Communities of Practice in the Public-Private-Partnership Sector for Neglected Diseases Drug Development: the Importance of Mindset Mapping

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Abstract

This research article explores the mindsets of Public-Private Partnerships and Clinical Trials Organizations (CTOs) and the potential conflicts when working on drug discovery and development in the Third World global infectious diseases sector. A Communities-of-Practice (CoP) approach has been adopted to more fully explore the underlying values, attitudes and practices of these two future partners. This exploratory study suggests that future collaboration will be dependent on the two communities understanding and interpretation of each others' sustainability drug development drivers. The authors present secondary research findings that suggest the positive contribution that cognitive mapping of a community's sense-making can have in understanding the community's likely engagement in any future joint enterprise. Proposed future research will explore the underlying sustainability drivers that may both push and pull CTOs to engage in future global infectious diseases discovery and development projects. The article concludes by discussing the implications for future sustainable drug development projects involving PPPs and potential new strategic partners.

Keywords: Communities-of-Practice, Public-Private Partnerships, Sustainability, Sense-making, Clinical Trials Organizations.

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Introduction

Global health institutions, governments and media agencies have identified the importance in tackling Third-World infectious diseases; and the World Health Organization (WHO) has taken an overall leadership role in crusading the problems and needs associated with combating AIDS, Tuberculosis (TB) and other neglected diseases in the Third World (Banta 2004; Voelker 2006). This publicity has created successes in some areas (Frantz 2005), but there are still major infectious disease killers that have very little in the way of research support or effective drug therapy. These future challenges have galvanized the medical and health communities to argue cogently for sustained research development support (Satcher 2001).

In recent years the pharmaceutical industry has acknowledged the importance and value of developing drugs and vaccines that address the disabling diseases rocking the poorer countries (Wechsler 2006). It is the onset of Public-Private-Partnerships (PPPs) that have injected new promise into this previously ignored drug development sector. Most PPPs have three types of partners: the public sector institutions or international agencies such as the WHO; the for-profit private sector including pharmaceutical companies and clinical trials organizations; and finally the non-profit making institutions like universities and philanthropic institutions, such as Bill and Melinda Gates Foundation and the Welcome Trust. These PPPs are now pushing to reduce costs and deliver affordable treatments that address the crippling global infectious diseases.

The challenge for these PPPs is the careful collaborative management of non-profit and profit organizational members, and the creation of identities, communities and practices that fit their primary global health goals. Part of this process is the understanding and interpretation of these innovative goals, both as they perceive it and how they expect future partners from other health-centric communities to perceive it. Existing Communities-of-Practice (CoP) research (Wenger 1999; Handley, Sturdy et al. 2006) on inter-community relationships and their values, attitudes and behaviour towards common goals provides some useful insights into the potential problems facing these new PPPs and their recruitment of new partners. This research study uses the CoP framework to analysis the similarities and differences of two communities' identities, communities, practices and meanings, those of the PPP and that of the clinical trials group. The purpose of this comparison is to identify potential enablers and barriers to their collaboration on any joint enterprise, specifically that associated with the development of drugs and treatments associated with global infectious diseases.

Drug Development in Global Infectious Diseases

Drug development has dramatically changed over the last 5 – 10 years, previous to this new drug development in the neglected diseases sector was at a very low level, most multi-national pharmaceutical organizations were either closing or scaling down their drug development research into this area. The advent of the WHO and philanthropic institutions efforts, like the Bill & Melinda Gates Foundation and the Rockefeller Foundation, has moved the third-world diseases issue to the top of the research agenda (Wechsler 2006). As a consequence PPPs such as the Medicines for Malaria Venture (MMV), the TB Alliance, and Drugs for Neglected Diseases Initiative (DNDi) have jointly launched over 63 new drug research projects from 2000 to 2004. The pharmaceutical organizations and Contract Research Organizations (CRO) renewed interest in this sector may be an attempt, by them, to deflect current criticisms on their environmental and social performance, the potential spin-off of more commercially viable drug products for the richer western marketplaces, or as a means to enter the major emerging drug markets, like India and China. Whatever the reason for the renewed interest in the global infectious diseases sector the ability of these PPPs to collect together partners capable and committed to developing new drugs and vaccines rests on the perceived values of these PPPs and the social processes underlying their superordinate goals. Increasingly the need is for a more sustainable development environment that both supports, on a more continuous basis, the development of new drugs and therapies for neglected diseases, and develops a community to support this. Sustainable development involves three dimensions environmental, social and economic, a definition that captures all three of these characteristics is: 'sustainable development seeks to meet the needs and aspirations of the present without compromising the ability to meet those of the future' (World Commission on Environment and Development. and Brundtland 1987). We can apply this almost directly to the example of sustainable drug developments in the neglected diseases sector.

