

Summary of Financing Global Health Ventures Workshop¹ September 25-27, 2005

A group of 52 people representing venture capital firms, foundations, NGOs and entrepreneurial ventures gathered in Cambridge, MA September 25-27th 2005 to evaluate strategies and innovative funding mechanisms based on the venture capital model and to determine the model's usefulness for investing in global health innovations.

The hosts of the workshop were Commons Capital (a socially-responsible venture capital fund) and CIMIT (The Center for the Integration of Medicine and Technology)/ Medical Access Program (MAP), a clinically-based non-profit organization focused on developing medical technologies for improving patient care in both developed and underserved patient populations.² These two organizations are working to catalyze investment in early-stage and growing businesses focused on combating the diseases of poverty in the developing world.

As a first step toward increasing investments in global health 'innovations', this workshop convened key stakeholders—foundations, entrepreneurs, global health experts and venture capitalists (both social and traditional) interested in investing in health products for the developing world. An Advisory Committee with representatives from The Bill & Melinda Gates Foundation, Bio Ventures for Global Health, CIMIT/MAP, Commons Capital, Kaizen Craft, PATH, and The Rockefeller Foundation, guided the development of this workshop.

We were ably led by our moderator, Dr. Lincoln Chen and two additional session chairs, Mario Gobbo and Cathy Clark. This document summarizes the overall conclusions from each session. There is no way to capture the rich and lively discussion in which we all participated, but this document will serve to summarize points of agreement and debate and as a record so that we can move forward from a common understanding. Key actionable follow-up is on pages 9-10.

C.K. Prahalad- 1st Keynote³

A keynote address by C.K. Prahalad, author of *The Fortune at the Bottom of the Pyramid*, challenged participants to turn some of the logic of the workshop on its head: he noted that we hypothesize that (social) VCs should perhaps lower their expectations but argued that if we want sustainable development, social actors should change the delivery systems and focus on making their business models attractive to traditional VCs. He asked the important question of whether "the poor" are a constituency or a problem to be solved, and argued that the bottom of the pyramid (BOP) is likely to be a new source of innovation and new markets. His cases, focusing on health care

¹ The workshop was funded by The Bill and Melinda Gates Foundation, The Rockefeller Foundation, The John M. Lloyd Foundation and Calvert Special Equities

² CIMIT is a consortium of the Harvard Medical School teaching hospitals, MIT and Draper Laboratory

³ Note that videos of both of the keynotes are available upon request.

companies in India were based on the principle that you need fundamentally to re-innovate to reach BOP markets. Four broad parameters, called non-negotiables, were put forth (a so-called four sided sandbox): 1) BOP deserves world class care; 2) Must have universal access (new price-performance levels); 3) Must be scaleable, the problems are huge; and 4) Start with price: Price- profit= design for cost, not cost+profit = price. Then, within these parameters, the new models should address the following: capital intensity, specialization, volume, patient acquisition, pricing, values and organization, workflow, talent leverage.

This keynote address provided a fresh, optimistic view of sustainable development with implications for the type of health entrepreneurs that VC, whether social or not, should engage. Innovations would include those which emerge *from* developing countries, those which specify design based on unique BOP markets, involve intense specialization and high volume, and involve new ways to access and serve patients in remote locations (demand creation). CK Prahalad sees the innovation process partially reversing itself in the next ten years—with innovations designed for the specific needs of the developing world emerging as new markets for the developed countries. The 'Bottom of the Pyramid' represents a wellspring of talent and entrepreneurial energy which if properly tapped can yield profits as well as sustainable development and improved health.

David Heymann- 2nd Keynote

Dr. Heymann, from the WHO, gave a global overview of neglected diseases highlighting technologies and innovations that had already been introduced and areas where resources and innovations are still needed. He noted that 45% of the deaths in developing countries are due to infectious diseases. He paid particular attention to new and existing 'push' and 'pull' mechanisms that facilitate the flow of vaccines and drugs for neglected diseases. Furthermore, he noted that for the past five years donor agencies were uninterested in 'drugs', but in a welcome policy shift, funding for 'pull mechanisms' is now acceptable. PPPs are trying to innovate with respect to how to get drugs out, and the next big step will be to evaluate these efforts.

For *vaccine preventable diseases* there is low utilization of the existing/new vaccines in developing countries except for targeted immunization programs. New vaccines needed include the following: Hep B, Hib, Yellow fever, Meningitis (Africa), and combination vaccines. There is also a continuing need for safe injection equipment and 'sharps' disposal.

