastructure?
The key elements are:

- Strong "bottom up" support from user community
- Freely accessible, comprehensive, persistent databases containing primary information (e.g. Genbank, Protein Data Bank, GBIF-affiliated databases, Australian Virtual Herbarium)
- Willingness to share data, rather than locking it up (e.g. Bermuda agreement of the Human Genome Project to put raw sequence data into Genbank within 24 hours)
- A vibrant community that improves the primary data and develops search engines to mine it (e.g. Celera Genomics, ANGIS)
- Multidisciplinary research groups where each discipline is a true partner
- No-one is treated as a mere service provider
- Forward-looking training and education
- Well -grounded in mathematics and statistics
- An upward career path for biological informaticists
- Adequate funding of biological informatics as a unique discipline, not a service industry

There are cultural barriers to overcome. Nathan Myhrvold, former CTO at Microsoft, said he is often asked, *'Can computer people be "real biologists"?* He usually answers, *'You tell me. When are you gonna treat them as real colleagues?' (*from "The Scientist", 11 Nov. 2003)

The National Strategy for Bioinformatics
Australia seems to be one of the few countries developing a national strategy for bioinformatics. India and South Africa are also pursuing such strategies. Current draft strategy builds upon excellent predecessor reports. Clearly, Australia wishes to reap some of the benefits from biological informatics.

Biological Informatics has become a powerful engine for growth. A recent report estimated the worldwide revenue from bioinformatics *per se:*

- USD 800 million in 2000,
- USD 2-4 billion is projected to be in 2007

But, more importantly, bioinformatics is the bedrock, upon which much of the multi-billion-dollar biotechnology industry rests.

How can Australia Build on Existing Strengths?
Australia was an early leader in biodiversity informatics. When the Global Biodiversity Information Facility was being planned, it had three models: ERIN, Australia; Instituto Nacional de Biodiversidad (INBio), Costa Rica, and CONABIO, Mexico.

Australia leads in linking together biodiversity resources (e.g. Australian Virtual Herbarium) and in developing systems for storing and describing taxonomic data (e.g. DELTA, LUCID, BIOLINK). Australia also has many excellent activities in bioinformatics. Other important caracteristics are:

- a unique flora and fauna
- a well-educated population
- an outstanding, vibrant research environment
- a well-developed, nimble commercial sector

Building on its existing strenghts, Australia can become a pioneer in linking genomic and biodiversity data, bioprospecting the country's unique biota and training a new breed of bioinformaticists, equally adept at mining genomic and biodiversity data. These individuals will be as eagerly sought after as current genomics informaticists.

Appendix 3 - Dr C. Kovac: Profile. Presentation Brief

Dr Caroline A. Kovac
General Manager
IBM Life Sciences, US

Caroline Kovac oversees the development of cutting-edge information technology at IBM for the life sciences market, which includes the biotechnology, genomic, e-health, pharmaceutical, and agri-science industries. She is responsible for overall strategy for Life Sciences, developing partnerships with other enterprises and directing IBM investments in this fast-growing market.

During Dr Kovac's tenure, IBM Life Sciences has become one of IBM's most successful new businesses. It provides innovative services and technologies that allow researchers to turn the vast quantities of biological data from the Human Genome Project and other research efforts into useful medical and scientific information. The convergence of IT and biology promises to help speed up drug discovery and the development of new treatments for genetic-based diseases.

Before assuming her current position in 2000, Dr Kovac held executive management positions at IBM Research, as head of computational biology and vice president of technical strategy and division operations. She joined IBM in 1983.

Dr Kovac is a member of Women in Technology International's Hall of Fame and is a member-emeritus of the IBM Academy of Technology. She holds a PhD in chemistry from the University of Southern California and a BA from Oberlin College.

EMERGING TRENDS AND OPPORTUNITIES IN THE LIFE SCIENCES INDUSTRY LANDSCAPE

Carol was asked to review the changing life sciences landscape driven by significant shifts in the industry, changes in large pharmaceutical companies, the role of the biotechnology, changes in research driven by the mapping of the genome, changes in healthcare on the way to targeted treatment, how various stakeholders are positioning themselves for success, and what new models are emerging for research, pharmaceutical companies, biotechnology and government in approaching these opportunities.

The following key questions were prepared for Carol to address in her presentation:

- How is the information industry responding to the changes in the life science landscape?
- What is the role of informatics in supporting these changes?
- What are some of the key challenges for industry participants (biotechnology firms, research, and governments)?
- What are some examples of best practice? (The US experience and how education and research strategies can assist in the development of a strong skills base; Collaborations between academia, biotechnology companies, pharmaceutical companies and health providers; Benefits of establishing collaborative research and development projects)
- What is needed to develop and progress Australia's national vision for informatics in biology and medicine?
- What are ways in which international stakeholders can engage with the Australian informatics community?

Dr Carol Kovac's Speech

Thank you very much, Peter. It's a pleasure speaking with you today about a topic that will not only affect the global life sciences industry, but will impact each and every one of us on a personal level as well. That topic is Information Based Medicine. There are some very exciting projects occurring around the world which I'll talk about later.

I predict that the first quarter of the 21st century will go down in history as the most exciting era in medicine. The decoding of the human genome in 2000 was the starting point ... This is leading to breakthrough discoveries about major diseases ... new drugs ... and innovative treatment programs that will continue to elevate the well-being and care of patients throughout the world.

As a point of reference, in the past 80 years, human life span in developed countries has risen approximately 20 years. A child born at the end of the last century can expect on average to live to the age of 78. Much of this increase in lifespan came about due to breakthroughs in scientific understanding in the 1920's and 30's -- understanding of infectious diseases, and the development of antibiotics and vaccines.
As a result, the impact of infectious diseases on human health has been greatly reduced in developed countries and some infectious diseases have been almost wiped out on the planet. Today, it is not influenza, pneumonia or tuberculosis at the top of the mortality list - it is heart disease, cancer, stroke and diabetes.

We stand now at the brink of discovery about the mechanisms of these and other diseases. If this new era of research and development brings another 20-year leap in human life span - our children and grandchildren may routinely live into their 100's!

