PROPOSAL TEMPLATE

Proposal Name: Open Source Drug Discovery

Submitted by: Open Source Drug Discovery Initiative, Council of Scientific and Industrial Research (CSIR), India

Please provide a description of the proposal (up to 500 words):

The proposal is an open source model of innovation for tropical infectious diseases. The lack of appreciable market that attracts the research investment of research based pharmaceutical enterprises hampers development of new drugs for such diseases. An alternative approach is to create a platform where the research and development of drugs for diseases of poor commercial interest that can be supported through an open collaboration across the public and private sectors has been envisaged. The entire drug discovery and development activities will be carried out with the objective of making the drugs affordable. The drugs so developed in the open source mode will be made available as generic drugs for industry to manufacture. Multiple players in the market will ensure accessibility and affordability of these drugs. The contribution to the research will be attributed to the respective contributor and the approach is IP neutral. The proposal envisages that public funds will support research and development of drugs, including clinical trials.

There is a working model following the above tenets in the Open Source Drug Discovery (OSDD) project (www.osdd.net). The technical feasibility of the proposal is demonstrated through the OSDD platform.

OSDD is a Council of Scientific and Industrial Research (CSIR), India, led initiative supported by direct funding from Government of India of about US$12 Mn with an overall project outlay of $46 Mn. Its vision is to provide affordable healthcare for developing world.

CSIR (www.csir.res.in) is one of the largest publicly funded research organizations in the world and has played a key role in the development of generic drug industry of India by providing them with technologies for manufacture of drugs.

Tuberculosis (TB) is the first target disease of OSDD due to its high incidence and mortality rates in India and other developing countries. OSDD has decided, based on its encouraging experience on the work done on TB to extend the open source program for malaria. The OSDD model is scalable and applicable to all diseases without market.

Launched in September 2008, OSDD has more than 4500 registered partners from more than 130 countries around the world. OSDD is an open innovation platform, where all the ongoing projects and the research results are reported on the web based platform http://sysborg2.osdd.net. In about two and a half years OSDD has filled up many areas of the drug discovery pipeline and plans to move to development phase in the near future. OSDD works like an assembly chain for drug discovery where anyone can join at any stage of the pipeline.
The following is the status of the projects after two and a half years of operation:

**Status: OSDD Projects**

[Diagram showing project status with numbers 18, 19, 9, and 6]

**Strategy**

The OSDD strategy is to derisk drug research in the precompetitive space through a collaborative open source model, up to clinical trials, and leave the competitive space of manufacture and delivery of drugs to the generic drug industry.

The OSDD approach has a strategy for all components of the drug discovery pipeline.

**The approach**

*Early stage discovery* (up to Lead Identification): The OSDD approach is to bring in open innovation and collaboration in early stage drug discovery through community participation where researchers from academia, research laboratories, industry, student community and others could collaboratively solve challenging problems relating to drug discovery. Such problems are posted on the portal as a project or an idea requiring solution by its proponents. The community then gets a chance to review it online. A principal investigator, mostly experienced scientists, will lead the projects which are addressing specific tasks on discovery. The projects will be funded by OSDD. Such projects will cover all aspects of drug discovery from bioinformatics to in vitro validation. The projects will have the benefit of community inputs as well as inputs from experienced scientists, or the industry partners. The result of the projects are available online for the community to review. This facilitates project monitoring as well as quality control. OSDD is managed by a Project Directorate with experienced scientists and administrators guiding it.

*Late part of discovery* (Lead optimisation and beyond): Projects will run as well defined industry comparable research programmes focussed on optimising
molecules. Both public sector institutions with experience in the field and Contract Research Organisations (CRO) with expertise in the field will be partners. The result of their work will also be available on the portal for community inputs.

**Clinical trials**: It is proposed to build 'clinical trials' facility under the OSDD programme supported by public funds (see, the section under Cross Cutting Issues). These trails will be co-ordinated to meet the registration requirements of the local authorities as well international guidelines.

