

**Key discussions and takeaways from
webinar on**

**“Clinical Research in AYUSH-
Challenges and Opportunities”**

**of Innovative Thought Forum (ITF),
Arogya Bharati (AB), LM College of
Pharmacy (LMCP) and AIC-LMCP**

19th June 2020

Programme

- Welcome and introduction by Mr S B Dangayach, Founder Trustee, ITF and National Vice President, Arogya Bharati
- Opening remarks by Dr Ramesh Gautam, Karyadhyaksh, Arogya Bharati
- Setting the stage by Padmashri Dr V Prakash, Former Director, CFTRI and distinguished scientist
- Perspective on framework of clinical trials in India in AYUSH by Dr N N Mehrotra, Former Addl Director, CDRI, Founder Director, CSE and Jeevaniya
- How to adapt and accelerate clinical trials in Ayurveda by Dr Indraneel Basu M D (Medicine), PGCD (Diabetology), Leading investigator of clinical trials, President- Arogya Bharati Kashi Prant
- Clinical trials in Homoeopathy- challenges and opportunities by Dr R K Manchanda, Director, AYUSH, Govt of Delhi and former Director General, CCRH
- Innovation aspects of clinical trials in AYUSH by Dr Arun Maseeh Senior Vice President Medical Services, Troikaa Pharma Ltd, Ahmedabad, India with over 20 years of experience in senior positions in clinical research and medical affairs
- Adaptation of best practices of clinical trials applied in Modern Medicine for AYUSH by Dr Shivprakash Rathnam Founder of Synchron Research Services Pvt. Ltd. a CRO in 1998 - Synchron is the first CRO in India in Private Sector Founder of INTERVEIN, a central lab for clinical trials in 2006. Founder of Avance Phytotherapies in 2007 for alternative therapies for neglected diseases.
- Bridging the gap between clinical trials for modern medicine and AYUSH by Mr Bharat Doshi CEO & Founder; BioDev Services (an R&D management organization, providing solutions & services that make BioPharma R&D efficient & effective)
- My journey of clinical trials with AYUSH by Dr Lal Hingorani, Founder, Pharmanza Herbs Pvt Ltd and leading authority on herbal research New vistas in clinical trials for entrepreneurs by Dr Shrinivas Savle, CEO, AIC- LMCP
- Closing remarks and road ahead by Padmashri Dr V Prakash, Former Director, CFTRI

Important Points

- For Ayurveda, Siddha and Unani (ASU) or collectively called Indian system of medicine, separate rules for clinical trials framed by CCRAS
- Homoeopathy not having separate rules .Required to follow rules for Allopathy. New drugs and clinical trial rules, 2019 applicable to Homoeopathy by default despite basic difference in allopathy and Homoeopathy
- All clinical trial proposals for AYUSH to be submitted to CTRI under MOHFW. Thus MOHFW and ICMR final arbiter with AYUSH playing a subordinate role
- Inertia in ASU for clinical trials owing to most producers depending on classical approved books and lack of ecosystem for innovation all through. Similar situation in Homoeopathy

