PTF-PAC: CAC- Project Completion Report[1]

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Project name & PTF code: Save clinical drug trials ethically sound and corruption- free.

1-Project Goal:

1. The global standards and best practices in Clinical Drug Trials on human participants are respected and strictly complied with in hospitals and research institutions in the state of Kerala

2. There are strict and specific rules and regulations in the State with respect to clinical drug trials on human participants, and any one who violates them is liable to be Prosecuted and victims of such unethical practices are adequately compensated as per norms prescribed.

3. A critical mass is created in Kerala Society with respect to the ethical standards of clinical drug trials on human participants.

[1] It is suggested that the following Annexes be prepared first.

1. Activities (Inputs) table (see the suggested format attached).
2. Outputs Table (Plan vs actual –see the suggested format attached).
3. Outcomes/Results (update log frame)
4. Financial Progress Report (see the suggested format attached)
5. Human Interest Success stories. include photos and names
6. Materials/reports/toolkits published/disseminated and/r posted on the website

2 Project Objectives:

As specified in the Approved Project proposal	Status of achievement at completion
Objective 1: Awareness Building	**C**
Objective 2: Advocacy	**C**
Objective 3: Monitoring	**C**
Objective 4: Alliance Building	**C**

3. Project Area location: Central region of Kerala state

4. Project period: a) Original: March 1, 2011 to August 31st 2012 b) Actual: MARCH 31st 2013

5. Project Budget : INR 19,48,500.00 (USD 43300)

6. Budget utilized as on (date) : 19,40,965.00 (USD 43133)

7. Project Completion Summary (maximum five pages).

((Summarize project implementation and results achieved. This should include achievement of objectives. It should include a brief description of: (i) the activities that were carried out and the outputs that were produced due to the activities; and (ii) the results that were achieved (referring to the log frame / results framework for the project) and how the outputs and activities from the project contributed to accomplishment of each result. . In particular explain what impact the project had on reducing corruption and provide quantitative and qualitative information in support of the impact described. End this section with a self assessment of achievement of project objectives, what main obstacles have been encountered, if any, and what actions have been taken to overcome them and project efforts and experience with constructive engagement.

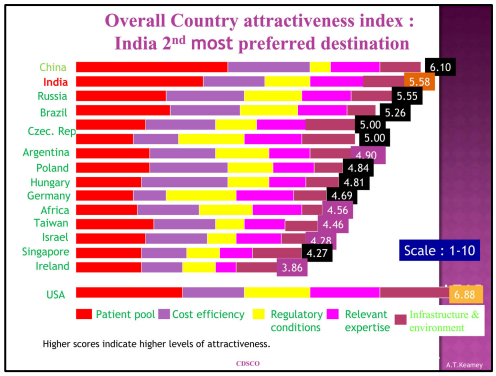
Please note that PTF policy is to post the completion report on its website. So please take extra care to ensure that your report is properly edited and is ready for publication.)

SAVE CLINICAL DRUG TRIAL ETHICALLY SOUND AND CORRUPTION-FREE

FINAL REPORT

Executive Summary:

The human drug trial market in India was worth USD 485 million in 2011[2] and with an astonishing compounded annual growth rate of 30%, it is predicted to cross USD 1 billion by 2016. Till 1990s most clinical research was carried out in academic medical centres, paid for by government money. However, commercial interests now rule the domain and financial bottom-lines override ethical and human rights concerns, with predictable results. According to official figures obtained from the Drug Controller General of India, through a Right to Information (RTI) query filed by medical rights activist Anand Rai, more than 2000 Indians have died due to serious adverse events (SAEs) caused during clinical trials from 2008 - 2011; around 670 fatalities were reported in 2010 alone[3].

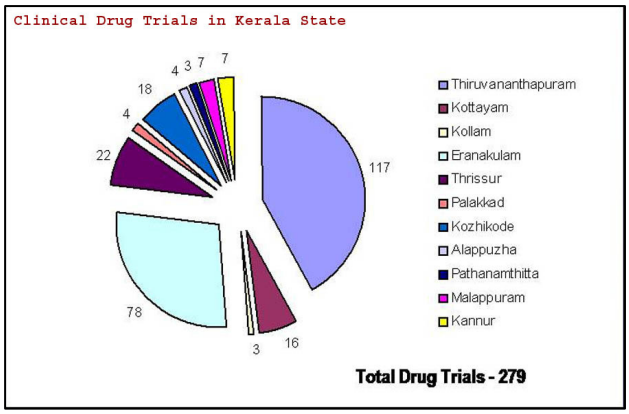


Why is suddenly India in the radar of the global pharmaceutical industries? A strange concoction of market advantage, lax regulation and human misery explains the surge. It is estimated that the price of bringing a new drug to market is, on average, $180 million. The bulk of that cost is devoted to human clinical trials — the most crucial and time-consuming phase of drug development. Faced with tight regulations at home and shrinking profits due to expiring drug patents, MNCs are looking at countries like India as low-cost laboratories; by

[2] Kaustubh Kulkarni and Matthias Williams (2012). Slow approvals put India's drug trials industry at risk. Accessed at http://www.reuters.com/article/2013/02/12/pharmaceuticals-india-clinical-trials-gr-idUSL4N0B42LV20130212

[3] Jason Overdorf (2011). India: deadly drug trials. Global Post, June 19 2011. Accessed at http://www.globalpost.com/dispatch/news/regions/asia-pacific/india/110618/india-health-drug-trials

shifting to India, drug companies can cut the cost of clinical testing by almost 60%. Eighty percent of the drugs that the United States Food & Drug Administration (FDA) reviews for approval now rely on some tests done on foreign soil, according to a 2010 report issued by the U.S. Health and Human Service's Office of Inspector General. Till January 2005, clinical trials of new drugs developed outside India were permitted only with a "phase lag". This implied that a phase 2 trial could be conducted in India only after phase 3 trials were completed elsewhere. Phase 1 trials of foreign drugs were not permitted, except for drugs of special relevance to India. However, in January 2005, an amendment of Schedule Y of the Drugs and Cosmetics Rules did away with the phase lag in international clinical trials. There are no longer any restrictions on "concurrent phase" clinical trials in India. Phase 2 and phase 3 trials of drugs discovered abroad may now be conducted in India in the same phase and at the same time as they are conducted in other parts of the world. It is now reported that further changes are in the anvil to allow Phase 0 trials also to happen in India. This has literally opened the floodgates for the gold rush.

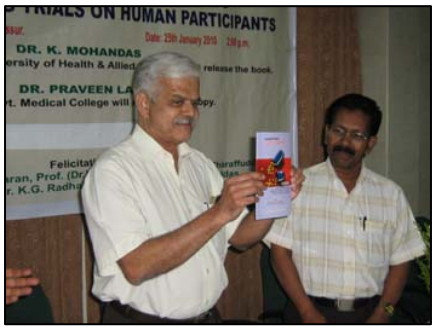


In 2009, Jananeethi, a non-governmental organization based in Thrissur, Kerala, initiated a pioneering research on clinical drug trials on humans with financial support from the Partnership for Transparency Fund (PTF). The project sought to identify human subjects who have underdone clinical drug trials to investigate about the process and the impacts. The methodology also pursued key informant interviews with medical professionals and other critical stakeholders in the clinical drug testing domain to build an evidence base to advocate for and seek effective remedial actions in the policy and practice spheres. This PTF-funded project (June 15, 2009 – June 14, 2010) highlighted many findings and pointers that called for immediate remedial actions. Key among them were the deliberate and willful denial of all information pertaining to drug trials, recruitment of patients without their knowledge and consent, denial of insurance coverage and compensation, and the complete breakdown of mandatory regulatory mechanisms like hospital ethics committees.

This exploratory phase resulted in some significant outcomes:

- Despite the cloak of secrecy surrounding the identities of clinical trial patients and the complete lack of any documentation pertaining to their participation in drug trial tests, Jananeethi was able to **identify five participants** who also agreed to share their experiences.

- As an immediate response to the finding that public awareness is virtually non- existent when it comes to mandated norms and standards related to the conduct of clinical trials, Jananeethi released a **Hand Book on Ethical Standards** of clinical trials with a foreword from Secretary, Department of Health and Family Welfare, State of Kerala. This buy-in from the highest executive body was a major victory for Jananeethi.



- For the first time in Kerala, information pertaining to data related to clinical trials was compiled and documented through personal interviews and using the Right to Information Act.

- Jananeethi's awareness and advocacy efforts resulted in the **cancellation of a scheduled clinical drug trial** for Migraine in adolescent children proposed by a clinical research organization involving huge amounts in a leading private hospital in Thrissur district.

- In a similar note, a leading private medical college in Thrissur **refused a large monetary incentive** made by a CRO for a proposed drug trial that would have bypassed global standards and best practices.

- **Guidelines for ethical standards** in drug trials were **included** in the curriculum for graduate medical students in Thrissur Government Medical College.

- Jananeethi project staff were repeatedly requested 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.

- Television channels and investigative journalists world wide are in regular contact with Jananeethi project staff on the progress of this study and the follow up actions

- Several orgainisations and individuals who work in their respective regions/states on similar issues have started **networking** with Jananeethi to advance the cause at the national level to leverage changes in policy and practice.

A review of the project carried out internally within Jananeethi and also, feedback from PTF resource persons reiterated that the gains made in this phase should be consolidated and effective entry points be identified to work at policy and practice levels. Three pathways were identified for deepening the work:

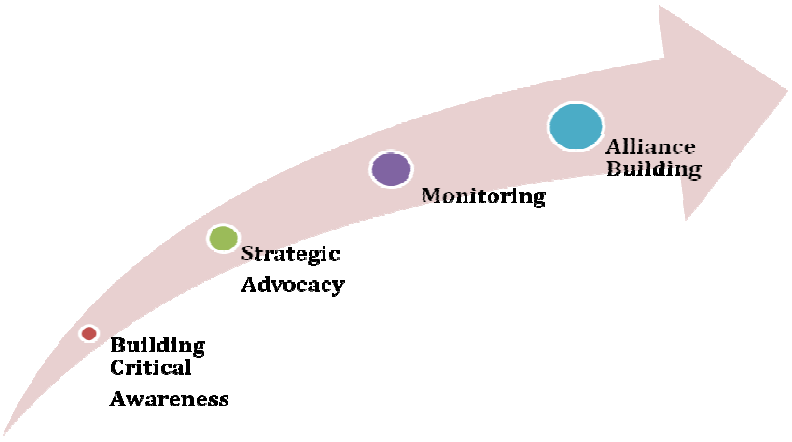
- A critical need to disseminate information on drug trials with all stakeholders
- Need for a specific legislation and for strengthening existing regulatory mechanisms
- Need for creating a critical mass/vigilant groups at the ground level to educate people about their rights and entitlements, especially in guarding against uninformed trials.

