

CAC South Asia – Review of Completion Report Submitted by Jananeethi, Kerala, India.

Key Project Data (From Completion report)

Date: September 9, 2010

Title of Project	A PROJECT TO COMBAT CORRUPTION IN CLINICAL DRUG TRIALS IN KERALA		
Project Code		Project Location	CENTRAL REGION OF KERALA STATE
Corruption Problem being addressed	CORRUPTION IN CLINICAL DRUG TRIALS		
Project Objectives	<ol style="list-style-type: none"> 1. To identify 5 human subjects to investigate actual process and impact. 2. To explore and document the level of corruption involved during their clinical drug trials for use in courtroom and public dissemination. 3. Lobby to make colleges' Ethics Committees truly independent as mandated and help increase accountability and transparency. 4. Liaising, mobilizing and capacity building other civil society groups, victims of corruption, media, academic institutions, activists to join advocacy and push for reforms. 5. To provide psycho-legal therapeutic services to the identified five victims of corrupt drug trials. 		
	<u>Planned</u>		<u>Actual</u>
Implementation period	<u>June 15, 2009 to June 14, 2010</u>		<u>June 15, 2009 to June 14, 2010</u>
Total Budget	<u>\$24,811</u>		<u>\$16,959</u>
PTF Contribution			
Top Results (actual)	<ol style="list-style-type: none"> 1. Start of serious investigations and documentation of the nature and extent of lapses and failures in following legal and ethical standards in conducting clinical drug trials which have been vastly growing in India. This seems to have significantly raised awareness among medical professionals, government officials and general public. Two notable outcomes of this effort are: <ol style="list-style-type: none"> a. One of the leading private hospital in Thrissur district dropped a clinical trial proposal by contract research organization worth rupees 60 lakh on the ground that the trial proposal did not satisfy the ethical requirements. This welcoming decision was taken after a detailed discussion by project coordinator Adv. Sunilkumar with the secretary and members of the Ethical Committee of the hospital. b. In another private medical college in the city of Thrissur, a Contract Research Organization 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. 2. Preparation and circulation of a handbook of guidelines on clinical 		

	<p><i>trials. Please clarify if the Guidelines have any legal force). The guidelines are already gaining in influence and use as is evident by inclusion of guidelines for ethical standards in drug trials into the curriculum of medical students in Thrissur Government Medical College. Permission has been given to Jananeethi project staff to address the medical students, undergoing training in pharmacology, on the statutory guidelines and universally accepted best practices in clinical drug trials on human participants.</i></p> <p>3. <i>Involvement of senior officials, technical specialists and concerned institutions, as well as the mobilization of support from these important stakeholders, in efforts to prevent undesirable practices and their impact on the subjects' well-being and human rights. Involvement of the State's Secretary of Health was an important step.</i></p> <p>4. <i>Jananeethi's work seems to have generated national and international interest. Several organizations and individuals who work on similar issues have linked their works with Jananeethi and hence the message goes across the borders Television channels and investigative journalists worldwide are reported to be in regular contact with Jananeethi project staff on the progress in exposing corruption in drug trials (Please include an illustrative list of these organizations in the completion report).</i></p> <p>5. <i>Although later than expected, identification of the five actual cases and their continued investigations are likely to add important value in achieving the project's goals.</i></p>
--	--

Completion Assessment¹

1. The Implementation Performance

- | | |
|--|-----------|
| a. Extent to which the planned project activities and outputs were completed. ² | 3 |
| b. Adequacy of financial reporting. ³ | 2 |
| c. Adequacy of documentation posted on the website ⁴ . | NA |
| d. Constructive engagement during implementation | 1 |
| e. Community empowerment activities. | |
| f. Focus on sustainability | 3 |

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

² Please compare the activities listed in the proposal and see if they were fully completed or partially.

³ The Grant agreements require that the accounts of project related expenditures be audited and certified as true and accurate by the Auditor of the CSO.

⁴ The PTF Grant Agreement stipulates that the Grant Applicant will “post the Grant Agreement, the Project Proposal, the final Project report, and statement of expenditures on its website and/or the PTF website”.

Comments and suggestions for improvement

* Several activities have been completed partially due to delays in identifying the cases. The proposal listed 16 activities for completion during the one-year project period in order to meet the above-listed five project objectives. Activity 1 was to conduct orientation workshop which has been completed. Activities 2 to 7 concerned the identification of five victims and working with them. However, the victims could only be identified very late in the project period. This prevented full completion of most of these activities. Activities 8 and 9 were to prepare guidelines for the functioning of the institutional ethics committees which are responsible to sanction drug trials and to lobby to implement mandatory requirements. But Jananeethi (the CSO) has not been able to complete this task yet. This needs explanation. Activity 10 was meant to lobby for inclusion non-medical members in Ethics Committee. There is no mention why this has not been done or at least substantially discussed. Other activities seem to have progressed reasonably well consistent with the ambitious goals and delayed success in identifying the five actual cases.