I believe it will happen because of the dramatic convergence of the life sciences, health care and information technology that we are seeing today. It is what we at IBM have come to call information-based medicine.

Here's how we define information-based medicine: It is a system of medical care that supplements traditional opinion-based diagnoses with insights gleaned from computerized data acquisition, management and analysis. The goal is to improve treatment outcomes by improving the accuracy of diagnostic decisions.

Let me share my thoughts with you on how the information industry is responding to this powerful new direction:

Information-based medicine will demand a new infrastructure to support research and development and the merger of clinical and research data. The first building block is technology for managing and storing the huge volumes of data being produced...from genomic research to medical studies and electronic patient records. Beyond this, technologies are needed to mine information repositories, and analyze, visualize and integrate data from disparate sources.

Collaboration and sharing of data among communities of physicians and researchers is already proving to be a powerful new tool in medicine. For example, the University of Pennsylvania, building on IBM grid technology, has developed a shared digital mammography archive enabling physicians to better and more accurately diagnose breast cancer for women across North America.

The IT industry is also providing technologies to help protect the confidentiality, security and privacy of research and patient data.

IBM and others in the information industry are responding to the need for powerful supercomputing platforms with systems that provide increasing storage capabilities, powerful data management tools, and faster, more affordable and highly scalable computing platforms. For example, we are building the world's most powerful Linux supercomputer for Japan's largest national research organization, the National Institute of Advanced Industrial Science and Technology, for life sciences research. The system will be able to perform more than 11 trillion calculations per second, making it the third most powerful supercomputer in the world, according to the independent TOP500 List of Supercomputers.

Informatics supports the transformation to information-based medicine by providing the tools that allow researchers and clinicians to access large amounts of biomedical information easily. Breakthroughs in discovery will come from the ability to use computation to recognize patterns, draw inferences, and ultimately create working models of human biology. The challenge is incredibly complex. Today, we are working to create better technologies for managing unstructured data sets and for drawing insights from diverse, distributed information.

We are moving to an era of information-based medicine sooner than many thought possible. Still, there are hurdles that must be overcome to realize the full potential. Most important is the need for a global

network of key players which includes private industry, medical research centers, and government agencies. Whether we are talking about the largest pharmaceutical company or the smallest biotech, collaboration is a vital element of their success. Large pharma and biotech have become increasingly reliant on their collaborations to fund and bring new drugs to market. And our most successful innovations in information-based medicine are coming from multi-disciplinary collaborations and projects around the world.

One of the great success stories is the collaboration underway in Kobe, Japan. This project will integrate patient clinical information and genetic data to advance personalized healthcare. The long-term benefits of this project will improve treatments for cancer, heart disease and a myriad of other major illnesses. And in the short term, will help revitalize the Kansei regional economy, stricken by the 1995 earthquake in Kobe. The project, spearheaded by the Translational Research Informatics Center, involves IBM, the city of Kobe, the Kobe General Hospital, RIKEN -- Japan's Institute of Physical and Chemical Research -- and Osaka University.

Another challenge we must address as a community is the need for standards for interoperability, integration, and data exchange. International organizations such as Interoperable Informatics Infrastructure Consortium and the Clinical Data Interchange Standards Consortium need the active involvement of industry -- including IT, pharma and biotech companies -- as well as academia and government.

I've mentioned several examples of best practices. There is one more I'd like to talk about which is not about technology, but about people. I believe the most exciting breakthroughs in the new biology will be created at the frontiers where scientific disciplines converge. This demands participants who can operate comfortably at the intersection of biology, chemistry and information science. I applaud universities, such as the University of Queensland, which are beginning to restructure their curricula to encourage cross-discipline collaborations and research initiatives. Access to the brightest, most interdisciplinary thinkers will be a key success factor for companies and governments aiming to drive value in biological discovery and medicine.

Where does Australia fit into all of this? I see both opportunities and challenges. Australia must establish a unique global position in its life sciences efforts. During each visit to Australia, I make it a point to meet with key life sciences players in the public and private sectors, and I am always struck by the energy and innovative directions that I encounter, which support this goal.

In my view, Australia has taken a somewhat different route from its Asian neighbours in life sciences. Unlike other nations, battling for their share of the large pharmaceutical manufacturing pie, Australia has firmly set its sights on growing its internal R&D capability and fostering an environment that encourages innovation and discovery. I believe this will serve you well in the long-term.

You have an advanced, world-class healthcare system, you have long supported biomedical research, and you have traditionally been early adopters of technology. Australia could leverage these assets in the area of clinical genomics.

Australia's regulatory framework protects intellectual property and also helps build investor confidence, especially for R&D activities in the highly competitive biotech industry. You also have a globally recognized research infrastructure in your universities and research organizations, such as the Commonwealth Scientific and Industrial Research Organization.

And unlike many Asian nations, where the primary funding for initiatives is coming from government, you have equally fostered a private investment community that is able to draw technology from the fertile Australian research community into the marketplace for business value and economic development.

In a nutshell, you've created a terrific environment for biomedical innovation. I urge you to make it even better through global partnerships and alliances. These collaborations among universities, research centers and biotech companies with international organizations will help attract more investment and R&D talent, and accelerate research leading to new drugs and better treatment options.

In a global marketplace, everyone is vying for the same investment and partnership opportunities. You have a wonderful opportunity at the Gap Forum to establish an agenda for putting Australia in the forefront of the use of information technology in biology and medicine. I encourage you to use the time to develop a network of relationships that can benefit you, your organization, and country. We at IBM look forward to working with you on this exciting frontier!

Thank you for allowing me to share my thoughts with you today.

Appendix 4 – Dr D. Swanton: Profile. Presentation Brief

Dr David Swanton
Manager Biotechnology Development
Pharmaceutical & Biotechnology Branch
Innovation Division, Australian Government
Department of Industry, Tourism and Resources

Dr David Swanton has a first class honours degree in Science and a doctorate in Theoretical Chemistry from Sydney University. After working as a scientist in Canada, West Germany and at the Australian National University, he joined the Australian Public Service to round out his career.

David is currently Manager of Biotechnology Development in the Australian Government Department of Industry, Tourism and Resources, and has policy responsibility for the National Stem Cell Centre (Australia's Biotechnology Centre of Excellence) and the $40m Biotechnology Innovation Fund. He is also leading the development of the National Bioinformatics Strategy.