**Marketing Strategy**: The key objective of the OSDD marketing strategy is to make drugs accessible and affordable. OSDD will use the existing business model of generic drug industry to deliver drugs to the market. While the discovery and development upto registration is supported through public funds, once approved the regulatory authorities, the approved drugs will be available to the generic drug industry without any exclusivity. This will ensure more than one player in the market. The market competition will lead to the optimum pricing which a market can absorb. The competition will ensure wide reach of the drugs to the market ensuring access. MSF has documented that generic competition pushes prices down in the market. (3). Therefore the OSDD business model is to let the market forces operate to determine accessibility and affordability.

OSDD model does not contemplate a royalty on the drugs sold since the discovery and development is supported by public funds. This is because any addition of royalty will lead to increased prices, which will have to be born by the patients who are mostly from poor background. In addition, in a country like India, the government administers most of the DOTS therapy free by procurement of drugs from open market and free distribution through the DOTS centres. Any addition of royalty will only add burden to the exchequer that has already invested in research and development of the very same drugs. Therefore OSDD model contemplates to make available the drugs to any generic drug industry which meets certain standard manufacturing practices to manufacture and deliver the drugs.

**Delinking the R&D Costs**: The above strategy of OSDD essentially delinks the research and development costs of the drugs. The price of the product will be determined by market forces. Market competition will spur accessibility.

**Cost Effectiveness of the Model**: The OSDD approach is to conduct early stage research in highly collaborative fashion involving best minds from across the world. In development stages it involves partners like contract research organisations who are used by the pharmaceutical industry in their own areas of operation as they are cost effective. The conduct of research and development in the countries having disease burden, yet having competencies, brings in skills at highly affordable scale. The model is scalable and capable skill development in parts of the world (see, section under cross cutting issues). Finally, the generic drug industry based market model makes OSDD approach highly cost effective.
OSDD Approach to Drug Discovery: A New Paradigm

OSDD brings in the concept of open innovation and product development partnership concepts on the same platform and leaves delivery of drugs to market forces.

OSDD Collaborative model
At the early stages of discovery, OSDD puts in place a collaborative model with large community participation, but at development stage collaborates with industry/contract research organisations and other publicly funded organisations.

The drug discovery process in OSDD project has been divided into ten workpackages. These work packages operate parallelly and anyone with required competence can join any of the packages. The work packages enable monitoring the progress of the project.
Describe and justify the potential public health impact\(^1\) of the proposal:

OSDD is a generic scalable model for drug discovery in tropical infectious diseases and therefore its public health impact is high.

The vision of OSDD is affordable healthcare to the developing world. The first target disease of OSDD is tuberculosis and is working on extending its presence to Malaria. Its potential in drug discovery is demonstrated in the case of tuberculosis.

OSDD has large potential public health impact for the developing world as demonstrated in the case of TB. There has been no major break through which can substitute the lengthy DOTS therapy for tuberculosis. The editorial of *Nature* of 25 June 2009(4), quoted Margaret Chan, Head of the World Health Organization, as stating that the field of TB research has been too isolated and inward-looking. It also quoted Anthony Fauci, Head of the US National Institute of Allergy and Infectious Diseases as stating that generations of advances in research and technology have bypassed TB research. The OSDD approach is to bring research on Mycobacterium tuberculosis to the open so that researches across the world can share and collaborate, thereby bringing many eyeballs to the problem.

OSDD has two candidates in the hit to lead phase on TB. These molecules are being worked up on an open source mode in collaboration with private partners, with the promise that if these are successful, they will be licensed non exclusively like a generic drug. Thus OSDD has already contributed to improving the pipeline of TB drug discovery.

OSDD work on Malaria will start as soon as government funds are available for the purpose. The funding is expected to begin in the financial year 2012-13.

