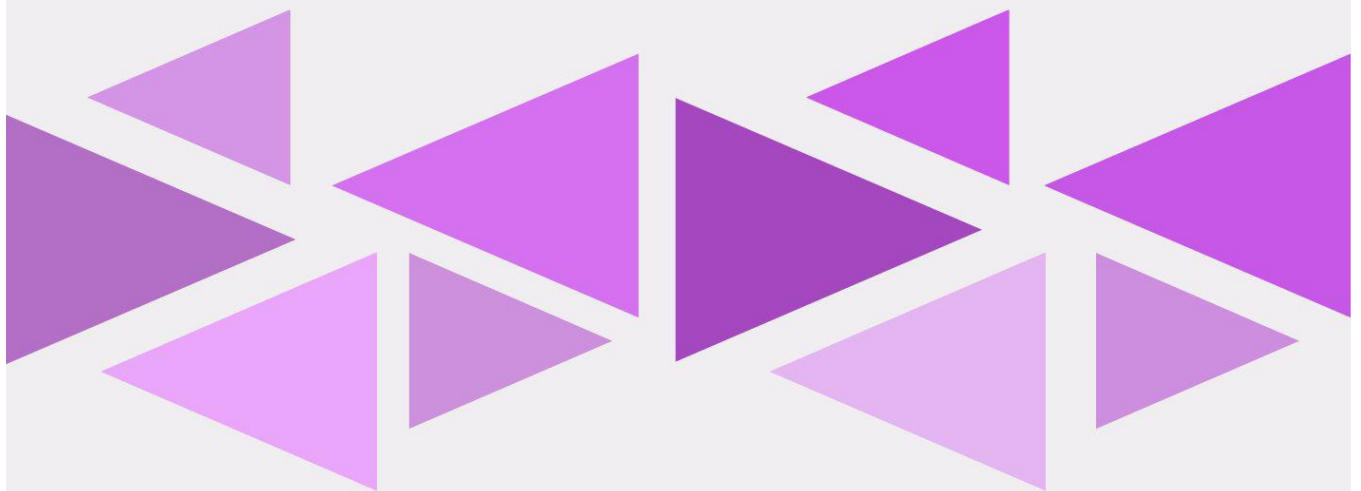




**Kolkata Gynecological Oncology
Trials and Translational Research Group**



ANNUAL REPORT

2022-2023

OUR MISSION

KolGo Trg is motivated and driven by the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic cancers to provide better alternative.

OUR VISION

To translate the version into reality, KolGO Trg and its team of best healthcare professionals and scientific researchers are focused on creating a platform transcending, geographical and other barriers.



Dr. Asima Mukhopadhyay

Founder & Director, KolGO Trg

Consultant Gynaecological Oncology and Lead cytoreductive surgery, James Cook University Hospital and Northern Cancer Alliance, UK

Clinical Senior Lecturer (honorary), Newcastle University, UK

Professor, School of Allied Health Sciences and Translational Medicine, Sister Nivedita University, Kolkata

GCIG- member Executive Board of directors

IGCS International Mentor,

Global Curriculum Program (Nepal and India) and Program lead, India

IGCS Research Publication Committee Co-Chair Programme Director,

MCh Gyn Oncology (Cytoreductive surgery)- Tee side University , UK

Programme Director, ESGO fellowship, India 2019 Wellcome Trust IA Clinician Scientist awardee

Editor, VSI, Global issue Gyn Oncology Reports

KolGO Trg is a dedicated SIRO (2022) for women’s cancer re- search and the only Indian and South Asian organization to re- present in International Clinical Trials consortium GCIG (Gyn Cancer Intergroup) and as an IGCS (International Gyn Cancer Society) organizational partner. Formed in 2018, as a non-prof- it organization and a registered society in West-Bengal. It fo- cuses on developing a collaborative platform involving scien- tists and clinicians in the region/India, working on research areas relevant to the needs of women’s cancer in India and de- veloping innovative Made-in-India studies that can be an exem- plar for generating evidence globally, especially in re- source-adapted-settings. We have participated and initiated several academic clinical trials, generated/participated in high- impact publications and represented India in global platforms on academic research since 2018. Our domain of expertise in- clude:-1) Clinical Trials:- LMIC-centric, adaptive design ap- proaches focusing on toxicity-adjusted (including financial) sur- vival endpoints 2) Trials on targeted therapies/ biology driven targeted strategies (PROVAT/HIPEC-HR) and biomarker devel- opment (HRDIAC) 3) Implementation research: Nurse-led ge- netic counselling/ awareness studies to improve uptake of ge- netic testing in hereditary cancers (NUGENA) 4) Observational Studies: HPV testing/treatment, nurse/ANM training, and awareness(COBRA) in the remote Tea-garden workers of the Hi- malayan Foothills (PRECERCA) ; 5)Translational: Bio-banking of trial-samples to support current/future research ; 6) Training unit for Clinical Research and Statistics (collaboration- Sister Nivedita University and Newcastle University 7) Quality-of-life and Survivorship/advocacy studies 8) Ensure Indian participa- tion and representation in International academic.

Current Governing Body (elected)

Elected in GB meeting held on 12.06.2023

President

Dr. Susanta Roychoudhury,

Chief, Basic Research

Saroj Gupta Cancer Centre and Research Institute, Kolkata

Ph.D., FNA, FASc, FNASc, FAScT

J. C. Bose Fellow

Former Chief Scientist, CSIR-Indian Institute of Chemical Biology

Former Professor, Academy of Scientific and Innovative Research (AcSIR)

President, Indian Association for Cancer Research (IACR)

Vice President

Prof. Dr. Sharmila Sengupta,

Professor,

National Institute of Biomedical Genomics, Kalyani

PhD

Secretary

Dr. Asima Mukhopadhyay

Founder & Director,

Kolkata Gynecological Oncology Trials and Translational Research Group (KolGoTrg)

Consultant Gynaecological Oncology and Lead cytoreductive surgery, James Cook University Hospital and Northern Cancer Alliance,

