CAC South Asia – Questionnaire for Independent Project Completion Assessment
Jananeethi, Thrissur, Kerala

Title of Project	A Project to Combat Corruption in Clinical Drug Trials in Kerala
Project Location: The Central Region of the State of Kerala in India	
Corruption Problem being addressed: *(as described in the project proposal).* In the medical field, though the patients trust the doctor absolutely, the doctors misuse the trust for their personal gains- conducting drug trials for pharmaceutical companies without the knowledge and consent of the human being affected by it and earning large sums of money for their service. There are several rights for a human being undergoing drug trial. But they are either not informed or not aware of it, thereby exploited by the doctors and the pharmaceutical companies. Though the investigating doctor claims that there is insurance coverage, the truth is that the insurance is promised to the doctors/hospitals. Both the concerned hospital and the doctor get a number of benefits such as equipments, staffs, international exposures, gifts and other attractive monitory packages. But the concerned patient gets only few months medicine free of charge. In the five cases of drug trail identified by Jananeethi, it could be observed that the patients undergoing drug trial were very poor and their poverty and misery compelled them to avail free medicine without knowing that it was a drug trial. This is how the pharmaceutical companies, the hospitals and the investigating doctors encash on the ignorance, poverty and vulnerability of the patients for their gains. Even though the investigating doctors are paid by the hospitals, where they are employed they get to earn extra amounts by undertaking drug trails side by side. The Ethics Committees are also not independent and generally act upon the influences of the investigating doctors due to vested interests. The human subjects who risk themselves for trial do not have a stake in the trial and do not get any benefit either from the pharmaceutical companies or from the concerned hospitals/doctors. These are the most important corruption practices that exist in the clinical drug trials.	

	Planned	***Actual***
Implementation period	15th June 2009 -14th June 2010	15th June 2009 -14th June 2010
Total Budget (for one year)	Rs.1116500	Rs.763146
PTF Contribution	Rs.952775	Rs.648675

Project Objectives

As described at Project Approval (for two years)	***Status of Achievement at Completion***[1] ***(****in view of the Evaluator)* ***in the first year***

[1] Please use the following ratings scale and provide brief narrative. 1 = fully achieved, very few or no shortcomings; 2 = largely achieved, despite a few short-coming; 3 = only partially achieved, benefits and shortcomings finely balanced; 4 = very limited achievement, extensive shortcomings; 5 = not achieved.

1. To identify 5 human subjects who have undergone clinical drug trials from 2004 to 2008 in five medical colleges of Kerala State and to investigate about the process and its impact on them	**2**
2. To explore and document the level of corruption involved during clinical drug trials of the 5 subjects through investigation, evidence-building and fact-finding for use in the courtroom; for public dissemination in the media; and as first-hand material to lobby for systemic reforms which will reduce the opportunity for corruption to occur.	**2**
3. Using the evidence collected, lobby to make the Ethics Committee of the colleges truly independent (as mandated) and suggest other systemic reforms which will increase the accountability and transparency of its functionings – ensuring meetings are minuted and properly documented etc. – so that the opportunities for corruption in drug trials are reduced	**2**
4. Liaising, capacity building and mobilizing other civil society groups, victims of corruption, media, academic institutions, human rights activists to join the advocacy process and form a coalition to push for changes in the drug trial process to combat systemic corruption	**2**
5. To provide psycho-legal therapeutic services to the 5 victims of corrupt clinical drug trials (to be funded from Jananeethi contribution).	**1**

Executive Summary: (as mentioned in the project completion report)

The primary objectives of Jananeethi project were to regulate clinical drug trials under law, and to ensure ethical standards and best practices; to ensure transparency and accountability; to approve the rights of human participants in clinical trials; to check instances of corruption and unethical practices and to enlighten the civil society and other stake holders with regard to mandatory norms and rules to be complied with in a clinical trial. The baseline information gathered from our initial contacts with researchers, clinical practitioners, medical and para-medical staff, institutional heads and members of institutional review committees was quite disheartening and embarrassing. What surfaced most was the blissful ignorance about the statutory norms and universal ethical standards to be strictly followed in any clinical drug trial. There was apparently no interest in the concerned departments and institutions to rectify or to make good of the situation. Further, the emergence of the contract research organizations that have sprouted in almost all cities and towns were pushing themselves into hospitals, laboratories and even clinics of private practitioners.

Thus the overall scenario was gruesome. Our attempts to identify human participants in clinical trials were repeatedly foiled by concerned investigators/institutions on a reason that the matter was 'confidential'. All criminals and offenders went scot-free and nothing was left on paper to prove against them. No record was maintained, no consent form was properly signed and not even a single evidentiary document was traceable in any institution.

In the circumstances, the primary requisite was to create general awareness on the mandatory norms and statutory guidelines among all concerned. Jananeethi published a handbook on the guidelines and circulated it among all. It generated a discussion across the State among medical practitioners and researchers. The organization also held press conferences and issued press releases on the matter. In the mean time, several medical personnel who have been involved in trials were interviewed. Extensive consultations were also held across the country with eminent medical practitioners regarding the ethical standards in clinical trials.

