**The Dance of Power and Trust- Exploring Micro-Foundational Dimensionsin the Development of Global Health Partnership**

**Abstract**

The global health system has significantly evolved over the last 30 years, particularly since the UN Millennium Declaration in 2000. The transformation in global healthcare partnerships has been most visible in the area of neglected tropical diseases, where technological innovation is directly linked to social change. Numerous strategic partnerships between different actors, including pharmaceutical companies, global and national health institutions and philanthropic organizations and disease specific foundations populate the landscape of neglected tropical diseases and yet, we know little on relational and structural aspects underpinning the partnerships. Our research uses a rich longitudinal case study – a tripartite public-private partnership formed between a global health organization, a major pharmaceutical company and a research university to develop a new drug for the treatment of malaria in Sub-Saharan Africa. Development of new drugs are central to attain social change in a poverty stricken region. We adopt a micro-foundational perspective in analyzing strategic choices made by the partnership’s Product Development Team (PDT) and unravel the dynamic interplay between power – trust relationship in such strategic business partnerships.

**Keywords:** Micro foundational perspective, Public-Private Product Development Partnership; Power; Trust; Strategic Choice; Neglected Diseases

1. **Introduction**

The success of inter-organisational relationships requires significant investments in relational factors such as trust, commitment and satisfaction (Ring & Van de Ven, 1994; Vieira, Winklhofer & Ennew, 2008; Athanasopoulou, 2009; Crosby, Evans & Cowles, 1990; Villena, Choi, and Revilla, 2015; Malik, Ngo & Kingstott, 2018). Public private partnerships (PPPs) are considered as promising avenues in addressing such challenges in pharmaceutical innovation, particularly for neglected diseases (Varda et al., 2012; Tardivo, Santoro and Ferraris, 2017; Vecchi and Hellowell, 2018). Recent studies on PPPs highlight the importance of selecting partners with three core attributes, namely the extent of partner complementarities, the commitment of the partners and technical and compatible factors between them (Sandulli, Ferraris and Bresciani, 2017).

Despite the importance of relational factors, there is limited understanding of how power, trust and an organisation's technical and research capabilities influence performance outcomes in inter-organisational relationships (Goles, 2002; Levina & Ross, 2003). Recent research by Akhtar, Khan, Rao-Nicholson & Zhang (2019) point to the importance of the nature of power exercised and the knowledge generated from big data in effective co-creation of innovative relationships in global collaborative partnerships. Specifically, for innovative outcomes in global partnerships, diversity of employee characteristics is also seen as a critical attribute for sustaining innovative collaborations with external partners (Bogers, Foss & Lyngsie, 2018).

From a theoretical perspective, this paper contributes to the emerging literature on micro-foundations of strategic business partnerships by focusing on the role of power, trust, organisational capabilities, specifically in PPPs for drug innovation in the global health arena. This is an overlooked gap in the literature, which often results in failures in inter-organisational research in the context of global partnerships, especially ones that focus on micro-foundational aspects.

From a practical and policy perspective, the global health system has significantly evolved over the last 30 years, particularly since the UN Millennium Declaration in 2000 introduced eight Millennium Development Goals (MDGs), three of which are directly related to health, including; (a) reducing child mortality; (b) improving maternal health; and (c) combating HIV/AIDS, malaria and other diseases (see [www.who.int/mdg](http://www.who.int/mdg)). The MDGs[[1]](#footnote-2) were in essence quantified and time-bound targets for 2015 and are still viewed as central in attaining social changes in disease epidemic countries, especially in Sub-Saharan Africa. As a consequence, institutional arrangements addressing new drug development for the treatment of major diseases, such as HIV –Aids, Malaria and Tuberculosis, has attracted significant attention (Vakil and McGahan, 2016)

Historically, the institutional arrangement underpinning the global health system included key actors, such as the World Health Organization (WHO) and national Health Ministries of member countries that exert influence at national and global levels with norms and expectations that governed the nature of relationships amongst them. Since the Millennium Declaration, this institutional arrangement has undergone a significant transition with the emergence and influence of new partnerships such as Rollback Malaria, TB Alliance and Global Alliance for Vaccines and Immunizations. Furthermore, private global health foundations and philanthropic organizations, such as the Bill & Melinda Gates Foundation, Ford Foundation, W. K. Kellogg Foundation, Robert Wood Johnson Foundation, and Rockefeller Foundation have provided further impetus to this stream of global healthcare alliances. The emergence of new actors and changes in the institutional arrangement is argued to have profound impact in the area of drug development for neglected tropical diseases (NTD)[[2]](#footnote-3)and they have contributed in creating conducive conditions for collaborative development of new drugs for neglected diseases. In this respect, recent work by Munoz et al., (2015), note that more than 300 organizations from the private and public sectors (academic/research institutions, biotechnology companies and other medium and small firms, such as contract research organizations, and large pharmaceutical companies) participating alone or in partnership with each other, are involved in development of new drugs for neglected diseases (also see Pedrique et al. 2013). Product Development Partnerships (PDPs), which are essentially a type of PPP specifically formed to develop new products / drugs, contribute to more than 40% of new drugs being developed for neglected diseases (Bio Ventures for Global Health 2012).

Notwithstanding these developments, complexities underpinning the development of drugs for neglected diseases, remain underexplored in contemporary organisation and management research. In this context, our paper also contributes by offering a more detailed understanding of the power – trust dynamics underpinning strategic choices involved in the dynamic evolution of public- private PDPs. We adopt a longitudinal research design to track the development of an anti-malarial drug– CHALDAP, which was conceptualized by a group of university scientists in early 1980s. It was developed under a public-private partnership between a UK pharmaceutical company (henceforth called UK Pharma), the WHO TDR[[3]](#footnote-4), and the UK’s Department for International Development (DFID). CHALDAP, initially approved in 2002 by the UK Medicines and Healthcare Product Regulatory Authority (MHRA) was withdrawn in 2008 due to adverse results in clinical trials.

This specific case study of a public-private PDP provides us an opportunity to explore and capture the significance of micro-foundational aspects in managing global and strategic health partnerships in an environment undergoing rapid social and institutional change. Thus, the overarching objective of the paper is to use micro foundational lens to analyze the dynamic interplay of power and trust relationship in the context of strategic choices made by the key actors involved in leading and managing the PDP.

We adopt a processual approach to identifying and analyzing critical events that shaped the developmental process of this PDP (Pettigrew, 1987; Pettigrew, 1997; Langley et al., 2013; Yates, 2014). By adopting micro-foundational lens, we analyze the critical events by specifically focusing on strategic choices made by the key actors and in that context we untangle the complex power – trust relationship underpinning the choices. In essence, found the dynamic interplay between power and trust underpinned strategic choices those involved in the PDP made as the drug development programme attempted to co-evolve and adapt to institutional changes, particularly in the aftermath of the World Health Organization’s (WHO) recommendation adoption of artemisinin-based combination therapies (ACTs) for the treatment of uncomplicated malaria.