UK Clinical Senior Lecturer (honorary),

Newcastle University, UK Professor,

School of Allied Health Sciences and Translational Medicine, Sister Nivedita University, Kolkata

GCIG-member Executive Board of directors

IGCS International Mentor, Global Curriculum Program (Nepal and India) and Program lead,

India IGCS Research Publication Committee Co-Chair

Programme Director, MChGyn Oncology (Cytoreductive surgery)-Tee side University ,

UK Programme Director, ESGO fellowship, India 2019

WellcomeTrust IA Clinician Scientist awardee

Editor, VSI, Global issue Gyn Oncology Reports

Joint Secretary

Dr. Tamohan Chaudhuri,

Radiation & Clinical Oncologist,

Saroj Gupta Cancer Centre and Research Institute, Kolkata

MBBS, DMRT,MD

Joint Secretary

Dr. Ranajit Kumar Mandal, CNCI

Associate Professor & Head of the Department,

Department of Gynaecological Oncology

Chittaranjan National Cancer Institute, Kolkata

MD, DNB, PGDHHM

Treasurer

Dr. Rahul Roy Chowdhury,
Consultant Gynaecological Oncologist
Saroj Gupta Cancer Centre and Research Institute, Kolkata
FRCOG, PGC in Med Ed. (Brighton University)

G.B. Member

Dr. Biman Kumar Chakrabarty,
HoD, Gynae Oncology,
Saroj Gupta Cancer Centre & Research Institute, Kolkata
FRCOG (London), FACS (USA), FIMAAMS (India).
Post Doctoral Fellow Johns Hopkins University (USA).
Member ASRM (USA), Member ISAR-India
Ex.Prof. (G&O) Medical College, Kolkata.

G.B. Member

Dr. Santanu K Tripathi, MD, DM
Professor & Head,
Department of Clinical & Experimental Pharmacology
School of Tropical Medicine, Kolkata

G.B. Member

Dr. Somasekhar S.P.
Chairman-Medical Advisory Board, Aster International Institute of oncology
Aster DM Health care -GCC & India
Global Director - Aster International Institute of Oncology-GCC & India
MBBS, MS, MCh (Surg Onco), FRCS (Edinburgh)

G.B. Member

Dr. Neerja Bhatla
Doctor,
Head of the Department,
Department of Obstetrics & Gynaecology,
Room No. 3076, 3rd Floor, Teaching Block
AIIMS, New Delhi, India

Current Employees and Consultants:

1. Administrative Officer & HR	:	Raja Chakraborty
2. Accounts Officer	:	Abdul Rizwan Hossain
3. Statistician & Data Manager	:	Daity Bhattacharya
4. Study Coordinator	:	Tanushri Ghosh
5. Nurse Specialist & Research Administrator	:	Dona Chakraborty
6. Research Nurse	:	Rama Gupta
7. Research Nurse	:	Papiya Mukherjee
8. Office Executive	:	Sonali Mondal
9. Clinical Research Coordinator	:	Debapriya Banerjee
10. Health Care Worker	:	Bidya Basfore
11. Lead Statistician	:	Dr. Atanu Bhattacharjee
12. Lead for Project management and Training Courses	:	Dr. Amlan kanti Sarkar
13. Research Nurse	:	Rapti Rath

Research and other activities during the financial year 2022-2023:

Kolkata Gynecological Oncology Trials and Translational Research Group (KolGO Trg) is a Gynecological Cancer Research Group based in Kolkata, India and the only member of GCIG from South-East Asia. KolGO Trg is motivated and driven by the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of Gynecologic Cancers to provide better alternatives.

Given below different project achievements/advancements:

NuGenA

Nurse-led Genetic counselling in improving Awareness and implementation of screening services for hereditary women's cancer:

Objectives:

We are proposing a strategy where a nurse led genetic counselling service (intervention) whereby nurses/medical social workers after adequate training, will develop a community-based program for health education, cancer awareness and genetic counselling/referral services in Eastern India. This model has not been evaluated in Eastern India before and can be an exemplar of a cost- effective approach of involving both the provider and acceptor of existing cancerhealth services to improve primary and secondary prevention in

women's cancer. The key aim of this proposal is to evaluate whether such strategy will be acceptable, cost-effective, and scalable for all stakeholders i.e., patients, health care professionals, government/policy makers across diverse health infra- structural landscapes in low middle-income countries.

We have developed KolGoTrg database in REDCap, NuGenA leaflet and SOP.

Data update:

- Number of nurses educated/trained: 56
- Genetic counselling module developed: 3
- Awareness camps done: 2
- Patient public involvement/PPP model done: 1

COBRA counselling-

- No. of women counselled about cervical/breast cancers: 92
- No. Of women coming for screening: 3
- No. Of women counselled for vaccinations: 90

Centres interested to participate and who have had initial training of nurses (March 2023) through KolGoTrg NuGenA workshop:

KGMU, Lucknow- 2 nurses trained

AIIMS New Delhi – 1 nurse trained

UCMS, New Delhi – 2 nurses trained

Kalyan Singh Super Specialty Hospital, Lucknow- 2 nurses trained

10 centres in Nepal- 20 nurses trained

Hereditary cancer clinics have started at these sites following NuGenA training workshop

Training and initiation due in April- June 2023:

Bangladesh- 3 sites

Pakistan- Medical University Karachi IGCS training sites

Inclusion in IGCS nursing curriculum done. Discussion with SNU to develop certificate program

NuGenA achievements till date:

- NuGenA- named Charter champion project at the World Ovarian Cancer Launch at IGCS 2020 meeting
- KolGoTrg received Charter champion award by WOCC- Oct 2020 where NuGenA was mentioned
- NuGenA study and participants share the International stage on a dedicated program on hereditary women's cancer organised by WOCC- November 2021 with social media outreach
- NuGenA study presented at the AOGIN 2021 Conference December 2021

- Private donations from our Patron Dr Kaberi Banerjee and James Gurung /Puja Chettri in support for NuGenA

