

List of Speakers for Clinical Trial Workshop (Feb 10th, 2011)

Session I			
Sl. No.	Timing	Topic	Speaker
1.	09.00 A.M to 09.45 A.M	ICH GCP and bioethicalty issues	Dr. Subhrojyoti Bhowmick, M.D Consultant, Medical Information Services Pfizer India
2.	09.45 A.M to 10.30 A.M	Informed Consent	Dr. S. Ganapathy Ramanan Director and consultant Medical Oncologist Madras Cancer Care Foundation Chennai 600020
3.	10.30 A.M to 11.15 A.M	Introduction to clinical trials design	Dr. Subhrojyoti Bhowmick, M.D Consultant, Medical Information Services Pfizer India

Session II			
Sl. No.	Timing	Topic	Speaker
1.	11.15 A.M to 12.00 P.M	Statistical methods in trial design and end results analysis	Dr. P. K. Mohapatra Scientist E Regional Medical Research Centre, NE (ICMR) Department of Health Research, Govt of India 786001, ASSAM, India
2.	12.00 P.M to 12.15 P.M	Computers and data collection	Mrs. Roselind, Research Scientist III, NCRP, Bangalore

3.	12.15 P.M to 01.00 P.M	Integrating laboratory science with clinical work - the way forward	Dr. Pattatheyl Arun M.S., M.Ch. Consultant, Department of Head and Neck Surgery Tata Medical Center Cancer Hospital Kolkata. India 700 156
4.	01.00 P.M to 01.45 P.M	Facilitating Physician- Scientist interaction: Perspectives from a Scientist	Dr S. K. Ghosh Professor and Head, Biotechnology School of Life Sciences Assam University

Session III			
Sl. No.	Timing	Topic	Speaker
1.	02.15 P.M to 02.30 P.M	Funding Avenues for Fundamental and clinical research in NE: Part I	Dr. B.L Jaikhani Senior Consultant NERBPMC, DBT, Gov. of India, New Delhi
2.	02.30 P.M to 02.45 P.M	Funding Avenues for Fundamental and clinical research in NE: Part II	Dr. P. K. Mohapatra Scientist E Regional Medical Research Centre, NE (ICMR) Department of Health Research, Govt of India 786001, ASSAM, India
3.	02.45 P.M to 04.00 P.M	Research possibilities in the north east- Brain Storming Session	

List of Participants in Clinical Trial Workshop (Feb 10th 2011)

Sl No.	Name	Institute	Abstract/Poster Title	Contact Details
1.	Mr. Abhijit Mitra	Dept. of Biotech, Assam University		09954147027
2.	Mr. Arijit Bhattacharjee	Dept. of Biotech, Assam University		09401460341
3.	Mr. Mukunda Upadhya	Dept of Social Work, Assam University		9706589919

4.	Mr. Trikul Huda Mazumdar	Dept. of Biotech, Assam University		9954960302
5.	Mr. Sayantan Nath	Dept. of Biotech, Assam University		9401319044
6.	Mr. Nibendu Nath	Dept. of Biotech, Assam University		9401061647
7.	Miss. Priyanka Sarkar	Dept. of Biotech, Assam University		9706271920
8.	Miss. Peenaz Rahman	Dept. of Biotech, Assam University		9435579112
9.	Mr. Javed Hussain Choudhry	Dept. of Biotech, Assam University		9706498577
10.	Mr. Ramananda Ghosh Tarafdar	Dept of Life Science & Bioinformatics, Assam University		8876085617
11.	Dr. Sumit Goyal	Medical Oncologist, RGCI, New Delhi		9654312972
12.	Dr. Sandeep	Gyanecologist		9654312972
13.	Prof. S.K Ghosh	Dept of Biotech, Assam University		
14.	Prof. Munish Kumar	Dept of Biotech, Assam University		9435373330
15.	Mr. Gaurav Kaithwas	Dept. of Pharmaceutical Sciences		8876222878
16.	Mr. Jagdish Hansa	Dept of Biotech, Assam University		9401332859
17.	Mr. Jintu Dutta	Dept of Biotech, Assam University		9706939610
18.	Mr. Padmalochan Bora	Dept of Biotech, Assam University		9706698744
19.	Prof. Mahua Sengupta	Dept of Biotech, Assam University		9435171903
20.	Dr. Kuddush Ahmad	Dr. B Boroah Cancer Institute, Guwahati		9435115920
21.	Dr. S. B Medhi	Dr. B Boroah Cancer Institute, Guwahati		9864061697
22.	Mr. Vinodh Jaganti	NIPER, Guwahati	"Review on Cancer Chemotherapy"	8876944801

