2

Research

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Research Initiatives Benefiting the Public

Introduction

There is worldwide interest in holistic systems of healthcare especially their role in the prevention and management of chronic diseases and in particular, for conditions where allopathy has little to offer. Seven percent of India's population is in the 60+ age group. With the prospect of this percentage doubling in the next 15 years the country has to gear itself up for providing healthcare to millions of elderly people particularly those living in urban India where the joint family system is on the decline. There is therefore a search for anything that can maintain well-being and prevent illness. With increased life expectancy the burden of chronic diseases is bound to grow and non-communicable diseases particularly diabetes mellitus, cardio-vascular diseases, cancer, stroke and arthritis are predicted to become major health problems. A search for alternatives, adjuncts and adjuvants that can help ward off these diseases or mitigate pain and suffering has led to renewed interest in Ayurveda and other Indian Systems of medicine.

A section of the general public is convinced about the strength of traditional medicine but there is a constant demand for scientific validation of the principles on which Ayurveda, Siddha and Unani (ASU) systems are founded, particularly in respect of the efficacy and safety of the therapeutics used. Such a demand had motivated a large number of investigators to launch clinical research and drug standardization studies. Although such projects have been pursued over decades, the outcomes have been limited. It was therefore felt necessary to extend an opportunity to all the important players to give their own version of what has been achieved from the public benefit point of view and to assemble the responses at one place. This chapter encapsulates the responses received and suggests some changes in approach, given the standing of the outcomes and the suggestions of experts.

In the case of ICMR as well as the research councils of ASU, a conscious effort has been made to exclude literary research or other aspects of research which, although valuable, do not produce outcomes that can be quantified in terms of direct medical benefits.

However, in the case of the Department of Biotechnology (DBT) since they are in the business of directly addressing the need to conserve and preserve plants used in traditional medicine (besides other responsibilities), and have undertaken extensive studies resulting in successful *in situ* and *ex situ* cultivation of medicinal plants, the Department's reply has been reflected as relevant.

Methodology

Letters were written by the PI requesting the Secretary, Health Research and the Director-General of ICMR, the Director-General of CSIR, the Secretary, Ministry of Science and Technology and the Secretary, Department of Biotechnology to provide a description of the achievements made by the organizations in the area of research into traditional medicine in so far as the outcomes can be termed as having directly benefitted the public. It was requested that "promising leads" may be excluded so that the focus remains on what the public has actually received. All the organizations were cooperative. Personal meetings were held by the PI with Dr Katoch, DG, ICMR and the Secretary, Ministry of Science and Technology Dr. Ramasami. In the case of CSIR the Director-General Dr. Brahmachari convened a meeting where he asked the key directors of the relevant institutions of CSIR to join over video conference to discuss the approach and identify specific achievements worth including in the Report.

In the case of the Department of Biotechnology, the Secretary asked the PI to meet Dr. S. Natesh, Senior Adviser dealing with the subject.

As far as the research councils of ASU i.e., CCRAS and CCRUM are concerned, specific questions were posed to them which were responded to and have been incorporated as such. It goes without saying that the level of receptivity and the openness with

which responses were given by all the organizations was clearly possible only because the Department of AYUSH had addressed all the organization heads and requested them to give full co-operation to the PI. It is hoped that this account which brings out tangible, patient-centered achievements in the area of research in traditional medicine as reflected by the main scientific organizations would enable policy makers to understand the need for much greater integration and collaboration to derive optimum benefits from the funds that are allocated for research in traditional medicine. The organizations contracted are listed below:

1. Indian Council of Medical Research (ICMR)
2. Council of Scientific and Industrial Research (CSIR)
3. Department of Biotechnology (DBT)
4. Department of Science & Technology (DST)
5. Central Council for Research in Ayurveda and Siddha (CCRAS)
6. Central Council for Research in Unani Medicine (CCRUM)

Indian Council of Medical Research (ICMR)

After a meeting with the Secretary and Director-General of ICMR Dr. VM Katoch, the PI requested for information/data on the work of ICMR with special reference to benefits that the systems had given the public in the area of traditional medicine.

In a letter the PI requested that note on any product that had emerged as an outcome using traditional knowledge about plants and their healing properties, contained in the codified texts of Ayurveda, Siddha and Unani or on the basis of oral knowledge may be made available. In particular, if the public had received any therapeutic or palliative substance as an outcome of scientific work done by ICMR it was requested to be described, giving the history in brief, the benefits extended through the product including its application for wider use through industry.

In addition, ongoing collaborations including the Golden Triangle project were requested to be described if the outcomes were tangible in terms public benefit derived through such efforts.

As far as patents in the pipeline or where discussions with Industry were on-going, a status paper which captured the benefits that are likely to become available was requested for.

The response of ICMR is summarized below:

1. As early as in 1964, the ICMR had initiated a large national project '**Composite Drug Research Scheme**' (CDRS) that aimed at investigating the medicinal use of traditional remedies. The CDRS took up the first inter-disciplinary research through the joint participation of botanists, phytochemists, traditional medical practitioners, pharmacologists and clinicians. In 1969, the CDRS scheme was transferred to the then newly created Central Council for Research in Indian Medicine and Homoeopathy (CCRIMH).
2. During 1983-84, ICMR revived this activity in the form of a large national centrally coordinated multi-disciplinary, multi-centric disease-oriented research project covering eight refractory diseases. Under this new strategy, ICMR focused on the known deficiencies and problems of working with traditional remedies *viz.,* quality control and standardization of the products used in trials. This was needed to generate evidence-based data on the efficacy of these medicines. Therefore, the focus was on the standardization of existing treatment modalities of traditional medicine and involving practitioners of these systems. In addition to the Allopathic doctors who conducted the clinical trials as per the globally accepted practices and standards, Ayurveda, Siddha and Unani representatives as also representatives of CCRAS and CCRUM participated in this new initiative which took off in 1984.
3. This was preceded by discussions during 1982-83 about the feasibility of undertaking large multi-centric clinical trials to find 'evidence-based-medicine'. Six areas were taken up with the addition of a new study on snake bite. Systems were established to ensure that high quality standardized formulations were made available using reputed laboratories and a scientifically acceptable system of study design. Two Centers for Advanced Research were established at the Central Drug Research Institute (CDRI), Lucknow and Regional Research Laboratory (RRL - now called the Indian Institute of Integrative Medicine), Jammu. CDRI focused on traditional remedies.

The RRL Advanced Centre focused on standardization and quality control of traditional formulations to support clinical trials planned at various centers.

ICMR's Milestones in Benefiting Society through Traditional Medicine

Ksharasutra: Among the trials Ksharasutra, a medicated thread for the treatment of anal fistula was found to be a safe, ambulatory and cost effective alternative to surgery. Pharmacopoeial standards were laid down and the necessary dossiers were prepared including a video film on the procedure, as early as the 1990s. The material was handed over for inclusion in the Ayurvedic Pharmacopoeia. This thread is being widely used in various Ayurvedic hospitals and treatment centres and several research papers have been published in different scientific journals on the advantages of Ksharasutra over conventional allopathic treatment.

Picroliv for Jaundice: For viral hepatitis, the hepato-protective drug *Picrorrhiza kurroa* was found successful with new active principles kutkoside and picroside to be used together resulting in a combination called Picroliv (The compound has already undergone successful phase I and II clinical trials in India and is ready for phase III clinical trials since 2000). Several patents were filed by CDRI, Lucknow during 1985-95. *Finding:* The reason why this did not progress further is not known but the benefits to the public do not appear to have accrued as yet.

Vijaysar for Diabetes: Another compound Vijaysar *(Pterocarpus marsupium)* showed some promise become of consistently positive results but because Vijaysar is difficult to obtain due to its extinction the promise never became a reality. *Finding:* Since ICMR's work has proved its efficacy for diabetes, the work should not be closed as the findings have immense scope for public benefit.

Jamun for Diabetes: Jamun *(Syzygium cumini)* is another drug used for diabetes due to its medicinal properties. Four active compounds isolated from the fruit pulp have been characterized and also patented. *Finding:* The preparation is being evaluated by a Mumbai-based company for taking up clinical trials on human beings. This needs to be given utmost support and the follow up needs to be monitored by ICMR & Department of AYUSH for public benefit.

Overall Findings

According to ICMR no preparation or drug from the traditional medical systems of India has reached the public although there are several promising leads. Only Ksharasutra that was practiced in some hospitals even before it was evaluated by ICMR continues to be used successfully for anal fistula. Many industries had shown interest; some took the samples for testing and evaluation. However, no industry has shown interest in large-scale commercial production.

Currently, two ICMR Centres of Advanced Research are working in the areas of traditional plant-based remedies and medicinal plants. The Centre for Advanced Research for Reverse Pharmacology in Traditional Medicine at Kasturba Health Society, Mumbai set up in 2007 broadly aims at developing safe and scientifically investigated Ayurveda-inspired effective phyto-pharmaceutical products as well as preventive or therapeutic modalities for identified disease conditions. The Centre for Advanced Research on DNA Fingerprinting and Diagnosis of Medicinal Potential in Plants from Eastern and North-Eastern States in India at the Bose Institute, Kolkata aims at providing authentic identification of plants used for medicinal and other trade-related purposes.

ICMR's note laments that drug development efforts in the Allopathic systems receive massive funding from Pharma Companies which enabled these industries to participate at a competitive level globally. But there is no such support available for traditional remedies.

Council of Scientific and Industrial Research (CSIR)

A meeting was chaired by the Director-General of CSIR Prof. Samir K Brahmachari on 10th August, 2010. A video conference with the Directors of the relevant CSIR laboratories was also arranged. He requested the scientists to provide information/data to be incorporated in the Report relating to benefits that the ASU systems have given to the public.

Several interesting points emerged but the Principal Investigator requested the scientists to consider the following points while preparing their write-ups.

1. Since the purpose of the chapter on research was to highlight the benefits that people had

received as a result of research conducted, only products that had emerged should be described. More specifically if the findings were based on traditional knowledge about plants and their healing properties, contained in the codified texts of Ayurveda, Siddha and Unani, the benefits extended by the product were requested to be made available.

2. In addition, collaborations that were taking place during the last few years including the Golden Triangle project were requested to be described in case the outcomes are tangible in terms of benefits that have been derived through such efforts.

3. As far as TKDL was concerned, a status paper which captured the benefits that had been received through successfully combating the grant of patents based on traditional knowledge was requested to be made available giving up-to-date information which was quantifiable in terms of (i) patent applications successfully foiled and (ii) the returns in terms of achieving global primacy in this field.

CSIR's response was summarized under the following sub-headings:

i. NMITLI – Herbal Drug Development Project

ii. TKDL Project

iii. GTP Project

iv. Products Developed from Leads of Traditional Medicine

i. NMITLI – Herbal Drug Development Project

The New Millennium Indian Technology Leadership Initiative (NMITLI) is the largest R&D scheme to boost public-private-partnership efforts in the country. It looks beyond today's technology and thus seeks to build, capture and retain for India a leadership position by synergizing the best competencies of publicly funded R&D institutions, academia and private industry. Government finances play a catalytic role. NMITLI promotes innovation - centered scientific and technological developments as a vehicle to attain for Indian industry a global leadership position in selected niche areas.

CSIR launched a fully funded NMITLI project in 2002 to enable India to occupy a global leadership position in selected areas, including Ayurveda.

Herbal formulation for degenerative disorders like diabetes, osteoarthritis and rheumatoid arthritis, common hepatic disorders as well as for treatment of psoriasis have been validated and developed based on Ayurvedic concepts and using the reverse pharmacology approach.

Diabetes

The formulation comprises a standardized aqueous extract of a single herb. Pre-clinical studies in *ex vivo* animal models showed DNA protection, anti-inflammatory and anti-hyperglycemic activity. The formulation has shown specific pharmacological action pertaining to protection against STZ (Streptozotocin) induced damage, increase in angiogenesis, decrease in blood sugar levels in STZ induced hyperglycaemia models and a fructose fed model. Limited multi-centric clinical studies in patients uncontrolled on existing drugs, such as sulphonylurea and metformin, indicated a potential for the formulation as an anti-hypergylcemic, post-prandial insulin sensitizer with potential for use in diabetic complications e.g. cataract. The formulation is shown to be an effective adjuvant to sulphonylureas and metformin, with decreased dosage requirement. It also showed improved quality of life parameters.

Discussions are going on with industry for transfer of knowledge and preparation of a product dossier for commercial exploitation in India and its further development for global positioning through elaborate Phase III clinical trials.

Arthritis

The standardized formulation for treatment of painful knee osteoarthritis comprises three herbal extracts. From a series of studies involving permutations and combinations of identified botanicals, the best acting formulations were selected based on pre-clinical as well as on exploratory clinical performance in controlled, randomized trials. The formulations were finally evaluated in a 24 week, four arm drug trial (designed for equivalence with 80% power, p=0.05) on 440 patients. Analgesic rescue medication was not used in the final drug trial. The study has demonstrated the Ayurvedic formulations to be equivalent to standard doses of Celecoxib and Glucosamine, both used orally, in the treatment of painful OA knees. The safety profile of Ayurvedic formulation was better than Celecoxib. The

knowledge is ready to be transferred to an interested party for public benefit.

Hepato-cellular Protection

A standardized poly-herbal formulation comprising hydro-alcoholic extracts of 12 herbs was developed and validated through limited multi-centric clinical studies. The formulation was shown to be efficacious in a wide spectrum of liver diseases viz. infective viral hepatitis, drug induced tuberculosis, and metabolic non-alcoholic steato-hepatitis or NASH with silymarin and conventional drugs as comparator. It showed reduction in the acute phase inflammatory response and bilirubin in hepatitis B, protection against toxemia in patients on AKT therapy. Studies show hepato-protection with better clinical recovery and quality of life parameters.