Nurses trained in counselling	Initial sensitization of nurses: 56
Patients with ovarian and breast cancer counselled	Patients counselled: 83 Family members counselled: 102 Total: 185
Ovarian and breast cancer patients tested for BRCA	Patient: 51 BRCA Positive:6 VUS:3
At risk family members counselled	At risk family members identified: 30 Family members counselled of BRCA positive patients: 22
Family members tested for BRCA testing	BRCA positive family members tested for mutation:9
Risk reducing interventions advised	No. of family members advised for risk reducing intervention: 4
Endometrial cancer genetic counselling of at risk patients and relatives	No. of patients tested: 1 MLH1 positive: 1



Launch of NuGenA study at KolGo Trg 3rd annual meeting, 7th February 2021 Kolkata

www.kolgotrg.org



NuGenA study launch at Siliguri with sensitisation training of nurses, Matigara Tea Gardens, Feb 2021



NuGenA study launch at Kathmandu, Nepal with Nepal IGCS team and faculty at Nepal Cancer Care, Feb 2021



NuGenA study launch at Siliguri and Bagdogra army hospital with sensitisation training of nurses, Feb 2021



NuGenA study launch at CNCI Kolkata with sensitisation training of nurses, March 2021



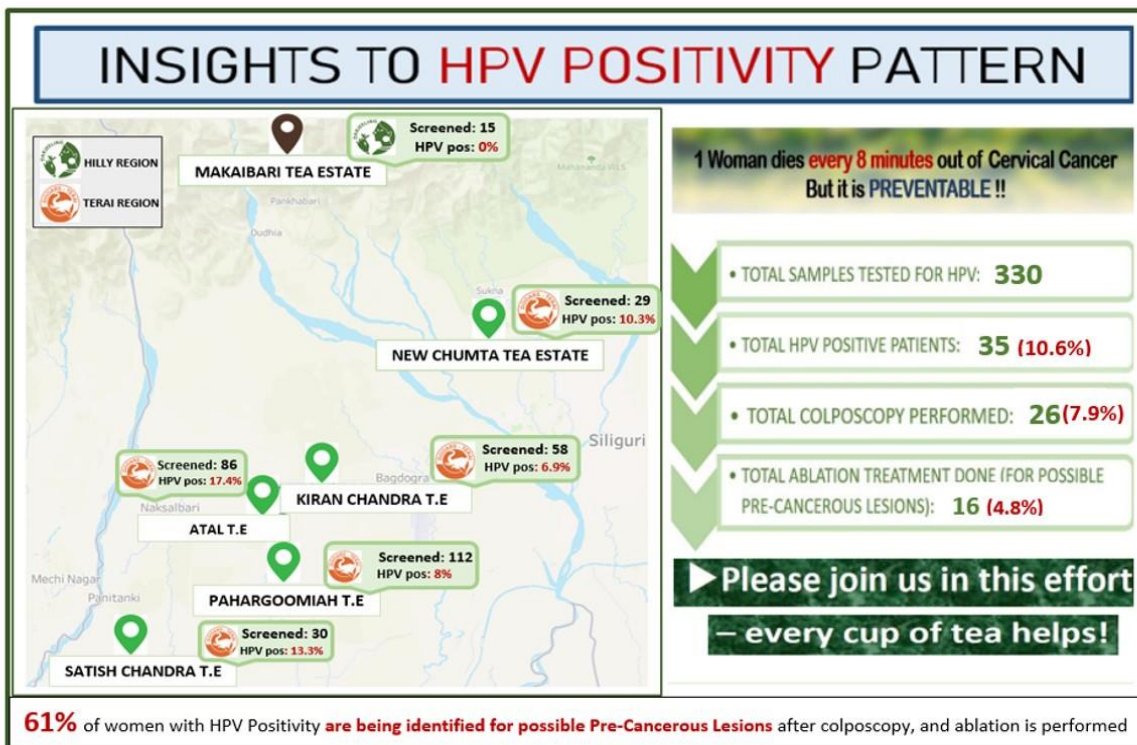
FIRST GENETIC COUNSELLING SESSION IN CNCI RAJARHAT CAMPUS

PRECERCA

Prevention of Cervical cancer

In WHO's global strategy for elimination of cervical cancer- endorsed by the World Health Assembly in 2020, there is a call for regular screening for 70% of women with a high-performance test and for 90% of those needing it to receive appropriate treatment. In developed countries with effective traditional cytology-based cervical cancer screening and treatment programmes, the mortality from cervical cancer has been reduced fivefold over the past 50 years. However, access to cervical cancer screening remains a major problem in rural areas and amongst working women, especially among the Tea Garden Workers who have lack of awareness as well as lack of time due to their busy work schedule. The overall lack of systematic screening results in women living in these areas from being devoid of early detection of cervical cancer. PRECERCA proposes a screen and treat strategy, on the same day using HPV DNA testing by gene Xpert technology which has been successful in some other settings too and is being increasingly used in several projects globally.

Tea Gardens included – 1. Atal Tea Estate, 2. Pahargoomiah Tea Estate, 3. Kiran Chandra Tea Estate, 4. Makaibari Tea Estate, 5. New Chamta Tea Estate, and 6. Satish Chandra Tea Estate.





PreCerCa Awareness camps and HPV Screening Programmes

HIPEC HR

Hyperthermic Intraoperative Peritoneal Chemotherapy

Study objectives

There are two major components of this study proposal-

1. We aim to study if there is a difference in efficacy, safety and treatment outcome after HIPEC in the frontline setting between HRC and HRD epithelial ovarian cancers.
2. We will assess whether HR status is a prognostic biomarker for treatment outcome following primary CRS and HIPEC (Intervention) compared to primary CRS and no HIPEC (standard adjuvant chemotherapy). Our hypothesis is that in the HRD subgroup which is chemo-sensitive, HIPEC may not confer any additional benefit after optimal cytoreduction; whereas it is the HRC subgroup where HIPEC will be beneficial due to its presumed action on DDR function (Compromise HR) and tumour micro-environment, thereby introducing a concept of Targeted HIPEC.

