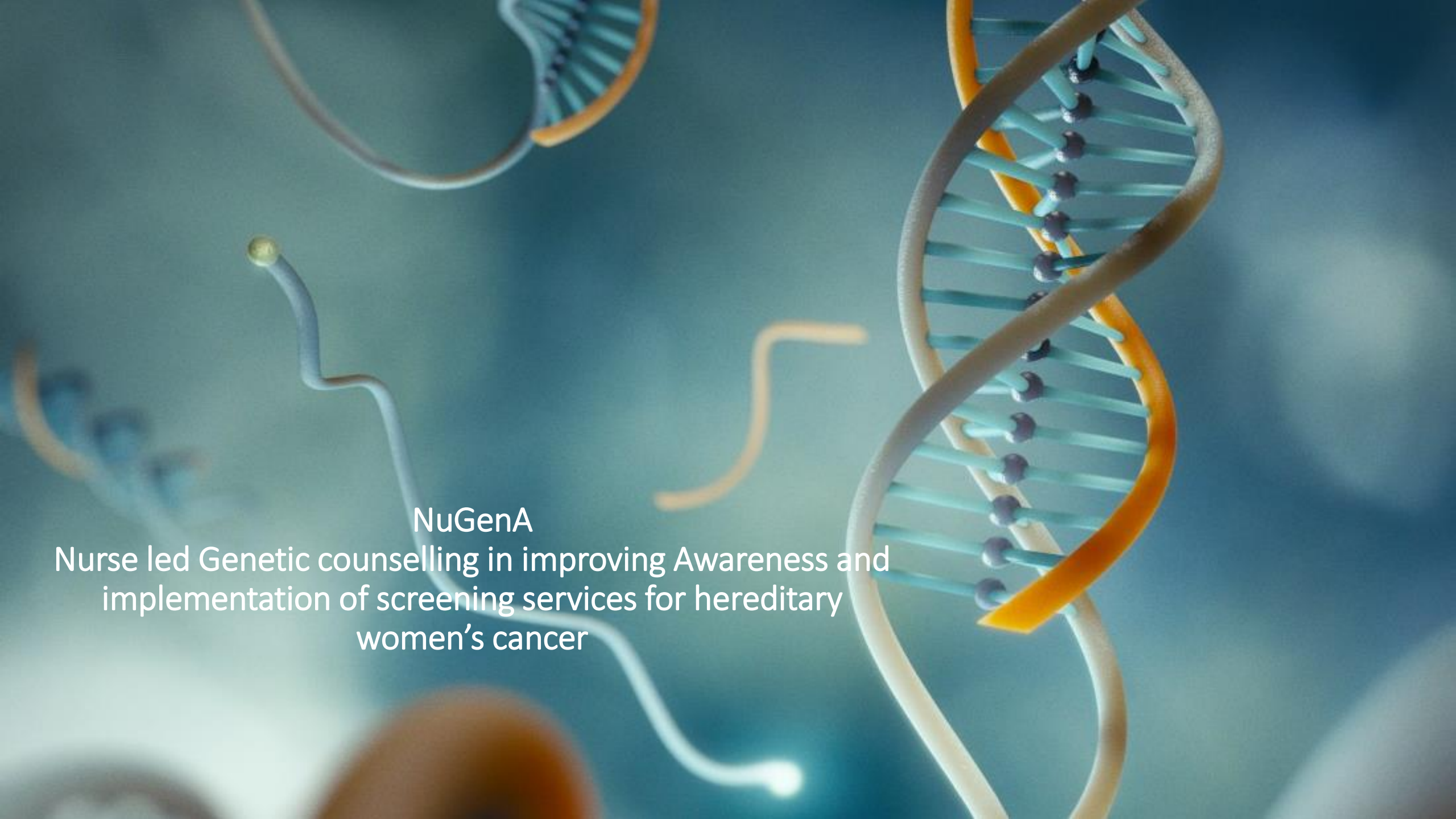
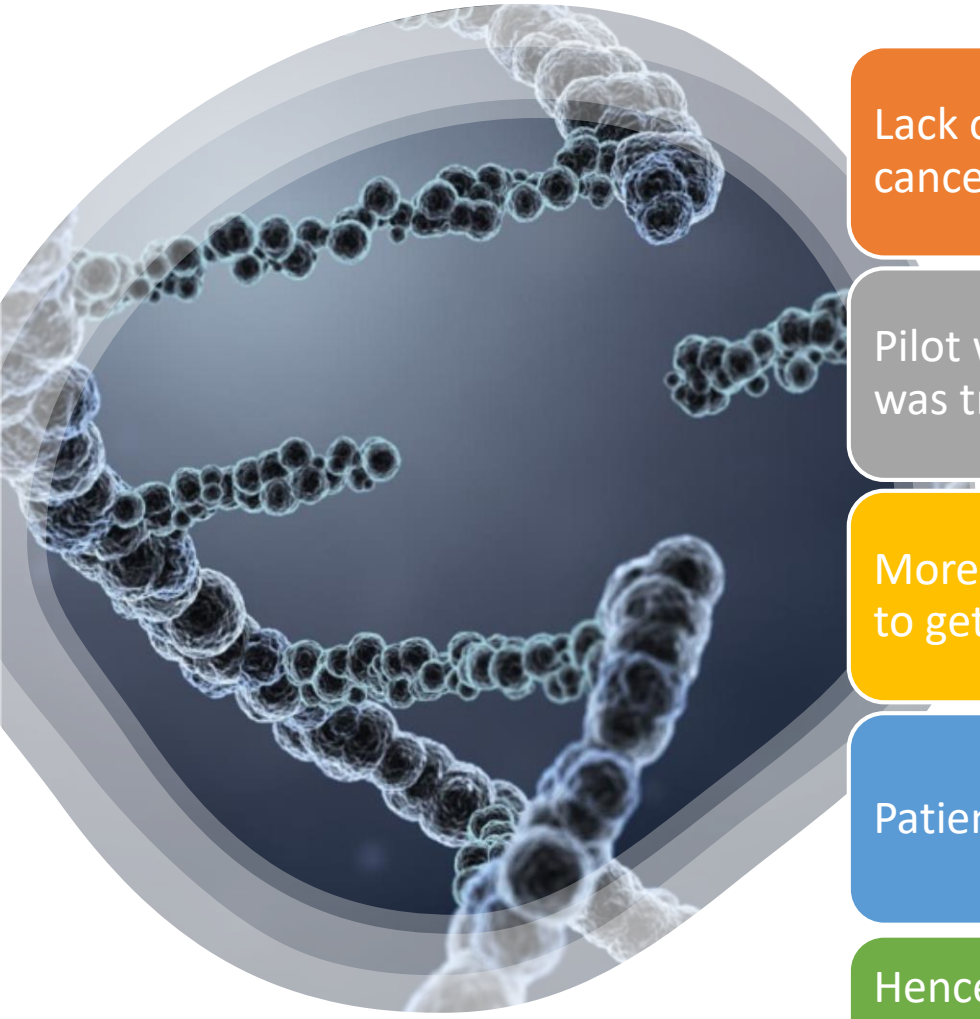