The remainder of the paper proceeds as follows. The next section provides a brief historical overview on drugs developed for the treatment of malaria, particularly in tropical and sub-tropical countries, as a case of social change. Section 3 outlines our paper’s guiding theoretical framework focusing on micro-foundations of strategic partnerships that is critical in providing insights into how certain actors exercised their strategic choices and made concomitant changes to the resources and project teams in response to changes operating at multiple levels. This is followed, in section 4, by an overview of our research design, which includes the description of the data collection process and the methodology used for the analysis. Section 5 and 6 show our results presented across key themes emerging from our longitudinal design, followed by the final section with a conclusion and implications of our paper.

**2. Theoretical Framework**

**2.1 Micro foundations of innovation**

Micro-foundations research aims at unpacking or ‘decomposing’ macro-level constructs by paying attention to the actions and interactions of members at various organizational levels (Baer et al., 2013; Foss & Pedersen, 2014). The fundamental argument that underpins micro foundational thinking is that, macro phenomenon, such as innovation and collaborations, are caused by micro level mechanisms, including human agents, structures and processes (Felin and Foss, 2005). In understanding the “roots of the phenomenon”, Felin & Foss (2005: 452) argue that micro-foundations allow a better understanding and explanation for the emergence of and changes in a macro level phenomenon. Thus, the micro foundational approach emphasises the essence of multi-level analysis in organisational and management research.

Recent studies on micro foundations of organisational innovation recognise the significance of human capital, particularly so-called knowledge workers who contribute in generating new ideas or knowledge (Rothaermel and Hess, 2007; Felin and Hesterly, 2007). Dixon, Meyer and Day (2014) note that for successful innovation outcomes organisations must invest in building dynamic capabilities of adaptation for developing strong routines of exploitative learning and dynamic capabilities of innovation through exploratory learning, experimentation, search and risk-taking. In a similar vein, Ferraris, Santoro, Bresciani and Carayannis (2018) highlight the importance of temporal ambidexterity in embedding new knowledge and exploiting existing routines for successful Smart City projects that typically involve public and private partnerships. Grigoriou and Rothaermel (2014: 568) in their study identified two categories of individuals, namely “productivity stars”, who are essentially knowledge or idea producers, and “relational stars”, who apart from possessing solid knowledge base are also great collaborators who succeed in establishing and brining benefits from networks of knowledge. The two types of individuals that are most prominently acknowledged in the literature have drawn insights from changes in the biopharmaceutical industry. Star scientists are attributed to drive innovation in the industry by via strategic partnerships (Zucker et al., 1998; Gulati & Higgins, 2003; Hess & Rothaermel., 2011; Anderson & Hardwick, 2017).

However, a closer review of this body of literature reveals that most studies that have explored aspects of micro foundations of innovation in collaborative context have ignored the cross-border aspects. In fact, those which have paid attention to cross border context such as, Angwin, Paroutis & Connell (2015); Paruchuri & Eisenman (2012) and Tarba, Ahammad, Junni, Stokes & Morag (2017) are far and few between. Even those with cross border focus do not provide significant insights on the how the nature and content of actions and interactions between individuals shape the development of such partnerships. Our paper is an attempt to fill this gap.

**2.2 Relational Micro Foundation Factors in Multiple Global Relationships**

The extant literature considers the inherent relationship between trust and control as one of the distinctive features of inter-organisational relationships (Das & Teng, 2001; Seppanen, Blomqvist & Sunqvist, 2007; Vanneste, 2017). Despite this stream of research, there is a limited understanding of how power, trust and an organisation’s technical and research capabilities influence performance outcomes in inter-organisational relationships (Goles, 2002; Levina & Ross, 2003). Extant literature highlights the essence of strong relationship quality (Goles, 2002; Lee & Kim, 1999) in reducing high degree of information asymmetry that exists between the contracting parties and averting potential failure in inter-organizational partnerships (Arino, de la Toore & Ring, 2005; Frest et al., 2011).

**2.3 Power - Trust relationship and Strategic Choice**

In this paper, we provide an indication of how relational factors of power and trust and organisational strategic choices of investing in certain technical and managerial capabilities can affect the quality of the relationship between the contracting parties. The extent of information asymmetry between key actors can have a positive or adverse effect on the quality and performance of relationship. Borrowing from the literature on inter-organisational relationships between software development service providers and their firms seeking to develop software products, issues of trust, power imbalance, and cultural distance between the collaborating or contracting parties has been noted to adversely influence relationship quality (Trang, Barnett & Tho, 2003). Conversely, a high level of relationship quality between the partners is often seen as an excellent predictor of their success (Lee & Kim, 1999).

Building on the resource-based view of a firm (Wernerfelt, 1984), technical capability architectures in strategic partnerships is seen as critical for sustained relationship quality and firm performance (Caniels & Gelderman, 2005; Croom, 2001; Day, 2000; Doney & Cannon, 1997; Goles, 2002; Plakoyiannaki & Tzokas, 2002). Trust between partners in inter-organisational relationships is noted as a key factor affecting sustained relationship performance (La Londe & Cooper, 1989). Trust has a negative association with opportunistic behaviour and maintaining the cost of negotiation, wherein low levels of trust can lead to termination of the relationship. Other studies have suggested that power plays an important and contingent role than trust does in managing relationships. It depends on the type of power in a relationship such as dispositional, coercive, or expert power to variously impact in both positive and negative ways in a relationship.

Certain academics have argued that power can serve as a functional equivalent of trust (Bachmann, 2001; Hardy, Phillips & Lawrence, 1998; Das & Teng, 2000; de Rond & Bouchikhi, 2004). In line with this contingency view of power, power affects in numerous ways in different relationships such that each actor in a relationship can implement different impacts of power (Dahl, 1957) such that specific types of power can impact particular associations in particular settings (Bacharach & Baratz, 1969; Dahl, 1957). For example, facilitative conceptions of power can impact significantly by changing one’s own and others’ interests in a relationship (Ball, 1975; Clegg, Courpasson & Phillips, 2006). Analysing expert power via third party firms or technical competence, or expert power, has the potential to reduce the negative effects of dispositional power (Glunk, Wilderon & Oglive, 1996). Tregaskis (2003), for example, found that learning through a firm’s network offers affordances of knowledge or expert power in inter-organisational relationships.

