

MEETING MINUTES
INCLLEN Board of Trustees Meeting
Virtual Meeting
December 11-12, 2020
Participants**Board Members:**

Marcel Tanner (MT) - Chairperson & Presiding Officer;
 Virander Singh Chauhan (VSC); K Srinath Reddy (KSR);
 C N Raghupathi (CNR); Jiyao Wang (JW); S Ghosh C (SGC);

RAB Members:

Francois Chapuis (FC), Hesham Fathey El-Sayed (HES), Peter Tugwell (PT),
 Srikant Bagdiwala (SB)

Regrets:

RAB members: Carlos G Restrepo (CGR)
(Representing on BOT)

Secretariat:

Narendra K Arora (NKA); Manoj K Das (MKD); Sanjay Aggarwal (SA),
 Divya Nair (DN) and Abhishek Agarwal (AA)

Board of Trustees (BOT) meeting was called to order at 16:00 Hrs on December 11, 2020 by the Chairperson.

1. Chair's Welcome

- The Chairperson (MT) welcomed all the Board Members, RAB members and Secretariat members to the INCLLEN Board Meeting. The Chair also welcomed Regional Advisory Board (RAB) members as observers and special invitees to the Board meeting.
- Apologies were received from RAB member, CGR, who was unable to attend this year's meeting.
- Chairperson mentioned that we are meeting virtually due to the global COVID pandemic challenge and have to adapt to the new normal status.
- The meeting agenda was reviewed and accepted as proposed.

2. Review of last meeting minutes

- NKA summarized the minutes of the INCLLEN BOT Meeting on June 16-17, 2019. The minutes were reviewed and approved.

3. Action taken report

NKA presented the actions taken on previous year's board decisions.

3.1 IIGH activities

3.1.1 *Program Portfolio:* As per the advice of the Board in 2019, the following activities were undertaken

- Focus of Program Portfolio: As per guidance of Board last year, the focus of the IEO was on vaccine trial preparedness, disease surveillance, digital health and health technology and development of centre for excellence. During the year gone-by several projects on these domains were developed and submitted for funding

- Current Program Status: In last one year, 10 projects were completed, 23 projects are ongoing and 35 new proposals were developed and submitted to various funding agencies. Out of 35 proposals developed, 14 projects have been funded and initiated, 3 proposals accepted and are in pipeline, 4 are still under review and 14 (20%) were rejected.
- 3.1.2 *International Collaborative Research Projects*: During last one year, 3 new multi-country proposals were developed and one new project has initiated:
- HPV epidemiology and vaccine impact (five countries; India, Ethiopia, UK, Australia and Canada) (initiated)
 - Risk factors for mild cognitive impairments among older adults (two countries: India and USA)
 - Against Tuberculosis (three countries: India, Brazil and South Africa)
- 3.1.3. *National network consolidation and expansion*: During last one year, 11 new intra-country multi-institution proposals were developed.
- DDESS site preparedness (ten sites)
 - COVID, Dengue & Chikungunya (six sites)
 - Probiotics in LBW newborn (six sites)
 - NDST for NDD screening (two sites)
 - HPV vaccine impact (three sites)
 - Vaccine confidence and safety (three sites)
 - COVID Implementation Research (three sites)
 - MITS for infant death (four sites in NE region)
 - LaQshya implementation (six states)
 - Malaria research (seven states)
 - Perinatal bereavement (five states)
- 3.1.3 *Expand funding base*: Funding base has been diversified with addition of new projects funded by Indian government funder DBT/BIRAC-India, ICMR, Unicef, and WHO. CSR funds from IBM India and SRS Lifesciences were received.
- 3.1.4 *Capacity building*: There are 3 active PhD students enrolled with one student recently submitted thesis and one new student registered. 9 Interns from various institutes have (NIE-ICMR, Jamia-Hamdard University, IIMR, Amity University, DPSR University) have completed internship.
- 3.1.5 *Developing digital repository*: The digital repository of the completed projects at IEO is available on INCLen website. The access to the repository can be given to CLEN members on request.
- 3.1.6 *Short courses*: The LAMP course for young and midlevel researchers are operational. We are planning to launch online Research Leadership course for young researchers/students
- 3.1.7 *INCLen SOMAARTH DDESS (Demographic Developmental and Environmental Surveillance Sites)*: INCLen has already established SOMAARTH DDESS sites in district Palwal Haryana (2009) and district Bareilly (2019). The third SOMAARTH DDESS site in NE region has been launched in Mawphlang, Shillong (2020). Recognizing the expertise and experience of INCLen, the Department of Biotechnology has entrusted INCLen with facilitating the establishment and handholding of six new DDESS/DHSS in different parts of the country and coordinating research activities at another four DHSS under DBT- National Biopharma Mission.

- 3.1.8 *Communication platform*: The social media and other communication platforms are yet to be initiated.
- 3.1.9 *Newsletter*: Could not be continued due to the on-going COVID-19 challenge
- 3.1.10 *Land procurement*: Put on hold and shall be discussed during the meeting.

3.2 Regulatory compliances

- 3.2.1 *Financial Management process*:
 - As advised by the Board last year, the complementarity between internal and external auditors has been ensured; now every aspect of financial processes are closely scrutinized by at least one of the auditors. Due to COVID situation, the regulatory of both monthly internal and quarterly statutory audit was interrupted.
 - Statutory audit for FY 2019-20 has been completed and tabled for ratification.
- 3.2.2 *Update on Income Tax case (years 2013-14 and 2014-15)*: INCLLEN appealed before Commissioner IT (Appeal); the case was subsequently decided in favour of INCLLEN. The IT Department (Assessing officer) decided to appeal against the decision and has moved to the Tribunal. The hearing is yet to begin.
- 3.2.3 *DSIR (Department of Science and Industrial Research) registration*: the registration as Scientific and Industrial Research organisation (SIRO) has been renewed till 2022.
- 3.2.4 *FCRA (Foreign Currency Regulation Act) registration*: The current FCRA registration is valid through October 31, 2021. As per the new FCRA amendment act 2020, the FCRA bank account needs to be opened in State Bank of India before March 31, 2021.
- 3.2.5 *Anti-sexual Harassment Report*: No case reported during last year.