NuGenA

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

Background to the study



Lack of knowledge especially in the community regarding onset/symptoms of cancer leading to late diagnosis

Pilot work in a regional cancer center in Kolkata, India where a research nurse was trained in various genetic clinics in India and UK

More patients and their relatives identified their risks and were encouraged to get themselves tested.

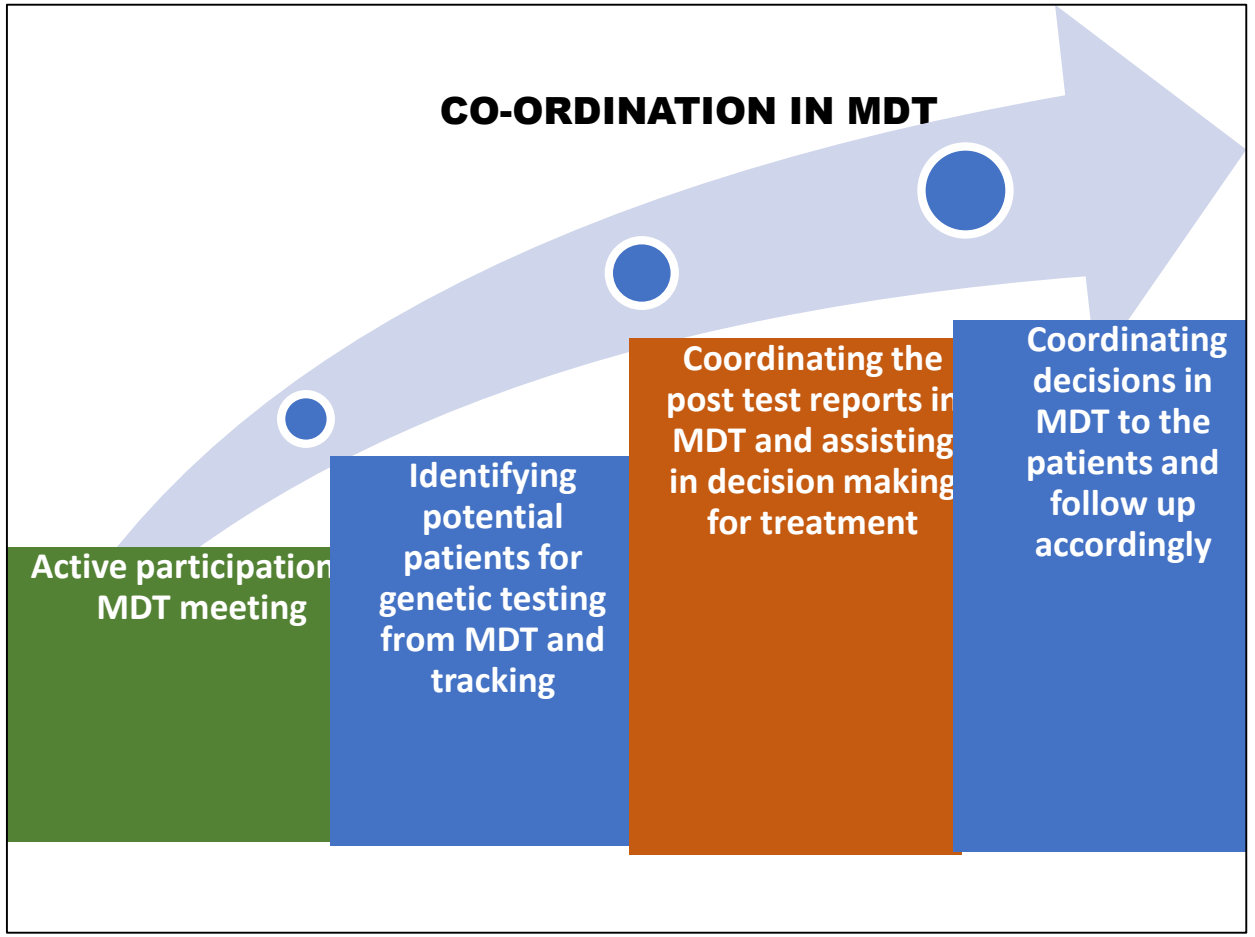
Patient-satisfaction/follow up rate and acceptance was remarkably

