

M S Ramaiah Medical College

Following is the list of collaborative activities for research, faculty exchange, student exchange/ industry - carried out over a period of 5-8 years.

Metha. G. Ras



Eli Lilly and Company (India) Pvt. Ltd.

Plot No. 92, Sector-32, Gurgaon - 122001 Haryana

Phone:+91-124-4753000 Fax:+91-124-4753012-13-14

CIN – U24239HR1993PTC034844 Website: www.lillyindia.co.in

OUS Templates
OUS LOA
Revised: 07 2014

21 Jul 16

Dr Nalini Kilara M. S Ramaiah Medical College & Hospital MSRIT Post, New BEL Road Bangalore, Karnataka – 560054

Dear Dr Kilara:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd. ("Lilly), Dr. Nalini Kilara, the principal investigator ("Investigator"), and M. S. Ramaiah Medical College & Hospital, MSRIT Post, New BEL Road, Bangalore, Karnataka - 560054 ("Institution") for the performance of the study ("Study"), entitled, "A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Compare NSAI (Anastrozole or Letrozole) plus Abemaciclib, a CDK4 and CDK6 Inhibitor, or plus Placebo, and to Compare Fulvestrant plus Abemaciclib or plus Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer" protocol 13Y-CR-JPBQ ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an employee of Institution. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

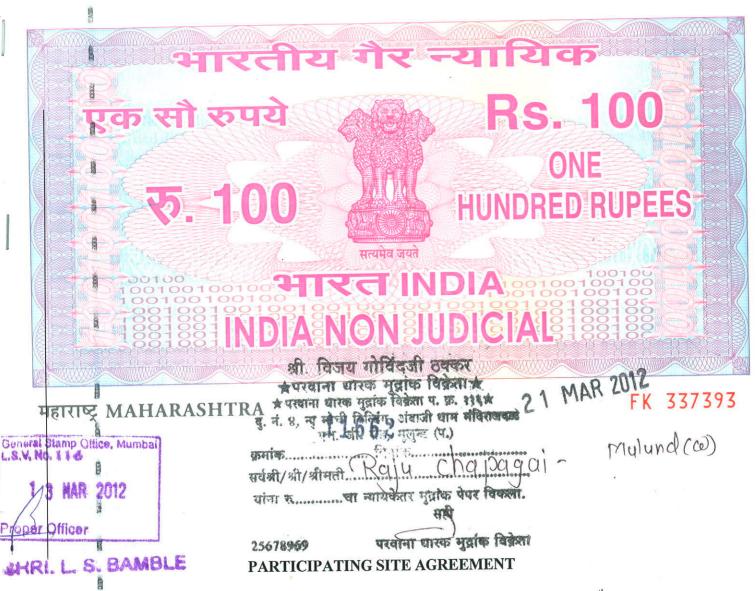
A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); and all other applicable national, state and local laws, regulations and standards. Investigator and Institution shall ensure that all of sub investigators, associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by: courier service to Sanjay Majumdar, Eli Lilly and Company, Sec 32, Plot 92, Gurgaon, Haryana, 122001. If you have any questions, please call Sanjay Majumdar at +91 124 4753118.

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.	AGREED AND ACCEPTED:
De la companya de la	Investigator
(Signature of Authorized Official)	Dr. Nalini Kilara
	27/7/2016
Rajeev Sharan Srivastava -Associate Director, Clinical Research	(Date)
21- JULY-2016.	
(Date)	
	AGREED AND ACCEPTED: M S Ramajah Medical College & Hospital, Bangalore Dr. NARESH SHETTY (Signature of Authorized Official) PRESIDENT- MIRCLE 26 7 12016
	(Typed or Printed Name and Title)
* * * * * * * * * * * * * * * * * * *	(Date)



This Participating Site Agreement (this "Agreement") is entered into this 9th day of March, 2012 (the "Effective Date"), by and between Outcome Sciences, Inc. d/b/a Outcome (hereinafter referred to as "Company") with an address at 201 Broadway Cambridge, Massachusetts, USA 02139, M S Ramaiah Medical College and Hospitals (hereinafter referred to as "Clinician Site"), with an address at New B E L Road, MSRIT Post Bangalore, Karnataka, India 560 054, and Dr R. Srinivasa (hereinafter referred to as "Principal Investigator") with an address at Dept of Neurology, M. S. Ramaiah Medical College and Hospitals, New B E L Road, MSRIT Post Bangalore, Karnataka, India 560 054, (the Company, the Clinician Site, and the Principal Investigator are each referred to individually as a "Party" and collectively as the "Parties").

