Standard Template for a Candidate Demonstration Project

Note: the questions with asterisk should be filled.

1.* Title of the project:
Affordable Diagnostic Tests for Cancer

2.* Submitted by:
Ministry of Health and Social Protection, Colombia
Knowledge Ecology International

3.* Target disease or health condition:
(Focus on type II and III diseases and special R&D needs of developing countries in type I diseases where there is an identified health technology gap.)

Identified health technology gap in Type I diseases: Cancer.

4.* The suggested health technology that project seeks to develop:
(e.g. medicine; diagnostic test; medical device; vaccine etc.)
The project seeks to develop better and more affordable diagnostics for cancer that can be widely used in developing country settings with low infrastructure requirements, including but not limited to tests that are useful in increasing early detection of cancer, and tests that identify useful bio-markers or other criteria that are beneficial in determining treatment options, such as determining if breast cancer patients are candidates for treatments associated with amplification or over-expression of Human Epidermal Growth Factor Receptor 2 (HER2).

5.* Project summary:  (Approximately 500 words)

Introduction and Context
The WHO is considering possible demonstration projects to explore open innovation models and financing mechanisms that de-link costs from product development. Among the “special R&D needs of developing countries in Type I diseases where there is an identified health technology gap” is the need to develop better and more affordable cancer diagnostic tools. There is an opportunity to test open source de-linkage approaches to the development of new tests for cancer, and there are projects that are feasible, realistic, and likely to demonstrate success within a five year period. There are many types of cancer for which existing diagnostic tools are inadequate, and specific cases or needs that will be
appropriate to treat as priority projects. The proposal is to create a fund for open source diagnostics for cancer that are affordable and appropriate for use in low infrastructure settings, allocating resources into different reward systems that offer different opportunities to improve cancer diagnostics.

**Focus**
The project will focus in particular on diagnostic tools that provide more affordable and more useful options in developing countries to provide (1) early detection of cancer, and/or (2) that identify useful bio-markers or other criteria that are beneficial in determining treatment options, such as determining whether breast cancer patients are candidates for treatments associated with amplification or over-expression of Human Epidermal Growth Factor Receptor 2 (HER2). This may include modifications to existing technologies, or entirely new technologies.

**Structure and Governance**
The project would be a demonstration project, and the funding would come from voluntary funding from like-minded governments and other donors. Several entities could be contracted to administer the project, and this could be resolved at a later date.

While taking a new interest in non-communicable diseases (NCDs), the WHO offers sober advice regarding cancer diagnostics that illustrates the consequences of the inequality of local health systems infrastructure:

> “Policies on early cancer detection will differ markedly between countries. An industrialized country may conduct screening programmes for cervical and breast cancer. Such programmes are not, however, recommended in the least developed countries in which there is a low prevalence of cancer and a weak health care infrastructure. Further, only organized screening programmes are likely to be fully successful as a means of reaching a high proportion of the at-risk population. Countries that favour cancer detection remaining part of routine medical practice, or that simply encourage people to seek specific tests at regular intervals, are unlikely to realize the full potential of screening.”

There may be elements of the WHO or other multilateral and plurilateral health entities that have the capacity, interest and inclination to explore new development models for cancer diagnostics. The project could also find a different existing institution or create a new entity that is open to new thinking on the opportunities to improve and use cancer diagnostics. There are several private sector organizations, both profit and non-profit, that are exploring open source tools for cancer diagnosis. Some, like the Nature Open Innovation Pavilion, which is a collaboration with the innovation prize manager InnoCentive, ([http://www.nature.com/openinnovation/index.html](http://www.nature.com/openinnovation/index.html)) are innovation prize platforms for acquiring solutions that are used in both proprietary and open development models, depending upon whom is funding the innovation prize. While open to many business models, neither Nature nor InnoCentive have an internal commitment to open source and de-linkage product development strategies. Groups like Faster Cures and BIO Ventures for Global Health (BVGH) also have feet in both proprietary and non-proprietary development models but have been fairly traditional as

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regards licensing of end products. Sage Bionetwork, DNDi, the India Council of Scientific and Industrial Research (CSIR) Open Source Drug Discovery (OSDD) program, and other groups exploring more open source licensing models, or an entity such as the Medicines Patent Pool (MPP), which is committed to open licensing of products and technology transfer in developing countries, could also play a role.

