

OPEN SOURCE PHARMA FOUNDATION



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Toward a New, Open Source Pharmaceutical Industry

The Need

The traditional approach to pharma R&D has failed to deliver in multiple ways:

- Efficiency. As measured by cost per new molecular entity, efficiency is by some counts *declining* exponentially.
- Health needs. The key health needs of billions of people, including infectious tropical disease in developing countries, and antibiotics globally, are simply being left unaddressed, with millions dying each year.
- Affordability. Drug prices are out of the reach of many, and can be higher than \$80,000 per patient annually.
- Absolute Expenditure. R&D costs on a risk-adjusted basis for a new drug are now estimated to exceed \$3 billion.

The Approach

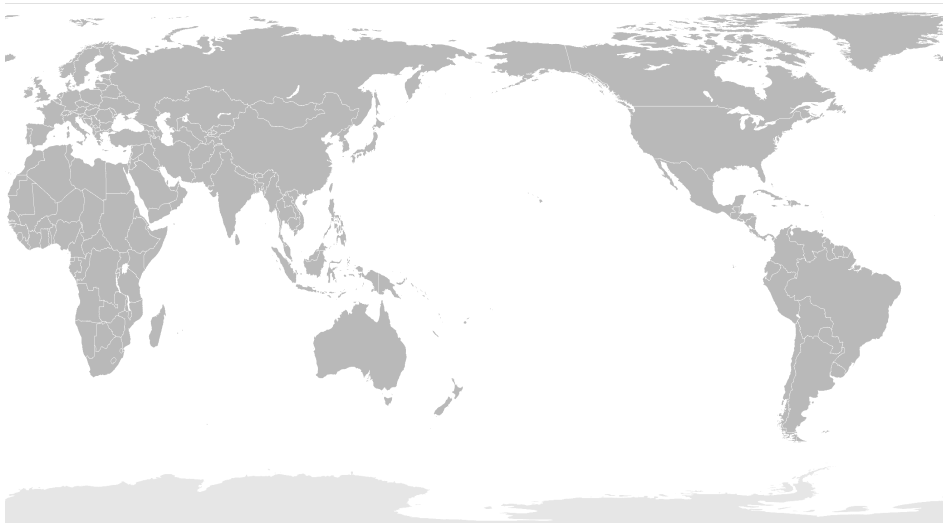
What is to be done?

Our concept is simple, and arguably the future: Open Source Pharma. Very simply, it is a new, high-tech way to produce affordable new cures. In four words: Affordable Medicine for All. In three words: Linux for drugs.

Inspired by Linux, and leveraging radical advances in computing power, crowdsourcing, and alternative approaches to IP, we can generate and catalyze new candidates and cures, to be manufactured by the existing generics industry, which can take them forward on a market, yet affordable, basis. We can create a world of affordable medicine for all. And along the way we can demonstrate a new methodology of pharma R&D, applicable to multiple diseases.

How is this possible?





Linux for drugs

Classically, the pharmaceutical process has three stages – discovery, development, and manufacture. In brief, open source pharma is a) crowdsourced and computer-driven drug discovery; b) IT-enabled clinical trials with open data and crowdsourced protocols, and c) generics manufacture.

More specifically, open source principles apply as follows:

- **DISCOVERY**

The discovery stage - in its earliest phases often called *in silico* drug discovery, or *virtual drug design* - is particularly amenable to computational and crowd-sourcing approaches. Leaders include India's Open Source Drug Discovery, and the University of Sydney's Open Source Malaria. Major completed projects include an annotation of the tuberculosis genome, done via crowdsourcing and over 700 students using Facebook and Twitter; publication of several papers based on *in silico* research; the awarding of over 100 student research fellowships in open source drug discovery; use of the national supercomputer system of India by scientists and students for open source drug discovery; and drug candidates approaching the clinical trial stage. If we can elevate the number of participants from scores to hundreds and thousands of researchers, and through intelligent approaches generate better drug candidates with lower failure rates at later stages, that will be a huge advance. Further, it is worthy to note that non-computer based, but still crowdsourced, approaches are also highly developed – for

example the global crowdsourced work in bacteriophages, where students and scientists collect soil and water samples.