Hence, Nurses after adequate training can be an excellent link to motivate patient-public initiatives and develop community-based awareness and health campaigns on familial disorders and genetic counseling.

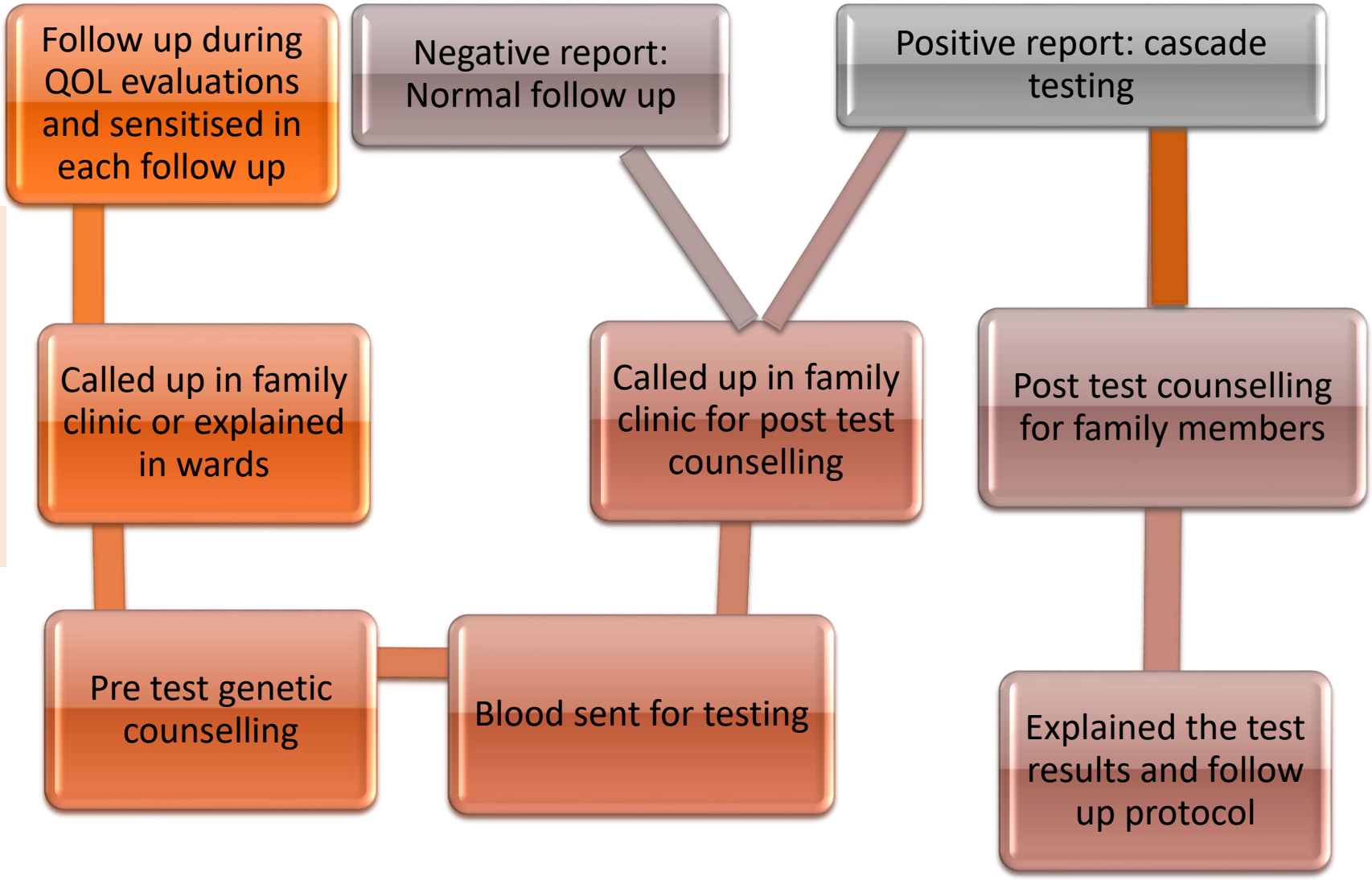
EARLY DATA: TMC Kolkata

EDUCATION AND TRAINING

- - 1 year pre test genetic counselling under the supervision of trained genetic counsellor , consultant gynae-oncologists and breast oncologists specialised in genetic counselling at Tata Medical Center, Kolkata (**sponsor STRAND Lifesciences**)