Purpose of Partnerships

Sustainable drug development has become an important market and business value driver, for both the private and public sector. Organizations are clambering to deliver these to their extended stakeholders, showing them that their business processes include these important value propositions. It is not surprising therefore that corporations, governments, non-governmental organizations (NGO's) and PPP's are endeavouring to benchmark their sustainability activities. Research conducted on the potential impact of sustainability on various business processes suggests four key areas: compliance-driven, profit/cost-driven, synergy-driven and community-driven (van den Brink and van der Woerd 2004). These sustainability

themes are explored to suggest there influence over the two communities activities and commitment towards the global infectious diseases drug discovery and development sector.

These sustainability drivers: compliance-driven, profit-cost-driven, synergy-driven and community-driven; may explain some of the rationale for both communities mutual engagement and joint enterprises in the global infectious diseases sector; but to understand the social interactions, and therefore their commitment, surrounding these new partnerships requires further exploration and interpretation of the social identity, community, practice and meaning behind them. The next section explores the use of the communities-of-practice learning model to explore the differentiation and integration of values, goals, behaviour and interpretation of these two communities-of-practice, and hence the rationale behind their engagement and commitment towards joint drug developments.

Communities-of-Practice: the Social Process

In studying sustainable drug development partnerships, or joint enterprises, associated with collaborative working practices, innovation research (Brown and Duguid 1991) attests to the importance of social constructivism, of building an understanding of the participants' view of the social world, and therefore the identity, community, practice and meaning that underpins these Communities-of-Practice (CoP). Wenger (1999) identified three dimensions associated with the coherence of community members in these CoPs: their roles, norms and values formed by their interactions with one another; the understanding surrounding their superordinate goals, goals that can only be achieved when coming together (Sherif 1975); and their shared experience of their social world, which results in artefacts and symbols conveying additional meaning associated with the partnership. The fourth element of Wenger's (1999) social theory of learning framework is practice, the resulting behaviours of these community members.

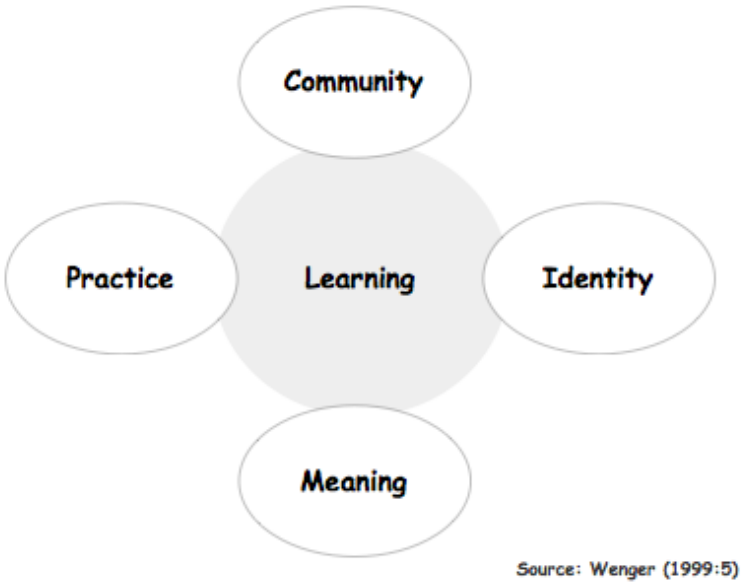

Figure 1. Wenger's (1999) Social Theory of Learning Framework

This social theory of learning framework, see figure 1 above, integrates four components necessary to characterize social participation as both, a process of learning, and of knowing:

Meaning a way of talking about ability, individual and collectively, to experience their life and the world as meaningful;

Practice a way of talking about the shared historical and social resources, frameworks, and perspectives that can sustain mutual engagement in action;

Community a way of talking about the social configurations in which our enterprises are defined as worth pursuing and participation is recognizable as competence;

Identity a way of talking about learning that changes who we are, and create personal histories of becoming, in the context of our communities. (Wenger 1999)

The community learning process draws on the communities' experiences, competencies and training. In turn, these are embedded within their interpretative systems (Fiol 1995), and used by them to attribute meaning to others' collective actions, organizational/Industry events and community outcomes, and also contributes towards the development of their thought worlds (Schein 2004). These community thought worlds reflect the social world, as they perceive it, and are the implicit rules by which they attribute meaning to their position and task within the organization or industry (Rafiq and Saxon 2000), and inevitably influences their engagement with any other communities, formally or informally.