- **DEVELOPMENT**

The development stage –encompassing pre-clinical and clinical trials, is the most expensive and a principal bottleneck. By availing ourselves of the latest in IT-enabled approaches, we can bring down costs by a factor of 2 or more, while yielding more data. Apple Computer's new ResearchKit, for example, developed in part by Open Source Pharma movement member Sage Bionetworks, indicates the power of mobile telephony in medical research – and evinces the interest of a powerful new player in this type of approach. Another key aspect is the clinical protocols- the critical stage at which a large proportion of trial costs are determined. The protocols can be enhanced via crowdsourced review, as per the methodology of movement member and Boston startup Transparency Life Sciences. And the data itself (with rigorous anonymization and privacy protections) can and should be made public, open, and searchable, which will obviate the wasteful pursuit of disproven and colossally expensive avenues. And by conducting trials in India, costs can be further reduced.

- **MANUFACTURE AND DISTRIBUTION**

The last stage, affordable manufacture and distribution, is already in place. The generics industry, with a stronghold in India, can be conceived of as an open source manufacturing industry, as it is built on principles of being patent free and producing



Affordable medicine for all

affordable cures for pennies a pill. And distribution and adoption, a huge challenge in other areas of the social development sector, are relatively trouble-free in health: national and private health systems reach billions, and people are used to taking medicines.

Thus, an end-to-end comprehensive open source system is possible. We could create the world's first open source drugs, which would be inherently affordable, and target major diseases such as TB. And the lessons from the new methodologies could make drugs everywhere more affordable.

The Dominance of Open Source Software

In the software field, open source software (defined roughly as crowdsourced, created through transparent processes, essentially zero cost to the user, and patent free) has actually dominated certain market segments by leveraging the brainpower and idealism of thousands.

Table 1: Open Source Software Market Dominance¹

Market Segment	Open Source Product	Market Share
Mobile phone operating systems	Android	83%
Tablet operating systems	Android	75%
Supercomputers	Linux	97% of top 500
Cloud Computing	Linux	75% of large companies
Web Servers	Apache and others	65%

Even more intriguing is the *LAMP Stack*, the set of open source software that has literally powered much of the Web (e.g. Facebook, Amazon, Twitter, and more)(Table 2). The robustness and low price and common accessibility of the LAMP Stack is arguably what enabled the Web to bloom. Startups (and large companies) did not need to pay for expensive Web technology infrastructure, which radically reduced the price of innovation.²

¹ Source: "2015: Open Source Software Has Won, But it Isn't Finished" Glyn Moody, <http://www.computerworlduk.com/blogs/open-enterprise/open-source-has-won-3592314/>

² A successor of sorts is the MEAN Stack: MongoDB, Express.js, Angular.js, and Node.js.



Table 2: The LAMP Stack

Software Program	Function
Linux	Operating System
Apache	Web Servers
MySQL	Database
PHP/Perl	Web Scripting

The question arises – could we create a LAMP Stack for pharma? An open source, commonly available resource that would dramatically bring down the cost of R&D and empower armies of innovators?

Open Source Pharma Vision Statement

As enunciated and unanimously adopted by the participants at the first annual Global Open Source Pharma conference at the Rockefeller Foundation Bellagio Center in Italy, either in their individual or organizational capacities and by many since, the founding principles of Open Source Pharma are set forth as follows:

<http://www.opensourcepharma.net/about.html#vision>

VISION

Medicine for all.