- -2 months training in Cancer Genetics Clinic, Tata Memorial Hospital, under the supervision of Dr. Rajiv Sarin.
- -Research co-ordination with Barts Cancer Institute, Queen Mary University of London, UK for SIGNPOST Study.(**sponsor DST-UKIERI**)
- -Coordination with EORTC group



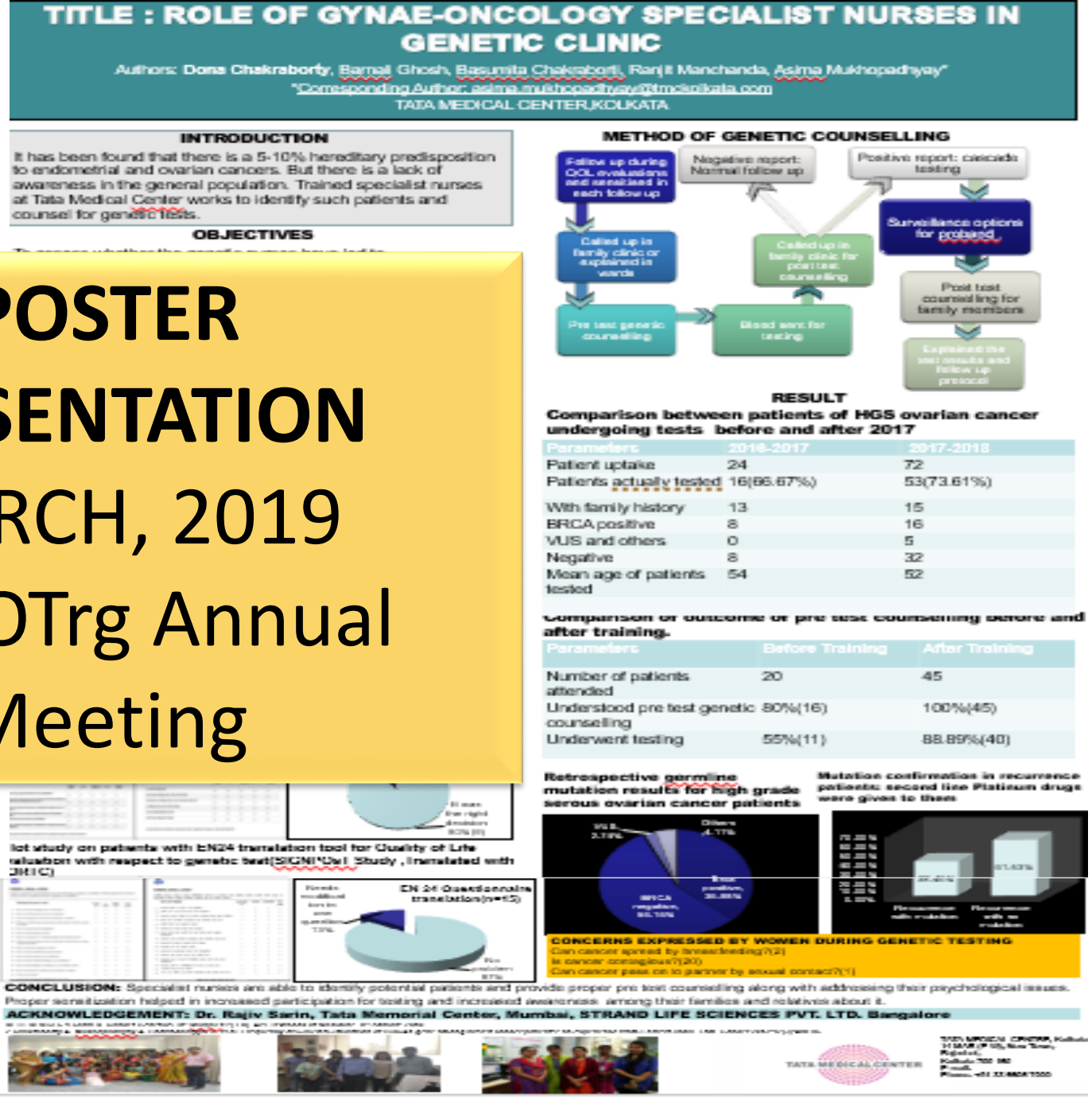
METHOD OF GENETIC COUNSELLING



POSTER PRESENTATION

MARCH, 2019

KolGOTrg Annual Meeting



Aims of the study

Overarching goal: Development and implementation a nurse-led genetic counselling service and evaluation