This learning process is highly subjective, based as it is no sense-making of their own, and others', collective actions, and the value orientations associated with this joint enterprise. This suggests a further

element to their sensemaking process, that associated with the cultural dynamics (Hatch 1993), that is, one where communities confer additional meaning to the observed, or expected outcomes, via the use of symbols. This is especially the case with joint enterprises that have industry-wide significance and require multi-partner activities. These symbols are interpreted differently by the communities, as they attempt to equate them with their own thought worlds, and the perceived and desired value orientations they have. These symbolic interpretations associated with engagement of the communities members' in wider industry communities, especially with activities which span many years, becomes a powerful tool by which communities' retrospectively sensemake (Weick 1995) their own, and others', collective actions, industry events and community outcomes.

Community Identities

Dougherty (1992) suggested that a community of persons engaged in an activity, like drug development, could develop shared understanding about that activity, and these insights would create distinct thought worlds. Collaboration within and between these communities is likely to be influenced by this shared understanding of their social reality (Schein, 1992). The communities' thought worlds are the implicit rules by which they attribute meaning to their position and task within the community (Rafiq and Saxon, 2000), and the means by which they judge, appraise and criticise their own, and others', collective actions. These thought worlds are going to be different for the various communities, and are significantly influenced by the different schooling and training that these members originally had, and their experiences since working (Dougherty, 1992). These community thought worlds determine the way in which they organise their attitudes and feelings (Schein, 1992), and their subsequent collective actions associated with drug development activities. It is because of these differences in the communities' thought worlds that barriers are created, which in turn may inhibit collaboration between them (Dougherty, 1992). There are often fundamental differences in the PPP partnership agreements between large and small pharma organizations. For example, the smaller pharma organizations are mainly concerned about profit margins if the drug is successful, whereas larger pharma organizations are largely concerned about limiting their losses (Nwaka and Ridley 2003). CTOs, on the other hand, are looking at the longer-term benefits of involvement in global infectious diseases drug developments in modifying their corporate image and positioning themselves in the emerging developing country markets (Frantz 2005).

Table 1: Identity Perspective of PPPs and CTOs

IDENTITIES (VALUES AND GOALS)	PUBLIC-PRIVATE-PARTNERSHIPS	CLINICAL TRIALS ORGANIZATIONS
Thought Worlds – value and experiences of drug development in Global infectious diseases	There are principal clusters of PPP's in the global infectious diseases area, those involved in drug development and those focusing on access to these new medicines (Widdus 2005). Big Pharma companies are not necessary, smaller drug development partners can merge better with the discovery partners, they understand our needs(Croft 2005) . Recognizing the need to develop wider drug development portfolios to spread risk and hasten the development of drugs. To this end they must act as managers, and bring together expertise and resources from outside the partnerships at crucial times (Widdus 2005). Small and large pharma organizational partners of these PPPs have different perceptions on any payback from drug successes in this sector (Nwaka and Ridley 2003).	CRO's present themselves to pharma organizations as the most cost-effective means to conduct clinical trials and access their experience (Wadman 2006). Most CROs are reluctant to become involved in projects that cannot pay the market rates (Nwaka and Ridley 2003). But some CROs like large pharma organizations are looking at the longer-term benefits of a positive corporate image and the strategic issue of positioning themselves within the emerging developing country markets (Frantz 2005).
Value-orientations – interpretation of actions and aspirations of what they would like to see	Public sector and Non-Governmental Organizations have largely failed to gather skills and resources to tackle diseases of the developing world, and Public-Private Partnerships are aware of the needs to engage the for-profit private sector (Widdus 2005).	Experienced Contract Research Organizations (CRO) understand the importance of delivering to the specific needs of the drug sponsors (Hecker, Preston et al. 2003). Increasingly, pharma organizations are going to CROs because of their access to investigators and trial patients the world over (Wadman 2006).

The value orientations associated with the communities' thought worlds can reflect an organizational- or industry-wide value orientation (Beatty 1988) and/or be influenced by other factors or professional biases: financial, customer, competitor, employee, entrepreneurial and product (Beatty 1988; Martin 1992; Alvesson 2002). Organizations, or other communities, may influence these community value orientations by their declared strategies and superordinate goals, goals normally beyond the reach of individuals' experience and efforts (Sherif 1975; Siguaw and Brown 1994; Kwantes and Boglarsky 2004), or by the key industry leaders in the form of inspirational objectives or goals (Flaherty *et al.*, 1999). But these community value orientations also result from their own perception of role appropriateness, and this is likely linked to their thought worlds (Flaherty *et al.*, 1999). Clinical Trials Organizations (CTO) are increasingly aware of the complications arising from drug sponsor partnerships, and the associated goals, and the impact this can have on delivering value-adding services, clinical trails, regulatory services and other trials-based competencies. But at the same time they are keen to address new markets where their valuable assets (patients and investigators) could be utilized (Wadman 2006). Research has identified two specific types of value orientations: perceived and desired. The perceived value orientations of a community are a combination of those values that they interpret from the organizational or industry-based goals and their perceived role, and those from observing theirs and other communities' collective actions (Flaherty *et al.*, 1999). The desired value orientations represent a community's aspirations and are those values that they desire to have based on their interpretation of future needs, those of the industry, organization, the community's, and ultimately the

end-sufferer. In the PPPs, there is an honest appreciation of the need to engage the for-profit private sector in drug development partners to access their skills and resources that can accelerate the overall drug discovery, and then the subsequent development and delivery of these to those most in need (Widdus 2005).