* The third tranche will be released after receipt of the revised completion report that is ready for publication and the audit report of 2010 accounts of Jananeethi; it is noted that the auditor certified accounts of the grant receipts and expenditures are already attached to the Completion Report. Please advise status of Credibility Alliance accreditation; this must be completed before approval of Phase 2 funding.

* Engagement with officials and practitioners has been intense.

2. The Results:

- | | | |
|--|----------|----------|
| a. Accomplishments of the results specified in the logframe and/or project proposal. | <u>3</u> | |
| b. Clarity of Quantified and demonstrable results | <u>3</u> | |
| c. Community empowerment outcomes | | <u>3</u> |
| d. Robustness of the evidence for the results narrated in the completion reports. | <u>3</u> | |
| e. Responsiveness of authorities to constructive engagement. | <u>2</u> | |
| f. Value added of peer learning activities and events. | <u>2</u> | |
| g. Project contribution to CSO partner capacity to carry out anti-corruption work. | <u>2</u> | |
| h. Prospects for benefits of the project being sustained s | <u>1</u> | |

Comments and suggestions for improvement.

See the comments and suggestions in the results section of the Key Project Data above.

3. Summary of Assessment.

a. Overall Achievement Rating⁵

2

***Guidance.** The degree to which the project achieved, or seems likely to achieve, all or most of its objectives. Please base this rating on the detailed assessment above.*

The Project's overall goals were ambitious for the stated period but the abuses in clinical drug trials is a very serious problem in India and this subject is worthwhile and timely. While such abuses will not be prevented so quickly, the project's initiation itself seems to have started significant outcomes and results in the short period since project initiation. . This project is likely to substantially reduce the blatant disregard of law and unethical practices in drug trials.

b. Commentary on 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 project has made good start. Noteworthy result appear to be the publication of the Handbook on the Ethical Guidelines and the impact it has already made as evident from the cancellation of two trials for non-conformity with guidelines, adoption of the guidelines in the teaching curricula at medical college and the media and peer interest generated. The completion report can be improved by listing the names of peers who are linking up with Jananeethi and more detailed description of the cancellation of trials and adoption in curricula.

4. **Dissemination:** *Please list any outputs of the project that, in your view, would be appropriate for wider dissemination through CSO Partner and/or PTF PAC websites. Examples are tool kits/manuals/guidelines etc.*

⁵ The degree to which the project achieved, or seems likely to achieve, all or most of its objectives.

The Handbook on Ethical Guidelines is a key output. Jananeethi appear to have disseminated it well. It would be good to add more details in the completion report on dissemination done.

It is recommended that an effort be made to put a link on project at key websites that show up on Google search when looking for corruption in clinical trials.

This project will should have additional important outputs, examples and guidelines which will be worthwhile to disseminate in other parts of India. Most probably they will be ready only after another year of efforts.

5. **Next Steps:**

- a. **Please revise the Completion Report.** According to PTF policies the completion reports are made public by posting them on PTF website (www.PTFund.org) and PTF organizes an independent assessment. We recommend that Jananeethi revise the completion report to improve presentation of results (suggestions for this are noted above) and eliminate duplication of information as a consequence of flaw in the guidelines provided by us. Jananeethi should make other revisions that they consider useful before the report becomes public and is subjected to independent assessment. The third tranche will be released after receipt of the revised completion report that is ready for publication and the audit report of 2010 accounts of Jananeethi; it is noted that the auditor certified accounts of the grant receipts and expenditures are already attached to the Completion Report. Please advise status of Credibility Alliance accreditation; this must be completed before approval of Phase 2 funding.
- b. **We are favorably inclined to support the Phase 2.** Extension of the this project for another year would allow time to complete of the investigations and reviews of the identified cases, to disseminate the findings and to further advocate for better drug trial guidelines and practices, to lobby to improve the composition of the Ethics Committee, and to lobby for introduction of mandatory requirements that every medical practitioner investigator submit written affidavit. Jananeethi could proceed to prepare the full proposal following the guidelines provided by PAC.

PTF would like to see a reduction in number of results indicators and a sharper focus on objective # 2 that focuses on reduction/prevention of corruption. To what extent do you think the unethical practices were related to corruption? We need to distinguish between the unethical medical practices and corrupt practices.

- c. **Independent Assessment.**, PTF is intending to organize an independent assessment to be carried in October 2010 subject to PAC and Jananeethi convenience. Further details will follow.