In light of these recommendations, Jananeethi submitted a request to PTF to implement a follow up phase of activities. Phase-2 commenced on March 1, 2011 with an original end date of August 31, 2012. However, due to spillover of activities, the project timeline was subsequently extended to March 31, 2013.

The overarching objectives of the Phase-2 project, themed as 'Making Clinical Drug Trials Ethically Sound and Corruption Free' were:

1. Ensure that the global standards and best practices in Clinical Drug Trials on human participants are respected and strictly complied with in hospitals and relevant research institutions in Kerala State.
2. Ensure that the victims of unethical and uninformed drug trials are adequately compensated as per norms prescribed.
3. Create a critical mass in Kerala Society with respect to the ethical standards of clinical drug trials on human participants.

In pursuit of these goals, the project envisaged the following activities:



A brief narrative of the activities carried out is described below:

1. **Building Critical Awareness**: Acknowledging that an informed public is the best defence against potential abuses, Jananeethi embarked on a multi-pronged approach to raise critical awareness. Focused and strategic activities carried out include:

   - Conducted weekly sensitization programmes on areas of public concern in clinical drug trials for medical and paramedical students and staff, community workers, elected representatives to local bodies, civil society organizations, media personnel, service providers etc.
   - Conducted quarterly workshops for medical practitioners, researchers, hospital managements and members of ethical (review) committees on best practices in clinical drug trials.
   - Prepared an 'information kit' in the local language (Malayalam)providing basic information regarding ethical standards and best practices in clinical drug trials. This information kit containing guidelines of clinical trials, rights of the human participants, services provided by the Help Desk of Jananeethi, contact details of regulatory bodies and few case studies was distributed among participants of sensitization programmes and training sessions.
   - A **Charter of Rights of Human Participants** was prepared as a key rights-based advocacy document and disseminated widely as part of the information kits and resource materials for the sensitizing and training programs.

2. **Strategic Advocacy**: Given the highly invisible nature of the issue and the lobbying power of powerful vested interests, human drug trials are seldom discussed in legislatures and other key stakeholder forums. A key thrust in this phase of the project was thus to set an agenda to review and interrogate the issue with key stakeholders. Activities towards this include:

   - Made representations in the second quarter of the project to both the Union and state Governments for the enactment of specific legislations on clinical drug trials.

- Individual briefings were provided to **40 members of the Kerala Legislative Assembly** and six of them participated in a consultation organized by Jananeethi in the capital city of Trivandrum. A briefing note was drafted for legislators to create an informed debate in Kerala Assembly.
- Met the Secretary of Health, Government of Kerala, the Director of Medical Research and Education, and the Heads of three medical colleges in the first quarter to ensure their full support and cooperation in checking unethical practices in clinical drug trials.
- High-level meetings were held with heads of Institutional Ethics Committees / Review Committees to apprise, assess and evaluate the various steps taken to enforce best practices.
- Thematic workshops were conducted for key stakeholders medical practitioners, researchers, hospital managements and members of ethical (review) committee members on best practices in clinical trials and ethical norms and standards. A key success in this regard was the convening and briefing of the members of the institutional review boards and apprising them of their duties and responsibilities as well as sharing best practices.

THE HINDU 03 Sept. 2012

Call to monitor drug trials

Participants are not informed about being part of a drug trial, says study

Staff Reporter

- **Human drug trial market in India is worth $400 million, according to the study**
- **As many as 670 fatalities were reported in the country in 2010 alone**

THRISSUR: Jananeethi, a Thrissur-based non-governmental organisation, which conducted a study on human drug trials in the State, has stressed the need for legislation with stringent provisions to protect the rights of trial participants.

Sharing the findings of its three-year-long study, director of Jananeethi George Pulikuthiyil said that, at present, the protection of the rights of the participants depended solely depend on the personal integrity and honesty of the doctor and his team conducting drug trials.

"With the country emerging as a safe haven for drug trials on humans, a new legislation is necessary to combat corruption and malpractices. Commercial interests now override ethical concerns and human rights. It is the most marginalised and vulnerable in society who become victims of these anomalies," Mr. Pulikuthiyil said.

A State-level mechanism should be created to monitor drug trials, he said. According to official figures, more than 1,500 Indians have died in the course of clinical trials since 2008. Around 670 fatalities were reported in 2010 alone, the study noted.

It is estimated that the human drug trial market in India is worth $400 million. And it is growing at an annual rate of 30 per cent. The study found major flaws in securing informed consent of the patients for drug trials.

"The existing national and international guidelines on clinical drug trials make it mandatory that participants be recruited only after securing their informed consent. Our findings revealed that none of the participants were informed that they were part of the trial. Further, the details of drug trials, risks and possible side effects of the trials were not communicated to the participants."

The patients were not given a copy of the signed informed consent form thus depriving them of any documentary evidence to prove their participation in a given trial. The study also found that no insurance coverage or compensation package was offered to the participants though guidelines clearly advocated it.

At present, insurance coverage is available only to the doctor who conducts the trial in order to meet any liability that may occur due to adverse effects on a participant during the conduct of the clinical drug trial. "Once the trial drug is found effective the trial participants of the drug trial are entitled to get that drug either freely or at a subsidised rate. But this beneficial practice is not observed here. As a result, once the drug hits the market, these poor patients are not able to buy it because of its exorbitant costs," Mr. Pulikuthiyil said.

The research also questioned the capacity of the ethics committees to check illegal practices in drug trials. Maintenance of ethical standards in clinical drug trials is the major function of the ethics committees. But most of the members were totally ignorant about their role and responsibilities, the research team noted.

The composition, selection and function of the ethics committees needed a thorough review and revamping in order to make the bodies more effective, it said. "The deliberate denial of information on drug trials was another disturbing factor. The area of drug trials remains totally opaque. Even queries posted under the RTI Act failed to elicit any details. Most of the requests were turned down by the authorities citing the 'patient confidentiality' clause. It is high time to review the confidentiality clause that goes against the interests of trial participants."

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- Participated in discussions in various media channels like the state run All India Radio, leading TV channels and FM radio stations to spread awareness on the issue. News briefings from Jananeethi were extensively covered in all major vernacular and English newspapers in Kerala.

- A blog – www.jananeethi.blogspot.com – was created and information regarding drug trials, including findings from Jananeethi have been uploaded for wider dissemination and sharing.
- A **Public Interest Litigation (PIL)** has been filed before the High Court of Kerala for the inclusion of ethical guidelines in the course curriculum of medical students. Following the admission of the writ petition, notices have been served to respondents like Drug Controller General of India, central and state governments. Decision from the court is pending in this matter.
- Jananeethi put up a stall at the Thrissur Pooram (the most famous temple festival in Kerala) Exhibition grounds for nearly two months. An estimated **200,000** people from all walks of life visited the stall.

3. **Monitoring**: Jananeethi placed a lot of emphasis in creating conduits and structures to raise public awareness on the issue of unethical drug testing. Steps initiated in this regard included:

   - A ***Help Desk*** started functioning from Jananeethi premises from the inception of phase-2 to provide correct information to people with regard to clinical drug trials, and to investigate and act upon complaints regarding unethical practices and corruption in the area of clinical drug trials.

   - Highly decentralized citizen watchdog initiative called **Kerala Health Watch** was set up in all the 14 districts. The groups are well represented by activists and leading public personalities.

4. **Alliance Building**: Recognizing the need for a broad-based coalition to address the issue more effectively, Jananeethi organized consultations and formed consortiums during the project phase.

- Critical linkages were established with leading national institutions like the Centre for Ethics and Rights, Mumbai, All India Drug Action Network, SAMA, Mumbai, Institute of Pain and Palliative Care, Thrissur and the National University of Advanced Legal Studies (NUALS), Kochi.

- Strategic alliances have also been created with the National Campaign for People's Right to Information (NCPRI – Kerala Chapter).
- Efforts to start a state-wide consortium of organizations working on medical ethical issues commenced with start-up meetings in two districts.

5. Major results and outcomes:

A project of this nature needs a longer timeline to demonstrate its impact. Given the opaqueness of the issue, the intricate web of stakeholders and the reluctance of victims to openly come out and lodge complaints, project goals had to be recalibrated and nuanced out. For Jananeethi, the very fact that the issue became central in the health sector discourses is a major indicator of success. By working at different levels and with different stakeholders, Jananeethi has been able to convene interest and commitment from most key actors on the need for reforms, review and monitoring. Jananeethi's efforts also had a ripple effect in terms of opening up entry points for other actors like the media to pursue independent trails and lift many layers of secrecy surrounding the issue.

Major impacts and outcomes are discussed below:

1. As a result of increased media attention and pertinent questions raised in the legislative assembly, the Government of Kerala constituted an Expert Committee to investigate allegations on unethical drug trials in the state. Two of the three members of the Committee, Dr Anoopkumar Thekkuveetil and Dr V. Ramankutty are close associates of Jananeethi and had played a major role in the conduct of workshops and sensitization programs.

2. The Kerala Chapter of the Indian Medical Association also set up an independent committee to investigate the issue and draft recommendations.

3. Following Jananeethi's briefings with the elected members of Kerala Assembly, submissions were raised by members on this issue and the Health Minister of Kerala

informed that the Government will take strict action after receiving report from Ethics committee

4. A major development during the period was a 'sting camera' operation undertaken by a leading media channel, India Vision, that unearthed cases of unethical drug trials and corruption. The reporters of the channel were first briefed on this issue by Jananeethi during one of the earlier media interface meetings.

5. Admission of Public Interest Litigation from Jananeethi in Kerala High Court, and subsequent issue of notices to Central and State Government Authorities reflected the judiciary's interest and concern on the issue.

6. The creation of Kerala Health Watch Groups in all the districts in the state has laid a strong and credible foundation for civic monitoring and activism on health-related issues.

6. Reflections on the Project

This phase was an extension of an earlier project commenced by Jananeethi. The design and implementation of the project would not have materialized but for the strong belief and support from PTF. The flexibility that PTF allowed in pursuing emerging pathways and recalibrating activities and timelines gave a rare bandwidth to the project to explore out-of-the box options and innovative collaborations.


3 METRO JOURNAL

Jananeethi fights against unethical clinical trials

The nature of the issue being explored makes it extremely difficult to track and study. It is only because of Jananeethi's long standing track record in the state and its extensive linkages with multiple stakeholders that the key actors in the issue – actual patients – were identified and agreed to share their experiences. The emphasis on constructive engagement also worked in the project's favor. Instead of sensationalizing the issue and creating political rhetoric, Jananeethi pursued a path of discussions and informed briefings and played the role of a convener in getting key stakeholders to come to the table and discuss the issues.

The issue of unethical drug testing has opened up many other fronts to look at accountability mechanisms and their status in the health sector in Kerala. The Kerala

Health Watch Group is perfectly poised to take on the role of a watchdog to support victims of corruption and abuses at very local levels.

