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SOLICITATION OF COMMENTS ON STIMULATING INNOVATION IN MEDICAL TECHNOLOGIES

Executive Summary

The Department of Health and Human Services (HHS) has expressed a desire to facilitate and accelerate the pace at which new discoveries in the basic sciences are translating into new medical technologies (i.e., drug and biological products, medical devices) and made available to those who provide care to patients. In response to this concern, HHS has asked for ideas about how the Department and its agencies can work more effectively together to facilitate the discovery, development, approval, and application of new medical technologies.

The environment within which new medical technologies are discovered, developed, approved, and applied to clinical practice is extremely complex, involving many stakeholders with multiple, sometimes conflicting, motivations. Nonetheless, we do see some efforts toward HHS's objective of facilitated and efficient discovery, development, and application, including the National Institutes of Health (NIH) Roadmap, the collaboration between the NIH National Cancer Institute (NCI) and the Centers for Medicare and Medicaid Services (CMS), and various technology transfer programs. Yet challenges remain in achieving an environment that encourages innovation in medical technology, that expeditiously reviews and approves new technologies, and that collaborates and interoperates efficiently.

HHS has posed seven probing and insightful questions, all aimed at extracting creative and useful ideas that will help the Department achieve its objectives of facilitated and accelerated medical technology innovation. SAIC is pleased to have the opportunity to provide our thoughts, observations, and suggestions in this critically important area. In addressing these questions, SAIC has drawn from case studies of successful transitions from government-funded research to commercial application; examples of innovative and successful approaches to organizational effectiveness; existing and emerging medical and life-science-related standards; as well as our own methodologies and experience in helping organizations develop actionable strategies.

1. INTRODUCTION

The Department of Health and Human Services (HHS) has expressed concern about the pace at which new discoveries in the basic sciences are translating into new medical technologies (i.e., drug and biological products, medical devices) for patients. In response to this concern, HHS is soliciting ideas for how the Department and its agencies can work together to facilitate the development and approval of new medical technologies. The circumstances that prevail today suggest that this may be an auspicious time to spur innovation in medical technology. This paper is SAIC's response to the HHS's request for suggestions on how HHS and its agencies can stimulate innovation in the development of medical technologies.

In Section 2, we examine the scientific and regulatory environment within which today's medical innovations are discovered, developed, approved, and applied in clinical practice. We examine the roles, responsibilities, and interrelationships among the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ), within HHS, as well as relevant roles within the Department of Defense (DOD), the Department of Energy (DOE), industry, and academia. Within the context of this environment, Section 3 summarizes the challenge HHS is seeking to address.

Section 4 contains SAIC’s responses to the seven questions posed in the solicitation. SAIC is pleased to have the opportunity to provide our thoughts, observations, and suggestions about how HHS can best spur innovation and accelerate the pace at which medical technology moves from the laboratory into clinical practice. HHS will receive some valuable insights and suggestions through this solicitation. However, we believe that achieving the kind of changes in policies, practices, programs, and interactions that HHS seeks will require a concerted and carefully orchestrated effort. We further believe that such a transformation in how organizations behave and how business is conducted can best be realized through a formal, collaborative program involving all of the key stakeholders. We will elaborate on this later in this response.

2. UNDERSTANDING THE CURRENT ENVIRONMENT

To provide HHS with meaningful and useful suggestions for encouraging, supporting, and accelerating innovation in medical technology requires a solid understanding of the environment within which such innovation currently takes place. In this section, we describe the current environment, including organizational roles and responsibilities, and interrelationships among NIH, FDA, CMS, CDC, and other relevant organizations, as well as relationships with academia, industry, and health care. **Exhibit 1** depicts what could be viewed as the “ecosystem” that currently discovers, develops, regulates, distributes, and consumes medical technology. Federal agencies are highlighted.

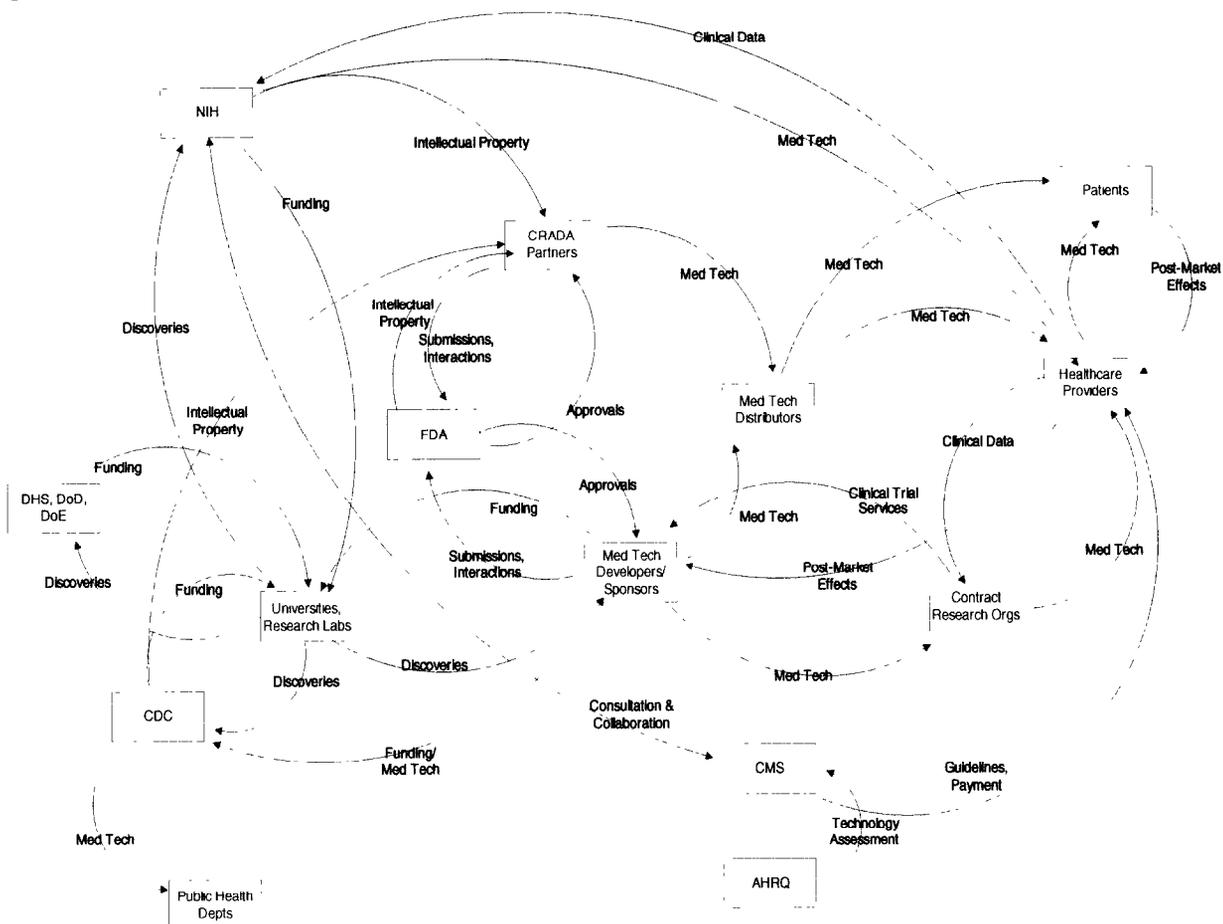


Exhibit 1. The Ecosystem within which new Medical Technologies are Discovered, Developed, Regulated, Distributed, and Consumed is Extensive and Complex

2.1 KEY STAKEHOLDERS

The key stakeholders within this ecosystem are identified in **Exhibit 2**, which also identifies the role of each stakeholder and the interrelationships among the stakeholders.

Stakeholders	Roles & Responsibilities	Interrelationships
Agency for Healthcare Research and Quality (AHRQ)	AHRQ provides to CMS technology assessments that are used to inform CMS's coverage decisions and to provide information to Medicare carriers.	<ul style="list-style-type: none"> ■ CMS
Centers for Disease Control and Prevention (CDC)	Monitors public health, and identifies needs for disease countermeasures, such as vaccines and prophylaxes. Funds discovery research, development and production of medical technology. Provides medical technology to public health agencies. Provides intellectual property to CRADA partners for development of medical technology.	<ul style="list-style-type: none"> ■ Universities, research labs ■ Medical technology developers/sponsors ■ Public Health Departments ■ CRADA partners
Centers for Medicare and Medicaid Services (CMS)	CMS administers the Medicare program, and works in partnership with the States to administer Medicaid, the State Children's Health Insurance Program (CHIP), and health insurance portability standards. CMS provides quality standards and guidelines to healthcare providers and pays for healthcare services. CMS and the NIH/National Cancer Institute (NCI) are developing an agreement that will address how the two agencies can work together in 5 areas of technology, science, and patient care (see Section 2.2.2 below). CMS uses the AHRQ to perform technology assessments.	<ul style="list-style-type: none"> ■ State Medicaid & SCHIP ■ Healthcare providers ■ NIH/NCI ■ AHRQ
Cooperative Research and Development Agreement (CRADA) Partners	A CRADA is a written agreement that enables a federal agency and a private business or other entity to work together on a project (see Section 2.2.3 below). CRADAs enable the transfer of intellectual property from federal laboratories to private businesses, providing a means to leverage federal R&D efforts and to create teams for solving technological and industrial problems. CRADA partners use intellectual property provided by the NIH, FDA, and CDC (and other federal agencies) to develop medical technology, for which they may receive patents and licenses. Technology developed through a CRADA relationship is subject to the same FDA approval process as any other technology.	<ul style="list-style-type: none"> ■ NIH ■ FDA ■ CDC ■ Medical technology developers/sponsors ■ Medical technology distributors
Contract Research Organizations (CRO)	CROs provide clinical trials services to medical technology developers, including clinical data management, biostatistics, research report writing, and clinical trial/site management. Medical technology developers provide the medical technology the CROs use in clinical trials. CROs then work with providers to conduct clinical trials and to receive and manage the data collected.	<ul style="list-style-type: none"> ■ Medical technology developers/sponsors ■ Healthcare providers

