



The Problem: Massive Health Needs Left Unaddressed

The pharmaceutical industry has failed to deliver in countries both rich and poor - for neglected disease, for antibiotics, and for affordable cures generally. According to the WHO, only 10% of global health R&D is devoted to diseases of the global poor. New drug prices in OECD markets can exceed \$80,000 annually. Per Tufts, it takes \$2.5 billion and 10-15 years to develop a new drug. Productivity in the pharmaceutical industry (as measured by spending per new molecular entity) has been *declining* exponentially- eRoom's Law rather than Moore's Law. The needs of billions are left unmet by an industry ripe for upending.

A radical, alternative, end to end, open source pharmaceutical system dedicated to breakthroughs in affordable medicine is possible. It would leverage exponential advances in computing power and collaborative technologies; alternative approaches to intellectual property; and the vast reach of the generics industry.

The Approach: Linux for Drugs

We seek to develop a new paradigm for drug discovery. Open source software such as Linux and Android are crowdsourced, patent-free, affordable, and market-dominant. In brief, open source pharma is 1) crowdsourced and computer-driven drug discovery; 2) IT-enabled clinical trials with open data and crowdsourcing (including a possible results-based financing mechanism to fund them), and 3) generics manufacture.

Funders

- Ratan Tata and the board of the Tata Trusts have committed \$3M (\$1M per year for 3 years) to establish the Open Source Pharma Foundation, first office in India, but an international group.
- Geneva-based Global Fund to fight AIDS, TB, and Malaria, via its India Health Fund
- EU-funded European & Developing Countries Clinical Trials Partnership (project financial support)
- Rockefeller Foundation
- Open Society (Soros) Foundations (pre-OSPF)

The Status: Achievements to Date

Clinical Trials: *OSPF hopes to commence phase 2 clinical trials in 2018, nearly 10 years ahead of schedule versus a big pharma model and at less than 1/10th the cost.* The approach hinges on repurposing of already approved generic drugs that are "in the open" in terms of intellectual property, and testing them for efficacy against tuberculosis. A partnership agreement with the Chennai-based NIRT, the National Institute for Research in Tuberculosis, has been signed. An NIRT-OSPF clinical trial exploring the efficacy of metformin, a commonly used diabetes drug, against TB has received ethical approvals and been prospectively registered on the government of India clinical trials web site- www.ctri.nic.in, CTRI No. 011176 . We will imbue clinical trials with open source methodologies to the maximum extent feasible; gradually at first and increasing over time.

Vision: The Open Source Pharma statement of vision, mission, and 10 operating principles have been adopted by members of leading global institutions, including the WHO, Medicins Sans Frontières, the NIH, France's INSERM, the national lab system of India's Open Source Drug Discovery (OSDD) program, leading research universities, and Big Pharma. See www.opensourcepharma.net/vision.

Partnerships: An open source *in silico* drug discovery lab is being established at the National Institute of Advanced Studies, on the Indian Institute of Science campus in Bangalore.

Publications: Three scientific papers published in international peer-reviewed academic journals.

Achievements by the broader movement, including by partner OSDD, include a crowdsourced annotation of the tuberculosis genome by hundreds of students using Facebook and Twitter; awarding over 100 student online research fellowships; creating a network of open source researchers; holding the world's first open source pharma global conferences (at the Rockefeller Bellagio Center in Italy, and a castle in Germany); and access to the national supercomputer system of India for crowdsourced open source drug research.

Media

Articles in *BBC*, *The Economist*, *The Lancet*, and national newspapers in India have mentioned the movement.

Next Steps

Drug Development: *"find a treatment for tuberculosis"*

- Explore new treatments via repurposing existing generic drugs
- Conduct open call to commence what is perhaps "world's first open source clinical trial"
- Conduct *in silico* computational projects to develop treatments for TB

Platform Development: *"create global open source pharma ecosystem"*

- Build India's (and the developing world's) first PDP (Product Development Partnership, a nonprofit drug development company), to conduct clinical trials for neglected disease
- Augment platforms for international scientific collaboration (e.g. open source plug-in for scientists.com)
- Explore innovative results-based finance mechanism (via G-20)
- Software: Develop "LAMP stack for drugs" – affordable open source software for use in drug discovery, as an alternative to current highly expensive software, to democratize innovation
- Gamification– Create a "Fold-It" (popular protein folding game) for Drugs"
- Education: grant and manage fellowships of students, supporting the next generation ("finding the person who will find the molecule")
- Conferences: conduct global open source pharma conferences
- Public Awareness/Policy: work with patient communities; social media; publish white papers

Overall goals:

- Build open source pharma movement and innovation model
- Work towards alternative end to end pharma system; create world's first open source treatment
- Target- exponential results: Reduce cost by 90+% and time by 50+% over standard big pharma model

Partial List of Players in Open Source Pharma Foundation

- Tanjore Balganes, Ph.D. (former head of R&D Astra Zeneca India; co-founder, board member)
- Samir Brahmachari, Ph.D. (former head, CSIR/national lab system of India; founder, OSDD; global pioneer in field of open source drug discovery; advisor)
- Jaykumar Menon, J.D., M.I.A. (McGill University; human rights lawyer and social entrepreneur; co-founder, board member)
- Bernard Munos, MBA (ex-Eli Lilly; pharma innovation expert/Forbes contributor; author of influential papers in Nature on pharma innovation; named one of 25 most influential people in biotech; co-founder)
- Allison Randal (software developer and open source strategist; board member and ex-President of Open Source Initiative; co-founder of FLOSS Foundations; advisor)
- Nibedita Rath, PhD (scientist in biotech firms and OSDD; principal scientist - medicinal chemistry)
- Zelalem Temesgen, M.D. (head of TB Center, Mayo Clinic; scientific advisor)
- Matthew Todd, Ph.D. (University of Sydney; founder, Open Source Malaria; co-founder)

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