Psoriasis

Psoriasis is a chronic skin condition, which is recognized for its peculiar clinical symptoms characterized by circumscribed red patches covered with white scales resulting in itchy flaky skin. It ranges from a few spots to large areas all over body. Psoriasis frequently affects the face, scalp, trunk and limbs. No preventive/curative therapy exists for psoriasis. The available drugs and therapy provide only symptomatic management.

A single plant-based oral herbal anti-psoriasis formulation has been discovered which has shown quick and painless remission for extended periods of time. It reduces the Psoriasis area and Severity Index (PASI) score by 90% in affected persons. IND, Phase-I and Phase-II clinical trials have been completed. Presently the formulation is undergoing Phase-III clinical trial.

ii. Traditional Knowledge Digital Library (TKDL) Project

TKDL is a proprietary and original database. TKDL integrates diverse disciplines such as Ayurveda, Unani, Siddha, modern medicine and modern science; it is available in several languages including Sanskrit, Arabic, Urdu, Persian, Tamil, English, Japanese, Spanish, French and German. TKDL is based on 148 books of Indian Systems of Medicine, which are available at a cost of US$ 1000. These books are the *prior art* and can be sourced by any individual/organization. TKDL acts as a bridge between these books and international patent examiners. The TKDL technology has created a unique mechanism through which a Sanskrit *shloka* can be read in German by a patent examiner at any International Patent Office on a computer screen.

TKDL was started as a collaborative project between Department of AYUSH and CSIR and the aim was to prevent misappropriation of codified traditional knowledge contained in Ayurveda, Unani and Siddha by claiming patents before International Patent Offices. Its genesis dates back to efforts to refute patents on the wound healing properties of *Turmeric* at the USPTO and the anti-fungal properties of *Neem* at EPO. In 2000, a TKDL expert group estimated that about 2000 erroneously patents concerning Indian systems of medicine were being granted each year at the international level, mainly due to the fact that India's traditional medicine knowledge was confined to Sanskrit, Hindi, Arabic, Urdu and Tamil, which were neither accessible nor understood by patent examiners abroad.

TKDL has overcome these language and format barriers by scientifically converting and structuring the available information into 34 million A4 size pages of the ancient texts in five international languages, namely, English, Japanese, French, German and Spanish, with the help of information technology tools and a novel classification system – Traditional Knowledge Resource Classification (TKRC). The objective behind the creation of TKRC is not only to give a structured classification to Indian Traditional Medicine but also to use it as a retrieval tool.

Today, India through TKDL is capable of protecting thousands of ISM based medical formulations similar to those of Neem and turmeric. On an average, it takes five to seven years for opposing a patent granted at an international level which may cost $ 0.2-0.6 million to be set aside. TKDL has directly benefited the public in three ways. Firstly, unnecessary rebuttals funded at public cost have been avoided. Second, the country's primacy both in the area of traditional knowledge and its capacity to preserve, codify and expound on its knowledge base has been recognized. Thirdly, the public is assured that the repository of TKDL will be available on call for generations to come and the knowledge will not disappear with the passage of time.

India has signed TKDL Access Agreements with

- European Patent Office (EPO) (February, 2009)
- German Patent Office (October, 2009)
- United States Patent & Trademark Office (November, 2009)
- United Kingdom Patent Office (February, 2010)
- Canadian Intellectual Property Office (September, 2010).

Negotiations are under way to conclude the Access Agreement with the Intellectual Property Office of Australia and the Intellectual Property Office of New Zealand.

A significant impact has already been realized at EPO during the last 18 months. Beginning July 2009, a TKDL team has identified 200 patent applications at EPO which concern Indian systems of medicine and third party TKDL evidence has been filed at EPO. In two such cases EPO has already set aside its earlier intention to grant patents after it received TKDL evidence. In one case the applicant modified his earlier claims. In another 23 cases, applicants decided to withdraw their four-to-five year old applications on being confronted with TKDL evidence which is a tacit admission of bio-piracy by the applicants. It is expected that in the balance 175 cases, either EPO would reject these applications or applicants themselves would withdraw their wrong claims/patent applications in the coming months.

India has also identified more than 400 such pending patent applications at USPTO, which are based on Indian Systems of Medicine. Pending patent applications have been identified at the patent offices in Canada, the UK and Australia. It is expected that all these pending patent applications would be cancelled by the respective patent offices or will get withdrawn by the applicants.

India is the only country in the world which has set up an institutional mechanism (TKDL) and is able to prevent grant of wrong patents through an e-mail and at zero cost. Other countries need to fight for 10-12 years and have to spend millions of US dollars to meet legal and other expenses even for opposing a single patent.

A recent study carried out by a TKDL expert team has revealed a sharp decline (44%) on filing of patent applications concerning Indian systems of medicine. TKDL is therefore proving to be an effective deterrent against bio-piracy.

The details of applications where EPO based on TKDL evidence decided to set aside its earlier intention to grant patents and details of applications filed at EPO where applicants themselves decided to withdraw their claims/patent application after they were confronted with TKDL evidence are attached in **Annexure-I.**

iii. Golden Triangle Project (GTP)

The Golden Triangle Partnership (GTP) Programme was launched in the year 2005 as an innovative scheme with Department of AYUSH, ICMR and CSIR as equal partners to study Ayurvedic formulations/ medicines using modern tools and technologies for: (1) Validating these as safe and efficacious therapies for Indian and global use. (2) Identifying a few formulations as complementary agents to modern drugs. (3) Helping Indian traditional drug industry to scientifically standardize the raw materials and finished products for global acceptability of these drugs.

Under the programme CSIR was entrusted with the responsibilities of (i) standardization of identified Ayurvedic formulations and their ingredients based on marker compounds and (ii) Physico-chemical analyses and toxicity studies of eight herbo-mineral preparations namely *Rasa Sinduar, Kajjali, Rasa Manikya, Basanta Kusmakara Rasa, Arogya Vardhini Vati, Maha Yogaraj Guggulu, Makaradhwaja* and *Mahalaxmi Vilas Rasa.*

Standardization of Ayurvedic Formulations: CSIR carried out complete standardization studies using modern physico-chemicals and analytical technologies on the material received. Standardization of herbal formulations and raw materials was carried out based on microscopic and macroscopic examination, pharmacognostic studies, microbial contamination, heavy metals and pesticide residue content, aflotoxin and chemical analysis based on quantitative determination of the chemical markers in most of the cases.

Chemical analysis and Toxicity Studies of Herbo-Minerals: The physico-chemical analyses of all the above mentioned eight herbo-mineral preparations were completed viz. the physical and chemical characterization was carried out by National

Chemical Laboratory (NCL), Pune; Indian Institute of Chemical Technology (IICT), Hyderabad and National Institute for Interdisciplinary Science and Technology (NIIST), Thiruvananthapuram. The 90 days sub-chronic toxicity studies were carried out on animals. The study reports of all eight herbo-minerals have been completed and reports submitted to CCRAS/Department of AYUSH.

According to CSIR these are the most comprehensive studies ever carried out on Herbo-minerals and help in local as well as global positioning of traditional knowledge.

iv. Products Developed from Leads of Traditional Medicine at IIIM, Jammu

(i) The use of piper has been referred to regularly in the Ayurvedic formulations. As a result of extensive R & D, it has been found that piperine isolated from *Piper nigrum* acts as a bioavailability enhancer for specific drugs. Using piperine, a new formulation has been developed in this institute for tuberculosis patients in which the dosage of Rifampicin has been reduced to less than half thereby reducing the toxicity caused by long term use of Rifampicin. The formulation has been licensed to Cadila Pharmaceuticals, Ahmedabad. Cadila Pharma in collaboration with IIIM, Jammu conducted all the phased clinical trials as per the requirement of DGCI. The product has been launched in the market on 1st November, 2009 by the trade name Resorine.

(ii) *Vitex negundo* is a plant known for its medicinal properties. Extensive research work was conducted at IIIM, Jammu. A fraction with two markers compounds was standardized which showed strong hepatoprotective activity. It was licensed to Medley Pharmaceuticals, Mumbai, which has launched the product by the trade name **Liv-1** in the market.

(iii) *Boswellia serrata* is also mentioned for its use in four conditions of arthritis. A formulation based on marker compounds was standardized and developed for use in arthritis. The technology was transferred to Gufic India, which is marketing the product as an anti-arthritic preparation.

(iv) *Tinospora cordifolia* has special mention in Ayurveda for its use as an immunomodulator and is adaptogenic activity. IIIM, Jammu standardized the agrotechnology of this plant and also developed a process for the preparation of a standardized extract based on two marker compounds. This technology was transferred to M/s Nicholas Piramal (Piramal Life Sciences), Mumbai.

(v) Based on Ayurvedic literature, *Withania somnifera, Emblica officinalis, Bacopa monnieri, Curcuma longa* and *Tinospora cordifolia* find repeated use in many of the ayurvedic formulations. Four new formulations have been developed as positive health promoters for aging, cancer and diabetes patients to increase the quality of life among the patients suffering from these diseases. These formulations are presently undergoing clinical trials and are registered with clinical trials registry of ICMR, New Delhi.

Department of Biotechnology (DBT)

Department of Biotechnology (DBT) is engaged in the following activities:

- ***In situ* conservation:** Establishment of biosphere reserves, national parks, wildlife sanctuaries, sacred groves and other protected areas are examples of *in situ* method of conservation. A few such conservation areas have been declared as medicinal plant *in situ* conservation areas. Forests in the three Southern States of Kerala, Tamil Nadu and Karnataka are being utilized through the joint efforts of the forest department of these states and Foundation for the Revitalisation of Local Health Tradition (FRLHT), Bangalore.
- ***Ex situ* conservation:** Conservation of medicinal plants *ex situ* (outside the natural habitat) is undertaken by cultivating and maintaining plants in botanical gardens and parks through long – term preservation of plant propagules in gene banks (seed bank, pollen bank, DNA banks etc) and in plant tissue culture repositories and by cryopreservation.
- DBT established the country's first National Facility for Plant Tissue Culture Repository (NFPTCR) at the National Bureau of Plant Genetic Resources (NBPGR), New Delhi, in 1986. This facility has carried out *in vitro* conservation of several threatened agri-

horticultural species including medicinal plants. NFPTCR has taken a lead in cryopreservation of agri-horticultural species including medicinal plants such as *Allium tuberosum, Dioscorea spp.* and *Rauvolfia serpentina*.

- DNA Bank of medicinal and aromatic plants has been created at Central Institute of Medicinal & Aromatic Plants (CIMAP), Lucknow under the auspices of National Gene Bank of Medicinal & Aromatic Plants established by the DBT. A total of 562 accessions of 35 species are conserved in the DNA Bank at CIMAP, Lucknow. The important species whose DNA is conserved include: *Artemisia annua, Alliam sativum, Bacopa monnieri, Catharanthus roseus* and *Taxus wallichiana.*
- DBT has established a network of four National Gene Banks (NGB) dedicated to medicinal and aromatic plants. These are:-

    1. Central Institute of Medicinal and Aromatic Plants (CIMAP), Lucknow;
    2. National Bureau of Plant Genetic Resources (NBPGR), New Delhi;
    3. Tropical Botanical Garden and Research Institute (TBGRI), Trivandrum and
    4. Regional Research Laboratory (RRL/IIIM), Jammu.

The main objective of the NGBs is to conserve medicinal and aromatic plants of endangered/ threatened/rare species of proven medicinal value and those extensively used in the traditional systems of medicine.

These banks are equipped with state-of-the-art facilities to carry out conservation of the materials. Each gene bank has four major components: field gene bank, seed bank, *in vitro* bank and cryobank.

DBT was requested to provide information on the following:

a. Rare/threatened/endangered species of proven medicinal value, used in traditional medicine specifically.

b. Plants extensively used in Indian traditional system of medicine.

c. Plants which are difficult to propagate.

d. Plants with significant R&D leads for the future development of drugs.

e. Plants which are commercially important.

DBT sent the following responses:

a. Farmers/cultivators are getting well-characterized quality planting material of rare, endangered and threatened species such as *Aconitum heterophyllum* (Atees), *Nardostachys jatamanasi* (Jatamansi), *Picrorhiza kurrooa* (Kutki), *Sassurea costus* (Kuth, Kustha), *Swertia chirayita* (Chirata, Charayatah) These are used in Indian traditional systems of medicine;

b. Scientists/Researchers are able to obtain authentic plant material from the repositories having significant R&D leads for future development of modern drugs;

c. Farmers/Cultivators are getting well-characterized quality planting material of species such as *Podophyllum hexandrum* (Bankakri), *Nothapodytes nimmoniana* (Ghanera), *Taxus wallichiana* (Himalayan Yew) etc. which are a source of high-value phyto-pharmaceutical compounds.

Germplasm Bank for Ayurvedic medicinal plants has been established at Arya Vaidya Sala, Kottakal, Kerala with 1686 accessions belonging to 145 species. A seed bank consisting of 109 accessions belonging to 44 species has also been established. The Herbarium contains 600 species details of which have been preserved. The Raw Drugs Museum contains 256 samples. A data based for images and a field gene bank has also been developed alongwith a herbarium and a Museum. Ten species are being conserved in an *in vitro* bank. Protocols for *in vitro* conservation of *Holostema ada-kodien, Kaempferia rotunda, Trichosanthes cucumerina, Geophila repens and Rubia cordifolia* has been developed. Efforts have been initiated for utilization of a collection of rare and endangered medicinal plants involving researchers and industry.