In previous roles David has managed the Prime Minister's Science and Engineering Council and has been heavily involved in the development of the Australian Government's legislation on gene technology and research involving embryos.

"BIOINFORMATICS: A NATIONAL PERSPECTIVE"

Australian Biotechnology is characterised by:

- Strong growth in 1999-2003
    - Private companies from 170 to 260
    - Listed companies from 19 to 48
    - Annual revenues doubled to $2.5billion approximately
    - Jobs from 3900 to ~8770
- 60% of biotechnology revenues in Asia-Pacific
- 5th highest in OECD for public R&D expenditure on biotech as % of GDP
- Half Australia's S&T articles are in life sciences
- 55% of biotech companies spun out from unis and research institutions

Australian Bioinformatics – the current picture:

- Small number of companies
- Research institutions: WEHI, IMB, CBiS
- State based consortia: VBC, QBC, WABC
- Key infrastructure: APAC, ANGIS
- Biotechnology Australia: audit, submissions, background info, interim report

The Government's initiatives in Bioinformatics:

- Australian Government's Innovation Statement, Backing Australia's Ability (2001)
- National Biotechnology Strategy (2000)
- National Bioinformatics Strategy (current)
- Bioinformatics as a priority goal of National Research Priorities

Funding in Bioinformatics:

- ARC, NHMRC grants: ARC centre, ANGIS
- $750k to Garvan Institute
- $20m Tasmanian bioinformatics initiative
- $40m Biotechnology Innovation Fund, 6 projects/$1.45m bioinformatics
- P3
- State and Territory Government support for unis, research institutes

National Bioinformatics Strategy:

- NHMRC's 'Pittard' Report, 2000
- DITR's 'Littlejohn' Report, 2002
- House of Reps 'Bailey' Inquiry, 2001
- Australian, State, Territory officials
- Issues include: Education, Research and Development, Infrastructure, Commercialisation and Public Good
- Interim Bioinformatics Report (May 2003)
- Consultation, consideration by governments and implementation of approved strategy

"SWOT" analysis of Australia's Bioinformatics Industry:

- Strengths - quality of researchers, skills, and computing resources
- Weaknesses - 'few' high quality interdisciplinary researchers, poor linkages, coordination, lack of strategy
- Opportunities - application in niche markets, including biodiversity
- Threats - failure to retain skilled workers, international competitors moving ahead

Australia should aim to develop internationally competitive firms and research capability to capture global opportunities in health, pharmaceuticals, agriculture and environment arising from Bioinformatics applications.

Appendix 5 - Topics of the GAP Forum

The following are the key topics for discussion and lead questions proposed prior to the Forum by the Steering Committee members (including the meeting objectives and desired outcomes):

THE INDUSTRY

Strengths Weaknesses Opportunities and Threats in Australian Informatics

- What are the strengths of the Australian Bioinformatics Industry?
- What has been done to capture the opportunities here, and what still needs to be done?
- What are niche areas of Australian expertise in Bioinformatics?
- How does Australian expertise translate into products and outcomes for economic and social gain?
- What are emerging trends in the world's life sciences industry landscape?
- What are new models for research, pharmaceutical, biotech and Government in approaching the opportunities in the Bioinformatics sector?
- What are the strengths of the US Bioinformatics Industry?
- What are the strengths of Europe's Bioinformatics Industry?
- What are the ways in which national and international stakeholders can be engaged with the Australian Bioinformatics Community?

GOVERNMENT AND POLICY

A coordinated national approach

- Where should Australia place itself to secure its position between key global players and to be an acknowledged participant of the next major international projects in Bioinformatics?
- What are the areas Australia needs to concentrate on for its own unique purposes?
- What is needed to develop and progress Australia's national vision for Informatics in Biology and Medicine (as provided in the National Bioinformatics Strategy)?
- What constitutes world's best practice in the area of Informatics in Biology and Medicine?
- Who is working on developing world's best practice policies in the Informatics in Biology and Medicine area?
- How is best practice regulated?
- What standards currently exist for the Bioinformatics industry in Australia and around the world?
- How can stakeholders gain a commitment to strategy development for a greater degree of coordination amongst Australian stakeholders?
- What are the policies that can link health infrastructure spending decisions to research and industry outcomes?
- How can policies achieve scale, and benchmarks against world's best practice for health informatics and related research?
- What is the role of taxation and funding in Bioinformatics?
- How can Government facilitate the strategic partnering for a greater benefits of all stakeholders?

THE HEALTH INDUSTRY

Leveraging information management to drive better outcomes

- How do health informatics impact on patient management and the health industry?
- What opportunities are there for Informatics to improve productivity in the health sector?
- What are the growth strategies for the national health informatics sector with investment and commercial opportunities?

INFORMATION TECHNOLOGY

Establishing a globally competitive IT infrastructure

- What are the capability requirements for different applications of Informatics to achieve clear industry outcomes (e.g. simple database construction for health records vs analysis of genetic material vs complex systems analysis vs environmental bioinformatics etc)?
- What kind of IT infrastructure would need to be put in place or changed in order to take advantage of the opportunities?
- How the processing and analysis of large volumes of data through informatics models can improve outcomes for health related industries?
- How can stakeholders capture the value from Government spend on grants for IT enablement in terms of existing investments in infrastructure and people?
- How can an increased level of IT investment in health budgets provide benefits?
- What are other challenges facing the computation side of biology?

BUSINESS

Investment and commercial opportunities

- How can business and Government work together to stimulate Australia's global role in Biological and Health Informatics?
- What are Australian and global investment trends and commercial opportunities for the health informatics sector?
- What growth strategies are in place in Australia for the health informatics sector?
- What growth strategies are in place overseas for the health informatics sector?
- What is the perspective for industry developments from Australia's current position?
- How can organisations generate profits through the growth of the sector?
- What has been done nationally and internationally to commercialise bio informatics technology and what still needs to be done?
- How can business companies reinforce their credibility for both Government and Academia in commercialising research and technology?

