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Research Involvemnt :
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Co Investigator : Zinc Sepsis Trial III
PI : Cholera Vaccine Trial III

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Conducting a phase III clinical trial in children during the COVID- 19 pandemic: Experience and lessons learnt from a clinical research facility of Nepal

Investigator Team:

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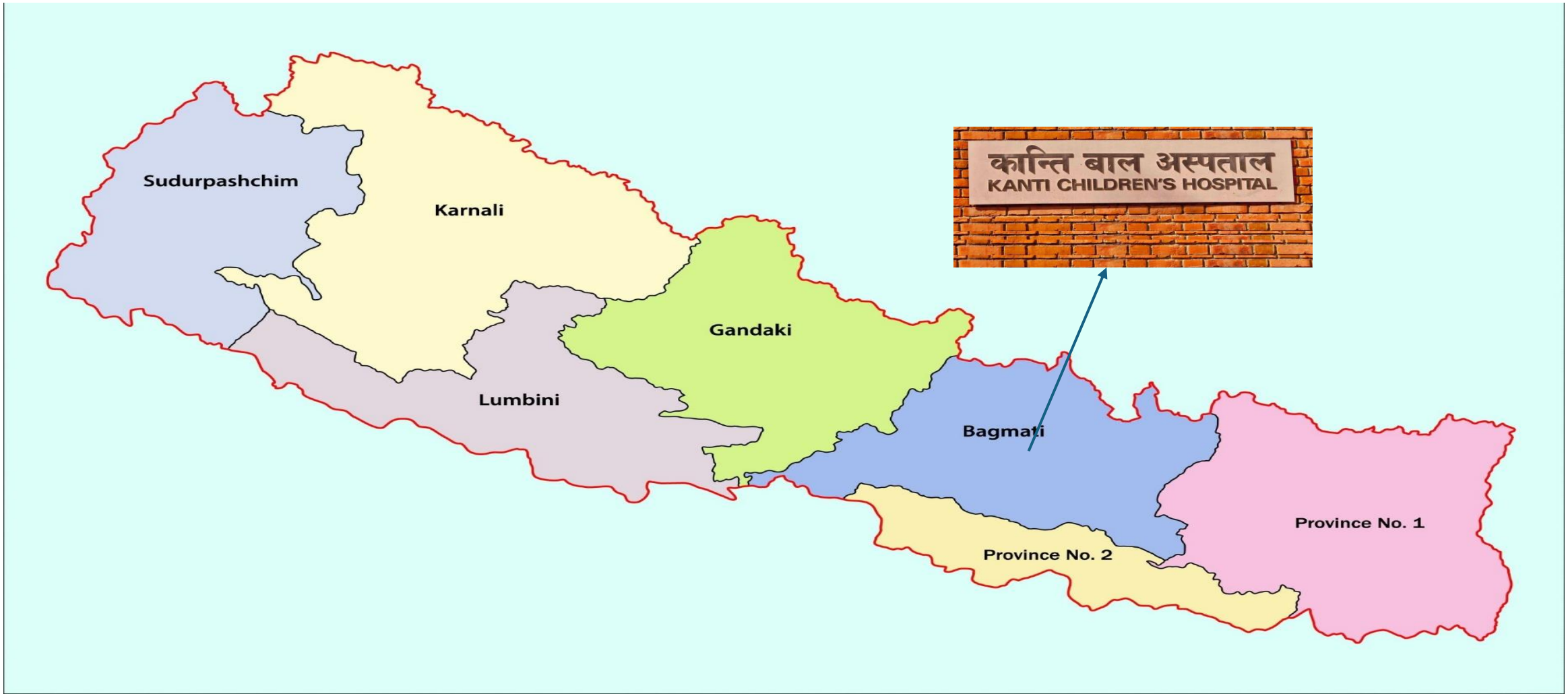
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KANTI CHILDREN'S HOSPITAL

Background

- Clinical trials in humans are vital to test safety and efficacy of new interventions
- complexity in case of children
  - related regulatory guidelines,
  - stringent time frame
  - financial burden

Background Cont....