Department of Science and Technology (DST)

Department of Science and Technology (DST) was requested to provide information on the projects/ products that have given direct benefits to the public through the work undertaken or supported by the DST over the years, relating to the Traditional Medicine Sector. The following response was received from DST in relation to Traditional Medicine.

Drugs and Pharmaceuticals Research Programme (DPRP)

DPRP scheme was initiated by DST in 1994-95 for promoting R&D in the drugs and pharmaceuticals sector. It aims at synergising the strength of R&D institutions and Indian pharmaceutical industry for the discovery and introduction of new drugs, covering all systems of medicine. Thirty six projects are continuing at present (**Annexure-II**). Of these, 27 projects were collaborative projects awarded between 2003 and 2010 and have been initiated with universities and institutes. Another five projects were in the nature of facility projects and another five were loan projects. None of these projects awarded to institutions, Universities and manufacturers were reported to have yielded any outcomes of importance from a public benefit point of view as yet.

The Secretary, DST was requested to express his personal views on the following issues and his replies are carried in full in the ensuing portion relating to responses of experts.

ASU Research Councils

There are four Research Councils under Department of AYUSH which coordinate scientific research in different aspects of respective systems, both fundamental and allied. These Councils which have been established for Ayurveda and Siddha, Unani, Homeopathy, Yoga & Naturopathy are apex bodies responsible for research in the concerned systems of medicine. They are fully financed by the Government of India.

In this sub-chapter, the focus is on the benefits that have accrued to public through efforts made in the field of Clinical Research and their outcomes, confined only to Ayurveda, Siddha and Unani medicine.

Methodology

Both the Councils were asked to furnish the information on following aspects. A copy of the questionnaire is at **Annexure-III**.

1. Top 5-6 Research Projects undertaken for the last 10 years which have led to the identification of products which in the view of the Council were able to provide substantial mitigation/ cure in specific medical conditions. Some of the questions are as follows:
   - Indicate the place/places where the research was undertaken separately for each such product, the number of patients who were treated and the reason why the product is considered as being more "successful" in terms of the outcome, than other medically oriented research studies undertaken over the last 10 years.
   - Indicate briefly a description of the medical condition/disease for which the product was found useful and give an idea of the extent of such usefulness and the basis on which the conclusion about such usefulness has been decided.
   - Indicate the reason why the patent applied for may not have been granted along-with the date of filing of the patent and the efforts made to undo any shortcomings pointed out by the patent granting authority.
   - What steps have been taken to make practitioners aware about the usefulness of the product? Are the products being made available to practitioners other than the centres run by the Council?
   - What has been the response of the practitioners and on what basis is the response being given?
   - One of the aims of biomedical research is to give leads to industry so that they can use the research work done to manufacture and market the products for the benefit of the public on a wider scale. If the identified products/leads have not been made available to industry then how has the principle of cost effectiveness been satisfied?
   - In respect of each product please indicate whether there are any issues of availability of raw drugs, standardization which would make bulk manufacture difficult?
2. Description of those drugs which appear to have largest application in hospital or community settings after excluding the treatment of communicable diseases, i.e. Malaria, Filariasis, etc. for which a well established and successful treatment regimen

is available in the Allopathic system of medicine.

3. To indicate the number of patients who were included in the last 10 years under various clinical Research Projects and independently by providing the treatment in the IPDs and OPDs run by the Council in various units throughout the country.
4. What better system is suggested for improving the offtake of the most promising products which have been identified as a result of clinical research?

Central Council for Research in Ayurveda and Siddha (CCRAS)

Central Council for Research in Ayurveda and Siddha (CCRAS) presented itself as an apex national body engaged in promoting research in Ayurveda and Siddha through a network of 35 Institutes/ Centres/Units located all over the India. It is also engaged in forging strategic alliances with similar clinical and research establishments in order to understand through research the cause, prevention and management of diseases. It is also expected to formulate patterns of research on scientific lines related to fundamental as well as applied aspects of Ayurveda and Siddha, propagate knowledge and assist institutions in conducting research.

More specifically, CCRAS undertakes a Clinical Research Programme, the cultivation of Medicinal Plants as well as Medico-Ethno Botanical Surveys, Pharmacognosy and Pharmacological Research and Literary Research. It works as the convener and coordinator for the Ayurvedic Pharmacopoeia Committee and the Golden Triangle partnership projects.

Major Research Projects Undertaken During the Last 10 Years by CCRAS

The Council reported about 10 coded formulations which were developed but only standardization and pre-clinical studies were undertaken. No clinical trial has apparently been completed to show the efficacy of the products. In the past (20 years), the Council had obtained patents for anti-malarial formulation in the year 1980 and for Psoriasis in 1987 but not after.

When asked whether the non-patented drugs formulated by the Council are in use for treatment, it was stated that a large number of beneficiaries were being treated by using the Council's formulations as well as other formulations in 18 CCRAS units where the outcomes were found to be "very positive". The basis on which the Council has concluded that the formulations were found to be efficacious was not spelt out but the diseases where particular success was claimed were *Amavata* (Rheumatorid arthritis), *Amlapitta* (Hyperacidity), *Svasa* (Bronchial asthma), *Sandhi vata* (Osteo-arthritis), *Gridhrashi* (Sciatica), *Arsha* (Hemorrhoids), etc.

During the last 10 years, the Council has initiated/ conducted the following clinical trial:

Clinical evaluation of anti-fertility effect of Pippalyadi Yoga, a classical herbo-mineral formulation

The National Committee for Research in Human Reproduction (NCRHR) reviewed the data about the contraceptive properties of different alternate systems drugs. An Expert Committee under the Chairmanship of Prof. Ranjit Roy Chaudhury Emeritus Professor, National Institute of Immunology (NII), New Delhi was set up to explore the possibility of developing a new and effective oral contraceptive. After extensive deliberations, it was decided to take up the clinical evaluation of Anti-fertility effect of Pippalyadi Yoga, a classical herbo-mineral formulation based on an Ayurvedic classical text Bhavaprakash. This was done on the basis of Intramural Research conducted by CCRAS. The toxicological and preliminary teratogenic study was conducted at NII, New Delhi. No toxicological or teratogenic effect was reported. An extensive teratogenicity study was conducted by *National Institute for Research in Reproductive Health* (NIRRH). No teratogenicity was observed.

The drug was supplied by National Institute of Pharmaceutical Education and Research (NIPER) to all the centers in the month of February, 2004 and the trial was restarted in the month of March-April, 2004 and continued up to December, 2006.

The progress reports received from the trial centers reported that the failure rate in the trial appeared to be unacceptable compared to conventional oral contraceptives. Hence, it was decided that the trial should be kept in abeyance for the time being.

Finding: The public did not get a contraceptive product despite considerable efforts which were made.

Research on the feasibility of introducing Ayurveda in the National Reproductive and Child Health Programme at Primary Health Centre (PHC) level

This is a collaborative research programme undertaken with ICMR for integration of Ayurveda and Siddha in to the Reproductive and Child Health Programme. Initially it is under implementation in two districts of Himachal Pradesh. The Ayurveda Regional Research Institute, Mandi and the Government Ayurveda College, Paprola have not given the outcomes.

Finding: This research initiative is well-intentioned but its inclusion in the RCH programme seems to be far from reaching the stage of being incorporated in the public health programme.

Process Patents Obtained

The Council has got a process patent for Bal Rasayan, a herbo-mineral preparation for general immunity and building children, in 2002. The patent was given to a pharmaceutical company M/S Upkaran Pharma in 2002 and an amount of Rs. 1,50,000/- has been received.

The patent for Ayush Ghuti is under process with NRDC as a herbo-mineral preparation meant for cough, cold, fever and diarrhoea.

Finding: No details of the status of securing the patent were provided.

Ksharasutra (A medicated thread for ano-rectal diseases)

Patent was obtained in 2002. It was indicated that NRDC was "approaching some industries for its commercialization". The medicated thread is being used in clinical treatment in any case.

Finding: After nine years, commercialization of the medicated thread remains uncertain. The use of this medicated thread is not as widespread as one might have expected particularly as there are several published papers besides ICMR's published work to show the effectiveness of ksharasutra treatment.

Patents filed but not approved so far

- A process for the preparation of a composition from *Swertia chirata* Buch. Ham. (Gentianaceae) having anti-carcinogenic (cancer preventive) and anti-tumour (cancer therapeutic) action. The process patent was filed on 26.3.2002.

  Finding: No progress was indicated by CCRAS.

- A Process for the Isolation of Amarogentin, Seco-Iridoid Glycoside possessing anti-carcinogenic (cancer preventive) and anti-tumour (cancer therapeutic) action. The process patent was filed on 26.3.2002.

  Finding: No progress was indicated by CCRAS.

- An Anti-Cancer compound Amarogentin, A Seco-Iridoid Glycoside with Anti-Carcinogenic (Cancer Preventive) and Anti-tumour (Cancer Therapeutic) Action. Patent Application No. 166/Cal/2002 dated 26.3.2002.

  Finding: It was reported that NRDC is pursuing the matter for obtaining the patent. No progress was made available.

- A process for the preparation of an Ayurvedic herbal compound preparation AYUSH MANAS for mental retardation. It was stated that the document has been transferred to NRDC and NRDC is approaching the industries for commercialization. It was also stated that the clinical trial is going on at two collaborative centres.

  Finding: Benefits to the public are unlikely to accrue in the near future if the clinical trial is still in progress and the process patent filed in 2009 is still pending.

- A process for the preparation of an Ayurvedic herbal compound "AYUSH QOL-2A" supportive therapy for the improvement of quality of life in HIV/AIDS patients has been transferred to NRDC but commercialization is awaited. It was reported that a clinical trial was being initiated at ICMR.

  Finding: The process is also at a nascent stage and benefits to the public might take a long time to become available.

Apart from these areas, according to CCRAS, the management of Bronchial asthma, Rheumatoid arthritis, Osteo-arthritis, has been successful. The details given by the Council are summarized below:

Top four areas where Council's work has benefited the public:

Bronchial asthma *(Tamaka Swasa)*

Bronchial asthma is a chronic debilitating disease and the causative factors include as allergies as well as genetic factors. Growing environmental pollution with rapid and extensive industrialization have been responsible for aggravation of this disease. The alarming rise in the incidence of bronchial asthma in metropolitan cities requires that a simple and easily accessible treatment is found. CCRAS reported that three studies were conducted in which 1000 patients were treated with different treatment regimens namely Sameerapanaga Rasa, Sirish Twak Kwatha, Pippali Vardhaman Ksheerapaka with Shodhana therapy.

Bronchial asthma *(Tamaka Swasa)*

Research data : 1998-2007

Number of patients : 1000

(*Reference : Annual Report 2007-08)

OPD data

Period : 2004-09

Number of patients: 34,319

Further, CCRAS is providing treatment for bronchial asthma in OPDs operating at different clinical units functioning under the Council. A total of 34,319 patients have been treated successfully during the period 2004-09.

Diabetes mellitus *(Prameha-Madhumeha)*

CCRAS reported that many herbal drug combinations are being successfully used for the control of hyperglycemia especially in non-insulin dependent Diabetes mellitus. Several drugs and combinations have been investigated in experimental and clinical studies.

This study has been taken up in CCRAS' Central Research Institute (Ayurveda), New Delhi as well as other centers. During 1998 and 2007, 81 patients were treated and the fasting and post-prandial blood sugar was assessed at various stages of treatment, besides clinical evaluation. The results indicated statistically significant reduction in fasting and post-prandial blood sugar levels along with clinical improvement and improvement in quality of life.

Diabetes mellitus *(Madhumeha)*

Research data : 1998-2007

Number of patients : 81

(*Reference : Annual Report 2007-08)

OPD data:

Period : 2004-09

Number of patients: 13,674

Further, CCRAS is providing treatment at OPD level at different clinical units and 13,674 patients have been treated successfully during the period 2004-09 with the identified drugs.

Haemorrhoids *(Arsa)*

The treatment is generally, preventive, symptomatic and palliative in modern medicine. Surgery is resorted as a last resort. Certain Ayurvedic para-surgical procedures, namely *Ksharakarma, Ksharasutra* and *Raktavasecana* were used by applying medicinal leeches.

Haemorrhoids *(Arsa)*

Research data : 1998-2007

Number of patients : 2294

(*Reference: Annual Report 2007-08)

OPD data : 2294

A study has been conducted on *Ksarasutra* application, an internal medication Kankayan Vati and Triphala Churna and local application of Kashishadi Taila on 2294 patients. The results were found encouraging in terms of relief in signs and symptoms of the disease and improvement in quality of life with lower recurrence rate.

Rheumatoid arthritis *(Amavata)*

Ayurveda has a unique approach assigning a crucial role for gastro-intestinal dysfunction in the treatment of the disease. The Council indicated that a number of herbal and herbo-mineral drugs and *Panchakarma* therapy have been used and evaluated in the management of Rheumatoid arthritis at the Council's centres.

Rheumatoid arthritis *(Amavata)*

Research data : 1998-2007

Number of patients : 1520

(Reference: Annual Report 2007-08)

OPD data

Period : 2004-09

Number of patients: 35,963

The outcomes of these studies indicate that the patients of Rheumatoid arthritis could be managed well with Ayurvedic therapies. It was also noted that the effects on these patients were lasting and relapse was rarely observed.

It was reported that patients suffering from Rheumatoid arthritis were receiving effective treatment at OPD level in the clinical units of CCRAS. During 2004-09, 35,963 patients of Rheumatoid arthritis were treated in the OPD.