The literature on process dynamics in inter-organizational relationships sensitise us to two key aspects relating to these social phenomenon. First, inter-organizational relationships follow unpredictable path as they (co) evolve over time, often responding and adapting to changes at multiple levels (Lewin and Koza, 2000, Das and Teng, 2002; Hynes and Wilson, 2012); and second, the process of evolution of such relationships are underpinned by iterative cycle of initiation, action, evaluation and (re) adjustment (Ring and Van de Ven, 1994; Doz, 1996; Arino and de la Toore, 1998; de Rond and Bouchikhi,2004; Berends and Sydow, 2019). Put simply, development of inter-organizational relation over time is underpinned continuous interactions between the partners who not only assess efficiency, equity and adaptability criteria but also undertake corrective actions. Hence, the argument that the interactional pattern as well as the corrective actions that partners arrive are influenced by the quality of relationship between individuals involved in directly managing the relationship (Arino, de laToore and Ring, 2000; Bruyaka, Philippe, and Castaner, 2018; Bidault et al., 2018). It is in this context that insights from strategic choice perspective (Child 1972) assumes significance. It posits the view that organizational decision makers or key actors choose the most appropriate strategy after evaluating existing position of their respective organizations. The process of evaluation necessarily involves expectations of an organization's internal and external stakeholders and the organization’s relationship to key stakeholders and its present level of performance. Thus, in the context of inter-organizational relationships, we argue that choices that partners make could be considered as outcome of assessment of options and ranges by decision makers’ or key actors, directly involved in managing the partnership (Doz, 1996; de Rond and Bouchikhi, 2006; . Helfat and Peteraf , 2015; O’Dwyer and Gilmore, 2018).

**3. Overview of Malaria and its Treatment- a Case of Social Change**

Malaria is considered as one of the most fatal infectious diseases in the world, which affects nearly five times as many people as Tuberculosis, HIV-AIDS, measles and leprosy combined together (Bremen, 2001, Ranford-Cartwright, 2004; Price et al, 2009; Wassmer and Grau, 2017). It is most widely prevalent in countries in Africa, particularly in Sub-Saharan Africa where almost 90% of malaria cases are reported and 92% of deaths from malaria occur (Lang & Greenwood, 2003; Craft, 2008; World Malaria Report, 2019). Sub-Saharan Africa, is characterised by a toxic relationship between acute poverty and malaria epidemic, each being a cause and consequence of of the other (Trouiller & Olliaro, 1999, Lang, 2003, Craft, 2008; Tusting et al, 2016). Hence, the assertion by Keusch et al. (2010) that malaria should not be seen merely as a medical problem rather considered as a complex socio- ecological whole wherein humans, mosquitos and parasites are interconnected.

In terms of social change, the historical evolution of the treatment of malaria has been categorized under three major periods (Alilio et al.; 2004; Keusch et al., 2010). The first period pertains to the years between late nineteenth century and early 1950s. The discoveries of the malarial parasite in 1880 and the malarial transmission cycle in 1887 (Harrison, 1974; Lucas & Gills, 1998) underpinned the commercial development of quinine based anti-malarial drugs in 1918. The syntheses of chloroquine in 1946 heralded a global approach to fight malaria (Loeb et al., 1946) but within a few years, resistance to quinine and chloroquine was observed in Colombia and Cambodia-Thailand border (Payne, 1987; Petersen et al., 2011; Phyo and Noste, 2018).[[4]](#footnote-5)

The second period, between 1950s and early 1980s, was characterized by rapid proliferation of multilateral initiatives to coordinate and control malaria. The Global Malaria Eradication Programs[[5]](#footnote-6) (which was the most prominent initiative) was discontinued in 1969, when it was recognized that overuse of dichlo-diphenyl-trichloroethane (DDT) has also resulted in development of resistance in the malarial parasite. By late 1970s, particularly after the end of Vietnam War, the R&D for new anti-malarial drugs, as was the case with other neglected diseases, came to a standstill[[6]](#footnote-7). Dearth of new drugs for neglected diseases during this period is attributed to lack of funding and resources and lack of interest of the pharmaceutical companies (Lang, 2008; Trouiller et al. 2002; Pedrique et al., 2013).

The third period was characterized by humanitarian crises resulting from malaria during 1980s and 1990s brought the disease to the global attention leading to many multilateral initiatives.[[7]](#footnote-8) Roll Back Malaria (RBM), launched in 1998[[8]](#footnote-9), was the most prominent of the various initiatives. Greater participation of philanthropic organisations contributed to the emergence of PPPs as the most effective approach to develop anti-malarial drugs (Moran, 2005; Keusch et al., 2009; Fernando et al., 2018). The formation of PPPs underpins the collaborative nature of innovation of new drugs for NTDs including malaria (Moran(b), 2005; Nwaka, 2005; Jakobsen et al., 2011). Notwithstanding the significance attached to the PPPs as the most viable vehicle to develop new drugs for the treatment and control of NTDs (WHO Report, 2004; Kaplan & Liang, 2004; Stolk, 2013;) and the steady increase of the formation of PPPs for the purpose (Ngoasong, 2009; Liese et al., 2010; de Vrueh & Crommelin, 2017), there is limited insights on the functioning and decision-making dynamics in these strategic partnerships (see for instance Munoz et al., 2015; Kelly et al., 2015; Muir et al., 2016; Citrin et al., 2017). It is in this evolving context of social change, i.e. movement towards a new approach - public private partnerships – to develop new drugs that makes our study important and interesting. Adopting micro-foundational dimensions helps us to unravel the power – trust dynamics that underpin strategic choices that decision makers in public-private PDPs make as their relationship as the drug development process develops over time.

**4. Research Design**

**4.1 Methodology**

Given that the predominant focus of this research is to explore the dynamic interplay between power and trust in the context of strategic choices of PDPs, we use a rich longitudinal case study pertaining to the development of a new anti-malarial drug, CHALDAP. CHALDAP was developed as public-private PDP and it involved three active (a UK University; a UK based pharmaceutical company; and Research arm of the global health organization) and one passive (UK Government’s Department for International Development – DFID) partners. Although the essence of PDPs have been documented in public health literature (see for instance, Moran, 2005a; Chataway et al., 2007), there is a gap in understanding relationship quality between the stakeholders in such partnerships (see for instance Munoz et al., 2015).

We, thus, defined our research question as follows: How does the interplay between power and trust influence strategic choices in PDPs as the multi stakeholder partnerships evolve over time?