For the *high mortality infectious diseases*: the situation is a fairly bleak one, with no vaccines, slow progress in vaccine development, failing antibiotics, highly endemic distribution of the diseases and an overwhelming need for sustained access to drugs and vaccines as well as research and development for vaccines, drugs and diagnostics.

For *disability-causing infectious diseases* like Schistosomiasis, Chagas, Onchocerciasis and trachoma, Leprosy, leishmaniasis, Guinea worm, lymphatic filariasis, deformities and Trypanosomiasis *rapid, effective diagnostics are still needed.*

Dr. Heymann noted that a constant 'pull' will bring the research along. Examples of 'Pull' mechanisms include the following: a) Polio vaccine demand forecasts provided to industry by WHO; b) Global Alliance for Vaccines and Immunization (GAVI); c) the new \$4b IFFI (bonds backed by future aid flows); and d) the potential for a uniform tendering

process for the Global Fund is a potential 'pull' mechanism under discussion. The audience noted the critical role of WHO as gatekeeper and its potential for greater 'signaling' to industry.

Dr. Heymann provided a comprehensive bird's eye view of the global epidemiological profile of neglected diseases. His presentation noted numerous places where new science, political will and innovation might enter the equation to provide new vaccines, drugs and diagnostics for the diseases of poverty. He ended by saying that VC needs to find the right fit where it can get in and out in a 5-year time frame.

Summary of the Workshop Sessions

Traditional VCs

Panelists: *Michael Lytton, Oxford Bioscience Partners; Ilya Nykin, Prolog Ventures; Vishal Gulati, Westbridge Associated; Marsha Wulff, WulffCapital*

The workshop began with a moderated discussion between 'traditional VCs' and other workshop participants. We confirmed many of our initial hypotheses regarding the fact that traditional VCs typically look for:

- Huge markets with a clear route to them
- Proprietary technology sometimes with a focus on a technology platform that has implications for more than one disease
- Strong management
- Profitable exits within short time frames (an average of 5-7 years)
- Geographic proximity is preferred
- Returns commensurate with risk (e.g. seek 3x on money. 20% IRR)

The discussants and the larger group also explored the following points related to traditional VC:

- As far as markets, the notion that poor people can represent potential new markets is not generally believed by VCs.
- Phase II/III investments popular now. Exit via acquisition.
- In 'global health' there's a complex constituency for exit (i.e. not big pharma) and there are regulatory issues, both of which make these investments risky to VCs
- On returns, VCs stressed the fact that GPs had a fiduciary duty to choose investments with highest financial returns
- If there is no established distribution channel (e.g. TB, dengue) the VC will want evidence of a partner for distribution
- Phase III guarantees are generally not considered very useful
- 'Pull' programs are generally not easy for small companies to deal with

With average investments of \$25-\$30M per deal, VCs pick and choose areas carefully. Some potential points of entry include the following:

- It was noted that therapeutics are a better business model (because unlike vaccines there are repeat customers)
- Time to approval is shorter for infectious disease (unlike, say, central nervous system innovations)
- Technology innovation is also seen as a good area for VC, if the potential markets are large enough.
- Delivery innovation is also a good place for VC, with lower barriers to entry

- Good potential for dual use product development
- VC is useful from Phase I – start of Phase III, but after that, companies can often get debt

While, in general, it did seem as though the traditional VC was simply not well-suited as a model for taking on neglected diseases, some participants came away convinced that traditional VC will invest in ‘global health’ given the right conditions and investment models, and that more work needs to be done to delineate markets and ensure that we’ve maximized investment from these sources.

Traditional VCs outside Europe/N. America

Panelists: Noah Beckwith & Davinder Sikand, Aureos Capital; Heather Sherwin, Bioventures; Raghu Mendu & Bobba Venkatadri, APIDC

The discussion continued with traditional VCs located outside Europe and North America. We heard from Aureos Capital (with an office in East Africa), Bioventures (South Africa) and APIDC (India).

APIDC- a fund of less than \$50M that takes a portfolio approach and makes investments of \$500K to \$2M in tele-diagnostics, an insurance company, pharmacy chain and a drug discovery company (risk is higher but IRR could be 40-50%) and seeks an overall return of about 25% to investors. They noted that there are more new drug approvals by the FDA in India than in any other countries—asking what has taken VCs so long to catch up. Aureos Capital has some 20 funds in emerging markets and has made six investments in healthcare and pharmaceuticals. Bioventures is a \$13.5M fund that has made eight investments to date.