Stakeholders	Roles & Responsibilities	Interrelationships
Department of Homeland Security (DHS), Department of Defense (DOD), Department of Energy (DOE)	DHS, DOD, and DOE fund research in technology to prevent, detect, and respond to chemical, biological, radiological, and nuclear attack. Also note that DOD's Military Health System is a "healthcare provider" as well.	<ul style="list-style-type: none"> ■ Universities, research labs
Food and Drug Administration (FDA)	FDA establishes and enforces standards for all medical technology. FDA works with medical technology developers (sponsors) to evaluate new medical technologies for safety and effectiveness. All medical technology must be FDA approved before it can be made available to consumers. Once approved, medical technology must continue to meet FDA standards. (See Section 3.2 below.)	<ul style="list-style-type: none"> ■ Medical technology developers/sponsors ■ CRADA partners
Healthcare Providers	Healthcare providers participate in clinical trials during the development of new medical technology. Most commonly, they work with CROs, who provide them medical technology and to whom they send clinical data. Providers receive FDA-approved technology from distributors. Once a technology is marketed, providers report adverse effects to the technology developer/sponsor. Healthcare providers receive care guidelines from CMS, as well as payments for services.	<ul style="list-style-type: none"> ■ CROs ■ Medical technology distributors ■ Medical technology developers/sponsors ■ CMS ■ Patients
Medical Technology Developers/Sponsors	Medical technology developers fund discovery research and develop medical technology based on discoveries. Developers work with CROs to conduct clinical trials, and they submit new technologies to the FDA for approval. Once the FDA has approved their technology, developers work with distributors to make the technologies available to providers and patients. Developers continue to assure that their marketed technologies comply with FDA standards. Through post-market surveillance programs, they receive reports of adverse effects from providers and patients.	<ul style="list-style-type: none"> ■ Universities, research labs ■ CROs ■ FDA ■ CDC ■ Medical technology distributors ■ Healthcare providers
Medical Technology Distributors	Medical technology distributors provide technology to patients either directly (for over-the-counter technologies) or through healthcare providers (prescriptions).	<ul style="list-style-type: none"> ■ CRADA partners ■ Medical technology developers/sponsors ■ Healthcare providers ■ Patients
National Institutes of Health (NIH)	NIH institutes, centers, and offices conduct and fund discovery research within various areas of interest. NIH is now implementing its Roadmap, which addresses enterprise-wide initiatives (see Section 2.2.1 below). NIH/NCI is collaborating with CMS to develop joint processes in 5 areas of technology, science, and patient care (see Section 2.2.2 below).	<ul style="list-style-type: none"> ■ Universities and research labs ■ CMS ■ CRADA partners ■ Healthcare providers
Patients	Patients are the ultimate consumers of medical technology. During technology development, they work with their providers to participate in	<ul style="list-style-type: none"> ■ Healthcare providers ■ Medical technology distributors

Stakeholders	Roles & Responsibilities	Interrelationships
	clinical trials. Once the technology is marketed, they obtain the FDA-approved technology from distributors (over-the-counter technologies) or through a prescription obtained from their provider.	
Public Health Departments	State and local health departments obtain medical-technology countermeasures from the CDC. They may work with healthcare providers to distribute the technology.	<ul style="list-style-type: none"> ■ CDC ■ Healthcare providers
Universities and Research Laboratories	Universities and research labs perform discovery research for government agencies and medical technology developers. Some of these labs are small businesses funded through the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs.	<ul style="list-style-type: none"> ■ NIH ■ CDC ■ DHS, DOD, & DOE ■ Medical technology developers/sponsors

Exhibit 2. Key Stakeholders, and Their Roles and Interrelationships

2.2 ACCELERATION AND COLLABORATION EFFORTS

Strategies to accomplish biotechnology discovery goals are diverse within the HHS. However, some current and emerging models suggest that a strategy to accomplish the goals of HHS is realistic and could shorten the time from discovery to use in clinical practice. For example, the FDA's expedited development and review process is designed to make those drugs with promise for serious or life-threatening diseases available expeditiously. Similarly, new forums between the FDA, CMS, and NIH/NCI are providing tools and information that will enable scientists to move medical technologies from bench to bedside more quickly. However, most NIH institutes involved in medical technology development lack such cooperative, rapid-acceleration initiatives with other HHS agencies.

While several impressive models exist, many medical technology discoveries are not effectively transferred or communicated outside their laboratories or with the FDA, AHRQ, and CMS. The result is uneven submissions from discoveries in areas such as heart and lung disease, arthritis, diabetes, eye conditions, neurological conditions, mental health, and substance and alcohol abuse. Also, the methodologies currently in place may be inadequate for rapidly evaluating and advancing new genetic, genomic, proteomic, and nanotechnology diagnostics likely to be recommended in the near future. These new technologies may expand the model for measuring success to include ethical, legal, and social dimensions.

Some of the stakeholders described above have already undertaken efforts to accelerate the discovery, development, approval, and distribution of new medical technologies and to facilitate interactions among the stakeholders. Some of these efforts may serve to inform the transformation HHS is seeking.

2.2.1 NIH Roadmap

The NIH Roadmap focuses on efforts that no single or small group of institutes or centers could or should conduct on its own, but that NIH as a whole must address. The Roadmap defines a compelling, limited set of priorities that can be acted upon and that are essential to accelerating progress across the spectrum of the institute missions. Three major themes comprise the Roadmap: New Pathways to Discovery; Research Teams of the Future; and Reengineering the Research Enterprise. Within each of these themes, a number of initiatives have been defined and are being launched in 2004.

The New Pathways to Discovery theme addresses the need to understand complex biological systems, and is developing new tools for today's biological researchers. NIH also has begun planning a series of nanomedicine centers that will be launched in 2005. These centers will focus on the quantitative measurement of biological processes at the nanoscale and the engineering of new tools to intervene at the nanoscale or molecular level. The Research Teams of the Future theme recognizes that the scale and complexity of today's biomedical research problems demand that scientists move beyond the confines of their own disciplines and explore new organizational models for team science.

The Reengineering the Clinical Research Enterprise theme addresses the most difficult and most important challenge identified by the NIH Roadmap definition process. This theme recognizes that exciting, basic-science discoveries demand the continuance and expansion of clinical research, while striving to improve efficiency and to better inform basic science. Clinical research needs to develop new partnerships among organized patient communities, community-based physicians, and academic researchers. Critics of the nation's current clinical research system have cited several factors that promote inefficiency, including poor integration of existing clinical research networks, inadequate training mechanisms for clinical investigators, inconsistent data standards and database requirements, and lack of information. The NIH Roadmap calls for the development of regional translational research centers and a National Electronic Clinical Trials and Research (NECTAR) network that will link current and emerging clinical research information systems so that data and resources can be shared within and across clinical research networks, across studies and across institutions [Zerhouni 2003a].

2.2.2 CMS-NCI Collaboration

CMS and NCI, both components of the HHS, are developing a joint Memorandum of Understanding that will address how the two agencies can work together in five areas of technology, science, and patient care:

1. Developing joint processes for identifying high-priority clinical questions about the optimal use of new cancer technologies and for conducting post-approval studies to address these questions.
2. Defining a systematic process for consultations between CMS and NCI experts on the evaluation of new diagnostic and therapeutic cancer technologies for the purposes of payment and coverage decisions.
3. Developing more efficient methods of collecting clinical evidence on new cancer technologies and strategies for making this information more widely available to patients, clinicians, and researchers, including the possible inclusion of CMS claims data on NCI's cancer BioInformatics Grid (caBIG).
4. Developing a joint process for the prospective identification and evaluation of emerging technologies such as molecular imaging so that reimbursement policies will fully anticipate promising new cancer technologies and to help expedite their adoption in the marketplace.
5. Identifying opportunities for sharing data and resources aimed at improving the quality of care for cancer patients and addressing additional concerns such as cancer health disparity issues, reducing unwarranted variation in treatment patterns, and improving palliative and end-of-life care.

CMS and NCI intend to work together to help ensure that the reimbursement framework can adapt to these potentially critical changes. The CMS-NCI collaboration will better align the two agencies in order to make possible earlier access to safe and effective promising new technologies for the treatment of cancer. CMS and NCI also have agreed to work together to develop collaborative efforts to identify and initiate high-priority clinical trials in areas where

clinicians and patients have said that they need more and better clinical information to guide their decision making about new or competing treatment regimens.