Finally, long lasting impacts are only possible through sustained actions on many fronts. The seed grant provided through this project gave the critical opportunity to build evidences, coalesce stakeholders and create broadbased people's organizations. This momentum need to be sustained, nurtured and capacitated to create lasting and meaningful changes. Jananeethi is committed to meet these challenges and leverage the learnings and insights from this project to its broader mandate of human rights work in Kerala.

7.1 Strategies used to achieve project goal and objectives

- Constructive engagements with stake holders
- Sensitization Workshops and Awareness Programs
- Media Sensitization and Engagements
- Information Tools and Out reach programs
- Formation of Help Desk and Health Watch Committees
- Use of Right to Information Act
- Field Investigation
- Representations to Central and State Governments

7.2 Project activities (Include a summary here and attach details in Annex 1)

Project Activities of the second phase was designed in such a way so that it will ensure the fulfillment of project objectives. From the take away learning's of first phase there were four main objectives formulated with the technical assistance of PAC. For each objective there were specific activities to fulfill in the time frame proposed in the Project PPM. For objective 1 Awareness Building there were five new activities and one activity (5a) carried from phase one. For Objective 2- Advocacy there were nine new activities and one carry forwarded activity (14a). For objective 3- Monitoring and Objective 4- Alliance Building there were 2 activities each. Altogether there were 18 activities falling under four broad objectives. At the end of the project period we are happy that we could fulfill majority of the activities in the prescribed time frame and without much change. We faced difficult situations in organizing programs for doctors and other stake holders due to their attitude as well as their busy schedule. Among the 18 activities Actvity No-13 was dropped due to a later realization of its in effectiveness. Another activity we could not fully achieve was the

proposed meeting of Members of parliament. We tried our best to execute the same with the help of Centre for Legislative Advocacy and Research, New Delhi. But we were unable to organize the meeting due to reasons beyond our control.

7.3 Project outputs (Include a summary here and attach details in Annex 2)

Second phase of the project mainly emphasized on awareness building and advocacy so that there will be a vigilant and literate society who are empowered to question the unethical practices of drug trials and to claim their rights when it is violated. It is in this context we designed outputs which can disseminate information on drug trials to public at large. An information kit consisting IEC materials was made for distribution among various stake holders. This consists handbook on ICMR guidelines, jananeethi findings on drug trials, a caution notice, and rights of trial subjects with Jananeethi services for the general public. Badges, banners, posters and stickers on drug trial were made and exhibited and distributed during public meetings and sensitization sessions. Guidelines for the functioning of the ethics committee prepared and distributed among ethics committee members. Jananeethi Blog was created for circulation of information drug trials through internet. Representations were submitted to different authorities inviting their immediate intervention in to drug trial issues. News paper reports and articles were also published for attaining the attention of general public.

7.4 Project Impact on Corruption (Outcomes /Results) (Include a summary here and attach details in Annex 3)

Our project save clinical drug trials ethically sound and corruption free aimed at an ideal world of drug trials where drug trials are being conducted in accordance with the best practices of drug trials, with full knowledge and consent of drug trial participant and ensuring all the rights. During the project period in order to achieve the desired goals and to reach the ideal world of drug trials we mainly focused on four key objectives 1-Awareness Building 2- Advocacy 3- Monitoring 4- Alliance Building. These objectives are framed on the basis of the learning's from the first phase of the project. Unethical practices and corruption were rampant in drug trial system still due to the confidentiality, secrecy and lack of transparency and accountability it was extremely difficult for us to pierce in to the dark side of drug trial. During the first phase we documented the corruption, loopholes and concerns of drug trial scenario and based on the learning's we concentrated on awareness building advocacy programs. In order to strengthen the anti un ethical drug trial campaign we tried to create a critical mass and vigilant groups through capacity alliance building sessions and initiatives. Based on the eighteen months of the project period and three month extension period we can confidently say that we have achieved to great extent the desired outcomes

in the journey towards a corruption free and ethically sound drug trial system. Through hundreds of awareness building programs we could disseminate information on drug trial to large masses that will in turn function as watchdog against unethical drug trials. The planned outputs of the project helped to disseminate information with much ease. Jananeethi intervention in drug trial system sensitized the key stakeholders like Doctors, Ethics Committee Members, Academicians, Bureaucrats, Media and Legislative members. This resulted in creating a societal conscious against medical doctors and hospitals that resort to unethical and corrupt practices while conducting drug trials. Media was highly sensitized by our intervention which ultimately resulted in bringing significant changes in the system. Government of Kerala constituted an Expert committee to look into the allegations of drug trials in Kerala. Indian Medical Association Kerala Chapter also constituted a committee to look into the concerns raised against drug trials. Our continuous campaign against drug trials also resulted in raising questions before Legislative Assembly of Kerala by MLA'S. There were already 11 questions raised in the assembly to Health Minister of Kerala regarding the unethical conduction of drug trials and role of Kerala Government to curb this problem. To all such questions Honourable Minister of Health answered that Government has constituted an expert committee and is waiting for their report. He also admitted that at present Kaerala Government is helpless as the entire system is regulated by DCGI office of Central Government. This concern has been raised by Jananeethi from the inception of the project, and this is going to be critical question of law before the Kerala High Court when our Public Interest Litigation will be heard. Another positive impact of our work is that Dr Praveen Lal Dean of Research Kerala University for Health Sciences informed that university is taking steps to formulate guidelines for the effective monitoring of drug trials carried in the Government Medical Colleges and Institutions. At the end of project period though it will be unrealistic to say that we have achieved sent percentage of project impact we are undoubted in saying that our efforts had made significant impact in the drug trial scenario in kerala. Though the project period ended, the commitment of Jananeethi to people's right to health care and their right to know will not let the organization to leave the matter as it is. Jananeethi has resolved to stay consistently in the field, though limited to certain focused area, such as State Regulation of Clincal Drug Trials, Informed Consent, Ethics Committee, Rights of trial participants and maintaining a Help Desk for victims of mal practices in the field. The eye of Jananeethi will remain fixed on these five areas and will carry forward our commitments.

7.5 Self-Assessment of Project Progress:

Include aspects of your team's capacity and contributions, community involvement and support; any significant impact seen and external factors affecting project success – positively or negatively for the project period.

At the end of of the project period, we are quite sure that our efforts have brought significant changes in the clinical trial scenario in Kerala. Now the Government of Kerala has constituted an expert committee to look in to the un ethical practices that is taking place in this area. Indian Medical Association Kerala Chapter has also constituted an independent committee to look in to the allegations. We also believe that the public interest litigation filed before the Kerala High Court will also bring significant changes to curb un ethical issue involved in the clinical drug trial system. Many Members of Legislative Assembly of Kerala are now aware of the situation which is evident from the 11 questions raised to Health Minister Kerala regarding the concerns on drug trials. Another significant impact that can be seen from the ground is the development of a critical mass in the society who are sensitized and empowered to check the un ethical practices of drug trials. Constructive Engagements with personnel and resultant Media intervention played a vital role in bringing changes in drug trial system. In spite, of these positive changes we are also quite aware of the fact that much more is needed to eliminate the corruption and un ethical practices. The success of the project goes to to the commitment of entire team and cooperation from authorities, social activists and consultants. One of the external factors that affected the project success positively is the similar interventions done by Dr. Anad Rai and his supporting groups in Madhya Pradesh. His Public Interest Litigation before the Supreme Court and court's observations so far in the PIL ensured wide publicity through out the country against unethical practices of drug trials.

8. Lessons learnt and their replicability:

Difficulties faced and measures adopted to overcome the same:-

Major difficulty we faced during the project period was the suspicious and negative attitude from the key stakeholders like doctors, hospital management etc. Due to this stand we faced difficulty in ensuring participation from them during consultation and sensitization programs. In order to overcome this we have made constructive engagements with doctors who holds good rapport in the medical filed and who stand with our concerns. So whenever we arranged programs for doctors we ensured that the program is partnered by individuals or institutions upon whom they trust. This played a key role in executing many consultation programs a successful one. To quote few examples our association with Paina and Palliative Care Society, Achuthamenon Centre for Public Health SCIENCES, Jubilee Mission Medical College, National University for Advanced Legal Studies played a vital role in giving a nonbiased approach from

the medical community. Another major problem we faced was to ensure the dissemination of our findings to large segments of the society. This was tackled by convincing the leading news channel reporters the significance of the issue and to highlight the same for bringing wider attention to problem. Our engagements with Mr Sarin senior reporter of India Vision paved a strong path in this regard. His investigation revealed the flaws and human rights violations which Jananeethi advocated for many years. This resulted in grabbing attention from Government and other non governmental agencies like IMA .This also provoked MLA'S to raise questions relating unethical drug trials before Kerala Legislative Assembly.

Successes met:-

1. Constitution of an Expert Committee by Government of Kerala to investigate allegations on unethical drug trials in the state. Committee consists Three experts includes Dr Anoopkumar Thekkuveetil and Dr V. Ramankutty who are close associates of Jananeethi and who endorsed findings of Jananeethi.
2. Constitution of Expert committee by Indian Medical Association Kerala Chapter.
3. 11 Submissions raised since 12/12/2012 before Kerala Legislative Assembly and Health Minister of Kerala informed that the Government will take strict action after receiving report from Expert committee
4. Unearthing unethical drug trials and corruption by India Vision Channel (August 16th 2012)
5. New rules from Drug Control General of India ensuring registration of drug trials , ethics committees , compensation to drug trial victims and appointment of Inspectors
6. Intervention from Supreme Court and National Human Rights Commission
7. Admission of Public Interest Litigation from Jananeethi in Kerala High Court, notice issued to Central – State Government Authorities
8. State level consultation on the need of regulation of drug trials for Members of Kerala Legislative Assembly- Trivandrum Hotel, Thiruvananthapuram on 13/12/12
9. Clinical Drug Trials: Need for an Effective Regulation- A Consultation - 27th June 2012 - 3.00 p.m. - Hotel Ruby Arena, Thiruvananthapuram.
10. Seminar on DRUG TRIAL & HUMAN RIGHTS. Held at Seminar Hall, NUALS, Kalamassery, Kochi on 11th August, 2012
11. Appraisal meeting of the Project: 'Save Clinical Drug Trial Ethically Sound and Corruption-free' - held at Hotel Pearl Regency, Thrissur on 31-8-2012

12. Jananeethi Stall on Thrissur Pooram Exhibition- 9th April 2012.
13. Media Programme Conducted at Thrissur Railway Station- 03.02.2012
14. Media Programme Conducted at Jyothi Engineering College- 01 – 02 – 2012 & 02 – 02 – 2012
15. Seminar on Best Practices in Clinical Drug Trials and Need for State Regulations (Consortium Meeting)- 2nd November 2011 at Lions Hall, Erattupetta in Kottayam district
16. Meeting with Dr.Rajeev Sadanandan IAS, Health Secretary,,Government of Kerala- 25th November 2011 at Health Department, Secretariat, Thiruvananthapura
17. National Consultation on Regulation of Drug Trials, in New Delhi on 26- 27 September, 2011
18. Comments on Clinical Drug Trial Submitted to National Human Rights Commission (NHRC) through Centre for Studies in Ethics & Rights (CSER), Mumbai
19. More than 150 sensitization programs on issues and concerns involved in the drug trial system covering more than 50,000 people.
20. Media programs done through AIR, Local Cable T.V. Channels and newspapers
21. Dissemination of Information through Information Kit, Jananeethi website and Jananeethi Blog
22. Whistle blowers and vigilant groups- Kerala Health Watch – in 14 districts of Kerala
23. Inauguration of Jananeethi Help Desk& Release of Information Kit. Held at 5 pm on 25th March, 2011, at Kerala Sahithya Academy, Thrissur
24. Institutional Review Committee - Appraisal Meeting. Held at Kerala Sahithya Academy, Vyloppilly Hall, Thrissur on 08/06/2011- 5.30 P.M
25. Workshop on Best Practices in Clinical Drug Trials on Human Beings Held on 2nd July 2011 at Chalissery Hall, D Block Jubilee Mission Medical College, Thrissur
26. Critical Alliance with NUALS, Pain and Palliative Care Society, Nature Life International and similar organizations and activists
27. Kerala University for Health Sciences is formulating a monitoring mechanism to ensure the conduction of drug trials ethically sound and corruption free.