Treatment outcome will be measured by:

- a) Time to progress b) Time to subsequent therapy
 - c) Cost of treatment d) Quality of life
2. Translational outcomes: Pre/ post heat tissue samples to study effect of heat
On DDR status b) ECM Matrix modulation c) Immune cell infiltrates and function

Quality of life

In order to identify the impact of the study on your physical as well as emotional well-being patients are asked to fill up the quality of life questionnaires. It comprises of some questions encompassing physical, psychosexual, emotional and social dimensions of health. The questionnaires are implemented before the surgery, 6 weeks after the surgery and then at every 6 months for a duration of total 5 years. A research nurse assists to fill up the questionnaire.

DATA UPDATE

Till date, 11 patients have been enrolled in the study, of whom 8 patients completed QOL 6 weeks post-surgery, nine completed 6 months follow-up, eight completed 1-year follow-up, and five completed 18 months follow up. Till date, 4 patients have died and 2 patients recurred.

IPIROC

Intermittent PARP Inhibitor in Recurrent Ovarian Cancer

Ovarian cancer treatment is a looming pandemic in India where over 30,000 women die each year, and its incidence is increasing rapidly. PARP inhibitors (PARPi) have radically changed targeted therapies for cancers with BRCA mutations or homologous-recombination deficiency (HRD) in ovarian cancers. However, the recommended daily dosing of PARPi is unfeasible for the Indian/ resource adapted patient cohort where low BMI and anemia is prominent. KolGO Trg's study, IPIROC aims at facilitating the access of life saving drug Rucaparib, such that it is equally accessible to every women affected with Ovarian Cancer worldwide, thus addressing financial and health toxicity without compromising survival.

Currently, we are carrying on with our Proof of Concept Exploratory study for determining the best cohort who would get benefited from this intermittent dosing. Next, we plan to expand our study to a Randomized Controlled Phase 2 study to conduct a prospective pragmatic study in ovarian cancer patients, prescribed daily dosing of rucaparib and study tolerability, toxicity, efficacy, quality of life, affordability/cost-effectiveness, willingness to pay and patient satisfaction to a daily dosing schedule in the Indian population.

Pilot exploratory cohort for feasibility (Ethics approval for academic study) in platinum-sensitive-recurrent-ovarian-cancer with visible currently recruiting women (N=8) for a 12-week single-arm window-of-opportunity-study. Intermittent dosing of rucaparib generic drug in platinum sensitive recurrent ovarian cancer with visible disease: women are showing durable response to this regimen beyond 6 months; all are asymptomatic post 42 weeks even with biochemical progression. Women, who are responding, want to stay on this regimen, as patient friendly, no loss of days to work, home-based trial monitoring, improvement of body image/wellbeing. Recruitment ongoing showing > 3-fold cost reduction for drug and no grade 3 toxicity/hospital admission/transfusion, leading to further reduction in opportunity costs (Manuscript accepted in International journal of Gynaecare, IJGC).

HOTROC

Hormone Therapy In Recurrent Ovarian Cancer

This multicentric international **study aims to evaluate and compare the safety and efficacy of Hormone therapy in asymptomatic women with a rise in CA125 but no measurable disease versus physicians counselling for observation (control) in Ovarian Cancer .**

So, this phase 2 randomized controlled study recruits patients with recurrent high grade serous cancers of ovary with rising trends of CA125 and no visible disease, progressed/recurred following standard therapy (Surgery –either primary or interval followed by platinum based chemotherapy) and never received hormone therapy in the past to assess stabilization and regression of disease .

The total number of patient's planned to be enrolled for all the centres are 300 and for the centres in India are 200.

INTERLACE

Induction Chemotherapy Plus Chemoradiation as First Line Treatment for Locally Advanced Cervical Cancer

Chemoradiation has been the standard treatment for advanced cervical cancer for a decade, but one third of women still die from a failure to control systemic disease . In a recent multicentre phase II trial of 46 women the investigators found that, 68% of women had tumours that responded to weekly induction chemotherapy prior to chemoradiation. The induction chemotherapy had acceptable toxicity and did not compromise the standard chemoradiation treatment. In addition, the overall survival and progression free survival at 3 years was 66% (95% CI 4779). These results, together with acceptable toxicity, provide justification for evaluating induction chemotherapy prior to chemoradiation in a randomised phase III trial .

The investigators aim to investigate in a randomised trial whether additional induction chemotherapy given on a weekly schedule immediately before standard chemoradiation leads to an improvement in overall survival. The investigators plan to recruit 770 women with locally advanced cervical cancer who are eligible for standard chemoradiation, they will be randomised to weekly carboplatin and paclitaxel chemotherapy for 6 weeks followed by chemoradiation or to chemoradiation alone. The trial will recruit for 4 years with 5 years of follow up period.

Actual Study Start Date	:	November 8, 2012
Estimated Primary Completion Date	:	February 2026
Estimated Study Completion Date	:	December 2026

ROCK MDT

MULTIDISCIPLINARY TUMOR BOARD

Introduction:

Multidisciplinary Tumor Board is an interdisciplinary collaboration of doctors from different specialities who review and discuss medical condition and treatment option of patients . MDT is a treatment planning approach , aims to provide the highest quality patient care according to evidence based guidelines . This intercollaborative approach brings more specialized service for a better patient care outcome in Cancer treatment . It Primarily includes specialists from Radiation Oncology , Medical Oncology , Radiology , Surgery , Pathology .

Aims:

MDT benefit patients via improved adherence to clinical guidelines and a better system of quality review . Rare tumor cases can also be brought forth the Tumor board , leading to improved decision making and quality of information as well as promotion of teamwork .

Tumor boards also beneficial for cancer survivors and lead to improved follow up . Owing to the whopping administrative cost involved in arranging meetings , **Virtual Tumor boards** are more preferable post Covid situation .