As a first step in their collaboration, the two agencies will work together to develop a strategic approach for prioritizing these clinical questions and adopting joint processes that will allow for better clinical data collection after new treatments are approved by the FDA. Building on the successful work between NCI and FDA, this new collaboration between NCI and CMS will better align the efforts of all three agencies.

The NCI and CMS will also work together to coordinate standards and develop tools to streamline their interactions and accelerate the overall development of evidence for new cancer drugs. These activities will become part of NCI's caBIG. CMS will engage appropriate clinical experts from NCI in all stages of national coverage determination development, reach out to experts identified by NCI, and as appropriate, convene expert workshops and other opportunities for public comment to address complex or crosscutting questions.

2.2.3 Technology Transfer Programs

The Federal Technology Transfer Act of 1986 (FTTA) amended the Stevenson-Wydler Technology Innovation Act of 1980; Executive Order 12591 of April 10, 1987; the National Technology Transfer Advancement Act of 1995; and other Public Health Service (PHS) policies to encourage interactions and collaborations among federal laboratories, state and local governments, universities, and the private sector. To enable these collaborations, FTTA created a mechanism called Cooperative Research and Development Agreement (CRADA) and provided incentives for federal scientists (royalties from licensed inventions), federal laboratories (additional research resources and expertise), and CRADA partners (exclusive licenses for patented inventions).

FDA, CDC, and NIH support collaborative research and development under CRADAs and has strong technology-transfer programs. NIH's Office of Technology Transfer (OTT) evaluates, protects, monitors, and manages the entire NIH invention portfolio to carry out the FTTA. The OTT oversees patent prosecution, negotiates and monitors licensing agreements, and provides oversight and central policy review of CRADAs. OTT also manages the FDA's patent and licensing activities. OTT is responsible for the central development and implementation of technology transfer policies for four research components of the Public Health Service – NIH, FDA, CDC, AHRQ. Current licensing opportunities, federal technology transfer policy, and technology transfer mechanisms are summarized on the OTT web site. Also available on this site are sample agreements and forms about new licensing opportunities relevant to industry's areas of interest. OTT provides a service whereby one can receive emails about new licensing opportunities

The FDA has internal procedures for establishing CRADAs, filing Invention Reports, and through a formal agreement with NIH's Office of Technology Transfer, licensing patented inventions and biological materials. The FDA also has a Fair Access and Conflict of Interest policy to safeguard the agency and the scientist while fostering collaborative efforts. CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) share a Technology Transfer Office that provides leadership and expertise to promote and effect the timely transfer of knowledge and technology for development of products and processes that can improve public health. ATSDR and the CDC's Centers, Institutes, and Offices offer a rich portfolio of technologies available to potential CRADA partners.

However, CRADAs may not be the most effective mechanism for transferring technology from the government into the private sector. Negotiations can be long and complex, and can involve legal interpretations and clarifications. Research under a CRADA must be consistent with the

Government laboratory's mission. CRADA research requires an investment from the collaborator, including personnel, services, and use of property. Licensing of intellectual property can be very complex and contentious. The collaborator is granted an exclusive license for jointly developed technology, with inventions made solely by government scientists remaining federal property that can be licensed by the private sector.

Ironically, some of the most successful CRADAs have created political backlash against CRADAs. One of the best examples is the CRADA that resulted in the development of the drug AZT (Retrovir) for the treatment of HIV-infection and AIDS. Through a CRADA with NIH, Burroughs Wellcome Company (now GlaxoSmithKline) obtained an exclusive patent for the drug. Two generic drug companies challenged the patent's validity and the sole assignment of AZT patents to Burroughs Wellcome. The generic drug companies claimed that Burroughs Wellcome's patents were invalid because they failed to properly attribute NCI researchers as co-inventors. Much of the original impetus and support for the patent challenge rose from economics – at the time, AZT was the only drug available for treatment of HIV-infection and cost about \$10,000 or more annually. The case went all the way to the Supreme Court, who upheld the patent [AZT 1996]. The AZT experience also prompted Congress to add a “fair pricing” clause to future CRADAs, further complicating the CRADA process.

3. UNDERSTANDING THE CHALLENGE

The concerns that HHS is addressing in this solicitation can be summarized in the following three challenges: 1) encouraging innovation in medical technology; 2) reducing the time line required to take medical technology from discovery through development, FDA approval, and translation into care delivery; and 3) improving inter-agency efficiencies.

3.1 ENCOURAGING INNOVATION IN MEDICAL TECHNOLOGY

Research advances are shifting the burden of diseases from acute, lethal forms to chronic illnesses. The medical community's success in diagnosing and treating conditions such as myocardial infarction and infectious diseases is improving survival rates. The combination of prolonged survival and aging “baby boom” and immigrant populations is resulting in an increase in the incidence of chronic and long-term diseases, such as congestive heart failure, cancer, Alzheimers Disease, Parkinson's Disease, diabetes, and obesity. Thus the focus of research and development needs to shift from the treatment of acute conditions to the prevention and long-term care and management of chronic conditions.

Further, rapid changes in environment and lifestyle have produced a disequilibrium between an individual's genetic make-up and that individual's ability to adapt to these changes. For example, the increased availability of food (particularly of “fast foods” rich in fats, carbohydrates, and salt), coupled with reduced physical activity, has resulted in an increased incidence of obesity and heart disease. Also, the real threat of bioterrorist attack has increased public awareness of the threat and intensified the urgency of finding solutions for detecting attack early and for responding quickly and effectively.

Finally, the rate of scientific and technological advancements is accelerating at an exponential rate. Responding to shifts in the nature of illness, the demographics of the population, and changes in the health threat environment, while effectively capitalizing on new and emerging science and technology, demands comprehensive strategies that are capable of adapting to change both in the problems needing to be addressed and in the potential innovations that can be brought to bear. As NIH Director Dr. Elias Zerhouni has observed, “The need has never been so pressing, the opportunities have never been greater, and challenges have never been more daunting” [Zerhouni 2003b].

3.2 REDUCING THE TIME LINE

In 2002, a study of the outcomes of highly promising basic research reported in 101 articles published between 1979 and 1983 in six major science journals were conducted. In the two decades since the promising technologies were exposed in the literature, only 27 had resulted in at least one published randomized trial, 19 of which had led to the publication of at least one positive randomized trial, and only 5 basic science findings were licensed for clinical use [Contopoulos-Ioannidis 2003]. This study clearly demonstrated that the time line from discovery to clinical practice was too long, and the success rate too low!

Today we see the result of this lengthy, costly, and high-risk time to market – a slowdown in the rate at which innovative medical technologies are developed and made available to patients. Despite today’s revolution in biomedical science addressing the prevention, treatment, and cure of serious illnesses, fewer drugs and biologics are being submitted for FDA approval. This trend is illustrated in **Exhibit 3**.

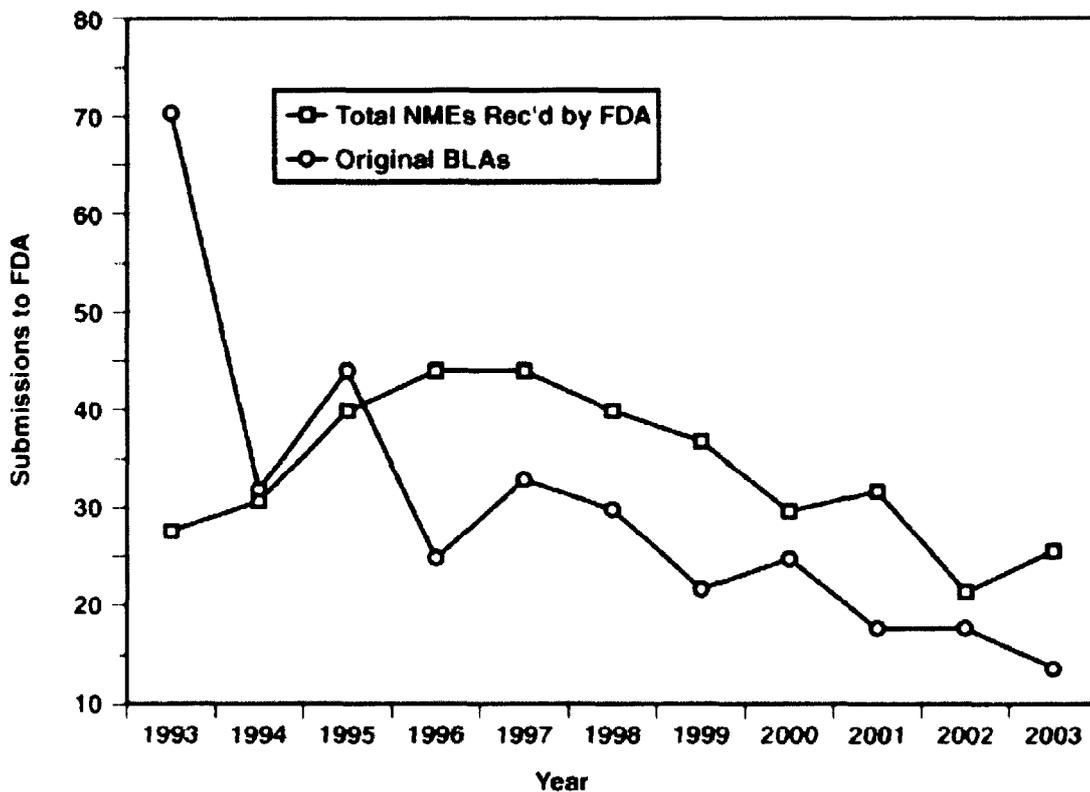


Exhibit 3. The 10-Year Trend in Major Drug (New Molecular Entities, NMEs) and Biological Product (Biologics License Applications, BLAs) Reflects a Marked Downturn [FDA 2004]