3.3 Board Matters

- 3.3.1 *Board membership*: Dr N K Ganguly has resigned for personal reasons. In the previous 2 years, Dr Jon Simon and Dr Geeta Sen had resigned. In view of the Trust Bye Laws of the INCLLEN Board, there is need for nominations for new Independent Board Member(s) including 4 Indian members and 2 International members. Additionally, there is also need for rotation of two RAB members on the Board. Board also need to discuss about the transition of Chairperson.

3.4 RAB and Network Activities

- 3.4.1 *Rotation of members of the RAB*: The RAB membership on Board to be done every two years.
- 3.4.2 *Induction of Young Researchers on the RAB*: As discussed in the last Board Meeting, the Regional CLENs committed to nominate Younger members on the RAB who are leading active research and capacity building programs in their respective countries and or regions.

4. Update on Program Activities

4.1 Research activities at IEO

MKD presented the update on the program activities at INCLLEN in the seven research portfolio.

He informed briefly about the 23 ongoing projects with their status. Since last BOT meeting, 14 new projects were initiated. The team developed a total of 35 projects, 14 projects have been funded and initiated, 3 proposals accepted and are in pipeline, 4 are

still under review and 14 (40%) were rejected. Board was briefed about the new proposals developed, projects launched and those completed. In addition, the capacity building activities and publications in the year were shared. The details about the research projects and publications are attached as *Annexure 1 and 2*.

4.2 INCLEN's contribution to COVID 19 Pandemic -Technical support to national and international bodies

INCLEN was heavily solicited to assist in very diverse covid-19-response activities at national and international levels reflected the broad profile of INCLEN. The contributions were and are as follows:

- NKA is member of the WHO-GACVS (Global Advisory Committee on Vaccine Safety) and chaired sub-group on country preparedness for vaccine safety surveillance. GACVS has now come out with global vaccine safety surveillance guidance document.
- MKD is part of the Brighton Collaboration to develop definitions for the AESIs.
- INCLEN team has been providing support to the India's national health policy and program in various capacities and components.
 - NKA has been spearheading and advising on several Government of India initiatives on COVID response and vaccine introduction.
 - NKA chairs several DBT-BIRAC-NBM committees to steer COVID 19 related vaccine, therapeutic and diagnostic research initiatives; GOI NTAGI Working Group on COVID 19 to advice on selection of the vaccine candidates, vaccine recipient prioritization, and review country preparedness for roll out of the vaccine and safety surveillance; and COVID-19 operational research group of ICMR.
 - MKD is leading a three state study on the re-instatement of primary health services disrupted during the pandemic.
- INCLEN team is also supporting the DBT-BIRAC effort for expanding the national community epidemiology and clinical trial facilities through handholding the establishment of sites, operationalize GIS mapping facilities at these sites and data management.

4.3 Publications attributable to INCLEN

In 2019, 29 publications were attributable to INCLEN including 27 from IEO, and 1 from China-CLEN and 1 from India-CLEN. In 2020 till now, 49 publications are attributable to INCLEN including 40 from IEO, 3 from LatinCLEN, 4 from China-CLEN and 2 from India-CLEN.

4.4 Ethics Committee

The Ethics Committee inducted 2 new members and 1 member rotated out. The EC met 6 times during 2019-2020. The regulatory registrations are valid. The Ethics Committee has proposed for change of name from INCLEN Independent Ethics Committee to INCLEN Institutional Ethics Committee. A resolution is being proposed for Board approval.

Discussion and Decisions (on action taken report and details of the program activities)

- The Board appreciated the engaged and dynamic (“aggressive”) approach adopted by IEO to write new proposal and attract new grants with diversified portfolio, expanding the funder base. Board was particularly appreciative of getting new projects funded by domestic corporate funders under CSR.
- *COVID activities by INCLen*: Board highly appreciated and applauded INCLen’s engagement in COVID response activities at national and global level. Board members suggested use the COVID activities as catalyst to energize global INCLen Network and generate possible collaborative activities. The COVID related Indian experiences can have global relevance particularly for the other low and middle income countries. Some of the younger members from the regions can be encouraged to connect with the IEO for initiating some of these activities.
- Board also discussed about the potential global Network implication of the HPV vaccine related studies in Indian context.
- Board discussed the importance of capacity building, mandate of the INCLen and opportunity to share the recent experiences of IEO’s engagement with COVID 19 pandemic and concluded that INCLen should expand the project linked efforts and have joint assignments and degrees with the global network.

4.5 Termination of INSPIRE project

MKD updated the Board on the course of events related to the INSPIRE (including the ICOSMOS part) initiated in collaboration with Johns Hopkins University (JHU), USA. The project components were funded by Pfizer and BMGF. There was concealment by JHU Investigators of the potential data usage for commercial usage in the patient consent forms. The JHU investigators did not reveal the nature of agreements that they have entered with their funders at the time of ethics submission in India and submission of the application for to the ICMR HMSC approval. These were considered a serious ethical issue by the INCLen Ethics Committee. He briefed the contentious issues related to data sharing and obligation of JHU with Pfizer for data sharing and unrestricted utilisation for potential commercial usage. As per the guidance from Ethics Committee, INCLen PI suspended the study on August 8, 2019. Later several rounds of communication were exchanged between the INCLen ethics committee and JHU Research Administration/IRB, but no amicable solution has been found so far. The INCLen team has already shared the full technical report and financial documents with the JHU Investigator team, Research Administration and the JHU Ethic Committee. INCLen simultaneously submitted the request to HMSC (ICMR) for cancellation of HMSC approval for the INSPIRE project. The balance payment amounting to USD 343,844 from JHU is still pending.