Composition:

MDT at KOLGOTRG comprises of the following members:

- | | |
|---------------------------|--|
| 1. Dr. Asima Mukhopadhyay | : Consultant Gynae oncologist and Chairperson of MDT |
| 2. Dr. Rahul Roychowdhury | : Consultant Gynae Oncologist |
| 3. Ms Dona Chakraborty | : Clinical Nurse Specialist |
| 4. Mrs. Tanushree Ghosh | : Study Coordinator |
| 5. Mrs. Sonali Mondal | : MDT Coordinator |
| 6. Mrs. Papiya Mukherjee | : Research Nurse |
| 7. Ms Rama Gupta | : Research Nurse |

Work procedure:

- The detailed procedure of MDT is written as follows :

MDT Coordinator maintains liaison with patient , patient family members , and doctors of Medical team , meeting virtually or face to face.



Interested patients who want to be a part of KOLGOTRG MDT , get intimation via mail/telephone .



Appointments are fixed by MDT coordinator on case to case basis , meetings are virtual or face to face in a physical setup at Subodh Mitra Cancer Hospital (Salt Lake , Kolkata)



Patients need to send their reports once the appointment is confirmed , before the actual date of appointment .



MDT Proforma are filled out duly for each patients
Patients need to bring them on the date of appointment for discussion .



Clinical research team and non clinical team come together and discuss with the patients regarding their current and previous medical history and appropriate management .



Patients are called back for follow ups coordinated by MDT Team and all documents are stored in hard copies and Red cap database .

EWS

Every Woman Study

Participating in a research study called “The Every Woman Study” in low- and middle-income countries, and we would like to invite to patient participate. The aim of the study is to identify the challenges and opportunities to improve survival for women with ovarian cancer. It does not involve the woman trying new medicines or procedures but is a survey that will take at least 20 minutes to complete. It will ask about patient any symptoms experienced, how were diagnosed, needs since diagnosis, and where would like to see improvements made in the diagnosis and care of women with ovarian cancer. The study is being funded by two not for profit organisations who are both committed to ensuring women with ovarian cancer get the best possible care no matter where they live. The World Ovarian Cancer Coalition has up to 200 patient advocacy group members from 50 countries, and the International Gynaecologic Cancer Society contributes to the prevention, treatment, and study of gynaecologic cancers and to finding ways of improving women’s quality of life. They are involved in training doctors in countries such as this. Whilst we will have to retain a separate paper record of patient name and unique identifier number, patient name will not be uploaded to the study electronic database with any answers. This means we will not be identifiable from patient answers.

Total patients and sites of recruitment from April 2022 to March 2023:

ROCK Regional Ovarian Cancer Centre, Kolkata)	CNCI (Chittaranjan National Cancer Institute)	SNU Sister Nivedita University Hospital – Subodh Mitra	TOTAL
17	14	4	35

Scientific Meeting updates:

Date: 03/04/2021	Theme: cervical cancer and endometrial cancer studies	Participants: Members KolGo Trg Chair: Asima Mukhopadhyay Rahul RoyChowdhury
Agenda	Discussion points	Deliverables within 4 weeks
<p>1. ReCerCa study (Recurrent cervical cancer study)</p>	<p>Project proposal, biobanking and data collection strategy discussed by Asima Mukhopadhyay as project has been submitted for CCRN grant application</p> <p>Biman Chakrabarty discussed that SGCCRI will have data on recurrent cervical cancer and patterns which can be used to develop a manuscript on retrospective data in the region. CNCI has started looking into the data on recurrent cervical cancer and patients who do not receive any treatment/ chemotherapy and the reasons</p>	<p>CTRI, HMSC application</p> <p>Cervical cancer translational research team to present ideas in the next meeting on projects on recurrent cervical cancer novel treatment options which has translational and clinical applications based on</p> <ol style="list-style-type: none"> 1. TCGA data analysis 2. SyMec data analysis 3. Interaction with Curie Institute 4. Lead from Immunology study leads by Shilpak Chatterjee <p>Puja Chatterjee will present immunotherapy options in cervical/ endometrial cancer next meetings and brainstorming to be done re. what can be done in our setting with repurposing</p>
<p>2. Endometrial cancer study</p>	<p>Dr Damayanti das Ghosh and Rahul RoyChowdhury discussed in silico data analysis for the TCGA data and identification of a subgroup amongst p53 mutants which may have a favourable prognosis.</p> <p>AM discussed whether survival data can be analysed in actual months in comparison to the good prognostic groups like POLE mutation</p> <p>Nabanita Chatterjee will work on molecular classification-based projects in CNCI with PhD students and also looking into role of lipids and circadian rhythm</p> <p>Biobanking to be started. AM has previous serum based samples</p> <p>Role of hormones in guiding end organ differentiation of pelvic serous cancers with p53 signature discussed with SRC</p>	<p>Present update in next meeting- manuscript submission to acknowledge discussion in KolGo platform in preparation of upcoming KolGo studies and grant applications</p> <p>At least start studies in the region in bench on molecular stratification in research settings including MMR testing as it will be difficult under clinical settings</p>

Date: 10/04/2021	Theme: Clinical Trials	Participants: Members KolGo Trg Chair: Rahul RoyChowdhury
Agenda	Discussion points	Deliverables within 4 weeks
HOTROC study update- RRC to present		
INTERLACE study update at CNCI and SGCCRI- Mou to present		Present update in next meeting
IPIROC phase 1 and phase 2 update-AM to present-? using biosimilars- 5 min		
GCIG participation guidance for 2021- AM to present		
Formation of KolGo Trg TMG SOPs- GSB to lead		
Clinical trials insurance policy for KolGoTrg- Dr Tripathi to discuss		
Grant contracts development- RRC to discuss appointment of legal expert		

Date: 10/04/2021	Theme: Clinical Trials Participants: Members KolGo Trg, Santanu Tripathi, Avijit Hazra Chair: Rahul RoyChowdhury	
Agenda	Discussion points	Deliverables within 4 weeks
HOTROC study update- RRC to present/AM to update	Primary endpoint to be fixed as Time to radiological progression to measurable disease from randomisation Exploratory end points- time to subsequent therapy and others	Present the concept at GCIG Further meeting to finalise

