GLOBAL IDEA

(INFECTIOUS DISEASE EVIDENCE AND ANALYSES)

Project Charter

Document Control Information

Document Owner

This table details the individuals/groups responsible for this document and their roles.

Role	Individual/Group Responsible
Owner	Prabhat Jha, Centre for Global Health Research, St Michael's Hospital and Dr David Brown, CIBC
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Audience/Users	Sponsors, Advisory Committee, and conference attendees

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1.0	September 7, 2004	David Brown and Prabhat Jha	Initial project charter draft	A
1.1	September 20, 2004	David Dunford	Change in charter format, questions for discussion added	A, M, D
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Note: The last column refers to the type of change where
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Project Information

Project Name Global IDEA (Infectious Disease Evidence and Analysis)

Key Project Personnel This table provides information about the stakeholders involved in creating the Project Plan.

Role	Name/Group
Corporate Sponsors	John Hunkin, CIBC and Dominic D'Alessandro, Manulife
Project Sponsors	Prabhat Jha, Centre for Global Health Research, St Michael's Hospital, University of Toronto, and David Brown, CIBC
Project Advisory Committee	Arthur Slutsky (chair) Robert Brunham Prabhat Jha Garry Aslanyan Michel G. Bergeron David Brown Kevin Kain Donald Low Allison McGeer Frank Plummer Nico Nagelkerke Others TBD
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Project Team	Judy Kopelow, Mohan Kumar, others TBD
Project Charter Oversight	Richard Venn, Corporate Development, CIBC
Project Charter and Business Plan Assistance	David Harrison and David Dunford, CSG, CIBC

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1. Executive Summary

1.1 Purpose of This Document

The Purpose of this document is to create a formal approved Project Charter used to guide a Project Manager through project execution. The primary uses of a Project Charter are to document planning assumptions and decisions, facilitate communication among stakeholders and document approved scope and schedule baselines. The project description will generally have less detail in early phases and more detail in later ones as the project characteristics are progressively elaborated.

A business plan will be developed after completion of this charter, which include some similar content, and some new content. For example, a "non-profit" business plan typically includes:

- Summary
- Service Definition and Positioning
- Market Assessment
- Environment Assessment
- Internal Capabilities Assessment
- Business Direction and Strategies
- Plans
    - Service Development Plan
    - Organizational Plan
    - Marketing Plan
    - Operations and Implementation Plan
    - Financial Plan
- Appendix on Management and Personnel

1.2 Project Overview

The objective of the project is to establish, within one year, a network of Canadian scientific professionals that can *effectively* research, gather knowledge and *advise* Canadian governments, corporations and agencies on infectious diseases that place *Canada* at risk and which reduce global development and economic opportunities.

The network will increase the *effectiveness* of research by creating a prioritized, coordinated, and collaborative research system that goes beyond the high-quality but separate research projects that exist in Canada today. Five Global IDEA "functional networks" would focus on the following: (a) epidemiology and mathematical modelling of priority infectious diseases; (b) vaccine development for HIV-1 and other priority infections, including evaluating vaccine efficacy safety; (c) rapid diagnostics for detection and management of diseases; and (d) female-controlled microbicides. The networks would each be managed by leading research centres in the country, and an overall small, efficient secretariat. The network will begin research within one year priority topics, and will have international collaborators in Africa, India and East Asia.

The network will provide scientific *advice* to Canadians on infectious diseases in a cohesive voice, allowing decision makers to take action swiftly and with confidence.

The network will focus on global diseases that are of the greatest direct or indirect threat to *Canadians*.

2. Project Need and Justification

The mission of Global IDEA is to ensure that Canada is prepared and has the scientific capacity to effectively control major global infectious diseases.

Global Infectious Diseases Are A Continuing Threat To Canadians

Global infectious diseases impact Canada both directly, when a disease travels to Canada, and indirectly, through Canada's trade and global development and global security.

In Canada, 438 people were infected and 44 died of SARS. Toronto was paralyzed for several weeks. The distortion of the health system and of the life of Canadians had an unprecedented economic impact (1).

SARS is not the only threat, but rather a potent reminder of the danger of novel organisms. More than 30 'new' infective agents have been identified since 1970, including Ebola, hepatitis C, and West-Nile Virus. There have been consistent projections that a major pandemic of influenza is only a matter of time (2), and this may well lead to several million deaths worldwide, and perhaps those of 58,000 Canadians.

In addition, infectious diseases are massively disruptive, in that their impact goes far beyond those directly affected, creating a drag on the economy overall (1).

Aside from dramatic epidemics, the insipient spread of resistance is a growing concern. Vaccine treatment is only possible for bacterial diseases and some viral infections. For other diseases, drug resistance is a concern. In the US, the number of patients newly infected with HIV-1 who carried a drug resistant virus had increased from 3% in 1995 to 12% in 2000. It is likely that antiretroviral drug resistance is common worldwide.

Canada's opening of immigration has brought unprecedented and two-way benefits of economic opportunity but has also made Canada very much likely to be affected by global infectious disease outbreaks. For example, half of Torontonians are foreign-born, meaning that spread of resistance and rapidly spreading infections will very much likely hit Toronto in the future.