It was again noted that the traditional VC model of 40% IRR will not work to develop products for neglected diseases. Key additional issues brought out included the following:

- Issues of language/expertise: Medical experts trying to translate into investor language. Investors have a hard time understanding medical/public health lexicon. How can we bridge gap for nervous investors?
- The essential point about the role of the Limited Partners in a VC Fund was discussed—the way to change VC investments is the ‘muscle’ - the Limited Partners or investors- as these are the people to whom the General Partners must answer.
- Invest within your own ‘zip code’ was seen as a prevailing requirement
- Regulatory requirements are a barrier—need to register in *each* country
- Pull of agencies to get drugs into market would be good to ameliorate early stage risk.
- Foundations/grants not geared to work with small companies
- The route to market is complicated by the dependence upon public sector delivery for many health innovations
- IP sales take the intellectual capital away from Africa.

Needed are the following:

- Networks and systems for finding deals

- PPPs : Product portfolio trying to build, not looking industry wide; doesn't pull in small companies right now.

Social VCs- 'Big ideas, relatively small pockets': with a little blue (social VC/foundations) and a little red (traditional VC), how do we create the purple dye?

Panelists: Jackie Khor, ProVenEx; Chris Elias, PATH; Denise Ciesielka, Acumen Fund; Christine Copple, ASM Resources Inc.; Kyle Peterson, Foundation Strategy Group; Willy Osborn, Commons Capital

We heard from several organizations already operating in the double bottom line (DBL) space as well as several hoping to develop new DBL/social VC funds in this space.

The Acumen Fund described their experience in providing loans and equity in relatively small disbursements (\$500K+) and focusing on distribution and downstream solutions. Foundation Strategy Group discussed their plan to develop a fund specifically for health care *delivery* in a few countries in Africa. Previous attempts to look at drugs and diagnostics required time frames that were too long, too much capital and skill sets that were out of their realm. ASMR described their experience developing a DBL fund for investments in health that allowed different returns to different types of investors (SBL and DBL). PATH discussed a search for a new kind of financing mechanism based upon their experience with a loan fund where it became clear that in many cases borrowers were actually in need of equity. Commons Capital is seeking to invest in global health but can't find willing partners with whom to syndicate. ProVenEx discussed their experience in co-investing with a traditional VC in Biosyn. CEI Ventures manages two VC funds and has invested in Chemogen.

Key issues that were brought out in the discussion included the following:

- A new financing mechanism may need to be capitalized by philanthropic and investor dollars. The concept is seen as too risky until proven.
- There's a need to combine the skills of VC with expertise of public sector. Can't make one from the other.
- Any such endeavor for global health must be coupled with technical and business assistance
- IRS / Governance is a concern: Non-profit may need to assess/decide on deal flow.
- Exits: financial exit vs. social exit. Approved by regulatory isn't exit for social component. How do we keep these two ideas coupled?
- Grants are restrictive, and loans are not enabling because they decrease the ability to take risk.
- Measurement: How do you measure risk/return for social impact?
- Within the DBL/social VC field we may want to distinguish between those seeking to develop a self-renewing fund and those seeking a high-growth fund or market rate returns.
- How to incentivize GPs is an important question for a DBL fund

The idea of a specialized Fund designed specifically to invest in global health solution companies was floated. Participants noted that we should call a spade a spade, asking

“Why not subsidize and pay for social returns?” developing parallel funding vehicles to provide subsidies. And in some cases simply continue to provide grants for neglected diseases. Some noted that large funders could really catalyze this industry. The new IFFI may even be a potential source of funding.

The group voiced the fact that this whole area feels “underpowered,” seeing a need for a new model that is radically different and that will meet the needs and expectation of both traditional VCs and Global Health Foundations. We also began to discuss the need for a transparent platform for exchange on the issue of global health investments—a platform that includes price history, knowledge in other areas, etc. to make the marketplace for global health more accessible.

Summary:

We left this session asking whether the move to social venture capital represented an incipient movement by foundations, one that could be better linked to the VC world in order to scale it. We also asked how co-investment could actually occur so that philanthropy could help to carve out a risk mitigated model in this space. We noted the need to be more explicit about social value asking, Can we put a monetary value to social values? And what is incentive for staff to deliver on social returns? How do we deal with the issue of social exits versus the financial exit and how to keep the two coupled?

Entrepreneurs: Is “controlled greed” the only sustainable business model”?