**4.2 Data collection**

We initiated our research in October 2008, only a few months after the PDP was terminated, and the research was carried out in three phases over a period of 13 months. In the first phase (Oct – Dec 2008), we interviewed two scientists, including the scientist who led the PDP since its informal inception in early 1990s. These initial interviews provided us a broad timeline of the development of the PDP and some of the key relational and structural issues that the PDP faced over the 18 years of its existence, more particularly since 2001, when the WHO recommended a change in policy pertaining to development of new antimalarial drugs. The interview culminated with getting access to minutes of meetings of the PDP from 2002 onwards until the termination of the partnership. In phase two (Mar– Jun 2009), we interviewed three senior members, each of who represented the three organizations that were actively involved in the partnership. These interviews helped us to understand (a) key issues relating to antimalarial drugs in particular; (b) rationale for each of the partners to participate in the partnership; (c) activities of their respective organizations in the PDP; and (d) mapping the critical events in the lifecycle of the PDP and garnering respondents’ perspectives on the rationale and significance of the events. In Phase three (July – Nov 2009), we further interviewed all the five respondents to clarify the information they had provided and cross questioning them based on information we had gathered from other interviewees, minutes of meetings and policy documents issued by the WHO. In all, apart from the interviews with the five interviewees, four of who were involved with the PDP all through its lifetime, our data sources also included minutes of each meeting between 2001 – 2008 (16 meetings in total); and technical committee reports and white papers released by the WHO on anti-malarial drugs; journal and newspaper publications and press releases on CHALDAP and press releases and other corporate documents from various other stakeholders. Rich information from the secondary sources, particularly white papers and policy documents pertaining to global malaria policy by the WHO and RBM were used to complement and corroborate information gathered from the interview respondents. Figure 1 depicts the 12 key events that shaped the development of CHALDAP partnership and Table 1 provides list of key interviewees.

Please insert Figure 1 over here

In essence, we followed guidelines set out adopt processual approach (Van de Van and Poole, 1995; Pettigrew, 1997; Langley et al., 2013) and used both first and second order analysis (Turner and Rindova, 2012). Consistent with this approach, we first wrote the case history (Yin, 2003; Eisenhardt, 1989) and then identified twelve critical events that shaped the development of the inter-organizational relationship. In the process, we created “thick description” of the (inter) organisational and institutional changes, which in essence provided the social and structural context for power – trust dynamics to manifest and these tensions underpinned the strategic choices made by the key decision makers. Put simply, changes at inter and intra organizational as well as institutional levels created conditions for manifestation of power – trust dynamics and in turn influenced the strategic choices made by the partners. In essence, the strategic choices pertained to – how to make the partnership work and facilitate development of CHALDAP. Table 2 provides a breakdown of the twelve events, identification of the strategic choices and micro-foundational dimensions.

Please insert table 2 over here

In adopting our methodological approach, we followed the recommendation of Dyer and Wilkins (1991) that one in-depth case study is more reliable and valid than multiple superficial case studies. Other scholars, for instance O’Reilly and Tushman (2013) and Bansal et al. (2018) have highlighted the essence of in-depth single case studies in unravelling underlying dynamics in (inter) organisational contexts.

**4.3 Case history**

Our study focuses on an exemplary case study, tracking the co-development of CHALDAP. The collaboration for development of CHALDAP was informally initiated in 1992 between researchers based at an UK university and Dr HJ[[9]](#footnote-10) who at the time was heading the ‘Diseases for Developing World’ Division in a UK based pharmaceutical company (Henceforth called as UK Pharma II). At that time, UK Pharma II was only one few companies involved in the development and marketing of drugs for neglected diseases. With the encouragement from Dr HJ, the scientists undertook further tests in Kenya to gather evidence regarding effectiveness of CHALDAP as compared to existing anti-malarial drugs. The partnership between UK Pharma II and the UK University, was formalized in 1996. Next year, the scientists and Dr HJ approached the WHO-TDR, which decided to join as a partner. Subsequently in 1998-99, the UK Government’s Department of International Development (DFID) joined the partnership as the fourth partner.

In 2002, CHALDAP attained approval from the UK Medicine and Health Regulatory Authority (MHRA) and subsequently the PDP was granted marketing license for the drug. The PDP decided to register the drug with health authorities in different Sub-Saharan African countries. CHALDAP was priced at US $ 29 cents for adults and US $ 18 children for a course of treatment, well below the US $1 that WHO considered as threshold price for any anti-malarial drug to be affordable to a wider population in Sub-Saharan Africa. However, in 2002-03, the WHO reviewed the global malaria policy and recommended all treatment for malaria should be combinational therapy, preferably containing an artemisinin derivative (ACT). Although CHAPDAP was a combinational drug but it did not contain an artemisinin derivate. Senior managers in the PDP did not anticipate this change in policy and tried to convince the WHO and Roll Back Malaria (Henceforth RBM) to allow CHALDAP to remain as a treatment option for malaria. Unable to convince the authorities, the senior managers in CHALDAP PDP decided to add an artemisinin derivate to existing CHALDAP to comply with the policy changes.

Around same time concerns were raised within the WHO and RBM regarding the safety of CHALDAP, particularly relating to its usage in Sub-Saharan Africa where where glucose-6-phosphate dehydrogenase (G6PD) deficiency was prevalent (Beutler et al., 2007). In this context, questions were highlighted on how clinical trials for CHALDAP were designed. On July 1-2 2004, RBM and another division within the WHO called Essential Drugs and Medicines department convened a technical consultation to assess the risks (and benefits) associated with CHALDAP. The findings of the report were leaked to a UK newspaper in June 2005, three months before the report was finally made public in September 2005. The report concluded that information regarding safety of CHALDAP was too limited to warrant its widespread and unregulated use. Notwithstanding these developments, the managers in the PDP rejected the findings of the report and unanimously decided to continue the development of CHALDAP in combination with an artemisinin derivative (called CHALDAP Plus). The Phase III studies for CHALDAP Plus took place in 2006-07 and it involved two trials. One trial was designed to establish efficacy of CHALDAP Plus by comparing it against an ACT and another trial was designed to establish the efficacy of CHALDAP Plus by comparing it against CHALDAP. Both the trials showed significant reduction in hemoglobin levels in patients with G6PD deficiency. On Feb 29, 2008, the PDT decided to terminate development of CHALDAP Plus and withdrew CHALDAP from the market.