The potential public health impact of OSDD is high as:

1. It works on drug discovery for TB and plans to extend to Malaria.
2. It has demonstrated the viability of an open source platform for drug discovery.
3. It has two molecules in lead optimisation and several ongoing projects on TB drug discovery.
4. It has involved large scientific community in TB drug discovery, with CSIR India, leading the drug discovery effort.
5. It mandates non-exclusive licensing and rides on the generic drug industry business model to ensure accessibility and affordability.
6. OSDD brings on its platform, public-public, public-private, academia-research laboratory and community participation to drug discovery. This is a generic and scalable platform.
7. The principles of OSDD can be applied to diagnostics for tropical diseases.
8. The marketing model will allow access at prices that are compatible with the resource restriction.

\(^1\) Principally CEWG criterion 1 but others may be relevant e.g. Equity/distributive effect including on availability and affordability of products and impact on access and delivery.
WHO support to OSDD would help in attracting and funding experts, particularly from developed countries to contribute to research on tropical diseases. It will also lead to competence building in developing countries through OSDD participative model. It will help expanding the model to neglected diseases like Filariasis, leishmaniasis and so on which are a problem in the developing world and yet has very limited research and development work in progress.

**Describe and justify the technical feasibility**\(^1\) of the proposal:

The viability of open source mode as a workable drug discovery platform has been demonstrated by the OSDD project with TB as the target disease. Its main achievements are listed below:

The OSDD platform has demonstrated the following:

1. **OSDD is on a hit to lead phase on two anti TB molecules.** These molecules are patent applied but contributed to the OSDD and are subject to OSDD IP approach (as discussed in the section Cross Cutting Issues) and will be available as a generic drug to all, if the molecule ultimately clears regulatory permissions.

2. **Engagement of Private Partners:** OSDD demonstrated that private partners can be actively engaged in open source approach and that intellectual property issues will not hamper such collaborations of open source projects with private partners. The two molecules discussed above are lead optimized in collaboration with two different private partners, who are renowned contract research organisations (CROs), with OSDD community actively interacting with them.

3. **Attracting Wetlab Scientist to Open Source:** OSDD has effectively integrated the insilico or computer based approaches with the actual laboratory experiments. OSDD has enthused a large number of wet lab scientists to work in the open source mode. A molecule library is being created by collaborative activity across a large number of institutions across India.

4. **Collaborative Crowd Sourced Model with community as a resource:** Its crowd sourcing approach has successfully curated an extensive annotation of Mycobacterium tuberculosis (Mtbc) which served as the primer for generating the largest ever metabolome and protein-protein functional network of Mtbc enabling identification of potential drug targets. This has facilitated better scientific understanding of the bacteria. OSDD has demonstrated that data intensive scientific discovery can be made possible using the above crowd sourced model involving young researchers who are willing to voluntarily solve problems for the sake of the satisfaction of solving challenges rather than for any monetary reward. As per published estimates, this innovative approach packed nearly 300 man-years into 4

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\(^1\) Principally CEWG criterion 4 but others may be relevant e.g. Rational and equitable use of resources/efficiency considerations
months (5).

5. **Training of Young Researchers:** The collaborative model of drug discovery of OSDD has created a large trained pool of young researchers trained in the science of drug discovery. This trained manpower is a human resource for the industry. The Women Scientists Forum of OSDD taps into the competencies of qualified women trained in scientific activities but are homebound due to family circumstances. The Young Scientists Forum of OSDD has been set up in a number of graduate and undergraduate colleges where students discusses the active scientific problems confronting drug discovery.

6. **Development of Resources for the Community:** OSDD has developed and provided the following online community resources:
   i. TBrowse - integrative genomics map of tuberculosis - linked more than a million datasets in standard format by community participation
   ii. Chembioutil - Enabling experimental researchers to perform comprehensive computational analysis in a collaborative and reproducible manner through a user-friendly interface.
   iii. Computational resources for drug discovery (CRDD). This part of the portal provides a comprehensive resource for all Open Source tools needed for drug discovery.