OBJECTIVE 1: statistical goals: To identify whether implementation of a nurse led genetic clinic in locoregional centres (hub and spoke model) supported by patient public involvement initiatives is a cost-effective strategy for hereditary women's cancer prevention measured by:

- Determining the prevalence of germline BRCA mutation (and HBOC) in a hospital-based patients (pilot) with ovarian and breast cancers (triple negative) and at-risk individuals in the family
- Identifying more (% increase) individuals at risk of developing hereditary gynecological cancers through awareness and screening campaigns compared to traditional non concerted hospital-based approaches.
- Improving the uptake of genetic testing and referrals which impact on increased number of at- risk individuals accepting risk reducing interventions.
- Cost- analysis of such approach where the cost of organization of health screening facility is part-borne by the local community.
- In a defined population cohort of women (Kalyani cohort of 20,000 women), collection of additional blood/ DNA samples and clinical data on family history suggestive of HBOC to determine the population level prevalence of BRCA mutations and at -risk individuals in family. BRCA testing will be done at a later date through separate funding.

Aims of the study

Objective 2: Qualitative and implementation goals

- Assess acceptability and embeddedness (population/ provider/governmental level)
- Compare local community satisfaction (rates and qualitative) between screening camps facilitated and organized by PPI and local champions versus those organized by conventional institutional initiated efforts
- Study willingness to pay (WTP) for screening and genetic testing in population attending the screening camps
- Assessing differences in service implementation (barriers and solutions and risk/harm) prospectively in rural versus urban and different socio-economic strata

Aims of the study

- **Objective 3: Systematic Biobanking through** a structured/NABL accreditable framework (KolGoTrg Biobank – Kolgotrg) - of the samples collected from above (cancer patients, healthy relatives at risk and population cohort) towards developing biomarkers for early detection/prevention in the future

Aims of the study

- **Objective 4: Training and education**

Evaluate the training program of developing nurse genetic counsellors as measured by success of implementing a West Bengal Health University affiliated course of genetic counselling and interest/uptake of nursing and allied health care professionals in attending such courses.

Research team required for the study

Clinical research team: Country Lead: KolGOTrg

Genetics: nurses trained in genetic counselling by the study team

Health informatics team: telemedicine support

Designated laboratory: storage,collection and process of samples

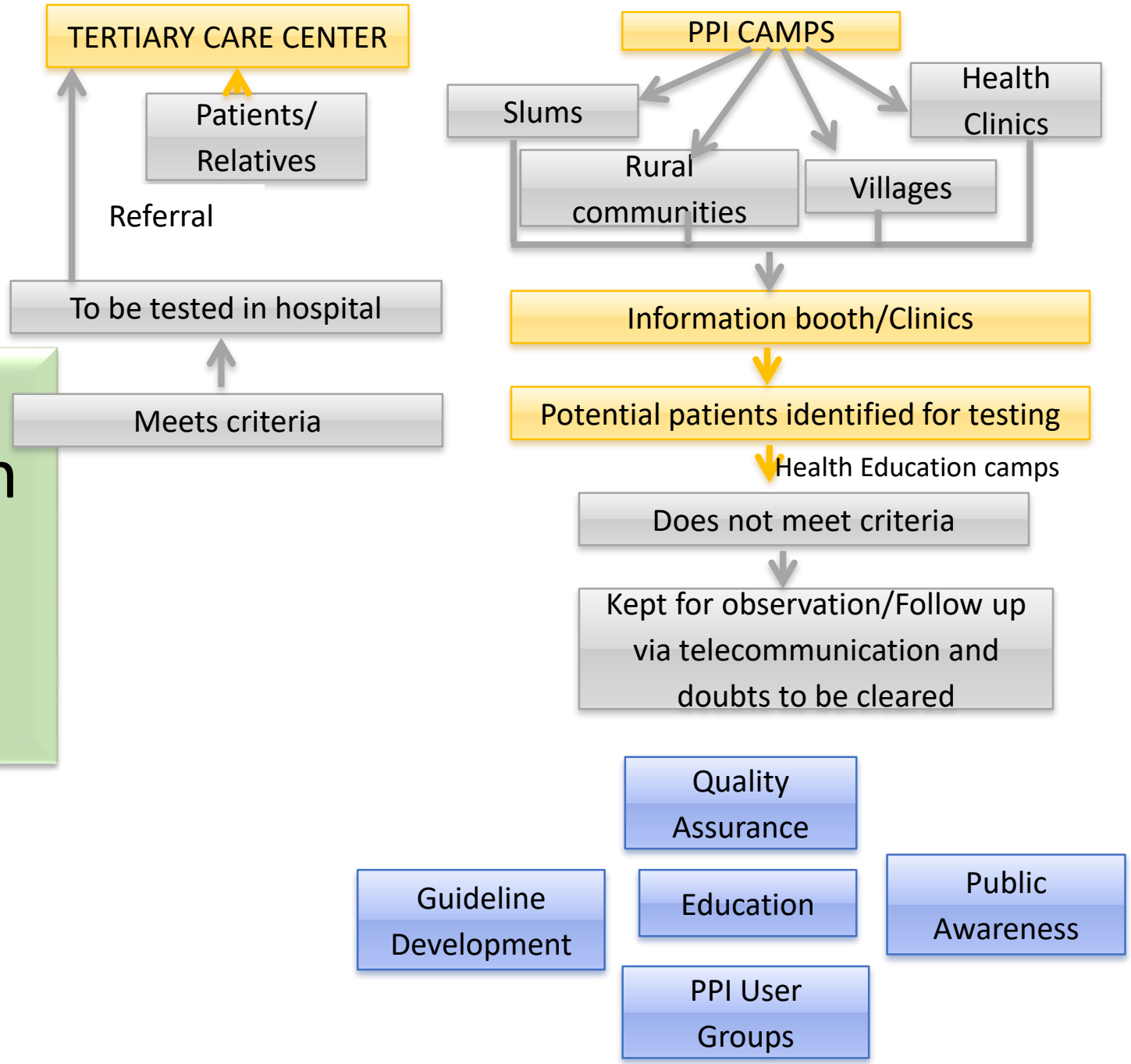
Health informatics team: for the Willingness to pay study