As number of applications the FDA has received for new medical technologies has declined significantly, the costs of product development have soared. The FDA attributes the reduction in the rate at which scientific discoveries are being translated into clinical practice to the fact that the medical technology development path has become increasingly challenging, inefficient, and costly. Because of rising costs, innovators often concentrate their efforts on products with the highest potential market return. Developing products targeted for important public health needs (e.g., bioterrorism), less common diseases, prevalent third-world diseases, prevention indications, and individualized therapy has become increasingly challenging. If the costs and

difficulties of medical technology development continue to grow, innovation will stagnate or decline, and the biomedical revolution is unlikely to deliver on its promise of better health [FDA 2004].

FDA's assessment of the problem is that the applied sciences needed for medical technology development have not kept pace with the tremendous advances in the basic sciences [FDA 2004]. We would agree and would add a corollary that the FDA's processes for assessing the safety and effectiveness of new technologies have not kept pace with scientific advances. Not enough is known about how to create tools to assess safety and effectiveness. Further complicating technology development and FDA approval are ethical questions associated with many of the technologies emerging today. The high rate of failures and interminable delays in clinical trials drive up costs, and developers are forced to use the profits from a decreasing number of successful products to subsidize a growing number of expensive failures.

On the critical path from scientific discover to commercial product, all medical technology developers must negotiate the three crucial scientific/technical dimensions shown in **Exhibit 4**. These three dimensions are interdependent, and success is never assured. The vast majority of development costs are attributable to these three dimensions [FDA 2004].

Dimension	Definition	Example Activities
Assessing Safety	Show that the product is adequately safe for each stage of development.	<ul style="list-style-type: none"> ■ Preclinical: Show that the product is safe enough for early human testing. Eliminate products with safety problems early. ■ Clinical: Show that the product is safe enough for commercial distribution.
Demonstrating Medical Utility	Show that the product benefits people.	<ul style="list-style-type: none"> ■ Preclinical: Select appropriate design (devices) or candidate (drugs) with high probability of effectiveness. ■ Clinical: show effectiveness in people.
Industrialization	Go from lab concept or prototype to a manufacturable product.	<ul style="list-style-type: none"> ■ Design a high-quality product: <ul style="list-style-type: none"> – Physical design – Characterization – Specifications ■ Develop mass production capability: <ul style="list-style-type: none"> – Manufacturing scale-up – Quality control

Exhibit 4. Medical Technology Developers Must Address Three Crucial Dimensions

The process for developing and approving a new drug is shown in **Exhibit 5**. The process for developing and approving medical devices is similar. During the preclinical research phase, a sponsor evaluates the drug's toxic and pharmacologic effects through *in vitro* and *in vivo* laboratory animal testing. Short-term toxicity studies conducted during this phase range from 2 weeks to 3 months, depending on the proposed duration of use of the substance in the proposed clinical studies. A successful preclinical-development program results in an investigational new drug (IND) application, which is the vehicle through which a sponsor advances to the next stage of drug development, clinical studies.

Clinical research and development comprises three phases. Phase 1 involves a small number of patients (around 20-100), takes a few months, and aims to demonstrate the drug's safety. Phase 2 can involve up to several hundred patients, can take multiple years, and focuses on effectiveness, while continuing to assess safety. Phase 3 involves from several hundred to several thousand patients and can take from one to four years, and assesses safety, effectiveness, and dosage.

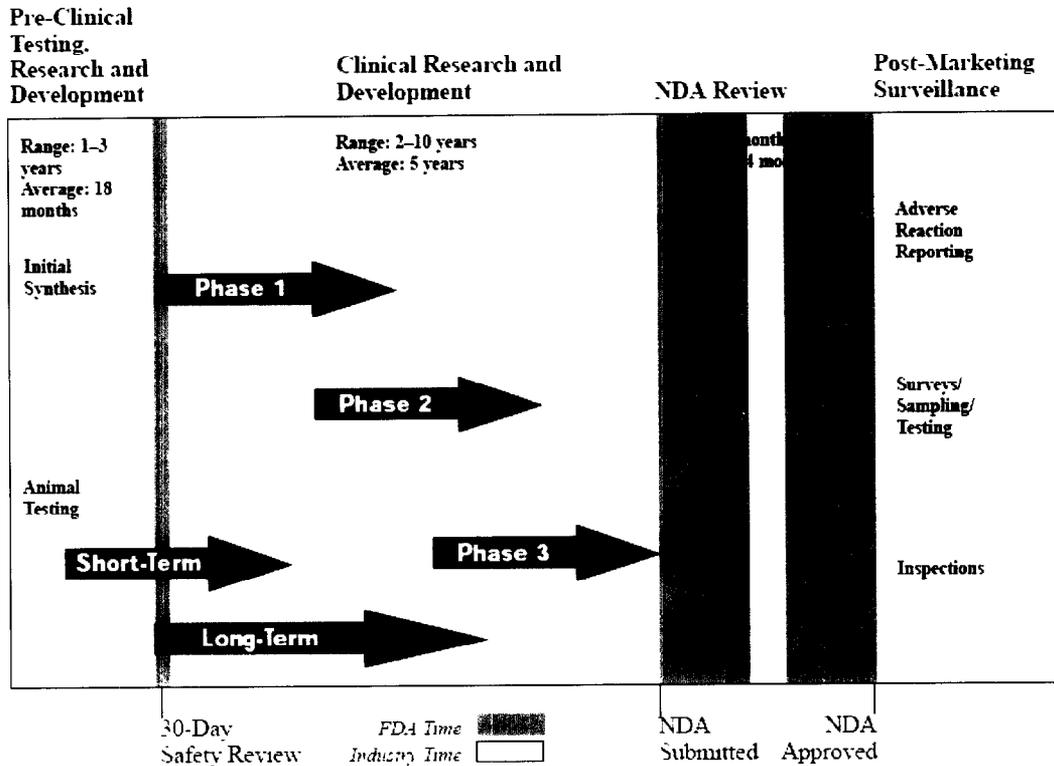


Exhibit 5. New-Drug Development Timeline [FDA n.d.]

Exhibit 6 shows an estimate, reported by the FDA, of the investment required to launch a new drug during two time periods. As this figure shows, from the beginning of discovery research, through drug development, clinical trials, and FDA approval to market the drug in the United States, a drug company spends over \$1.5 billion [FDA 2004]. In 2001, Tufts Center for the Study of Drug Development reported that of every 5,000 medicines tested, only five on average are tested in clinical trials, and only one of these five is eventually approved for patient use [Tufts 2001].

Cutting-edge medical technologies can introduce new risks that lengthen the process. A case in point is gene therapy, a technique for correcting defective genes responsible for disease development. A proposed clinical trial involving gene therapy requires the approval of at least two review boards at the scientist's institution and the FDA, and if the trial is funded by the NIH, it must be registered with the NIH Recombinant DNA Advisory Committee (RAC) [NCI 2004].

The first gene-therapy clinical trial began in 1990, and as of February 2003, 636 gene-therapy clinical trials had been undertaken worldwide, including 505 within the U.S. [Dibner 2003]. To date, the FDA has not approved any human gene-therapy product for sale. In January 2003, after learning that a second child treated in a French gene-therapy trial had developed a leukemia-like condition, the FDA placed a temporary halt on all gene therapy trials using retroviral vectors in blood stem cells. FDA's Biological Response Modifiers Advisory Committee (BRMAC) met at the end of February 2003 to discuss possible measures that could allow a number of retroviral, gene-therapy trials for treatment of life-threatening diseases to proceed, with appropriate safeguards. However, FDA has not yet issued a decision [ORNL 2004]. Gene therapy is a very powerful new technology with numerous, critical risks and ethical questions associated with it – which raises the question of how can HHS encourage such innovative technologies while at the same time manage the associated risks?