Project Extension Period – Programs- January - March of 2013

1. SEMINAR ON CLINICAL DRUG TRIALS-Best Practices and Regulatory Standards, 7th March 2013, Seminar Hall, Pain & Palliative Care, Thrissur.

2. Out-reach program on Unethical Clinical Drug Trial. Sakthan Thampuran Bus Stand, Thrissur, 1/2/13.

3. State wide campaign against unethical drug trials in association with Dr Jacob Wadakkenchery of Nature life International – March 1 – 14, 2013.

Operational issues within the organisation that were favourable / not so favourable:-

As the issue addressed by the project was not purely legal hence more research and continuous attention were demanded for effecting implementation of the project activities. Since the drug trial conduction are mostly done without patients consent or they were given false information. This posed a serious problem of convincing the general public regarding the un ethical and corrupt practices of doctors and hospitals. Often we were branded as anti doctor/ medicine activists so we were forced to adopt different approaches to show a independent and un biased face.

Operational issues with other stakeholders like government, community, panchayat/municipality etc. and how were they resolved:-

Our involvement with local self government institutions during the project period is not significant. But we were in regular contact with Govt. medical colleges, educational institutions and health centers for conducting awareness programs, ensuring participation of doctors during consultation and seminars and collect information on drug trials and systems. There was a mixed trend from the authorities and institutions. Many considered the issue seriously and extended their cooperation but few of them were very cynic and always showed a hostile approach. Their main allegation was that the drug trial system is purely a scientific procedure hence Jananeethi being a human rights organization is not competent to question the medical community. Realizing this we always tried to clarify our positions making consultations with experts in the field. We also posed a balanced approach before them as we are not against drug trials but we challenge the existing flaws and corruption.

***Explain where and how your experiences can be replicated*:-**

Our experience through this project can be replicated anywhere where drug trials are carried by doctors and hospitals ignoring the basic principles and human rights of drug trial subjects. As the issue of drug trials in Kerala are concentrated in few locations like Thiruvanathapuram , Ernakulam, Calicut and Thrissur districts if we concentrate more in these drug trial prone zones it can bring considerable impact in future .

9. . Constructive engagement:

Please include instances of useful interactions and constructive engagements with other stakeholders (government officials, media, CSOs, NGOs including other CAC partners etc.) and how they have helped further project success. Please name specific officials, offices that you have interacted with.

Constructive engagement with stake holders plays an important role in effective implementation of our project. Through out the project period we had many engagements with Doctors, Ethics committee members, Government officials, Media Personnel, Peoples Representatives (MLA) etc.

As part of the constructive engagement of the project, we had many useful interactions and constructive engagements with other stakeholders. Thanks to the dignitaries who by and large were very sympathetic to us and have promised their support and assistance during the process of our study.

Effective Stakeholder Engagements: First Quarter:

1. Mr.P.G.Thomas I.A.S, Collector, Thrissur
2. Dr.V.K.Ramankutty, Principal , Jubilee Mission Medical College, Thrissur
3. Mr. Subeesh, Program in charge , Kerala Vision Channel, Thrissur
4. Mr.Ranjith Nair, Senior Sub Editor, Kerala Vision Channel, Thrissur
5. Mr.Isan, All India Radio, Thrissur Station
6. Mr.Mahesh Guptan, Investigative reporter Malayala Manorama News Paper.
7. Ms. Rajalakshmi, ICDS Officer, Ollukara Block, Thrissur.
8. Ms.Seena M.Phil, Health Standing Committee Chairperson, Varantharapilly Panchayath, Thrissur
9. Mr.Senthilkumar, Vice Principal, Aswini College of Nursing, Thrissur
10. Mrs.Sherly, Principal, West fort Academy for Higher Education, Thrissur.
11. Beena Govind- Journalist, Mathrubhumi Daily, Palakkad.

12. C.S.Srinivasan, Health Standing Committee Chairman, Thrissur Corporation.
13. Sheela Edward, CDPO, Chitoor Block, Palakkad.
14. Ms.Omana, Principal, Govt.Nursing College, Palakkad.
15. Dr.P.P.Mohan, West fort High Tech Hospital, Thrissur
16. Dr. K.G.Radhakrishnan , Asst.Prf., Govt.Medical College, Thrissur
17. Dr.K.Ajithkumar, Member Secretary, Govt.Medical College, Thrissur.
18. Sobha Jayadas- CDS Chairperson, Adat Grama Panchayath, Thrissur.
19. Ms.Sundari, District Probation Officer, Palakkad.

Result:

During the first quarter of the project we had several constructive engagements with various stake holders for the effective implementation of project activities. Engagements with media persons were useful as it helped to organise programs in the media like AIR and television channel. It also helped to bring reports on the issue in the leading news papers like Malayalmanorama and Hindu. Engagements with officials from social welfare department like CDPO's and representatives from the local self government, Heads of educational institutions were useful as it enabled us to organise weekly and monthly sensitisation programs and quarterly workshops for the dissemination of basic information on clinical drug trials and to strengthen the voices against unethical trials. The above mentioned list is not exhaustive, we had meetings with committed people from different strata of the society for the formation of Kerala Health Watch and separate lists of members of Kerala Health Watch is attached with this report During the first quarter of the project we had several constructive engagements with various stake holders for the effective implementation of project activities. Engagements with media persons were useful as it helped to organise programs in the media like AIR and television channel. It also helped to bring reports on the issue in the leading news papers like Malayalmanorama and Hindu. Engagements with officials from socialwelfare department like CDPO's and representatives from the local self government, Heads of educational institutions were useful as it enabled us to organise weekly and monthly sensitisation programs and quarterly workshops for the dissemination of basic information on clinical drug trials

Effective Stakeholder Engagements: Second Quarter

1. Dr. Anoop Thekkuveettil, Scientist and Member Secretary – Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram.
2. Dr.Ipe Varghese, Registrar, Medical university, Kerala
3. Ms. Shaila, CDPO, Valappad
4. Fr.Benny Manappatt, Director, KAIROS, Bernacherry, Kannur.
5. Dr.Jithedranath, Sultan Bathery,Wayanad
6. Mr. Biji Thomas, Senior Reporter, Manorama News, Thrissur

7. Ms.Thanka, Principal, Nursing School, Thrissur
8. Ms.Mariyama, Principal, Elite School of Nursing, Thissur
9. Mr.Babu, Faculty member, Govt.Nusing School, Manjeri
10. Mr Arun, Senior Reporter, Asianet News, Thrissur
11. Dr. P. Lakshmanan, Principal, Govt. Training College & Secretary, Wayanad Sarva Seva Mandal, Sulthanbathery.
12. Mr. M.K. Ramadas, Sr. Program Reporter, Amrita T.V., Wayanad.

Result:

Dr. Anoop Thekkuveetil who is an authority in the filed of ethical standards of clinical drug trials accepted our invitation and delivered key note address at the quarterly meeting held at Jubilee Mission Medical College. He offered is support and cooperation for the success of our project. Dr Ipe Varghese, Registrar of medical University appreciated our efforts and guided us for the execution of project activities. Meetings with news reporters helped to bring attention of the leading news channels in to the grey areas of drug trial conduction and hope that they will cover this issue in their channels. Engagements with Principals of Nursing Colleges and CDPO helped us to organise weekly and monthly sensitisation programs. During the second quarter we had several stake holder meetings with office bearers of civil society organisations and other individual activists which helped us to form Kerala Health Watch in several districts. (List of Health Watch Members attached) We also met local cable TV/Cable network reporters and that engagements helped us in doing programs in the respective channels on clinical drug trial issues.

Effective Stakeholder Engagements: **Third Quarter**

1. Dr. Rajeev Sadanandan IAS, Health Secretary, Kerala.
2. Engagements with resource persons and Participants of National Consultation, held at New Delhi.
3. Dr. Anoopkumar Thekuveettil, Sree Chitra Tirunal Institutre of Medical Science, Thiruvananthapuram
4. Dr. Girish Menon, SCTIMS, Thiruvanthapuram.
5. Engagements with resource persons and participants of regional consultation on Second Universal Periodic Review held at Bangalore organised by Working Group on Human Rights (WGHR) and SICHREM and at the National Consultation on Second UPR at New Delhi organised by WGHR.
6. Dr. K. Rajagopal, Information Commissioner, State Information Commission, Kerala.

Result:
The most important stakeholder meeting done during the reporting quarter is the meeting with Dr. Rajeev Sadanandan IAS, Health Secretary Kerala. The meeting was successful as he agreed and accepted our recommendations with regard to the regulation of drug trial conduction in Kerala. He agreed to constitute an expert body to take stock of the drug trial conduction and asked us to recommend few experts to be considered for the team. We had effective interaction with the resource persons and participants of National consultation on the need of regulation of drug trial conduction held at New Delhi. We also got an opportunity to submit our findings at Regional and National consultation on Second Universal Periodic Review organized by WGHR, held at Bangalore and New Delhi. We also appeared before the Information Commission Kerala under RTI and got favorable decision from the commission. Engagements with Principals of Nursing Colleges and CDPO helped us to organize weekly and monthly sensitization programs. During the third quarter we had several stake holder meetings with office bearers of civil society organizations and other individual activists which helped us to form Kerala Health Watch in several districts. (List of Health Watch Members attached.