23.	Mr. Mahesh. V	NIPER, Guwahati	"Role of Telomerase in Various Disease"	9508865811
24.	Mr. A.V Kiran Kumar Reddy	NIPER, Guwahati	"mTOR- A New Pathway to Target in Oncology"	8876946306
25.	Mr. S. Venu Gopal	NIPER, Guwahati	"mTOR- A New Pathway to Target in Oncology"	8876944803
26.	Miss. Rosy Mondal	Dept of Biotech, Assam University		9435588267
27.	Mr. Ramkrishna Pal	Dept of Biotech, Assam University		9401543721
28.	Mr. Fazhur Rahman	Dept of Biotech, Assam University		9401393804
29.	Dr. Arijit Guha	Dept of Biochemistry, AMCH		9435669539
30.	Dr. Ritesh Tapkire	Surgical Oncologist, CCHRC		
31.	Dr. S. Bhattacharjee	SSNS, Silchar		
32.	Mr. Bijay Kumar Das	SSNS, Silchar		9435374398
33.	Dr. J. K Deb	CCHRC		9435374398
34.	Mr. M. Joyraj Bhattacharjee	Dept of Biotech, Assam University		9954148709
35.	Dr. Nishmitanda	MDHRC		9435071638
36.	Dr. Sumeru Singha	G.C College		9706660645
37.	Miss. F.S Roselind	Scientist, NCRP, Banglore		9448955446
38.	Miss. Priyanka Das	Scientist, NCRP, Banglore		9880829290
39.	Dr. Iqbal Bahar	CCHRC		9435034399
40.	Dr. Rayhan Majumdar	CCHRC		9435072684

41.	Miss. Farheen Khan	Aligarh Muslim University, Aligarh	A Comparative Prophylactic Study Between Spheroplast and Heat Killed S. Typhimurium"	9559902405
42.	Prof. D. P Roy	CCHRC		9435232496
43.	Dr. Vikash Mahajan	Chennai Apollo Hospital		9444050369
44.	Dr. S. Ayyappan	Chennai Apollo Hospital		9841047464
45.	Dr. Sanmay Ganguly	Cancer Centre Welfare Home & Research Institute, Kolkata		9433032852

Cachar Cancer Hospital & Research Centre, Silchar organized a one day workshop on "Clinical Trials- How and Why" on February 10th, 2011 to commemorate its 15th Hospital day.

The objective of this workshop was to enable the participants to:

1. Understand that good research can be done in the north east as is being done in other parts of India.
2. Identify personnel whom they could approach for collaboration/assistance/mentorship for their research questions.
3. Know ways of seeking funds for research.
4. Know how to build bridges with the basic science community.

The workshop faculty included:

1. Dr. Subhrojyoti Bhowmick, M.D
Clinical Pharmacologist, Medica Superspecialty Hospital, Kolkata;
Consultant, Medical Information Services, Pfizer India.
2. Dr. S. Ganapathy Ramanan, M.D., D.M.
Director and Consultant Medical Oncologist, Madras Cancer Care Foundation, Chennai and
Managing Trustee, Cancer Research and Relief Trust and Cancare Foundation, Chennai
3. Dr. P. K. Mohapatra
Scientist E, Regional Medical Research Centre, NE (ICMR), Department of Health Research, Govt of
India, Dibrugarh
4. Mrs. Roselind Herbert
Research Scientist III, National Cancer Registry Programme, Bengaluru.
5. Dr. Pattatheyl Arun, M.S., M.Ch.
Consultant, Department of Head and Neck Surgery, Tata Medical Centre Cancer Hospital
Kolkata
6. Prof. Dr. Sankar. K. Ghosh
Professor and Head, Department of Biotechnology, School of Life Sciences, Assam University, Silchar.
7. Dr B.L. Jaikhan, M.D.
Senior Consultant, Health and Medicine, North Eastern Region Biotechnology Programme Management
Centre, Department of Biotechnology, Govt. of India. New Delhi and former Head of Department,
Laboratory Medicine, All India Institute of Medical Sciences, New Delhi

A summary of the lectures by different speakers follows.

1. ICH Good Clinical Practice (GCP) and Bio ethicality Issues: Dr. Subhrojyoti Bhowmick

In his introductory lecture, Dr Bhowmick emphasized the need for implementing good clinical practice (GCP) in conducting clinical trials. This would ensure accurate and credible data and results. It would also protect the rights and confidentiality of trial subjects. Impeccable ethical and scientific standards are mandatory in planning and conducting trials.