RESEARCH

Networking and funding

- How Australia's vision translates into funding for research?
- What are the benefits of the establishment and management of collaborative research and development projects?
- How can Australia establish a network between industry and the research sector on both a national and global scale?
- What are IT solutions that researchers in biotechnology, pharmaceutical research, genomics, proteomics and healthcare are using to turn data into scientific discovery and new treatments for disease?
- What are perspectives of researchers who are generating IP and buying services?

EDUCATION

Immediate and long-term needs of the sector in Bioinformatics

- What are short, medium and long term needs of Australia's education sector caused by the growth of biological and health informatics?
- How will education and research strategies Australia-wide assist in the development of a strong skills base?
- How would the different capability requirements for different applications of informatics impact on education?
- What needs to be done nationally to ensure collaborations between academia, biotechnology companies, pharmaceutical companies and health providers?

LEGAL

Legal and ethical issues facing Informatics

- What are the legal issues facing Bioinformatics?
- What are the ethical issues to consider with the use of different types of Bioinformatics (particularly in a medical context)?
- What can be done about IP protection in this industry?

Appendix 6 - "Reading List" recommended

To stimulate the discussion at the Forum, a reading list was prepared by the speaker, Dr Edwards, and the Steering Committee members, and distributed to the participants prior to the Forum. The items were:

- "Weaving a Web of Wealth", published by the Australian Academy of Science after July 1999 Biodiversity Informatics Conference in Canberra (the paper can be reviewed at http://circa.gbif.net/Public/irc/gbif/pr/library?l=/pdf_files_press&vm=detai)
- "The Human Genome Project: Lessons from Large-Scale Biology", Science, 11 April 2003, vol. 300, pages 286-290 (see App. 12 in attachment)
- "Pharma 2010: The Threshold of Innovation" (IBM) (see App. 13 in attachment)
- The Interim Bioinformatics Report (May 2003) of the Bioinformatics Expert Task Force (see App. 14 in attachment)

Participants were also invited to consider the following comment about today's (wealthy) pharmaceutical industry from the Wall Street Journal:

"Most drugs don't work well for about half the patients for whom they are prescribed, and experts believe genetic differences are part of the reason. The technology for such genetic testing is now in use... . But the technique threatens to be so disruptive to big drug companies - it could limit the market for some of their block-buster products - that many of them are resisting its widespread use."

A fair assessment? I don't know. But given what I do know about the big drug companies, with their penchant for hyper-complexity and increasing addition to conglomeration ... and to those blockbuster drugs ... I suspect it's quite fair."

(From "Re-imagine!" by Tom Peters, DK Ltd, 2003, p36)

Appendix 7 - List of attendees for GAP Forum on Informatics in Biology & Medicine 2003

Mr Malcolm Allen
Executive Director, Morphepius

The Hon., Dr Michael Armitage
Director – Sciences
Australia & New Zealand, SGI

Mr Karim Barbara
General Manager Business Development
Telstra Research Laboratories

Mr Tony Best
Director, Public Sector
IBM Australia

Ms Syvilla Boon
Ministry of Science & Medical Research

Ms Lorellie Bow
Group Manager Industry Sales
Telstra Research Laboratories

Ms Julia Bowen
Director of Consulting Services
Asia Pacific
Cerner Corporation

Prof David Bowtell
Director of Research
Peter MacCallum Cancer Centre

Mr Lawrence Bremner
COO BioComm Services

Mr Andrew Brockfield
Senior Specialist
High Performance Computing
IBM Life Science Solutions

Ms Paris Brooke
Policy & Communications Manager
AusBiotech

Mr Patrick Callioni
Chief General Manager
Information Economy, NOIE

Dr Amanda Caples
Director Biotechnology
Victorian Department of Innovation,
Industry & Regional Development

Ms Lynette Clunies-Ross
Victorian Government I
BM Executive

Mr Glen Colville
Section Manager
Internet Applications & Management
Telstra Research Laboratories

Prof Richard Cotton
Director, Genomic Disorders
Research Centre

Prof Trevor Dix
Deputy Director
Victorian Bioinformatics Consortium
Monash University

Dr Annabelle Duncan
Chief Molecular Science
CSIRO

Dr Renée Dutton
Platform Technologies Coordinator;
Science, Technology and Innovation
VIC Department of Innovation, Industry
and Regional Development

Prof Simon Easteal
Advanced IT Advisory Committee
Division of Information, Australian
National University

Dr Jim Edwards
Executive Secretary
Global Biodiversity Information Facility
Denmark

Dr Gary Egan
Head Neuroimaging Group
Howard Florey Institute

Prof Peter Fritz
Chair GAP Forum
Global Access Partners

Prof Michael Georgeff
Faculty of Information Technology
Monash University

Ms Mary Guiney
Victorian Government Sales Director
Victorian Government

Dr Beverly Hart
Chief General Manager
ICT Industry & Intellectual Property
Division, Department of Communications,
Information Technology and the Arts

Mr John Hayton
Executive Director
Intelligent Island Tasmania

Mr Richard Hill
Partner, Health Care, ISSC

Dr Bob Jansen
Senior Research Fellow
Centre for Health Informatics, UNSW

Dr Wendy Jarvie
Deputy Secretary
Australian Government Department of Education, Science & Training

Ms Jennifer Jones
Department of Communications, Information Technology and the Arts

Dr Tim Littlejohn
Regional Manager
AP - Solutions Specialist
IBM Life Science Australia

Dr Stephen Livesey
Chief Scientific Officer
NSCC - National Stem Cell Centre

Mr Warren McDonald
Chief Information Officer
Proteome Systems

Mr Rob Merriel
Business Development Manager
Corporate & Clinical Support Services, Melbourne Health

Dr Graham Mitchell
Principal, Forsight Associates Pty Ltd

Dr David Mitchell
Research & Business Leader,
Biotechnology & Health Informatics
CSIRO Mathematical & Information Sciences

Ms Mary Murnane
Deputy Secretary
Department of Health and Ageing

Mr Oleh Nakone
Business Development Manager
Merck Australia Pty Limited

Mr Scott Nesbitt
Biotechnology Development,
Pharmaceutical & Biotechnology Branch
Innovation Division, Department of Industry, Tourism & Resources