- Research, development and trials in Traditional Chinese medicine (TCM) backed by the Govt of China. Lot of activity resulting in mainstreaming of TCM even in Corona pandemic with around 85 per cent patients treated with TCM
- In house research and trials limited to a few companies .Contract research organisations (CRO's)not active for AYUSH. Govt efforts under projects like “Golden triangle” unproductive
- CCRAS guidelines found very cumbersome and costly. Not many enterprises or individuals keen due to poor returns on investment to be made on the trials
- Successful work by a few companies like Troikaa Pharma Ltd NasoB12 bio availability studies in randomized double blind comparative crossover study
- Not many people aware about Himalaya Drug Company, maker of Ayurvedic and herbal research products with annual business of Rs 2500 crores. Opportunities really huge for new entreps
- Clinical trials comprise a large variety of studies from simple to complex .Due to overall lack of awareness even simple trials or studies not pursued by most in field of AYUSH
- National Institute of Health (NIH) supported efforts of Dr P Banerjee to evolve protocols for many serious diseases like cancer. These accepted in many countries but not in India. Need for an objective look at them in India
- Some simple studies like by Dr Dean Ornish for reversing heart disease accepted by even insurance companies in U S A. But not accepted in India
- Attempts made to integrate Allopathy and AYUSH tried by CSIR,ICMR and AYUSH under “golden triangle” project with poor outcomes
- Ayurveda and Homoeopathy educational institutes neither inclined nor equipped to instil a desire among practitioners to support scientific documentation or trials or research
- Even after independence, Indian system of medicine and Homoeopathy always given little importance both in public and private healthcare. Most funds and attention dedicated to modern medicine or allopathy with emphasis on curative
- Promotive and preventive parts relegated to a nominal status. Public health made a part of several other ministries with Health ministry mainly driving curative part
- Good opportunities for treatment of several rare diseases where allopathic companies not interested or incapable. Success achieved by a few innovative entrepreneurs like Dr Shivprakash Rathnam in Alzheimer’s disease
- Likewise great opportunity in nutraceuticals with proper trials, research and quality production both in international and local markets by entrepreneurs like Dr Lal Hingorani
- Consumers demanding evidence for wide acceptance, big markets for AYUSH formulations backed by suitable evidence based studies
- Support now available from likes of Atal Incubation Centre at LMCP on all counts. Initial funding and mentorship available from many quarters

Key Takeaways

- Need to create set of rules for new Homoeopathic drugs and clinical trials that will reflect unique features and principles of Homoeopathy
- Need to review and recast rules in respect of Ayurveda, Siddha and Unani (ASU) to make them consonant with unique characteristics of these sciences
- Urge government to earmark proportionate funds for research ,developments and trials in AYUSH for curative as well as use for promotive and preventive aspects
- Sensitise all the educational institutes for AYUSH to give importance to documentation and evidence building in their practices
- Create a demand for clinical trials for all new drugs for supporting an ecosystem for CRO's in AYUSH
- Learn from success of companies like Himalaya Drug, Patanjali etc for creating and tapping huge business opportunities all over the world
- Create a positive image of AYUSH through rational clinical trials and evidences
- Look at unserved rare diseases or orphan diseases for successful results through AYUSH
- Motivate current allopathy based CRO's to look at AYUSH as a sunrise sector the moment proper trials are done
- Track CAM in other countries know clinical trial protocols that they have been following
- Learn from TCM trials in China for COVID19
- Design innovative study models for meeting desired objectives in a holistic ,cost effective and time effective manner
- Create an autonomous framework for AYUSH due to lack of competency in it of ICMR, DGCI and others meant for biomedical or allopathic sector
- Keeping outcomes similar ,work for progress of each science on it's merits and strengths with proportionate policy and fund support
- Need to be customer or market centric in all aspects to expand universe of AYUSH

Actionable Points

1. Prepare new homeopathic drug and clinical trial rules that are simple and capture unique features of the science
2. Attract ASU companies to carry out simple clinical trial projects meeting end goals while simplifying rules in line with unique characteristics of ASU
3. Thrust to patient centric trials and studies for cost and time effective solutions
4. Create big data and registry of clinical trials in open source mode supported by proper documentation

5. Supporting clinical trial outfits for AYUSH and creating demand for such activities

Legend

ASU- Ayurveda, Siddha and Unani

CCRAS-Central council of research in Ayurvedic sciences

AYUSH- Ayurveda, Yoga and naturopathy, Unani, Siddha and Homoeopathy

CTRI- Clinical trial registry of India

MOHFW- Min of health and family welfare

ICMR- Indian council of medical research

TCM- Traditional Chinese medicine

CSIR- Council of scientific and industrial research

CRO- Contract research organisation

CAM- Complementary and alternative medicines

DCGI- Drug controller general of India

YouTube link

Part: <https://youtu.be/MSLvqt0yP5w>

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