**5. Findings and Discussion**

Child (1997) defines strategic choice as “the process by whereby power holders within organizations decide upon courses of strategic actions” and the choices and actions are to be made “through initiatives within the network of internal and external organizational relationships – through pro-action as well as reaction” (Child 1972: 2). Thus, strategic choice and particularly resulting actions are a *“political phenomenon*” (Child 1997: 46), which we argue, reflect on-going tensions between power and trust as inter-organizational relations develop over time. In essence, strategic choices partners make are temporal by nature, and create conditions for subsequent actions. We adopted micro foundational lens to analyse the interplay between power and trust underpinning strategic choices, which in a practical sense results from the interaction between individuals and decision makers in inter-organizational relationships (Felin and Foss, 2005; Barney and Felin, 2013) and their assessment of various options. In analyzing the events, we focused our attention on (a) why did the event take place, i.e. the social and structural conditions underpinning the events; (b) nature and orientation of strategic choices; and (c) how did ‘power relations’ or / and ‘trust relations’ between the partner organizations or individuals, who were either directly or indirectly involved contributed to the strategic choices per se. Thus, we organized our analysis under two broad categories, namely strategic choices made by the CHALDAP PDP in response to (a) inter and intra organizational changes, i.e. changes within and between the partner organizations (section 5.1); and (b) institutional changes, i.e. policy changes in the institutional field context (section 5.2). Thus, we identified and explored the interplay of power and trust at different levels of analysis (Abell et al., 2008; Foss, 2010), as the CHALDAP PDP evolved over its lifecycle (Ring and Van de Ven, 1996; Doz, 1998; Salk, 2006).

## 5.1 Strategic choices at organizational and inter-organizational levels – Formation and maintenance of the CHALDAP PDP.

***5.1.1 Informal relationship between UK University scientists and Head of Tropical Diseases, Pharma II***

This event pertains to the formation of an informal partnership between the scientists from UK Uni with Dr HJ from Pharma II. The two scientists had been exploring relevance of combinational drug containing chloprognuanil and dapson, as a viable solution against malaria resistance. From a scientific and technical point of view, in 1980s, combinational drugs were uncommon and their efficacy were not well known. However, Dr HJ trusted the scientific knowledge of the two scientists and was willing to support their work. Interestingly, Dr HJ did not make any commitments ether to fund the clinical trials or establishment of any formal partnership at a later date, nonetheless he ensured that sufficient amount of compounds of chlorproguanil and dapsone were available for clinical trials. The subsequent strategic choice - formalization of partnership between UK uni and Pharma II to co-develop CHALDAP, after the scientists undertook clinical trials of the two drugs administered in combination, is underpinned as much by the attributes of the two star scientists (Gulati & Higgins, 2003; Anderson &Hardwick, 2017) as by the relational quality amongst the key individuals (Arino et al., 2001; Goles, 2002; Lee & Kim, 1999).

***5.1.2. Involvement of the WHO-TDR as third partner***

Within UK Pharma II, Dr HJ headed the Tropical Disease Team, which for administrative purpose, was located within the International Business division and was not considered as part of Pharma II’s R&D division. Almost a year after the CHALDAP PDP was formed, no budget was allocated and Dr HJ had exhausted his existing budget. His divisional head refused to provide any additional support to undertake developmental activities for CHALDAP and advised him to “go find funds from somewhere else” (UK Uni Scientist 1). This development highlights at one level power dynamics within Pharma II and in that context the existence of Dr HJ’s team within the organization. Whilst it was undertaking R&D work albeit for neglected diseases, his work was not considered central to Pharma II’s overall R&D. So, he was reliant on generosity of the Head of International Business Development to fund his R&D activities. At another level, according to the UK Scientist 1, the issue of not providing funding for CHALDAP PDP was essentially about the concept of combinational drug. He asserted: “*I do not think it was about money at all rather it was about the risk. The amount of money to develop was not that much because we were combining two existing drugs but if you wonder about the risk you get a different picture. The concept of combinational drug was still in its infancy and the view was like if there are three groups who say they think this is a good idea, they feel more secure than if there is one group to take the liability…they weren’t keen to take the risk on their own only…”* (UK Uni Scientist 1).

The interplay of power and trust between Dr HJ and his Divisional Head underpinned the strategic choice made by the CHALDAP PDP in approaching the WHO TDR to fund the development of CHALDAP.

At its end, WHO-TDR was also looking to fund ‘translational research’ following an internal review. Thus, WHO-TDR was more willing to join the PDP as the third partner. The WHO-TDR emphasized that the PDP must develop and make CHALDAP available to market at less than $1USD per dosage. The partners agreed that the cost of CHALDAP development would be shared between UK Pharma II and WHO-TDR on a 50:50 basis. The company would undertake pharmaceutical development whereas the WHO-TDR would fund and organize the necessary clinical work for registration of CHALDAP.

***5.1.3 Involvement of the DFID as the fourth partner***

In 1997, the newly elected Labour Government in the UK established Department for International Development to commit to and oversee developmental activities in less developed regions of the world. The UK government hosted the 1999 G8 summit with a specific focus on addressing challenges pertaining to communicable diseases. During the summit, the CEO of UK Pharma II, briefed ministers about his company’s efforts to develop drugs for NTDs. In this backdrop, the work of Dr HJ and his team attained greater prominence within the organization and as a consequence the profiles of the developmental projects he was undertaking, including the CHALDAP PDP, were further enhanced (Lang, 2003). Following the conversation between the CEO of Pharma II and the Secretary of State for International development, DFID decided to become the fourth partner in the CHALDAP PDP. In many respect, the joining of DFID, enhanced the profile of CHALDAP PDP as well as helped in reducing negative effects of dispositional power towards the activities of Dr HJ and his team (Glunk, Wilderon & Oglive, 1996; Tregaskis, 2003).

***5.1.4 Merger of UK Pharma II with UK Pharma I – formation of UK Pharma***

The merger between Pharma II and Pharma I presented the most critical challenge to the CHALDAP PDP. There was lack of clarity during the initial stages regarding the new company’s approach to tropical diseases in general and CHALDAP PDP in particular. Unlike UK Pharma II, which was only one of the few pharmaceutical companies at that time to have a dedicated tropical disease research unit, albeit within the International Business division, UK Pharma I was not particularly known for drugs for tropical diseases[[10]](#footnote-11). But the new CEO of UK Pharma decided that the company would increase its focus on tropical diseases and dedicated a new campus in Spain for that purpose.

The survival of CHALDAP programme within the new setting was attributed to two factors. First, the CHALDAP PDT had already made significant progress and was in the process of submitting documents for registration with MHRA. Second, and more importantly it had gained institutional legitimacy owing to the involvement of DIFD and the WHO-TDR as two key partners. This further highlights the assertion that an organization’s network not only provide knowledge but also accord expert power, particularly in strategic partnerships (Tregaskis, 2003).