The indirect consequences to Canadians of global disease, while further from home, are also compelling. Global infectious diseases such as HIV/AIDS, malaria and tuberculosis kill more than 6 million people worldwide. Several million children die from preventable infections. In Africa, the number of AIDS-related deaths has soared to one in five of adult deaths, leading to a

decline in life expectancy to 46 years. A recent Harvard Business Review article states that, "very simply, AIDS is destroying the twin rationales of globalization strategy: accessible labor and fast-growing markets." (3). Without strong trading partners, Canada's prospects for growth and prosperity are more limited. Such burden contributes deeply to poverty, to destabilization of governments and eventually to global insecurity (4).

The Best Canadian Response is a Global Response

Because global economies and people are increasingly interconnected, the spread of infectious disease required global solutions to local problems. For example, there is little doubt that the next pandemic influenza will originate from East Asian local markets that mix humans, poultry and domestic animals. Similarly, spread of resistance to HIV-1 drugs is likely to arise from various parts of the world.

Tackling these diseases also improves the prospects to quickly reduce rapidly spreading infections. For example, Chinese surveillance capacity has fallen in recent years, leading both to slow responses against HIV-1 and against SARS. Rapid Canadian response also means the ability to work globally, both in terms of access to study priority diseases where they arise, and in learning from global experience. Consider the following examples:

- The experience learned from "ring" vaccination strategies in eradicating smallpox in Africa or Asia, which might help us in a bio-terror attack
- Tracking of global resistance patterns so as to inform local drug formulary and related choices
- Understanding global evidence of correlates of acquired or innate immunity to HIV-1 will inform vaccine development
- Methods for combination therapy to treat tuberculosis have arisen from research in India

Finally, because major infectious threats are sporadic in Canada, Canadian researchers can keep their skills, knowledge and ability to respond sharp by focusing on global diseases. Canadian capacity in genomics, proteomics and cell biology has been historically strong. Such knowledge will be key to develop new drugs and vaccines, including DNA-based vaccines (5), and to understanding resistance (6). DNA technology is also being applied to diagnostics, most notably polymerase chain reaction technique (7). This large Canadian capacity could benefit from increased access to globally relevant datasets, research collaborators and scientific opportunities.

The rapid creation of the Public Health Agency of Canada (PHAC) is a welcome development to tackle domestic disease control priorities. The PHAC will provide the 'front-line' response to epidemics, and will work within Canada's large public and clinical health infrastructure to improve responsiveness.

Global IDEA provides a key complement, which is the rapid mobilization of knowledge and evidence-based strategies to complement routine services and emergency response. Moreover,

Global IDEA has the ability to pull in knowledge of what works and what does not from around the world because of its global focus and emphasis on large, worldwide collaborations. Partnerships with research, medical, public health communities, and civic communities in developing countries are an essential component of Canadian research, as this is where most infections are occurring. For example, Phase III trials of HIV/AIDS vaccines and microbicides will need to be conducted in developing countries (8). Thus Global IDEA effectively expands the available resources, networks and pool of scientists available to the PHAC to tackle priority diseases.

Cohesive Scientific Advice on Infectious Diseases Is Required in Canada

In the wake of the SARS incident it became clear that there was no coherent voice of science on which the government, corporations and the community at large could depend for consistent, timely scientific advice. The fragmentation of both research and knowledge contributed to a confusing picture of events that placed the Canadian public at risk, and deeply affected commerce and general day-to-day human activity (9).

This scenario will likely be repeated in the future if a network like Global IDEA is not established. For example, if there were smallpox epidemic, decision makers would likely receive contradictory advice from different experts. One immunologist may think that closing airports is a good idea, while another epidemiologist may think that that would be counterproductive.

The Global IDEA network provides a mechanism to facilitate a rapid exchange of ideas among leading Canadian scientific professionals. Then the Global IDEA network will be in a position to advise Canadian governments, corporations, and agencies on infectious diseases in times of crisis with a cohesive voice, allowing decision makers to take action swiftly and with confidence.

A Coordinated Scientific Network Speeds Discovery

Scientific research into of control tools (and the ability to measure their effectiveness), development of vaccines, drugs and diagnostics have been central to successful infectious disease control programs worldwide. Prominent scientists from around the world argue that to speed scientific advancement (such as the development of a vaccine for HIV/AIDS), a rapid and iterative process is required (8) consisting of:

- Agreement among stakeholders to a common vision to coordinate activities
- A collaborative research system that goes beyond individual projects
- Multidisciplinary problem solving consortia of scientific professionals
- A well-coordinated “enterprise” to drive scientific effort
- A series of coordinated centers, each with critical mass, focus, and scientific expertise
- Creative new public and public-private partnerships that drive discovery effort and manage the risks and costs of scientific development