- NIH data: 1
  - about 80% of the clinical trials in the US missed their timelines due to issues on patient's recruitment and enrollment.
  - 11% of clinical research sites failing to enroll even a single participant,
  - 37% of sites under-enrolling,

  Lesson : recruitment strategies must be considered à priori and addressed throughout the duration of the study
- During the COVID-19 pandemic CT became challenging because
  - multiple infection control measures such as social distancing, lock-down of the societies,
  - increased work load of hospital workers

1,*A Paradigm Shift in Patient Recruitment for ClinicalTrials; 2017. Internet source, Available from: http://clinithink.com/wp-content/uploads//2017/01/Clinithink-WhitePaper-012717.pdf.*

Objectives

- to highlight the overall experience and challenges we faced while conducting a new clinical trial on a non- COVID vaccine, at a government children's hospital during the COVID-19 pandemic.

Methods

- ‘A phase III, Multicenter, Observer-blinded, Randomized, Active Controlled Trial to Evaluate Immune Non-inferiority, Safety and Lot-to-Lot Consistency of Oral Cholera Vaccine Simplified Compared to Shanchol TM in 1– 40 years old healthy Nepalese Participants,’ was planned with a sample size of 2530 in Nepal.
- This study was conducted at four sites in Nepal over a period of 20 months.
- We focused on experiences from Kanti children’s hospital site where we recruited and followed 632 children from age strata 1 year to 14 years, from October 2021 to June 2022, after securing all required regulatory and ethical approval in Kanti children hospital and Nepal.

Experinces (Findings)

Preparation for clinical trial

- Social distancing was maintained in all the rooms,
- each room equipped with hand sanitizers and wash basins.
- Only one participant with her or his parents was allowed in at a time in each room.
- All participants and staffs used the PPE as per WHO guidelines.
- Number of unscheduled visits was supposed to be less asper travel constrains.

- increased the cost and spaces

Regulatory and ethical consideration:

- New enforcement of law regarding Vaccine trials

- study team had multiple consultations with the Council of Ministers and the Ministry of Health and Population
- lengthened with additional ‘steps’ that were required before the trial could be started

Training, Staff and participant Recruitment

• **The GCP training was conducted virtually. Some others were conducted inperson.** • **The training was extended to potential back-up staff making the number of trainees double the number of required staffs.**	• **The combination of the initial virtual training and physical on-site training later on, proved to be an effective method.** • **More staffs**
• Recruitment of trial participants: • The potential participants were contacted with phone and the information was shared about the Participant information sheet. • They were called as per appointment. • Gordians does not want to loose their kids school	• The Trial site was opened for extra hour and school holidays.

Consent

• The written consent was practiced	• but it was perceived to have verbal and visual consent would be enough.

Communication with site staffs and stakeholders

• In the setting of a pandemic, the face-to-face communication between site staff, the sponsors and Clinical Research Organization (CRO) may be affected, especially in cases of multicentric clinical trials. • Scanned copies of formal letters were sent via email. • We had to physically visit the office of National Health Research Council (NHRC), a regulatory body of research, to receive acknowledgments of various documents submitted to during the trial, which could have easily been replaced by providing“auto-reply” to the e-mail sent, or by establishing an ad-hoc web portal.	Scope of improvemt

Retention and safety follow up

- As provisioned by the protocol, safety follow ups could be done either by telephone calls or through home visits by a site staff.
- In our study, all safety follow ups were performed through telephone calls by a medically qualified study staff and home visits were completely avoided

. In a pandemic situation, a flexible study protocol which allows various ways of follow ups of participants helps to minimize follow up loss or protocol deviations.

Conclusion

- Adjustments in trial site opening and closing time, lengthy regulatory clearances, the modification of physical infrastructure of trial sites, special consideration in preparing extra human resources, increased virtual communication from training to reporting and increased trial cost are the main factors and observations we observed during this trial.