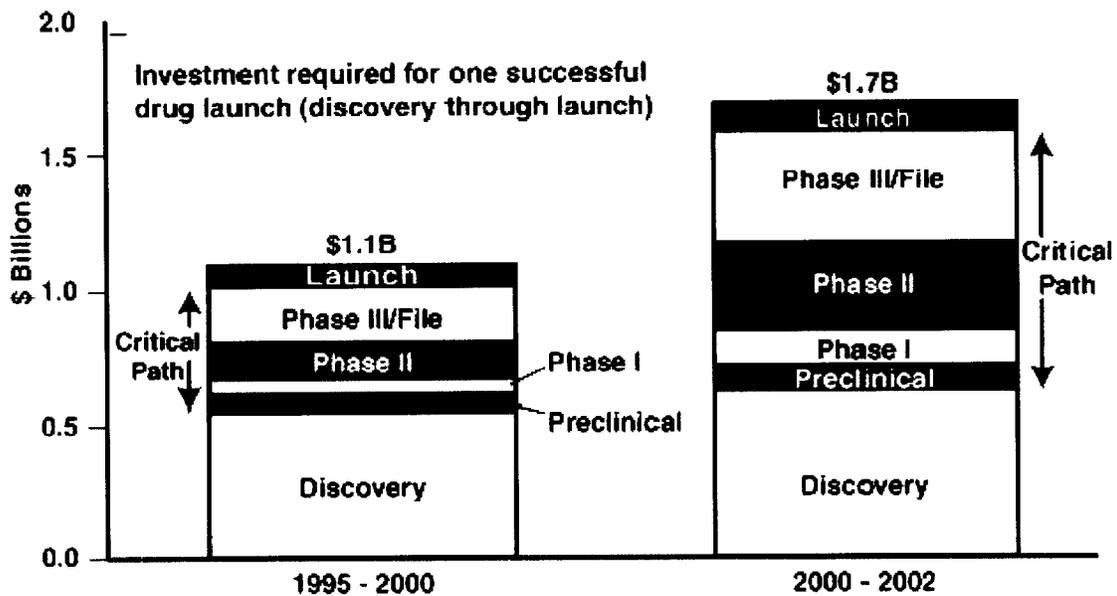


Exhibit 6. The Investment Required to Launch a New Drug is Escalating [FDA 2004]

3.3 IMPROVING INTER-AGENCY EFFICIENCIES

As discussed in Section 1, many stakeholders are involved in medical-technology discovery, development, approval, distribution, and translation into clinical practice. These stakeholders include a number of government agencies, as shown in Figure 1, including the HHS and several of its agencies, NIH, FDA, CDC, and CMS. More funds are being invested in biomedical science in the U.S. than ever before. To minimize duplication of funding and to help HHS and its agencies reap the greatest benefit from their investments requires that they work together to facilitate the development and approval of new medical technologies.

4. RESPONSES TO SEVEN QUESTIONS

In this section, SAIC provides our thoughts, observations, and suggestions in response to the seven specific questions posed by HHS.

4.1 WHAT STRATEGIES AND APPROACHES COULD HHS IMPLEMENT TO ACCELERATE THE DEVELOPMENT AND APPLICATION OF NEW MEDICAL TECHNOLOGIES?

The Internet, one of the most successful government-funded technology innovations in history, is an instructive example of how strategies and approaches can affect (positively or negatively) the speed of development and application of new technology. Several government strategies were key in the early development of the Internet:

- **Government and industry involvement.** DOD's early recognition that a viable network for defense would require civilian markets led to funding of "generic" research in academia and industry, producing many key technological advancements.
- **Non-competitive with existing technology.** Acknowledgement of the vulnerabilities of the switching technology used by the telephone system minimized the competitive strength of the existing telecommunications industry.

- **Organizational innovations.** Organizational innovations were key, including: self-governance; multi-agency collaborations, such as the National Science Foundation (NSF) and the Defense Advanced Research Projects Agency (DARPA) working together on standardization; and community collaboration through Requests for Comments (RFCs).
- **Open source.** Open-source code facilitated the development of new Internet applications. While the DOD recognized the importance of involving civilian markets, it also recognized the need for separation of the military network from the civilian network. So in 1983, the network was split into MILNET, for military purposes, and ARPANET, for industry, academic, and government research use. When ARPANET was transferred to the NSF's NSFNET, growth was accelerated by the NSF funding policy.
- **Government support of its own investments.** NSF required that universities receiving federal funding provide Internet access to all qualified users. However, transfer of Internet technology into commercial use was constrained by the NSF's acceptable use policy, which prohibited use of the NSFNET for commercial purposes. Two key changes in strategy, plus two key technological breakthroughs, led to the explosion in the use of the Internet for commercial purposes worldwide:
- **Government non-interference in use.** The NSF's decision, in 1991, to abandon its acceptable use policy.
- **Privatization.** The passing of control from the NSF to private firms, in 1995.
- **Unconstrained spin-off.** The development of the HyperText Mark-up Language (HTML), in 1991, and the first Web browser, Mosaic, in 1993.

The Internet experience offers several important lessons for accelerating the development government-funded technology in general and medical technology in particular. Some of these lessons suggest the following recommendations to HHS:

1. HHS should adopt a focused strategy, with cross-organizational cooperation, minimal bureaucracy, and open and frequent communications.
2. The FDA should get its academic and industry partners involved in developing new toolkits for assessing safety and effectiveness – that include new scientific and technical methods such as predictive modeling, biomarkers for safety and effectiveness, and new clinical evaluation techniques. The FDA also should create a mechanism to enable its partners to help them plan and prepare for the assessment of new “outside the box” technologies that will challenge existing processes.

An innovative, strategic approach to addressing the challenge of assessing such cutting-edge technologies is the NCI's newly established Nanotechnology Characterization Laboratory (NCL). The NCL is part of a major NCI-wide thrust to use nanotechnology to enhance the way we detect (e.g., image), diagnose, and treat cancer. To both encourage the development of nanotechnology-based medical products and to accelerate the approval of these products, the NCL will perform and standardize the pre-clinical characterization of nanomaterials developed by researchers from academia, government, and industry. The NCL will serve as a national resource and knowledge base for cancer researchers, and will facilitate the accelerated regulatory review and translation of nanomaterials and devices into the clinical realm.

3. HHS should prioritize the areas in which medical technologies are needed and then assign teams responsibility for facilitating and accelerating the discovery, development, approval, and translation of these technologies, with minimal government bureaucracy and constraints. The teams should include representation from multiple agencies, as well as academic and industrial partners, and should support “generic” as well as specific discovery investigations.

The FDA's new Office of Oncology Drug Products (ODP) is an example of these two strategies. Recognizing the need for a more targeted approach to regulatory review and approval, the FDA is bringing together a "critical mass" of oncologists who can help academic, government, and commercial researchers develop new, more targeted therapies. The ODP and the Oncology Program will provide technical consultation between FDA centers, facilitate cross-agency expert consultation, provide a forum for discussion and development of regulatory policy and standards; and serve as a focal point for agency interaction and collaboration with professional societies, the NCI, and other stakeholders [Strattner 2004].

4. HHS should encourage and support the development of "open" medical technology that is standards based and that can be built upon to create new innovations. One approach might be to facilitate the expansion of the open-source caBIG platform to include commercial pharmaceutical companies by supporting the establishment of a "Red Hat like" company. Achieving "openness" in medical technology is particularly challenging within the current framework. We recommend that HHS reexamine the CRADA process in terms of its ability to support "open" technology and accelerated technology development. HHS also should examine other approaches to technology transfer, including successful approaches used by DARPA, the National Institute of Standards and Technology (NIST), the NSF, and the DOE.
5. HHS should reward collaboration among its own agencies and its academic and industry partners, in efforts to discover and develop innovative medical technologies.
6. HHS should encourage and facilitate patient involvement in medical innovation. Enrolling patients in clinical trials is a primary factor in cycle-time reduction. Consumers are a very powerful change agent as well as an important component to getting new technologies through clinical trials. The motivated and empowered "baby boom" population could be leveraged to help educate patient populations on the potential direct and indirect benefits of participating in clinical trials, with the objective of making clinical-trial participation (with patient consent) a natural by-product of the routine care process.

We suggest HHS consider conducting an experiment in which an accelerated process, constructed using the inputs collected from this solicitation, would be exercised and evaluated. HHS could involve industry and academia in planning for the experiment. Their involvement could serve to both validate the experimental process and to begin socialization of HHS's intentions and potential changes. To minimize the effects of vested interests, we recommend using an independent third party to develop the experimental design and to serve as project manager. The results of the experiment could then inform the process of developing a process to be put into practice.

4.2 HOW CAN HHS HELP ITS AGENCIES (E.G., NIH (AND ITS GRANTEES), FDA, CDC, AND CMS) TO WORK TOGETHER MORE EFFECTIVELY TO ELIMINATE OBSTACLES TO DEVELOPMENT OF MEDICAL TECHNOLOGIES?

We believe the greatest barrier to effective collaboration among HHS agencies, and indeed to collaboration among any group of people or organizations, is the perceived need to protect turf. Each HHS agency perceives a need to protect its own mission, including its people, its programs, and its intellectual property. Further complicating the situation is the individual need to protect turf – which results in further closure and resistance. Human beings, as well as organizations, take comfort in their ability to preserve those aspects of their lives that provide security and stability. Change of any kind is perceived as undesirable and threatening. So the unfortunate fact is that as HHS seeks to transform itself into an organization that encourages innovation, that facilitates and accelerates the discovery and development of new technologies, and whose

agencies work together collaboratively to achieve these objectives, resistance to working together is likely to intensify and new obstacles are likely to appear.