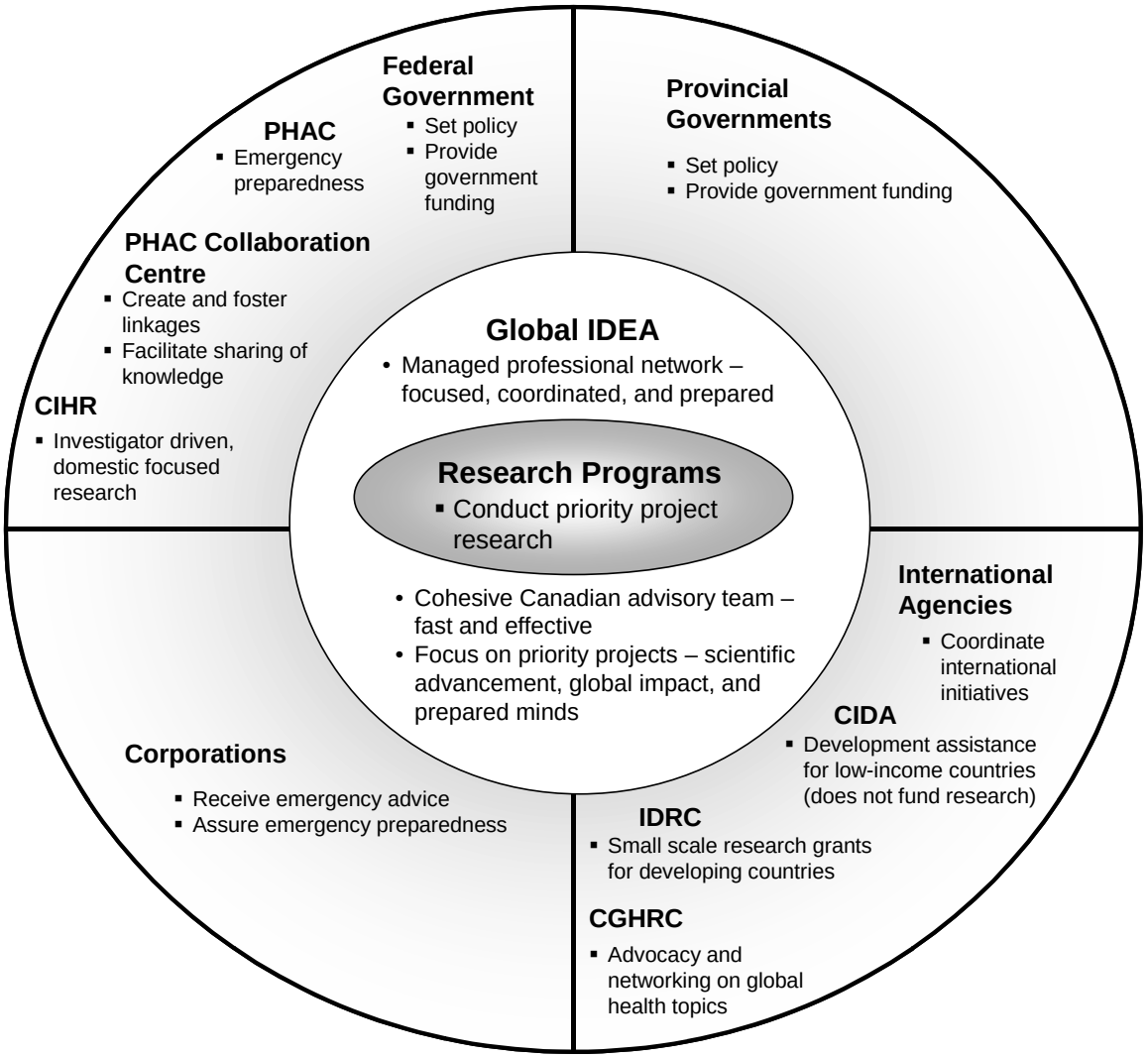
In Canada, no such solution exists. PHAC has been charged with the mandate to provide emergency preparedness and "command and control" in the event of an infectious disease emergency, but is not a coordinated enterprise to drive scientific effort. The PHAC is developing "national collaborating centers" that foster linkages among researchers and the public health community, but no one centre can bring to scale the ability to access worldwide knowledge and research experience in improving front line services. Hence is the need for a Global IDEA network.

There are many facilities in Canada with infectious disease mandates. This includes departments of infectious disease and microbiology at every major university, and specific centres of excellence such as the BC Centres for Disease Control, the National Microbiological Laboratory in Winnipeg, the Centre for Global Health Research and the McLaughlin Centre for Molecular Medicine at the University of Toronto, and the Infectious Diseases Research Center of Laval University in Quebec City. But this capacity has been under-utilized. The opportunity exists for modest incremental funding to re-direct their efforts towards global threats, and to do so in a more harmonized manner.

The Canadian Institute of Health Research (CIHR) has recently developed innovative strategies for battling SARS, such as the Canadian SARS Research Consortium and Canadian Rapid Research Response Team (10). Global IDEA adds value to CIHR by focusing on high priority, product-driven research (versus the usual investigator-driven approach of CIHR), by building cooperative versus competitive networks, and by bringing global scale to CIHR's largely domestic focus.

The Canadian infectious disease scientific community has recognized the need for increased coordination and collaboration, and has proposed the Global IDEA network as a public-private partnership to drive scientific effort, filling a critical void in the Canadian infectious disease research landscape (see the chart below).