He quoted examples from recent history from India and abroad demonstrating the consequences of violating GCP norms. He discussed the regulatory guidelines and structure of various institutions like ICH and ICMR. He also talked about the shared responsibility of investigators, sponsors, regulatory bodies, ethical committees and clinicians when conducting clinical trials. Composition of ethics committees and training for such committee members was also explained

2. Informed Consent: Dr. S. Ganapathy Ramanan

Dr. Ramanan spoke on the need for informed consent in conducting ethically appropriate clinical trials. It is a basic right of the individual being enrolled to be informed about each component of the study: the research nature of the study, the nature of randomisation and the possibility of being in the control or study arms along with the possible benefits and risks involved. Monetary inducements even if implied indirectly are unethical. Patients must have the right to decline to participate or withdraw from the study at any point of time without their further care by the physician concerned being prejudiced.

He elaborated on the guidelines outlined in the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, ICH GCP guidelines and the ICMR guidelines. He also talked about the procedure for taking a detailed consent during a study.

3. Introduction to Clinical Trials Design: Dr. Subhrojyoti Bhowmick

In this lecture, Dr. Subhrojyoti Bhowmick talked about the role of a robust clinical trial design in the successful implementation of any clinical trial. He started with formulation of a research question or hypothesis with relevance to the proposed study. He elaborated on the components and types of study design like case-control studies, randomized studies and their clinical outcomes with examples when implemented in a clinical trial.

4. Statistical methods in trial design and end results analysis: Dr. P. K. Mohapatra

Dr. P. K. Mohapatra stated the importance of statistical methods in epidemiological and clinical studies. He highlighted different aspects and types of observational and interventional studies through examples. He explained the methodology for sampling a given population for a research study. He demonstrated how large sample sizes increase precision and reduce confidence intervals. He also elaborated cohort, case control and cross sectional studies with well defined examples.

5. Computers and data collection: Ms. Roselind Herbert

Ms. Roselind Herbert demonstrated the data entry software developed by the National Cancer Registry Programme for use in hospital registries across India and highlighted the role of computers and information technology in collection and retrieval of scientific data.

6. Integrating laboratory science with clinical work - the way forward: Dr. Pattatheyl Arun

Dr. Arun succinctly explained the need of integrating laboratory work with clinical trials to maximize the outcome of translational research. In his talk, he stated the current therapeutic strategies against cancer involving surgery, radiation, chemotherapy and their limited outcomes.

He emphasized the importance of research training both for basic scientists and clinicians. After a brief history of cancer research, he moved on to recent advances in blocking multiple pathways in cancer cells through small

molecule inhibitors. He presented his work in trying to block nuclear NF-kB p65 phosphorylation at serine 276 by protein kinase A and reasons for failure of this approach which involved activation of several other alternate pathways. He strongly advocated the need for more interaction between clinicians and scientists and incorporation of research training in medical syllabi.

7. Facilitating Physician- Scientist interaction: Perspectives from a Scientist: Prof. Sankar. K. Ghosh

Prof. S.K Ghosh strongly emphasized the importance of scientist and clinician interaction in the present scenario in India. He opined that lack of such collaboration is one of the reasons for slow progress in the field of cancer research in India.

He elaborated on factors causing cancer through mutations in the gene. He presented his work on mitochondrial DNA.

8. Funding avenues for fundamental and clinical research in NE: Dr. B.L Jailkhani

Dr. B. L Jailkhani spoke on various aspects of research proposal development for seeking research grants. He emphasized on the differences between a well written research proposal and a poor one. He explained the process of applying for grants from the DBT.

9. Funding avenues for fundamental and clinical research in NE: Dr. P. K. Mohapatra

Dr. P. K. Mohapatra elaborated on the components of research proposal writing for different funding agencies. He explained the reasons why funding agencies reject most research proposals and the measures to avoid this.

SWOT analysis for conducting medical research in the north east of India

Strengths:

1. Large pool of treatment naïve population with a diverse gene pool
2. Geographic area with limited population making it easier to cover entire communities for intervention.
3. Follow up of patients can be 100%
4. Potential for networking major institutions in the region and recruiting patients across the entire region.
5. Pool of doctors, scientists and investigators who can be easily trained in GCP. Ease of implementing SOPs.
6. Ethics committees not available in many centres and can be constituted in a robust manner complying with the requirements of regulatory agencies like the ICMR.
7. Disease patterns sometimes different from the rest of India.
8. Good data on cancer incidence available with the NCRP website.
9. Costs for such studies can be kept low and more patients will be able to access low cost care subsidized by the study. This is of special relevance to the community in this region.
10. Training resources available in the region.