Discussion and Decisions

- The Board noted the sequence of activities and actions by JHU and supported and endorsed the actions by INCLen to ensure adherence to law of the land, upholding the rights of the study participants under the national data protection laws and rights of the Indian investigators over their custodian ship of the data and scientific propriety to be part of the publications.
- Board also noted that INCLen incurred heavy opportunity cost of doing other meaningful studies due to the termination and engagement in the closure activities.

- Board also advised INCLEN to put in place measures to avoid such instances in future and all agreements must be scrutinized closely and with due legal diligence before proceeding with any projects and collaborative activities.
- Board was informed that in case the JHU does not release the outstanding amount and resolve the related issues, INCLEN team shall explore the possibilities of informing the regulatory, ethical and scientific institutions in USA.
- Finally, the Board instructed that ED shall seek Board guidance if there is need for escalating the case to higher level for financial recovery.

Personal Data Protection Bill: Board discussed about the Personal Data Protection Bill being processed in India and enquired about the compliance and anticipated challenges. NKA responded that INCLEN has been following the existing guidelines and data safety/security measures. He assured that any additional efforts will be taken once the bill is passed by the parliament.

5. Administrative and financial issues

5.1 Finance report

SA presented the financial report of the year 2019-20 and the statutory auditor, Mr Rethinam (on behalf of V Shankar Iyer & Co) joined. The auditor informed the Board that there were no observations and all expenditures had been done as per the guidelines and for the purposes for which the funds were meant for.

The summary financial report is: (i) income for the year – 1.1m USD; (ii) expenditure – 2.27m USD; (iii) variance between the projected FY2019-2020 budget and actual expenditure was 53% (less); (iv) total surplus at the end of FY 2019-20 was 0.29m USD; (v) projected budget for the FY 2020-21 is 1.99m USD with administrative expenditure of 0.22 m USD; (v) the projected admin budget for the first quarter of FY 2021-22 is 48K; and (vi) the monthly internal audit and quarterly statutory audit plan for December 2020 onwards was shared with the Board.

Board was appraised about the recent amendment in the FCRA guideline, which mandates opening of the FCRA bank account in a State Bank of India, New Delhi on or before March 31, 2021. The documents for the Board members are to be submitted for the bank account opening and further processing.

The HR fringe benefit liabilities have been streamlined with leave encashment, and gratuity fund created with LIC of India. No anti-sexual harassment grievance was reported and no legal lawsuit exists against the organisation or any staff.

The income tax related case is pending and delayed probably due to the ongoing COVID challenge.

The list of resolutions placed before the Board for ratification/passage are as follows:

- Appointment of Statutory Auditor for the financial year 2020-21
- Appointment of Internal Auditor for the financial year 2020-21
- Appointment of Legal Consultant for the financial year 2020-21
- Opening of the designated SBI FCRA Account
- For State Bank of India account operations
- For other banking operations
- For filing Income Tax Return and other income tax related filings
- For fund investment in permissible channels

- For hiring of office space, as per need
- For assets procurement
- For land purchase, as per need
- Change in name of the ethics committee

Discussion and decision

- Board appreciated the rigorous financial management practices followed at the IEO under the guidance of Finance Committee. Due to disruptions in the regular internal and external audit exercises in the last 12 months, Board advised to discuss with the auditors and explore possibilities of undertaking regular audit exercise digitally.
- Board advised to submit a written enquiry to the GST department for applicability of GST for the Trust, although the GST registration have been surrendered. In case of no response, a reminder may be sent after 1-2 months to track the development.
- Board advised that the resolutions be circulated by email for signature by the members.
- Board advised to resume the quarterly Executive and Finance Committee calls.

6. Board members nominations

NKA briefed the status of Board membership including the vacant positions and scheduled rotation of both independent and RAB membership. According to INCLEN Trust Bye Laws, 9-15 Board members are required to be on the Board with 60% or more need to be Indian Citizens. He shared that out of the 16 nominations suggested by various Board members during 2019, from India, three from health sector and one expert in international relation were selected for consideration. Two international nominations were proposed for possible consideration. The potential names were:

Indian nominee

- Anurag Agarwal (Director, IGIB, Delhi)
- Sanjay M. Mehendale (ex-DDG, ICMR, now at Mumbai)
- Shalini Bharat (Professor, TISS, Mumbai)
- Anil Wadhwa (Ex Foreign Secretary, Government of India)

International Nominee

- Albert Hoffman (Harvard School of Public Health, USA)
- E. Kim Mulholland (LSTHM, UK and Murdoch Children's Hospital Melbourne, Australia)

Discussion and decision

- Board endorsed the proposed nominations. Board advised to improve substantially the gender balance and regional representation for additional members:
 - Board and RAB members were requested by the end of December 2020 to nominate a prominent female bio-medical scientist/ health administrator from the African Continent as the next international independent member.
 - In the same spirit, Board suggested to identify another potential independent female Board member from India for the Board meeting in 2021.

- MT reiterated his statements from 2019 that he would like to stepdown as Chairperson and handover to the new Chairperson at the next Board Meeting in 2021. It was also discussed and agreed that VSC will be the Co-Chairperson till then and takeover as Chairperson from MT during the next Board meeting.
- RAB nomination on the Board: Currently RAB members from China CLEN (Jiayo Wang) and Latin CLEN (Carlos Gomez) are the international RAB members along with permanent RAB member from India CLEN. Both representatives from China and Latin CLEN have completed their terms and shall be rotating out from 2020 onwards and replaced with two new international RAB representatives: – Francois Chapuis (EuroMedCLEN) and Srikant Bagdiwala (CanUSACLEN). Board also nominated ChinaCLEN President, ZHU Chouwen as special invitee to Board of Trustees. Their terms will be for two years when they will be replaced by members from other two international RAB members.

7. Work plan

NKA presented the work plan for year 2020-21 and 2021-22 (till next full Board meeting).