**Approach**
There are a vast array of diagnostic needs for cancer in general, and particular challenges associated with patients that have low incomes, and/or when testing is conducted in resource poor settings with poor infrastructure. The project would set up two different innovation funds, each implemented in connection with different types of prizes, an open source dividend, and open licensing of intellectual property rights associated with the innovation for use in cancer diagnostics.

*Priority Cancer Diagnostics Prize Fund (PCD-PF)*
The Priority Cancer Diagnostics Prize Fund (PCD-PF) would identify areas where innovations in diagnostics are considered most feasible and beneficial, given existing information about opportunities and health impacts. For example, there is a need for an affordable, low infrastructure accurate test for HER2+ breast cancer, in order to improve access to treatments that may be appropriate for approximately 20 percent of breast cancer patients. Another possible priority is the early identification of cervix uterine cancer, a disease with disproportionate impact in developing countries. The PCD-PF would effectively be a set-aside of funds to mobilize innovation for needs identified by public health officials. The managers of the PCD-PF would hold public consultations biannually to consider identification of diagnostic needs that would qualify for the PCD-PF.

*The General Cancer Diagnostics Prize Fund (GCD-PF)*
The General Cancer Diagnostics Prize Fund (GCD-PF) would provide rewards for successful innovations that accomplish any of the following objectives:

1. Lower the cost of cancer diagnostics in developing countries
2. Improve the accuracy and usefulness of cancer diagnostics in resource poor settings with low infrastructure

Unlike the PCD-PF, any innovation in cancer diagnostics would qualify, even if they were not pre-selected to be among the areas of “priority” need.

*Several types of innovation prizes*
The range of prizes that will be used by the PCD-PF and the GCD-PF will include:

1. “Interim results” prizes to reward solving specific technical challenges, such as those listed in the Nature Open Innovation Pavilion,
2. End product prizes, which will perhaps be particularly useful for the PCD-PF, which will provide an inducement both to develop commercial products and that are evaluated as being used and useful, and also to openly license the intellectual property rights from the innovation.
3. Periodic prizes for innovations that contribute to lower prices for testing.
4. Periodic prizes for improving accuracy and/or reducing infrastructure needs of diagnostic tests.
Open Source Dividend
The open source dividend will be a sharing of prize money with persons or entities that openly share knowledge, data, materials and know-how, when that sharing contributed to a successful outcome that resulted in an innovation prize.

Open Licensing of Innovations
Many monies from the prizes funds would only be available to persons who openly license relevant intellectual property including patents, data, regulatory test data and know-how, for use in cancer diagnostics.

Competitive Intermediaries
One challenge for innovation inducement prizes is to place a value on an interim result that may or may not prove useful to end users of diagnostics, or to create the appropriate end-points for the interim challenge. A system of competitive intermediaries seeks to mitigate criticisms of specific decisions by creating a system whereby donors can choose to fund more than one intermediary to manage such prizes. Over time, the benefits of each intermediaries decisions will be observable, and donors can continue to reallocate funds between intermediaries based upon dynamic changes in management strategies and objectives and evidence regarding performance. This can be thought of as similar to the use of multiple managers of pension fund assets, each making subjective decisions, and each competing for resources. The competitive intermediaries can be for-profit, non-profit or a mixture of for profit and non-profit institutions. The competitive intermediaries could also be located in developing countries, with close ties to developing country health systems or potential manufactures of low cost diagnostic tests.

6.* Public health need that the proposed project aims to address:
(Explain the public health need in terms of burden of disease; prevalence; incidence; fatality rate; geographical spread; current interventions and their limitations; and what proposed new technology would change in terms of disease prevention, control, diagnosis, treatment etc. If detailed information is not possible at present then please provide some basic level information) (Approximately 400 words)

In a recent speech about cancer, WHO Director General Margret Chan said:[1]:

“Cancer causes around 7.9 million deaths worldwide each year. Of these deaths, around 70 percent or 5.5 million are now occurring in the developing world. A disease once associated with affluence now places its heaviest burden on poor and disadvantaged populations. If no action is taken, deaths from cancer in the developing world are forecast to grow to 6.7 million in 2015 and 8.9 million in 2030. In contrast, cancer deaths in wealthy countries are expected to remain fairly stable over the next twenty years. . . .