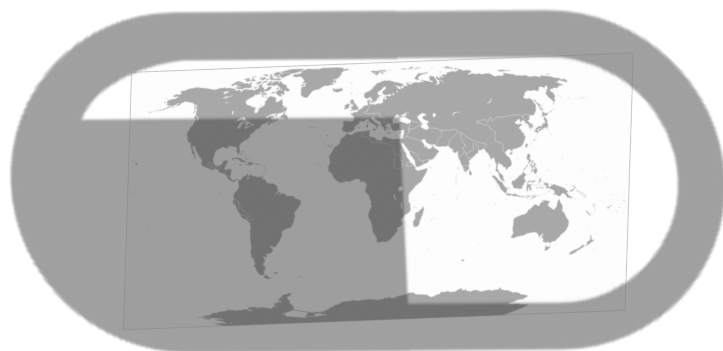
MISSION

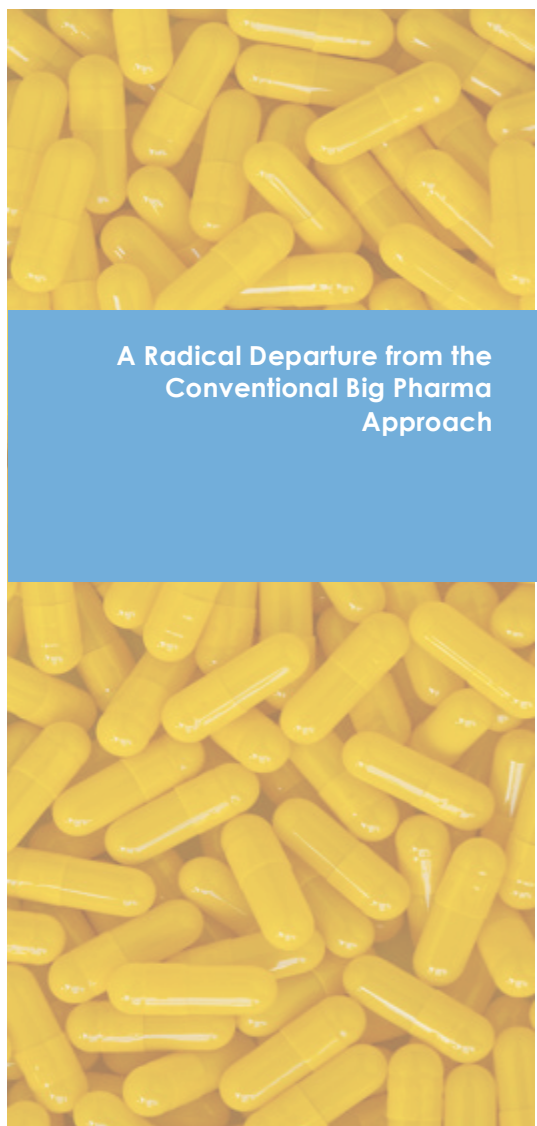
Create a movement that includes existing initiatives and develops an alternative, comprehensive, open source pharmaceutical system driven by principles of openness, patient needs, and affordability.

OPERATING PRINCIPLES

1. Employ radical openness, sharing, and transparency.
2. Leverage the global brainpower of the crowd.
3. Adopt open and innovative approaches to the management of intellectual property and financing.
4. Create monetary and nonmonetary reward systems for R&D that are alternatives to the prevailing proprietary model.
5. Support open access to papers, data, and other research outputs.
6. Convene and mobilise thought, opinion, and community leadership in reshaping R&D.
7. Combine small, nimble, cost-effective facilitating structures able to harness the power of individuals and entities.
8. Deliver affordable products.
9. Place patients and their interests at the center of the R&D model and the pharmaceutical system.
10. Develop a portfolio focused on critical gaps in global health where traditional market approaches are failing, e.g., anti-infectives.

Please note: The above statement was adopted by participants of the July 2014 Bellagio Center conference in their individual capacities. It does not necessarily represent the views of the organizations to which they belong.





A Radical Departure from the
Conventional Big Pharma
Approach

Importantly, the influential and acclaimed adopters of the Open Source Pharma vision statement (in their individual or organizational capacities) come from across sectors, geographies, and stages of the pipeline:

OPEN SOURCE PHARMA VISION STATEMENT ADOPTION

<u>Sector</u>	<u>Adopter</u>
Multilaterals	WHO
National Governments	USA's NIH India's CSIR France's INSERM
NGOs	Medicins Sans Frontieres Cures within Reach
Universities	Oxford Paris McGill University of Sydney
Big Pharma	Johnson & Johnson's Janssen Labs Boehringer Ingelheim
Pharma Startups and SMEs	Transparency Life Sciences Taros Pharmaceuticals
Think Tanks	Innothink Faster Cures Sage Bionetworks Aralak Institute

Why Open Source Pharma is Different

Open Source Pharma is of course a radical departure from the conventional Big Pharma approach.³

A number of alternative approaches to pharma do exist, including biotech startups, nonprofit product development partnerships, private sector crowdsourcing platforms, and open innovation partnerships. An important distinction is that they lack open approaches to IP (and thus the affordability component), crowdsourcing, and true sharing and openness. One should distinguish between *open innovation*, which could mean two companies collaborating, and *open source*, where the effort is open to, and leverages, the entire world.

There are a few current open source-type approaches to pharma. Prominent among these are OSDD, which enjoys the benefits and strictures of being part of the Government of India, and Professor Mat Todd's Open Source Malaria. These would each be extended – beyond early stage discovery to all stages of drug development, to other parts of the globe, to having better IT platforms.