- NKA proposed 'Thrive to Transform' approach for the coming 2-3 years. The key plans and strategies proposed for Board consideration were:
- Strengthening the DDESS platform for furthering research agenda: It is based on the following strengths and achievements.
 - o Induction of INCLEN into the DBT National Biopharma Mission program as a partner and also mentor for new sites
 - o Three INCLEN DDESS sites in India that covers diverse geographies and populations
 - o Access to the network of DDESS/DHSS in India under the DBT Mission, where INCLEN is coordinating and technically supporting the other sites
 - o INCLEN's participation in disease surveillance (COVID/Others diseases) at the INCLEN sites and other DDESS network
 - o Ongoing preparation for clinical trials at DDESS sites
 - o The effort shall leverage the software and GIS platform developed for data collection and management
- Preparation of GCP Compliant INCLEN SOMAARTH-DDES Sites (Palwal, Bareilly and Shillong) for clinical trials and public health interventions: This shall be leveraged on the following components:
 - o Access to large and diversified population with database which is GIS linked
 - o Ongoing research activities at the DDESS sites
 - o Well developed and functional e-data collection and data management system and experience of development of the new technologies (IQDAS, mCTG, NDST, etc.)
 - o Engagement with the DBT, ICMR, CSIR and other Government data integration initiatives
 - o Established linkages with the local, state and national health system at the sites
 - o Proposed development and exploration of niche opportunities like GIS epidemiology, big data analytics

- Capacity building programs particularly research leadership linked to the projects and core surveillance
- Expanding new domains for research and translation: Based on the past experiences and emerging opportunities we propose for establishment of the division of informatics, Artificial Intelligence/Machine Learning and big data analytics
 - Resources have been budgeted for hiring of Data Scientists and research staff:
 - Faculty members in artificial Intelligence, machine Learning, deep learning, computational algorithm and big data analytics
 - Business Analyst and Developer
 - Research Associates/Assistants: Analysis and Building Team
 - Biostatistician and software team
 - Procurement of hardware and software
 - Preparing an ecosystem for multidisciplinary learning and capacity building
 - A budget of USD 25K was proposed for this unit development.
 - Explore funding support and development of new proposals for sustaining the unit
- Establishing Centre of Excellence in Vaccinology, Vaccine Safety and Acceptance
 - INCLen has proposed development of a centre of excellence in vaccinology, vaccine safety and acceptance and submitted a proposal to DBT-Wellcome India Alliance. The proposal has been shortlisted for final review in January 2021.
 - The proposed unit shall focus on
 - Clinical trials and research
 - Expanding the research mandate to document the other impacts of vaccination
 - Creating research and training programs with induction of PhD and Fellows
 - Establishing collaborations with partner organisations, universities and professional associations for student/fellow exchange program
 - This shall also encourage fellows and PhD students from other regions and INCLen's network to come and work on INCLen projects. (Students can be registered either in their parent countries or India and pursue field work based at Indian study sites)
- Exploring new donors/ funding opportunities
 - Exploring health and bio-medical science related opportunities in bilateral and multilateral country arrangements that aligns with the national health diplomacy policies and strategies
- Network activities
 - Explore bio-medical research opportunities under the Bilateral and Multilateral political and economic treaties between countries. It was for this reason, we proposed a retired senior Indian diplomat as Board Member to facilitate these activities.
 - Interested INCLen members from the Network will be contacted to leverage Indian COVID experience for developing collaborative programs.

Discussion and decision

- The Board endorsed the proposed work plan 2020-21. The Board appreciated the plan for exploration of the bilateral and multilateral opportunities.
- Board suggested the RAB members to suggest and induct active Researchers keen to participate in collaborative research and capacity building programs.

8. Board Executive Session

Board had an executive session. Following the executive session, Board Chair, MT briefed Secretariat about the following decisions:

- Board was happy to note the progress, activities done and efforts made during the challenging and hard times of the Pandemic.
- For the new Board members induction, an introductory meeting shall be planned in January 2021.
- Term of the ED (NKA) will be renewed for three years w.e.f. January 2021. Board advised for a thorough succession planning for harmonic transition. NKA shall propose a transition plan for Board approval at the next Board meeting.

The Chair thanked the Board members, RAB members, and Secretariat for organisation, participation, and conduct of the meeting and for the spirit of partnership and collaboration. The Board meeting was officially closed with best wishes for the New Year to the Board, the ED, the Management team, Secretariat and the whole INCLLEN community

Annexures

Annexure 1: Program update (2019-2020)

Annexure 2: Publications (2019-2020)

ANNEXURE 1

OVERVIEW OF INCLIN ACTIVITIES

Summary of projects operated through IEO

Sl no	Research Areas	Completed	Ongoing Projects	New Projects
1.	Surveillance and Program Evaluation	2	9	12
2.	Vaccinology and Vaccine Safety	2	3	4
3.	Implementation Research	2	3	7
4.	Environmental Health	0	1	2
5.	Digital Health & Technology Assessment	1	6	7
6.	Transdisciplinary Convergence for Health	2	1	3
7.	Extramural Research Management	1	0	0
	Total	10	23	35

- **New Projects Launched** – 14
- **New projects sanctioned in the pipeline** – 3
- **New proposals under review** – 4
- **New projects declined** – 14

Funding Agencies

Area	Completed projects	Ongoing projects	New projects
Indian	<ul style="list-style-type: none"> • ICMR • WHO 	<ul style="list-style-type: none"> • DBT/BIRAC • DST • ICMR • MoHFW • IBM • SRS life 	<ul style="list-style-type: none"> • DBT/BIRAC • ICMR • DST • IBM
International	<ul style="list-style-type: none"> • BMGF • WHO • JHU/Prizer • Wellcome Trust 	<ul style="list-style-type: none"> • BMGF • MRC UK • WHO & P95 • PMNCH (WHO) • GCC • Unicef 	<ul style="list-style-type: none"> • MRC-UK • Unicef

List of Ongoing and New Projects
Surveillance and Program Evaluation

Ongoing projects

Study Title	Area	Funder	Period
Dementia Science Programme: Incidence/ Prevalence/Risk analysis of dementia and basic research thereof PI: Dr N K Arora Coordinator: Dr Divya Nair	India (3 sites)	Department of Biotechnology	2017-2023
Intussusception in Infants: Multisite Hospital Based Surveillance in India PI: Dr Manoj Das	India (19 sites) 2 districts	BMGF	2014-2020
National Certification Committee for Polio Eradication (NCCPE) and National Verification Committee for Measles-Rubella Chairperson: Dr N K Arora	India	Govt of India	2008 onwards