Drugs which have community level application

The Council was asked to indicate areas which are suitable for being followed under Public Health Programmes. According to the response given, Ayurveda has good outcomes in the following areas:-

(i) Enhancing quality and quantity of breast milk

In the area of enhancing the quality and quantity of breast milk, it was reported that standardization, safety/toxicity studies had been carried out and no significant changes were noted in the blood chemistry, haematology and weight of the experimental animal. Some mortality occurs in the animals when higher doses are given. The ingredients for use in the preparations for breast milk enhancement are:- Satavari (*Asparagus racemosus*), Zeera (*Cuminum cyminum*), Satapushpa (*Anethum sowa*) based on their pharmacological activities.

(ii) Dysfunctional uterine bleeding

While clinical studies are going on, the ingredients used are from three plants, namely, Nagakeshara (*Mesua ferrea Linn),* Durva (*Cynodon dactylon)* and Laksha.

Overall findings

1. From the experience of the research projects and patents sought by CCRAS in the last 10 years, it is evident that little has been achieved by way of tangible benefits accruing to the public through the patent route.
2. On the other hand, if CCRAS' Ayurvedic and Siddha formulations have led to improvement in the condition of patients or helped better clinical management, it is necessary for a wider public to be given access to this treatment on a voluntary basis.

Central Council for Research in Unani Medicine (CCRUM)

The Council has been pursuing research studies covering different areas but this sub-chapter only deals with the area of clinical research which essentially refers to medical treatment administered under the research programme. The findings are based on the responses received.

Clinical treatment has been given to patients in two categories — either as a part of the research programme or as a part of general treatment offered. The Council has stated that since the drugs were developed on the basis of research and "the process patenting and patent rights is yet to be awarded, the drugs could not be made available in the market". That begs the question as to how treatment was being offered over decades if the drugs were to be restricted to patients who came only under the research programme, presumably after following a voluntary enrolment programme.

Over the last 30 years, not a single patent has been obtained by CCRUM. In most cases where success has been claimed patents have not even been filed. Wherever they have been filed, no indication was given of the present status except to say that they are "under process". The responses did not show that CCRUM was persevering with the applications or trying to ascertain from NRDC the reasons for delay or non-acceptance.

In response to the questionnaires the Council selected six diseases and in respect of these reported that almost two lakh patients had received treatment as part of clinical care throughout the country ranging over various periods during the last three decades. The Council claimed relative "success" in managing the six conditions and referred to specific drugs that had been used. In that case the drugs and treatment should be offered to a wider section of the public and not restricted to only those who happen to visit the small centers. The drugs are the same ones found in the classical texts, only the permutations and combinations have been altered on the lines of what an individual practitioner does, which is permitted by law.

Vitiligo (Bars)

Vitiligo (which is known as Bars in Unani Medicine) is a disfiguring dermatological condition.

CCRUM initially started research on Vitiligo at its Central Research Institute of Unani Medicine (CCRUM), Hyderabad in the year 1972. Based on the reference available in the Unani classics, a number of new formulations were subjected to therapeutic trials in different treatment groups. The Hyderabad centre has so far registered over 85,771 patients of vitiligo from 1972 to 31st March 2010. Eleven formulations were extensively tried on a total of 29,734 patients fulfilling the criteria as per protocol.

The Council has applied for provisional patent. The content of the formulations (all plant-based) have been standardised and quality control parameters have been developed. Safety evaluation of these drugs has also been done at the Council's centres.

Vitiligo *(Bars)*

Research data: 1972-2010

Number of research patients studied : 29734

OPD data

Period: 1972-2010

Number of patients : 58037

These formulations have shown significant therapeutic effects in arresting the further appearance of new spots or execerbation in the size of the patches besides repigmenting the depigmented patches. The response varied from 62-89% depending on the chronicity, part of the body effective the type of patch and patient's own temperament.

No untoward side effect was noted with the use of these drugs even on long term use .A few cases of skin blisters were managed with coconut oil or external application of skin creams. The drugs were stated to be cost effective in comparison to modern drugs with an average treatment cost only Rs. 2 to 3 per day.

There is a great demand for providing treatment for Vitiligo patients particularly in the coastal regions including Kerala, Orissa, and West Bengal where the incidence of the disease is high compared to northern states.

Sinusitis (Iltehab-e-Tajaweef-e-Anf)

Sinusitis is an inflammatory disorder of the upper respiratory tract which affects all groups within the population.

The treatment of Sinusitis in conventional medicine includes the use of antibiotics, antihistamines and decongestants. But continued use of strong medicines have side effects.

CCRUM initiated research on Sinusitis in the year 1980 at CCRUM, Hyderabad. Based on the classical references available a number of new formulations were prepared and subjected to therapeutic trials. Over the years 5,091 patients of Sinusitis were registered. Out of these 4,928 patients fulfilled the criteria as per protocol and were registered for the study. Trial of two different drugs were conducted in two separate groups first consisting of 2,948 patients and the second 1,980 patients. Over 93% patients responded to the treatment. Out of these over 54% showed 100% subsidence in the disease with radiological clearance using a particular combination; another 35% patients showed 100% subsidence with radiological clearance with treatment of the other combination. Assessment was made on the basis of subsidence in the clinical signs and symptoms and radiological clearance of Sinuses through X-ray examination.

Sinusitis *(Iltehab-e-Tajaweef-e-Anf)*

Research data: 1980-2010

Number of research patients studied : 4928

The ingredients are all plant based and have been standardized and quality control parameters have been developed. Safety evaluations of these drugs have also been done at the Council's centres at Regional Research Institute of Unani Medicine at Aligarh.

The average duration of treatment is eight weeks. No untoward side effects were noted. Unani treatment provides non surgical intervention with few chances of recurrence. The drug is very cost effective and the daily treatment cost is Rs. 4 to 5 only. Duration of treatment varies from 2-3 months depending upon the chronicity of the disease.

The Council also extended treatment facilities for Sinusitis at other Centres.

Infective hepatitis (Iltehab-e-Kabid)

Infective hepatitis is one of the most common liver disorders. Although it is a self limiting disease, it often persists over long periods leading to complications. There is no specific treatment for this disease in modern medicine and generally hepatoprotective drugs prepared from plant origin are recommended. Other options are expensive.

CCRUM started research on infective hepatitis at its centres at Hyderabad and Chennai. Based on the references available in Unani classics, eight formulations were subjected to screening in cases of infective hepatitis on a total of 2078 patients at Hyderabad and 1874 patients at Chennai. CCRUM data showed significant reduction in symptoms after three weeks and normalizing of the biochemical parameters. One particular formulation was reported to have given a highly positive therapeutic response. The assessment was on objective parameters. In the case of Hepatitis-B, E marker studies were also conducted.

Infective Hepatitis
(Iltehab-e-Kabid)

Research data: 1980-2010

Number of research patients : 3952

The drugs have been standardized and quality control parameters have been developed; safety evaluation has also been done. The uniqueness of this drugs is that they are effective in simple jaundice or hepatitis-A or hepatitis-E caused by contaminated water and also in the treatment of hepatitis-B virus by normalizing the biochemical parameters and improving the liver function.

The drug is available at all the clinical centers under the Council and is very cost effective. The per day treatment cost is Rs.3/-. One to three weeks treatment is required for simple jaundice, Hepatitis-A, Non-A, Non-B and Hepatitis-E. However, Hepatitis-B requires long term treatment ranging from three to six months.

Rheumatoid arthritis (Wajaul Mafasil)

Rheumatoid arthritis is a chronic disease. The prevalence and incidence of Rheumatoid arthritis is twice more in women than men. The disease often deprives the patient of his independence and can disrupt the lives of family members and other care givers.

People with arthritis experience a decline in community involvement and difficulties at the work place. In spite of research advancement in the treatment of Rheumatoid arthritis, there is no cure. If the disease reaches a chronic stage the use of pain killers, steroids and corticosteroids becomes unavoidable. Based on references available in the Unani classics, CCRUM formulated six simple combinations and subjected them to therapeutic trials at different centres. Initially the work was started at Chennai in the year 1979 where preliminary screening of certain combination of drugs was done. The drugs showed significant therapeutic effects in the preliminary screening. Later more combinations were formulated and the trials were extended at others centres at Lucknow, Bhadrak, Mumbai, New Delhi, Srinagar and Bengaluru. Out of these six regimes that were subjected to therapeutic trials one particular coded combination of drugs was tested initially on 319 cases which showed 35% complete remission and 47% partial remission in the patients. In 18% there was no response to the treatment. Later 8,000 patients fulfilling the research criteria were registered for study. 7529 patients completed the study in different treatment groups. The cases were diagnosed on the basis of the signs and symptoms of the Unani classification and the cases were classified as per standard criteria of possible, probable, definite and classical stages.

Rheumatoid arthritis
(Wajaul Mafasil)

Research data: 1979-2010

Number of research patients : 8000

OPD data

Period : 1979-2010

Number of patients : 42070

Bronchial asthma (Zeequn Nafas)

Bronchial asthma is a chronic disease, which is the result of the inflammatory condition in the bronchi. The CCRUM initially started research on Bronchial asthma at the Clinical Research Unit, Chennai in the year 1972. Based on the reference available in the Unani classics some new drugs were prepared and subjected to preliminary screening at Chennai. Later in the year 1982 studies on bronchial asthma started at Allahabad, at Mumbai and Srinagar. Based on the findings of

preliminary screening at Chennai, some improved formulations were developed and subjected to therapeutic trials at different clinical centres. At Allahabad a coded formulation was evaluated on 2453 patients, and trial of another coded combination was under taken at Srinagar on a total of 2559 patients. A comparative trial of both these combinations was conducted at Mumbai on 1048 patients. Out of these one particular drug UNIM-352 emerged as the best drug for bronchial asthma.

Bronchial asthma
(Zeequn Nafas)

Research data: 1980-2010

Number of research patients : 6007

OPD data

Period : 1980-2010

Number of patients : 4650

The Centre at Srinagar has emerged as a leader for the treatment of Bronchial asthma in the valley. This centre started clinical study on bronchial asthma in the year 1984.

In one particular group out of the 2559 patients registered, 2086 completed the trial. 1544 (74%) patients responded to the treatment. Response varied according to the type and severity of the disease. 479 (22%) patients showed complete remission, 646 (30%) major improvement whereas, 417 (19%) showed minor improvement. 544 (26%) patients showed no response. In the responding cases frequency of use of inhalers was reduced significantly. The quality of the life of the patients and their physical activities improved significantly. The drug acts as a bronchodilator and an antihistaminic, emulcifient and saline expectorant. It improves lung functions and corrects digestion as well.

The average duration of treatment is 120 days. No untoward side effect was noted with the use of these drugs.

In the Allopathic system the frequent use of bronchodilators, cortisone and inhalers provides only temporary relief. Unani drug UNIM-352 provides relief in signs and symptoms as well as reducing the severity and frequency of the attacks. The drug is reported to be cost effective.

Kit Medicines

In its response, CCRUM also drew attention to various Kit medicines which had been found useful for treating common/seasonal ailments. There are 24 formulations in the kit and these are being prescribed at the Council's centres, in their mobile OPD's and in their health camps even today. The drugs are prepared out of common condiments and items used in cooking but they have been found to be useful for conditions like headache, skin problems, constipation, cough, body ache, boils, conjunctivitis and toothache. Commercial exploitation is already in progress and the council receives about Rs five lakh annually. The Council would like these medicines to be included in the ASHA's kits.

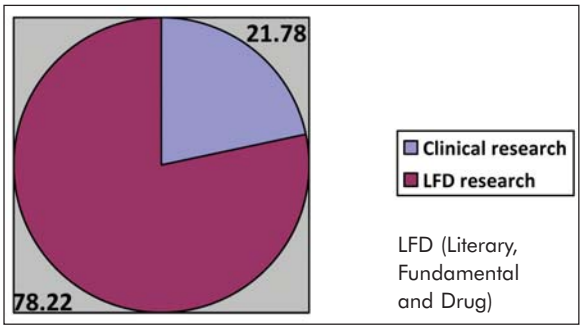
Ayurveda Research Conducted in Educational Insitutions

Research at doctoral and postgraduate levels: A number of clinical research projects are taken up each year either as Extra Mural Research Project or in fulfillment of academic requirements. A bird's eye view of the topics and the institutions that contribute the most is available in a study conducted at Institute for Post Graduate Training & Research Centre (IPGT&RA), Gujarat Ayurveda University, Jamnagar. (Comparative research work could not be located for Siddha and Unani research.)

At present more than 60 Ayurveda colleges all over the country have started postgraduate courses in nearly 26 specialties of Ayurveda. Nearly **700 PhDs** have been awarded in Ayurveda for research work undertaken since the initiation of the postgraduate education in Ayurveda. More than **800 post-graduate theses** are submitted in a year as part of partial fulfillment of the post-graduation degree. The study found that hardly 100 research papers are published annually in Ayurvedic journals.

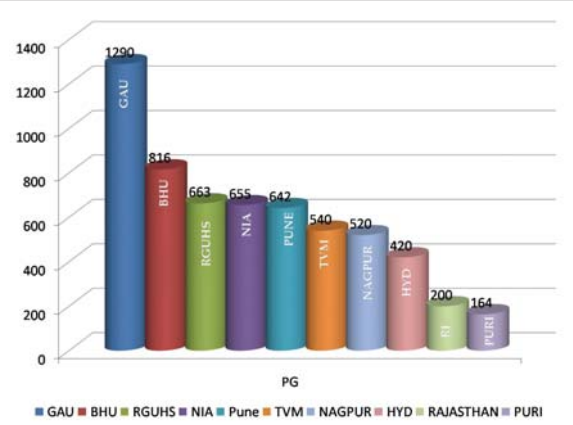
The second edition of "Researches in Ayurveda-2005" by Dr. MS Baghel, Director, IPGT & RA, Jamnagar contains the titles of 7500 theses. Among them, 1213 theses pertained to clinical studies; Clinical comparative studies accounted for 399 papers, randomized clinical trials and controlled clinical trials numbered 11 each. Clinical studies accounted for 21% (1634/7500) of the theses after examining all the research conducted from 1973 to 2005.