7. **Open Access Repositories:** Biological research often require access to physical biological materials. OSDD has set up open access repositories to facilitate such access. These are:
   i. A Biological Repository of strains, clones etc.
   ii. A Chemical Repository of small molecules
   iii. Open Access Screening Facility

8. **Large Scale Screening of Compounds in Open Mode:** OSDD has screened more than 20,000 Chemical Compounds against Mtb out of which about 40 compounds have been identified for further development. This is probably one of the largest screening of molecules against TB ever done in India by a public research institutions.

9. **Development of Science 2.0 Portal:** OSDD brought Science 2.0 to drug discovery. Its scientific portal has a semantic search facility with an RDF data store driving it. It has a semantic-web architecture that seamlessly integrates social networking with various steps of implementing scientific projects in drug discovery. This portal thus connects complementary expertise in order to facilitate projects demanding varied skill sets and infrastructure. This portal was developed by OSDD community in collaboration with the Indian IT company Infosys Ltd.

10. **Publications:** Following papers have been published by the OSDD community/PIs with OSDD funds in two and a half years:


A number of other publications are under review.

11. Making Open Source Drug Discovery Work: There has been several discussions about open source approach to drug discovery before OSDDD. There were few initiatives with this intent as well. However, none has progressed the way in which OSDDD has progressed. It has demonstrated that Open Innovation can work in the field of pharmaceuticals. Open Source approach is a workable model for drug discovery, government of India is progressive and innovative to adapt such innovative approaches.

Describe and justify the financial feasibility\(^1\) of the proposal:

**FUNDING**

The drug discovery in itself is expensive. What OSDDD offers is a model to reduce this cost. The industry estimate is that drug discovery costs $800-1000Mn. The experience of CSIR is that drug discovery can be done at much lower cost. OSDDD estimates that one candidate drug can be brought into clinical trial phase III in India with about $ 200 Mn investment.

**Current OSDDD Funding**
The expenditure for the discovery phase of OSDDD is estimated at$46 million.

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\(^1\) Principally CEWG criterion 5 but others may be relevant e.g. Cost-effectiveness.
Government of India (GOI) has supported the project with $12 million for the first phase. OSDD proposes to raise equivalent amount of funding from multilateral/bilateral agencies and philanthropic organizations. The fund from GOI is currently being utilized to finance ongoing projects within India.

In addition to government funding OSDD has raised private/philanthropic funding. M/s Infosys Ltd, a leading IT solutions provider of India, has developed a science 2.0 semantic search portal for drug discovery which would have cost a substantial amount, if developed in competitive space.

OSDD has also received philanthropic funds. When it organised a collaborative Mtbb annotation program, a philanthropic organisation called India 800 donated 120 laptops to reward the best contributors in the community.

As the funds from GOI is only for projects carried out in India, OSDD faces some difficulties in funding international collaborations. Since it has participants from 130 countries, there are proposals for collaboration and funding the overseas partners is an issue to contend with. There are some models which have emerged. There is a collaborative work being undertaken on the OSDD platform with leading scientists from premier institutions in India like Indian Institute of Science (IISc), National Centre for Biological Sciences (NCBS) collaborating with Sir Tom Blundell’s group in University of Cambridge, UK. The UK part is funded by the University of Cambridge, while OSDD funds the Indian expenses.

The commitment of Government of India and other partners reflects their belief that OSDD is a financially feasible and viable model.

**Open Peer Review and TransparentProject Funding Mechanism**

OSDD releases the funds it has received from GOI through a transparent open peer review mechanism. All project seeking funds are placed online for open peer review of experts as well as the community. A project is selected for funding only if the online review is favorable. The PI who seeks the funds has an opportunity to know the observations of the community and be able to defend his proposal online. The entre funding is therefore through a transparent and open process. This will ensure rational and equitable use of the financial resources.

**Accountability and Involvement in Governance:** The open peer review process and the ability of community to provide inputs on the projects and its funding ensures complete transparency and accountability. Each Principal Investigator who receives funds will have to show the result of the work on the open portal. This ensures community participation in governance and decision making of the whole process.