New projects-Successful and initiated

Study Title	Area	Funder	Status
Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy of Probiotic Supplementation for Prevention of Neonatal Sepsis in 0-2 Months old Low Birth Weight Infants in India PI: Dr N K Arora Coordinator: Dr Ramesh Poluru	India (6 sites)	Indian Council of Medical Research; MRC-UK	2020-2022
Establishing SOMARATH DDESS in Mawphlang & Sohiong block of Shillong & Assessing the burden of Dengue & Chikungunya PI: Dr N K Arora Coordinator: Dr Neha Gupta	India (Shillong)	BIRAC (Department of Biotechnology)	2020-2023
Establish serial sero-surveillance to monitor the trend of SARS-CoV-2, Dengue and Chikungunya infection transmission in the general population, India PI: Dr Shikha Dixit	India (Palwal)	BIRAC (Department of Biotechnology)	2020-2023
Perceptions regarding MITS in stillbirth & neonatal death in Gorakhpur PI: Dr Manoj Das		Indian Council of Medical Research (ICMR)	2020-2021
Case study on early childhood development: India PI: Dr Manoj Das		PMNCH (WHO)	2020-2021
Implementation framework for cross-border collaboration on vaccine preventable diseases in line with IHR framework Coordinator: The INCLIN Trust International		SEAR-WHO	2020-2021

New project – Approved (pending agreement)

Study Title	Area	Funder
Causes of death in infants north-eastern region of India by minimally invasive tissue sampling (MITS) technique: An ICMR Task Force Study PI: Dr Manoj Das	India (four sites)	Indian Council of Medical Research (ICMR)

New projects-Not successful

Study Title	Submitted to
Psychological, social and economic impact of perinatal bereavement services on parents and families in India PI: Dr Manoj Das	MRC-UK
Determining the effect of antiviral innate immune response and pre-existing antibodies on dengue quasi-species diversity and disease outcomes in hyper-endemic communities PI: Dr N K Arora	Wellcome Trust
Biosocial Processes Modulating the Influence of Social Adversity on Mild Cognitive Impairments among Older Adults: A Population-Based Prospective Cohort Study from Northern India PI: Dr N K Arora	NIH, USA
Perinatal bereavement and its psychological, social and economic impact on parents and families and development of sociocultural appropriate support services in India PI: Dr Manoj Das	Indian Council of Medical research (ICMR)
Application of Geo-spatial Artificial Intelligence in predicting Non-adherence and Susceptibility pattern to Treatment of Tuberculosis (AGAINST-TB) PI: Dr N K Arora (Co-PIs from South Africa & Brazil)	BRICS Secretariat (DST, India)

Vaccinology and Vaccine Safety

Ongoing projects

Study Title	Area	Funder	Period
Multi-centre Active AEFI Sentinel Surveillance in India PI: Dr N K Arora Coordinator: Apoorva Saran	India (23 sites)	UNDP, BMGF	2016-21
Global Vaccine Safety Multi-County Collaboration Project : Safety in Pregnancy PI: Dr N K Arora Coordinator: Apoorva Saran	India and five countries	WHO/P95	2019-2020
Generating epidemiological, economic and attitudinal evidence to inform policy-making about HPV introduction in India and Ethiopia PI: Dr N K Arora Coordinator: Dr Manoj Das	India (3 sites) and Ethiopia (2 sites)	Newton Fund: MRC & DBT	2020-2023

New projects-under review

Study Title	Area	Funder
Modeling impact of HPV vaccination on the cervical colonization with high risk HPV genotypes comparing immunized and non-immunized girls and prevalence gradient between daughter-mother dyads PI: Dr N K Arora Co-I: Dr Manoj Das	India (two sites)	Indian Council of Medical Research (ICMR)
Enabling Vaccine Safety Environment in India- Monitoring vaccine safety indicators and strategies to overcome vaccine hesitancy (Centre of Excellence for Vaccinology & Vaccine Safety Research) PI: Dr N K Arora CO-I: Dr Manoj Das		DBT-Wellcome Trust India Alliance
Phase III RCT to Assess the Safety and Immunogenicity of Gam-COVID-Vac Combined Vector Vaccine (Sputnik-V) for SARS-Cov-2 Infection PI: Dr A Agarwal		Russian Direct Investment Fund

Implementation Research

Ongoing projects

Study Title	Area	Funder	Period
Promoting Family Integrated Early Child Development (during 1000 days) in Urban Slums (Fine Child 3-3-1000) PI: Dr Manoj Das	India (Delhi)	Grand Challenges Canada	2018-2021

New projects-Successful and initiated

Study Title	Area	Funder	Period
Reinstating and sustaining the maternal and child health services during and after the COVID crisis PI: Dr Manoj Das		Indian Council of Medical Research (ICMR)	2020
How initial implementation learning could be contextualized for district wide scale-up of PSBI management for sick young infants PI: Dr N K Arora Coordinator: Dr Rupak Mukhopadhyay		Unicef and BMGF	2020-2021

New projects-approved (pending agreement)

Study Title	Area	Funder
Improving quality of care for mothers and newborns: research to improve performance of LaQshya program in four states of India PI: Dr N K Arora	India (six states, 20 districts)	Ministry of Health & FW, Govt of India

New projects-Not successful

Study Title	Submitted to
Saving lives in sick young infants in two districts of Haryana PI: Dr Rupak Mukhopadhyay	HCL Foundation
Strengthening ANC & PNC service delivery and Innovation-Implementation Research PI: Dr Rupak Mukhopadhyay	BMGF & WHO
Optimizing place of treatment and antibiotic regimens for young infants presenting with signs of possible serious bacterial infection in Palwal District of Haryana PI: Dr N K Arora	BMGF
Ensuring delivery of comprehensive primary health care through recently established Health and Wellness Centers in India PI: Dr Rupak Mukhopadhyay & Abhishek Agarwal	MRC UK