Overall Academic Research – Area of Research



LFD (Literary, Fundamental and Drug)

Overall Academic Research – Institution-wise -

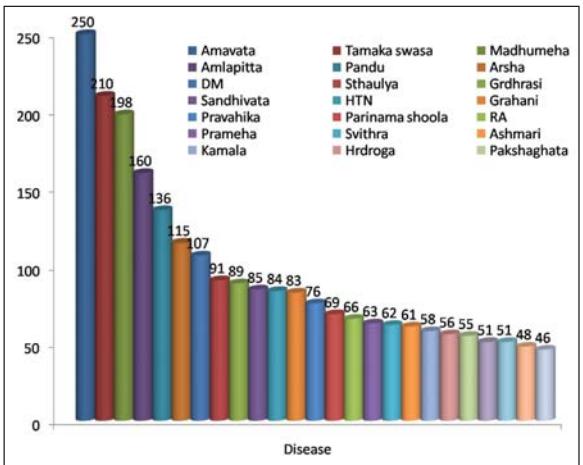


GAU – Gujarat Ayurved University; BHU – Benaras Hindu University; RGUHS – Rajiv Gandhi University of Health Sciences; NIA – National Institute of Ayurveda, Jaipur; TVM – Trivandrum, Kerala; HYD – Hyderabad

Clinical Research Priorities – Disease-wise

Rheumatoid disease like Amavata was found to be the most researched topic in PG clinical research. All available treatment modalities have been tried along with internal medications. Generally in clinical trials either a single drug is tried or known formulations are taken up on a particular condition. In the majority of the theses, comparative effect of Shodhana Chikitsa (Purificatory treatment) and Shamana Chikitsa (Palliative treatment) have been evaluated. After Panchakarma came into existence as a separate specialty, Panchakarma (Bio-purificatory therapeutic pentad) modalities have been compared with treatment of diseases by administering drugs.

All research work is mainly in the form of short



Amavata – Rheumatoid arthritis; Amlapitta – Acid peptic disorders; DM – Diabetes mellitus; Sandhi vata – Osteoarthritis; Pravahika – Amoebiasis; Prameha – Diabetes; Kamala – Jaundice; Tamaka swasa – Bronchial asthma; Pandu – Anaemia; Sthulya – Obesity; HTN – Hypertension; Parinama shoola – Duodenal ulcer; Svitra – Vitiligo; Hridroga – Heart disease; Madhumeha – Diabetes mellitus; Arshas – Piles; Gridhrasi – Sciatica; Grahani – Irritable bowel syndrome; RA – Rheumatoid arthritis; Ashmari – Renal calculi; Pakshaghat – Paralysis.

sample studies. Even in the major Government supported research institutes the financial limit is Rs 10,000 per project. However, due to the paucity of published research in Ayurveda, such work is often quoted to claim an evidence base for the success of the treatment. In the majority of projects the sample size is very small and the sampling method is generally not specified. There seems to be polarization in respect of the clinical work undertaken, covering particular areas, which has hampered advancement of knowledge on other areas.

Ayurveda in Peer Reviewed Journals

Scientific studies cannot make progress without the publication of research findings and authors must welcome and withstand peer review. Research in Ayurveda is, however, seriously handicapped by the paucity of peer reviewed journals which would appeal equally to scientists as to the Ayurvedic community.

A study done by Bhushan Patwardhan and Ashok DB Vaidya[1] clearly indicates that number and impact of scientific publications based on Ayurveda is far less as compared to Traditional Chinese Medicine (TCM).

1. Patwardhan, Bhushan and Ashok DB Vaidya. "Ayurveda: Scientific research and publications." *Current Science,* 97, no. 8 (2009).

The authors have searched and compared citations on Ayurveda (including the use of terms like Ayurvedic and Ayurveda), Yoga, TCM and acupuncture using science databases including *Scopus*, *Pubmed*, *Scirus* and *Google Scholar* (Table 1). TCM remained way ahead of Ayurveda in majority of the journals selected for this study (Table 2).

Table 1. Comparative citation* for Ayurveda and TCM in science database

Category	*Scopus*	*Pubmed*	*Scirus*	*Google Scholar*
Ayurveda	1216	451	80045	23900
TCM	16096	16191	137414	218000
Yoga	2101	1250	1014471	228000
Acupuncture	22420	14081	720748	190000

*Citation figures as on 21 June 2009.

Table 2. Comparative citations* of Ayurveda and TCM in high impact journals

Journal	Impact factor	Ayurveda	TCM
NEJM	52.589	0	23
Nature group	29 to 26	66	257
Science	26.372	6	45
Lancet	28.638	29	629
JAMA	25.547	16	466
BMJ	9.723	62	80
PNAS	9.598	0	15
DDT	7.7	0	4
JBC	5.581	0	1
e-CAM	2.535	25	23
JEP	2.047	58	126
IJMR	1.67	7	0
AJCM	1.122	2	129

*Citations limited for presence in 'title, abstract or keywords' as on 21 June 2009.

Ayurveda Citations

However during the last 15 – 20 years there has been a sharp increase in the number of articles on Ayurveda in international journals (Figure 1). The authors concluded that the scientific community and government should further intensify systematic efforts and encourage collaborative research to bridge this gap and strengthen the presence of Indian Ayurveda in high-impact journals.

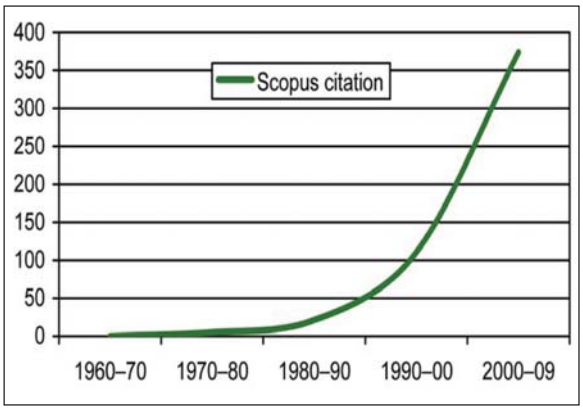


Figure 1. *Scopus* citations as on 21 June 2009 for Ayurveda in 'title, abstract and keywords'.

Examination of peer reviewed journals: Various peer reviewed journals of 2009 -10, which focused on Ayurveda were got reviewed by the PI to find the focus of present research in peer reviewed journals. Approximately 250 papers on different topics and observations were scrutinized by Dr. Sathya N Dornala, Ph D, (who worked part time with the PI).

The major journals reviewed were:

1. International Journal of Ayurveda Research (IJAR)
2. Journal of Ayurveda and Integrative Medicine (JAIM)
3. AYU Journal of Research in Ayurveda

On review it was found that the majority of research was focused on the following areas (given in decreasing order of priority):

1. Diabetes
2. Rasayana and Ageing
3. Arthritis (Osteo & Rheumatoid)
4. Preclinical studies
5. Skin diseases
6. Standardization of Bhasmas
7. Quality control of Ayurvedic formulations
8. Scientific relevance of Ayurvedic concepts

Consultation with Experts on New Ways of Approaching Clinical Research

Introduction: The PI held discussions with a wide range of experts engaged in conducting clinical research of ASU treatment. She wrote to numerous experts whose names were given by different sources and the Department of AYUSH. A copy of the letter is at **Annexure IV**. The main extract or the PI's letter is re-produced below:

"While decades have been spent in trying to standardise ASU medicine in the hope that one day the products will be used by industry and will be mainstreamed into medical practice, the evidence is that this has not happened. Many promising openings have had to be discarded before reaching the phase 3 trial stage. Even where one or two products were identified after completing all the rigours of research, following modern medicine parameters, the products were not utilised by industry.

And yet we claim that ASU has something to offer whether as a stand-alone therapy or as an adjuvant or adjunct. This claim has to be put to the test in a way that the public benefits directly and it is time that we thought of doing things differently. For doing so we need to change track and allow the physician to treat the patient in an individualistic, holistic way and find a way of judging outcomes through a comparison of medical parameters of similarly diagnosed patients having a similar level of impairment or illness who have been treated through the allopathic system. The choice of patients should be through voluntary option given in the OPDs of allopathic hospital departments and the choice should be left to the patient to opt for allopathic treatment or ASU treatment."

Outcome of advice given by experts: The PI sought the guidance of a wide cross-section of experts who were engaged in ASU research whether this approach had any validity. Detailed responses were received from several experts but the comments of Dr. Ashok Vaidya, Dr. Urmila Thatte, Dr. Bhushan Patwardhan, and Dr. Ram Manohar bear special mention. The words of the Secretary S&T Dr. T Ramasami at the end of this section summarise what most experts have suggested in one way or the other.

"A paradigm shift in Ayurvedic research is an urgent need for global health. The evidence of quality, safety and efficacy from therapeutic outcome studies (TOS) will be such a new path. A governance and research management structure needs to be highly empowered so as to derive definite benefits of TOS to the people. The resources-human, financial and infrastructural – will have to be adequately provided on an on-going line. There is a strong chance that TOS will lead to significant health benefits in chronic metabolic and aging disorders. This could have a major impact on global health." *(Dr. Ashok B Vaidya, Research Director, Medical Research Center- Kasturba Health Society; ICMR Advanced Centre for Reverse Pharmacology in Traditional Medicine (ACRIT), Mumbai)*

"There is an urgent need to promote research in research methodology in ASU area. We need to think of out of the box methods – better inclusion/exclusion criteria, different controls, a look at "therapies" as "black boxes", a true collaboration between the ASU and modern medicine physician in evolving end points and efficacy-safety variables. This collaborative research will bridge the gaps and lead to a wider acceptance of the systems. We need to introduce Ayurveda in modern medicine teaching colleges – first as an elective at least. In much the same way we need to promote research methodology and scientific writing workshops for the teachers in Ayurveda colleges." *(Dr. Urmila Thatte, Professor and Head, Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai)*

"Issues related to appropriateness of conventional, biomedical and clinical models for evaluating efficacy of systems of traditional medicine remain critical. A holistic, whole systems approach seems better suited to study therapeutic efficacy and pharmacodynamics of traditional medicine. Instead of randomised controlled trial is normally used as the gold standard, routine biomedical research, strategy of pragmatic or whole system clinical trials may be better suited for Ayurveda." *(Dr. Bhushan Patwardhan, Editor-in-Chief, Journal of*

Ayurveda and Integrative Medicine; Vice-Chancellor, Symbiosis International University, Pune.)

Commonality of the views expressed by experts: The views of Dr. Ram Manohar of the Ayurvedic trust in Coimbatore are important because he was a part of a study funded by the National Institutes of Health (NIH) Bethesda, USA in which RCT was conducted on Rheumatoid Arthritis. For the first time Ayurvedic physicians were allowed to individualize the treatment and modify it in the course of the trial. Because of this development what he has to say gains importance:

"It is indeed true that research in Ayurveda is not properly directed. There is no clear road map and the priority areas have not been identified.

Current research is centered on activities like standardization of drugs and formulations for obtaining licenses to market these products, or bio-prospecting i.e. screening herbs to identify new chemical molecules. There have also been interesting initiatives to explore the science behind Ayurvedic theory and this has led to emergence of approaches like reverse pharmacology, ayurgenomics and the like. However, this kind of research has not addressed fundamental questions related to the way Ayurveda is actually being practiced and public concerns about safety, efficacy and relevance of Ayurveda in the public health care system.

For example, all the standardization work by research institutes and pharmacies have not satisfactorily answered questions concerned with safety of Ayurvedic medicines. The quality and standards of Ayurvedic medicines is hardly assured and there are growing concerns regarding safety. Bioprospecting, Reverse Pharmacology, Ayurgenomics are all approaches that seek to appropriate Ayurvedic knowledge for the advancement of modern medicine in the ultimate analysis. This kind of research does not focus on the role that Ayurveda can play as an independent system of medicine in conjunction with other approaches to health care in the pluralistic health care set up in India.

The focus has to shift to the actual practice of Ayurveda and how it impacts public health. This is the line of research adopted by countries like US, Europe where Complementary and Alternative Modalities of healing have become popular.

We need to study Ayurveda in real life clinical settings in all the diverse ways that it is practised. We have to come up with the criteria that will enable the public to discern between what is credible and not credible when it comes to available Ayurvedic interventions. We have to come up with data that addresses basic concerns regarding safety and efficacy of Ayurvedic interventions in the form that they are being offered to the public today." *(Dr. Ram Manohar, Director of Research, The Ayurvedic Trust, Coimbatore, Tamil Nadu)*

Importance and Impact of the Study by Dr. Ram Manohar and his Group – An Example of Good Clinical Research

The National Institutes of Health, USA funded Randomized Clinical Trial comparing whole Ayurveda intervention against Methotrexate was conducted at the Ayurvedic Trust, Coimbatore in collaboration with the University of Washington, Seattle and University of California, Los Angeles. Through this study a new protocol for conducting double blind, placebo controlled Randomized Clinical Trials to evaluate complex and individualized Ayurvedic interventions has been developed.