On average, 70 percent of cancer patients in developing countries are diagnosed at a very late stage of illness, when treatment is no longer effective.”
Among the many studies that provide evidence for Dr. Chan's claims is a paper by Shulman and others, calling attention to the disparities in the timing of diagnosis of breast cancer between developed and developing countries, which says:[2]

"Available evidence on stage at diagnosis, though scarce, indicate that a very high proportion of cases in the developing world are detected in late stages. In many under-served populations, a majority of women present with advanced disease; the figure is as high as 78% in black women in South Africa. In contrast, in the United States the majority of cases are detected in localized stages of the disease (Stages I and II), a third is regionally advanced (Stage III), and only 5% are distant-stage metastatic (Stage IV). (citations omitted)

The following data from the 2010 Shulman paper illustrates the disparity in the rates of diagnosis in breast cancer when it is still the more treatable Stage I/localized.

<table>
<thead>
<tr>
<th>Table 1: Percent of patients diagnosed at Stage I/Localized</th>
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<td>Region/Country</td>
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<td>Latin America</td>
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<td>Mexico</td>
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<td>Peru, Lima</td>
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<td>Brazil, Sao Paulo</td>
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<td>Brazil, Puerto Alegre</td>
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<td>Asia</td>
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<td>India: Mumbai</td>
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<td>India: Trivandrum</td>
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<td>Jordan, Amman</td>
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<td>Africa</td>
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Another example of the need for more affordable and accessible diagnostics concerns the gaps in testing breast cancer patients to determine if they are candidates for treatments such as trastuzumab or pertuzumab that target the HER2/neu protein. As many as 1 in 5 patients with breast cancer may benefit from such treatments.

In 2013, two applications were presented to the 19th Expert Committee on the Selection and Use of Essential Medicines to include trastuzumab in the WHO list of essential medicines. [3,4]. Trastuzumab is currently sold by the originator at prices of $5,000 to $9,000 per gram in most countries, and priced at more than $1,000 per week in many countries, although with patents expiring and countries willing to grant compulsory licenses, experts expect prices to fall dramatically as biogeneric alternatives enter the market. However, the diagnostic tests to determine if a patient is HER2+ are also costly and rarely available in many developing countries. The high cost and limited availability of the HER2 diagnostics was a factor in the failure of the WHO Expert Committee to include trastuzumab in the WHO essential medicines list in 2013.

**Notes on the Global Incidence of Cancer**

Cancer has been described as a disease of affluence, in part because of the relative higher incidence of deaths from cancer in high income countries. For many types of cancer, the odds of having cancer increase with age, and higher income countries often have longer life expectancies, and better access to health care which means fewer people die from non-cancer related illnesses. That said, most cancer deaths occur in developing countries. The WHO estimates that in 2011, 69 percent of cancer deaths occurred in countries that the World Bank defines as low or middle income.[10]

The average age of persons dying of cancer is lower in developing countries. For persons under 50 years old, 89 percent of cancer deaths occurred in low or middle income countries. For high income countries, 62 percent of cancer deaths occur at 70 years or older, and 5 percent are persons under 50. For low and middle income countries as a group, 36 percent of cancer deaths are persons 70 or older, and 19 percent are persons under 50.[10]

7.* Explain which new and innovative approaches and mechanisms to supporting financing and coordination of R&D this project would demonstrate?

(This is a very important part to be filled. The idea of these demonstrations projects is “to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken” (WHA66.22).
The 66th WHA considered these demonstration projects as part of the efforts to “take forward action in relation to monitoring, coordination and financing for health research and development”. The assembly decided to identify such projects that: “(a) address identified research and development gaps related to discovery, development and/or delivery, including promising product pipelines, for diseases that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken; (b) utilize collaborative approaches, including open-knowledge approaches, for research and development coordination; (c) promote the de-linkage of the cost of research and development from product price; and (d) propose and foster financing mechanisms including innovative, sustainable and pooled funding; (2) The demonstration projects should provide evidence for long-term sustainable solutions.” (Approximately 300 words)

The project pools funds from several different donors.