Digital Health & Technology Assessment

Ongoing projects

Study Title	Area	Funder	Period
Developing district-level forecasts of vaccine coverage and inferring vaccine confidence using public health datasets Co-PI: Dr N K Arora (PI: IIT Delhi)	India (three sites)	Department of Biotechnology (G Challenge India)	2019-2021
Improving Immunization Data Quality for Action: Biometry Beneficiary Linkage and Data Convergence for Monitoring PI: Dr Manoj Das	India (one state)	Department of Biotechnology (G Challenge India)	2018-2021

New projects-Successful and initiated

Study Title	Area	Funder	Period
SOMAARTH-e-Data management platform for quality assured electronic data collection, documentation, reporting, analysis and archival of community based DDESS and associated research studies PI: Mr Neeraj Kashyap	India (10 sites)	BIRAC/Department of Biotechnology	2020-2023
Artificial intelligence driven Neurodevelopmental Disorders (NDD) Screening Tool: An INCLIN-IBM Initiative PI: Dr N K Arora Coordinator: Dr Vaishali Deshmukh	India (two sites)	IBM	2020-2021
Developing a public health informatics platform in India for a systems view of health and diseases Co-PI: Dr N K Arora (PI: IGIB-CSIR) Coordinator: Dr Neha Gupta	India (multiple sites)	Department of Science and Technology, GOI	2019-22

Diagnosis of pneumonia and respiratory illnesses using digital stethoscope and algorithm in children and adults PI: Dr Manoj Das	India (six sites)	2019-2021	SRS Life Sciences
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New projects-Not successful

Study Title	Submitted to
Combating malnutrition: Application of machine learning for predicting childhood stunting PI: Dr Neha Gupta	BIRAC-DBT
Stereoscopic Retinal Imaging Solutions for Tracking Chronic Illnesses (SRISHTI) PI: Dr Rakesh Pillai	BIRAC-DBT Incubation grant
Artificial Intelligence Platform with Geospatial Recording for Public Health Sciences (AI-Graphs): INCLEN CARE PI: Shikha Dixit	ICMR

Environmental Health

Ongoing projects

Study Title	Area	Funder	Period
Delhi Air Pollution Health and Effects (DAPHNE)	Delhi (India) Edinburgh (UK)	Department of Biotechnology	2017-2021

New projects-Approved (pending agreement)

Study Title	Area	Funder	Period
Spatial Epidemiological Approach to Malaria Elimination Research	India (10 districts in five states)	Malaria Elimination Research Alliance, India	Under review

New projects-Not successful

Study Title	Submitted to
A community based smart solid waste management model PI: Dr Divya Nair	BMGF/BIRAC-DBT

Transdisciplinary Convergence for Health

Ongoing projects

Study Title	Area	Funder	Period
Harmonized One Health Trans-species And Community Surveillance For Tackling Antimicrobial Resistance PI: Dr Manoj Das	India (6 institutes)	Department of Biotechnology (Grand Challenge India)	2019-2021

New projects-Under Review

Study Title	Area	Funder
Effect of Zinc Oxide and Silver nanoparticle formulation on infected wound healing in humans, animals and fishes PI: Dr Manoj Das	India (one state)	BIRAC (Department of Biotechnology)

New projects-Not successful

Study Title	Area
Environmental risk factors for co-existence of Salmonella typhi and Acanthamoeba from typhoid fever in children in urban Delhi, India Submitted to: Bill and Melinda Gates Foundation	BMGF

International Collaboration- Ongoing Projects

Study Title	Area
Global Vaccine Safety: Multi-country Collaboration on Maternal Immunization safety	(7 countries) India, Iran, Ghana, Tanzania, Spain, Zimbabwe, S Africa
Generating epidemiological, economic & attitudinal evidence to inform policy-making about HPV introduction in India/ Ethiopia	(5 countries) India, Ethiopia, UK, Australia, Canada

International Collaboration- New proposal developed

Study Title	Area
Biosocial Processes Modulating the Influence of Social Adversity on Mild Cognitive Impairments among Older Adults	2 countries (India and USA)

Capacity Building- Ongoing Activities

	Activities	Time-period
<u>1</u>	Research Leadership and Management Program (LAMP)	Annual
<u>2</u>	Africa India Mobility Fund (Dr Divya Nair)	2020
<u>3</u>	ADVAC fellowship (Dr Manoj Das)	2020

Technical Support to Government of India

	Study/Activity Title	Program	Ministry	Period
1	COVID implementation research	Research	ICMR	2020 onwards
	Mission COVID- Scientific Advisory Group	COVID response	DBT	
2	COVID vaccine induction in India		MoHFW	
	NTAGI Working Group for COVID-19 Vaccine roll-out in India		MoHFW	
3	Support to DESS sites for surveillance data management platforms	Vaccine development	DBT	2020 onwards
4	Vaccine development and evaluation program	Multiple vaccines	DBT	2019 onwards
5	Adverse Events Following Immunization in India (support for the of AEFI surveillance program)	UIP	MOHFW	2008 onwards
6	Introduction of Rotavirus, Pneumococcal conjugate, Td vaccines under UIP	UIP	MOHFW	2016 onwards
7	Several other technical committees at ICMR, DBT, MOHFW	Multiple	MOHFW/ DST	Ongoing

Technical Support to International Policy

Study Title	Agency	Period
WHO SAGE working groups - GVAP, Typhoid, Measles and Rubella, PCV - IA2030 Monitoring, Evaluation & Action	WHO	2014 onwards
Global Vaccine and Research Forum	WHO	2016 onwards
Research Priority Setting in maternal and child health	WHO	2016 onwards
WHO STAGE for MNCH, Adolescent & Nutrition	WHO	2020 onwards
WHO Vaccine safety (GACVS) - National COVID-19 Preparedness WG	WHO	2019 onwards
External Evaluation of NITAGs	WHO	2019-20
Development of Vaccine Blueprint Action Plan 2020-2030	WHO	2019-20
Maternal Immunization and safety of COVID 19 vaccines	BMGF	2020 onwards
Global Vaccine Data Network	Multi-donor	2019