**Why Funding is Needed:**

1. OSDD is a scalable and replicable model and an alternative innovation model in drug industry. It can bring affordable drugs to the market. Its spinoffs include skill development and capacity building across the developing world.

2. In the absence of market forces, supporting of research into tropical diseases
requires public funding. The OSDD approach is that these funds should be accessible to a wide array of competent individuals and institutions in an open and transparent manner harnessing multiple resources. As the discovery and development takes place in the countries where the disease occurs, and where the discovery activities can be cost competitive, the discovery can be carried out at an affordable cost. OSDD estimates that, in a disease like TB, a candidate can be brought into clinical trials through its platform, in a span of 5 years, at an investment of $100 Mn.

3. An area where substantial funding is required is in the conduct of clinical trials. The most appropriate way to optimise the cost of clinical trials is to conduct them in countries having the disease burden.

Many pharmaceutical companies are getting clinical trials done in India, China and South Africa on diseases of their interest. Clinical trials can be conducted on tropical infectious diseases in these countries and other affected countries at a fraction of the cost of conducting of such trials in developed economies. Public funds will have to be invested in:

i. to set up clinical trial infrastructure in the disease endemic countries with trial capability

ii. conduct of clinical trials in places with competence and infrastructure.

It is estimated that state of the art clinical trial infrastructure can be set up in publicly funded hospitals in disease endemic countries for an amount of $ 25 Mn per facility.

In OSDD approach the conduct of clinical trials will have to be funded by the public sector but under the supervision of internationally reputed clinicians. Funds will need be set apart for conduct of clinical trials.

OSDD is investing in setting up state of the art clinical trial infrastructure for tuberculosis in India. This infrastructure can be used by any entity for future clinical trials on TB and since such trials are done in collaboration with public sector hospitals, are considerably affordable. Additional funds are required to set up clinical trial infrastructure in other diseases.

4. The current funding challenge that OSDD is facing is the funding of international collaborators in projects involving partners outside India as the funds from GOI are limited to India. An international funding will align a large number of researchers around the world on the open source projects which will improve the science of drug discovery of tropical infectious diseases. It will also develop competencies in a number of developing countries.

5. Additional funding will facilitate higher international participation in OSDD and its extension to other tropical diseases like filariasis, leishmaniasis and such other neglected tropical diseases that affect predominantly the poor.

The specific proposal here is to set apart funds for OSDD model of drug discovery and development for the diseases that affect the developing world and do not have market potential to attract pharmaceutical industry investment. The model is a generic one and can be adopted by any research organisation willing to lead the
drug discovery effort. The OSDD initiative of CSIR is willing to train other organisations in the developing world to adopt this approach.

Describe in what way the proposal addresses cross-cutting issues\(^1\):

**Approach to Intellectual Property:**

OSDD has a scalable and IP neutral business model to make drugs affordable and accessible to the developing world.

A key premise of OSDD is that when it comes to health we need to have a balance between health as a right and health as a business. In the case of tropical diseases the market based incentive mechanisms do not operate. Patents as a mechanism to ensure Return on Investment (ROI) from the market fails to play the role it plays as a driver of innovation in the pharma industry. Intellectual Property as a legal system has limited role to play in fostering innovation in tropical diseases. Therefore the OSDD approach to drug discovery and development is IP neutral.

Affordability and accessibility remain the core concerns of delivery of drugs for tropical diseases. The only successful market based model that is ensuring both these aspects is the generic drug industry business model where the market competition is driving the prices to affordable levels and makes competitors seek extended market reach ensuring accessibility.

The fundamental principle of OSDD is affordable healthcare to the developing world. Anything that is developed in OSDD will be available to the developing world in open source, generic mode, without price monopolies. This means that there will be no market monopoly associated with OSDD drugs, diagnostic or delivery mechanisms.