Weaknesses

1. Concept of trials and their benefits not clear to doctors, investigators and scientists – need for sensitization and training exists. GCP workshops have to be conducted.
2. Present quality of documentation inadequate in most centres.
3. Ethics committees have to be constituted, trained and SOPs laid down and implemented.

4. Infrastructure has to be developed.
5. Data base for non malignant diseases non-existent.
6. Widely prevalent issues with security in the north east.

Opportunities

1. National and global recognition for research in the North East of India
2. Revenue for institutions
3. Opportunity to develop human resources and infrastructure and thereby improve patient care.
4. Increases career options for physicians and scientists
5. Newer treatment options made available to the community – improves awareness in the community about their right to access standard health care
6. Development of regional, national and international collaboration.

Threats

1. Commercialisation of research and possibility of scientific fraud.
2. Increasing dependence on sponsors/ pharmaceutical industry
3. Potential for exploiting a naïve population that is unaware of their rights
4. Potential for bad publicity for ‘research’ if not handled with care and sensitivity
5. A paradoxical increase in costs as infrastructure and human resource maintenance costs rise.

Recommendations:

1. Train clinicians, basic scientists and other investigators in GCP, trial design and methodology and statistics.
2. Set up institutional/ region central ethics committees and train its members.
3. Set up a north east region central biostatistics unit to cater to the entire region.
4. Set up institutional tissue banks.
5. Encourage documentation and data collection in a disease specific manner – set up registries for genetic diseases, cardiovascular diseases etc. – these should be easier in the north east when compared to the rest of the country – the experience of the NCRP can be tapped for this.
6. Network all the centres with equal distribution and sharing of resources and responsibilities.

At evening 5-30 p.m.

“15th Hospital Day” of the Cachar Cancer Hospital and Research Centre (CCHRC), Silchar-15 observed in a befitting manner. Main function start at 5 p.m. on 10th Feb, 2011 at CCHRC

More than 150 people of this valley and NE states, other states present at this occasion.

Mr. Kabindra Purkayastha, M.P. (L.S), Mr. Gautam Roy, Minister of State, Govt. of Assam attended at this function.

Mr. Kabindra Purkayastha and Mr. Gautam Roy announced donation of Rs.10 lakhs each for the development of this hospital from their M.P. Lad fund.

Mr. Gautam Roy handed over RS. 1 lakh cash at this function.

And other gentle man donated Rs. 5000 cash at this function.

Two members of the society, namely Dr. Chinmoy Choudhury, former General Secretary, now vice chairman (resource) and Mr. Jyotirindra Chandra Dutta, former Chairman of the Cachar Cancer Hospital Society were felicitate for their works for the CCHS.

More than 100 enlighten citizen of this Barak Valley, public leaders, politicians. doctors, members of CCHS and staffs of CCHSRC. present at this function.

PROGRAMME

10/02/11(Foundation day)

- ***Workshop on clinical trials***
 1. Introduction
 2. The Clinician-Scientist Partnership : Avenues in the Indian Context:
 3. What ails Physician- Scientist interaction?: Perspectives from a Scientist- Head of a Lab –Regional University
 4. Conducting clinical trials in India: a blueprint for action:
 5. Human tissues for cancer research: An introduction to tissue repositories.
 6. Avenues for funding Clinicians for cancer research in India :
 7. Poster Session (II half)

Posters related to ongoing research in cancer from post doctoral fellows of Regional Universities. Interaction with clinicians

11/02/11(Preconference workshop)

- 07.30AM Breakfast
- 08:00 AM –04:00 PM –Live Surgery
- 11:00AM – Tea
- 01:00-02:00 PM – working Lunch
- 05:00 PM- 07:00 PM - Inauguration
- 07:00 PM - cultural programme –
- 08.30 PM Dinner.

ON 12/02/11(AONEI Annual Conference)

- 08:00AM to 10:00 AM - Proffered Papers (G I oncology)
- 10:00 AM –01:00PM – Ca Esophagus
 - 1. Epidemiology & Etiopathogenesis
 - 2. Pathology and Diagnosis
 - 3. Endoscopy
 - 4. Imaging
 - 5. Surgical management
 - 6. Radiation therapy
 - 7. Chemotherapy
 - 8. Palliative care
- 01:00-02:00 PM Lunch Break
- 02:00 – 06:00 PM – Proffered papers (Non- G I)
- 07:00 PM – dinner symposium Gall bladder cancer