Ms Jane Niall
Executive Director, Office of Science & Technology, Victorian Department of Innovation, Industry & Regional Development

Dr Arona Offenberger
Metropolitan Health & Aged Care Services, Victorian Department of Human Services

Mr Tony Palanca
Regional Manager, Life Sciences ANZ
IBM Australia

Ms Rosemary Paxton
Director, BioConnection

Mr Craig Pennifold
General Manager, Pharmaceutical & Biotechnology Branch
Innovation Division, Department of Industry, Tourism & Resources

Dr Andrew Perrignon
Chief Executive Officer
Northern Health

Prof Alan Pettigrew
Chief Executive Officer
National Health and Medical Research Council (NHMRC)

The Hon. Bronwyn Pike
Minister for Health, Victoria

Prof Leon Piterman
Head of School
Primary Healthcare Monash University

Prof Tony Rebuck
Chief Executive Officer
Clinical Trials Victoria

Dr Gerry Roe
Office of Science & Technology
VIC Department of Innovation, Industry and Regional Development

Dr Bruce Ross
Life Sciences Consultant
IBM Life Science Solutions

Dr Kirby Siemering
Senior Scientist, Research & Technology
Australian Genome Research Facility

Dr Ian Smart
Deputy Director
Information City Victoria Management

Mr Andrew Stanley
Director, Research and Evaluation
Branch, South Australian Department of
Human Services

Mr Randall Straw
Executive Director
Multimedia Victoria, Victorian
Department of Infrastructure

Dr David Swanton
Manager Biotechnology Development,
Pharmaceutical & Biotechnology Branch
Innovation Division, Department of
Industry, Tourism & Resources

Prof Ah Chung Tsoi
Pro Vice Chancellor, Information
Technology and Communications
University of Wollongong

Prof Deon Venter
Murdoch Children's Research Institute

The Hon. Matt Viney
Parliamentary Secretary
Innovation and Industry, Victoria

Dr Lynne Williams
Director, Economic Policy
Department of Premier & Cabinet,
Victoria

Ms Pam Williams
Department of Premier & Cabinet,
Victoria

Mr Bill Yeadon
Business Development Manager
Victorian Partnership for Advanced
Computing (VPAC)

Prof Albert Zomaya
School of Information Technologies
Sydney University

Appendix 8 – Workshop facilitators' profiles

Dr James L. Edwards
Executive Secretary
Global Biodiversity Information
Facility (GBIF)
Denmark

See Profile in App. 2, page 30

Dr Tim Littlejohn
AP – Solutions Specialist
IBM Life Sciences

Dr Tim Littlejohn joined the IBM Asia Pacific Life Sciences team in March 2003, after working with IBM for over 18 months in Australia through his own company BioLateral. In this position Tim demonstrated his ability to effectively combine the disciplines of IT and Bioinformatics.

Tim's background includes a Ph.D. and post-doctoral research in molecular genetics, assignments with international IT consultants Accenture, a period as director of Informatics at the Canadian Genome Program, and Head of the Australian National bioinformatics facility ANGIS. Most recently, Tim formed and was a director, CEO and CSO of bioinformatics companies Entigen Inc in 1998 and BioLateral Pty Ltd in 2001. He has extensive experience in commercialising bioinformatics, having raised significant investment from venture capital and government sources to accelerate the growth of the bioinformatics companies he has run. Tim is also co-founder of APBioNet, the Asia-Pacific bioinformatics network, and is an organiser of the 2003 ISMB conference, the major international bioinformatics conference.

Tim has been involved in the Australian bioinformatics and biotechnology industry for many years, through supplying technologies and services to biotechnologists across Australia and the world and through his active involvement in the industry. His industry activities include serving on the editorial board of the IDG journal Australian Biotechnology News, leading the Australian Federal Government's Bioinformatics Industry Opportunity Taskforce, and through participation in many industry development activities including an active membership in AusBiotech, the Peak Biotechnology Industry body in Australia, where he was recently (November 2002) appointed as inaugural National Convenor of AusBiotech's Bioinformatics Special Interest Group (ABSIG).

His role in IBM is Business Development Executive for small and medium Life Sciences businesses across AP with emphasis on leveraging his experience and expertise for the development of specific relevant solutions in biotechnology and creation of alliances to broaden IBM offerings across the board.

Dr David Mitchell
Research & Business Leader, Biotechnology & Health Informatics
CSIRO Mathematical & Information Sciences

Dr David Mitchell is a Research & Business Leader, responsible for Biotechnology & Health Informatics within CSIRO's Mathematical and Information Sciences Division. David manages the Division's research in areas such as bioinformatics for human health and agribusiness, biotech imaging, and health informatics. He is also responsible for the Division's commercial endeavours in the area and has been incubating a potential spin-out based on CSIRO's proprietary array analysis technology.

David studied molecular biology at Adelaide University and came to Sydney to undertake a PhD in Molecular Virology with Gerry Both in CSIRO Molecular Science. Together they

completed the first genomic sequence of Rotavirus, one of the very first complete genome sequences ever.

Abandoning Sydney for Switzerland, David was a Swiss National Foundation Postdoctoral Fellow at the Swiss high containment facility for animal viruses in Basel where he worked on rapid DNA diagnostics. Following that, he worked for a couple of years on industrial enzymes with the Biotechnology Unit of F. Hoffmann-La Roche's Vitamin and Fine Chemicals Division. There he investigated accessing microbial genetic diversity for industrial applications, work that lead to two patents and formed the basis of the Roche product in the area. David left Roche to devote full time attention to Life Systems Design, a company he established in 1992.

Following his return to Australia in 1997, David completed a Master in Entrepreneurship and Innovation, Swinburne University's entrepreneurial equivalent of an MBA. David has worked in various start-up companies in the Life Sciences area and joined CSIRO's Corporate Business Development & Commercialisation team as an Investment Manager in 2002. He has recently accepted his current position with Mathematical & Information Sciences.

Dr Ian Smart
Deputy Director
Information City Management Victoria

Dr Ian Smart has a career that spans research, government and business. He commenced his career as a research scientist, completing a PhD in immunology with Professor Bruce Knox at Melbourne University. After a number of years in research, covering aspects of plant research, animal and human health, Ian took a position within the Victorian Government.

