

**Celebrating 15
Glorious Years!!**

Research @ Jehangir

Volume 7, Number 7 |

30th January 2022 |

Periodic Newsletter



Recent Updates

- Completed enrollment of **1,600** participants in **2 months across 10 hospitals** for a medical device study for prevention of COVID-19. Study is **entirely virtual** using e-Consent, e-Diary & e-TMF.
- Initiated a Clinical Data Management project for a **Phase 2 study of 676 patients** with Dengue Fever involving **36 Hospitals** across India
- Completed a 6 month study on Nutritional supplementation in children aged between 3.9 to 6 years. **Enrolled 140 participants** within **5 weeks** during the pandemic.
- Successfully completed a **US FDA virtual inspection** for a Dermatology study. **Zero Non conformities** or 483s recorded.
- Completed a specialized **Medical Writing** assignment for a large FMCG company wherein **literature review** and reporting in **Common Technical Document (CTD)** format was done to substantiate 15 claims on established functions of **5 nutrients**.
- Jehangir Centre for Learning (JCL) has signed **MoUs** with reputed institutions such as **MIT World Peace University, Sinhadag Group of Colleges** etc. Moreover JCL has enrolled over **150 students** for courses in Clinical Research in 2021
- Linq Labs completed **3 bio-banking projects** in Primary membranous nephropathy, Non-alcoholic steatohepatitis and in Renal Cell Carcinoma within the agreed timelines.
- JCDC has been granted **re-accreditation** by AAHRPP for a further period of **5 years**.
- Collaboration with an **Electronic Trial Master File Service (eTMF)** provider for managing TMF documents on real-time and bring efficiencies of remote monitoring & real-time oversight
- JCDC conducted an **investigator initiated study** on Cerebral Venous Sinus Thrombosis (CVST) conducted by **Poona Vascular Group** (10 eminent neurologists led by Dr. Pradeep Divate). The study got published in **JAPI**. 2021 Sep;69(9):11-12. PMID: 34585885



Publications

- Partha Basu, MD, Sylla G Malvi, PhD, Smita Joshi, PhD, Neerja Bhatla, MD, Richard Muwonge, PhD, Eric Lucas, MSc et al., Vaccine efficacy against persistent human papillomavirus (HPV) 16/18 infection at 10 years after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicentre, prospective, cohort study. **Lancet Oncology** VOLUME 22, ISSUE 11, P1518-1529, NOVEMBER 01, 2021
- Khadilkar A, Dhongade A, Agrawal N. Impact of Oral Nutritional Supplement on Growth, Nutrient Intake and Frequency of Illness in Children aged 4-6 years: A Randomised Controlled Study. *Journal of Clinical and Diagnostic Research*. 2021 Nov, Vol-15(11): 11-16. DOI: 10.7860/JCDR/2021/49599.15605
- Oza C, Khadilkar V, Karguppihar M, Ladkat D, Gondhalekar K, Shah N, Khadilkar A. Prevalence of metabolic syndrome and predictors of metabolic risk in Indian children, adolescents and youth with type 1 diabetes mellitus. *Endocrine*. 2021 Nov 5. DOI 10.1007/s12020-021-02924-6. Online ahead of print. *Endocrine*. 2021. PMID: 34741238
- Khanna D, Yalawar M, Saibaba PV, Bhatnagar S, Ghosh A, Jog P, Khadilkar AV, Kishore B, Paruchuri AK, Pote PD, Mandyam RD, Shinde S, Shah A, Huynh DTT. Oral Nutritional Supplementation Improves Growth in Children at Malnutrition Risk and with Picky Eating Behavior. *Nutrients* 2021
- Zengin A, Kulkarni B, Khadilkar AV, Kajale N, Ekbote V, Tandon N, Bhargava SK, Sachdev HS, Sinha S, Scott D, Kinra S, Fall CHD, Ebeling PR. Prevalence of Sarcopenia and Relationships Between Muscle and Bone in Indian Men and Women. *Calcif Tissue Int*. 2021 May 9. DOI: 10.1007/s00223-021-00860-1. Epub ahead of print PMID: 33966094.

Picture Gallery



Linq Labs New Office in Camp



MoU signing with MIT WPU



MoU signing Sinhadag group



Staff Party Oct 2021

Medical Devices- A New Frontier

New Indian regulatory environment conducive to rapid growth and development



Dr. Ravindra Ghooi

Chief Scientific Advisor, Chairman Ethics Committee, JCDC

A robust health system has numerous components, with drugs being the most widely known one. The Covid pandemic brought two other components in focus, they were devices and diagnostics. When faced with a hitherto unknown pathogen, the man on the street began talking about different diagnostic kits, and when the infection wave peaked, about respirators and oxygenation equipment. Though in use for over hundreds of years, the importance of devices became appreciated widely only recently.

Drug regulation began in the country with the passing of Drug and Cosmetics Acts and Rules thereunder, in 1940 and 1945, but comprehensive Device rules appeared only in 2018. As a result, there has been very little development and testing of devices. Development of drugs and drug trials have overshadowed the device industry for long. The Clinical Trial registry of India (www.ctri.nic.in) lists only 690 device trials among the 20,000 plus clinical trials registered since its inception.

With the formulation of Medical Device Rules, there is greater interest in devices and their trials have started rising in the country. There are other reasons for increased interest in local development devices too, lower input requirement and government support. Development of a new drug is a long and arduous process, requiring over a decade's effort of a large multidisciplinary team and costing almost 2 billion dollars. Device development however, can be accomplished by a small dedicated team and takes just a couple of years with an input of less than a million dollars.

In addition to the Ministry of Science and Technology, many Institutes are at the forefront supporting development of both drugs and devices, but for reasons enumerated earlier the focus is on devices. Our country has already established a leadership in Information Technology, machine learning and artificial intelligence is an extension of the same. With these technologies, Indian devices should gain international recognition. With more medical devices being developed in our country, the dependence on imports will reduce and as with drugs, India might become a major device exporting country.



JCDC has been involved in validation studies for various medical devices

such as needle free injections, bone grafting technology, Alternative to N95 masks, smart watches, self-sampling kit for cervical cancer screening, Breath analyzer for cancer screening, device for cure of Carpal tunnel syndrome etc.

Contact Us

For any ideas, suggestions, feedback please do not hesitate to contact us

JCDC: www.jcdc.co.in
JCL: www.jclindia.co.in

Linq Labs: www.linqlabs.com
HCJMRI: www.hcjmri.org.in

Social:    