Effective Stakeholder Engagements: Fourth Quarter

1. P.J.Francis, Honourable District Collector, Thrissur.
2. Mr.Vinod Bhanu, Executive Director, Centre for Legislative Research and Advocacy, New Delhi.
3. Ms.Nibby Ann Mohan. Reporter, City Journal, Thrissur.
4. Dr.Baburaj, Senior DMO, Southern Railway, Thrissur
5. Engagements with doctors of health centres, Health Inspectors and CDPO's.
6. Mr.Krishna Prasad, Health Inspector, Medical Department, Southern Railway, Thrissur
7. Mr.Shiju, Lecturer, Department of Mechanical Engineering, Jyothi Engineering College, Thrissur.
8. Mr.Babuji, Social Activist and Convenor Ashtamudikayal Samrakshana Samiti, Kollam
9. Shiny Jacob Benjamin, Internationally acclaimed document director and Senior program Officer, Jaihind Television

Result:
Mr.P.J Francis, Honourable Collector of Thrissur District was kind enough to hear us about our initiative and engagement with him became highly strategic because it was his benevolence which helped us to get a stall in the Mega Festival Exhibition of Thrissur. Through this we are going to address at least 1.5 lakh people during a period of one and half month. Engagement with Mr.Vinod Bhanu was very important as he is helping us to organise the meeting at New Delhi .Interview with Ms.Nibby Mohan was quite useful for us because it was this interview which made her to publish an article in her news paper City Journal. Engagements with

Dr.Baburaj and Mr Krishna Prasad health officials of SouthernRailway, Thrissur, became as critical as it motivated them to organise a media sensitisation program on drug trial concerns.

Engagment with Mr. Shiju, lecturer at Jyothi Engg.College was helpful in two ways. It was he who took initiative to make sure that we get a space at THARANG – Tech Fest organised by the Jyothi Engineering College. He also invited us to organise a sensitisation session for the students of his college during summer camp. Mr Babuji a reputed and known activist in Kollam District was the person who took lead role in the formation of Kerala Health Watch, Kollam Chapter. Ms.Shiny Jacob Benjamin, renowned document director is in regular contact with us who is going to make a documentary on clinical drug trials. Engagement with Ms Shiny helped us to share our experience so far which is definitely going to included in her work. As in the previous quarters we had extensive engagements with officials of different departments like Health, Social Welfare and Panchayath, which was indispensable for organising large number of awareness programs.

Effective Stakeholder Engagements: Fifth Quarter

1. P.J. Francis, Honourable District Collector, Thrissur.
2. Mr. Vinod Bhanu, Executive Director, Centre for Legislative Research and Advocacy, New Delhi.
3. Dr. V.K. Ramankutty, Professor at Achutha Menon Centre for Health Sceiences Thiruvanatham
4. Mr. Sree Soab, Reporter Mathrubhumi Daily, Thrissur
5. Mr. Shijo, Reporter News Channel
6. Mr. Manoharan, President Thrissur Exhibition Committee
7. Dr. Hari, Wayanad
8. Mr. Rajendran and Mr Stalin, Kerala Sasthra Sahithya Parishath, Pathanmthitta

Result:

Meetings with Honourable collector Mr P.J.Francis and Mr Manoharan , President of Pooram Exhibition Committee was of great importance as it helped us to do the exhibition program at Thrissur Pooram Pavilion. Honourable collector was also kind enough to inaugurate the stall and encouraged our work with his motivational words. We are in regular contact with Mr Vinod Bhanu which is highly critical to organise the appraisal meeting in New Delhi. He has assured us to help in convening the proposed meeting as early as possible. Meeting with Dr.V.K.Ramankutty was useful as he assured his help in organising an appraisal meeting at Thiruvanathapuram. Dr Hari is the petitioner in a PIL filed before the Kerala High Court against the ongoing Pentavalent Vaccination program implemented in Kerala by the Government. He has extended his cooperation to Jananeethi in our fight against unethical drug trials. Mr Sree Soab and Mr Shijo promised to report the issue and findings of Jananeethi through their News Paper and News Channel. Engagments with Mr Rajendran and Mr Stalin is going to help us in formation of Kerala Health Watch in Pathanamthitta District.

Effective Stakeholder Engagements: Sixth Quarter

1. Mr.Justice Thottathil Radhakrishnan, High Court of Kerala
2. Mr. Justice K.T.Sankaran, High Court of Kerala
3. Mr. Sarin, Senior Reporter, India Vision Channel
4. Mr.Shaju , Reporter Channel
5. Dr.N.K.Jayakumar, Vice – Chancellor NUALS
6. Dr. M.C.Valsan, Professor at NUALS
7. Dr. N.R.Madhava Menon, Legal Luminary
8. Dr. V.K.Ramankutty, Achutha Menon Centre, Sree Chitra, Thiruvanathapuram
9. Dr Anoopkumar Thekkuveetill, SCTIMS, Thiruvanathapuram.
10. Dr.Mala Ramanathan, Achutha Menon Centre
11. Dr Girish Pai, Public Health Researcher
12. Mr Rajendran and Mr Stalin, President and Secretary KSSP Pathanamthitta.
13. Ms Anupama S., Student, NUALS.
14. Dr. Mohanan Nair
15. Mr.Jeemon Jacob, Staff Reporter, Thehelka, New Delhi
16. Ms Bony Jacob, Lecturer, College of Social Work, Thiruvananthapuram
17. Dr.Faisy, Environmental Scientist

Result:

The above list is not exhaustive. Our engagements with media persons like Mr.Sarin and Mr.Shaju helped us to sensitise and discuss the issues in drug trials through out the state of Kerala. Our association with NUALS (National University for Advanced Legal Studies, Kochi) is the result of our constructive engagements with eminent personalities like Dr.N.K.Jayakumar, Dr.M.C.Valsan and Ms. Anupama. Engagements with these stakeholders helped us in organising one of our best program,s the state level seminar on clinical drug trials. We also received their promise and support in drafting a model bill to be presented before the MP'S AND MLA'S. Dr. Madhava Menon, and other listed doctors were really helpful in making the state level consultation held at Thiruvanathapuram really a successful one. Mr.Rajendran and Mr Stalin helped us in the formation of Kerala Health Watch, Pathanamthitta.

Project Extension Period :

1. Dr Jacob Waddakkumchery, Health Activist, Nature Life International Kochi
2. Dr Divakaran, Director Institute of Pain and Palliative Care, Thrissur
3. Dr. Sudheendra Ghosh, Principal Govt Medical College, Thrissur
4. Dr Laila, NRHM Cordinator , Paina and Palliative CareThrissur
5. Adv Subi Babu, Deputy Maayor, Thrissur Corporation
6. Dr Anoopkumar Thekkuveetil, SCTIMST, Thiruvanathapuram
7. Dr Praveen G Pai, Public Health Expert

Result:
During the extended project period we had constructive engagements with various dignitaries for the effective implementation of the proposed activities. During the period of extension association with Dr Jacob Wadakkumchery became as vital as it helped us to organize a state wide campaign against un ethical practices of drug trials. Dr Divakaran, Dr Laila helped to organize a one day seminar for doctors in association with Pain and Palliative Care Society Thrissur. Dr Sudheendra Ghosh inaugurated the seminar and emphasized the importance of Ethical issues during the drug trial conduction. Dr Anookumar Thekkuveetil and Dr Praveen G pai delivered key lectures which helped to sensitize the doctors regarding various concerns of clinical drug trials. Meeting with Deputy Mayor Adv Subi Babu helped us in getting permission to conduct out reach program at Sakthan Thampuran Bus Stand Thrissur

10. Community Empowerment:

Explain the specific interventions that led to community empowerment. Also explain Community Organisations Developed or Supported through this Project. ***Please list and comment on quality of CBO contribution to the objectives of CAC:-***

During the second phase of project period our key emphasize was community sensitization and in return community empowerment. This was done remarkably well through different intitives like awreness programs , workshops, seminars, media programs news paperreports etc. As the project was more on a research base specific CBO,S were not developed or supported by Jananeethi as such. Only initiative in this line was the formation of health watch committees in the fourteen districts of kerala. But it was not conceived as community based organization but visualized as a collective of human rights and health activists. Their involvement was like a watchdog group in their concerned districts to monitor and report un ethical drug trials noticed by them. Drug trials being carried in a clandestine manner these groups were not successful in identifying any drug trial issues in their respective districts. Their contribution was more useful in arranging awareness programs for the public.. But this group is highly potential so in the sustainability angle of the project their potentials can be tapped to address not only drug trial cases but health issues in future.

11. Peer learning:

Please comment on the peer learning experiences in terms of:

1. **your organisation under review and**
2. **you reviewing other organisations and**
3. **comment on the quality of such exercise and contribution to success of CAC project**

1. During the second phase of the project we were reviewed by SVYM, Mysore CAC partner and Mr Vargheese from PAC. It was a fruitful exercise to us as it helped to realize our strengths and weaknesses. Major problem we faced was the odd nature of project compared to the rest of projects under CAC. Our work was more a study angle hence we faced difficulty in providing the reviewers quantifying figures.

2. During the second phase we reviewed two CAC partner organizations a- SVYM, Mysore by Adv George Pulikuthiyil b- AYUSUAKAM, Odisha by Adv. Sunilkumar. As the process found very useful because it provided us valuable insights which can be adapted for strengthening our project activities.

3. The idea of peer learning is very innovative proposition and we found it very useful. Some of their suggestions were well taken and are being followed. However, it would have made more sense to us if the peer groups had any thing common with us. Unfortunately, only Jananeethi is working on the corruptions involved in drug trials. Our counter parts in the CAC programme are all involved in either NREGS or PDS. Hence they had very little to contribute as they had no exposure to the problems we are fighting with.

12. Project sustainability:

Technical:	• ***What measures have been taken to ensure sustainability of project processes like knowledge generation, constructive engagement and community empowerment adopted in the project?*** Jananeethi intervened in the issue of drug trials not merely from a project implementation but as a fight against corruption. So our efforts to make the conduction of drug trials ethically sound and corruption free is not ending with the project period. Our initiatives during the project period will ensure this fight lasts till the goal is reached. We have formed health committees in fourteen districts of Kerala though their contribution during the project period

	was limited in organizing awareness programs these groups can be strengthened to fight against corruption in the health sector. Through our sensitaization programs and IEC materials we have disseminated information on drug trial concerns to large segment of people. These empowered and sensitized groups will ensure that more and more people get sensitized on the issue in future. We can identify some obvious impacts taking place in area of drug trials like Governmental interventions and court interventions which is going to be pivotal in sustaining the project process in future. Our • ***What plans for upcoming initiatives to ensure sustainability of project outcomes?*** We can identify some obvious impacts taking place in area of drug trials like Governmental interventions and court interventions which is going to be pivotal in ensuring the drug trial conduction ethically sound and corruption free. To sustain the impact we will strengthen our constructive engagements with stakeholders to see that the momentum is not paused. Again we will be following the PIL filed before the High Court of Kerala to ensure positive orders which is indispensable to ensure the conduction of drug trial ethically sound and corruption free. We have plan to locate the MLA ,S who wre briefed by Jananeethi on the concerns of drug trials and the need of state intervention in regulating drug trials. We are specifically targeting those MLA's, of Kerala Legislative Assembly who raised questions against unethical drug trials in the Assembly. We also have plan to advocate with expert committee members appointed by Kerala Government specifically with Dr Anoopkumar Thekkuveettil and Dr V.Raman Kutty to see who are in close association with Jananeethi since first phase of the project to see that all our concerns are addressed in their report .
Social:	• ***How much ownership does the community have of the process?*** Not Applicable • ***How far the community is independent in dealing with the corruption issues on their own?*** Through the sensitization of community the community is aware of the malpractices that is taking place in the filed of drug trials. But due to the