Panelists: Helen Lee, *Diagnostics for the Real World*; Anne-Marie Corner, *Cellegy*; Una Ryan, *AVANT Immunotherapeutics (public)*; David Green, *Project Impact (non-profit, product to market)*; Carol Nancy, *Sequella*

In this session, we heard from entrepreneurs about their challenges trying to attract VC funding for their endeavors. One entrepreneur noted “we couldn’t hit profile for VCs, no matter how the story was spun.” The lemming issue was cited—“Nobody wants to be the first to invest in a US company focused on TB.” One publicly traded company with three products on the market, investors want every dollar to count. Current investors won’t take dilutive capital. If they could buy in at premium, one could argue that it increases value. Biosyn represents a company in which hard-core VC and DBL funding (ProVenEx) were integrated in one company.

Other gaps were identified—particularly in the part of the product development pathway between Phase III and market. Entrepreneurs noted that it was not necessarily true that if you get to Phase III a clinical partner will pay for it. Have to give 90% of profit to partner if they invest in Phase III. Costs go up by large orders of magnitude as you get to Phase III. Patents also represent a huge cost. Grants can’t pay patent, legal, business development or phase III clinical trials financing costs. Some noted that no company will take dilution of an investor group at the point they have sales. The Board would have fiduciary responsibility not to take dilutive high cost capital. Venture Phase I to Phase III but not an appropriate vehicle at Phase III.

Another key issue is if a company is successful, how will it tackle distribution? Some entrepreneurs stressed this as the biggest hurdle they face: they’ve developed the product and now face the fear that it will not be distributed. Others noted the need to

work with companies in the developing world that know how to register, market, distribute in the developing world.

In sum, it was widely agreed that it is difficult for VC to fund such ventures—at some level, the venture market as a whole says that the returns are not commensurate with the risk involved. Certain diseases and innovations have fallen through the cracks—they don't address the needs of the VC or the foundations. Entrepreneurs summed up what's needed to move the field forward:

- Need to set up funds that are completely differently structured from traditional: a new model, new dollar amounts, new timeline
- Long-term market pull, market creation for these drugs, devices, diagnostics or a fund that offers part grants part equity.
- Need new ecosystem that has strong tech platform to enable syndicated financing.
- Need to fill downstream gaps (phase three through commercialization and distribution)
- Perhaps concentrate more on dual use technologies where VC interest could be attracted for 'developed world' use

Social Impact Assessment:

Social and financial bottom lines: Is one the cake, one the icing?

“Just because a disease is bad, doesn't mean what you do is good or relevant”

Panelists: *Cathy Clark, RISE; Michael Free, PATH; Jonathan Rosen, CIMIT-MAP; Rustom Masalawala, Kaizen Craft*

Cathy Clark presented an overview of the field of social impact assessment taking us through an impact value chain, challenging us to distinguish between outputs and outcomes and carefully describing the way that mission and theories of change must be evaluated. PATH presented its 'screening and monitoring for social impact' methodology noting first the technology's 'health impact and stakeholder acceptance', 2) the attributes of the technology relevant to target populations 3) marketing issues relevant to developing countries and critically, ways to ensure social impact after exit. CIMIT/MAP described their Individual Patient Impact Profile and Rustom Masalawala presented key overarching challenges to implementing metrics—including the critical issue of 'reporting overload.'

The ultimate metric?

A rich and dynamic discussion on metrics ensued. Participants asked whether financial sustainability is the ultimate metric. In some cases, like microbicides, social impact (HIV prevention) is correlated with financial return (market success). Others noted that for a drug for a neglected disease, clinical trials or making it through regulation would represent the highest standard for assessing impact. But some argued that “sales does not equal use--consistently, effectively” and that sales was an output measure, but not an outcome measure. Beyond moving the product, a more downstream metric in this space was put forth: simply, “lives saved”

Some discussion of the investor perspective also occurred-- as an investor looking at the presales stage, how do you know you're on the right track? We also asked whether a social investor would dilute interest from 'single bottom line' funds?

We are already witnessing some innovative examples, but whether they have a scalability and interactive space, room for syndication, remains to be seen. We need to continue to persist to create systems changing idea. The discussion made apparent that the field needs to mature with creative thinking and live experimentation beating a path to better metrics and cases for learning.

Dr. Chen also noted that some profound health contributions, not amenable to metrics include the development of penicillin, abolition of yellow fever, development of medical schools with the Flexner report, microfinance, etc.