Education and training: KolGOTrg/local centres

Statistical team

Data Management team: Data will be stored in REDCap

Model of Patient-Public Involvement in NuGenA



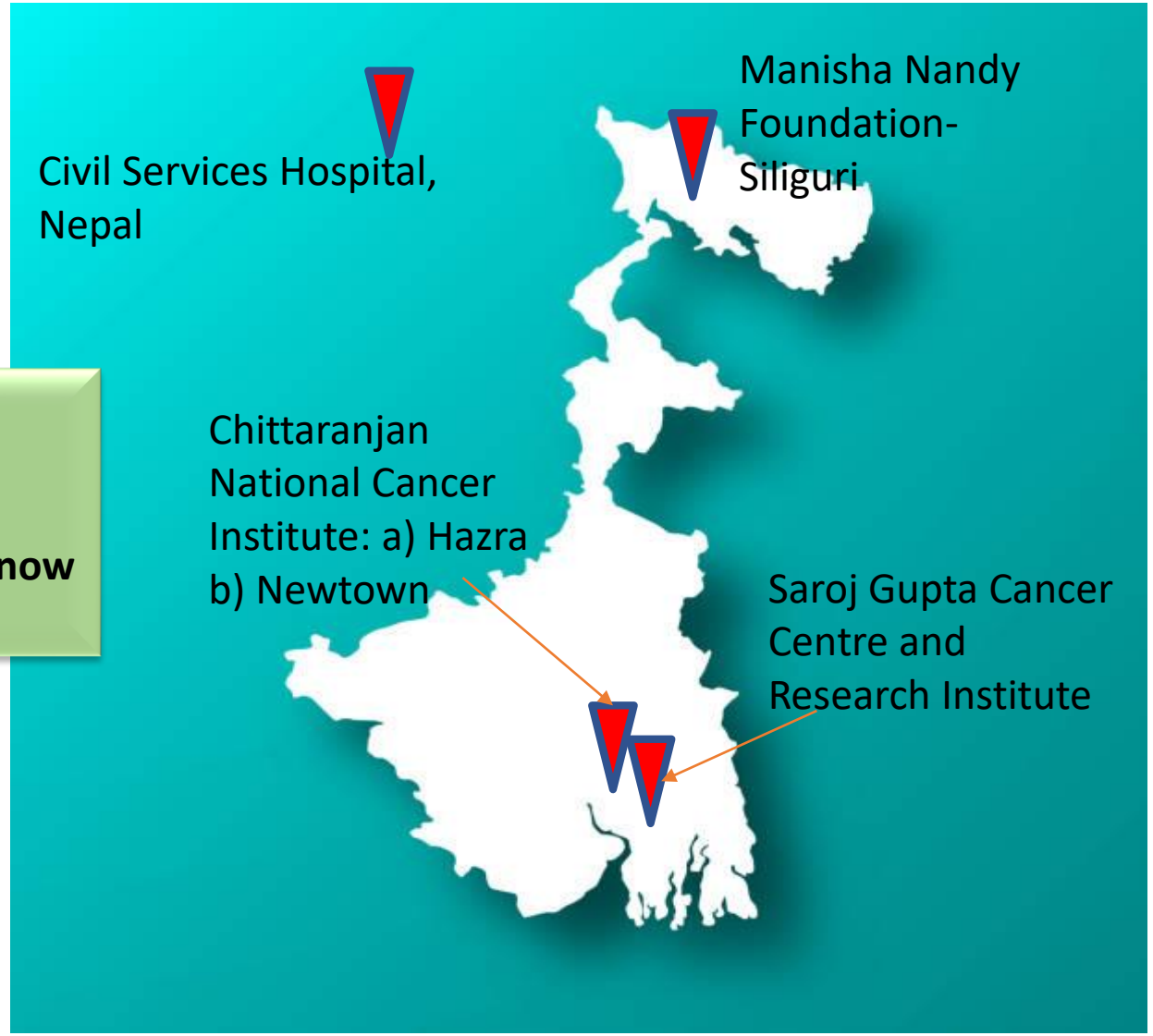
Questionnaires implemented and their rationale