	<p>Need to open discussion re- whether double randomise between letrozole vs megestrol which will increase sample size at primary randomisation between hormone vs observation or we can use other methods of balancing like minimisation/ stratification as difference in letrozole vs megestrol is likely to be for secondary endpoints like toxicity/ cost</p> <p>Trial design:</p> <p>Fix Ca125 definition for trial entry</p> <ol style="list-style-type: none"> 1. GCIG (twice upper limit of normal i.e., 35x 2=70) 2. Or increasing trend for nadir 4 weeks apart (in cases where it is less than 70) <p style="text-align: center;">↓</p> <p style="text-align: center;">CT scan</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; width: 30%;"> <p>No measurable disease- then randomise 1:1 to hormone vs observation</p> <p style="text-align: center;">↓</p> <div style="border: 1px solid black; padding: 5px;"> <p>Primary outcome measure: time to progress to radiologically measurable disease in both Control (3 months) and intervention group (Clinically relevant 3 months benefit i.e., 6 months from randomisation)</p> <p>Secondary- TTST/ TTSP, disease progression rates at fixed interval, cost, QOL, satisfaction in patients</p> <p>Need to decide how to balance the distribution of hormones (Letrozole or Megace) in the hormone group- 2ndary randomisation or minimisation/other methods rather than physician choice to decide on the type of hormones to be used</p> <p>Also the subsequent protocol after radiological progression- physicians choice/ criteria for surgery/ chemotherapy and stratification interval</p> </div> </div> <div style="width: 30%;"> <p>If measurable disease- not in trial for randomisation, but collect data on standard of care and outcome</p> </div> </div>	
GCIG participation guidance for 2021- AM to present		Mou will circulate in the group
Formation of KolGo Trg TMG SOPs- GSB to lead	Not discussed	
Clinical trials insurance policy for KolGoTrg- Dr	Detailed discussion.	- Dr Tripathi to develop the document. SOP

Risk of bias if different Ca125 levels at entry and its impact on time to disease progression and how to address this. Whether we should restrict to value below 70

<p>Tripathi to discuss</p>	<p>It was agreed by all clinician GB members (BKC, RRC, RM, AM and ST) that the alternative model as proposed by Dr Tripathi for academic clinical studies to be adopted by KolGo (Appendix 1- page 3)</p> <p>Pre-defined SOP for compensation for trial participation in low-risk academic studies for categories of death/ non-death injuries (Appendix 1) directly related to trial participation/ intervention</p> <p>Independent ISMC and ethics committee of KolGo Trg along with local ethics committee to review claim and compensation</p> <p>During funding application for trials- 10% to be reserved for insurance. This will generate a corpus which can be carried over as unlikely to be utilised. Till we develop a corpus, existing models to be used for insurance will be used.</p> <p>PI can decide whether this model will be suitable for their individual trial or need to take high premium insurance</p> <p>AM suggested that for the ICMR extramural funding call- we write a proposal to Study cost effectiveness and utility of adopting a novel model of trial insurance/ indemnity for academic clinical trials in India</p> <p>Outcome Measure: No of claims/ amount of compensation required/ whether cost recovery could be achieved for running academic clinical trials. How many years could be covered by such a scheme: i.e, with 30 lakhs one time corpus for 10/15/20 years or as proposed by Dr Tripathi i.e., 10 lakhs initially followed by 3 lakhs year? (comparator: standard insurance policies if it were taken for the group where high premium is paid per year)</p> <p>Budget: 30 lakhs for corpus for 3 years to address 5 academic clinical trials 10 lakhs for manpower 5 lakhs- travel/ workshop 5 lakhs- contingency/research cost for measuring outcome/ benefit using health economic models/ consultancy</p>	<p>and terms and conditions</p> <p>Legal advisor of KolGo Trg will facilitate further discussions</p>
<p>Grant contracts development- RRC to discuss appointment of legal expert</p>		<p>Next meeting</p>

Date: 24/04/2021	Theme: Prevention and observational studies	Participants: Members KolGo Trg Chair: Ranajit Mand
Agenda	Discussion points	Deliverables within 4 weeks
1. NuGenA study	<p>Project proposal, update and recruitment strategy discussed by Dona Chakrabarty and Asima Mukhopadhyay</p> <p>Presentation was made by Dona Chakrabarty re. the update of the project and recruitment</p>	<p>CTRI, HMSC application</p> <p>Manuscripts in preparation</p> <p>IGCS abstract will be submitted</p> <p>Will request SGCCRI to participate</p> <p>MOU with Durgapur Mission Hospital is being processed</p>
2. Point of care HPV study	<p>Dr Asima Mukhopadhyay discussed proposed collaboration with Cepheid India and meeting with International team to start a project on gene Xpert HPV testing in North Bengal tea garden workers</p> <p>Proposal submitted and pilot will be funded. Sankhadeep to develop parallel translational studies and involve PhD students.</p> <p>Dr Mandal suggested strategy to include vaginal microbiome studies along with hpv testing- AM will communicate with Cepheid</p>	<p>Present update in next meeting</p> <p>RRC to approach tea board members to scale up/ support this study</p>
3. AI study in cervical cancer screening	Ranajit Mandal discussed the respective DBT funded studies and areas in integration.	Update in next meeting
4. Combined manuscript	Development of a combined manuscript on regional efforts for cervical cancer prevention towards achieving WHO elimination goals. Am volunteered to present a backbone of the strategy	Update next meeting
5. BIODIVARSITY study	Asima Mukhopadhyay presented the concept of the BIODIVARSITY study looking into the role of Arsenic exposure	Update next meeting