## 5.2 Strategic Choices and Changes in the Institutional environment and New Malaria Treatment Guidelines

***5.2.1. Formation of Roll Back Malaria (RBM) Partnership and new guidelines for malaria treatment***

By mid-1990 malaria accounted for almost a million deaths in Sub-Saharan Africa (see Snow et al., 2001; Rowe et al., 2006) and as a consequence, the WHO was severely criticized for its failure to play a central role in controlling malaria in the region (Yamey, 2004; Snow et al., 2001; Rowe, 2006). In this backdrop, the WHO, World Bank, UNDP and UNICEF partnered to establish the Roll Back Malaria partnership, the first major effort against malaria in almost four decades[[11]](#footnote-12), with the goal to reduce incidence of by half by 2010 (Nabarro and Tayler, 1998; Balter, 2000). The formation of RBM highlighted lack of trust in the capacity of the WHO to effectively reduce incidence of malaria and at the same time, the formation of RBM also indicate to the emergence of new power structure, so far as the institutional field pertaining to malaria treatment and prevention (Narashiman and Attaarn, 2003; Yamey, 2004).

However, by beginning of the millennium, there was growing skepticism regarding functioning and success of RBM. In fact there was a growing perception that no significant progress towards controlling malaria[[12]](#footnote-13) has been achieved. The civil war in many Sub-Saharan African countries[[13]](#footnote-14) coupled with complete resistance to existing antimalarial drugs had worsen the situation. In this backdrop, the WHO announced a new guideline for the treatment of malaria, particularly in the areas, such as Sub-Saharan Africa where resistance to existing drugs was very high. The new policy called for use of combination drugs to control malaria but the combination drug must contain derivatives of artemisinin, a plant based compound.

The change in policy had two significant implications for CHALDAP, which was in the process of registration and expected to be available in African countries. First, although CHALDAP was developed as a combination drug, under the new guidelines it was considered as a mono therapy since dapsone was not an anti-malarial drug[[14]](#footnote-15). And second, CHALDAP did not have an artemisinin compound and hence, under the new guideline, without an addition of an artemisinin compound, it could not be made available in Sub-Saharan Africa. The changes in the WHO’s guidelines came as a complete surprise to the CHALDAP PDT, even though WHO-TDR, the research arm of the WHO, was one of the key partners in the CHALDAP development programme. The change in policy for malaria treatment and lack of communication from the RBM to WHO-TDR regarding the policy changes highlights the changes in the power structure at institutional level and capture the strengthening and centralization of of dispositional and coercive power with RBM, which consequently adversely affected the relationship quality and trust between the CHALDAP PDT team and WHO-TDR as well between the CHALDAP PDT and RBM.

**5.2.3. *Initiation of CHALDAP Plus***

The CHALDAP PDT decided to develop CHALDAP Plus (CHALDAP with an artemisinin derivate called artesunate) after they failed to convince the RBM and WHO to reconsider their recommendations regarding malaria treatment. This event highlights the changing power dynamics within the WHO, wherein RBM, whose role was to implement control initiative, virtually decided that the specific type of drugs it would like to be made available to it and it also highlighted the breakdown of trust relationship between CHALDAP PDT and RBM.

***5.2.4. Technical consultation meeting convened by the WHO – RBM***

CHALDAP was granted approval by the UK Medicines and Healthcare Product Regulatory Agency (MHRA) in 2003 and it was made available in the market though local private pharmacies in almost 23 countries in Africa. In this backdrop on July 1-2, 2004, the WHO and RBM convened a meeting with another WHO division called Essential Drugs and Medicines (EDM) department to assess risks and benefits of using CHALDAP in Africa. It is estimated that approximately 20-25% of population in Sub-Saharan Africa are considered to be G6PD deficient (see Nikoma et al., 2009) and considering these figures, the technical committee raised questions on whether and how screenings were done for G6PD when the clinical trials for CHALDAP took place. CHALDAP PDP had not considered G6PD screening before enrolling patients and the prevailing view within the CHALDAP PDT was:

*“any specific screening of patients was not necessary and in real life it was not possible also. We discussed that in the PDT. In these countries, at least 20% of patients are G6PD deficient. Unless we miraculously randomly took these patients and we didn’t get any of them G6PD deficient! I refuse to believe that when you are enrolling 1000 patients there won’t be somewhere near 20% would be G6PD deficient.”* (Representative, WHO-TDR)

The meeting of the technical committee posed a critical challenge to the CHALDAP PDT – whether the CHALDAP PDT should continue or it should terminate the development of CHALDAP *plus*. The CHALDAP PDT, wanted assurance from the WHO-TDR and WHO and RBM on whether there is support for development of CHALDAP *plus.* Interestingly notwithstanding the concerns highlighted by the WHO’s technical committee, the CHALDAP PDT received that assurance from the representative of WHO-TDR to continue development of CHALDAP Plus. The notes from the minutes of the meeting provide evidence regarding this:

*‘…JL[[15]](#footnote-16), speaking on behalf not just of TDR but the entire WHO, wishes to convey the interest of WHO to the continued development of CHALDAP plus. All interested groups in WHO (including RBM) see CHALDAP plus as potentially a valuable addition to the armory of anti-malarial drugs (ACT in particular) if safety and efficacy is demonstrated. TDR was fully behind the continued development of CHALDAP plus’* (MoM, 08.07.04)[[16]](#footnote-17)

The continued support from the WHO and its divisions confounded the members of the PDT but they decided to continue the development of CHALDAP Plus. The view amongst the members of the CHALDAP PDT was that people within WHO and RBM viewed CHALDAP as an irritant when drive for malaria control and eradication had become ACT centric. This event and the strategic choice to continue development of CHALDAP Plus also captures the underpinning interplay of power, residing with institutional actors, RBM in particular, and the distrust between CHALDAP PDT and RBM.

***5.2.5. Leaking of the Technical Committee’s report in The Sunday Times***

On 12 June 2005, report of the Technical Committee was leaked to The Sunday Times. The article, under the title ‘Health experts warn over ‘dangerous’ malaria drug’ warned British public about UK Pharma’s plans to make CHALDAP available in 34 countries in Africa. The experts who leaked the report criticized UK Pharma and by extension CHALDAP PDT for not making CHALDAP available in the UK. The members of the CHALDAP PDT refuted these accusations and informed that the reason why CHALDAP was registered with the UK MHRA was because it one of the most reputed regulatory authorities and the people in the UK do not suffer from the same type of malaria in Africa[[17]](#footnote-18). One of the scientists from the UK university and member of the PDT highlighted this incident as an “illustration of the immense politics and harassment” they faced due to their involvement in CHALDAP development.