Over a period of about 15 years, he was involved in biotechnology regulation, industry policy and development and in the Coode Island Review, following the explosion at the major hazardous chemical storage facility. His last government position was in Multimedia Victoria, where he was the architect of the Skills.net program, which has reached more than 100,000 Victorians and provided them with access and training in the Internet. In addition, Ian managed the Libraries Online, the Digital Gallery, the Jewish Museum and the Open Channel projects.

After leaving the State Government, Ian joined Melbourne IT, eventually being appointed Manager of Strategy. Included in his responsibilities at Melbourne IT was the management of the incubator, which included such companies as Bluetongue, and Ian was tasked with expanding this incubator, which he did in conjunction with JTP in the successful $8 million tender for a BITS incubator (Information City Victoria) with the Australian Government.

After a period as an independent consultant, working with JTP on the Creative Industries Project with the Queensland University of Technology and the Capital Project with RMIT University, Ian Smart was invited by Mr Robert Crompton to join Information City team to develop a program to commercialise public sector research. He invented the Mentre program, a surrogate entrepreneur program, which has successfully spun off 7 companies, 6 from public sector research and 1 from the private sector.

Dr David Swanton
Manager Biotechnology Development
Pharmaceutical & Biotechnology Branch, Innovation Division
Australian Government Department of Industry, Tourism and Resources

See Profile in App. 4, page 36

Appendix 9 - Workshop groups' presentation

GROUP 1. PROJECT: "NATIONAL BIOINFORMATICS CENTER"

The idea is to build a national centre with a core competency in bioinformatics, which would have the ability to carry out large-scale genomic projects and other applications as well. It should entail the following:

- **Infrastructure** - both people and computing environment (hardware & software) are crucial; the amount of data coming out of genomics projects is immense these days, requiring skills and the power of processing;

- **Skills** – We need to build on Australia's experience, get a critical mass of skills together to carry out these sorts of projects and that sort of skill base;

- **Education** - the Center can provide a place for postgraduates to carry out research, to guide undergraduate courses and also to reach out to secondary schools and put bioinformatics on the agenda of higher education;

The Centre should enable:
- a critical mass of people to analyse and store biological data;
- the interoperability of data sets, in order to create some sort of standards system within the country;
- an access to high bioinformatics capability for Australian biotech (especially small companies and small institutes), eliminating duplication of effort;
- a better management of resource utilisation and expertise;
- a central contact point for Australian bioinformatics;
- a better management of IP;
- a link to existing centers, facilitating large scale Australian projects (the current project of the Australian Genome Research Facility to sequence the Kangaroo Genome is one of the first opportunities for Australia to partake in big science in the genomics arena).

- **Management**
  - standard corporate model
  - a central office that would coordinate, speak for the whole group and act as the common entry point, but would have partners (existing Bioinformatics labs groups)
  - flexibility: the organisation should have the ability to change direction and move quickly

- **Funding**
  - a mix of public (State & National government) and private funding
  - a subscription model
  - charges for provision of services
  - funding from licensing of IP

- **Markets**
  - a subscription model (as one way of accessing the markets which would be providing the services to the biotech community)
  - an access to other countries, regional NZ and Asia (through a big science project)
  - involvement of other research organisations, relationships with large life-science and / or IT firms

- **KPIs**
  - the number of subscriptions
  - time to sustainability or self-funding
  - the amount of repeat business

- the number of publications in quality journals
- the number of products developed
- the number of graduates from courses and the number of workshop attendees
- value of collaborations, national and international in particular

GROUP 2. PROJECT: "TO CREATE AN INFORMATION SYSTEM TO AID GENETIC DIAGNOSIS OF NEUROLOGICAL AND PSYCHIATRIC DISEASES"

The Group 2 had a slightly different approach, which was encapsulated in the title of their project - to create **a generic platform for bioinformatics-based disease identification**, a pilot project focused on National Health Care improvement, within the broad electronic health record concept (discussed during Day One of the Forum). This specific service should bridge from the clinical endpoint through the development of service provision, technologies and companies back into the current research activities.

- **Outline of Project -** *Provision of clinical diagnostic service for neurological and psychiatric diagnosis based on human brain genetic mutation database*

  A new service would directly benefit the community and would be underpinned by improved research in that particular area across the country. Furthermore, this work is already well integrated into the international context (the Human Mutation Society has six databases around the world which are being developed; the neuroscience facility is an area of strength both within Melbourne and nationally). Such a project requires the further development of the health capability in **infrastructure** (i.e. the IT infrastructure), **training and education** (a crucial part to being able to improve or enhance this type of new service delivery within the whole concept).

- **Management**

  The first step would be an initial feasibility study, with a project management team of stakeholders, clinical service deliverers and basic research organisations. The glue between them would be existing providers of IT infrastructure and services, as well as new targeted service deliverers. A strong representation from investment partners is also crucial.

- **Funding Model**

  50% of such an initiative could be funded by a national Centre of Excellence covering health informatics. The other 50% may be generated through respective research communities and through endeavours by the partners in this project. The funding sources would need to include further development of the databases, with the related research being undertaken with NHMRC, ARC, NIH and NSF grants. The clinical service provision would involve the Health Department. The commercial partners would be involved in linkage type projects through the ARC or, potentially, through the R&D start programmes.

- **Access to markets**

  This type of service may directly integrate into current diagnostic service providers, but it requires a significant enhancement of that current capability. Secondly, the clinical testing against a specific genetic mutation would be one possible opportunity for pharmaceutical companies to look at the infrastructure there and to take advantage of it. Thirdly, the instrument manufacturers would potentially see it as a leading edge bioinformatics service, and may therefore want to be involved in providing new technologies to enhance the information in the databases.

- **KPIs**

  A KPI would be an improved Health Care outcome through the enhanced and more **accurate diagnoses** of neurological and psychiatric diseases. Patients going to a neurologist or a psychiatrist could take a blood sample, get a gene characterisation, get it queried against an existing database and know if anyone of a number of genes related to increased expression in psychiatric disorders was identified. That would be a specific outcome measure that we would hope to achieve. Other outcome measures would be **improved targeting of drugs and reduced polypharmacy** which should arise as a result of better diagnosis and more targeted treatment; **an increased private investment** in the development of these new types of services through IT companies and the consequent **employment benefits** that would flow to our community.