In competitive sports, the need for the team to work together to win a game is more important than the individual performance of a particular player. Similarly, HHS leadership needs to place greater emphasis on its agencies' working together to achieve a common goal than on each agency's individual accomplishments. HHS needs to insist on collaborative participation toward the Department's goals, reward agencies for working together toward the common good, and enable agencies to share credit and recognition for collaborative successes.

Some HHS agencies already are taking steps toward working together more efficiently. The NCI-CMS agreement is one example. While each agency has a distinct mission, they share some common needs in support of those individual missions. By recognizing and commending the NIH/NCI and CMS for working together in science, technology, and patient care, and by encouraging the broader adoption of the methods and processes they develop, HHS can not only reward NCI and CMS, but can demonstrate by example the value HHS places on such collaborative efforts. By working together, HHS and its agencies can leverage their collective investments and eliminate obstacles to the development of new medical technologies.

Joint program offices will also facilitate inter-agency communications. That is, placing individuals from multiple agencies on a team working on the same area of medical innovation will force them to work together toward the mutual goal. Placing a very senior person who is free of agency bias in charge of these inter-agency teams is critical, as it will help ensure that the focus remains on the collaboration and exploitation of common needs.

4.3 HOW CAN THE HHS SCIENTIFIC AND REGULATORY AGENCIES WORK MORE EFFECTIVELY WITH CMS TO ELIMINATE OBSTACLES TO DEVELOPMENT?

The mission of CMS – providing cost-effective healthcare coverage for individuals – is quite different from the missions of other HHS agencies. CMS' focus is on lowering the cost of providing appropriate care to patients. The five areas identified in the agreement between CMS and NCI reflect this focus: the optimal use of new cancer diagnostic and treatment technologies and implications for coverage and reimbursement. While CMS is intensely interested in the efficacy of new technologies in the treatment of diseases such as cancer, strategies and technologies that support prevention are not well aligned with the CMS mission.

For example, Medicare does not provide coverage for routine physical examinations, useful in detecting problems early and preventing problems in the future. Although CMS does provide coverage for a few screening procedures, in general, CMS does not reimburse for screening procedures on people who are well. A search of CMS' coverage database for the keyword "screening" produces three results: colorectal cancer screening, prostate cancer screening, and screening pap smears and pelvic examinations for early detection of cervical or vaginal cancer. By denying coverage for screening and early-detection procedures, CMS is effectively hindering the development of new technologies that support the prevention, screening, and early detection of diseases and conditions.

However, the preventive and early-detection programs administered by the CDC and state health departments hold great value for lowering CMS' healthcare costs. For example, the states' Breast and Cervical Cancer Early Detection Programs, administered by CDC, can significantly reduce CMS' cost for cancer treatment. CDC's National Immunization Program provides leadership for the planning, coordination, and conduct of immunization activities nationwide. The state of Georgia's Cancer Awareness and Education Campaign is another example of how preventive efforts by states and CDC can help CMS reduce its costs.

We applaud CMS' commitment to outcomes-based medicine. However, we believe that outcomes-based prevention and early-detection are highly relevant to CMS' mission as well, and need to be pursued with as much vigor as treatment. Indeed, effective prevention and screening programs could lead to significant cost savings by helping covered individuals avoid disease and by detecting disease early, thereby reducing the extent of treatment needed. We recommend that CMS form an alliance with the CDC similar to that it has put in place with the NCI. The goals of this alliance might parallel those of the NCI agreement:

1. Developing joint CMS-CDC processes for identifying high-priority clinical questions about the optimal use of new strategies and technologies for the prevention and early detection of diseases, and for conducting outcomes-based studies to measure the effectiveness of these strategies and technologies.
2. Defining a systematic process for consultations between CMS and CDC experts on the evaluation of new preventive and early-detection technologies for the purposes of payment and coverage decisions.
3. Developing more efficient methods of collecting clinical evidence on new preventive and early-detection technologies, and strategies for making this information more widely available to patients, clinicians, and researchers.
4. Developing a joint process for the prospective identification and evaluation of emerging preventive and early-detection technologies so that reimbursement policies will fully anticipate promising new technologies and to help expedite their adoption in the marketplace.
5. Identifying opportunities for sharing data and resources aimed at reducing the incidence of preventable diseases and conditions and addressing additional concerns such as health disparity issues, and reducing unwarranted variation in prevention and early-detection patterns.

4.4 WHAT FORUMS SHOULD HHS USE TO SURVEY CONSTITUENTS ABOUT OBSTACLES TO INNOVATION (E.G., PUBLIC MEETINGS, CONTRACT RESEARCH, FOCUS GROUPS)?

A number of types of forums can be effective in gathering constituents' perspectives about obstacles to innovation. State, national, and professional organizations that focus on biomedical informatics can provide valuable venues. Of those mentioned as examples, we believe focus groups with participants selected to represent a cross-section of the population produce the best results. Quite often, public meetings attract the "six sigma" of the population who has specific agendas and vested interests, rather than the broad representation HHS needs.

We believe that in order to transform the existing environment into one that supports, encourages, and rewards innovation, and that facilitates the translation of biomedical research into clinical practice, HHS needs to put into place a well constructed program that is conceived, executed, and managed like any other successful undertaking. The program should be led by HHS, with strong, incentivized commitment and participation from all of the key stakeholders – including the NIH, FDA, CMS, AHRQ, and CDC, from HHS, as well as relevant organizations from outside HHS, such as the DOD, DOE, DARPA, NIST, NSF, academia, and industry.

The methodology SAIC has used to assist customers in developing strategies for achieving complex, multi-organizational transformations such as this is well suited for the recommended program. Our methodology involves a series of collaborative workshops that are designed to extract from the participants their knowledge and understanding of the current processes and relationships; the culture within which the transformation must occur; the policies and programs that are effective today; and participants' honest views of strengths, weaknesses, opportunities, and threats. This methodology produces a prioritized list of actionable programs for achieving

the envisioned transformation. This methodology, as it might be applied to the challenge HHS has articulated, is described in **Appendix A**.

This methodology forms and nurtures a collaborative working relationship among the participants and forces them to abandon their proprietary interests to work toward a common goal. Because the collective vision and the set of programs necessary to achieve that vision are the products of a collaborative effort, buy-in emerges naturally from the process. So at the end, rather than being forced to step up to a strategy mandated from the top, the participating organizations own the strategy, and the participants continue to provide value as champions within their individual organizations. SAIC would welcome an opportunity to discuss this approach further with HHS.

4.5 HOW CAN THE PORTABILITY OF INFORMATION BETWEEN HHS AGENCIES BE OPTIMIZED?

While many people think that electronic connectivity is the key to information portability, connectivity is but one piece of the puzzle. Electronic connectivity allows the rapid exchange of “data,” or bits. However, portability of “information” – i.e., meaningful bits – requires that both the sender and the receiver ascribe meaning to the bits in the same way. This requires standards – not only standards for data transport, but also for messaging, context, and vocabulary. Furthermore, the data must be protected during transport to assure that sensitive information is not disclosed to unauthorized entities and that data are not manipulated or corrupted during transmittal. Standards helpful in this regard include:

- IPsec Virtual Private Networking (VPN)
- Public Key Infrastructure (PKI)-based authorization and digital signatures
- Lightweight Directory Access Protocol (LDAP)
- Electronic Business eXtensible Markup Language (ebXML)
- Health Level 7 (HL7) Versions 2.x transitioning to 3.x
- eXtensible Markup Language (XML) family of standards
- Hypertext Transport Protocol (HTTP) and Secure HTTP (HTTPS)
- Simple Object Access Protocol (SOAP)
- Systematized Nomenclature for Medicine (SNOMED[®])
- Logical Observation Identifiers Names and Codes (LOINC[®])
- Clinical Data Interchange Standards Consortium (CDISC) family of standards
- FDA XML Data Format (FDADF)

In approaching data sharing and portability, a primary consideration is the need for the individual data owners to retain control over how and with whom their data are shared. Agencies are likely to resist sharing if they believe they will lose control over the data or subject their data to undue risk. Further, because the data held by each agency include both data useful only to that agency and data that could be useful to other agencies, and because these data do not uniformly conform to standards such as those identified above, building a centralized, shared repository for all HHS data is neither reasonable nor feasible, and we would not recommend that approach. A key consideration in transforming HHS from a collection of individual agencies, each owning and retaining its own data store, to a collaborative, data-sharing enterprise is that the change needs to be evolutionary so as to minimize disruption and resistance.

Further, the agencies are likely to have a need to enforce their own data security policies both within their enterprises and for exchanges with other agencies. Under these circumstances, we believe multiple approaches to data sharing are needed, each associated with its own level of

owner control, openness, and risk. For example, data sharing alternatives could include a shared data repository consisting of standardized data contributed by individual agencies and available to all; automated messaging of data as they become available; and publish-subscribe protocols enabling each agency to publish data it chooses to make available to others.

Also, we have observed that multiple HHS agencies are adopting very similar sets of standards. For example, the NCI's caBIG standards have much in common with the CDC's Public Health Information Network (PHIN) standards. This is not at all surprising since both have a need to collect, store, process, and share clinical information. However, the two agencies, as well as HHS, could reap both financial and timeline benefits from working together in adopting such standards.