The project would require open licensing of all innovations qualifying for rewards, and fully embrace the end-to-end de-monopolization of research inputs, outputs and end products while preserving a role for entrepreneurial decision making and market incentives.

The project uses innovation prize funds, which themselves are innovative, and implements the open source dividend approach to stimulate upstream sharing of knowledge, data, materials and technology.

The novel use of competitive intermediaries would demonstrate the ability to implement decentralized and competitive management systems in a field often plagued with conservative group think and centralized points of failure.

8.* Evidence of market failure/research landscape:
(Explain why there has been no investment in this technology or why investment has not resulted in access to the health care product.) (Approximately 200 words)

A combination of factors have led to an under-supply of high quality low cost cancer diagnostics that can be used in low infrastructure settings. Low income patients are not perceived as an attractive market for cancer diagnostics, because they lack resources for out of pocket expenditures and because public health systems in many countries have not considered treatments for cancer a priority. Also, the high costs of patented drugs are both a barrier to providing treatment, and a disincentive to test patients.

National governments can overcome patent monopolies on drugs and other products, by granting compulsory licenses (such as compulsory licenses on Sorafenib patents in India, or the compulsory licenses on Docetexel, Letrozole, Erlotinib, and Imatinib in Thailand), by encouraging voluntary licensing, by creating higher standards for obtaining patents, or by changing the system of rewarding drug development, such as the Cancer Prize fund approach proposed in 2008 and 2009 in the World Health Organization discussions on innovation and intellectual property rights.[5]. In such cases, a developing country may be motivated primarily to address the drug or vaccine access concerns, although proposals such as the Cancer Prize Fund could be used to focus innovation rewards on products, regimes and delivery mechanisms that are more appropriate in resource poor settings.
While governments have some options for overcoming high prices on cancer drugs and vaccines, there does not currently exist a strategy to deal with the vast disparities in access to diagnostic technologies and services in the field of cancer. This can be contrasted to the significant effort underway to improve point of care diagnostics for Pulmonary tuberculosis (TB) and HIV/AIDS, and possibly for fever.

As regards end products, it is well known that there is a major divergence between the private and social value of diagnostic innovations. From a social point of view, having the technology available at margin cost is optimal, as long as this is consistent with funding the R&D in the first place. The problem is the current business model, which depends upon product monopolies and high prices to stimulate innovations. Government funding of development costs through grants is a partial but incomplete solution, both because the grants often do not preclude monopoly patenting of inventions, and also because governments, while having an important and perhaps under-utilized role, are limited in terms of their ability to manage product developments for diagnostics, at least as regards the diverse possibilities that might be usefully explored. What the project seeks to do is to create a mechanism specifically designed to establish new market incentives to replace what is currently missing and thus provide inexpensive diagnostic tests for cancer that can be used to treat poor persons in resource poor settings with low infrastructure requirements.

There are also many well known market failures as regard upstream research inputs and processes. Among these are the failure of researchers to share knowledge, data, materials and technologies, leading to under-utilization of the inputs, costly duplication of efforts, or legal barriers to using or pursuing certain research strategies. There are also inadequate economic incentives to invest in R&D projects to achieve useful outcomes that fall short of a commercially successful result. The prize fund approach, including in particular the open source dividend, but also other types of interim results prizes, creates rewards and incentives to share knowledge, data, materials and technologies. Cash prizes can also be used to reward interim research results, and if connected with open licensing policies, make the results more widely available.

9. **The scientific and technical feasibility:**

(Describe the scientific and technical basis for the proposed technology in terms of the state of the art e.g. candidate molecules; biomarkers; pipeline; previous efforts, if any, to develop same or similar technology etc. Include some risk analysis) (Approximately 500 words)