Community Coherence

The coherence of communities defines how they apply their thought worlds, and value orientations, to their practices, and to study this you can look at three dimensions of coherence: mutual engagement, joint enterprise and shared repertoire (Wenger 1999).

Mutual engagement is dependent on the willingness of the community to engage in common practices, but without the need to have homogeneity of all values and thought worlds, but that they have homogeneity of those important ones that need to be shared to support the superordinate goals of the community. The CTO industry shares it knowledge and experience through the process of natural migration of these scientists and medics from institution to institution. But more formal partnerships are difficult across the for-profit and not-for-profit sectors, as there mission, cultures and incentives differ (Gelijns and Thier 2002).

Collective enterprise is a negotiated process of commitment and accountability over the duration of the project or membership of the community, and one that engenders and directs social energy (Wenger, McDermott et al. 2002). Medicines for Malaria Venture (MMV) are not unique amongst PPPs in taking onboard all partners concerns regarding risk and rewards associated with their engagement (Nwaka 2005), this often results in a balance between intellectual property, profits and protection of information to competitors. These organizations (MMV, Global Alliance for Tuberculosis Drug Development GATB, and Drugs for Global infectious diseases Initiative DNDi) all have a set of common goals and that is to discover, develop and deliver affordable drugs quicker and with lower risk, and thus improve overall drug development success in the global infectious diseases area (Nwaka and Ridley 2003).

The shared repertoire of the community, are the experiences and language they use to express their membership and identity of this community. PPPs like Medicines for Malaria Venture (MMV) have been created and developed to address a woefully neglected area of anti-malarial drug development. Their strength, like other PPPs, has been the marshalling of complementary partners to direct and focus effort on discovery and development of new drugs and treatments for these global infectious diseases (Nwaka 2005).

Table 2: Community Perspective of PPPs and Clinical Trials Organizations

COMMUNITY – ENGAGEMENT AND CONSENSUS	PUBLIC-PRIVATE PARTNERSHIPS	CLINICAL TRIALS ORGANIZATIONS
Mutual Engagement – doing things together	Examples of mutual engagement include the Global Fund to Fight Infectious Diseases, HIV/AIDS, Tuberculosis, and Malaria which received a $200 million injection from the UN and USA governments (Satcher 2001).	There is competition amongst the clinical research institutions, where CRO offer efficiency in institutional board review approval, patient recruitment and data management. AHC's have a richer source of patients with well-documented disorders. The CTO industry as a whole shares these clinical researchers, investigators and scientists knowledge and experience (Gelijns and Thier 2002).
Collective Enterprise – a collective understanding of a joint requirement on all.	PPPs like MMV, GATB and DNDi have common goals associated with discovering, developing and delivering new affordable drugs with tighter timeframes ,and more collaboration to minimize risk and improve drug development success (Kettler 2003; Nwaka and Ridley 2003).	There is still a lack of commercial interest in taking part in drug developments for infectious diseases found predominantly in developing countries (Hampton 2004).
Shared Repertoire – its evidence of collective stories and meaning about the value of the community and being part of it.	PPP's acknowledge the unattractiveness of malaria and other tropical diseases to entice R&D funding from commercially-driven organizations (Nwaka 2005). But new funding from various agencies has increased PPP activity associated with drug development, and brought-in pharmaceutical companies.	PPPs look to CRO to provide the experience and knowledge associated with testing in humans, and the formulation and dosing to achieve a safe and efficacious clinical trials process leading to a successful drug delivery (Nwaka and Ridley 2003).

All of the above provide some concept of the shared meaning and coherence of the community's feelings, and that which supports their practices.

Community Practices

When studying action-outcome relationships, researchers are in fact studying a communities', or a community members, ability to learn by trial and error, the ability to change their actions to achieve certain desired outcomes (Van de Ven, Angle et al. 2000). The relationship between collective actions and outcomes, and the interpretation and sensemaking by those who observe it, are the foundations of 'organizational learning' (Van de Ven, Polley et al. 1999). Organizational learning research (Argyris and Schon 1996; Appelbaum and Goransson 1997; Montuori 2000) has suggested that two types of learning are prevalent in ambiguous and uncertain times: adaptive and generative learning. There are other terms used to describe these types of learning: for adaptive learning, there is 'double-loop', 'trial and error', 'testing' and 'rational' learning; for generative learning there is 'triple-loop', 'superstitious' and 'discovery' learning. Van de Ven, Angle *et al.* proposed that adaptive learning relates to the feedback between collective actions and outcomes, specifically:

> "…that outcomes are a function of actions that are believed to lead to those outcomes and are not a result of spurious unknown factors" (Van de Ven, Angle et al. 2000:205).