List of Completed Projects

S. NO.	Study Title
1	Research Program to Emphasize Public Health Significance of Childhood Pneumonia
2	Indian Network for <i>S pneumoniae</i> and PCV Impact Research (INSPIRE) (Terminated)
3	Immunization Impact on Cognition Outcomes and School Monitoring Outcomes Study (I-COSMOS): A pilot study (Terminated)
4	Implementation Research on management of PSBI in young infants (0-59 days) where referral is not feasible in 2 PHC areas of the Palwal (Haryana)
5	Improving Quality of Care for Mothers and Newborns at District Hospitals and FRUs of three Districts of Haryana.
6	Socio-behavioural Research for feasibility of conducting MITS to determine causes of death in under-five children in India
7	Scoping the Path to Leadership in India
8	Healthy birth, growth and development knowledge integration initiative
9	Generating Models of Trans-Species Antibiotics Resistance Pathways: Application of System Dynamics tools in One-health Systems Approach
10	Evaluation of national immunization technical advisory group (NITAG) in South East Asia Region

ANNEXURE 2

List of Publications with IEO team as authors

Year 2020 (Till Nov 2020)

Published

1. Deshmukh V, John S and Arora NK. Utilization of Postnatal Healthcare Services Delivered through Home Visitation and Health Facilities for Mothers and Newborns: An Integrative Review from Developing Countries. *The Indian J of Pediatrics*. Mar 2020;87(3):207-216.
2. Privor-Dumm LA, Poland GA, Barratt J, Durrheim DN, Knoll MD, Vasudevan P, Jit M, Bonvehí PE, Bonanni P and International Council on Adult Immunization. A global agenda for older adult immunization in the COVID-19 era: A roadmap for action. *Vaccine*. July 2020.
3. Prinja S, Bahuguna P, Chugh Y, Vassal A, Pandey A, Aggarwal S, Arora NK. A Model Based Analysis for COVID-19 Pandemic in India: Implications for Health Systems and Policy for Low-and Middle-Income Countries. *medRxiv*. Jan 2020.
4. Arora NK, Das MK, Poluru R, Kashyap NK, Mathew T, Mathai J, Aggarwal MK, Haldar P, Verstraeten T, Zuber PL, INCLIN Vaccine Safety Study Group. A Prospective Cohort Study on the Safety of Infant Pentavalent (DTwP-HBV-Hib) and Oral Polio Vaccines in Two South Indian Districts. *The Pediatric Infectious Disease Journal*. May 2020;39(5):389.
5. Agarwal A, Garg G, Kumar A, Chaudhary K. A Study to Assess the Gaps in the Knowledge and Practices of Anganwadi Workers in a Rural Area of Meerut-A Situational Analysis on Umbrella ICDS Scheme. *International Journal of Science and Research*. July 2020;9(7):605-609.
6. Bhatnagar A and Kapoor R. Assess Retention of knowledge, attitude and practices of community health worker regarding childhood Pneumonia and diarrhoea. (Allahabad, Gonda and Bareilly Uttar Pradesh). *International Journal of Current Advanced Research*. March 2020;9(3):21540-21546.
7. Sultana A, Sharma R, Hossain MM, Bhattacharya S, Purohit N. Burnout among healthcare providers during Covid-19: Challenges and evidencebased interventions. *Indian J Med Ethics*. July 2020.
8. Mathew JL, Das MK, Kumar P. Cluster Randomized Trial Evaluating Impact of a Community-based Microfinance Scheme on Childhood Nutritional Status. *Indian Pediatrics*. May 2020;57: 459-464.
9. Arora NK, Das MK. COVID-19 vaccine development and the way forward. *Indian Journal of Public Health*. June 2020;64(6):108.
10. Jeet G, Sharma A, Goyal A, Prinja S, Pandey A, Mandal S, Rao MV, Aggarwal S, Arora NK. Determinants of COVID-19 incidence and mortality: A cross-country analysis. *medRxiv*. January 2020.
11. Agarwal A, Bano T, Garg SK, Chopra H, Jain S, Singh G. Dietary Predictors of Anaemia among Children Aged 12-35 Months. *Journal of Clinical & Diagnostic Research*. July 2020;14(7):5-8.
12. Das MK, Sood M, Tambe MP, Sharma TD, Parande MA, Surwade JB, Salunkhe NM, Patil SS, Pawar B, Guleri R, Kaushal C. Documentation of vaccine wastage in two different geographic contexts under the universal immunization program in India. *BMC Public Health*. Dec 2020;20:556

13. Hossain MM, Sultana A, Ma P, Fan Q, Sharma R, Purohit N, Sharmin DF. Effects of natural environment on mental health: an umbrella review of systematic reviews and meta-analyses. Psyarxiv. January 2020.
14. Chan G, Storey JD, Das MK, Sacks E, Johri M, Kabakian-Khasholian T, Paudel D, Yoshida S, Portela A. Global research priorities for social, behavioural and community engagement interventions for maternal, newborn and child health. *Health Research Policy and Systems*. Dec 2020;18(1).
15. MacDonald N, Mohsni E, Al-Mazrou Y, Andrus JK, Arora N, Elden S, Madrid MY, Martin R, Mustafa AM, Rees H, Salisbury D. Global vaccine action plan lessons learned I: Recommendations for the next decade. *Vaccine*. July 2020;38(33):5364-71.
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17. Mourya M, Kumari B, Tayyab M, Paarcha A, Rahman A. Indices based assessment of built-up density and urban expansion of fast growing Surat city using multi-temporal Landsat data sets. *GeoJournal*. Jan 2020.
18. Vaswani V, Saxena A, Shah SK, Palacios R, Rid A. Informed consent for controlled human infection studies in low and middle income countries: Ethical challenges and proposed solutions. *Bioethics*. Oct 2020;34(8):809-818.
19. Das MK, Arora NK, Gupta B, Sharan A, Kameswari K, Padmalatha P, Prasad GR, Shad J, Shyamala J, Kumar SH, Nagender Y. Intussusception in children aged under two years in India: Retrospective surveillance at nineteen tertiary care hospitals. *Vaccine*. Oct 2020;38(43):6849-57.
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21. Singh A, Kapoor R. Is Second Hand Smoke associated with Child's Nutritional Status? A Meta-Analysis. *Research Square*. Oct 2020.
22. Kumari B, Tayyab M, Ahmed IA, Baig MR, Khan MF, Rahman A. Longitudinal study of land surface temperature (LST) using mono-and split-window algorithms and its relationship with NDVI and NDBI over selected metro cities of India. *Arabian Journal of Geosciences*. Oct 2020 ;13(19):1-9.
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25. Das MK, Seth S, Mundeja N, Singh AK, Mukherjee SB, Juneja M, Khuda P, Fatima R, Bhatnagar A. Promoting family integrated early child development (during first 1000 days) in urban slums of India (fine child 3-3-1000): Study protocol. *Journal of Advanced Nursing*. Apr 2020;76:1823-1830.