Discussion: "Harnessing greed and passion together" **Ideas for follow-up**

Big picture conclusions

In general, we were, as a group, convinced by CK Prahalad's argument that an enormous untapped market exists at the Bottom of the Pyramid. The huge population in the developing world would rather pay something for private sector care than expend precious resources for poor quality care and bribes in the public sector. We agreed that the margins are out there. We agreed that we needed to better tell the story the way CKP did—there are opportunities for the investor—we have not adequately told the story to traditional VC.

Participants saw the key challenge we face as being able to aggregate capital and mitigate risk: a mechanism to harness greed and passion at the same time.

It was noted that the fundamental 'gap' we are facing is not \$100M needed for a fund, rather, it is public sector collapse and consequently the billions required from public sources to remedy this situation. Within this larger context, the question becomes how to get existing actors to increase performance (financial/social), in part by quantifying market size and moving social DBL investing into this space. We are thus looking at a *strategic double bottom line*.

We concluded that in the 'global health' space, grants are restrictive and are generally not scaleable or sustainable. Furthermore, foundations are not geared to work with small companies on quick time frames. Loans reduce entrepreneurs' risk taking and traditional VC is not likely to step into this arena except at the margins. And, our evidence from DBL/social VC experiences showed that in practice many 'pieces of the puzzle' were already being tried, but as a whole, the field represented lots of smaller underpowered efforts. Yet foundations are needed as tenant anchors in venture funds signaling to other investors and 'credentialing' the venture, for their endowment capital, for their willingness to take risks, for their domain knowledge and expertise and their links to new pull mechanisms like the PPPs. And likewise VC is needed as a partner in developing new mechanisms because their model brings proven success in scalability and sustainability, their ability to move large sums of capital, their fiscal discipline and their due diligence and business building expertise.

Ideas for innovative new financing mechanism(s)

We noted the need for a financing mechanism that is completely different from traditional models. A range of suggestions included the following:

- A larger fund structure, some interlocking operative scheme that works as a mutually agreed upon network, funded in part by key global health foundations
- A whole series of funds would be a better approach- a number of funds in different countries rather than a behemoth bureaucracy
- A holding company to buy out early investors and see out the social impact
- A separate fund for distribution—for distribution, TA and marketing of stalled, existing products
- Still others cautioned that we need to get more granular about analysis: types of innovation that are most promising (e.g. evaluate the claim that there's a tremendous business opportunity for quick diagnostics) and further evaluation as to whether VC was the right mechanism at all.
- Rather than simply saying the traditional VC model doesn't work, could we think of a new arrangement in which the role of the traditional VC could be complementary to other activities specifically designed to mitigate risk
- Others note the need to better delineate the space at the margins where traditional VC could be tapped to leverage and build on the points of overlap in global health
- Put together a fund for companies in the 'global health' space but subsidize the social part of the double bottom line: a new paradigm for the 21st century (invest side by side for technologies housed within VC backed companies)

Key Actionable Follow-up

1) Task Force with Working group(s)

Participants expressed interest in a small working group or set of working groups to address the following:

- Creation of a mechanism for sharing developing world market information
- Survey of all VCs to do a full analysis of the pipeline for neglected diseases
- Design the structure of a fund (or set of funds)
- Brainstorm broader changes to the investment ecosystem

Some participants cautioned that our goals would best be met via actual projects, investments and proof of concept rather than engaging in theoretical debate and construction.

2) Platform for Knowledge-sharing: Generally, we agreed that some kind of platform for knowledge-sharing was needed in this space. Some location for information on true market size and a mapping out of expanding markets could provide valuable information and 'common ground' for investors and entrepreneurs.

3) Development of mechanisms for **long-term market pull and market creation**

4) Entrepreneurs could be their own success stories working to galvanize the field and proving that global health companies can succeed and have impact—both social and financial

5) Follow up meeting of this group after Task Force has done some of the further research and thinking

Participants agreed that this group should meet again, once some further progress has been made in thinking through the issues identified in this meeting. (IOWH offered their offices as a venue.) The overall sentiment was that it would be a disappointment if the energy and ideas generated during the workshop weren't acted upon in concrete ways. The group was very much interested in meeting again.

Straw man fund

In order to spark discussion about the specifics of the kind of fund the group is envisioning, Willy Osborn of Commons Capital sketched out a 'straw man fund' (see Appendix). This sketch was used as a heuristic to lay out some of the key issues surrounding the development of such a fund:

- Size of fund: minimum \$100M
- Neglected disease/health issue focus
- Health product focus (the whole spectrum, blended portfolio?)
- GP incentivization
- Geographic focus (country, region)
- Exit values – How do you exit with blended value?