GROUP 3. PROJECT: "AUSRALIA'S WORLD LEADERSHIP IN ICT BASED HEALTH CARE"

The idea is to establish Australia as one of the world leaders in ICT based health care within 5 years. To do this, we will establish a new institute focused on ICT base health services, bringing together leading organizations and individuals in ICT; health, bioinformatics, and economics. The first project of the Institute will be in chronic health management, to be run on a clinical trial basis. We aim to be unique and able to deliver dramatically better results, because our base assumption is that the health care system involves highly heterogeneous and autonomous components (i.e. doctors, hospitals, pharmacies etc.) and that the underlying behavior of the system (and therefore of the health care system) requires highly adaptive systems. We will be the only institute worldwide that is taking this flexible, distributed, adaptive approach to building the underlying systems to deliver ICT-based health care.

- **Management -** *highly leveraged bringing in leading partners by providing access to resources, infrastructure, technologies and better funding opportunities*

  The way we aim to manage the Institute is to drive it from the business side and to build on our existing strengths. We believe that one of the key problems in Australia is that we are often pushed by technologies. Our aim here is that the business side (customers) will drive the way the center works. To do this, we have to bring together customers, technologists and economists to help us make sure that what we are building is economically and socially not only viable, but also valuable. We want to bring together **a small core of experts from ICT, health, biotechnology and economics**. The Institute will be a relatively small organisation, running projects across a core set of partners. Those partners will come from those four areas, so it will involve hospitals, biotechnology research organisations, ICT groups (both from the research side and the corporate side).

  We aim to leverage the expertise we currently have in all those areas, bringing them together in a way that is managed as a business. We will be running two or three projects, driven by the market (i.e. the health care providers), but based on some very innovative technologies in adaptive systems. The initial aim is to demonstrate value very quickly and to get a return on investment, integrating existing technologies. Over time, this will enable us to identify research opportunities and will show where we need to invest to build scaleable systems. It will also enable small to medium enterprises to fill in the holes of the technology solutions we have, providing valuable proof points for their technologies.

- **Access to markets** – *portfolio approach; identification of industry projects with major suppliers and quick access to markets; longer term projects developing new products and services; commercialisation through spin offs*

We will involve significant partners and global corporate companies (such as IBM) which will provide the major paths to market. Equally, there are certain technologies and services that will likely be able to be spun out from the Institute on the side. There will be opportunities independently taken up by small to medium enterprises (for example, in providing export services to South East Asia, or in developing a particular technology that can be applied not only in health services but also in other e-commerce applications). One of the key elements is to have demonstrable large-scale projects to establish our branding as one of the world centres of ICT-based health care.

One of the first projects would aim to provide a significant difference in both quality and cost of care for a major chronic condition (such as diabetes), not only in a hospital setting, but throughout the community. This would mean that, for example, a diabetic could walk into a pharmacy and the pharmacist be notified of any inappropriate or dangerous drug; in a community health centre or in a remote community, the diabetic would get the same advice on treatment as in a hospital. When old and at home alone, they would have monitors sending information back to a decision support system, which will alert physicians or health care providers to the event. In these ways, we dramatically change access, cost and quality of care for the diabetic community. We would run the projecdt under a clinical trial model, in order to get measurable outcomes which we can then use to demonstrate the benefits of the approach.

- **Funding -** *direct sales of products/services/data; Government and Corporate; spin offs equity; DHS when products services validated*

  Initial funding will come from the innovative side of government, both Australian Government and States; from matching funds of corporates, matching resources from Universities and academic institutions and CSIRO. As we develop and prove that the technologies work, then the funding will shift from the innovative side of Government to the Department of Human Services and others. We can expect some funding to come from intellectual property and services such as consulting. Indeed, there is a real opportunity here, because - just like Google controls your access to database – we will control access to some very important outcome related data, which can be combined with genomic information.

- **KPIs -** *business case produced; health well-being approach*

  KPIs are both on the health side and the business side. On the health side – less adverse events, less people having to see doctors, less deaths, less time spent in hospital etc. Measures on the business side – how many SMEs have managed to exploit the technologies, how many new services we have helped establish, how many pharma companies have been encouraged to invest, how many export dollars have we earned directly or indirectly from the technologies we offer, and so on.

GROUP 4. PROJECT: "AUSRALIAN NATIONAL CLINICAL TRIALS REGISTRY"

- **Outline of Project - Linking research / clinical trials / commecialisation to generate improved therapeutic benefits and outcomes and national Wealth**

  There are a lot of host organisations in Australia that are doing great things, but their ability to communicate is not as effective as it could be. There is an opportunity to create a mechanism (and by this We mean a commercial entity) that would bring that Wealth of information and knowledge together.

- **Build on existing environment**

  The context for us was to look at research and clinical trials environment that exists in Australia - great clinical trial networks, some world class research institutions and organisations, well published and well received internationally.

- **A for-profit organisation**

  This is a consumer driven context. At the end of the day, the consumer is the one who utilises the health system, the therapeutics etc., it is their pocket or their cheque book which often determines the outcome of where our research might go. We also felt that this should be a for-profit-driven organisation. The Government has to look at initial funding (as you do with anything that is of national interest). Along the way, this is going to generate a lot of potential income - not only for the participants, stakeholders and shareholders in this organisation, but from various services or intellectual property. We see this as eventually becoming a very significant standalone organisation, which offers the world an opportunity to look at Australia and adapt particular models generated from here, and to come and participate with us in that financial gain and modeling context.

- **Australia is uniquely positioned right now to do this successfully and to provide a model for global distribution**

  Our advantage is that we have not gone down the track yet to establish what our infrastructural needs are going to be. The players have not yet set themselves in concrete, so they will be more predisposed to looking how to work with one another to create and infrastructure and an industry in a clustering effect. In essence, what we are trying to establish here is **a supply chain**. Once established, it allows us the opportunity to look at the value chain propositions that come along. We believe that the international community will certainly not only look at the model as one of adoption, but will see the opportunity to participate in a very unique and developed spatial place that would not exist anywhere else in the world.