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27. Jahagirdar S, Chatterjee A, Behera S, Mohapatra A. Response to the COVID-19 pandemic in India: Case studies on leadership in crisis situations. *International Journal of Health & Allied Sciences*. Apr 2020;9(5):81.
28. Das MK, Arora NK, Poluru R, Tate JE, Gupta B, Sharan A, Aggarwal MK, Haldar P, Parashar UD, Zuber PL, Bonhoeffer J. Risk of intussusception after monovalent rotavirus vaccine (Rotavac) in Indian infants: A self-controlled case series analysis. *Vaccine*. Sep 2020.
29. Bajpai M, Kakkar B, Gupta E, Kumar G, Mohapatra A. Seroprevalence and trend of human immunodeficiency virus infection among Indian blood donors: A systematic review and meta-analysis. *Global Journal of Transfusion Medicine*. Jul 2020;5(2):129-34.
30. Bhatnagar A. Short reports on covid- 19 cases in India: recovered cases, active cases and death cases reported state wise. *International Journal of Current Research*. 2020; 12(6): 11927-11930.
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36. Das MK. Pediatricians Viewpoint. Cluster Randomized Trial Evaluating Impact of a Community-based Microfinance Scheme on Childhood Nutritional Status. *Indian Pediatrics*. 2020; 57 (5):463-464

Accepted publications (under production)

1. Das MK, Arora NK, Kaur G, Malik P, Kumari M, Joshi S, Rasaily R, Chellani H, Gaikwad H, Debata P, Meena KR. Grief reaction and psychosocial impacts of child death and stillbirth on bereaved North Indian parents. *PLOS ONE* (PONE-D-20-30229R1)
2. Jena PK, Sarangi R, Behera N, Sahoo SK, Dash AK, Tripathy BB, Mohapatra SSG, Gupta B, Arora NK, Das MK. Epidemiology of intussusception among children under-two years of age from 2010-2017 in Odisha, India. *Journal of Gastroenterology Research* (Ref: JGR-4-027)
3. Das MK, Singh D, Sharma S. Media news on vaccines and vaccination: The content profile, sentiment and trend of the online mass media during 2015-2020 in India. *Clinical Epidemiology and Global Health* (Ref: CEGH-D-20-00612)
4. Das MK, Arora NK, Kaur G, Malik P, Kumari M, Joshi S, Rasaily R, Chellani H, Gaikwad H, Debata P, Meena KR. Perceptions of family, community and religious leaders and acceptability for minimal invasive tissue sampling to identify the cause of death in under-

five deaths and stillbirths in North India: A qualitative study. *BMC Reproductive Health* (Ref: REPH-D-20-00374R1)

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2. Hariharan D, Das MK, Shepard DS and Arora NK. Economic burden of dengue illness in India from 2013 to 2016: A systematic analysis, *Int J Infect Dis*. Jan 2019; 84: S68-S73.
3. Das MK, Arora NK, Rasaily R et al. Exploring family, community and healthcare provider perceptions and acceptability for minimal invasive tissue sampling to identify the cause of death in under-five deaths and stillbirths in North India: a qualitative study protocol. *Reproductive Health*. 2019;16(3).
4. Das MK, Chaudhary C, Kaushal SK et al. Impact of Neonatal Resuscitation Capacity Building of Birth Attendants on Stillbirth Rate at Public Health Facilities in Uttar Pradesh, India. *Indian Ped*. May 2019;56: 369-373
5. Pentakota N, Thekkur P, Nair D et al. Is a Smartphone application effective in improving physical activity among medical school students? Results from a quasi-experimental study. *Int J Adolesc Med Health*. Mar 2019.
6. Portella AK, Paquet C, Bischoff AR, Molle RD, Faber A, Moore S, Arora NK et al. Multibehavioral obesogenic phenotypes among schoolaged boys and girls along the birth weight continuum. *PLoS ONE*. Feb 2019; 14(2).
7. Dasgupta R, Sharma S, Sharma N. Arora NK et al., Successful switch (tOPV to bOPV) in India: Tribute to a resilient health system. *Vaccine*. April 2019; 37(17):2394-2400.
8. Arora NK. An Indian Tool for Assessing Appropriateness of Pediatric Hospitalization: Author's Reply. *Indian Pediatr*. April 2019;56(4):334.
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10. Rooney B, Zhao R, Bates, KH, Arora NK et al. Impacts of Household Sources on Air Pollution at Village and Regional Scales in India. *Atmos. Chem. Phys*. June 2019;19: 7719–7742.
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15. Wazny K, Arora NK, Mohapatra A, Gopalan HS, Das MK, et al. Setting priorities in child health research in India for 2016-2025: a CHNRI exercise undertaken by the Indian Council for Medical Research and INCLIN Trust. *Journal of global health*. Dec 2019;9(2):020701.

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