³ Big Pharma is ripe for disruption for many reasons: its cited \$2+ billion cost to create a new drug; declining innovation (as measured by new molecular entities per millions of dollars invested); often high drug prices (e.g. \$84,000 for the Gilead hepatitis drug); and relative lack of attention to neglected disease (the most widely used TB drug, for example, is over 50 years old, with an 8+ month regimen for which compliance is notoriously difficult).



Functioning Mechanism

Open Source Pharma is a meme and a movement, a coalition of individuals and groups united by a single vision.⁴ It has a far reach: a WHO news article about the open source pharma approach went to 10,000 in the WHO community, a social media blast ("Thunderclap") about Open Source Pharma went to over 300,000 recipients.

As a new legal entity, the new Open Source Pharma Foundation, based in Bangalore, India, but a global effort, and with subsequent offices in other countries, will play a supportive role to the institutions and individuals in the movement, such as Open Source Malaria, OSDD, and others, akin to the Linux Foundation (which incidentally is also a partner), supplying them with contacts, students and researchers, funds, and other assistance.

Our overarching aim is to build the aforementioned end-to-end open source pharma system dedicated to delivering breakthrough affordable medicines, particularly in areas of public health need. We will do so by applying open source techniques and principles at each and every stage of the value chain, from discovery to development, manufacture, distribution and use, attempting to address each bottleneck or piece of the puzzle.

The Open Source Pharma Foundation's initial projects are the following (further detail in Appendix):

- PDP - Product Development Partnership, or nonprofit drug company
 - Led by Dr. Tanjore Balganes, former head of Astra Zeneca India
 - First PDP to be based in India, or indeed the developing world
 - Will develop TB and other neglected disease drugs, using open source techniques, via a spinoff entity.
- Platform – a series of outreach and experimentation activities to tap the global brain
 - General Public Outreach (web, patient communities, social media, citizen science and gamification, events)
 - Education (students and universities)
 - Scientific Community Outreach and Crowdsourced Science – create a wireframe to enable online collaboration; conduct crowdsourced science, involving scores to thousands of researchers

The future Open Source Pharma Foundation site in North America will have a software bank (to hold copyrights for drug discovery software and make it freely available), a thought leadership/policy center, crowdsource research, and help start an open source social benefit private sector company dedicated to affordable medicines.

Financial Support to Date

The Tata Trusts, via action of their Board, chaired by Mr. Ratan Tata, have committed \$3M (\$1M per year for three years) to establish the Open Source Pharma Foundation in India. For a formal announcement, please see http://srft.org/news/events/tata_trusts_commit.htm, and the front page of the Sir Ratan Tata Trust web site at <http://www.srft.org/>. Other funders for the Open Source Pharma movement include the Rockefeller Foundation and the Open Society Foundations.

⁴ See Bellagio vision statement from the 23 participants - from big pharma, small pharma, the WHO, the EU, universities, MSF, pharma innovation advocates, and open source theorists, across multiple geographies and all phases of the pipeline. <http://www.opensourcepharma.net/vision.html>



OSPF – Key Players

- Tanjore Balganes, PhD. *Co-founder, Board Member, Head of PDP unit.* Former head, and tuberculosis scientist, Astra Zeneca India. Former Project Head, Open Source Drug Discovery (OSDD) Unit of CSIR.
- Urmi Bajpai, PhD. *Scientific Collaborator.* University of Delhi. Crowdsourced research performed by biology undergraduates.
- Samir Brahmachari, PhD. *Senior Science Advisor.* Former DG, CSIR. Founder and Chief Mentor, OSDD. Founder, Indian Institute for Integrated Genomics and Biology. Member, Human Genome Commission. Bose National Fellow. Former Professor at Indian Institute of Science. Student of GN Ramachandran.
- Alina Grenier-Arellano. *Program Consultant.* Master's Student in Entrepreneurship, University of Amsterdam.
- UC Jaleel, PhD. *Director, Crowdsourced Science.* Convenor, Tata – OSDD Online Student Fellowships. Expert in crowdsourcing of science projects among large numbers of researchers and students.
- Peter Kolb, PhD. *Scientific Collaborator, Global Conference Organizer.* University of Marburg, Germany.
- Ariel Lindner, PhD. *Scientific Collaborator.* Co-founder, Centre de Recherches Interdisciplinaires, University of Paris. INSERM.
- Amanda McPherson, *Informal Advisor.* Advisor to, former chief of marketing, and early employee of Linux Foundation, which now has 100+ employees.
- Jaykumar Menon, J.D. M.I.A. *Co-founder, Board Member.* Professor of Practice, McGill University Institute for International Development. International human rights lawyer, scholar, and social entrepreneur.
- Bernard Munos, MBA, *Co-founder, Scientific Advisory Board.* 25 year Eli Lilly veteran. Founder, Innothink. Senior Fellow, Faster Cures. Forbes contributor. One of 25 most influential people in biotech, per Fierce Biotech. Board Member, Glenmark Pharmaceuticals, Mumbai.
- Ochoro Otunnu, JD, *Informal Advisor.* Co-founder, Africa Aids Initiative.
- Muli Ben Svi, PhD (Economics), *Senior Advisor.* 10 years as senior executive at Teva Pharmaceuticals, Tel Aviv, world's largest generic drug manufacturer. Ex-Brigadier General, Israeli Army.
- Matthew Todd, PhD., *Co-founder, Member, Scientific Advisory Board.* University of Sydney. Founder, Open Source Malaria. Noted figure in open source science.
- Tata Trusts. Mr. Ratan Tata is the chair of Tata Trusts board. He and other board members approved funding for OSPF after an in-person presentation. A Tata Trusts employee is a board member of OSPF.
- Andy Updegrove, JD. *Informal Advisor.* Partner, Gunderson Updegrove, LLP. Lawyer, specialist in open source and open standards, counsel to Linux Foundation.