- **Pre-screening form Inclusion/Exclusion criteria:** To identify whether a patient can be enrolled in the study
- **Baseline questionnaires:** Demographic questionnaires of each patient
- **Cancer Awareness Measures(CAM):** Interview based questionnaires to identify the knowledge level of each patient and their family members.
- **Family History form:** Pedigree diagrams briefing all necessary details of the family, including histories of cancer/developmental delays/abortions/TB etc.
- **Willingness to pay:** Patient willing to pay on basis of the benefits versus the actual cost the patient can bear.
- **Pre-test counselling satisfaction-regret scale:** Satisfaction/regret after counselling
- **Post-test counselling satisfaction-regret scale:** Satisfaction/regret after the test results
- **MICRA:** Anxiety/worry questionnaires encompassing genetic test.

Questionnaires and timeline

Questionnaires	1st visit	Pre-counselling	Post counselling	Pre-testing	Post- test report collection	Post test counselling
Pre-screening form Inclusion/Exclusion criteria						
Baseline questionnaires						
Cancer Awareness Measures(CAM)						
Family History form						
Willingness to pay						
Pre-test counselling satisfaction-regret scale						
Post-test counselling satisfaction-regret scale						
MICRA						

Centres currently participating in the study



Centres interested to participate:
KGMU, Lucknow
AIIMS New Delhi
Kalyan Singh Super Specialty Hospital, Lucknow
CMC Vellore

Achievements for NuGenA study

- 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

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 Siliguri and Bagdogra army hospital with sensitisation training of nurses, Feb 2021