	secrecy and confidentiality revolves around the drug trial system and the blind trust of patients on doctors make the situation still grim. We still believe that continuous efforts are required to strengthen the community to deal independently on the drug trial issues. • ***How far the community can independently organize the road shows or protests for their rights and curbing corruption?*** Not Applicable
Institutional:	• ***What are the organizational plans to continue the project on your own?*** Though the project period ended, the commitment of Jananeethi to people's right to health care and their right to know will not let the organization to leave the matter as it is. Jananeethi has resolved to stay consistently in the field, though limited to certain focused area, such as State Regulation of Clincal Drug Trials, Informed Consent, Ethics Committee, Rights of trial participants and maintaining a Help Desk for victims of mal practices in the field. The eye of Jananeethi will remain fixed on these five areas and will carry forward our commitments. One such initiative from our side is going to take place during the Thrissur Pooram during this mega event as done in the previous year with the support of PTF, this year also we are installing a stall in the exhibition pavilion . For one and half month (April/May) we will be disseminating information on drug trials to thousands of people who are going to visit the stall. • ***How far the CBOs formed/strengthened can work on their own?*** Not Applicable
Financial:	• ***Does the community financially contribute to the project?*** *No* • ***How much financial support can your organisation mobilize on its own from other donors?*** We have not been successful in mobilizing any financial support • ***Have any other donors expressed interest in supporting such initiatives?*** No offer till date.

Annexes to be attached to the Completion Report:

1. Activities (Inputs) table (see the suggested format below).
2. Outputs Table (Plan vs actual –see the suggested format below).
3. Outcomes/Results (update log frame)
4. Financial Progress Report (see the suggested format below)
   5. Human Interest Success stories (include photos if possible) and case studies
5. Materials/reports/toolkits published/disseminated and/r posted on the website

Annex 1: Accomplishment of Activities:

Project Activities Planned (Please reproduce what was in the Approved Proposal).	**Actual Project Activities.** (Please Describe what was actually done	**Status of completion**[4] **and (**Description of any major change in the activity with explanation as needed.)
Objective – 1: Awareness Building		
Activity-1: Weekly sensitization programmes on areas of public concern in clinical drug trials for medical and paramedical students and staff, community workers, elected representatives to local bodies, civil society organizations, media personnel, service providers etc.	During the first phase of the project we were mainly emphasized on the identification, collection and compilation of facts, figures, issues and concerns involved in the clinical drug trial system. To establish our stand we had identified and recorded the real experiences of five clinical trial subjects. The most important fact we realized from our experience in the first phase of the project was the existence of gross ignorance among the Doctors, Hospital Management, Ethics	**C**

[4] C= fully completed, NC = very limited or no completion, D= Deferred to Phase 2, IP=In progress.

	Committee members, Government officials and the public in general with respect to issues and concerns involved in clinical drug trials. This dangerous situation necessitates effective intervention from different sections of society to remove the grey areas of the present functioning of drug trial system in India. This realization forced us to put more emphasize on sensitization programs for the general public and for those who are directly and indirectly involved in the drug trial system. Weekly sensitization programs on clinical drug trials were organized for different sections of society including Anganvadi Teachers, Asha workers, and Medical and Paramedical students. Through this large segment of society got awareness on issues and concerns involved in drug trials. We implemented this activity in such a way that different sections of the society get involved in the issue so that they can be vigilant against the un ethical trials and also disseminate information on drug trials to the grass root level. **Details of the Classes –With Photos- Attached**	

Activity-2: Quarterly workshops for medical practitioners, researchers, hospital managements and members of ethical (review) committees on best practices in clinical drug trials.	This activity is meant to sensitize the top brass of people who are directly and indirectly involved with very system of clinical drug trial. To fulfill this objective a workshop on Best practices of clinical drug trials was organized in association with Jubilee Mission Medical College, Thrissur on 2nd July 2011. As reported in the quarterly technical reports due to the difficulty in organizing quarterly workshops for doctors we had conducted a one day seminar in association with National University for Advanced Legal Studies on 11th August. High Court Judges, Doctors, Medical students, Academicians, Lawyers and Law students were participated in the seminar. A detailed report and photographs on the seminar is attached with the report. We also arranged an appraisal meeting on 31st August in the presence of leading medical practitioners and Health Activists. **Reports Attached**	**NC (Partially Completed)**
Activity –3: Prepare an 'information kit' in the first quarter of the Phase II with -respect to basic information regarding ethical standards and best practices in clinical drug trials. This will be in Malayalam and will be distributed among participants of sensitization programmes and training sessions. The information kit will contain guidelines of clinical trials, rights of the human participants, services provided by the Help Desk of Jananeethi, contact details and few case studies.	An information kit as proposed was formally released by Dr.V.K.Ramankutty, Principal, and Jubilee Mission Medical College Thrissur on 25th March 2011. The information kit includes Rights of human participants, Services of Jananeethi Help Desk, ICMR Guidelines, and contact details of Jananeethi. The kit serves as a guide to those who are	**C**

	involved in the drug trial system and to the public in general. The kit is circulated during the weekly and monthly sensitization programs. **Report attached**	
Activity-4: Prepare badges/stickers and banners on good practices in the second quarter of the project and distribute among student participants of sensitization programmes in schools and educational institutions.	Banners and Stickers were prepared to be distributed during the sensitization programs organised specifically in this direction. We have organised following program for this purpose. **Details** 1. Venue- Govt. School, Pattikkad Date- 12-8-11 2. Date-22/12/2011, Venue Vimala College, Thrissur 3. Date-24/01/2012, Venue- Arafa B'ed Colege, Mullurkkara 4. Date- 25/01/2012, Venue-Jay BharathEngineering College, Perumbavoor, Kochi 5. Date-09/02/2012 Venue-Chinmaya Mission College, Kolazhy, Thrissur 6. Date-12/03/2012, Venue- National ServiceCamp, organized by Jyothi Enggineering Collge at ASSO, Attapadi, Palakkad District. 7. Date-12/06/2012, Venue-St.D'Paul College, MSW	**C**

	Department, Angamly, Resource Person- Adv.Suilkumar P. 8. Date- 14/06/2012, Venue- E.V.Kalamandalam, Adoor,Pathanamthitta District Resource Person Adv.Sunilkumar P. 10- Date-17-8-2012, Venue-Sree Sankaracharya University, MSW Dept., Tirur, Malappuram. Resource Person-Mr. Bijeesh E.S. 10- Date-22/08/2012 Venue-Sree Sankaracharya University, MSW Dept., Payyannur, Kannur District Resource Person- Adv Sunilkumar P. We have organized all the ten programs under this head. (**Photos Attached)**	
Activity-5: Devote one page of Jananeethi monthly journal (in Malayalam) to appraise its readers the corrupt practices in clinical drug trials and universally accepted best practices and Ethical standards in such clinical trials. This will be done from first month of phase II.	One page of the monthly Jananeethi Magazine, was devoted for publishing news relating to various issues on clinical drug trials. Through this information on Jananeethis, interventions in the drug trial issues Rights of Human participants, concerns of drug Trials reached to general public.	**C**

Activity-5a: Preparation of Charter of Rights of Human Participants. (Carry forwarded from Phase I)	Charter of Rights of human participants printed and it was distributed among participants of awareness programs and other stake holders.	**C**
Objective – 2: : Advocacy		
Activity-6: Make representations in the second quarter of the project to both the Union and State Governments for the enactment of specific legislations on clinical drug trials.	Representations in this regard were submitted to the following authorities for their attention and intervention. 1- Health Secretary, Govt Of Kerala 2- National Human Rights Commission 3- Representation to the Expert Committee constituted by the Govt of Kerala 4- Representation to Expert Committee constituted by Indian Medical Association Kerala Chapter. 5- Recommendations from the National consultation on the need of regulation of drug trials were submitted to the Central Government.	**C**
Activity-7: Meet Secretary of Health in Government, Director of Medical Research and Education, and Heads of medical colleges in the first quarter to ensure their full support and cooperation in checking un ethical practices in clinical drug trials.	As proposed we had met Institutional heads like Principals of Private and Government Medical colleges, Registrar of Medical University and other important officials. Meetings with these	**C**

	dignitaries were successful as they assured their cooperation and support for the effective implementation of the project. We had an effective meeting with Health Secretary, Kerala Mr.Rajeev Sadanandan IAS on 25th November, at Secretariat Thiruvananthapuram. Detailed report on the meeting is **attached**	
Activity-8: Quarterly meetings of heads of Institutional Ethics Committees / Review Committees to apprise, assess and evaluate the various steps taken to enforce best practices.	An appraisal meeting of members of Institutional Review Board was organised on 8th June 2011 at Thrissur. The meeting was a great success as members of various ethics committees including leading doctors attended the meeting and apprised the present functioning of ethics committees. The meeting revealed important facts which establish our stand on the ineffectiveness of ethics committees as a mechanism to check un ethical drug trials. As in case of Activity 2 due to the non cooperation from the hospitals we couldn't complete the activity in the planned time frame. A detailed report on the appraisal meeting is attached with report.	**NC (Partially Completed)**
Activity-9: Arrange in association with the All India Radio, Private Cable Network, FM	After the inauguration of Help Desk and Information Kit, on 26thand 27th of March	**C**

radio stations and other main stream television channels monthly programmes on the rights of human participants in clinical drug trials and the statutory norms thereon.	programs on clinical drug trial was aired by All India Radio, Thrissur Station. Adv.Geroge Pulikuthiyil, Adv.Sunilkumar.P, Adv.Faritha Ansari and Dr.K.G.Radhakrishnan commented on various aspects of clinical drug trial system and issues involved in the system After the constructive engagements with Mr.Subish (Presently with India Vision) and Mr.Ranjith (Presently with Jai Hind) form Kerala Vision a leading private cable network were convinced about the importance of the subject and done a campaigning program on the issues and concerns of clinical drug trials. 30 minutes recording was done at VISMAYA VISION at Aruvithura on Clinical Drug Trials and the Study being conducted at and services provided by Jananeethi. This will be shared among three local channels in and around Pala – they are Drussya, Vismaya and Channel One of Pala. Altogether these channels will be covering eight panchayats in the district of Kottayam. Kannur Vision, a	