It was pointed out that such a fund as it was sketched doesn't help less developed countries—we should consider a fund-to-fund investment strategy. We noted the vast gulf in the lexicon between the VC world and the world of global health. In addition, some time was devoted to parsing out the inherent tension between VC control and charitable purpose: If you set up a non-profit, is there enough substantial control for the mission and charitable purpose of the fund?

Other models from which to learn:

- Mark Kaplan noted that the SBIC format has worked in attracting capital to risky areas—leveraging funds with some investors participating with lower levels of return (straight equity).
- In addition the Sustainable Jobs Fund formed a stand-alone fund which has its own affiliated non-profit side by side.
- Sanjeev Krishnan noted that the TVB bank in India has an interesting model—only requiring a 4% return—if things go well and if they go poorly, the bank loses the money.
- DTI in the UK was mentioned as a fund in the UK with different returns to different investors.
- ASMR's 2nd fund has different LPs participating with different return expectations.
- Acumen and OPIC have teamed up in syndication with Acumen providing the risk capital.
- Legacy Fund was also mentioned as a model (straight VC)

Other initiatives with which to link

- BVGH- is developing product-specific business cases, estimating the size of the market and supporting alternative business models for neglected disease innovation
- Institute for One World Health- is a non-profit drug company that is not eligible for VC funding—yet its goal and mission is global health. They look for revenues, not profits. They note that a lot of companies come to them and that they are capable of providing them with early stage advice and TA.

- Ashoka: grant from RWJ to interact with investment banking and private banking to get into social investing and build a social investing platform ecosystem→ syndicated financing and deal flow to aggregate financing and investment (mezzanine financing and investment) with vetted participants, reputational rating system and facilitation of networking.
- Present our ideas at the Global Philanthropy Forum

Summary

Lincoln Chen summed up some overarching themes of the workshop, noting that this was perhaps a third wave of progress in philanthropy—the first being the early ‘feeding of the, the second being the focus on root causes third wave occurring in the wake of the collapse of Communism and in the face of no reigning ideology other than markets. We are faced with the question of how the public good gets accomplished. Lincoln traced two fundamentalisms—that of ‘wealth creation’ and that of ‘charitable do-good’ noting that non-profits were adopting for-profit models (venture philanthropy) while for-profits are increasingly concerned about social output. The workshop as a whole pointed to the fact that as the space between for-profit and not-for-profit converges a bit, there is room for new models and new approaches. The group was extremely positive about building upon the current momentum to seize an opportunity and create an innovative financing mechanism or set of vehicles to work in this space.

Limited Partner Investors

- Fdn Endowments
- Government
- NGOs
- HNWIs

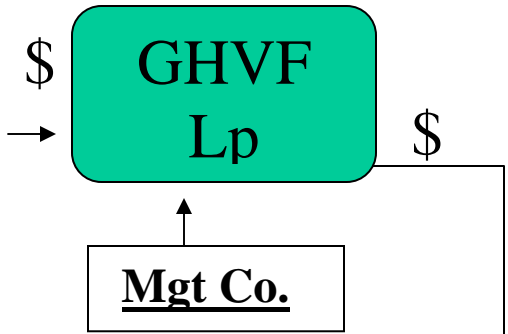
Non-investor donors

- Foundations, NGOs, Govt, HNWI

Non-profit or 501©3

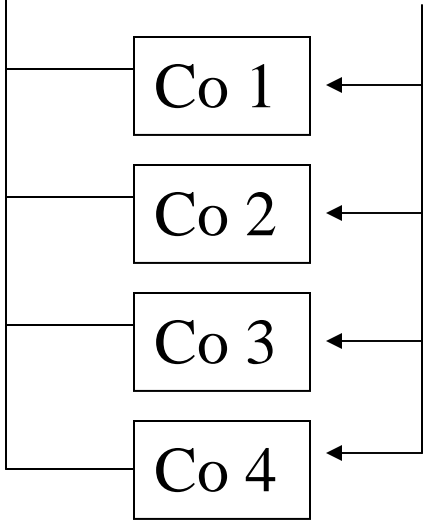
Donors provide grants/loans (non-investment) for

- Technical assistance
- Business assistance
- Regulatory



Partners (Pharmas, Biotechs, NGOs)

- Phase 3 clinicals
- Distribution



Appendix: Straw Man Fund