

Research @ Jehangir

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Quarterly Newsletter

Recent Updates

- JCDC has signed a **Sister Institution Relationship Agreement** with a major cancer hospital and research center in **Pennsylvania, USA**. Through this arrangement the two institutions will focus on Clinical Research collaborations which includes diagnosis, treatment, prevention, & scientific research in Cancer.
- Exceeded the enrolment target for recombinant **BCG vaccine** study for COVID-19 among High-Risk Subjects (CTRI/2020/04/024749) by enrolling **236 subjects**.
- At our Linq Labs bio-repository, we now have an inventory of approximately **10,000 Formalin Fixed Paraffin Embedded (FFPE)** tissue bio-specimens. All major cancer types i.e. Breast, oral, ovarian, colorectal cancer etc. are covered. For more details of our bio-repository please visit linqlabs.com/bio-bank
- At JCL, we have completed our **25th batch** of Post Graduate Diploma in Clinical Research. This batch has successfully been completed **virtually**.

Conducting RWE (Real World Evidence) Study during Pandemic

Task Force for Repurposing of Drugs for COVID-19 and Venture Centre, Pune commissioned a **Real World data** study named TRAC (CTRI/2020/05/025371) to understand the disease course and current treatments in use for COVID-19 in Pune. JCDC was selected as the designated ethics committee and CRO partner for the TRAC study. We are proud to share that we collected data from **500 patient files** from different hospitals in Pune within a short span of **2 months**. JCDC not only ensured the efficient data collection but also supported ethics committee approval, electronic case record form management and quality control for this study. JCDC has now begun work for the next cohort of 500 patients from various hospital in Pune with an aim to complete a total of **1,000 patient files by October 2020**.

We hope the results of TRAC study will give us useful information to prioritise drugs for further clinical research and also determine efficient clinical trial designs for COVID-19 in India



Publications

- Kajale NA, Patel PP, Khadilkar AV, Khadilkar V, Chiplonkar SA. Cardiometabolic Risk in Pre- and Post-Menopausal Women with Special Reference to Insulin Resistance: A Cross-Sectional Study. J Midlife Health. 2020 Jan-Mar; 11(1): 22-26. doi: 10.4103/ jmh.JMH_65_19. Epub 2020 May4. PMID:32684723
- Prevalence and factors associated with anemia in 6–18 years urban and rural Indian children and adolescents: A multicentre study. Indian J Child Health 2020; July 01
- Khadilkar V, Lohiya N, Chiplonkar S, Khadilkar A. Body Mass Index Quick Screening Tool for IAP 2015 with Charts [published online ahead of print, 2020 Jun 12]. Indian Pediatr. 2020;S097475591600197.
- Shah N, Khadilkar A, Gondhalekar K, Khadilkar V. Prevalence of Dyslipidemia in Indian Children with Poorly Controlled Type 1 Diabetes Mellitus [published online ahead of print, 2020 Jun 7].

Gearing up for the Oxford Covid19 Vaccine trial

It is our honour to partner with the Indian Council of Medical Research (ICMR) and Serum Institute as a centre for the prestigious Oxford Covid-19 vaccine study. (CTRI / 2020 / 08 / 027170).



Sir Cowasji Jehangir Bt.
 Chairman of Jehangir Hospital

“ As a gesture and our contribution to society we will conduct this study at our center for no charge i.e. pro bono. We will be waiving all professional fees for conducting the study

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We thank all of you for your overwhelming response and wishes for the success of this prestigious study. We are committed to do our best for this important project.

Managing Clinical Trials during a Pandemic



Publications

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- Shah N, Ekbote V, Khadilkar V, Khadilkar A. Distortion of dual energy X-ray images by faecal masses in a child with type 1 diabetes. *BMJ Case Rep.* 2020;13(5):e235312. Published 2020 May 21. doi:10.1136/bcr-2020-235312
- Shah N, Khadilkar A, Khadilkar V, Lad S. Rare association of Beckwith-Wiedemann syndrome with Hirschsprung's disease in an infant with hypoglycemia. *BMJ Case Rep.* 2020 Apr 26;13(4). pii: e235121. doi: 10.1136/bcr-2020-235121. PubMed PMID: 32341092.
- Kajale N, Khadilkar A, Mandlik R, Khadilkar V. Serum Cathelicidin Concentrations in Healthy Rural Indian School Going Children. *Indian J Pediatr.* 2020 Apr 15. doi: 10.1007/s12098-020-03291-2. [Epub ahead of print] PubMed PMID: 32297131.



Virtual EC meetings

During the Covid-19 pandemic and lockdown, JCDC Ethics committee has adopted a virtual model and as a result there was no impact on the functioning of the Ethics committee. Following are some of the highlights:

- Conduct of Ethics committee meetings using video-conferencing facilities. We have invested in an enterprise version of a video conferencing service to make this possible
- Screen sharing options used for presentation to the EC members during the EC meeting
- All Ethics committee submissions and communication done electronically
- Ethics committee members cast their voting electronically

The pandemic has fast tracked the Ethics committee function to an almost paperless and virtual working style.



Virtual Informed Consent

Until very recently conducting a virtual clinical trial was only seen as a promising future, but the ongoing COVID-19 pandemic has compelled the clinical trial industry and regulatory bodies to think about this. To complete ongoing clinical trials and to initiate new trials, ICMR and even FDA has drafted a guidance on conducting clinical trials of medical products during COVID-19 Public Health Emergency¹. One of the clauses of this guidance, Section 4.2 allows for obtaining an electronic/virtual informed consent from the study participants.

In this rapidly changing scenario, we at JCDC have adopted electronic informed consents from study participants without compromising on their rights and safety. As a part of our continuity plan, we are now equipped to obtain virtual consents especially in non-COVID trials, which are to initiate in near future.

Reference: 1. https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf

Can virtual Clinical Trials become the new normal?

Conducting clinical trials during the pandemic has forced us to contemplate if virtual clinical trial conduct can become the new normal. At JCDC, we managed to conduct several study activities virtually, although we did face certain challenges.

Study activities which could be conducted virtually

- Study startup processes, including feasibility completion, site qualification & initiation, Clinical Trial agreements, Ethics committee submissions etc.
- Site staff trainings and evaluations
- Subjects visits through video and telephone calls / home visits
- Investigational Product (IP) couriered to subjects' residence
- Monitoring of the Study IP using Continuous temperature monitoring devices
- Virtual Monitoring Visits using secure shared drive platform

Challenges

- Subjects unwilling to come to the hospital for study visits
- Difficulty in conducting investigations which need to be done at site like CT scans, MRI etc.
- Staff challenges due to quarantine and illnesses

Contact Us

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

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