Cancer diagnostic tests are so diverse any brief summary would be of limited use. But one recent example of an apparent diagnostic breakthrough is suggestive of the potential benefits from more open innovation models. Jack Andraka was 15 years old when he developed a new diagnostic technology for ovarian, lung and pancreatic cancer. The new invention is reported to be 168-times faster, 400-times more sensitive, and 26,000-times less expensive than the medical standard for testing pancreatic cancer, and according news reports is fairly easy to use. The inventor was motivated by the death by cancer of a family friend, and began his research as a hobby. In one account Andraka said “I didn’t know what a pancreas was. I just used Google and Wikipedia to do all of my [initial] research.” Later Andraka would mine countless open access articles from PubMed Central (PMC) and used Google to find his way around publisher paywalls.[6] His invention won the Gordon E. Moore Award
and extensive news coverage. In one account, he said he was then seeking patents to commercialize the technology, which reportedly costs only 3 cents per test. An open source diagnostic prize fund would be an important mechanism for inducing development of such a technology while preserving its low costs as a benefit to patients, and also stimulating similar breakthroughs.

The development of new tests for cervical cancer using vinegar are another example of how a research collaboration can produce a lower cost technology that is more useful in resource poor setting. This innovation involved collaborations between researchers in Johns Hopkins, the Tata Memorial Centre in Mumbai, India and the National Institutes of Health [7,9]. The authors of the study believe the new screening methods could save 72,600 deaths in resource poor countries annually [8]. It is likely that similar technology innovations are feasible, but some researchers may be more focused on technologies that can be patented and monopolized and commercially exploited. The use of innovation inducement prizes that reward improvements in health which do not rely upon product monopolies to generate rewards would draw more interest in the class of innovations that could not be monopolized even if they were patented.

10. Reasons for proposing:
(Provide details if any priority setting and/or selection criteria that has underpinned the consideration to take up this area of technology for development.) (Approximately 200 words)

The current system for financing new cancer diagnostics includes an extensive role of government funding of research, and reliance upon trade secrets and patents to protect investments in R&D. This results in inadequate sharing of knowledge and other R&D inputs, frequently high prices for tests, deficient investment in tools appropriate in resource poor settings with weak infrastructure, and acute global disparities in access to tests. To change the current system, it is necessary to build something new. This demonstration project proposal is an effort to create something more ambitious than a one-off example of a prize or an open source grant. Instead, the project seeks to create a system for supporting innovation that puts patients first, addresses the large needs of persons living in developing countries, and encourages sharing of knowledge and follow-on innovation.

Some of the issues and concerns addressed in this project have wider benefits, illustrated most recently in the United States’ debate over the patenting of the BRCA gene by Myriad Genetics. The United States Supreme Court has recently issued a number of rulings that have narrowed the patenting of genes and diagnostic tests, and in every dispute, the negative impacts of the patent system in blocking follow-on research and raising prices to patients have been contrasted with the benefits of creating incentives to invest in R&D. Ultimately, to eliminate the negative impacts of patent monopolies, one has to demonstrate that alternative methods of rewarding inventive activity and investments in commercial products exist outside of the grant of a patent monopoly on an invention.

11. Who could potentially develop the technology/carry out the research?
(Provide known details: individual researcher? Group of researchers? Research/coordination organization including PDPs? Group of research organizations)
working together? Combination of these; What would be the process of selection of developers?) (Approximately 100 words)

As illustrated by the example of the young inventor Jack Andraka (in Section 9), individuals as well as organizations could be suppliers of research. Many of the “solvers” who respond to the innovation prize contests managed by Nature or InnoCentive are individuals living in developing countries. Within the PAHO region there has been substantial growth in the number of persons who not only have the academic, professional or business background to contribute to R&D efforts, but who also benefit from the expansion of open access scientific literature, and other information resources now available from the Internet.

Universities, government agencies, research institutions and other non-profit organizations, businesses of all sizes, and networks of researchers and research organizations both within and between countries would also be among those who would potentially be suppliers of R&D.

Figure 1: Residency of “Solvers” for InnoCentive innovation inducement prize competitions

12. Who could potentially manufacture the final product?
   Multinational company? Local production? Joint venture? How the decision will be made about the producer? (Approximately 100 words)

With disclosure of know-how and open licensing of intellectual property, local production, small business production serving regional or global markets, joint ventures or large multinational manufacturing are all possible.