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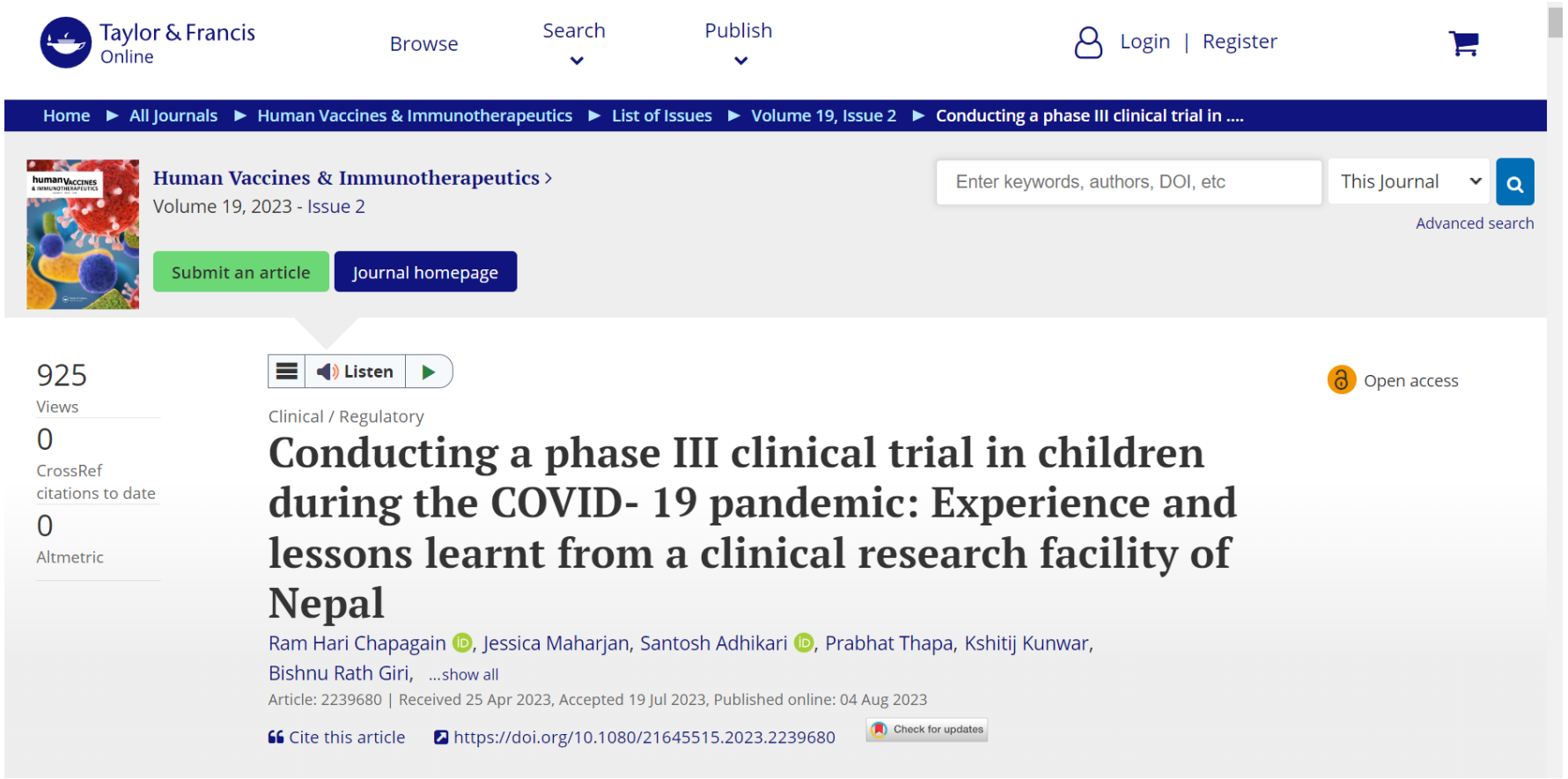

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