4.6 WHICH HHS POLICIES AND PROGRAMS EFFECTIVELY SPUR INNOVATION? WHICH POLICIES AND PROGRAMS AT NIH (AND ITS GRANTEES), CMS, FDA, AND CDC SHOULD BE EXPANDED TO HELP SPUR INNOVATION? DO ANY POLICIES AND PROGRAMS POSE OBSTACLES TO INNOVATION?

Recognition that some policies and programs may inhibit innovation is the first step toward resolving this concern. The next step is to do what private companies do when they realize that their policies and procedures may be out of step with their current business objectives. They conduct a policy review. SAIC's recent experience may suggest the kind of results HHS might expect to get from such a review.

In November 2003, SAIC selected a new Chief Executive Officer (CEO), only the second in our 35-year history. One of the first actions he undertook was a comprehensive review of our policies, with the objective of simplifying reporting and pushing responsibility and authority down to the lowest advisable level. A comprehensive review of all 70 of SAIC's administrative policies (accumulated over 35 years) was undertaken. Some policies had not been updated since 1980. The review team included broad representation from SAIC's line organizations and corporate staff. The objective for this effort was to assure 1) that each policy provided value to the company; 2) that empowerment was assigned to the lowest appropriate levels of management; 3) that policies supported increased efficiency of company operations; and 4) that every policy included a 3-year sunset provision. The review team was able to eliminate 25 of the original 70 Policies (36%) through deletion or consolidation. Significant changes were made to reduce bureaucracy, to increase operational efficiency, and to eliminate policies that no longer were needed.

We recommend that HHS undertake a similar, comprehensive, policy review across all of its agencies. Create a "blue ribbon" committee, and give them specific criteria and objectives for the review, including the policy's ability to spur innovation. Give the agencies an opportunity to review recommended changes and deletions and to defend existing policies and recommend alternative actions. Then convene a Red Team to review all recommended changes with respect to consistency with the criteria and objectives, as well as potential impact. We also recommend HHS broaden the scope of alternatives the review team considers to include not just effective policies and programs within HHS, but policies and programs within other government organizations and industry as well.

One policy we believe will be found to both spur and inhibit innovation is HHS's existing CRADA policy. We would encourage HHS to look outside the Department for other, more effective approaches to technology transfer. For example, DARPA, NASA, NSF, and NIST have less complex and arguably more effective technology-transfer mechanisms than HHS. DHS

sought DARPA's help in crafting its own approach to technology transfer, particularly to small businesses.

4.7 WHAT ROLE SHOULD BE PLAYED BY NONGOVERNMENTAL PARTNERS IN ASSISTING THE FEDERAL GOVERNMENT IN THIS PROCESS?

Nongovernmental partners can play a key role in achieving the desired transformation of HHS into an organization that supports, encourages, and rewards innovations in medical technology. Currently, nongovernmental partners, including universities and private laboratories, are performing discovery research for HHS agencies. Pharmaceutical companies and private foundations are sponsoring discovery research as well. Pharmaceutical companies, CROs, and CRADA partners are playing key roles in the development, clinical testing, and FDA approval of new medical technologies.

However, nongovernmental partners may have conflicting motivations with respect to HHS's objectives. For example, university researchers may be motivated to prolong research on a given technology, rather than to accelerate its progress. Similarly, CROs may be motivated to extend the length of clinical trials. Pharmaceutical companies are motivated to accelerate the development of new medical technologies from discovery to clinical use, but they are not motivated to develop open technologies. Healthcare providers may desire to use new technologies, but are not motivated to do so if the patient's insurance company (which may be Medicare) refuses to reimburse them. HHS is challenged to put into place incentives that will encourage its nongovernmental partners to work toward the common objective of accelerating the discovery and development of new technologies, and their translation into clinical practice.

A model that may be useful to emulate is the NCI's National Forum on Biomedical Imaging in Oncology (NFBIO), which was created in 1999 to facilitate partnerships between NCI and the imaging industry and other government agencies. NFBIO was created to address new biomedical opportunities and challenges in oncology, and to focus on the regulatory, coverage, and reimbursement issues for more developed and established technologies. The NFBIO annual meeting is co-sponsored by NCI, the National Electrical Manufacturers Association (NEMA), FDA, and CMS. The first NFBIO established an on-going dialogue between key government agencies, academic researchers, and industry about the challenges involved in developing and commercializing clinically useful biomedical imaging technologies. One of the most significant results was the creation of the Interagency Council on Biomedical Imaging in Oncology, which includes representatives from NCI, FDA, and CMS, and provides multi-agency advice to academic and commercial technology developers on projects related to cancer.

Another NCI model that could be applied to the problem addressed by this solicitation is HHS's objective is the public-private partnership between NIH, other research organizations, and pharmaceutical manufacturers for the purpose of increasing the percentage of newly diagnosed cancer patients who participate in Phase I and II clinical trials.

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Appendix A—Suggested Methodology for Defining and Launching a Transformation Program

In this Appendix, we describe the methodology SAIC uses in assisting clients in cross-organizational strategic planning and the transformation of business processes. We offer this for HHS's consideration as an effective approach to achieving the kind of transformation necessary to achieve HHS's objectives.

We recommend a cross-organizational Steering Committee be put into place and assigned responsibility for facilitating communications among participants, planning for the workshops; preparing and assuring the quality of program materials and activities; and helping to keep the program on track and focused on its overall goal, as well as key outcomes expected along the way.

Figure 7 is a top-level view of the suggested methodology, including the key outcomes expected from the five phases. **Exhibit 8** provides further detail regarding the goals, key activities, key outcomes, deliverables, and key milestones for each phase of the program.

Project Mobilization. During Project Mobilization, the Project Director and Steering Committee will identify and engage the organizations and individuals who will participate in the program. Participants should be knowledgeable of the current environment, processes, and issues, and should have the authority to represent their organizations and the ability to bring about change within their organizations.

Workshop 1. The selected participants will convene for the first time for Workshop 1, a full-day collaborative session that will officially launch the program. Workshop 1 seeks to produce "convergent thinking" – to help participants from diverse organizations, with different responsibilities, challenges, and perspectives develop a common and consistent understanding of the goals of the program, the methodology that will be used to collaboratively develop a plan of action, and the current environment. The common understanding will be developed primarily through formal presentations. Once that common ground is established, the group will reconstitute itself as three break-out groups, each focusing on a single area of interest. We suggest the following three topics for HHS's break-out sessions:

- **Motivating & Accelerating Innovation**—how to most effectively encourage, support, and reward innovation in medical technology
- **Inter-Organizational Process Reengineering**—how to accelerate the rate at which medical technology moves from discovery, through development and FDA approval, to clinical practice
- **Technology Enablers**—how technology can best be used to accelerate innovation and to facilitate the discovery of new medical technologies, their development, their approval, and their translation into clinical practice

In the break-out sessions, the participants will identify the policies and programs that are successful today and that can be built upon to achieve the objective of motivating and accelerating innovation. They will also identify the weaknesses that need to be remedied; the opportunities that can be capitalized upon; and the threats that can potentially derail the transformation effort. The results from each of the three break-out sessions will be synthesized and shared with all participants.

Workshop 2. While Workshop 1 encourages convergent thinking (i.e., giving all participants a shared understanding), Workshop 2 is designed to elicit divergent, creative thinking. That is, in Workshop 2 participants are encouraged to think about what could be, rather than what is.

Workshop 2 attempts to leverage the participants' shared view of the current environment, strengths, weaknesses, opportunities, and threats to envisage a transformed environment that encourages and rewards innovation and that rapidly moves medical technology from discovery through development and into application. Our primary objective for Workshop 2 is to identify and assess opportunities. Participants are encouraged to focus their energies on the desired state. They will be asked to identify opportunities for transforming the current environment into the desired environment, and then to define the "scope" and "scale" of those opportunities. Scope refers to the specific changes that are required, and scale identifies the impact those changes will exert on the current environment; for example, are the changes confined to a single organization, or will they impact multiple organizations, potentially both public and private.

The participants in this workshop are the invaluable resource because the combined knowledge, experience, and insights within each group will enable the groups to capture, describe, and focus the outcomes of the breakout sessions. Discussion will attempt to move toward a consensus-driven vision. Each of the breakout sessions will report back to the group its vision for the future and the opportunities it has identified. The results from each of the three break-out sessions will be synthesized and shared with all participants.

Workshop 3. Workshop 3 uses the outputs from Workshop 2 to identify a single, prioritized set of key initiatives that need to be undertaken. For Workshop 3, the three breakout sessions will converge into a single group. The workshop will begin with a formal presentation of the synthesized results from Workshop 2. Through collaborative, facilitated discussion, the group will converge on a single, agreed-upon set of initiatives, which they then will prioritize. The group then will break out into smaller workgroups to begin to develop an action plan for each of the highest priority initiatives (number to be determined). While we do not expect the group to develop action plans within such a short period of time, the purpose here is to immediately generate interest, excitement, and engagement in these initiatives. Ideally, each of these initial action plans will identify a goal, one or more potential sponsors, some key milestones, and the organizations most suitable to lead the effort.