Chart: Canadian Infectious Disease Research Landscape



The Global IDEA network of Canadian scientific professionals will focus on the global infectious diseases that represent the greatest threat to Canadians.

Canadian scientists will be better prepared to address new emerging diseases through coordinated and collaborative research. Global IDEA will drive the formation of coordinated "functional networks" of excellence, each with a "node", comprising the required critical mass and expertise to be world leaders in their area:

- Epidemiological tools for analyses and control of major infectious diseases such as influenza, HIV, tuberculosis and malaria (including "rapid response" capacity to deal with local epidemics): Lead node: CGHR-Toronto: Collaborators: MITACS-Toronto, BCCDC-Vancouver.

- Vaccine development for HIV-1, selected sexually transmitted infections and priority infections, including vaccine safety and efficacy: Lead node: ICID-Winnipeg, Collaborators: BCCDC-Vancouver, University of Toronto-Toronto.
- Rapid diagnostics for detection and management of diseases: Lead node: MCMM-Toronto, Collaborators: BCCDC-Vancouver, IDRC-Quebec City.
- Female-controlled microbicides: Lead node: IDRC-Quebec City, Collaborators: Laval University..

The Global IDEA network will in effect be a "network of networks", recognizing that each of these nodes have their own existing networks of relationships.

Expected outcomes: Reduced Risk for Canadians, Expanded Economic and Development Prospects, Improved Public Health Services in Canada

The incredible impact of controlling infectious diseases globally is impossible to ignore (1). The Commission on Macroeconomics and Health estimated that even a modest program to control major diseases globally would generate some some $500 billion per year from 2015-2020 (4) Smallpox eradication cost some $300 million but generated over $27 billion in cost savings over a twenty-year period (11) The rate of return for HIV prevention in Thailand is estimated at 12% to 32% annually. In the absence of prevention measures, AIDS in Thailand would have reduced the GDP by 15% by 2015 (12). Control of HIV-1 and malaria were recently judged by a global panel to provide rates of return far greater than most other development priorities, such as water and sanitation or efforts to improve governance (13). An outbreak of plague in India in 1994 may have cost several billion dollars in foregone travel and other retail revenue, but quick action against a smaller 2001 outbreak probably saved several billions of dollars (14).

How much richer would Canada have been without SARS last year? Tourism was diminished, impacting hotels and restaurants. Financial Services companies had to deploy emergency redundancy for critical services. General tension and uncertainty caused people to avoid public places, impacting the overall economic health of the country. How many young people, especially in vital sectors such as tourism, could have learned skills while employed?

Additionally, Canada might well reap the economic benefits of expanding global trade in biotechnologies. Part of the lack of spending on global health problems is because of a perceived low rate of return on investments. However, this may change for several reasons: several poor countries (India and China) are getting richer and will be looking at technological partnerships globally; intellectual property rules are being strengthened making the likelihood that "patent dodging" is likely to become less common; there are likely to be several global disease-specific efforts to mobilize funds to address the problem of major infectious diseases, such as calls for an accelerated HIV-1 vaccine initiative (8) and investments in global health research may generate technologies (e.g. DNA or immunological) that could be marketed in developed countries. The Financial Times recently stated that growth of biotechnological sector in India and China alone is likely to represent enormous growth opportunities (9).

3. Recommended Solution

The following table overviews the three deliverables of Global IDEA (in order of approach), along with a description of the value added by the Global IDEA network, the benefit to be achieved, and an estimate of the cost. Further information about the deliverables is included in Section 5, and further information about the costs is included in Section 7.

Deliverable	Global IDEA Value Added	Benefit Achieved	Estimated Cost
1. A managed professional network on global infectious diseases of infectious disease scientists, epidemiologists, clinicians and researchers from across Canada, with a small efficient secretariat	• Coordinate and drive Canadian scientific research on global infectious diseases, maintaining focus on highest priority projects • Raise both public and private funds to finance activities and grants • Provide access to existing peer review processes for grant applications or create new processes as needed • Provide a regular forum for sharing of ideas and collaboration • Provide a freely accessible repository of current information and best practice on infectious diseases	• Focused scientific effort on highest priority projects • More coordinated and rapid advancement of scientific development on global infectious diseases • Greater scientific preparedness for new infectious diseases • Streamlined grant application process, to keep scientific professionals focused on science	• $0.5 MM initial • $2.0 MM subsequent
2. A cohesive Canadian advisory team on global infectious diseases that would work in concert with established PHAC and other organizations.	• Provide a cohesive scientific voice to Canadian governments, corporations, and agencies on global infectious diseases,	• Faster and more effective response by decision-makers during infectious disease emergencies • Effective and	• Included above

	to allow decision-makers to act swiftly and with confidence • Act as a single coordinating body for related international agencies (e.g. WHO)	coordinated Canadian participation in global initiatives (such as a global HIV/AIDS vaccine "enterprise")	
3. Development of "Functional networks", based at centres of excellence: Phase I products to comprise • Epidemiological tools • Vaccines for HIV and other infections, and vaccine efficacy and safety • Rapid diagnostics • Female controlled microbicides Future nodes to cover: • Environmental infections • Animal-human health	• Create a series of coordinated centers, each with critical mass, focus, and scientific expertise • Potential to become international leaders in some nodes	• More rapid advancement of scientific development on global infectious diseases • Reduced risk to Canadians of being exposed to an infectious disease emergency where the scientific community can not quickly and effectively respond • Greater opportunity for Canada to positively impact the infectious diseases that threaten the world	• $14 MM seed grants • $250 MM subsequent government funding, over 5 years • Parallel and product specific requests

4. Scope Statement

The Scope Statement forms the basis for an agreement among project stakeholders (sponsors, leaders, and team) by clarifying both the project objectives and the project deliverables.