	local channel that covers the entire district of Kannur and partly Kasargod and Wayanad districts, spared 90 seconds exclusively at prime time news telecast on the 8th evening and 9th morning. We had received extensive media coverage after the strong comment emanated from Supreme Court of India. Leading News Channels in Kerala like India Vision and Reporter invited Adv George Pulikuthiyil and Adv Sunilkumar P for a live discussion on clinical drug trial issues On 16TH July and 17th Agust. All India Radio also telecasted a program on clinical drug trial on 19th July.of August.	
Activity-10: Publish at least one article in three months in a popular news paper/news magazine regarding the mandatory norms and best practices in clinical drug trials	News items on drug trial issues and Jananeethi's findings were published in the leading news papers. The main objective of this activity is to bring greater public attention into the ongoing scenario of clinical drug trial system and literate general public regarding the best practices of clinical drug trials. In this regard, while doing an investigative story on the	**C**

	various concerns of health care system in Kerala Mr. Mahesh Guptan Senior investigative reporter of Malayala Manorama a leading news paper in Kerala interviewed us and included our findings in his report and the same was published in Malayala Manorama Daily. Varthamanam Daily published reports on the unethical practises in Clinical Drug Trials in two parts, dated on the 8th and 9th ofAugust 2011.Siraj Daily published the report on the corrupt practices in Clinical Drug Trials on human Participants on the 9th of August 2011. 'Jananeethi fights against un ethical drug trials'-was published on 11th February 2012 in City Journal. News items on drug trial issues and Jananeethi's findings were published in the leading news papers including Hindu (News Paper Reports attached)	
Activity-11: Create a blog that publishes all our findings and relevant information connected with drug trials and link with similar activities in India and abroad.	A blog-named www.jananeethi.blogspot.com is created and information regarding the drug trial system, our findings and other useful information is shared in the blog.	**C**
Activity-12: Organize one appraisal meeting in Delhi for Members of Parliament, and 2 meetings in Thiruvananthapuram for Members of State	An appraisal meeting as planned was organised on 27th of June at Hotel Ruby Arena, Thiruvanathapuram. A detailed report on the	**C**

Assembly on the need of specific legislations for checking and regulating clinical trials on human subjects.	meeting is attached. Our efforts to convene a meeting of Members of Parliament in New Delhi could not become successful due to various reasons beyond our control. Only MP who is briefed and actively involved in the issue is Smt.Brinda Karat. Adv George Pulikuthiyil of Jananeethi was invited to the National Seminar on the need of regulation of drug trials in New Delhi where he shared our findings in front of various dignitaries including Smt Brinda Karat. During the session of Kerala Legislative Assembly around 40 members were personally met and they were briefed and information and findings of Jananeethi were submitted. We also personally invited them for a consultation to make them really aware on the current issues of drug trial scenario in Kerala. Based on our invitation six members of Kerala Legislative Aseembly came for the consultation held on 13/12/12 at Trivandrum Hotel. All of them stayed for two hours and patiently attended the presentation On our findings. During the presentation Dr Anoop Kumar Thekkuveetil member of expert committee constituted by the Kerala Government, Mr. Sarin Senior Reporter from India Vision, Dr Praveen Pai a Public Health Researcher were also present. They also shared their experiences during the meeting. All the members of the legislative	

	assembly convinced on the issue and promised that the same will be raised in Legislative Assembly. They admitted that the issue is very serious and intervention through a strong legislation is indispensable	
Activity-13: Talk to the Secretary of Ministry for Local Self Government in the second quarter of the project to include best clinical practices into the curriculum of KILA for newly elected people's representatives. (KILA - Kerala Institute of Local Administration).	Dropped	After analysing the practicality and effectiveness of the activity it was decided that it would be better to drop the item as it was not going to fetch any desired result as we envisaged, hence we dropped the activity after much discussion.
Activity-14: Give talks to the top brass of *Kudumbasree*, Self Help Groups, ICDS network etc at their monthly gatherings regarding norms to be followed in clinical trials	This was organised by meeting the CDPO in each Block to avail permission for making presentation on clinical drug trial system during the monthlygatherings of AnganvadiTeachers. It was successfullycompleted so far with the helpof officials form the socialWelfare department. Throughthese classes information onclinical drug trials, rights ofhuman participants, issues and concerns of drug trials arewidely disseminated.Details Attached	**C**
Activity-14a: Filing Public Interest Litigations in the Kerala High Court for the	1- WRIT PETITION(CIVIL 20140	

inclusion of the Guide Line in the course curriculum of medical students. (Carry forwarded from Phase I)	of 2012) Five human participants who were identified during the first phase were reluctant to go for a legal battle against the doctor because of their ill health and their trust on the doctor. Hence the legal steps envisaged during the first step were not carried out on this reason. The budget allocated for civil suit for compensation was later used for conducting Thrissur Pooram Exhibition with the permission from PTF/PAC. Writ in the form of Public Interest Litigation has been filed through Adv Dasiy Thampy of Kerala High Court. Writ petition is pending before the Kerala High Court. Notice has been served on the respondents like Drug Controller General of India, Central and State Governments. We are positively waiting for the decision.	**IP**
Objective 3: Monitoring		
Activity-15: Commence Help Desk at Jananeethi from first month of phase II to provide correct information to people with regard to clinical drug trials, and to investigate and act upon complaints regarding unethical practices and corruption in the area of clinical drug trials.	Help Desk at Jananeethi started functioning from March 1st onwards. It serves as a public utility hub for general public to gather information on clinical drug trials and to file complaint against unethical trials. Formal Inauguration of help desk	**C**

	wasdone by Honourable District Collector Mr.P.G.Thomas I.A.S, Thrissur. A detailed report on help desk inauguration is attached	
Activity-16: Establish Kerala Health Watch from second quarter of phase II linking individuals and civil society groups in all the districts of Kerala to monitor clinical drug trials on human persons and to report malpractice, if any.	Kerala Health Watch an initiative to link the individuals and civil society groups became a grant success by the support from committed personalities from different sections of society. It was formed to ensure the presence a vigilant group in every district to monitor the conduction of clinical trials and pose a threat to those who are involved in un ethical trials. Formation of Health Watch in Fourteen districts of Kerala State were completed and reports are **attached.**	**C**
Objective 4: Alliance Building		
Activity-17: Build up institutional contacts and networking with organizations and institutions in India and abroad for the promotion of best practices in clinical drug trials on human participants, from second quarter of phase II.	From the beginning of the project we put efforts to build up institutional contacts and networking. We were successful in establishing good relations with organizations and individuals who were working against un ethical drug trials. To point out few in this regard is Dr Amar Jesani of Centre for Studies in Ethics and Rights, Mumbai, Dr Gopal Dabade of AIDAN (All India Drug Action Net Work), SAMA New Delhi, Kerala Sastra	**C**

	Sahitya Parishath, Pain and Palliative Care, Health Action By People, NUALS (National University for Advanced Legal Studies) and similar other organizations and individuals (Details of individuals are given under the head of constructive engagements.)	
Activity-18: Organize a consortium of NGOs/CBOs in Kerala that work for the ethical standards in medical research and clinical practices. Organize its meeting once in six months to appraise situations in Kerala and outside with respect to new trends and challenges.	1- A meeting as proposed was organised at Kottayam on 02/11/2011 2-People's Assembly 75 NGO/CBO/CSOs in Kerala at VJT Hall, Thiruvananthapuram on 15th July 2012 Reports attached	**C**
NO COST EXTENSION PHASE: **January –March 2013** **Activities Planned**	**Actual Activities**	**Status**
Awareness Classses-10	**<u>Details</u>** 1-Date-12/1/2013, Venue-Madakkathara ADS office, Participants –ADS members Resource Person-Ms.E.Jayasree 2-Date-26/01/2013,Venue-Madakkathara CDS Office-Participants –CDS Members Resource Person-Ms.E.Jayasree 3-Date-28/01/2013, Venue-Kannambra Panchayath Hall, Palakkad Participants –CDS Members	**C**

	Resource Person- Ms.E.Jayasree 4-Date-3/2/2013, Venue- Karuvankkad ADS meeting Participants- ADS members Resource Person- Ms.E.Jayasree 5- Date-4/2/2013, Venue- Kizhakkenchery Panchayth Hall Participants –CDS Members Resource Person- Ms.E.Jayasree 6-Date- 05/03/2013 Venue-Nature life Hospital , Malappuram District Resource Person- Adv. P. Sunilkumar 7-Date: 06/03/2013 Venue: Nature Life Hospital, Kozhikode. Resource Person: Adv. George Pulikuthiyil. 8-Date-08/03/2013, Venue-Nature Life Hospital, Chambakkara, Ernakulam District Resource Person- Adp.Sunilkumar P 9-Date-09/03/2013 Venue: Sanketham Ashramam, Changanachery, Kottayam Dt. Resource Person: Adv. Sunilkumar P. 10-Date: 11/03/2013 Venue: Lions Club Auditorium, Nedumkandam, Idukki. Resource Person: Adv. Sunilkumar P.	

One Day Seminar	Date-07/03/2013 Venue- Seminar Hall, Pain and Palliative Care Society, Thrissur (Report Attached)	**C**
Out Reach Programs-Two	Though the original plan was to conduct two out reach programs our association with Dr Jacob Wadakkencehery helped us to organize more than two programs 1-Date- 1/2/2013 Venue- Sakthan Thampuran Bus stand , Thrissur. 2-Date: 02-3-2013 Venue: Ramavarma Hall, Kannur. 3- Date: 13-3-2013 Venue: YMCA Seminar Hall Kollam. 4-Date: 14-3-2013 Poojapura Mandapam Jn., Thiruvananthapuram.	**C**

Please follow order of PPM / Proposal for each of the objectives	**Give:** **1. quantitative figures** **2. qualitative information** **3. process followed to achieve each activity and** **4. evidence to verify the same**	

Annex 2: Planned and Actual Outputs

Outputs Planned (Please reproduce what was in the Approved Proposal).	**Actual Project Ouputs**	**Status of completion**[5] **(**Description of any major change in the outputs with explanation as needed.)
Information Kit and Help Desk	**Information Kit**	**C**
Badges and Stickers	**Badges and Stickers**	**C**
Posters and Public Notices	**Posters and Public Notices**	**C**
Jananeethi Blog	**Jananeethi Blog**	C
Representations and Suggestions to Government Authorities	**Representations and Submissions to Government Authorities**	**C**
Articles and News Reports	**Articles and News Reports**	**C**

[5] C= fully completed, NC = very limited or no completion, D= Deferred to Phase 2, IP=In progress.