Date: 17/04/2021	Theme: Ovarian Cancer Translational		Participants: Members KolGo Trg Chair: Susanta RoyChowdhury
Agenda	Discussion points		Deliverables within 4 weeks
Ovarian cancer Research direction	<ol style="list-style-type: none"> 1. Need to identify core member group from SGCCRI, CNCI, IICB for active participation in translational research. 2. The PI- Co-PI s of the group selected will run this program 3. There will be 3 (tentative) common translational/research theme contributed by the PI’s: <ol style="list-style-type: none"> a. DDR-p53/ PARP inhibitor axis area b. ImmunelInflammation/metabolism/microenvironment modulation c. Stromal cellular heterogeneity/CAF/stem cell/EMT plasticity 4. All the PI’s should have some applied angles on whatever topic they choose to research 5. Publications on common theme of the research areas discussed 		Identify core group members for each theme who will be willing to develop and execute: <p>PARP axis: SRC, AM, DDG</p> <ul style="list-style-type: none"> • Select subgroup patients • Which assay • Assess resistance mechanisms • Intermittent Parpl <p>Immune-Inflam/metabolism:</p> <p>SC, SB</p> <p>Functional stats f T cells in primary and recurrent setting</p> <p>Metabolic modulation to overcome immune and chemo resistance</p> <p>Spatial – SB</p> <p>Stromal cellular heterogeneity/CAF/stem cell/EMT plasticity-dormancy</p> <p>DDG, CM</p> <p>KolGoTrg projects and not individual projects to be supported by KolGo Trg as publication will be KolGo publications</p>
	in causation of early onset ovarian cancers and potential impact on PARPi therapy/ toxicity		

<p>Biobanking</p>	<p>Possible framework for NABL accreditation and audit discussed by Shuvojit Moulik and AM</p> <p>Members willing to use KolGo biobank should apply and should attempt cost it through their projects</p> <p>Ethics to be discussed. At present KolGo has MTA and MOU with individual institutes who will have their own project specific Ethics</p> <p>Asima to provide Newcastle biobank SOPs and audit tools to develop organisational and operational functioning- update will be presented at next meeting</p> <p>RRC will discuss with ST re ethics with patient as a unit</p> <p>BC discussed operational aspects and challenges</p> <p>AM discussed that patient is the unit and if patient signs consent form to participate and give tissue for KolGo trg biobank and KolGo Trg co-ordinated use of tissue for future research- this must be respected.</p> <p>It will be responsibility of biobank to disseminate how the samples were used for what type of research as determined by the core group- i.e., academic or academia-industry - collaboration. This will be determined by the biobank curator committee</p> <p>Consent form to mention that if any IPR is generated, patient will not get any money.</p> <p>Patient / family member has right to discontinue participation and then samples will be destroyed by biobank team</p>	<p>Create core group for review the process</p> <p>Core group: SRC, RRC, AM, ST, BC, SM</p> <p>Define roles and responsibilities of participants/ stake holders (institution or individual clinicians) and commitment.</p> <p>Prepare a document and circulate to participating member institutes adm authority</p> <p>Formal letter to stakeholders explaining purpose and benefits and attach document</p> <p>Write a protocol and SOP</p> <p>SRC will circulate a template for inclusion of relevant points</p>
<p>Grant applications</p>	<p>WB- DST BT- NuGenA study including Kalyani cohort submitted</p> <p>IPIROC study- to DBT and Wellcome Team Science- pending</p> <p>HIPEC-HR (GCIG study) – submitted to DST Core</p>	<p>Dr. Damayanti and Dr. Shuvojit to discuss on HRD assay, cell lines</p> <p>Grant submission update to be discussed at next meeting</p>
<p>Other issues</p>		<p>Buy yearly zoom link/ google meet</p> <p>Arrange once a 2 month lecture series of 2 talks 0 Biswarup will co-ordinate</p>

Date: 01/05/2021	Theme: cervical cancer and endometrial cancer studies	Participants: Members KolGo Trg Chair: Rahul RoyChowdhury, Dr Panda
RIP: Dr GSB		
Agenda	Discussion points	Deliverables within 4 weeks
Endometrial cancer study	<ol style="list-style-type: none"> 1) There was a discussion on different molecular categories of endometrial carcinoma with reference to the original TCGA paper, 2013 2) AM suggested of starting IHC from patient tissues, as it will cost around Rs. 2000/ per sample [as informed by CKP]. On the basis of MSI-specific IHC patients can be sent for genetic counseling for Lynch syndrome. 3) RRC pointed out the overlap of MSI with POLE and P53 that might lead to misclassification in absence of mutational data from sequencing. 4) DDG explained the overlap from her unpublished data mined from TCGA database as well as from original TCGA paper. 5) DDG also pointed out that p53 IHC will only reveal missense mutated protein and not truncated mutated ones. 6) CKP suggested of starting the MSI-specific MLH1 and MSH6 IHC at his lab at CNCI. 7) SGCCRI can also start initial IHC if antibodies are available. 8) Other members present were Dona Chakraborty , Puja Chatterjee, and others 	<p>Present update in next meeting- manuscript submission to acknowledge discussion in KolGo platform in preparation of upcoming KolGo studies and grant applications/ IGCS abstract submission</p> <p>At least start studies in the region in bench on molecular stratification in research settings including MMR testing as it will be difficult under clinical settings.</p> <p>AM will arrange to send FFPE from CNCI to CKP to start pilot work</p>

Date: 08/05/2021	Theme: Clinical Trials	Participants: Members KolGo Trg Chair: Rahul RoyChowdhury
Agenda	Discussion points	Deliverables within 4 weeks
HOTROC study update- RRC to present		
INTERLACE study update at CNCI and SGCCRI- Mou/ Twinkle to present		Present update in next meeting
SENTICOL update- Mou		
GCIg update on the Symptom benefit committee- AM Potential studies where KolGo will participate:	<ol style="list-style-type: none"> 1. Expression series of studies on survivors- Start the KolGo Surv study- identify long term survivors in the region 2. PADOVA- physical activity and exercise in pre op optimisation for ovarian cancer surgery 3. Economic study on PARPi and finding out QA PFS endpoints 4. HARMONICA- harmonising HRQOL measures 5. PEACE- end of life – patients and carers- questionnaire based 	
Formation of KolGo Trg EC - Dr Tripathi to discuss		

5th Annual Meet (4th February – 9th February, 2023)