This may be true of some action-outcome relationships (Montuori 2000), but others cannot be so simply resolved or understood. Research (Levitt and March 1988) has alluded to an illogical or invisible relationship between collective actions and outcomes that could only be explained by an additional learning type:

> "Superstitious learning occurs when the subjective experience of learning is compelling but the connections between actions and outcomes are loose or mis-specified" (Levitt and March, 1988:325).

Their research, along with other researchers studying generative learning (Appelbaum and Goransson 1997), implies a causal relationship between actions and outcomes, but not one previously experienced by the observee. Unlike adaptive learning, where change is less perceptible, generative learning results in significant change, where industry events often change the expected outcomes.

Table 3: Practices Perspective of PPPs and Clinical Trials Organizations

PRACTICES (ACTIONS, EVENTS AND OUTCOMES)	PUBLIC-PRIVATE-PARTNERSHIPS	CLINICAL TRIALS ORGANIZATIONS
Collective Actions – collective behaviours	Medicines for Malaria venture (MMV) reviews its drug development every year, there is fierce competition to fund other projects (Nwaka 2005). Just since 2000 over 63 neglected disease drug projects are in progress, with 18 drugs already in the trials stage, and two awaiting registration (Frantz 2005).	Pharmaceutical organizations want to use CRO's to manage their own fluctuations, resulting from their erratic pipelines (Wadman 2006). Increasingly, the small- to medium-sized pharma organizations are accounting for a considerable larger proportion of its clinical trials business portfolio.
Industry-wide Events – inter-community actions	One advanced of the PPP is the portfolio management, projects can be more easily terminated and new projects be taken on because of the flexibility in taking on additional intellectual expertise and capacity (Nwaka and Ridley 2003).	Long-term research capacity and expertise will reside in developing countries, and CROs have not been slow in opening up clinical units in these countries. it will take time and resource to build this expertise and intellectual capacity up (Nwaka and Ridley 2003).
Outcomes – results of collaboration and community actions	PPP's are as yet social experiments lacking the experience and history associated with delivering drugs to the marketplace. One perceived weakness is the ability to develop accurate performance measures in judging success of the drug developments (Widdus 2005).	The Northwick Park drug trial was a sharp slap on the hand for regulators and CTOs to reassess their clinical trial protocols. Particularly not to be pressured, by trying to cut time and cost, in skipping procedures or acting improperly (Wadman 2006).

The collective actions of the two communities often reflect the different community identities, their values and goals, as in the case of MMV in reviewing its product portfolio based on the drug's affordability to the third community (Nwaka 2005). But the PPP community is fully aware of the need to push for more neglected disease drug developments, by the end of 2004 more than 63 neglected-disease drug projects where in progress. This compares to only 13 new drugs being developed during the period from 1975 to 1999 (Frantz 2005). Certainly the collective actions of the PPPs are very much focused on increasing the drug pipeline efficiency and effectiveness.

The virtual R&D organisational structure of PPPs provides for more effective portfolio management, these flexible partnerships easily allow for the termination and the adoption of new projects, essentially because of the ease by which intellectual expertise and capacity can be taken on (Nwaka and Ridley 2003). CRO's have recognized the need to utilize, build and develop the intellectual capacity and expertise in the

developing countries, and are establishing clinical trials organizations in countries like China, India, South Korea and South Africa.

Increasingly as the big pharma erratic drug pipelines slowdown more and more of the CTO business is coming from the small- to medium-sized pharma organizations, and the PPP's are one part of this(Wadman 2006). The growth in outsourced CTO's has been driven by the pharma organizations desire to cut time and cost from drug developments, and there is a worry in the industry that this may put pressure on CRO's, in particular, to maybe skip procedures or just act improperly during the clinical trials (Wadman 2006).

Community Meaning

In the previous sections the author has explored the identities, community and practices binding these communities of practices. Any emergent community meaning represents their perceptions of the relationship between their own and other communities' actions, and the resulting outcomes. But these meanings are further complicated by the symbolisation that is bestowed on the community values or goals driving their actions. The community's symbolic interpretation can either support, or challenge, their sensemaking of current and future action-outcome relationships. Bulmer (1969) suggested that all symbolic interactionist approaches have three basic premises:

> "…the first is that human beings act towards things on the basis of the meanings that the things have for them… the second is that the meaning of such things is derived from, or arises out of social interaction that one has with one's fellows… the third is that these meanings are handled in and modified through, an interpretive process used by the person in dealing with the things he encounters…" (Blumer, 1969:2).

