Chronology of Events

1940 Drugs and Cosmetic Act, 1940 was passed.

1945 The Rules were notified as Drugs and Cosmetic Rules, 1945.

1946-48 The trials on human subjects were conducted during World War-II by Nazi doctors. During Nuremberg Trial, death sentence was given to 7 doctors and long year imprisonment to 10 doctors. This process resulted in evolution of "Nuremberg Code" laying down principles for doing experiments on human beings.

1948 Universal Declaration of Human Right (UDHR) adopted by United Nations, incorporating various Articles including Article 5 regarding inhuman or degrading treatment.

1964 Declaration of Helsinki adopted by World Medical Association elucidating ethical principles on human experimentation, incorporating principles of Nuremberg Code and Geneva Declaration of 1948. Amendments were made in the said Declaration by the World Medical Association discussing issues of Placebo trials and Post Trial Access.

1966 International Covenant of Civil and Political Rights (ICCPR) further expanded UDHR by incorporating concept of "free consent" for medical and scientific experimentation.

1980 "Ethical considerations involved in research on Human Subjects" 1980 was framed by the Indian Council for Medical Research (ICMR). These guidelines were revised in 2000 as "Ethical guidelines for Biomedical research on Human Subjects". They were further revised in 2006 as "Ethical guidelines for Biomedical research on Human Participants".

1988 Amendment made in the Drugs and Cosmetic (Eight Amendment) Rules introducing procedure for clinical trials of new drugs in India.

2001 Good Clinical Practice Guidelines taken out by Central Drug Standard Control Organization (CDSCO) of the Ministry of Health and Family Welfare (MOHFW), Govt. of India, discussing quality, audit, protocols for conducting Clinical Trials.

2002 International Ethical Guidelines for Biomedical Research involving Human Subjects were taken out by the Council for International organizations of Medical Sciences(CIOMS) in collaboration World Health Organization (WHO).

2005 Amendment in Indian Patent Act, 1971 made introducing product patent instead of process patent, thus enabling the drug companies to enjoy monopoly on newly discovered drugs.

2005 Amendment in Drugs and Cosmetic Rules, 1945 took place whereby amendments were made in relation to clinical trials as well as in Schedule Y

and Appendices. By this amendment, inter-alia, phase lag for drug trials was removed which allowed multi-country concurrent trials and significantly removed phase development time.

2005-2006 As a result of amendment of rules clinical trials started in various parts of the country.

The petitioners are referring to clinical trials particulary in M.P in the city on Indore to emphasis how the illegalities were committed, ethical guidelines were grossly violated and the health and lives of people particularly belonging to poor and vulnerable class was compromised.

The clinical trials were also conducted on children and mentally challenged persons , adolescent girls and women in Indore, Jabalpur and Bhopal in Madhya Pradesh. In Madhya Pradesh, drug trials were conducted on gas victims of Bhopal.

Besides Madhya Pradesh, drug trails were also done in Andhra Pradesh, Gujarat and other parts of the country. In Gujarat and Andhra Pradesh HPV vaccine trials were done on adolescent girls, resulting in deaths.

24.6.2011 The clinical trials conducted in Indore was subject matter of an investigation by the Economic offence Wing (EOW) of MP which submitted its report on 24-06-2011. It pointed out several illegalities in conduct of clinical trials. Some of the irregularities pointed out by the EOW are:

1. The Principal Investigators (PIO) were themselves the members or member secretaries in the Ethical Committees and these committees did not follow the standard practices and ethical guidelines fully.
2. The Principal Investigators also violated the Ethical Guidelines repeatedly.
3. The Principal Investigator and the Ethical Committee did not take appropriate steps as was expected from them in cases of Serious Adverse Effects (SAE).
4. CROs(Contract Research Organization), Ethical Committee and PIO did not follow the established principles of safeguarding the interest of the patients.
5. The core principles of informed consent were disregarded.
6. On several Instances the Principal Investigator contravened the Section 20 A (Professional Conduct) of the Indian Medical Council Act, 1956.
7. By accepting money for themselves and by undertaking sponsored foreign trips the Principal Investigator clearly contravened the "conflict of interest" doctrine.
8. The trials did not in any way follow the established rules which would have ensured profits to the institutions where they were carried out. The institutions did not gain in particular from the

trials carried out by the PIOs.

9. The patients on whom the drug trials were carried out deposed that no transparency was displayed while carrying out trials and they were even denied entitlements that were due to them.
10. In instances of Serious Adverse Effects the dictum of financial safeguard or insurance was contravened.

The report also pointed out that 6 doctors received Rs 5.10 crores and there were 81 serious adverse effects/ death as a result of clinical trials.

March 2011-December 2011	Debate took pace with regard to clinical trials in India, in the Rajya Sabha. In the final answers given by the Minister of Health and Family Welfare, it was acknowledged that there are loop-holes and weaknesses in the legal regime.
March 2009 –Dec 2010	Number of RTIs filed with MGM Medical College by number of doctors asking for information on Clinical Trials but information denied by MGM Medical College under Section 8(1D) of RTI Act.

12 July 2010 to December 2011	Debate in Vidhan Sabha- After attempts to obtain information under the RTI failed questions raised by MLAs in Madhya Pradesh Vidhan Sabha. The trials conducted specially in Indore was subject of discussion which have been referred to in detail in the Petition. In short, it came out from the debate that doctors in indore have been conducting trials on their patients, deriving huge income. Trials were also conducted on mentally ill patients, children and adolescent girls. The trials of drugs like 'Tadlafil' was conducted without approval of licensing authority,trials in private clinics by Govt doctors were done.
2010 to January 2012	Articles were published in several Newspapers and magazines wherein the fact of illegal and clinical trials in the country including Madhya Pradesh were highlighted. It was pointed out as to why India has become a centre for conducting clinical trials by the Multi-national drug companies.
2.1.2012	As per the News clippings of Indian Express, English daily, the State Government imposed a fine of Rs 5000/ only on 12 doctors involved in drug trials for not

providing relevant information to the state Government. No penalty or punishment was imposed on the Doctors who had conducted the illegal and unethical clinical trials.

5th January, 2012	Newspaper report in the Hindu wherein it was stated that 2 doctors of Indore who were involved in clinical trial of drug Tadalafil were restrained from conducting clinical trials for a period of 6 months.
January 2012	Writ petition filed by Swasthya Adhikar Manch, Indore in the Supreme Court of India