In Scope (Is/Does)

- Advise Canadian governments and departments, and act as a cohesive scientific voice, on global infectious diseases

    - Non-emergency (e.g. through a repository of information)
    - Emergency
- Be a flexible and responsive point of coordination between government and government agencies and research facilities (Universities, labs, and hospitals)
- Coordinate with other global research agencies regarding infectious diseases
- Raise funds
    - Federal and Provincial Government
    - Private Sector
    - Co-funding from research facilities
- Provide funding to priority projects in four nodes in Canadian research facilities
    - Domestic
    - Domestic with International/Developing Countries

Out of Scope (Is Not/Does Not)

- Direct all infectious disease research in Canada (e.g., such as public health lab-based strengthening)
- Coordinate all financial flows for health research in infectious diseases
- Provide command and control during an emergency situation regarding infectious diseases
- Establish government policy regarding infectious diseases
- Develop new infectious disease programs or departments at universities
- Fund for infrastructure improvements in local laboratory services

5. Project Characteristics

5.1 Project Approach

Global IDEA will help provide a scientific coordinating role between Canadian government agencies, Canadian scientists and laboratories, and major research programs worldwide:

- Work closely with ongoing federal and provincial efforts to develop an inventory of control tools for major infectious diseases.
- Work in collaboration with CIHR
- Work closely with Canadian scientists who have the ability to integrate various types of infectious disease sciences: from program/policy research, epidemiology and mathematical modelling, microbiological and genetic expertise
- Have linkages with other major research programs worldwide the most important of which is the WHO. As well, links would be made to the US National Institute of Health, US Centre for Disease Control and Prevention, the Chinese Academy of Preventive Medicine, the Indian Council of Medical Research, and the South Africa Medical Research Council.

Global IDEA will coordinate fund raising in order to fund high priority research:

- Global-IDEA aims to have sufficient funds to "buy out" time of collaborators from across the world on specific high priority research items. It would ensure that the additional funds are mostly for 'front-line" work rather than for physical infrastructure (such as new buildings or laboratories) – investments would be "software" and not "hardware"

Global IDEA will develop step-wise, to mitigate risk and address critical deliverables quickly:

1. Develop the network, organize a conference, and create a central Advisory Committee and secretariat as the hub

   - The Global IDEA Director General (with a small team of 3 staff comprising a business analyst/manager, research associate and admin assistant) plays leadership, fundraising and networking role. SMH is willing to provide space and administrative support for the Global IDEA Director General. A related model would be for the secretariat function and the Global Health office of the PHAC to be closely connected.
   - The GIDG will develop mechanisms of review – either new, or modification of existing mechanisms (e.g. CIHR, Genome Canada, Canadian Foundation for Innovation, National Centres for Excellence or a scaled up CIDA "Tier 1" competition might be used). No new bureaucracy would be created.

2. Rapidly expanding research infrastructure for priority projects

   - The first set of grants will expand research infrastructure (databases, networks, training, new studies, focused laboratory research). The emphasis will be on "software" and not hardware (physical space, new labs etc).
   - Global IDEA university partners will co-fund (chiefly in the way of protected staff time for research). Core space (wet and dry lab) will be contributed by host universities (with partners encouraged to make CFI/other physical space applications)
   - The early focus will be on epidemiological tools for the analyses and control of major infectious diseases, HIV-1 and STI vaccines, rapid diagnostics, and female controlled microbicides.

3. Pilot grants for proposal development, product development and business plans for each Global IDEA network node. Further information about the proposed activities and some details on the strengths of each node are provided below:

   - Epidemiological Tools for Control: Lead node: CGHR- Toronto.
     - This effort will bring together several key partners to develop epidemiological and mathematical tools for analyses and control of major infectious diseases such as HIV, tuberculosis and rapidly spreading SARS/influenza. These tools would provide "back up" to front-line efforts by the PHAC and local, national

and international agencies in control of major diseases. The specific efforts include:

- Catalogue all major infectious diseases, and control strategies for them, including quantitative reviews of what works and what does not. The catalogue would be continuously updated, and available widely for citation and use
- Greatly expanded program of mathematical and statistical modeling will be done. Already, a major collaboration on understanding HIV-1 transmission is underway by CGHR, Laval University and York University and in Health Canada. Specific topics, such as influenza control would draw on experts already working in those areas, such as MITACS (based at York University). The BCCDC Division of Mathematical Modeling (DMM) has developed software to build contact network models that capture the pattern of human interactions that can lead to disease transmission at different levels of resolution. This novel and powerful mathematical toolkit offers valuable insight into the patterns of respiratory and sexually transmitted disease transmission and the impact of various control strategies.
- The CGHR at St. Michael's Hospital/University of Toronto would be the host institution, but core activities would be in several centres (reporting to a common manager). This would aim to hire about 7-10 more scientists, epidemiologists, mathematical modelers and others within 3-5 years (including dedicated time of staff at other centres). SMH will offer initial space, logistic support and co-funding for the Tools Team.
- CGHR and partners have extensive collaborators in developing countries, including the world's largest study of human health (covering 1.1 million households with 6 million people in India). Tools collaborating Centres in Africa, China and India would be selected to develop similar sets of skills and approaches. The ID Tools Team would also be closely linked with WHO
- Note: While SARS had a large impact on Canada, the next virus may be totally different. Developing control strategies for such a situation may be more relevant than preparing to "re-fight" the previous war. Activities will include assessing the effects of public health measures on transmission, and determining how to quickly assess key epidemiological parameters. This is even more important given that drugs are unlikely to be available when a new virus arrives

- Vaccines for HIV-1 and other priority infections: Lead node: ICID-Winnipeg
  - The International Centre for Infectious Diseases (ICID) is an umbrella organization that brings together expertise from the University of Manitoba, National Microbiological Laboratory, the NRC Institute for Biodiagnostics, and the Manitoba government. It brings unique scale and skills to the study of infectious diseases, including a strong history of training, and existing collaborations in Kenya and India.
  - Vaccine development would focus on "catalytic" and pilot funding for the ICID-led consortium. Primary targets would be on extending novel acquired

and innate immunity to HIV-1 as shown among high risk women in Kenya. A core group comprised also of Kelly McDonald and Rupert Kaul at the University of Toronto would work to identify candidate approaches for vaccine development, and would submit these to two larger and ongoing initiatives: the Grand Challenges in Global Health and the Accelerated HIV-1 Vaccine Enterprise.

- The BC Centre for Disease Control is a provincial centre of excellence for the prevention, detection, and control of communicable and environmental diseases. The BCCDC offers a nucleus of research and clinical services that inform best practice interventions for disease control and foster strategic communication channels with policy makers, health practitioners and the public. The BCCDC has specific expertise in vaccine discovery for respiratory viral diseases such as SARS, influenza and for sexually transmitted pathogens such as Chlamydia trachomatis using innovative genomic and proteomic technologies. It also has expertise in vaccine efficacy and safety trials - while significant progress has been made over the past few years to make vaccines safer and more effective, the BCCDC in partnership with the Vaccine Evaluation Centre has an opportunity to conduct research that improves vaccine safety

- Rapid diagnostics: Lead node: MCMM-Toronto.
  - MCMM represents a unique convergence centre, bringing a true multidisciplinary team of scientists in bio-medical sciences, computational genomics, molecular therapeutics and diagnostics together to focus on major infectious disease threats. The goal will be to accelerate the translation of molecular discovery into effective and appropriate therapeutics and diagnostics for global threats such as malaria, HIV, tuberculosis and emerging pathogens. MCMM Global Health scientists have a proven track record of innovation and successful development and validation of the 1st rapid, standardized, real-time molecular diagnostic assays for major infectious. They are now designing and creating the next generation of diagnostic assays capable of detecting and characterizing multiple pathogens at point-of-care, including nanotech multiplex diagnostics. Simultaneous genomic and proteomic profiling – detection and characterization of multiple pathogens at point-of-care.
  - As the provincial reference laboratory for emerging and reemerging pathogens, BCCDC has the research expertise in genotyping pathogens, nucleic acid tests such as RT-PCR and immunodiagnostic testing. The BCCDC in partnership with UBC has submitted a proposal to Genome Canada for funding of an integrated research program that applies genomics and proteomics technologies to rapidly identify and develop diagnostics.
  - The Infection Disease Research Centre (IDRC) Laval University, Quebec City: Microbicides and rapid diagnostics against major infections. It has 250 researchers and research personnel working on preventive tools of the future like: rapid (<1 hr) diagnostics, new vaccines and microbicides. IDRC has

developed diagnostics by exploiting genomic information to develop useful tests for the rapid (<1h) detection of DNA and RNA targets from infectious agents.