This study is perhaps the first ever instance of so many things falling into place correctly. The research team was built through collaboration with leading Universities in the United States. One of the most eminent rheumatologists in the field of modern medicine led the study. The study was funded by the National Institutes of Health, the apex body for medical research in the United States. The results of the study got published in the best research journals for rheumatology in the world. The methodology employed in the study won the appreciation of even strong critics of Complementary and Alternative Medicine.

The pilot study validated the methodology and also provided preliminary evidence that individualized Ayurvedic treatment is as effective as Methotrexate without the risk of serious side effects. The study indicates that Ayurveda can offer treatment as a stand alone therapy. Supplementing Allopathic treatment with Ayurvedic medicines may lead to undesirable consequences.

The outcomes of this study was presented at the American College of Rheumatology and published in high impact journals such as Annals of the Rheumatic Diseases and Journal of Clinical Rheumatology.

The study design has also been recommended as the blue print for future studies on traditional, complementary and alternative systems of medicine in the journal Focus on Alternative and Complementary Therapies.[2]

The views expressed by Doctors, Vaidya, Thatte, Patwardhan and Ram Manohar seem to be on all fours with what the Secretary, Department of Science and Technology Dr. T Ramasami wrote in answer to questions posed by the PI.

1. Do you think that traditional medicine concepts have relevance today? What has been your experience?

"In my personal view, concepts behind the traditional medicine from ancient civilizations enjoy greater relevance today than that they did in the past 100 years. While modern medicine has delivered healthcare solutions for several diseases, affordability and accessibility of healthcare systems in the modern world have posed challenges.

Affordability and accessibility criteria on the one hand and the integrative biology embedded in the traditional medicine make them even more relevant for the management of chronic and neglected diseases than modern medicine.

While modern medicine is highly valuable in increasing the longevity of human life, ancient systems offer an opportunity to add some quality into a prolonged life.

Modern medicine has been outstanding in areas of diagnosis, interventional medicine as well as surgical correction. However, the underlying principles of modern medicine are based on reductionism and applications of molecular and system biology. It is difficult to factor-in feedback and other natural responses to drugs given the genetic variety of human subjects. Consequently, extensive clinical trials based on animal models and human subjects as well as long gestation time have become essential. These demands do tend to make the discovery of drugs through modern R&D paths investment intensive.

Traditional medicine based on centuries of empirical observations and inductive logic and integrative biology offers better scope for management of chronic and life style diseases than modern medicine. The world is coming to realize the value of our traditional forms of medicine.

2. Have the research projects supported through DST given outcomes beneficial to the community in terms of identified outcomes?

"DST has supported research and development projects in both public and private institutions since 2003-04. These projects have broadly supported the standardization of herbal drug formulations based on traditional medicine systems. Management of diabetes, HIV/AIDS and arthritis has formed the major focus of research supported by DST.

2. The study team consisted of experts from both India and USA -The USA team mainly comprised of Dr. Daniel Furst (Clincal Lead Investigator), Dr. Manorama Venkatraman (Program Director), Cathryn Booth La Force (Principal Investigator, US Side) and Mary McGaan (Data Manager) and The India team mainly comprised of PR Krishna Kumar (Project Director), Dr. P Ram Manohar (Principal Investigator, India Side), Dr. KG Raveendran (Treating physician-Ayurveda), Dr. PG Sekhar (Treating physician-Allopathy), Dr. Reshmi Pushpan (Study Coordinator), Dr. Anita Mahapatra (Pharmacist) and Mr. Jidesh (Data Manager).

Honest answer is that it may be too early to recognize beneficial outcomes from the research projects supported under Drug and Pharmaceutical Research Programme of Department of Science and Technology. Investments into creation of facilities for standardization of formulations from traditional medicine have been made during the last five years. These are likely to provide some useful gains in the standardization of formulations.

3. Would you recommend a better way of R&D? What would you recommend for altering the ways of conducting research in the area?

"I would not like to refer to changes but I would like to propose as a better method of performing R&D in the area, would propose an alternative and newer way. In my opinion, the grammars of Alternative and Modern Medicine do not match. Both forms of medicine are valuable in their own ways but the R&D tools of modern medicine may not seem to fit the needs of traditional medicine.

Modern medicine is based on reductionism and understanding of the chemical biology of diseases and statistical assessment of drug responses on live systems. Animal models and clinical trials on human subjects form the basis of drug discovery. It employs the tools and grammar of discovery science and learning from closed systems and laboratory observations.

Traditional medicine employs the tools of integrative biology and empirical observations of healthcare outcomes on human subjects (made over centuries) and uses the concept of personalized medicine. These concepts do not lend themselves to application of animal models. While sophisticated analytical techniques could be gainfully employed, it seems rather difficult to subject the traditional medical formulations to clinical pharmacological studies employed for modern medicine without introducing ambiguities.

Ayurveda and Siddha treat man as a part of an ecosystem while modern medicine tries to rely on drug-host responses at molecular and system biological levels. If man is a part of an ecosystem, inspiration for solutions to human health related problems could in principle be sourced from the plants of the same ecosphere. The question is whether such forms of medicine could be globalised or not.

We need to retrofit the two systems built on widely different grammar. Traditional medicine is based on empirical observations collected over long periods of time. Modern medicine is structured with the rigor of laboratory findings under controlled conditions. Traditional medicine relies on the principle of connecting a grid of causes with a grid of effects while modern science is built on the structure of a single cause coupled with a single effect. Therefore, new paradigms are required to leverage the mutual benefits of modern ad traditional medicines to benefit each other. As a scientist trained with the tools of rigor and an analytical approach but as some bearing faith in the value of traditional medicine, I would like to propose a new approach for revalidation of formulations from traditional medicine using modern tools, without sacrificing the merit of traditional practice. I may like to propose the following.

Let us select and identify 100 patients treated through traditional medicine for say arthritis. The treatment protocol might have employed different formulations based on genotype of patients. This is no issue. Based on the history of treatment, we classify our targeted patients based on their "Prakritis" or genotypes. We then analyse their body fluids using the analytical tools of modern science rather rigorously and search for evidence of biomarkers. For example, in the case of arthritis some proteins and their degradation products could be traced. If there are any statistically significant trends and correlations between health and disease status of the 100 patients treated only by through traditional medicine are compared to those treated using modern medicine, we could derive a more suitable revalidation system for traditional medicine using modern analytical tools. Subjecting traditional medicine to animal models as employed by modern systems may not be appropriate for revalidation. Extrapolation from mouse to man in traditional medicine is not feasible. We need to study effects on men and men only. We could equally well retrofit my concept to diseases other than arthritis as well. DST is mounting a coordinated research project on "Ayurvedic Biology". We need to work at the cross borders of science enrolling human beings as unit of observation rather than molecules, cells and animals".

Recommendations Relating to a New Approach for Clinical Research

The recommendations are presented under three sub-headings:

1. Recommendations relating to improving public confidence through research

Recommendations to reorient clinical research: A bold decision needs to be taken in the 12th Plan to support what the Secretary S & T has argued in favour of. In order to make that possible, funds would need to be provided to research organisations that undertake biomedical research, the bottom line being that the therapeutic work would be done exclusively by the ASU physician; but the inclusion and exclusion criteria, the examination of the pathological and other reports would be done by experts who have no stake in the success or failure of the outcomes but are looking for convincing proof that ASU therapeutics and interventions work. Each project should be undertaken collaboratively as given in the example of the US NIH funded study reported by Ayurvedic Trust Coimbatore and substantial funds should be set aside for supporting such research.

Recommendations on multidisciplinary group to oversee all clinical research: Against this background what is needed is to have a multidisciplinary group that would be able to agree upon protocols, facilitate the selection of patients that volunteer for ASU treatment as officially offered in response to a Notice in an allopathic clinic dealing with that speciality. The disease areas to be taken up may include dermatology, rheumatoid arthritis, bronchial asthma and diabetes to start with. The monitoring group should have one or two interventional experts in the field of Complementary and Alternative medicine to build credibility. Practitioners who have been engaged in treatment from the Ayurveda, Unani or Siddha Research Councils should be included in the Monitoring Committee to ensure that research is centered on genuine ASU treatment. In addition there should be other members from scientific disciplines to ensure that good science is employed in conducting research. Giving the responsibility like CCRAS & CCRUM will not work although their professional staff can become the conduit to impart treatment to patients which they have been doing for years at the Councils' centres.

Recommendations on uplifting the councils' vision: If necessary the Scientific Advisory Committees (SACs) and Technical Committees of the Councils should be restructured to allow for this infusion of a multidisciplinary spirit. However a mere change in the SACs would not suffice. The Councils of the Department of AYUSH do not have the requisite exposure or wherewithal to be able to successfully validate ASU therapies in real life clinical context or to conduct and document clinical research with the rigour acceptable to international peer reviewed journals. The Councils have been directed by several Technical Committees over the years to narrow down research to drug combinations a single formulation and follow a standard allopathic protocol to conduct research. Unless the outlook of the Councils is widened and the research staff is exposed to international standards of clinical research, it would be difficult for them to raise themselves to suddenly conduct high quality research. Funds should be set aside for observational study tours to institutions in India and abroad after drawing up MoUs Selection should be after interview and not on the basis of seniority.

2. Recommendations relating to the creation of a multidisciplinary group for providing advice on enhancing collaborative efforts

Discussion: It is apparent that organisations like ICMR, CSIR, DBT and Department of Science &Technology (DST) are contributing in several ways to enhance what can be best derived from traditional medicine knowledge. However to have greater coordination and oversight a high-level group should meet at least every six months to review the extent to which the research work is likely to benefit the public. In fact that should be a constant benchmark to judge the usefulness of ASU clinical research.

ICMR has the wherewithal to draw up protocols for therapeutic outcomes studies. It can act as a conduit to counsel patients visiting the speciality clinics in allopathic institutes and to help register them for undergoing ASU treatment as a part of therapeutic outcome research. Otherwise lay patients may not understand all aspects of the research and the stature of ICMR would convince them that the clinical trials have a strong multi-disciplinary foundation and government support.

CSIR has been able to pass on the outcome of research based on the properties of plants for the use of industry. But asked whether the off-take is growing or static, no response was given. Admittedly the question was beyond the area of responsibility of an individual scientist: it is necessary therefore that CSIR monitors the extent to which the outcome of the technology/processes transferred to industry is being utilised because that is a clear reflection about the usefulness of the drug. Even if this goes beyond the mandate of CSIR, periodic follow up of the extent of benefit public has received needs quantification. In the area of drugs based on traditional medicine it will give confidence and credibility to the findings if they are based on ASU or tribal or folk knowledge.

DBT is already contributing towards the conservation, preservation, in situ and ex situ cultivation of medicinal plants. In the chapter on medicinal plants and on drugs, there was a constant lament from dealers of medicinal plants, manufacturers and practitioners about the irreversible shortage of key medicinal plants. Greater interaction between DBT and the National Medicinal Plants Board on a continuous basis would help focus on critical areas e.g. whether the propagation of Vijaysar for controlling diabetes which was proved by ICMR, can be started as it is reported to be extinct.

DST has promoted and supported a large number of projects related to the ASU sector listed at Annexure-II. The details should be known to Department of AYUSH which is funding similar projects. While this may be happening already there is a need to share information more collaboratively for mutual benefit.

Recommendations to enhance collaborative efforts: A quarterly meeting of the Secretary AYUSH, Secretary Health Research/DG ICMR, Secretary DST, DG CSIR and DBT, with the limited purpose of reviewing outcomes that have benefited the public would provide greater impetus for research, introduce course correction and would produce outcomes which are of direct advantage to the public. Such meetings are already being held to give a direction to new initiatives. However a joint stock-taking for intra-mural and extra-mural research funded form Government funds from the point of view of public benefit would alert those who are responsible for conducting research to remain focused on that goal.

3. Clinical research and patient care experience generated by CCRAS and CCRUM

Public benefit: The therapeutic outcome claims of the two Councils have been officially reported to Government and to Parliament for decades. If so, a wider public ought to benefit from the work done by the Council. In the last 20 years – in fact much longer not a single product patent has been granted to CCRAS. But enormous clinical work has in fact been done and the areas of strength have been identified. Therefore the public would benefit much more if CCRAS/CCRUM were asked to open special treatment centres where case management using identified drugs could be made available on a wider scale. If public funds were used for past work which had positive outcomes, members of the public need to know where such treatment can be accessed and the management of patients needs to be planned professionally so that they are not turned away because of poor management.

Curtailment of in-house clinical research: According to the law, if formulations follow the classical dosage form and ingredients, no further trials are needed. In that case, continuing clinical research in an open ended manner simply by trying new permutations and combinations of the same drugs is wasteful; this is because these pursuits have shown negligible outcomes in terms of acceptance for patent or for adoption by industry. Instead the Councils should be made responsible for acting as a conduit for getting standardised drugs manufactured centrally through a public sector company under the Department of AYUSH or outsourced to good manufacturers in the private sector. The logistics of raw material quality, production of standardised drugs and their timely despatch to treatment centres can be done by the Council staff many of whom are engaged in routine, repetitious clinical research which amounts to little more than offering rudimentary treatment in a peripheral kind of way.

Patent route needs complete rethinking: The process of acquiring patents appears to have no significance because no industry has shown interest in using the research findings of CCRAS and CCRUM over decades. Most large manufactures have their own in-house research facilities and have not used CCRAS or CCRUM's research findings.This route of conducting in-house clinical research should therefore be abandoned as such research

has not proved the effectiveness or efficacy of the treatment in a way that medical research requires.