Global Conferences

The OSPF is an outgrowth of the first global conference on Open Source Pharma, held at the Rockefeller Foundation Center in Bellagio, Italy in July 2014. The Bellagio center is known for launching globally significant ventures, such as the Green Revolution, and the Global AIDS Vaccine Initiative. The 23 participants came from an array of sectors, geographies (principally Europe, North America, and India) and from all stages of the pipeline.

The meeting brought together for perhaps the first time the neglected disease community, pharma industry innovation critics, and open source theorists. All ascribed to a common vision, mission, and operating principles statement in their individual or representative capacities.

The WHO subsequently included a report of the meeting in its newsletter to thousands of professional staff,⁵ and a social media blast reached over 300,000 people.⁶

The 2nd Annual Global Open Source Pharma Conference (OSP2) was held over 3 days at Castle Rauischholzhausen, just outside of Frankfurt, Germany in September 2015. Participants brainstormed powerful new ideas for the open source movement, including the world's first open source clinical trial, a wireframe to organize global researchers and resources, an open source pharma investment fund, and using repurposing strategies to radically accelerate and decrease the cost of powerful new and affordable drugs in areas of severe health need, which are being taken forward. On an economic note, the conference evinced OSPF's outstanding fiscal management and resourcefulness. The entire OSPF net expenditure, including labor, meeting rooms, lodging, board, was less than \$4000. OSP2 was covered on the front page of a leading global tech news outlet,⁷ and sparked discussion by the founders of the open source software movement. Future conferences will be held in conjunction with the Mayo Clinic, and in Silicon Valley.

⁵ <http://www.who.int/tdr/news/2014/open-source-pharma-mtg/en/>

⁶ <https://www.thunderclap.it/en/projects/15157-medicine-for-all>

⁷ <http://science.slashdot.org/story/15/09/05/1825252/what-is-open-source-pharma-and-why-should-you-care>

Media Coverage

Coverage of the Open Source Pharma movement includes the following:

- Economist Magazine, November 28, 2015: "Billion Dollar Babies"
<http://www.economist.com/news/business/21679203-high-cost-rd-used-explain-why-drugs-giants-merge-and-why-they-must-charge>

Ensuring that the benefits of greater research efficiency are fully passed on to governments and health insurers would require drastic changes, such as, say, abolishing the patent system and finding some other way to incentivise basic research. **Among the more imaginative ideas in this vein, the open-source pharmaceuticals movement** is experimenting with using prizes as an incentive for teams of volunteer scientists to work on new treatment approaches. Once invented and tested, the drugs would be free for any firm to make.