Annex 3: Project Outcomes/Impact

Project Impact Indicators	Baseline Value	End of project Value	Sources and evidence to verify the results

Please refer to the log frame in the proposal submitted as per the agreement. Report on all indicators included in the Logframe.			
1Direct Participants – persons under drug trials			
1-1 -No. of persons identified under drug trials	5	5	***1-Methods/Tools for collecting information*** 1-Right to Information Act 2- Field Investigation 3- Constructive Engagements with Doctors 2- ***Sources of Information, Explanation*** Personal Information shared by a Doctor Identification of drug trial participants was a major task to be completed in the first quarter of First Phase. But the task became so difficult to that extent we even contacted a private detective for the identification of human subjects. This delay also posed serious blocks in the execution of other activities of first phase. Because most of the activities were designed

			based on the identification and recording of experiences of actual human subjects. Finally after many days of efforts we could identify a doctor who has a strong social commitment to our help. It was his information formed a basic source of information. We have collected information on the clinical trial by interviewing all the five participants in a trial based on a common questionnaire (in Malayalam) and by personal interaction with them and with their family members. Only one of the patients had the information that she was participating in a study by the doctor treating her. All others had no idea that they were recruited into a clinical trial. Nobody had got the copy of signed informed consent form; they did not know that there was a consent form at all. This study was done by the doctor secretly even without

			the knowledge of the hospital management. No payment was made to the patients who lost their daily wages, and who incurred expenses for traveling and for other related matters. Institutional Review Board of the hospital was unaware of the study. No patient had suffered any serious adverse event except one who mentioned about some stomach pain during the study period. The doctor who conducted the study informed one of the patients that it was a study by Amala Institute of Medical Sciences, while the patient belonged to another hospital. In the reply received from the Amala Institute of Medical sciences Act they have not mentioned about the trial in question. When we enquired about the details of the trial in the hospital we came to know that all the documents related to the trial had been taken by the Doctor.

1.2 No. of identified persons (under drug trials) fully aware of the negative effects of	0	5	Participants of drug trial were interviewed on common questionnaire and they were briefed on the various aspects of Drug trial. Can be verified from the audiotapes of the trial victims.
1.3 -No. of cases of negative effects of drug trials reported	5	9	1-Constructive engagements with doctors and ethics committee members 2- Sensitization of Media1- Personal information shared by two doctors who are also members of ethics committee of respective hospitals in which they work where they opposed two unethical trial proposal 2-Media sensitization and discussion done with Mr Jeemon and Mr Sarin Senior Reporters of Thehelka and India lead to the exclusive coverage on unethical drug trials in Kerala by India Vision News Channel. India Vision Report on 16th August 2012. Health and

			Research Centre a clinic in Thiruvanathapuram was attacked by public based on the revelations of un ethical; practices adopted by the clinic. Kerala Government and Indian Medical Association constituted expert committees to look into the allegations. We are extremely optimistic in the recent initiatives especially because Dr Anoopkumar Thekkuveetil and Dr V Ramankutty who were with us since the beginning of the project were included in the Three Member Expert Committee of the Government. Dr V .Mohanan Nair who lead the consultation organized by Jananeethi in Thiruvanathapuram is included in the IMA Committee. We believe these steps will bring considerable changes in the drug trial scenario in Kerala.

Indicator-2- Participation of different categories of stakeholders in awareness programmes on drug trials			
2.1- No. of citizens participated	100	50000	1-Awareness programs on clinical drug trial issues for ICDS members , members of General public College Students, etc 2-Exhibition programs like Thrissur Pooram Exhibition, Jyothi Engineering College, and Railway ETC. Second Phase of the project was designed based on the learning's from the first phase. The crucial realization we had at the end of first phase is that key stake holders of the drug trial system like Doctors , Ethics Committee members, Principal investigators hospital management and public at large were entirely ignorant about the various issues and concerns of drug trials. It is this realization lead us to conduct mass awareness programs for

			disseminating information of drug trials and to share our findings.
2.2- No. of medical professionals/ researchers participated	50	1100	1- Consultation Meetings with doctors. 2- Workshop for doctors and Ethics Committee members, 3-Awareness programs at Medical Colleges, Nursing Colleges 4- Weekly classes arranged in association with Primary Health Centres During the consultation meetings specifically the Thiruvanathapuram consultation, Seminar in association with National University of Advanced Legal Studies, Kochi , Pain and Palliative Care Society ensured significant results. Awareness sessions conducted at Medical Colleges , Nursing Colleges , Primary health centers ensured participation from Doctors , Nurses , Nursing Students, MBBS students Health Inspectors etc. (Reports attached)

2.3- No. of people's representatives participated	5	25	1- Awareness sessions held at panchayath community halls. Health Watch meetin During the implementation of our project there was no sessions specifically meant for people's representatives. Hence there participation in the awareness programs is comparatively low. Few representatives were present during some awareness programs conducted at Panchayth Community Halls. Few people's representatives participated and became members of District wise Health Watch committees formed in different districts of Kerala.
2.4- No. of social activists participated	50	500	Awareness programs , constructive engagements Personal and institutional contacts ensured the participation from reputed activists .Health watch formation in all the 14 districts were solely for

			these groups. (Reports Attached

3 Corrupt cases in clinical drug trials			
3.1- No. of corrupt cases identified	5	9	1-Right to information Application 2-Personal information gathered through constructive engagements with doctors and ethics committee members 3-Media investigation
3.2- No. of identified corrupt cases brought to the notice of authorities	0	4	1-Representation to Health Secretary 2- Briefing on unethical issues of proposed drug trials with doctor who were also members of ethics committee 1-Personal meeting with Health Secretary 2- Personal meeting with doctors During the first phase we could identify five human participants who were subjected to unethical drug trials. But due to their health condition (at the time we had met them they were undergoing dialysis twice a week) and their trust upon the doctors made them reluctant to take up any legal action. Realizing their plight

			we did not compelled them to initiate legal action. But we had recorded their experiences as drug trial participant who later formed a base for our assumptions and further activities.

3.3- No. of corrupt cases positively addressed by authorities	0	4	1- Cancellation of two unethical trials based on the protest raised by doctors in the ethics committee who were briefed on unethical practices of proposed drug trial by us. 2- Appointment of Expert committee by State Government to look in to the allegations leveled against Health and Research Centre, Thiruvanathapuram. Expert committee constituted by Indian Medical Association Kerala Chapter After the India Vision Report on Unethical drug trials in Kerala Kerala Government constituted a committee to investigate the drug trial scenario in Kerala. Government sealed Health AND Research Centre in Thiruvanathapuram where large number of unethical trials were carried out. Dr Anoopkumar Thekkuveetil and Dr. Ramankutty who were closely associated with

			Jananeethi in execution of the drug trial project as consultants were the members of the state level committee. Our findings were also shared before the Expert committee of Indian Medical Association who were also taking stock of the alarming situation of drug trials in Kerala.

4- Improvements/Changes in the legal systems to effectively address corruption in drug trials – through Court interventions	0	**1- WRIT PETITION (CIVIL 20140 of 2012)**	Five human participants who were identified during the first phase were reluctant to go for a legal battle against the doctor because of their ill health and their trust on the doctor. Hence the legal steps envisaged during the first step were not carried out on this reason. The budget allocated for civil suit for compensation was later used for conducting Thrissur Pooram Exhibition with the permission from PTF/PAC. Writ in the form of Public Interest Litigation has been filed through Adv Dasiy Thampy of Kerala High Court Writ petition is pending before the Kerala High Court. Notice has been served on the respondents like Drug Controller General of India, Central and State Governments. We are positively waiting for the decision.
5- Media responses/reports on clinical drug trials			
5.1- No. of Visual Media / Radio reports	1	20	Constructive engagements and personal sharing of findings with reporters. Media Report telecasted through Leading news channels,

			cable television networks, All India Radio

5.2- Positive responses/follow ups of the authorities on the visual media reports	0	1	Constructive engagements with Mr Sarin senior reporter India Vision Channel Exclusive telecast of unethical drug trials in Kerala by India Vision Channel which exposed the unethical practices of drug trials in Kerala especially against Health and Research Centre Thiruvanathapuram. It eventually opened the closed eyes of Kerala Governemnet which was lead to the constitution of the Expert Committee by the Government. It also compelled the Indian Medical Association Kerala Chapter to form an expert committee to look into the allegations.
5.3- No. of Print media reports	4	15	Constructive engagements and personal sharing of findings with reporters (Copies attached)
5.4- Positive responses/follow ups of the authorities on the print media reports	0	0	N/A
6- Response of the Panchayaths and other local organizations against corruption in drug trials			
6.1- No. of Panchayaths constructively involved in drug trials	N/A	N/A	Our proposed strategy in the project proposal was to include the best clinical practices in the

			curriculum of Kerala Institute for Local Administration (KILA) premiere institute of government of Kerala to impart training to members of local self government bodies. We had two round discussion with Director and Senior Officials of KILA. From the discussion it was realized that such initiative will not be practicable and useful and hence we decided to drop the activity. The same was intimated to PAC through our Quarterly Report.

6.2- No. of other local organizations (including citizens groups) involved constructively in drug trials	5	25	1-Identification of working groups on drug trials 2- Formation of Health Watch groups Personal contacts and Internet During the second phase we had formed 14 health watch committees consisting around 30 members in 14 districts of Kerala including social activists from various spectrums of society. During this tenure we also established significant relations with leading state/national level NGO'S in Kerala and India.
7- Discussions and Responses in Parliament and Legislative Assembly on Clinical Drug Trials			
7.1- No. of MPs involved in the issue of drug trails	0	0	Our efforts to convene a meeting of Members of Parliament in New Delhi could not become successful due to various reasons beyond our control. Only MP who is briefed and actively involved in the issue is Smt.Brinda Karat. Adv George Pulikuthiyil of Jananeethi was invited to the National Seminar on the need of regulation of drug trials in New Delhi where he shared our findings in

			front of various dignitaries including Smt Brinda Karat.

7.2- No. of MLAs involved in the issue of drug trials	0	43	During the session of Kerala Legislative Assembly around 40 members were personally met and they were briefed and information and findings of Jananeethi were submitted. We also personally invited them for a consultation to make them really aware on the current issues of drug trial scenario in Kerala. Based on our invitation six members of Kerala Legislative Aseembly came for the consultation held on 13/12/12 at Trivandrum Hotel. All of them stayed for two hours and patiently attended the presentation On our findings. During the presentation Dr Anoop Kumar Thekkuveetil member of expert committee constituted by the Kerala Government, Mr. Sarin Senior Reporter from India Vision, Dr Praveen Pai a Public Health Researcher were also present. Theyalso shared their experiences during the meeting. All the members of the legislative assembly convinced on the issue and promised that the same will be raised in Legislative Assembly.

			They admitted that the issue is very serious and intervention through a strong legislation is indispensable
7.6- No. of changes/improves made by the Assembly on the drug trials systems	0	1	As the meeting for MLA"s was concluded on 13th December. we believe that our constructive engagements with members of legislative assembly will bring significant changes in regulating drug trials in Kerala. One of such change is positive step from the assembly was the submission raised before the Assembly on the issues of drug trials and Health Minister of Kerala replied that the Expert Committee report is awaited and on their findings suitable action will be taken to ensure the conduction of drug trials in Kerala ethically sound and corruption free.

Annexure 4: Financial Progress Report

Annexure 5: Materials/reports/toolkits published/disseminated and/r posted on the website

Adv. George Pulikuthiyil
Executive Director.
30th March 2013

Adv. Sunilkumar P.
Project Co-ordinator
30th March 2013