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Has OSDD fulfilled its promise?

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Has OSDD fulfilled its promise?

Open Source Drug Discovery (OSDD) - the pet project of Prof. Samir K Brahmachari, former director general (DG), was launched on September 2008. It introduced the concept of 'open source' to drug discovery, for the first time ever. Launched with the motto of 'affordable healthcare', OSDD tried to collectively aggregate the skills of researchers in academia, research laboratories, and industry to discover drugs particularly targeting neglected diseases.

OSDD describes its objectives as follows:
â€¢ To create a CSIR-led Team India Consortium with international collaboration to lead an open source drug discovery program.
â€¢ To develop a novel comprehensive systems biology approach to generate a comprehensive interaction map of the pathogen (ongoing).
â€¢ To discover and develop New Chemical Entities (NCEs) for Mycobacterium tuberculosis including drug resistant and latent tuberculosis. (First phase activity being carried out).
â€¢ In the second phase, clinical trials will be undertaken.
â€¢ To make the new drug available as a 'generic' drug without IP constraints, available in the open, so that the industry anywhere in the world could manufacture and distribute, ensuring that the drug reaches patients at affordable prices.

On its seventh anniversary, we analyse how many of its objectives have been achieved.

Disease like TB, malaria, and Leishmaniasis etc., are poor man's diseases, thus there is no return on investment for pharma companies to invest in it, so are generally avoided by these companies. There is need for alternative strategies for discovering new drugs outside the pharma industry, with this objective and with the motto of affordable healthcare, CSIR launched OSDD program.

OSDD first targeted the TB because of its high mortality rate. India is also dubbed as TB capital of the world claiming 1,000 lives daily and no new drugs have been discovered for the past several decades. OSDD tried to bring research on Mycobacterium tuberculosis, to the open sky so that researches across the world can share and collaborate, for finding the solution to this deadly disease. Towards this, a, Phase II B clinical trial for a new combination regimen for MDR-TB has been initiated.

The combination therapy, involving three drugs namely PA 824, Moxifloxacin and Pyrazinamide for MDR-TB, will be taken up for Phase II B clinical trials. OSDD has acquired the necessary approvals for conducting Phase 2B trial. The completed formalities include: regulatory clearance granted by DCGI, obtained the necessary drug entities, appropriate packaging and labeling, identification of labs for carrying out investigational studies during the trial, appropriate insurance regimen etc. Recruitment of patients for the clinical trials of combination therapy on MDR-TB patients is expected to start in a couple of months. The trial involves a 3 arm study using a combination of PA 824, Moxifloxacin and Pyrazinamide.

The trial is soon to start at National Institute of Tuberculosis & Respiratory Diseases (NITRD, erstwhile LRS Hospital), New Delhi, informs Dr Sarala Balachandran, project director, OSDD. She added, "This novel combination has been in licensed from The Global Alliance for TB, a non-profit organization. CSIR-OSDD has the license to progress the combination through different stages of clinical trials. This new drug combination will be made available at an affordable cost without any royalty to the needy patients in the country."

Funding

Funding for clinical trial and OSDD's other activities is through CSIR (Ministry of Science and Technology, Government of India) the core funding body of OSDD is from the CSIR. In the 11th plan, Government of India has earmarked Rs 45.96 crore (about $12 million) for the project. This has been extended till March 31, 2015 with additional funding of Rs 838.00 lakh. For funding for the 12th plan EFC has been approved. The process for getting cabinet note approved is ongoing.

Additionally, Sir Dorabji Tata Trust has awarded a grant to enable Council of Scientific & CSIR for operating TATA CSIR-OSDD Fellowship (TCOF) to support students who will participate in the process of 'crowd sourcing' as a method of research on open source discovery of drugs for neglected diseases like Tuberculosis (TB) and Malaria. The grant amounts to Rs 3 crore for a period of three years.

"One of the significant achievements of OSDD includes leveraging the potential of crowd sourcing to reannotate the genome of Mycobacterium tuberculosis. The activity has been the largest crowd sourced activity till now and has been successful in actively involving the Indian student community at large. OSDD has also been successful in building up a host of open source facilities aiming to equip researchers with easily accessible resources to enable their research including facilities like Open Source Chemical Repository - OSDDChemat CSIR-CDRI and Open Screening Facility at CSIR-IICT along with open source Computational Resources for Drug Discovery," said Dr Sarala Balachandran.

According to Prof. Samir K Brahmachari, "OSDD have made Indian students work together. Various labs across India are working together. It has created research opportunities for Indian students. 90 chem PI along with over 400 students are sysnthesing chemical molecule. Many other molecule re-discovered and are at various stage of development. In addition, we are now developing a system biology based computer modelling of an organism by which we can identify new ways of drug targets which are non-toxic. In addition, thousands of students have been trained."

"Another substantial attainment is building in-silico computational model of M-TB. Where we computationally modelled 1,152 reactions involving 890 genes i.e. one-fourth of the mTB gene with 961 metabolites in computer. The paper will be published soon, it will be first of its kind, commented Prof. Brahmachari. It has published 20 papers so far, as per OSDD's website.

In the course of time, it has successfully collaborated with many international organisations, like medicine for malaria venture MMV; Royal Society of Chemistry (offers fellowships to OSDD students), The Systems Biology Institute, University of Indiana

(PI-PI collaborations), University of Cambridge (the cambam collaboration, to validate the drug project/targets), DNDi (for Leishmaniasis research) and OSDD has currently entered into agreement with Global TB Alliance for developing PA-824 in India. Today 8,000 students across 130 countries are associated with OSDD.

OSDD through its exclusive internships for women has attracted and promoted scientific temper in the women of this country.

Mission 'affordable healthcare'

OSDD's mandate was to discover new molecule whether that molecule will be taken up for trial is not its mandate, even development was not its mandate, however we made it a mandate in phase II of the study, for which we have not received any budget. With the leftover budget of the study, we are trying to develop some drug. So discovery part, yes, we are absolutely the best in the world. Development is a slow process, but we will try our best. Right now the only focus is to eradicate TB completely from India, to bring down the number of deaths to 100 as opposed to 1,000 at present. It will cross one milestone after the other. Its milestone will be fulfilled when eventually it will help in reducing the number of deaths. The objectives set for OSDD are met, commented Prof. Brahmachari.

According to him, "OSDD is not a project. It is a movement started in India. CIR-led team. What started as an initiative, six years back is now a global phenomenon. I don't see today anybody in the pharma industry who has not heard this term OSDD". The biggest achievement of OSDD is in bringing the term, open source pharma. Now on similar lines, Australia has launched open source malaria and also, various researchers across the globe have come together for open source pharma.

"It might not be 100 percent success, but we are way better than what we started." said Dr U C Jaleel, principle investigator, CSIR OSDD research unit. He added, "It is the first Indian system where many scientists are directly addressing the problem of TB. And also, it has created a whole new research ecosystem for drug development and made aware of the need for collaborative effort for drug discovery of the neglected diseases."

Perhaps the biggest achievement of OSDD is the recognition of open source platform for drug discovery, so much so that Mr Matthew Todd (Associate Professor, University of Sydney) is coming to India, to write a book on OSDD.

By and large, OSDD has evolved as a globalized platform and emerged as a major alternative for the drug development for neglected diseases. Since drug discovery is a long process, typically takes 10-15 years, hopefully in the years to come, it will launch a drug. My target is 2022, when at least we can introduce some medicines in the market, sums up Prof. Brahmachari.