Modify aims and objectives of the Councils: The Department of AYUSH should consider altering the aims and objectives of CCRAS and CCRUM to assign the Councils a specific role in providing diagnosis and treatment for 6 -8 identified diseases and conditions. Stocks of medicines should be available in the selected centres, either manufactured at reputed pharmacies or under license from Indian Medicine Pharmaceutical Corporation Limited (IMPCL). The personnel from the centres can be rotated around to work in the new treatment centres as the Councils' staff although transferable have always resisted a change of locale.

Campaign about treatment centres: The Department of AYUSH should consider launching a campaign about the newly established CCRAS and CCRUM run treatment centers. A centralized web site should inform the public about each centre and the specialised treatment available at the facility. The details of the centres should be listed alongwith a Google map to show the locations. The advantage would be that at least in the areas where ASU drugs formulated by CCRAS/CCRUM have a strong potential for cure/mitigation of disease conditions, information on where to go, for what, would be easily available. Most of the identified drugs formulated by the CCRAS do not contain minerals or metals and the efficacy of the ingredients and their continued use over years has been established. CCRAS should run speciality centres for specific conditions viz., rheumatoid arthritis, bronchial asthma, hemorrhoids and fistula. Siddha Medicine for psoriasis and for manipulation of pressure points through varma therapy (described in the chapter on Practice would also be sought after). By involving the Council's staff there would be credibility as these persons would be Government employees.

CCRUM has been able to treat a large section of the public by providing treatment for Vitiligo, Eczema, Psoriasis, Rheumatoid arthritis, Bronchial asthma and Sinusitis. It is therefore necessary to set up Specialty Centres to treat these conditions using Unani Medicine which has been found to be very effective.

Recommendations related to budget requirements: In the 12th Plan funds would need to be earmarked for giving a direction to these recommendations with the aim of bringing the fruit of three decades of research and clinical experience gathered from using the Council's coded formulations. Funds will need to be assigned for:

- **Creation of 6-8 modern centres** for treatment of specific conditions with consultation rooms and a waiting area separately for patients who come with appointment. For paid patients there should be a registration charge of Rs 200/ per consultation and specific timings for paid consultation in the evenings. For those who come without appointment they should be treated in the OPD in the forenoon free of cost. A Revolving Fund should be created for each centre to be utilized for improving day-to-day functioning of the centre. The Special Centres should maintain patient records on the computer; the special consultation area should be air-conditioned, should have clean toilets and printed literature answering the questions that patients generally ask about the centre/ doctor/medication. In case of rush there should be a Receptionist who can manage the appointments so that patients know how long they would need to wait. The Specialty Centre's Manager should have an MBA or a degree in hospital management to be able to pay adequate attention to management and delivery of efficient services in clean surroundings. This should not be done in-house as the culture within CCRAS/ CCRUM is tolerant of rather low house-keeping standards which paid patients will not accept. It also militates against professionalism.
- Both CCRAS and CCRUM have abundant space to start such speciality clinics in their larger Institutes elsewhere in the country. The National Institutes of Ayurveda, Siddha and Unani Medicine, besides several other institutions located at Hyderabad, Delhi, Chennai and several other cities also have good surroundings and enough space with a little re-adjustment.
- **Production of the formulations** for free supply and sale to paid patients coming to the treatment centres by outsourcing to good manufacturers (with oversight of raw material used and processes followed). The quality of the packaging and labeling has to inspire confidence. Funds would be needed to step up production initially until the centres break

even and can pay for the drugs from fees collected from paid patients and the sale of medicine.

- **A media plan to build awareness** about the availability of facilities at the Specialty centres through television, radio and print media should be sustained for at least one year and stepped up for three months in each subsequent year for which a budget provision should be made.
- **A budget for payment to part-time consultants** engaged from the private sector for supporting the running of the Centers should be made on condition they use the Council's formulations. (The logic is to use the Councils' formulations which are the product of work undertaken at public cost over decades. This will not affect private manufacturers or practitioners but will offer the public confidence about the credentials of the treating physician and the quality of the drugs.)

The foregoing initiatives can help open the benefits of decades of in house work to offer treatment to a much larger section of patients who suffer from these chronic medical conditions and are in search of reliable Ayurveda, Unani and Siddha treatment. By having speciality paid clinics, everyone in society would get a chance of availing of ASU specialised treatment which has a high success rate in specific areas.

Funding for clinical research

For funding the therapeutic outcome clinical research studies and encourage allopathic research institutes like AIIMS, PGI Chandigarh, GB Pant Hospital, Delhi, the Department of AYUSH should make adequate provision to make such research meaningful. The treatment can go on in any ASU institution but the reporting and study of diagnostic and pathological reports should be left to an independent multidisciplinary group to examine and record their findings. A generous budget should be set aside for promoting such therapeutic outcome clinical research involving multi-disciplinary groups.

Annexure-I

Details of Cases where TKDL Evidence led to Patent Claims being rejected or withdrawn

1. List of cases set aside

   (i) EPO decided to grant patent to M/s. Data Medica, Padova SPA, Italy on 19.2.2009 for use of **Pista** as an **anti-cancer** drug. TKDL Unit, CSIR, India submitted evidences on 09.07.2009, then EPO set aside its earlier intention to grant patent on 14.07.2009.

   (ii) EPO decided to grant patent to M/s. Perdix Eurogroup SL, Spain on 02.04.2009 for use of watery extract of **kharbooza /melon** as an **anti-vitilgo** cream. TKDL submitted evidences on 08.07.2009, then EPO set aside its earlier intention to grant patent on 28.7.2009.

2. Details of cases where applicant modified the claims are given below:

   (i) EPO decided to grant patent to M/s. Livzon Pharmaceutical Group Inc., China on 25.02.2010 for use of **Kalamegha** and **Mint** for the treatment of **Avian influenza**. TKDL submitted evidences on 20.05.2010, then EPO set aside its earlier intention to grant patent on 10.6.2010. Subsequently, the applicant modified its claims on 05.07.2010.

3. Details of applications filed at EPO where applicants themselves decided to withdraw their claims/patent application after they were confronted with TKDL evidence are given below:

   (i) M/s Purimed Co. Ltd., Korea filed a patent application on 09-06-2005 for treatment of **heart diseases** using **Indian lotus**. TKDL submitted evidence on 17.07.2009. On 04-08-2009, applicant withdrew its claims/patent application.

   (ii) M/s Jumpsun Bio-Medicine Co., Ltd, China filed a patent application on 06-03-2006 for treatment of **obesity** and/or **diabetes** using **Bengal gram/Chana**. TKDL submitted evidence on 11-06-2009. On 20-11-2009, applicant withdrew its claims/patent application.

   (iii) M/s Amcod Limited, Kenya filed a patent application on13-09-2005 for treatment of **diabetes** using **Neem, Gheekawaar** and **Daal Chini**. TKDL submitted evidence on 01-07-2009. On 24-11-2009, applicant withdrew its claims/patent application.

   (iv) M/s Clara's ApS, Denmark filed a patent application on 19-09-2007 using **Haldi/ turmeric, Zeera, Adrak/Ginger** and **Pyaaz/ onion** as a **slimming agent**. TKDL submitted evidence on 25-08-2009. On 30-10-2009, applicant withdrew its claims/patent application.

   (v) M/s Cognis IP Management, Germany, filed a patent application on 09-03-2007 for the treatment of **obesity** using **Gheekawaar**. TKDL submitted evidence on 20-07-2009. On 27-11-2009, applicant withdrew its claims/patent application.

   (vi) M/s Evonik Goldschmidt, Germany, filed a patent application on 30-11-2007 using **Arjuna** as an **Anti-ageing/anti-wrinkle agent**. TKDL submitted evidence on 07-09-2009. On 27-01-2010, applicant withdrew its claims/patent application.

   (vii) M/s Unilever Nv, Netherlands, filed a patent application on 18-06-2004 using **Grape juice** and/or **Apple juice** as a **cardio tonic**. TKDL submitted evidence on 17-07-2009. On 04-08-2009, applicant withdrew its claims/patent application.

   (viii) M/s Kapur MBBS, B., Dr., Great Britain filed a patent application on 13.06.2007 using **Opium, Spinach** and **Saunf/ Fenugreek** as **immuno- modulator agents.** TKDL submitted evidence on 16.02.2010. On 18-02-2010, applicant withdrew its claims/patent application.

   (ix) M/s Natreon Inc, USA, filed a patent application on 27-07-2006 using **Ashwagandha** for the treatment of stress, sleeplessness and anxiety. TKDL submitted evidence on 06-07-2009. On 25-03-2010, applicant withdrew its claims/patent application.

(x) M/s Jan Marini Skin Research Inc, USA, filed a patent application on 22-02-2007 using **Brahmi, Tea leaves, Ashwagandha, Turmeric** as **anti ageing** and **anti-inflammatory agents**. TKDL submitted evidence on 02-07-2009. On 08-04-2010, applicant withdrew its claims/patent application.

(xi) M/s Avesthagen Limited, India, filed a patent application on 15-08-2003 using **arjuna** as **cardio tonic** and for the treatment of **obesity** and **diabetes**. TKDL submitted evidence on 08-07-2009. On 06-04-2010, applicant withdrew its claims/patent application.

(xii) M/s Naveh Pharma Ltd, Israel, filed a patent application on 29-03-2007 using **Rose** and **Sweet violet** for the treatment of **diseases of throat**, e.g. **pharyngitis**, and **sore throat**. TKDL submitted evidence on 24.07.2009. On 15-04-2010, applicant withdrew its claims/patent application.

(xiii) M/s GW Pharma Limited, Great Britain, filed a patent application on 11-10-2006 using **Bhaang** for the treatment of **cough and bronchitis**. TKDL submitted evidence on 21.05.2010. On 24-06-2010, applicant withdrew its claims/patent application.

(xiv) M/s Ocumedic APS Denmark, filed a patent application on 22-11-2007 using **Naarangi** for the treatment of **disease of eye**. TKDL submitted evidence on 14.06.2010. On 06-07-2010, applicant withdrew its claims/patent application.

(xv) M/s Jaffe, Russell M. USA, filed a patent application on 07-11-2006 using **Babool** for the treatment of **constipation, indigestion and diabetes**. TKDL submitted evidence on 30.06.2010. On 06-07-2010, applicant withdrew its claims/ patent application.

(xvi) M/s Indena S.p.A. Italy, filed a patent application on 12-06-2008 using **Abuqanus** for the treatment of **Asthma and Breathlessness**. TKDL submitted evidence on 23.07.2010. On 26-07-2010, applicant withdrew its claims/patent application.

(xvii) M/s Haelan Schweiz, Switzerland, filed a patent application on 13-06-2008 using **Alsi and Pomegranate** for the treatment of **diseases of heart, skin and diabetes**. TKDL submitted evidence on 12.07.2010. On 26-07-2010, applicant withdrew its claims/patent application.

(xviii) M/s Bios Line S.p.a. Italy, filed a patent application on 10-12-2008 using **Mint, turmeric and Olive** for the treatment of **dysentery**. TKDL submitted evidence on 14.06.2010. On 29-07-2010, applicant withdrew its claims/patent application.

(xix) M/s Ache Laboratories, Brazil, filed a patent application on 14-12-2007 using **Grape** for the treatment of **Diabetes, obesity and hypertension**. TKDL submitted evidence on 01.07.2010. On 01-09-2010, applicant withdrew its claims/ patent application.

(xx) M/s Mercian corporation, Japan, filed a patent application on 17-10-2006 using **Grape** for the treatment of **skin marks and acne**. TKDL submitted evidence on 07.06.2010. On 04-08-2010, applicant withdrew its claims/patent application.

(xxi) M/s Al-Jassim, Rawaa *et al*, United States, Great Britain and Germany, filed a patent application on 02-03-2000 using **Black seeds** for the treatment of **conjunctivitis and allergic disorders**. TKDL submitted evidence on 18.06.2009. On 18-08-2010, applicant withdrew its claims/patent application.

(xxii) M/s Bionature E.A. Limited, Nicosia/ Cyprus, filed a patent application on 16.02.2007 using **Pistacia lentiscus** for the treatment of **inflammation**. TKDL submitted evidence on 23.06.2009. On 22-09-2010, applicant withdrew its claims/ patent application.

(xxiii) M/s Phytrix JV, LLC, USA, filed a patent application on 07.05.2008 using **Phyllanthus** for the treatment of **HIV associated diseases**. TKDL submitted evidence on 03.08.2010. On 28-09-2010, applicant withdrew its claims/patent application.