- **Establish the mechanism for a successful Australian biotech/health industry**

  Creating the mechanism for a successful Australian biotech/health industry through that supply chain will allow proper communications and the flow of information data. The commercial opportunities, that will come out as a result, will allow us to compete internationally in a much more dynamic environment, and get Australia recognised at the world level for many of events that might occur - not only in research clinical trials, but also in things like pharmaco economics (which currently do not benefit from the beauty of being able to communicate effectively with one another).

GROUP 5. PROJECT: "HEALTH INFORMATION MANAGEMENT"

The idea of Group 5 resonated very Well with a couple of the previous projects - they focused on health information management systems.

- **Structure -** *Private / PPP; focus on specific projects; health care delivery, R&D*

  We would like to see it as a for-profit organisation, recognising the need for engagement with government in various guises and different ways, and therefore the need to set up a public/private partnership of some kind. What was very clear was that We did not see this thing fitting into existing public sector institutions and organisations. It would be project-based and would take

as pilots a number of things already mentioned (including mental health, cancer, asthma and other specific diseases), but taking into account what Dr Kovac's said about being systematic and not trying to do something incremental in relation to particular diseases, but seeing it as a pilot and enabling prospective work at the population level.

- **Beneficiaries** - *Consumers, Investors*

  We would endorse very strongly the points made by the previous speaker about this being consumer driven.

- **Investment** - *Government / Corporate (ICT, Pharma, Business); philanthropy, private equity, VCs, revenue - customers*

  In terms of how we would fund this organisation initially, we would rely on Government funding and corporate investment, particularly from the ITC industry, the pharmaceutical industry and the insurance industry. Philanthropy hasn't been mentioned yet. We believe that this thing could be packaged up as having some very substantial public good outcomes, which may attract philanthropic investment and then private equity, VC and, ultimately, revenue generation through IP and services.

- **5 year deliverables** - p*ublic good; financial returns*

  We looked at 5 year deliverables. The very obvious outcomes here: improved health; increased employment; global reach; improved health literacy; engagement with issues and resolution of issues relating to privacy and ethics; value being added very substantially to the existing research effort; reduced health costs; new products in terms of information systems, diagnostics, therapeutics, health management systems, intellectual property; further ongoing investment and, ultimately, a system that is profitable and therefore sustainable.

Appendix 10 - Pressroom

From "Forum to address sluggish bio-IT". By Karen Dearne
"The Australian", 02 December 2003, p. 30

"The possibility of creating a "big science" project to boost Australia's profile in bio-IT and health informatics is to be discussed at a high-level meeting in Melbourne this Week. […]

"Australian's growth in bioinformatics is currently slower than in other countries, especially in Asia", a GAP spokesman said. "Informatics in biology and medicine requires the input of feeder industries, government and investors. It's agreed the industry here is fragmented and there is a need for centralisation."

IBM Asia-Pacific bioinformatics specialist Tim Littlejohn said the forum would look at how health and life sciences "have turned into information industries, because they are now so information driven". […] "One of the big challenges for Australia is the lack of big life-science projects compared with the US, Europe and Japan", he said. […]

Meanwhile, the proposed National Bionformatics Strategy will have an airing behind the closed doors. Department of Industry, Tourism and Resources general manager of pharmaceuticals and biotechnology Craig Penninfold said the forum was an ideal opportunity for consultation, because the strategy would be finalised early next year. "We're ready to start exploring where the work of the forum could interlink with that of the national strategy", Mr Penninfold said. "Basically, We're looking to capture global opportunities for bioinformatics in health, big pharma, agriculture and the environment. Australia certainly has some strength in research and in pharmaceuticals already, but we have yet to really exploit the potential."

GAP will play an ongoing role in the industry's business and policy development through a government consultative committee to be established this week."

Victorian biotechnology e-bulletin
Science Technology Innovation
December 2003

Victoria hosts Informatics in Biology and Medicine Forum

A unique Forum to address issues in informatics in biology and medicine was held on 4-5 December in Melbourne. Senior members of both the biotechnology and ICT industry came together to discuss the growth opportunities for Australia in the field of informatics.

Forum participants included senior representatives from ICT and biotechnology companies, Australia's medical research community and Victorian and Australian Governments. All came together to participate in round table discussions and workshops designed to focus on areas of strengths for the future of Australian informatics.

Outcomes that will drive more effective systems for health management were a major focus of discussions during the Forum. A Consultative Committee has been formed to ensure that the outcomes of the Forum are actively pursued.

The Forum was convened by Global Access Partners Pty Ltd. Through its influential networks, GAP gains results through high level discussions which bring about shared knowledge, progress and inform governments on policy with a view to creating real and lasting change for partners and participants.

Appendix 11 - Letters of thanks and congratulations

"Dear Peter, I would like to take the opportunity to thank you for your foresight and commitment to implement the Informatics in Biology and Medicine Forum earlier this month. There has been considerable positive feedback from many of the Forum attendees. I am aware of a number of new network that have been created through Forum's implementation. It is pleasing to observe the increased level of enthusiasm with which these new networks are being pursued. Thank you for your commitment to ensure that the dialogue will continue through the development of a consultative committee. I look forward to hearing about the emerging outcomes."

Dr Amanda Caples
Director, Biotechnology
Department of Innovation, Industry & Regional Development, Victoria

"It was a great pleasure to meet you and participate in your forum with a very interesting group of people."

Dr Andrew Perrignon
CEO Northern Health

"Dear Peter, it was good to meet you at what I thought was a very productive forum, and look forward to further contact on this project."

Prof Leon Piterman
Head of School, Primary Healthcare, Monash University

"Thank you for the forum – it was directly relevant to what we are doing at Melbourne Health and through Bio21."

Rob Merriel
Business Development Manager
Corporate & Clinical Support Services, Melbourne Health

"The day was great."

Prof Richard Cotton
Director, Genomic Disorders Research Centre

"Congratulations on a most excellent workshop, I thought it was fabulous!"

Rosemary Paxton
Director BioConnection

"Thank you for a very informative and well run conference."

Prof Michael Georgeff
Faculty of Information Technology
Monash University