In the second half of the first year in the struggle against engulfing unethical practices leading to corruption, the organization was able to identify five human participants in a clinical drug trial. Each participant was visited at his/her residence, detailed discussions were held based on a scheduled questionnaire. What emerged from the discussions was that every norm of a good practice was flouted. Hence Jananeethi started the engaging constructively with the government departments, institutional heads, media and other stakeholders. The effort was to build up a critical mass in the society with regard to the clinical trials and the organization has been successful in few hospitals and research institutes so far. Te organization further proposes to engage the media and develop communication strategies on large scale in the second phase of the project.

Top Three Results (actual). *In view of the Evaluator)*	1. Five human subjects undergone clinical drug trials were identified and their experiences captured during and after drug trial. 2. Prepared and published a hand book on ethical guidelines in clinical trials 3. Selected stakeholders such as the members of Ethical Committee,

	Institutional Review Board etc. made aware of the ethical standards and other related issues in connection with drug trials
Overall Achievement Rating[2] *in Evaluators view. Use numeric rating as well as narrative. See footnote 2.*	**2**

Commentary to support overall assessment

Guidance. *Please provide a narrative to accompany your overall achievement rating taking into account your overall assessment (in a maximum of 20 lines) of taking into account quality or project design, implementation performance and results achieved. Reasons for rating of 4 or more may please be explained here. It is suggested that this be written last after the detailed assessment (Section 2 below) has been done and Overall Achievement Rating determined.*

The focus of work undertaken by Jananeethi – 'Corruption in Clinical Drug Trials in Kerala', is a very severe and sensitive issue. For identifying the issues to be addressed requires relevant technical and professional skills and the project can be taken up only by devoted and committed team who can take risk. The interaction with the project team and a few other stakeholders provided the testimony that the team has undertaken a very challenging task and are ready to face any challenges in connection with addressing the issue. So far they were able to identify 5 human beings who had undergone drug trials in a private hospital in Thrissur and initiated a process of collecting and documenting the process and outcome of such trials and the level and type of corruption involved in it. They were also able to sensitize a few Ethics Committee members about this, which in turn will help initiate corrective action in the specific hospital.

Considering the quality of the project design the organisation was able to elaborate clearly the corruption problems. But the objectives are not much specific, accurate, measureable and time bound. Similarly in case of result framework and constructive engagement plan, more detailed explanation was needed to improve the quality of design. In case of community empowerment there is not much specific activities worked out hence rated moderately satisfactory. But in the case of implementation performance it could be observed that in the first year the organization was able to implement several programmes satisfactorily except community empowerment initiatives. The accomplishments of the results are also satisfactory, except community empowerment.

The project requires longer period of interventions to achieve majority of the output/outcome specified in the project proposal because it requires a multidimensional approach and strategy to identify the real corruption issues, development of necessary case studies, documentation/report to be shared with the policy makers, public advocacy and policy lobbying and facilitating the effective implementation of the existing law/enactment of new policies/laws.

[2] The degree to which the project achieved, or seems likely to achieve, all or most of its objectives and produced the outcomes projected in the logframe attached to the Project Proposal. The rating be based on, and consistent with, the detailed ratings in the Completion Assessment section.

Completion Assessment[3]

1. *Quality of the Project Design*

a. Elaboration of the corruption problems to be addressed.	**1**
b. Clarity and relevance of the objectives to the corruption problem being addressed.	**2**
c. Proposed Community empowerment activities	**2**
d. Coherence of Results Framework (Logframe)	**2**
e. Constructive engagement plan	**2**

Comments: *(to support/explain rating and overall assessment)*

1. The discussion and observation pointed out that the organization was able to elaborate the corruption problem in drug trials fully in the context of health sector in Kerala.

2. Though there was no further detailing out of the objectives for first year, considering the results proposed for the first year it was observed that the clarity and relevance of objectives, coherence of results framework and constructive engagement plan were satisfactory.

3. In the proposal, the community empowerment plan is proposed for the second year, however certain activities in this regard were taken up in this year itself like the display of a board in the district Government Hospital on the rights of human beings on drug trial.

4. Considering the severity and sensitivity of the issue, whatever the organisation did so far was commendable. The team was confronted with a lot of challenges during the initial periods of their intervention, which delayed the processes of implementation. Though the quality of the project design was satisfactory, the reason for the delay was mainly due to such challenges.