Markets are the key determinants for delivery of drugs. The drugs will be discovered and developed with public funding. Once a drug is approved for use by the regulatory agencies, OSDD will depend on the business model of generic drug industry which made drugs affordable in the developing countries. OSDD developed drugs will be available for any industry player with appropriate manufacturing practices to distribute the drugs to the market. The market competition will ensure accessibility and affordability.

A cornerstone of any scientific investigation is attribution. OSDD ensures that all contributions made on OSDD are attributed to the concerned. Intellectual Property, in addition to its other roles, plays a role in attribution (of authorship, invention, etc). Therefore in an open source scientific environment of drug discovery for tropical diseases IP could have a limited role. This limited role will have to be played within the premises of affordability and accessibility.

When a community collaborates, it does so with some basic rules that

\(^1\) "Cross-cutting Issues" refers principally to CEWG criteria 7-12, if not addressed elsewhere in the submission e.g. Potential for delinking R&D costs and price of products.
governs such collaboration. In OSDD these rules are laid out in the OSDD sign in license which all community members have to adhere to. It treats the entire information available on the portal as ‘protected collective information’. It mandates common ownership of the data and research results, sharing of such data, contribute back of improvements to the protected collective information. Such Protected Collective Information is held on behalf of OSDD community by CSIR as a trustee holder with legal powers and authority for legal action.

OSDD also understands that researchers may be contributing patented inventions to OSDD or there may be cases where the inventors worked in an open source environment yet would like to file patents. OSDD will encourage such patenting only for ensuring attribution to the inventors and for proving the non-obviousness of the research.

In cases where OSDD inventions are covered by patents, it will be used only to ensure:

i. Affordability and accessibility, by ensuring that the drugs are licensed non exclusively, utilising open competition in the market, removing the monopolistic nature of IP for access in developing countries;
ii. for ensuring quality control of downstream drug manufacturing, by licensing to only those entities who employs quality processes;
iii. that the subsequent innovations which follows on the existing patent developed in open source also in open source through its viral clauses.

OSDD will honour all patents granted, and at no circumstances will OSDD hamper further research on any of its patents by any group anywhere as these patents will be available with an open source license which enables further research.

While OSDD approach to research and development is IP neutral, it shall respect the intellectual property of others.

There may be situations where OSDD may have to enter into collaborations with industry partners who works on the IP based model. In such situations the OSDD approach shall be to ensure that research on tropical diseases progress and result in drugs and that such drugs are licensed to OSDD on an exclusive basis in specified countries where OSDD through its proposed marketing model will make these drugs available at affordable prices through manufacturing like a generic drug in the developing world through non exclusive licensing to the generic manufacturing companies who have acceptable manufacturing practices.

**OSDD Approach to Clinical Trials**

One area where doubt has been expressed around the world is on how open source could work in clinical trials.

A study conducted by London School of Economics (6) surveying major
pharmaceutical industry involved in drug discovery revealed that none of the research based pharmaceutical enterprises are willing to invest in risky clinical trials for neglected diseases, particularly as these trials conducted in the developed world are expensive. This is not a desirable situation as the pipeline of drug candidates will remain dry in tropical diseases. OSDD model believes that the alternative is publicly funded clinical trials involving public institutions where infrastructural and other capacity has to be built up for conduct of trials. OSDD understands that introducing more TB drugs in the market which is an absolute necessity will be possible only if it offers to conduct clinical trials of molecules developed by it or developed by others on the condition that it holds the rights to the drug in developing countries so that the drugs are available like generic in developing countries. With the good will OSDD has generated and the participation of public funded institutions the cost of trials can be brought down considerably on the open source platform.

The countries with disease burden have a special responsibility to solve the problem. India has high disease burden and a cost advantage but infrastructure necessary for the conduct of trials in TB may have to be built up. OSDD will demonstrate the applicability of this model in the case of TB. This approach is disease and country neutral (any developing country) and can be scaled up.