5th Annual Meet



4th-5th February, 2023-Kolkata
6th-7th February, 2023-Darjeeling
8th-9th February, 2023-Siliguri



Organised by -

Kolkata Gynecological Oncology
Trials and Translational Research Group

in association with-



4 th February 2023	Topic of Discussion	Speaker
8.30 am- 12.30 pm	<p>Welcome address: Prof Biman Chakrabarty (Venue: Suraksha) Diagnostics Newtown Conference Room)</p> <p>Translational end points on clinical trials: Brainstorm and update</p> <ul style="list-style-type: none"> • IPIROC 3, HIPEC HR, HRDAIC, PROVAT and BIODIVARSITY- Asima Mukhopadhyay/ Kaushik Sengupta/ IICB/MAHE/ Suraksha • Translational Grant application – Damayanti Das Ghosh, Susanta Roy Chowdhury, Biswarup Basu • DBT Cancer biology grant application in cervical cancer (Putting SyMec to practice): Sharmila Sengupta, Shilpak Chatterjee 	
1.00 pm- 3.00 pm	<p>Break for snacks/ Tour of Clinical and lab site by delegates/ Lunch on own</p>	
3.00 pm - 6.00 pm	<p>Brainstorm session: new proposals (Venue: ITC Royal Kolkata)</p> <ul style="list-style-type: none"> • IPIROC 3 brainstorm and protocol development- Asima Mukhopadhyay (Sponsor: BDR Pharma) • Planning Pragmatic studies in India and Health policy implementation: Santanu Tripathi • Endometrial cancer de-escalation strategies/ RAINBO participation- Rahul Roy Chowdhury (Sponsor: Strand life Sciences) • Endometrial cancer study idea- Kailash Narayan • Bringing precision to medicine to newly diagnosed ovarian cancer- Chanchal Goswami (Sponsor- Astra Zeneca) • Newer Diagnostics in Cervical cancer Screening _ Ranajit Mandal (Sponsor: Tata MD) 	
7.00 pm- 9.00pm	<p>Dinner symposium at ITC Royal Kolkata: Centralizing diagnostics for Oncology research (Sponsor: Suraksha-KolGo Trg)</p> <ul style="list-style-type: none"> • KolGo- Suraksha Academia Industry collaboration and future directions -Asima Mukhopadhyay and Somnath Chatterjee • Need for centralized oncology and radiology services for clinical research and trials - Amit Oza • Current status of Molecular diagnostics in Gyn Cancer practice and Research- Michael Bookman • Importance of LVSI assessment in Oncopathology- Kailash Narayan • KolGo Trg biobank update (Cloud LIMS)- Shuvojit Moulik 	

5th February, 2023	Workshop Venue: Westin Hotel Kolkata
8.30-10.30 am	<p>Education and Harmonization update</p> <ul style="list-style-type: none"> • GCIG strategic vision for LMIC- Michael Bookman and Amit Oza • KolGo Trg overview and participation of SAARC / SAFOG countries- Asima Mukhopadhyay • IGCS global curriculum program in India and researcher development – GCIG young investigator program (Michael Bookman/ Amit Oza/Asima Mukhopadhyay) <p>Quality of life/Symptom Benefit and Health Economic study update (Sponsor Medgenome)</p> <ul style="list-style-type: none"> • Every Women Study- LMIC- update • Analysis plan for SOCQER IND/ HEPTRC and Willingness to pay studies • NuGenA (Nurse led genetic counselling and awareness) study update- Dona Chakraborty • PreCerca (Prevention of cervical cancer) and PREGNANCY update – Asima Mukhopadhyay
11 am- 1.30 pm	<p>Brain storming sessions: New/ ongoing proposals/ Translational studies (Sponsor: Curotherm Solutions)</p> <ul style="list-style-type: none"> • Update of ongoing/ GCIG studies (INTERLACE/ SENTICOL/ DEBULK/ OVIHIPEC 2/ HIPEC-HR)- • Cervical cancer new study ideas: <ul style="list-style-type: none"> - PARP RAD and RECERCA study: Asima Mukhopadhyay and Puja Chatterjee - Immunotherapy study idea (Translational Proof of concept)- Jyotirup Goswami - LMIC trial ideas: Kailash Narayan
1.30 pm- 2.00 pm	<p>Break for refreshment</p>
2.00pm- 6.00 pm	<p>Symposium followed by Dinner: Parp inhibitor in ovarian cancer update (Sponsor: BDR Pharma)</p> <ul style="list-style-type: none"> ▪ Development of Rucaparib: Science and Serendipity- Professor Nicola Curtin ▪ Parp Inhibitor in Frontline management of ovarian cancer- Amit Oza (Immediate Past Chair GCIG) ▪ Parp inhibitor in management of Recurrent ovarian cancer- Michael Bookman (Chair Elect, GCIG) ▪ IPIROC study (KolGo Trg) update and future grant

	<ul style="list-style-type: none"> ▪ application - Asima Mukhopadhyay ▪ Made in India PARP inhibitor project: CSIR, Govt of India ▪ Patient participation in research- Sarbojaya group meeting
6th-9th February	KolGo Trg : Darjeeling-Siliguri Workshop
6 th - 7 th February 9 th February	<p>KolGo Trg study Protocol development, finalization and discussion: Venue: Darjeeling Mayfair: Small group session (Closed)</p> <p>Live workshop on CIN treatment – North Bengal Medical College</p>
8 th February 5.30 to 8 pm	<p>PreCerCa (Point of care HPV testing in Teagarden workers) Workshop: Stakeholder meeting- Mayfair Siliguri (Mahananda Hall)</p> <p>Dinner Symposium (Sponsor: Cepheid)-: Guest of Honor: Professor Neerja Bhatla (AIIMS, New Delhi) and Gwynn Stevens Thorburn</p> <p>Collaborator: Manisha Nandi Foundation, Suraksha Diagnostics, , North Bengal Medical College, and Rotary Club of Kolkata Urbana</p>



5TH ANNUAL MEET
2023