In September 2005, almost fifteen months after the technical committee was set up and three months after the content of the report was leaked by one of the members, the WHO published the report that concluded:

*‘CHALDAP should be used only when there is a confirmed diagnosis of malaria. The potential risks associated with CHALDAP use in areas where G6PD deficiency is prevalent outweigh the benefits if the drug is used for presumptive treatment. In areas where G6PD deficiency is prevalent and a reliable clinical or laboratory diagnosis of anaemia and a test for G6PD deficiency cannot be obtained, a suitable alternative to CHALDAP should be used. If there is no suitable alternative, CHALDAP should be used taking into account all the associated risks…. The information on the safety of CHALDAP is still too limited to warrant its widespread, unregulated use’* (Report of the Technical Consultation Convened by WHO, 2005: 23)

The CHALDAP PDT, immediately convened an emergency meeting and strongly refuted the conclusion:

*‘The PDT partners were UNANIMOUS in the view that the report is premature, that it contains major scientific flaws, that it is selective in its use of published literature, and that many of its recommendations are unsupported by the data…’* (MoM 27/28.09.05)

The PDT concluded that the report of the Technical Committee as well as leaking of the content of the report was an attempt to sway public opinion.

*‘(PDT) AGREED THAT the WHO-RBM report on CHALDAP, the leak of the draft Report from WHO to the Sunday Times and resultant rumours have had major impact on the public perception of the CHALDAP PDT project’* (MoM, 27/28.09.05)

The major concern for the PDT was WHO’s continued ambiguous position on the future of the development of CHALDAP *plus*. This incident reflects, at one end lack of transparency and trust of RBM towards the CHALDAP team and on the other end demonstrates use of media in influencing public interest. Within this backdrop of dynamic interplay of power – and (dis)trust, the CHALDAP PDT continued to develop CHALDAP Plus.

***5.2.6. Termination of CHALDAP and CHALDAP plus programmes***

By the end of 2005, the Phase II study of CHALDAP *plus* was complete and the PDT received had provisional approval for Phase III trials from the WHO-ERC[[18]](#footnote-19). The Phase III studies took place in 2006-07 and involved two trials. Although in both the studies CHALDAP *plus* was found to be as effective as the current ACT, a reduction in the hemoglobin levels of patients with G6PD deficiency was observed.

The findings of the two studies were discussed in the PDT meeting that took place on Feb15, 2008. In the lights of these data:

*‘PDT was an agreement that CHALDAP plus could not be deployed in Africa for widespread public health use. The product would carry a contra-indication in G6PD deficient patients and all patients would need to be tested. This is not practical. The PDT agreed to the proposal from UK Pharma and MMV that development of CHALDAP plus should cease and that the product should not be registered…’* (MoM: 15.02.08)

Accordingly, on Feb 29, 2008, UK Pharma issued a press release to inform the termination of CHALDAP plus projects. The press release stated:

*“…on the basis of the data available from both the trails, UK Pharma and MMV have decided to terminate further development of CHALDAP plus. UK Pharma has also commenced a product recall process at pharmacy level in Kenya, for CHALDAP, this being the only market with recent sales of the product…”* (UK Pharma Press Release, 29.02.2008)

The final meeting of the PDT took place on April 2, 2008. The Scientist from UK University who had led the PDT throughout its existence chaired it. He thanked all the individual members of the PDT as well as respective organisations for their support for the collaboration and the members of the PDT appreciated his leadership in driving the PDT to achieve the objectives it set out to achieve. The collaboration was dissolved at the end of the meeting.

**6. Conclusion**

In this paper, we aimed to explore the dynamic interplay between power and trust in context to in global strategic partnerships and we adopted micro dimensional lens to analyse the interplay of these two constructs at inter-personal, inter and intra organizational and institutional levels in specific context to the strategic choices the CHALDAP PDT made as the CHALDAP PDP evolved over time. The backdrop of the co-development of CHALDAP, an anti-malarial drug specifically developed for the Sub-Saharan Africa, represents an illustration of an attempt to contribute to social changes in the region. The complex relationship between malaria and poverty in the region, in particular, is long recognized in the global public health domain (see Sachs and Malaney, 2002; Teklehaimanot and Mejia, 2008). Global health partnerships are a distinctive feature of the domain of global health system and yet, there has been limited studies on how such partnerships function and develop over time (Munoz et al., 2015). We find that the interplay between trust and power, underpin the strategic choices key decision makers involved in the CHALDAP PDT made as they attempted to adapt the partnership to changes at intra-organisational, (within partner organisations), inter-organisational (between partner organisations) and institutional (changes in institutional structure and changes in global policy) levels.

# **6.1 Implications**

Multi foundational research aims to unpack macro level constructs by paying attention to the actions and interactions of members at various organizational levels (Baer et al., 2013; Foss and Pedersen, 2014). Our study, based on a longitudinal analysis of strategic choices, made by PDT in a multi stakeholder oriented PDP formed to develop an antimalarial drug, highlights the dynamic interplay between power and trust at different levels of analysis. We posit the view that changes at multiple levels, create conditions for interplay between power and trust relations, which in turn underpin the strategic choices decision makers make. In this backdrop, we posit that drive to attain legitimacy often influence the strategic choices.

## 6.1.1 Theoretical implications

Micro foundational literature that specifically focuses on innovation recognize the significance of knowledge workers (Rothaermel and Hess, 2007; Felin and Hesterly, 2007), in general and more particularly the contribution of and so called ‘productive and relational stars’ (Grigoriou and Rothaermel, 2014) in enhancing successful innovation outcomes in organizations. In similar vein, research on biopharmaceutical industry has sensitize us to the activities and contributions of star scientists in driving innovation by often by forming strategic partnerships with industry actors (Zucker at al., 1998; Hess and Rothaermel, 2011; Anderson and Hardwick, 2017). Notwithstanding these insights, there is limited insights on how star scientists, particularly in the arena of neglected diseases, form partnerships to legitimize their scientific concepts and translate them into tangible products. Findings from our case analysis captures the tensions emanating from interplay between power and trust as the members of CHALDAP PDT attempted to legitimize their innovation – a new antimalarial drug.

Our findings also contribute to the stream of micro-foundational research that specifically pays attention to trust – control dimensions in inter-organizational relationships. We find that strong relational quality reduces information asymmetry and enhances trust (Arino et al., 2003; Goles, 2002; Lee and Kim, 1999), as it was evident in initially formation of informal relationship between the two UK Uni scientists and Dr HJ in Pharma II and at the same time lack of relational quality diminished trust between the CHALDAP PDT and RBM in particular after the WHO recommended change in treatment for malaria.

## 6.1.2 Managerial implications

## Micro foundational research emphasis multi-level analysis of macro level phenomenon. Multi-level analysis emphasise identification of relationships between entities at different levels and particularly such an approach sensitise managers to how different variable influence actions and interactions of individuals, which in turn influences functioning at a collective level. In our exploratory research in this exemplary case study highlights the strategic choices key actors involved in managing the CHALDAP PDP made during the course of the evolution of the partnership. Our analysis, particularly capture the interplay between power and trust dynamics at multiple levels and their implications on the choices of the managers.