- The Hindu – Business Line, September 29, 2015: "Tata Trusts support OSPF — the 'Linux for drugs'"
<http://www.thehindubusinessline.com/economy/tata-trusts-support-creation-of-open-source-pharma-foundation/article7703087.ece>
- Financial Express, October 1, 2015: "Tata Trusts Supports Creation of OSPF"
<http://www.financialexpress.com/article/pharma/latest-updates/tata-trusts-supports-creation-of-ospf/144334/>

Tata Trusts Supports Creation of OSPF



Financial Sustainability

Financial sustainability and leverage can be achieved in multiple ways:

- Crowdsourcing volunteers. In the first instance, the crowdsourcing of scientific volunteers is radically inexpensive. OSDD has shown that scores and even hundreds of researchers can be coordinated with a core scientific staff of 2-5.
- Revenues. In the long term, revenues can also be generated – via consultancies, goodwill payments from OECD markets for any new drugs, and, if achievable, priority review vouchers, which have garnered in some limited cases hundreds of millions of dollars.
- In kind. Via leveraging the in-kind resources of academic and government and pro bono private sector scientific institutions, existing distribution systems, and the business model of the generic industry.
- Inexpensive public goods. Delivering public goods at a fraction of conventional cost structures provides tremendous value for money for public and philanthropic funding sources.

Post 5-Year Plan

After a five year period, we would hope to see Open Source Pharma physically established both in India and in North America, with influence worldwide, and to have it become a growing movement and model, demonstrating an urgently needed alternate approach for creating affordable new cures, particularly for neglected diseases.

We may expand from a focus on TB to other neglected diseases, and to other low-revenue areas such as antibiotics, and even to affordable drugs for lucrative diseases such as cancer, to disrupt pharma as a whole, with the aim of “medicine for all.”

Drug development is a long-term game – clinical trials in India take 8 to 9 years. Within 5 years, we would seek to have a new cure for TB, the second largest infectious disease killer globally, well underway, and into Phase 2 clinical trials. We would also seek to have “project” funding, rather than mere “core funding”, at level of perhaps 10x, in place.

We would see a transformation in subject matter - from a focus on education, awareness, and purely computational work, into wet lab and further downstream work, as capacity in India grows, paving the way for a more complete pharma industry in India. As the model catches on, commercial and revenue possibilities would mature, as happened in the Internet space.

Most critically, the world's first open source drugs would be on or well on their way to market, demonstrating a new open source pharma ecosystem. They would save literally save millions of lives and ameliorate untold suffering. And along the way, via the India office, and leveraging India's prowess in IT, we would hope to have inspired and guided thousands of young science students and researchers, reaching beyond the elite institutions to the immense untapped talent of India, who are currently suffering from an overly abstract educational system, and trained them in actual scientific inquiry in service of grand human challenges.



Appendix A

Additional OSPF Program Detail

1) PDP

A historic effort – this would be the first PDP (product development partnership – a nonprofit drug company) to be based in the developing world. This would be ultimately spun off into an independent nonprofit corporation, created under India's Section 8, and thus eligible to receive both grant funding, as well as private sector funding.

It would engage with other PDPs to conduct clinical trials for neglected disease in India.

Amplifying the need, under the law, in order to introduce a new drug into India, clinical trials must be conducted in India. There is a dearth of groups that could organize such trials, as it is insufficiently lucrative for big pharma, and as current NGOs lack the capacity.

In addition to being the first Indian PDP, the venture is also unique among PDPs because it pursues an open source approach, bringing to bear efficiency and power of the new open techniques, as exemplified by the radical work of OSP member Transparency LS, a Boston-based group that brings efficiency to clinical trials (via crowdsourced input into design, and via mobile and advanced IT for the trials themselves, which today are often still conducted via paper and fax). It will also explore opening up the data. The new company would work specifically on TB, but could work across all neglected diseases, another distinction from existing PDPs.

2) Platform

The remainder of the OSPF would conduct a series of catalytic activities and experimental projects in the open source arena, in outreach, crowdsourcing and education, to help create an alternative pharmaceutical arrangement and R&D model dedicated to affordable cures.

A. Public Outreach/Movement Building

1. Social Media/Web/Event Planning (~1 FTE)⁸

- Maintain the opensourcepharma.net web site.
- Continue social media efforts on Facebook, Twitter, Storify, Thunderclap, Medium.
- Help organize the roughly annual Open Source Pharma global conferences (next conferences may be with Mayo Clinic and in Silicon Valley)

2. Patient Community Organizing (~1 FTE)

- Work with patient groups (e.g. for TB) to spread awareness of their issues – a key element; much of the progress in neglected disease was done after advocacy around the Doha Round.

3. Funding and fundraising support – for OSP members and affiliates

⁸ Near future idea: Work with Stanford's Professor Vijay Pande, to create a SETI or a Fold-It for neglected disease, to engage the masses. SETI, the Search for Extra Terrestrial Intelligence, allows millions of citizens to donate their computers to the SETI cause. The famed Fold-It protein game allows laypeople to participate in biomedical research.