Annexure-II

Traditional Medicine Projects funded by DST

S. No.	Project Title	Institute/Industry Name – Beneficiary (Financial year)
i)	Collaborative Projects	
1.	Scientific evaluation of safety and efficacy profile of herbal Siddha formulation (Kodiveli) in the management of Rheumatoid arthritis.	SASTRA University, Thanjavur (2003-04).
2.	Development of a novel herbal ectoparasiticidal product.	Central Institute for Research on Goats, Mathura, U.P. (2003-04).
3.	Standardization and modernization of Ayurvedic herbal formulations using modern techniques.	Indian Institute of Integrative Medicine, Jammu. (2003-04).
4.	Efficacy and safety evaluation of Siddha medicine HIVS-2003 for HIV/AIDS.	Jawaharlal Nehru Centre for Advanced Scientific Research, Bengaluru (2003-04).
5.	Development of herbomineral and plant-based disease oriented immunomodulator formulation.	Indian Institute of Integrative Medicine, Jammu (2003-04).
6.	Scientific evaluation of safety and efficacy profile of Siddha formulation (KARBOGI) in the management of Leucoderma.	SASTRA University, Thanjavur (2003-04).
7.	Cardoguard tablet delineation of molecular mechanism of action and its efficacy in the regression of ventricular hypertrophy.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum (2003-04).
8.	Development and standardization of therapeutic herbal formulation(s) for the management of alopecia and skin disorders.	Ramnarain Ruia College, Mumbai (2003-04).
9.	Quality assurance and validation of some Ayurvedic formulation for life-style related and gynaecological disorder.	Indian Institute of Chemical Technology, Hyderabad (2004-05).
10.	Development of botanical immunomodulators as adjuvants for improving vaccine efficiency.	University of Pune, Pune (2004-05).
11.	Development of drugs for the medical therapy of glaucoma using natural products.	Delhi Institute of Pharmaceuticals Sciences and Research (DIPSAR), New Delhi (2004-05).
12.	Scientific evaluation of safety and efficacy profile of Siddha formulation advocated in the prevention and management of coronary heart disease.	SASTRA University, Thanjavur (2004-05).
13.	Scientific evaluation of safety and efficacy profile of an Ayurvedic Herbal Formulation (RO5) in the management of Diabetes mellitus.	Sri Ramchandra University, Chennai (2004-05).
14.	Chemical standardization and biological evaluation with a view to increase efficacy of herbal medicines.	Indian Institute of Chemical Biology (IICB), Kolkata (2004-05).
15.	Development of new anti-amoebic agents.	Jamia Millia University, New Delhi. (2004-05).

S. No.	Project Title	Institute/Industry Name – Beneficiary (Financial year)
16.	Scientific evaluation of safety and efficacy profile of novel molecules from the marine herbals for drug development in the management of Malaria.	Manonmanium Sundernar University, Thirunelvelli (2005-06).
17.	Scientific evaluation of safety and efficacy profile of an Ayurvedic Herbal Formulation (AR7) in the Management of Rheumatoid arthritis.	Sri Ramachandra University, Chennai (2005-06).
18.	Studies on the Bioavailability, toxicity, safety and characterization of Bhasmas produced by traditional and modern manufacturing processes.	Indian Institute of Chemical Technology, Hyderabad (2005-06).
19.	Isolation, molecular characterization and biological evaluation of anti-diabetic principle(s) from a few Indian medicinal plants.	Visva Bharati, Santiniketan / IICB, Kolkata (2006-07).
20.	Development of drugs for the medical therapy of diabetic retinopathy using natural products.	DIPSAR, New Delhi (2006-07).
21.	*In vivo* standardization of a Siddha herbal formula for obesity.	SASTRA University, Thanjavur (2007 – 08).
22.	Development of Mechanism based Antidiabetic Formulation, Standardization from Indian Traditional Herbs viz., Bioavailability, Stability studies.	Karpagam Arts and Science College, Coimbatore (2008 - 09).
23.	Standardization, validation and development of herbal formulation for the treatment of neuropathic pain.	PSG College of Pharmacy, Coimbatore (2008 - 09).
24.	Development, standardization and safety of a poly-herbal formulation in the management of obesity associated hyperlipidemia.	Sri Ramachandra University, Chennai (2008 - 09).
25.	Antiaging and anti - wrinkle formulation with matrix metalloproteinase inhibitory activity from natural resources.	Jadavpur University, Kolkata (2009- 10).
26.	Design, development and pharmacological evaluation of novel topical aerosol spray of anti-artiritic herbs used in traditional practices.	KMCH College of Pharmacy, Coimbatore (2009-10).
27.	Isolation and characterization of safer and potent antiviral components from few potential medicinal plants to effectively treat and control infections of Human Herpes Virus-1 (Herpes Simplex Virus-1), Human Herpes Virus-2 (Herpes Simplex Virus-2) and Human Herpes Virus-3 (Varicella Zoster Virus) *in vitro* & *in vivo* studies.	Presidency College, Chennai/ IIIM, Jammu/ TANUVAS, Chennai (2009 –10).
ii)	Facility Projects	
28.	National facility for analysis of herbo-metallic products.	Indian Institute of Chemical Technology, Hyderabad (2005-06).
29.	Establishment of facility for identification, chemical characterization, standardization and quality control of medicinal plants found in tribal area in Central India.	Banaras Hindu University, Varanasi (2007-08).

S. No.	Project Title	Institute/Industry Name – Beneficiary (Financial year)
30.	GMP Pilot Plant for extraction, formulation and packaging of traditional (ISM) Herbal Medicinal Formulations.	Indian Institute of Integrative Medicine, Jammu (2007-08).
31.	National facility for the development of Herbo-metallic preparations of Ayurveda, Siddha and Unani.	SASTRA University, Thanjavur (2008-09).
32.	National R&D facility for Rasayana Products in Indian systems of Medicine.	Foundation for Revitalization of Local Health Traditions, Bengaluru (2009-10).
(iii)	Loan Projects	
33.	Development of a novel formulation for the prevention and management of coronary heart disease by using tribal plants and development of a novel formulation for the prevention and management of neuro-degenerative disorders by utilizing herbal plants found in tribal locality of Vindhya and Satpura Hills.	Tulsi Ayurvedic Products & Research Pvt. Ltd., Bhadohi (2005-06).
34.	Development of a standardized herbal product for management of Non Insulin dependent Diabetes Mellitus (NIDDM).	Natural Remedies Pvt. Ltd., Bengaluru (2005-06).
35.	Development of quality herbal formulation (R06A) and its scientific validation for the management of Renal Calculi.	Rumi Herbals Pvt. Ltd., Chennai (2005-06).
36.	Development of an indigenous immunirestorative herbal formulation - Jyoti Amritum for HIV/AIDS.	M/s Thirteen Herbs & Cure Pvt. Ltd., New Delhi (2007-08).

Annexure-III

Questionnaire relating to Clinical Research issued to CCRAS and CCRUM

Q.1. In the last 10 years which top (best 5-6) research projects undertaken by the Council have led to the identification of products which were in the view of the Council able to provide mitigation or cure from a specified medical condition?

(a) Name each such product and indicate the date on which a patent was filed or has still to be filed. If the patent has not been filed, please indicate the present position.

(b) Indicate the place/places where the research was undertaken separately for each such product, the number of patients who were treated and the reason why the product is considered as being more "successful" in terms of the outcome, than other medically oriented research studies undertaken over the last 10 years.

(c) Indicate briefly a description of the medical condition/disease for which the product was found useful and give an idea of the extent of such usefulness and the basis on which the conclusion about such usefulness has been decided.

(d) Indicate the reason why the patent applied for may not have been granted along with the date of filing of the patent and the efforts made to undo any shortcomings pointed out by the patent granting authority. Also indicate reasons for not filing for patent in case the product falls among the most successful outcomes of research conducted by the Council.

(e) (i) How many patients have been treated, centre wise using this product/treatment regimen.

(ii) What steps have been taken to make practitioners aware about the usefulness of the product? Are the products being made available to practitioners other than the centres run by the Council?

(iii) What has been the response of the practitioners and on what basis is the response being given? (Were the practitioners asked orally or is it by virtue of repeated orders being placed or any other reason?)

(f) The ultimate aim of the biomedical research undertaken by the Council is to give leads to industry so that they can use the research work done to manufacture and market the products for the benefit of the public on a wider scale. If the leads identified by the Council have not been made available to industry then how has the principle of cost effectiveness been satisfied if the product is only being used at limited centres run by the Council?

Q-2. What better system would the Council like to suggest for improving the offtake of the most promising products which have been identified as a result of research?

Q-3. In respect of each product please indicate whether there are any issues of availability of raw drugs, standardization which would make bulk manufacture difficult?

Annexure-IV

Letter sent by the PI to Experts relating to a new Approach to Clinical Research

Date: December 6, 2010.

Subject: New Approach to Clinical Research

Dear All,

I have been in touch with some of you during the last few months. With some others I'm touching base after several years. I'm therefore sending a generic letter about which I have held a discussion with some of you.

Around six months ago, the Joint Secretary in the Department of AYUSH Shri DD Sharma had written to you about a project that I have undertaken relating to the benefits that traditional medicine (Ayurveda, Unani and Siddha Systems) have given the people and the gaps that need to be filled when the 12th plan is formulated.

In the last few months I have been trying to talk to as many persons as possible to understand developments that have taken place in the areas of research, education, practice, drug standardisation, quality control and availability of products – all from the point of view of specific benefits that have accrued to the public through projects supported by government or as a part of individual effort.

In the area of research I have been in touch with ICMR, Department of S & T, CSIR, DBT, CCRAS and CCRUM. Undoubtedly the efforts made by different organisations have been commendable but seen from the point of view of products and services that have been made available to a wider public, the outcomes are small. A lot of effort has gone into trying to standardise the ASU drug, and to use it either for clinical research or for identifying the active principles. Considerable work has also been done on medicinal plants but again the direct benefits that the public have received have been largely undefinable.

At this point due to increase in life expectancy, the large-scale growth of non-communicable diseases exacerbated by lifestyle changes, pollution of the environment and the stress of modern living, people have to live with disease, pain and impairment for long years. Debilitating conditions caused by arthritis, diabetes, hypertension, the aftermath of accidents and stroke and a host of gynaecological conditions have left a kind of public searching for alternatives and adjuvants from alternative medicine. More and more people are willing to opt for ASU treatment but since they belong to an educated class they insist on understanding the basics of what goes into the making of the medicine; they would like to be assured that there are no impermissible substances and that harmful and toxic substances are not present. They would also like to be assured about the competencies and skills of the practitioner. Except for a few clinicians and products manufactured by highly reputable pharmacies, the general picture is not inspiring.

The irony is that on the one hand the states licence hundreds of ASU products as medicine and the preparation of the pharmacopoeias to ensure standardisation is given high priority. The products are actually selling in the market as classical drugs or as patent proprietary products and a certain section of the public is accessing them through practitioners or on their own. But in the absence of any quality assurance, a wider public and particularly those who are educated and astute remain curious but suspicious about the products. Even so some are not averse to trying them for chronic conditions provided that there is satisfaction about the credentials of the practitioner and concerns about the quality of medicine — particularly toxicity issues are vouchsafed for.

One of the main problems is that the ingredients are either written in Sanskrit or in botanical terms. While it is true that patients ask no questions about the composition of allopathic drugs, that paradigm does not apply to ASU products where the drugs have not gone through the conventional route of research. The consumer demands to know what the constituents are and he is not impressed with either rhetoric or emotion.

While decades have been spent in trying to standardise ASU medicine in the hope that one day the products will be used by industry and will be mainstreamed into medical practice, the evidence is that this

has not happened. In trying to register efficacy and safety through randomised controlled trials (RCTs), the ASU approaches to determining the prakriti or temperament of the patient have been abandoned. Many promising openings have had to be discarded before reaching the phase 3 trial stage. Even where one or two products were identified after completing all the rigours of research following modern medicine parameters the products were not touched by industry. If we continue to do more of this kind of research, it is not going to benefit society. Lamenting the non-availability of quality raw material will also not satisfy the public. The cultivation of medicinal plants and the certification of plants obtained from the forest is a laudable goal but we all know how difficult it is to put it into action notwithstanding the efforts made by NMPB.

And yet we claim that ASU has something to offer whether as a stand-alone therapy or as an adjuvant or adjunct. This claim has to be put to the test in a way that the public benefits directly and it is time that we thought of doing things differently. For doing so we need to change track and allow the physician to treat the patient in an individualistic, holistic way and find a way of judging outcomes through a comparison of medical parameters of similarly diagnosed patients having a similar level of impairment or illness who have been treated through the allopathic system. The choice of patients should be through voluntary option given in the OPDs of allopathic hospital departments and the choice should be left to the patient whether to opt for allopathic treatment or ASU treatment. No referrals need be sought. Detailed counselling should be undertaken to convince the patients that he would be partaking in a research study using ASU medication and the credentials of the practitioner, the oversight mechanisms, concerns about the quality of the medicine and the ingredients used should all be answered during the counselling session. The specifics of treatment would need to be answered by the treating physician once the research commences.

The protocol should require rigorous independent monitoring of parameters by a multi-disciplinary group, again overseen by a higher body to see that there has been no bias.One hundred Rheumatoid Arthritis (RA) or Osteo Arthritis (OA) patients from allopathic clinics and 100 patients that opt for ASU treatment can be treated – the latter individualistically by the ASU practitioner. The oversight body having multidisciplinary experts would examine the developments relating to agreed parameters to observe the degree of improvement or absence of improvement. The protocol for ASU treatment should permit the physician to modify and alter the drugs depending on factors like age, sex and the presence of other conditions.

Standardisation of the ASU drugs already in the market should not be insisted upon but the toxicology of each of the contents/applications should be got done to exclude non-permissible substances. In the first instance non-bhasma products may be used but when the law permits the use of medicines containing metals and minerals, the patient should be counselled about the ingredients and such formulations may be administered only if the patient opts for the same. No ethical issue would come into play as the drugs would be as referred to in the classical texts and following the pharmacological requirements and are already licenced and available in the market. They would be administered by the Ayurvedic physician and a record of the treatment would be maintained to be overseen by the two multidisciplinary monitoring committees referred to earlier.

I would be grateful for your guidance as to whether this approach has any validity and whether you would be able to suggest the skeleton of a protocol which involves all the disciplines that would be needed to examine the parameters of the patient and to comment upon the outcomes.

The idea is in its nascency. It has not been fleshed out and nor has it been discussed with experts other than all of you. I'm hoping that as an old friend and a person interested in the development of ASU medicine you would guide me with frankness and also correct me if I have committed a gaffe. I would be happy to include what you have to say in the Report that I'm writing. If you disagree with the approach or would like to make a different kind of suggestion I would be only too happy to refer to your point of view.

Regards,

Shailaja Chandra