Findings and Recommendations. During the **Findings and Recommendations** phase of the program, the findings and recommendations will be documented and published, and the action plans will be completed. The results will be presented to the leadership of each participating organization, and published. Each action plan will include the following 12 profiles:

1. **Program Description**—scope, goals, objectives, critical outcomes
2. **Change Profile**—what needs to change
3. **Technology Profile**—what technologies are needed
4. **Key Skills Profile**—specialized skills needed
5. **Impact Profile**—impact on organizations, current policies and practices, processes, etc.
6. **Intangible Impact Profile**—secondary impacts
7. **Program Cost Profile**—estimated costs
8. **Key Milestones**—major activity completions
9. **Timeline/Schedule**—top-level timeline
10. **Stakeholder Profile**—each stakeholder's perspective
11. **Risk Profile**—risk assessment
12. **Organization Readiness Profile**—readiness of the lead organization to undertake the initiative.

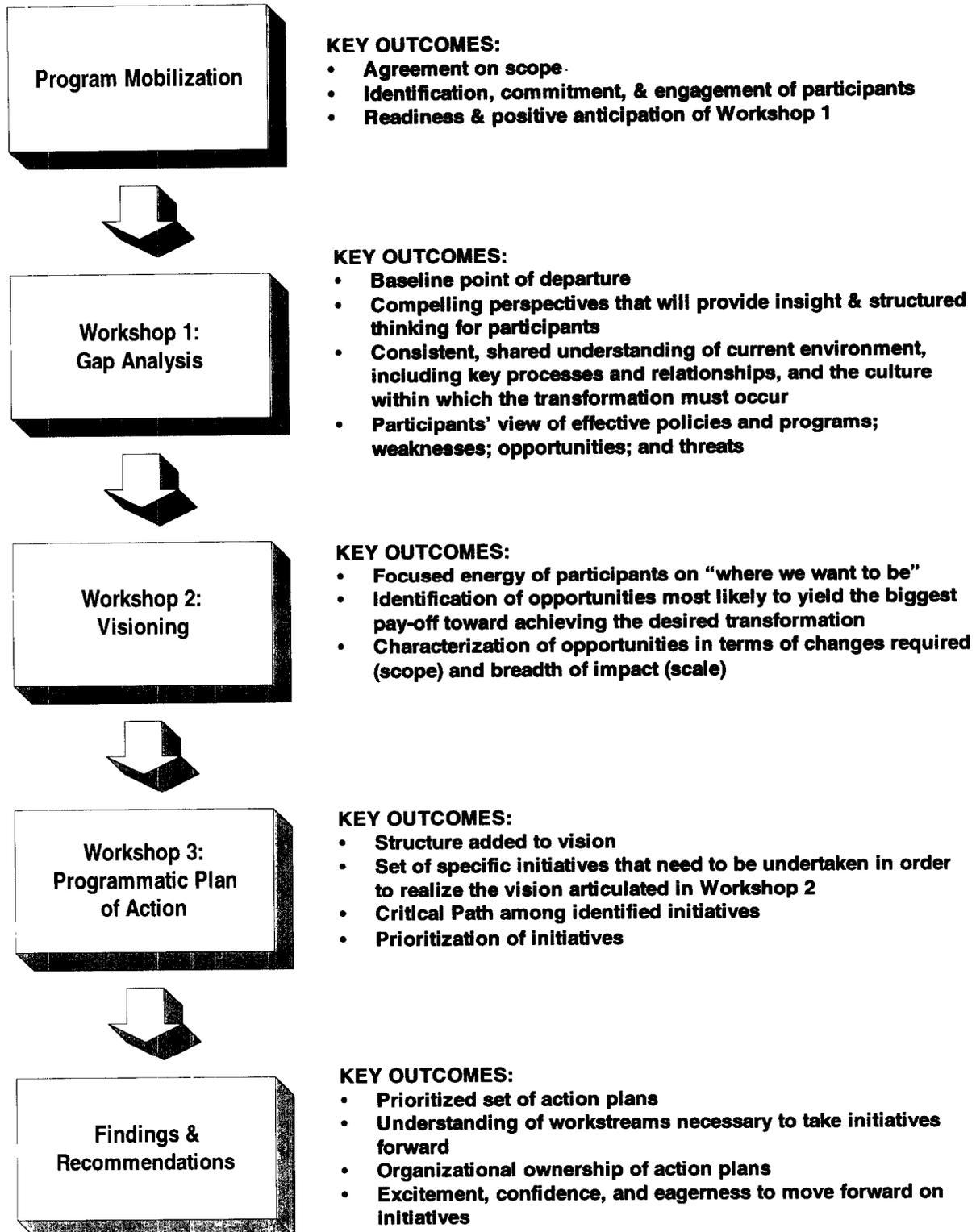


Exhibit 7. Overview of Transformation Planning Methodology

PROGRAM PHASE					
	Program Mobilization	Workshop 1: Gap Analysis	Workshop 2: Visioning	Workshop 3: Plan of Action	Findings & Recommendations
Goal	<ul style="list-style-type: none"> ■ Establish program leadership ■ Prepare ■ Identify & engage participants 	<ul style="list-style-type: none"> ■ Introduce program goals and methodology to participants ■ Establish mutual understanding of current environment ■ Agree on terms & definitions ■ Identify successful policies and programs ■ Identify weaknesses, opportunities, & threats 	<ul style="list-style-type: none"> ■ Generate creative ideas ■ Define and assess opportunities for achieving the desired transformation ■ Define scope and scale of opportunities 	<ul style="list-style-type: none"> ■ Make decisions ■ Identify and prioritize initiatives that need to be undertaken 	<ul style="list-style-type: none"> ■ Document and publish results ■ Develop actionable plans for taking recommendations forward
Key Activities	<ul style="list-style-type: none"> ■ Make logistical arrangements for Workshops ■ Identify and get commitment from participant organizations and individuals ■ Prepare for Workshop 1 – structure workshop, frame questions for discussion, identify and train facilitators ■ Prepare materials for Workshop 1 	<ul style="list-style-type: none"> ■ Present program overview ■ Present roles, relationships, and key processes ■ Define terms & definitions ■ Conduct 3 break-out sessions: Motivating & Accelerating Innovation; Inter-Organizational Process Reengineering; and Technology Enablers ■ Capture & synthesize participants' views of strengths, weaknesses, opportunities, & threats ■ Prepare for Workshop 2 – structure, frame questions, identify & train facilitators ■ Prepare participant preparation materials for Workshop 2 	<ul style="list-style-type: none"> ■ Conduct 3 sessions (same topics as for Workshop 2) each of which will define and assess opportunities for transforming current practice, and will identify the scope and scale of the transformation that needs to occur. ■ Capture & synthesize participants' ideas ■ Prepare for Workshop 3 – structure, frame questions, identify & train facilitators ■ Prepare participant preparation materials for Workshop 3 	<ul style="list-style-type: none"> ■ Conduct single session ■ Using opportunities identified in Workshop 2, agree on a single, prioritized set of initiatives that need to be undertaken ■ Capture list of key initiatives ■ Begin development of action plans for an agreed-upon set of initiatives ■ Develop critical path among initiatives 	<ul style="list-style-type: none"> ■ Document findings and recommendations ■ Complete development of action plans ■ Publish results ■ Lay groundwork for acting upon results

PROGRAM PHASE					
	Program Mobilization	Workshop 1: Gap Analysis	Workshop 2: Visioning	Workshop 3: Plan of Action	Findings & Recommendations
Key Outcomes	<ul style="list-style-type: none"> ■ Agreement on scope of project ■ Identification, commitment, and engagement of participants ■ Readiness and positive anticipation toward Workshop 1 	<ul style="list-style-type: none"> ■ Understanding of program goal and methodology ■ Consistent, shared understanding of current environment ■ Participants' views of current strengths, weaknesses, opportunities, and threats 	<ul style="list-style-type: none"> ■ Focused energy of participants on "where we want to be" ■ Participant concurrence on the desired outcome in 3 areas of interest ■ Identification of scope and scale of transformation needed 	<ul style="list-style-type: none"> ■ Single, consensus-driven set of opportunities for achieving desired transformation ■ Prioritized set of initiatives that need to be undertaken ■ Critical path among identified initiatives ■ High-level action plans for top-priority initiatives 	<ul style="list-style-type: none"> ■ Program findings are made public ■ Plans assigned to sponsors for action ■ Excitement, confidence, & eagerness to move forward on initiatives
Deliverables		<ul style="list-style-type: none"> ■ Workshop 1 presentation materials ■ Workshop 2 preparation materials 	<ul style="list-style-type: none"> ■ Workshop 2 presentation materials ■ Workshop 3 preparation materials 	<ul style="list-style-type: none"> ■ Prioritized list of initiatives ■ Critical path ■ High-level action plans 	<ul style="list-style-type: none"> ■ Final report ■ Action plans
Key Milestones	<ul style="list-style-type: none"> ■ Project Start 	<ul style="list-style-type: none"> ■ Workshop 1 	<ul style="list-style-type: none"> ■ Workshop 2 	<ul style="list-style-type: none"> ■ Workshop 3 	<ul style="list-style-type: none"> ■ Final Recommendations

Exhibit 8. Goals, Key Activities, Key Outcomes, Deliverables, and Milestones