- Innovative Finance:
 - Q-AMC. Develop and market idea for a new results-based financial instrument- a \$250+M “Q-AMC”- Quasi-Advance Market Commitment from G-20 governments. Q-AMC would fund open source/affordable IP regime drug candidates for neglected disease that have already cleared Phase 1 clinical trials. Would address key bottleneck. Project coordinator: Prof. Jaykumar Menon. Advisors: Prof Thomas Pogge, famed Yale professor and founder of Health Impact Fund, Mel Spigelman, CEO of TB Alliance.
 - Open Source Pharma Fund. A social investment fund with investors from big pharma, government, and philanthropy, with pooling and tranches of payouts depending on the lucrativeness of the disease. Project coordinator: Andy Updegrove, Esq., of Gesmer Updegrove LLP.
 - Grants
 - Open Source Grants. Provide grants to open source projects proposed by researchers and organizations. Funding decisions and grant criteria to be made by advisory committee. Potentially require grantees to show other funders or fundraising plan. Form possible open source alternative to NIH research grant model, with affordability and openness guarantees built in.
- #### 4. Citizen Science
- Gamification
 - Explore creating an analogue to Fold-It, the popular protein folding game, for open source science and for neglected disease. Potential collaborators include Stanford’s Professor Vijay Pande (involved in Fold-It). Potential project manager: Frederick Lim, ex computer game programmer and former Morgan Stanley banker.

B. Education

- Work with students (graduate and undergraduate⁹), and young scientists
- Expand existing Tata Open Source student fellowship (over 100 student participants to date)
- Further expand Open Source Women’s Fellowship
- Further expand practice of awarding funds to students, not to PIs, and making fellowship “portable”, to totally change power dynamic in education.
- Universities:
 - Explore setting up programs at universities/converting their existing programs to open source. (Note that many universities have net negative revenues from their patent licensing programs).
 - Endowed Chair. An endowed chair at a university for research into neglected disease, given to a university, on condition that the research be open source. As a point of reference, endowed chairs at IIT-Delhi are as little as Rs 30 to 100 lakhs / USD \$50-\$150k <http://alumni.iitd.ernet.in/?q=content/chairs>, whereas chairs in the US cost roughly US\$1-5 million.

⁹ Future idea: Undergraduate Research Centre. Grant to coordinate an undergraduate open science research program into neglected disease, drawing from the untapped resource of thousands of undergraduate (or early graduate) science students nationwide, so many without guidance, and enabling them to participate in real research, in service of a social cause. (Possibly the most transformative element- mobilizing the masses of students). Interested partners: DNDi- Geneva, Delhi University.



C. Crowdsourced Science/Scientific Community Outreach

1. Coordinating large numbers of scientists in low-capital drug discovery work

- In Silico Research/Small Molecule Design Centre. Computation and crowdsource-heavy research, including projects such as i) designing bespoke molecules via cheminformatics and bioinformatics that are open source candidates for cures for neglected disease and putting them up on the web, ii) annotating genomes of other neglected diseases, iii) examination of off-patent cancer drug literature for affordable cancer cures.

2. Exploring a "Facebook for small molecules"

- An online platform where partners who have a particular small molecule, or need a small molecule, can connect

3. Wireframe for open source pharma research, serving as a portal and means of connection and collaboration for players at all stages of the pipeline on a given disease.

4. Support for partner initiatives

- Via crowdsience

5. Repurposed drug research

- Not "drug rescue" (pursuing abandoned drug candidates), which receives much of the attention, but rather focusing on already approved and already affordable generic drugs, exploring their potential for use against other diseases.
- Repurposing approved generics is radically cheaper and faster than de novo development, and generates affordable cures. It seems that no comprehensive scan of already approved generic drugs has been attempted.

6. Breakthrough venture: Creating the world's first "open source clinical trial" (See Appendix B).



Appendix B

World's First Open Source Clinical Trial

A Systematic Approach to Develop an Open Source Repurposed Generic Drug

Funders: European Developing Country Clinical Trials Partnership (EDCTP) and OSPF (both agreed in principle).