## 6.1.3 Limitations and future research

This study is a rich and in-depth account of the evolution of a public-private PDP formed to develop a new antimalarial drug and in this context we adopted micro-foundational lens to analyze strategic choices managers made as the PDP evolved. The micro-foundational lens helped us to unravel the power – trust dynamics underpinning the strategic choices. Considering paucity of longitudinal research on global health partnerships in general and public-private PDPs in particular, our study fills a distinct gap and yet more longitudinal case study research is needed to generate unique insight into how these collaborations work in practice. Nevertheless, this study like many others have certain limitations. For instance, this study is based on one case study and while the findings offer a useful understanding of how power and trust manifested themselves within the study, the findings may not be generalizable to all other cases of global health partnerships.

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1. The era of the MDGs came to a conclusion in 2015-16 with the launch of 17 Sustainable Development Goals (SDGs). The three MDGs related to global health feature in the list of SDGs. The UN called upon members’ states to achieve the 17 Sustainable Development Goals by 2030. [↑](#footnote-ref-2)
2. Neglected diseases are the tropical infectious diseases that primarily affect population in tropical and sub-tropical countries. Low income and high debt, poor sanitation and lack of access to healthcare characterizes these countries. These socio-economic conditions contribute in the transmission and proliferation of vector borne diseases, including malaria, dengue, chagas’ disease, lymphatic filariasis and leishmaniasis. According to the WHO, these vector borne infectious diseases account for almost 17% of the global burden of all infectious diseases and considered as the leading cause of mortality, disability and poverty in tropical countries in tropical countries, where almost 73% of the population lives on less than US$2 per day and 51% of the population lives on less than US$1.25 per day (see for instance Chen and Ravallion, 2008; Hotez and Kamath, 2009). [↑](#footnote-ref-3)
3. TDR is the Special Programme for Research and Training in Tropical Diseases, is hosted at the WHO and apart from the WHO, it is also sponsored by United Nations Children’s Fund (UNICEF), the United Nations Development Fund (UNDP) and the World Bank. [↑](#footnote-ref-4)
4. Various WHO reports highlight that quinine is still used as either first line or second line therapy for severe malaria in many parts of the world, mostly in Sub-Saharan Africa. [↑](#footnote-ref-5)
5. The first global effort to eradicate malaria was initiated in 1955. The Global Malaria Eradication Program was initiated in 1955 in the backdrop of eradication of malaria in the United States by the use of DDT. The experts in the WHO considered DDT as the ‘silver bullet’ in fight against malaria (see Najera, 2011; Whittaker, 2014). Interestingly African countries, which were under malaria endemic, were excluded from the Global Malaria Eradication Program on the grounds that it was “premature to carry operations in locations with bad roads, large rural populations and precarious health systems” (Fee, 2016: 20). [↑](#footnote-ref-6)
6. Notwithstanding the global burden attributed to NTDs, between 1975 and 1999 only 13 drugs were developed for the treatment of neglected diseases (Trouiller et al., 2002; Parker and Allen, 2011), including three antimalarial drugs (Lang, 2003). [↑](#footnote-ref-7)
7. Alilio et al. (2004) listed six specific malaria focused multilateral initiatives that were initiated between 1992 and 1999. [↑](#footnote-ref-8)
8. The landscape of global health system, specifically in the context of malaria, underwent the most significant change in 1998 with the launch of Roll Back Malaria Partnership (RBM). RBM was conceived by global institutions, including the WHO, United Nations Children’s Fund (UNICEF), United Nations Development Fund (UNDP) and the World Bank and aimed to halve malaria death by 2010 and halving it again by 2015 (Narasimhan and Attaran, 2003). [↑](#footnote-ref-9)
9. Details withheld for confidentiality reasons. [↑](#footnote-ref-10)
10. Although Pharma I did not have had any significant presence in NTD category, Wellcome Trust had ongoing research partnerships with TDR (see for instance Morel, 2000). It inherited Malarone, an antimalarial drug, when it acquired Wellcome plc in 1995. Malarone was considered to be most expensive anti-malarial drug, priced at $42 USD for adult treatment course when it was introduced in 1996 (see Shretta et al., 2001). [↑](#footnote-ref-11)
11. No coordinated global effort to control or eradicate malaria was initiated after the abandonment of the Global Malaria Eradication Program in 1969. [↑](#footnote-ref-12)
12. Between 1997 and 2002, 35 areas in Africa experienced Malaria epidemics (Source: World Health Organization Communicable diseases 2002: Global Defence Against the Infectious Disease Threat (Geneva, 2002), 174.) [↑](#footnote-ref-13)
13. Between 1998-2003, some of the countries in Sub-Saharan Africa were in the midst of civil wars, which had a significant implication on widespread malaria epidemic in that reason (Act Now, Malaria Report, 2003). [↑](#footnote-ref-14)
14. The WHO’s Technical Consultation report, 2001 delineates the difference between combination therapy and mono therapy. It defined combination therapy as ‘two or more blood schizontocidal drugs with independent modes of action and different biochemical targets in the parasite…In the context of this definition, multiple-drug therapies that include a non-antimalarial drug to enhance the antimalarial effect of a blood schizontocidal drug are not considered combination therapy’ (p. 7).

    [↑](#footnote-ref-15)
15. The representative from WHO-TDR, who was associated with CHALDAP development since WHO-TDR became partner in 1996-97, left the organisation after he and his colleagues in CHALDAP PDT failed convince WHO and RBM to let CHALDAP be available in the market as a mono therapy. He became a leading figure in setting up MMV and remained member of the CHALDAP / CHALDAP *plus* PDT as representative of MMV, which had provided funding for development of CHALDAP *plus.*  [↑](#footnote-ref-16)
16. Notwithstanding the unequivocal assurance from the representative of the WHO-TDR, the CHALDAP PDT remained concerned about WHO-TDR’s ambiguous position on issues relating to further development of CHALDAP *plus*. In the next meeting that took place on 07.09.2004, the PDT further sought a ‘definitive and united lead’ on WHO-TDR’s position. But this time WHO-TDR did not provide them with any specific assurance (Minutes of Meeting, 07.09.2004). [↑](#footnote-ref-17)
17. Chin and WelUK Pharma IIy (2004) suggest that historical evidence point to Plasmodium vivax as the most likely cause of malaria in the UK. CHALDAP, was developed for treatment of malaria caused by Plasmodium falciparum, which is prevalent in Sub-Saharan Africa. [↑](#footnote-ref-18)
18. All research involving human participants that is supported by the WHO undergoes final review by the WHO-ERC (Ethics Review Committee). The ERC does not accept proposals directly from the investigators. Proposals are submitted to the ERC by WHO responsible technical officers from technical departments who work closely with the Principal Investigator and are in charge of that particular project. [↑](#footnote-ref-19)