2. *The Implementation Performance (in the First year)*

a. Extent to which the planned project activities completed	**1**
b. Extent to which the planned outputs completed.	**1**
c. Community empowerment initiatives implemented	**3**

[3] Ratings Scale: 1 = Highly Satisfactory or Likely; 2 = Satisfactory/Likely ; 3 = Moderately Satisfactory/Likely; 4 = Moderately unsatisfactory/Unlikely; 5 = Unsatisfactory/Unlikely; 6 = Highly Unsatisfactory/Unlikely; NA = Not Applicable

d. Constructive engagement during implementation	**2**
e. Focus on sustainability	**2**

Comments:

1. During the discussion and sharing with the organizational team it could be learned that they faced a lot of resistance from the authorities of the private and government Medical Colleges to gather information related to drug trials even though they used provisions under RTI. Hence, there was an undue delay in starting the proposed activities on time. But the organisation was able to complete majority of the activities proposed for the first year- except community empowerment.

2. The implementation performance with regard to completion of planned activities and outputs are observed as highly satisfactory and satisfactory respectively with regard to constructive engagement implementation and focus on sustainability.

3. With regard to community empowerment, the organisation prepared and set up a board displaying rights of human being on drug trial in front of district hospital in Thrissur. This was the only activity under community empowerment, even though the proposed activities are scheduled for the second year.

3. *The Results*: (in the First year)

a. Accomplishments of the results specified in the logframe	**1**
b. Responsiveness of authorities to constructive engagement.	**2**
c. Effectiveness of community empowerment initiatives	**3**
d. Value added of peer learning activities and events.	**2**
e. Project contribution to CSO partner capacity to carry out anti-corruption work.	**1**
f. Prospects for sustainability of project activities	**2**

Comments: *(Please briefly explain the ratings and any noteworthy aspects)*

1. Even though addressing the issue was very risky, the technical and professional competency of the project team of Jananeethi and their strategy helped them accomplished the results proposed for the first year in highly satisfactory way.

2. The organisation was able to sensitize at least some doctors and Ethics Committee members of a few hospitals and some senior bureaucrats on the issue of drug trials during the first year. Some initial steps were also taken to sustain the efforts they

initiated. For instance, in one hospital after the intervention of the organization in sensitizing the Ethics Committee, the Committee rejected the whole proposal for undertaking clinical drug trail in the hospital. The performance for items b, d and f was satisfactory. The organization took only one initial step for community empowerment as it was proposed for the second year, hence rated moderately satisfactory.

3. The organization was also successful in the preparation and circulation of a handbook of guidelines on clinical trials. One of the major results was that the principal of the govt. medical college Thrissur included ethical standards on clinical trials in the syllabus of the medical students.

4. Another result can be seen in terms of response that Jananeethi has received from like-minded groups from across the world through the internet and group mailing systems. Regular updates from such groups on the current practices and issues of clinical drug trials as well as the means adopted to address them have helped the organization to move forward in the right direction.

4. Impact of the project on reduction in corruption

The issue of fighting corruption in clinical drug trials is a challenging one and not much has been done in this respect in the country so far. As it is a sensitive issue, which involves the health and life of individuals, it demands immediate attention and significance. Jananeethi is doing a commendable job in this sector. The consistent efforts of the organization have led to some changes at the grassroot level indicating towards a reduction in corruption level, if not completely transforming the corruption scenario. For example, one of the leading private hospitals in Thrissur district dropped a clinical drug trial proposal by contract research organization worth Rs. 60 lakh on the ground that the trial proposal did not satisfy the ethical requirements. In another private medical college in the city, a Contract Research Organization (CRO) consistently and persistently made attempts to impress members of the Ethical Committee and Research Committee of the hospital. The members challenged the CRO based on guidelines published by Jananeethi and the CRO was unsuccessful in striking a deal with them.

The above mentioned instances reflect that there is a change being brought about in the behaviors and attitudes of the concerned people, though it will take some time to fully achieve the goal of a corruption free drug trial system in the state.

5. PAC-PTF Advice (Please consult CSO Partner)

a. Value added of PTF technical advice
b. Value added of PAC technical advice

Comments: *(In your comments please include Strong and weakest points of PTF-PAC interventions and suggestions for improvement*)

Though there is an added value of PTF and PAC technical advice, the project team stated that they got the support mainly from PAC. Further, they pointed out that the technical advice received from PAC during the project period was useful.

Strong Points:

Orientation for discussing and clarifying the project context, relevance and preparation of project proposal, feedbacks, peer learning opportunity, visit of PAC coordinator and sharing.

Weak Points:

Confusion in reporting format without considering the unique nature of the project undertaken by the organization; lack of PTF interaction; lack of common understanding on the general format for project development and reporting. Lack of proper planning in advance to ensure continuity of the project activities in the succeeding years as proposed in the project. Undue delay in approving second year project resulted in dropout of project staff and uncertainty in continuation of the project.

Suggestions for Improvement:

1. Support from PAC should be given for periodic review and regular feedback to implement the project effectively. Necessary steps should be taken to approve the second/third year activities of a project proposed for 2/3 years before the completion of the previous year. If there is any delay in approving the project for the succeeding years some contingency grants should be provided to continue the programme, which can be adjusted with final approved programme.