Applying these approaches to the research analysis of the interpretative process associated with these global infectious diseases drug development initiatives (Blumer 1969), and the engagement of PPPs, suggests three distinct stages in the analysis of the communities' retrospective, and prospective, sensemaking of the others' collective actions, industrial events and community outcomes. Firstly, the analysis of the community's actions, their engagement with the different partnerships, would be based on the imparted meaning of the PPPs' strategic drug development values and goals towards this disease sector. Secondly, the analysis of the community's prospective, and retrospective, sensemaking of the PPPs' goals, and therefore the symbolisation of these, would be influenced by other communities' actions. Lastly, the communities' interpretative systems, their shared meaning, would be both supported and modified by the retrospective and prospective sensemaking undertaken by the community when attempting to impart meaning to the observed action-outcome relationship.

Contract Research Organizations (CRO) have emerged in the marketplace from a basic need of large Pharma organization to improve R&D efficiency and effectiveness, both speeding up drug development pipelines and cutting the costs of the clinical trials processes (Moran, Ropars et al. 2005). These CROs are using this market opportunity to build-up expertise and competencies that would benefit the small pharma organization and their larger pharma competitors.

Table 4: Meaning Perspective of PPPs and Clinical Trials Organizations

MEANING (CURRENT AND FUTURE)	PUBLIC-PRIVATE-PARTNERSHIPS	CLINICAL TRIALS ORGANIZATIONS
Retrospective Sense-making – understanding the action-outcome relationship using existing interpretative systems.	The funding problems of the past have in the short-term been filled by one or two philanthropic organizations, but drug developments takes 10 years or more, is the funding sustainable (Croft 2005)?	CRO understand the drivers in large pharma's drive on more cost-effective R&D development of profitable drug candidates, and that they are being used by pharma to cut costs and increased efficiencies (Moran, Ropars et al. 2005). CRO are in a unique position to be able to offer R&D services as a very competitive rate.
Prospective Sense-making - altering their interpretative systems to create meaning from the action-outcome relationships.	Public-Private Partnerships are a new community-of-practice that provides a unique solution to an age-old problem, bringing together the public, medicine expertise, and private, ability to turn drug knowledge into safe and effective medicines, sector, managing these knowledge and expertise pools (Croft 2005).	Increasingly, small pharma organizations and PPPs are dependent on outsourcing to CRO's to help in trials, manufacture and increasingly preclinical development. CRO's are building up expertise and competencies in offering these added-value services, as both a way to attract these smaller companies and to increase their intrinsic value (Moran, Ropars et al. 2005).

The community prospective and retrospective sensemaking is influenced by their symbolic interpretation of their community goals. The resulting community meanings either strengthen, or modify, their interpretative systems. These interpretative systems are the shared meaning which accounts for the collective actions, industry events and community outcomes observed over time (Dougherty 1992). Public-Private Partnerships prospective sensemaking of drug developments in global infectious diseases is their new role to bridge the gap between basic research and clinical development, to at least prove the efficacy of a prospective drug (Croft 2005), to provide a medium through which public and private sector could collaborate on drug developments.

This section of the article has identified the social processes of interaction between the PPPs and CTOs. Showing how interactions are both enhanced and modified by the on-going sensemaking of both communities. It also suggests that the thought worlds concerning how collective enterprise and mutual engagement can help each achieve their community's goals, helps also to build and sustain their overall identity. But the short-term current activities of PPPs and CTOs is threaten by the longer-term need to address the more substantive challenges represented by addressing the sustainability drivers associated with development new drugs and treatments for the Third World's global infectious diseases.

Drivers in Global Infectious Diseases

This article has already discussed the critical need for more sustainable drug development resources and commitment to global health problems. Part of the challenge for these Public–Private-Partnerships (PPP) and Clinical Trials Organization (CTO) is the recognition of the importance of addressing the sustainability development expectations of this sector's multiple stakeholders (Public-funders, Governments, Pharma industry, and sufferers) and any other future community partner, and the social interaction problems arising from getting this future commitment. So what are the sustainability development drivers for this sector of the marketplace, these were identified the 'Purpose of Partnerships' section above?

Sustainability Development Drivers

Research into the early development of these PPPs, in undertaking drug discovery and development in the Third World infectious disease areas, suggests that sustainable development is a critical factor in determining the success of these Communities-of-Practice (CoP), at least by those hoping to benefit most. The authors have utilized the van der Woerd et al. (2004) framework below to initially pose four potential sustainable development themes, and the impact they may have on future partners' motivation and commitment to the collective enterprise:

Figure 3: The Two Communities' Challenges

SUSTAINABILITY DRIVERS	PUBLIC-PRIVATE PARTNERSHIPS	CLINICAL TRIALS ORGANIZATIONS
Compliance-driven sustainability issues	Developing business models and tools applicable for these PPP's (Croft 2005). Being business-like in decision-making over projects, leadership and general management of the tricky drug development pipeline (Kettler 2003).	CRO are addressing these public-driven drugs markets as a source of growth and of differentiation from their competitors (Moran, Ropars et al. 2005).
Profit/Cost-driven sustainability issues	Currently philanthropic foundations, like Bill and Melinda Gates Foundation and the Rockefeller Foundation are major players in the support of global health initiatives, but is this sustainable (Folkers and Fauci 2001)? PPPs have the additional problem of moving projects from discovery into development with the inherent issues of agreeing criteria and the selection of a new development partner (Nwaka and Ridley 2003).	In the drive to bolster expertise and competencies in the global infectious diseases therapeutics areas, infectious and viral diseases, CTO's are keen to partner with PPPs to attract funding for late stage clinical development and obtain skills (Moran, Ropars et al. 2005).
Synergy-driven sustainability issues	Most the early PPP regulatory successes are from the identification and screening of available compounds from other indication areas, and then bringing these to market (Nwaka and Ridley 2003). The surprise is that there is very little in the way of policy incentives (Industry or Government focused) that directly supports PPPs, and their collective actions toward global infectious diseases drug developments (Moran, Ropars et al. 2005).	Increasing the PPPs are accounting for over one-third of the public sector revenue for out-sourced clinical trails development (Moran, Ropars et al. 2005). Perhaps the longer-term problem with CRO involvement over the full-length of the clinical trialling process is the securing of full-funding.
Community-driven sustainability issues	Increasingly, PPP's are receiving funding from institutions that have an eye on the economic, social and ecological balance of	For some large CTO's making investment decisions on 'it's the right thing to do' is the major driver behind their involvement

	corporate responsibility (Renslo and McKerrow 2006). The PPPs focus is on specific diseases, but with limited product deliverables, as yet (Nwaka and Ridley 2003).	(Wechsler 2006).

The extracts above are initial secondary research findings of these two communities' perspectives on these four general sustainability drivers, most often influencing industry trends and activities. A useful starting point is to both explore a definition of these sustainability drivers and how they may apply to the two communities.

Compliance-driven Drug Development

Compliance-driven sustainability issues can be influenced as much by the different communities' perspective of regulation and obligation as it could be by some broader community understanding. Each community needs to understand its obligations to its existing stakeholders before letting itself be influenced by any third-part community culture. For the PPPs this is very much focused on developing a longer-term business model that is more attractive for more sustained funding by third-parties (Philanthropists, governments and other investors). The current range of drug discover and development business/portfolio models have not kept up with the needs of the community, and future research and help is needed to develop more efficient and effective tools (Croft 2005), both for the PPPs and any future partner wishing to joint the community. Increasingly PPP are having to move from being public-oriented businesses to being for-profit organizations capable of making hard decisions about 'killing-off' projects, and doing what's best for delivering new products (Kettler 2003).

CRO are reaching a period of consolidation, one that requires that they seek new areas of growth and differentiation from each other, the global infectious diseases marketplace is one such opportunity (Moran, Ropars et al. 2005). One that brings with it a responsibility to find a way to address the unique problems of PPPs', their difficulties in obtaining long-term funding and the constant pressure to discount their commercial rates.

If future engagement of partners in these Public-Private Partnerships is dependent on broader differentiated goals, then communities need to understand these and broaden the scope of these drug development projects to deliver multiple outcomes, or at least understand the underlying rationale for these partners' commitment and future motivation?

Profit/Cost-driven Drug Development

Profit and cost-drivers are key to Not-for-Profit and For-Profit organizations, CROs expect their clients to pay commercial rates, PPPs are concerned about overall costs, and specifically about managing their limited resources.

PPPs have benefited by the billions and billions of dollars committed by these philanthropic institutions, Bill and Melinda Gates and Rockefeller foundations, but an important question is are these funds sustainable longer-term (Folkers and Fauci 2001)? For the PPPs the short- to medium- requirement is to seek other funds that can boost or cover for any drop in funding from these major contributors. With these funds come additional partners, these multiple partners bring with them additional problems of moving projects from discovery to development, and agreeing those criteria, and with selecting additional development partners (Nwaka and Ridley 2003).

CTO's have an underlying need to assimilate knowledge and expertise from a wide range of therapeutic areas, the global infectious diseases sector is one very large marketplace, with multiple therapeutic areas and therefore opportunities. CTO's are keen to partner with PPP's to obtain both funding to facilitate their clinical trails development, and at the same time, accumulate the skills associated with technical, scientific and clinical global infectious diseases expertise, access to facilities like country clinical trials sites, and most importantly knowledge of developing countries markets, regulatory and health authority procedures and practices (Moran, Ropars et al. 2005).

Understanding these current and future partners' engagement in PPPs, particularly regarding future re-imbursement, holds the basis for their longer-term involvement, and the degree to which they seek out these opportunities?