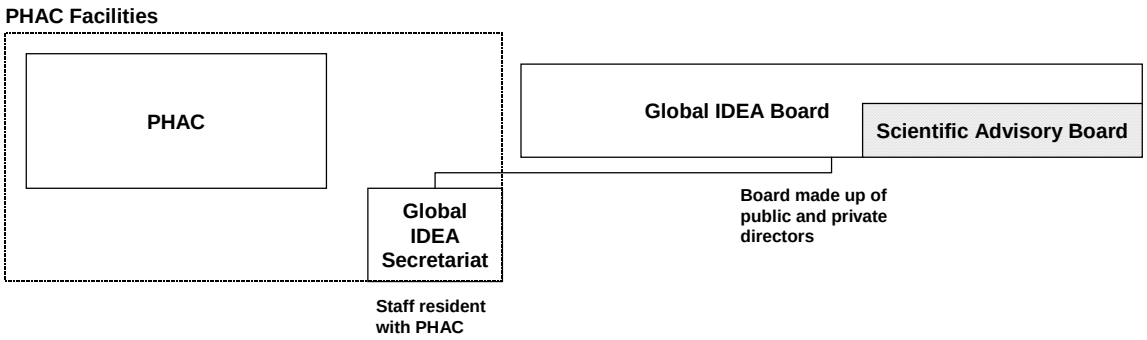
- Female-controlled microbicides Lead node: IDRC, Laval University- Quebec City:
  - Microbicides to protect women against HIV/AIDS and other sexually transmitted diseases are a high priority of the United Nations (UN) and the WHO. The consistent and careful use of male condoms represents an effective barrier against sexually transmitted infections (STIs), but unfortunately, their use is not widespread. More attention is now given to female-controlled methods (microbicides) for the prevention of STIs since many women are unable to negotiate condom use.
  - Over the last ten years, IDRC has developed a vaginal microbicide gel formulation containing sodium lauryl sulfate (SLS), called the Invisible Condom® that could be effective to prevent the sexual transmission of HIV, HSV and other STIs as well as to prevent unintended pregnancy. It is now in a Phase I/II study involving 452 women in Cameroon; trial is being implemented.

4. Implement Global programs. Expanded global programs for each of the priority diseases will require additional funds to achieve scale of collaboration. These funds would need to be mobilized from government of Canada (including the recent Throne Speech that promised to do more in global health) and international foundations (such as the Bill and Melinda Gates Foundation forthcoming announcements for its "Grand Challenges" and HIV-1 accelerated vaccine development.

Global IDEA governance will be a private/public/voluntary partnership:

- A proposed governance structure is one similar to Global Fund (http://www.theglobalfund.org/en/) or IAVI (www.iavi.org), with a board comprised of both public and private directors. The small secretariat, in this proposed structure, co-resides with an existing government agency – in this case, likely the PHAC (see Chart, below).

Chart: Global IDEA Governance



- Public participation will include key federal institutions, such as PHAC, CIHR, CIDA and others. Private participation on the board will comprise those who participate in the funding of the network.

- The governance model will ensure that Global IDEA has the autonomy and flexibility to move quickly, have high energy and accountability, and the ability to focus on specific priority products.

- The governance model would also emphasize cooperation but with adequate safeguards of peer review and scientific excellence. Moreover, the governance model would shift from the interim secretariat based at one of the key nodes (CGHR-Toronto) to a fully autonomous, but small and efficient group.

5.2 High-Level Requirements

High-level requirements of the Global IDEA project:

- Develop a value proposition for Global IDEA that it is compelling and clear to all stakeholders (governments, corporations, agencies)
    - Successful preparation for and handling of future infectious diseases emergencies could not be assured without the participation of Global IDEA
    - Global IDEA has a clearly differentiated mandate from other stakeholders
- Gain the support of the PHAC and CIHR, and obtain PHAC's agreement that Global IDEA will act as the cohesive scientific voice in Canada with respect to global infectious disease emergencies
- Establish a network of Canadian scientific professionals within one year, including a secretariat and periodic conferences
- Complete at least one high profile catalyzing project within the first two years of its mandate
- Raise sufficient funds (from governments, corporations, and/or partners) within the first two years to:
    - Support the network and secretariat
    - Provide seed funding for priority projects
    - Provide seed funding for the development of the nodes and networks

5.3 Constraints

The main constraints for the Global IDEA project are as follows:

1. Access to funds for secretariat, seed funding for projects, seed funding for nodes, and full funding for projects
2. Coordination with and recognition from PHAC, CIHR, and other key stakeholders
3. Access to appropriate resources (project manager, etc…)

4. Interest and availability of time from the Canadian scientific professional community

5.4 Assumptions

Key Assumptions:

- Corporations will provide the seed funding Global IDEA and also help lobby the federal government about the importance of a cohesive scientific discovery enterprise against global infectious diseases, as they are deeply concerned about Canada's preparedness for another infectious disease emergency
- Canadian corporations will direct more of their R&D efforts towards initiatives such as Global IDEA
  - The speech from the Throne (February 2003; October 2004) called for directing 5% of domestic R&D (or about $20 billion) or about $1 billion toward global environmental and health concerns
- The Canadian government will fund priority projects on infectious diseases through the foreign aid budget, if those projects are developed in conjunction with developing countries

The Canadian government will provide funding for Global IDEA priority projects through money recently committed to expanded overseas developmental assistance

- Partners will be willing to co-fund priority projects
- There is "spare capacity" in the research facilities in Canada
- The mandate is clearly differentiated from CIHR and other stakeholders
  - CIHR will continue to focus on domestic priorities, and investigator-driven research proposals. Specific CIHR initiatives such as training grants can add value to Global IDEA and vice versa by expanding considerably the physical and human infrastructure for Canadian scientists.
- PHAC will retain a focus on rapid response against communicable diseases and combating a limited set of priority diseases

5.5 Risks and Mitigation

Key risks and their mitigations:

1. Resource risk (low). Given the limited resources available, a frugal step-wise approach is required with multiple team approval and consensus measuring assessments along the way
2. Government approach risk (moderate). As the landscape that includes the Canadian Public Health Agency and the interest of the Canadian government is not clear, the project can move forward expecting a fair degree of flux
3. Research Availability risk (tbd). Funding and competing time of senior scientists

6. Project Schedule

6.1 Key Deliverables and Milestones

Key Deliverables and/or Milestones	End Dates
Form network for IDEA	Completed
Complete Project Charter	October 31, 2004
Increase visibility of the problem with media, op eds and November conference	November 10, 2004
Distribute Project Charter and Conference outcomes in Ottawa	December 2004
Complete Overview Business Plan, including Financials, and obtain Approvals	December 15, 2004
Complete Project Implementation Plan	TBD
Complete overseas consultations- including India at the Indian Science Congress (Jan 2005)	January 2005
Distribute concept note and engage key decision makers in Ottawa	Prior to Feb 2005 budget
Disseminate Project Charter to Gates Foundation and engage their team on possible co-funding	TBD
Secure commitments for phase 1 funding from universities and private sector	March 2005
Launch global IDEA including commitments of matching funding/support from major foundations, CFI, partnering governments by G-8 summit, with Canada taking leadership role	June 2005
Start priority research at 2-4 nodes, and secretariat/network functions	July 2005
Obtain full funding for Global IDEA for years 1-2	December 2005

7. Project Budget

1. Initial funding of $0.5 MM - CIBC/Manulife Grant of $0.3 MM (matched by CIDA contribution of $0.1 MM for international delegates travel to November conference and SMH/U of T for $0.1MM).
    - November conference (held, and summarized in publications (1), and in press/media/op eds).
    - Form advisory committee and limited staffing of interim secretariat

2. Funding of $2 MM to form a small secretariat, formalize advisory boards/governance and structure, conduct a survey of all potential resources in Canada and globally, and create a common network and communications ($2 MM, including co-funding of $0.4 MM and seconded CIBC/Manulife Project managers totaling $0.4 MM)

3. Seed grants of $14 MM over 24 to 30 months (starting March 1, 2005), including matching contributions by Universities of $4 MM, to begin Priority projects:
    a. Epidemiological tools for analyses and control of major infectious diseases ($6 MM, including $1.0 MM co-funding). To begin implementation within six months, including three global partners in Africa, India and East Asia
    b. HIV-1 and STI vaccines ($2 MM including $1.0 MM co-funding) to be paired closely with forthcoming HIV-1 vaccine enterprise for Bill and Melinda Gates Foundation.
    c. Female microbicides ($2 MM including $0.5 MM co-funding) to be paired closely with global microbicide initiative of WHO/Gates Foundation.
    d. Rapid Diagnostics ($3 MM including $1.0 MM co-funding) to be paired closely with forthcoming initiative WHO/Gates Foundation and NIH priorities on rapid diagnostics.
    e. Pilot grants for proposal development, product development and business plans for each Global IDEA network node ($1 MM, including $0.1 MM per proposal times five proposals, and an open call for proposals for $0.3 MM,).

4. Phase two funding to aim for federal government for $250 MM (to be re-directed from traditional overseas development assistance), over five years. Parallel and product specific requests to Bill and Melinda Gates Foundation, CIHR, NIH, Wellcome Trust, and others (NOTE: Global IDEA partners have already applied for some $35 MM US through the Gates "Grand Challenge" Competition).

8. Project Stakeholders

Role/Name	Organization/Group	Responsibilities
Project Sponsors		
John Hunkin	CIBC	• Champion of the project to external parties • Resolve conflicts in goals, resources, approach, and issues • Provide guidance and resources as required • Provide input and expectations • Challenge and validate deliverables • Promote the project
Dominic D'Alessandro	Manulife	
Prabhat Jha	Centre for Global Health Research, St Michael's Hospital, University of Toronto	
David Brown	CIBC	

Role/Name	Organization/Group	Responsibilities
Project Scientific Advisory Committee		
Robert Brunham	British Columbia Centre for Disease Control	• A high-level scientific advisory board comprising leading global scientists, representatives from WHO, the CDC, federal and provincial governments, and representatives from the Canadian business community would meet regularly to review the progress of Global-IDEA
Arthur Slutsky	St Michaels Hospital	
Prabhat Jha	St Michaels Hospital	
Garry Aslanyan	Canadian International Development Agency	
Michel G. Bergeron	Infectious Disease Research Centre, University of Laval	
David Brown	CIBC	
Kevin Kain	McLaughlin Centre for Molecular Medicine	
Donald. Low	Mt Sinai Hospital	
Allison McGeer	Mt Sinai Hospital	
Frank Plummer	Health Canada National Microbiology Laboratory	
Nico Nagelkerke	Leiden University Medical Center	
Others TBD		
Project Team		
TBD	•	• Overall project execution • LoB work stream project plans and execution • Complete project documentation and business case preparation • Act on or resolve issues • Coordinate project resources
Project Management		
TBD	•	• Guide project direction • Engage Project Team
Key Resources		
TBD	•	• As required by the Project Team, to support and deliver project components

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