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

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

FIRST GENETIC COUNSELLING SESSION IN CNCI RAJARHAT CAMPUS

LOCAL AWARENESS CAMP AT DUMDUM, KOLKATA THROUGH PATIENT_PUBLIC INITIATIVE

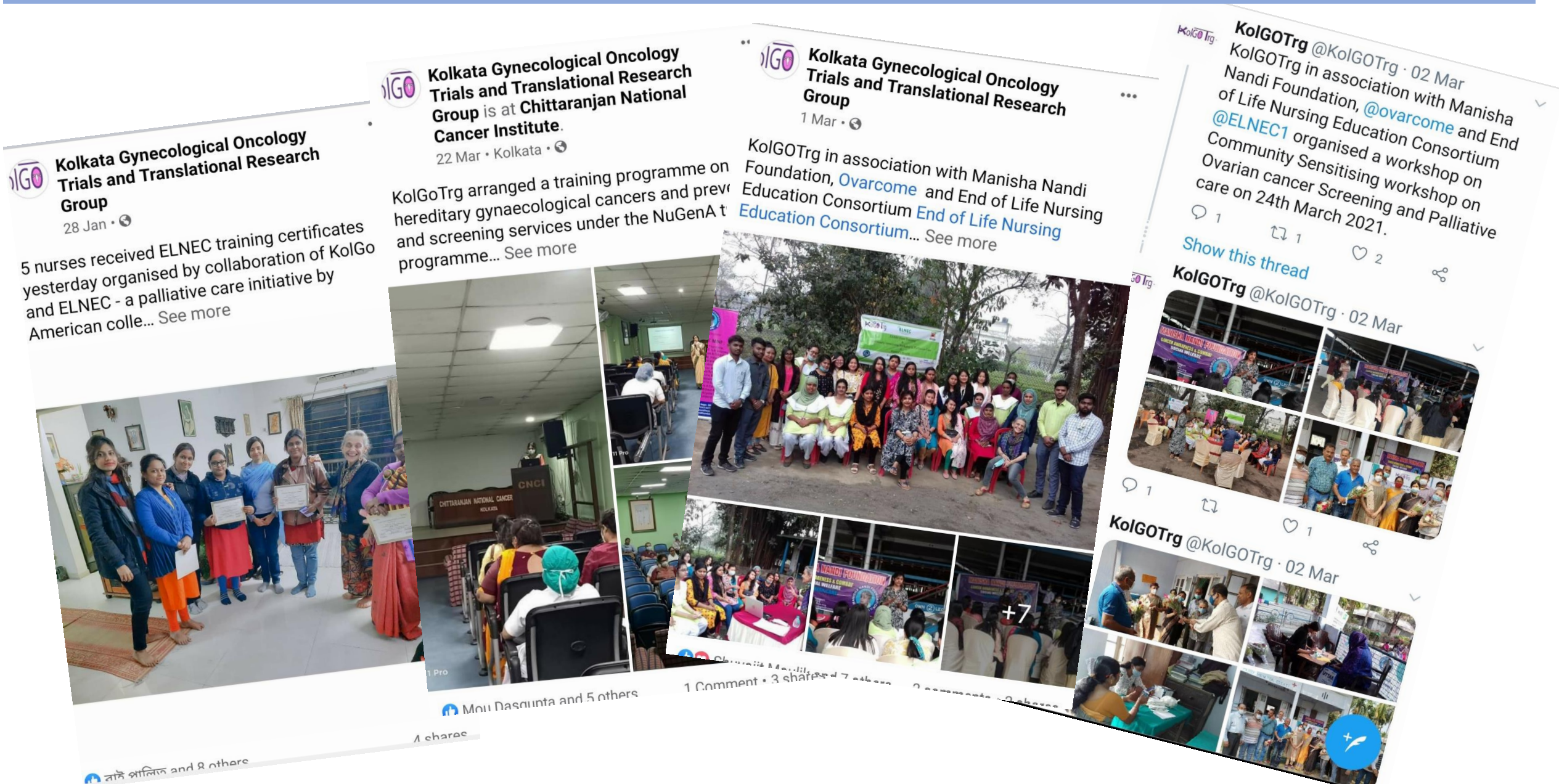
FEEDBACKS

Mandira Chakraborty (PPI member, left): I myself have been tested to be Lynch positive and I know how it feels to know what risks of cancer I have and what risk my siblings and children have. I now know what to look for and how to handle a risk rather than wait for another mishap happen to me or my family. I know the importance of getting tested. It was possible because of you and your team. It feels wonderful to be a part of a study where you identify such risks and help them benefit from testing

Sr. Swati Ghosal (Nursing Superintendant,CNCI, right) : It is a very new concept for us. We have read about hereditary breast and ovarian cancer in our syllabus but haven't received any formal training about genetic counseling and pedigree analysis. It is essential for us to get trained so that we are able to identify potential patients and refer them for testing. Moreover the concept of nurse-to-nurse referral is very new and innovative and I feel it will enhance our role in the healthcare profession even more. It is so exciting to know that nurses will be leading in camps and clinics in India which is basically a concept in developed countries!"

Susmita Pal (PPI member): It is important to know about hereditary cancers, especially because we know we can prevent it in many generations of the family. I have faced cancer and I know how worse the journey is. I would never want any of my family members to go through the same thing. If there is something which helps you identify whether your family members have a chance to get cancer, I think they should absolutely go for it. We are immensely thankful to OVARCOME and the funders for supporting this novel initiative

SOCIAL MEDIA UPDATES



Future directions

We are very thankful to OVARCOME for believing in NuGenA and supporting this initiative during its early days. All thanks to this that NuGenA has been awarded CHARTER CHAMPION by the WORLD OVARIAN CANCER COALITION(WOCC), and has been awarded INTERNATIONAL INNOVATION GRANT from ASCO for continued support and funding for the initiative (www.kolgotrg.org)

Press release: https://youtu.be/RnANb-D_h5c

Further planning of the study depending on the EASE model of implementation

EASE MODEL FOR FUTURE STRATEGIES:	
Ethical	No. of person willing to participate vs no. who could participate depending on incl/excl criteria No. of persons who opted out of the study
Acceptable	No. of patients who underwent counselling No. of patients who underwent testing No. of at-risk family members who underwent counselling No. of at-risk family members who underwent testing
Sustainable and scalable	No. of patient/family members who wants to organise screening(PPI/snowballing) No. of sites initiated No. of nurses trained in genetic counselling No. of patients recruited from different sites
Effective	Effectiveness of the model calculated based on patient uptake.
Early diagnosis and treatment	No. of patients referred to preventive oncology follow-ups No. of nurses underwent preventive screening No. of patients underwent preventive surgery 5 year follow-up of patients and response assessment

Acknowledgement

Newcastle University / Centre for Cancer

Nicola Curtin
Yvette Drew
Luke Vale

NGOC Northern Gynaecological Oncology Centre

Ann Fisher
Ali Metin

CNCI

Sarojini Gupta Cancer Centre & Research Institute

TATA MEDICAL CENTER

CSIR-Indian Institute of Chemical Biology

IISER KOLKATA

KolGOTrg
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Ratnaprabha Maji
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Vaishali Mulchandani
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Barnali Ghosh
Dona Chakrabarty
Aparajita Bhattacharya
Twinkle Sinha
Mou Das
Ajit Mukhopadhyay

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Michael Bookman
Amit Oza
Iain McNeish
Mary McCormack
UCL CTU
Ted Trimble

Collaborators
Ranjit Manchanda
Dipanjan Chowdhury
WOCC

UKIERI
UK-India Education and Research Initiative

wellcome trust DBT INDIA ALLIANCE

CANCER RESEARCH UK

Department of Biotechnology
Ministry of Science & Technology
Government of India

strand

JIV DAYA FOUNDATION
Dallas Texas

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