Synergy-driven Drug Development

The overall change in the dynamics of R&D in drug developments has had a profound impact on the competitiveness of small pharmaceutical organizations and PPPs. Effectively, these organizations have benefited from the growth in virtual partnerships, extending their core competencies and skills by outsourcing trials, manufacturing and preclinical developments.

Early PPP regulatory successes have come from the identification and screening of existing compounds from other indication areas, and then the rapid development of these (Nwaka and Ridley 2003). Accessing this knowledge and experience is essential in achieving 'Quick Wins', but the hard-task of discovering new treatments is now a real challenge for these PPPs.

CTO are a contract service organization, they don't have the Intellectual Property that other partners have, Pharmaceutical organization have drugs and Charity Organizations often have the Mindspace for their respective diseases, and therefore are motivated only by the revenue and the longer-term positioning of themselves within this growing market sector (Moran, Ropars et al. 2005).

To increasingly engage further partners into these PPPs requires understanding and developing 'win-together' approaches to capitalise on their existing organizational goals, but identifying these will involve positivist engagement, who will do this and how?

Community-driven Drug Development

The level of public and private interest in global infectious diseases R&D is at an unprecedented level (Moran, Ropars et al. 2005), but the level of collective activity cannot be sustained without an important balance between economic, social and ecological drivers. This balance can only be maintained in the longer term if businesses develop framework upon which they and other current and future partners can engage in these Public-Private Partnerships whilst delivering on their broader strategic objectives.

PPPs like MMV and GTAB have a very specific focus on disease areas, but have yet to deliver any significant medicine or vaccine into the field (Kettler 2003; Nwaka and Ridley 2003). For some partners the investment opportunity is about responsibilities to society at large, or its just the right thing to do, either way the decision to become involved is made at the CEO level, and is measured alongside other corporate social responsibility activities, and ultimately helps contribute to organizations image and reputation (Wechsler 2006).

Not every CTO is in the privileged position to be able to make commitments to these PPP's based on it being the 'right thing to do' (Wechsler 2006). Some CTO's will be driven by the economic perspective, looking at the benefits of knowledge of developing country product profiles, and guarantees of public demand (Moran, Ropars et al. 2005). These public skills associated with the global infectious diseases market are of important economic value to CTOs, and have both social and ecological benefits to the PPPs and these target populations.

Trying to stimulate changes in business models of existing pharma organizations may be less effective than motivating and engaging organizations that already have a predisposition towards the global infectious diseases sector. But either way, the challenges in understanding these balances is important to the overall process of selecting future partners, for both the PPPs and the CTOs.

Discussion and Further Research

A review of the identity, meaning, practice and community of these two Public-Private-Partnerships (PPP) and Clinical Trials Organizations (CTOs) gives us an opportunity to reflect on the convergence and divergence of these two communities' values, attitudes and practices. Yet, there are advantages and disadvantages of these communities in coming together and working collaboratively, the advantages are:

1. To enhance the future sustainable drug development opportunities by utilising their highly developed competencies in clinical trials, and their potential interest in developing facilities in these third world countries;
2. For the PPP it a route to access key resources to supplement their own;
3. For the PPPs it is the most cost-effective means by which to manage their programme of drug and treatment development;
4. For both the PPP and CTO it provides an opportunity to respond quicker to the problems of global health diseases, where millions of people are dying from treatable maladies

The potential barriers to these two communities working together are:

1. Forcing PPPs to become more business-like in their drug developments, seeking partners who can offer competence and professionalism in their project management, may drive them seek more ethical partners who will meet the high-standards of their stakeholders, particularly their funders;
2. But at the same time realising that private enterprises (e.g. CTOs) are driven by profits and costs, their stakeholders are looking for longer term benefits;
3. For private and public partners there is the longer issue of securing adequate funding, this can act as a deterrent for some partners in becoming involved in the first place.

Public-Private Partnerships have become a significant strategic tool in the renewal of interest by private and public enterprises in the long-term sustainable drug and treatment developments needed to address the significant problems associated with the Third World's infectious diseases crisis. There are many issues facing these PPPs, but a significant problem is the one of recruiting and holding partners. These partners represent the longer-term need for specific core competencies associated with delivering drugs and treatments. The challenges for the PPPs are like any new-born entity, to grow and build strength and sustainability into its discovery and development drug pipelines.

Future research is needed on the evaluation of the effectiveness of these future partnerships; can they deliver the added value initial perceived? A detailed evaluation of the life cycle of these partnerships, the deliverables at all stages of the processes, from the initial engagement and project start-up right through to

the project termination, successful or otherwise. Finally, more research is needed on exploring the drivers and motivations of the different partners, do these change during the stages of the project, and how can the partnership as a whole manage these, thus maintaining commitment.

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