The experience of CSIR in conducting clinical trials is a guiding point. Two important points govern the principles under which clinical trials will be conducted under the CSIR/OSDD umbrella but with the Open source concept. The main features guiding success:

- The clinical trials under OSDD program will be conducted with substantial partnership from publicly funded hospitals, in where OSDD is planning to invest to build facilities for clinical trials. Additional expertise will be sought from private pharma in the country as well as experts from large international pharma who are committed to helping in the progress of molecules in the neglected disease arena. In order to ensure that appropriate processes and documentation required for clinical trials and during the conduct of it are maintained to internationally acceptable standards, the clinical trials will need be conducted in collaboration with CRO’s or industry partners with experience in the field.

- Private pharma will be inducted as a stake holder very early in the process of conducting clinical trials. The arrangements with the different stakeholders ensure that the drug will be made available to the generic industry in India for manufacture which in turn ensures ‘affordable pricing’.

In all cases where clinical trials are conducted by OSDD, these will be conducted to standards prescribed by international and national regulatory authorities and the data will be also be made available in the public domain.

Thus, OSDD has a clear alternative approach for the expensive clinical trials conducted in secrecy and at high cost. OSDD approach is that clinical trials for tropical diseases have to be de risked by investing public sector funds and involving
public institutions in the countries where disease occurs. This will bring down the
cost of clinical trials. OSDD ensures that clinical trial data, sans personal details, is
made public so that community inputs are available while conducting clinical trials
and for later designing of new trials.

OSDD will also make the commitment that these trials will be conducted following all
national regulations following the best ethical practices in a transparent manner and
will be monitored by an independent group. Their observations will also be available
on the portal for the community.

**Capacity Development and Additionality:** OSDD model of involving large number
of young researchers in academic institutions in drug discovery through online
collaboration is replicable across the developing world. It could lead to skill
development in drug discovery among the youth in developing countries as it
encourage large number of researchers to participate in drug discovery through
online collaboration under the guidance of expert scientists who may be located in
other parts of the world. This will help the pharmaceutical industry as it provides
trained human resources who have worked on real life drug discovery problems.
Provision of such trained manpower may lead to development of scientific research
in the developing countries as well as the availability of manpower trained in
pharmaceutical research leading to setting up of local industries.

The ability to train a huge manpower by guiding them online, without requiring
physical presence is an important spinoff and therefore a significant additionality of
the project.

CSIR India, which leads OSDD is willing to involve any number of research
organisations or researchers from developing world in this initiative. It is also willing
to train other research organisations to lead OSDD like model in their countries.

**Potential Synergy with other Models:** The OSDD marketing strategy and IP
approach synergises OSDD with other drug discovery and development approaches
including that of established pharmaceutical companies. OSDD can take forward any
promising candidate at any stage of drug discovery through its platform.

It open portal and open projects enables even prize funds to operate to boost solving
of challenging problems relating to drug discovery thereby facilitating to attract the
best minds to solve research problems of importance to tropical diseases.

**Identify key steps necessary to begin implementation and key issues to be
resolved for implementation to begin:**
OSDD is a working model which offers a translational platform for drug discovery in
neglected diseases with its capability demonstrated in the case of TB. This platform
can be replicated to other diseases. CSIR which has implemented OSDD is willing
lead or to train any organisation willing to take forward drug discovery in the open
mode to any other disease. OSDD can be replicated to other diseases without much
time lag in implementation.

OSDD model contemplates using existing skill sets and resources and therefore will
not have the lag of infrastructural development, particularly in using research and
development infrastructure. In the case of clinical trial infrastructure which may have to be set up, it is expected that by the time a molecule reaches that stage in the drug discovery process, such facility will be set up and available. In the case of TB, OSDD is contemplating setting up of such facility in India shortly or use the existing resources where available. Therefore there is minimum time to implementation of the project.

Funding is the key issue and once it is available the existing OSDD platform can be replicated to other diseases. The model is generic and scalable for any organisation to adopt and take forward.

Provide the evidence base for the proposal including literature references and other relevant information:

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