Stage	Description	Partners
Open call(s) for repurposing candidates	Already approved generic drugs with potential to be repurposed for major patient impact in areas of real public health need. Possible categories: 1) TB, ii) other specified disease, iii) potential catch all category.	Cure Accelerator, by Cures Within Reach (confirmed) Innocentive (likely) Collectively, built in audience of thousands of scientist-solvers
Open comments on the submitted repurposing candidates	Crowd comments on submissions	Crowd of thousands of scientist-solvers
Possible open comments on the evaluation criteria	Crowd may comment on selection criteria itself	Crowd of thousands of scientist-solvers
Selection of candidates	Committee chooses candidates to be moved forward to human interventional clinical trials (Phase 2)	Cures Within Reach (repurposing clinical trials NGO)
Crowdsource clinical trial protocols	Crowd comments on and improves upon draft trial protocols	Transparency Life Sciences (Boston company specializing in crowdsourcing of clinical trial protocols)
Utilize IT and mobile in trials	Bring the latest in IT and mobile to enhance clinical trials and reduce costs	Transparency Life Sciences Sage Bionetworks (co-creator of Apple Computer's medical Research Kit)
Crowdsource volunteers	Potentially elicit, via crowdsourcing, volunteers to enlist in the trials, and to help conduct the trials	
Open data in clinical trials	Make anonymized data available without delay	AllTrials (www.alltrials.net)
World's First Open Source Clinical Trial	All of the above adds up to the world's first open source clinical trial	
Multiple Candidates	Systematic program to take perhaps 10 ideas forward, so as to have 1-3 drugs emerge.	
Affordable Generic Drug	Any ensuing drug is generic and affordable, and targets an area of major public health need	

We would pursue the above protocol for multiple entities- perhaps 10 candidates, so as to have 1-3 new therapies emerge. The ensuing drug itself would be open source of sorts, and generic. It would be affordable, and target a major public health need.



Appendix C

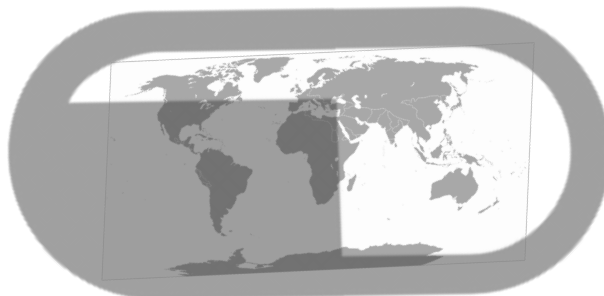
Biographies of Leadership

1. **Tanjore Balganesh**

Dr. T.S. Balganesh was the Project Head of the Open Source Drug Discovery (OSDD) Unit of CSIR, the national laboratory system of India. He obtained his Ph.D. from the Indian Institute of Chemical Biology, University of Calcutta, India and subsequently spent post-doctoral years with Dr. Sanford Lacks at Brookhaven National Laboratories Brookhaven (NY, USA). Later he was associated with Professor Thomas Trautner at the Max Plank Institute for Molecular Genetics at Berlin (Germany). He joined Astra Research Centre India as a Senior Scientist in 1987. He took over as Head of Research at AstraZeneca R&D India in 2000 focusing the unit on discovering novel drugs for the treatment of Tuberculosis. Further as a VP Discovery Research AZ, he handled all the research activities of this R&D unit.

2. **Jaykumar Menon**

An international human rights lawyer, scholar and social entrepreneur, Jaykumar Menon is currently Professor of Practice at the McGill University Institute for International Development, in Canada. He holds a JD and a Master of International Affairs from Columbia University and completed a BA and one year of medical school at Brown. His research, teachings and practice focus on open innovation approaches such as crowdsourcing, innovation prizes and open IP to realize human rights and next generation economic rights including the right to food, water and health. He is a founder of the Open Source Pharma Foundation, which aims to help generate breakthrough affordable new cures in the areas of public health.



3. **Bernard Munos**

Bernard Munos is the founder of InnoThink, a consultancy that focuses on pharmaceutical innovation—specifically, where it comes from and how to get more of it. He was previously an advisor for corporate strategy at Eli Lilly, where he focused on disruptive innovation and the radical redesign of R&D. His research has been published in Nature and Science and profiled by Forbes magazine. FiercePharma named him one of the 25 most influential people in biopharma. He is a Board Member of Glenmark Pharmaceuticals, Mumbai.

4. **Matthew Todd**

Mat Todd was born in Manchester, England. He obtained his PhD in organic chemistry from Cambridge University in 1999, was a Wellcome Trust postdoc at The University of California, Berkeley, a college fellow back at Cambridge University, a lecturer at Queen Mary, University of London and since 2005 has been at the School of Chemistry, The University of Sydney where he is Associate Professor. He is the founder of Open Source Malaria.