13. What could be the role of WHO, if any, in this demonstration project to bring this venture to fruition? (Approximately 200 words)

The WHO may solicit recommendations as regards priority needs for cancer diagnostics, and provide
14. Please outline a timeframe and projected milestones for the project covering the first 5 years. This should also highlight the immediate actions that need to be taken? (Approximately 200 words)

Year 1:
Determine which governments/private donors are interested.
Create a committee representing donors.
Obtain initial pledges.
Begin consultations on priority needs.
Begin mapping potential suppliers of innovation

Year 2:
Formalize legal structures for receiving, escrowing, and spending money.
Enter into agreements with multiple entities to manage prize contests.
Launch first prize contests.
Adopt Version 1 of priority needs.

Year 3:
Award first innovation prizes, including prizes for technical challenges, lowering testing costs or improving results.
Evaluate prizes awarded in year 2.

Year 4:
Continue management of prize contests.
Revise list of priority needs.
Solicit new round of funding.

Year 5:
Continue management of prize contests.
Evaluate all prizes contests, including challenges that have and have not resulted in winners.

15. What is the intellectual property (IP) landscape relative to this project? Is there any IP, e.g. patents that need to be licensed in to be able to develop and market the product in developing countries? How would IP and related intellectual assets, including knowhow, proposed to be managed in this project? (Approximately 400 words)

The intellectual property landscape for diagnostic devices is a challenge. There are a proliferation of patents relevant to diagnostic devices, and many companies rely upon extensive trade secrets to protect diagnostic device platforms. The patent landscape is often less of an issue in developing countries than in the United States or countries like Canada, Germany, France and the UK,

For end product prizes, a developer will have to demonstrate a feasible path to the market.
The prizes, including in particular end product prizes, will make it easier to acquire voluntary licenses on necessary patents, if not as regards global rights, but within some geographic areas.

The open source dividend and the interim prizes will expand opportunities for follow-on R&D.

Some major funders of research have certain global rights in patents, and are in a position to require open licensing of patents.

16.* What would be the strategy to ensure access to the product once it is developed?

(Access is an important dimension of these demonstration projects, it is important for the projects to begin with the end in mind, explain how this project would deliver the technologies to the needy patients i.e. price and affordability; modes of supply; storage; prescription; dispensing; and compliance; WHO will develop guiding principles for ensuring access to any products coming out of the demonstration projects) (Approximately 400 words)

The open licensing of intellectual property associated with research grants, contracts and innovation prizes is designed to enable more competition and lower prices for the tests. The grants and prizes will be used to fund development of products that have low costs to manufacture and operate, and which can be used in resource poor settings with minimal infrastructure.

End product prizes can use price caps, market penetration tests, requirements for business plans for commercializing products in developing countries, and other measures to supplement other economic incentives to expand access to products.

17. How could the project be financed paying particular attention to the need to demonstrate new and innovative forms of financing? Also provide an estimated cost of the project. (Approximately 200 words)

In the academic discussions of diagnostic costs, reimbursement costs are sometimes justified by value of information models, which compare the economic value of outcomes with and without testing. In such analysis, a diagnostic technology is perceived to have value if it reduces false negatives or false positives, if it expands access to useful treatments, avoids use of inappropriate or unnecessary treatments, and if it permits earlier, more effective and less costly interventions. Companies that sell diagnostic tests and services have successfully lobbied governments, reimbursement agencies and private insurance companies around the world to pay for this valuable information. What is lacking are global systems to pay the cost of producing information that becomes widely available, and is supplied by open source approaches. This demonstration project can only begin to create a multi-state cooperation on the financing of incentives need to ensure that innovations are delivered and made available to the public via open source methods. The challenge is to use or redeploy the same sources of funds that are currently being spent on the closed propriety systems, that rely upon secrecy and monopolies, and which have so many flaws, to support the production of innovations in diagnostic technologies as a public good.
18. How could the project be governed and coordinated paying particular attention to the need to demonstrate better way of coordination? (Approximately 200 words)

19. Have any donor agencies/governments already indicated interest in supporting the project? (Approximately 200 words)

References


[4] Union for International Cancer Control, Dana-Farber Cancer Institute, Center for Global Cancer Medicine, Review of the available evidence on Trastuzumab for Inclusion in the WHO Essential Medicines List as an anti-neoplastic agent. January 9, 2013


controlled trial in Mumbai, India. J Clin Oncol 31, 2013 (suppl; abstr 2)