WHEREAS, Company has entered into a Master Services Agreement with Merck KGaA, Darmstadt, Germany and into a Project Addendum with EMD Serono, Inc. the sponsor of the Study in the USA territory, affiliated to Merck Serono SA-Geneva, 9 Chemin des Mines, 1202 Geneva, Switzerland, the sponsor of the Study in non-USA countries ("Sponsor"), both affiliates of Merck KGaA, to manage a prospective observational long-term safety registry of Multiple Sclerosis patients who have participated in cladribine clinical trials according to the valid observation plan attached hereto (the "Study"). This study does not include any medical intervention;

EMR700568-012 Site Agr India (2012)

2

Page 1 of 16

Agreement. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement, effective as of the Effective Date.

OUTCOME	SCIENCES, INC.	CLINICIAN SITE
Signature:	Milly M. Sult	Signature:dav
Print Name:_	Jeffrey M. Sachs	Print Name: Dr D C Sundaresh
Title:	VP/General Counsel	Title: President-Clinical Research
Date:	2630n 2016	Date: 13 June 2012
		PRINCIPAL INVESTIGATOR
		Signature:
	Oscome Legal Local	Print Name: Dr. R. Srinivasa
	No.	Title:
	Approved by: No Tun Zur	Date:6/6/20(2





MEMORANDUM OF UNDERSTANDING ON ACADEMIC COOPERATION BETWEEN THE UNIVERSITY OF GRONINGEN, THE NETHERLANDS AND THE GOKULA EDUCATION FOUNDATION (MEDICAL), BENGALURU, INDIA

The University of Groningen (Rijksuniversiteit Groningen), Broerstraat 5, 9712 CP Groningen, the Netherlands, represented by its President, Prof. Jouke de Vries, and

The Gokula Education Foundation (Medical), MSR Nagar, MSRIT Post, Bengaluru - 560054, India represented by Sri M.R. Sreenivasa Murthy, Chief Executive, GEF(M) hereby agree to this Memorandum of Understanding on scientific and educational cooperation.

This MoU is to provide for, but is not limited to, the exchange of staff, scholars, students and/or academic information and materials in the belief that the research and educational processes at both universities would be enhanced and that mutual understanding between their respective staff, scholars and students would be increased by the establishment of such exchange programmes.

Article 1

The universities agree to promote the following exchange programmes, based on their respective academic and educational needs:

- 1. Exchange of scholars and staff.
- 2. Exchange of undergraduate and graduate students.
- 3. Exchange of academic information and materials.
- 4. Joint research activities and publications.
- 5. Joint supervision of double degree PhD students.
- 6. Participation in conferences and academic meetings.
- 7. Other academic exchanges that both universities agree to.

End to the town of the town of

Article 10

This Agreement does not establish a legal partnership, joint venture, employment relationship, or relationship of agency between the institutions. Neither institution may act as an agent on behalf of the other institution on any matter, including in matters with the other institution's national government.

Article 11

In the event that a translation of this Agreement is prepared or signed by the institutions, the English language version will govern in the event of a conflict between the English language version and the translation.

Article 12

No amendment to this Agreement will be valid unless signed by authorized representatives of each institution.

Article 13

Both institutions shall designate a programme officer to develop and co-ordinate the specific programmes agreed upon.

Article 14

This MoU shall become effective from the moment it has been signed and dated by both parties and remain valid for a period of five years. It is also understood that either institution may terminate the agreement at any time, giving the other not less than 6 months' notice of its wish to terminate, in order to avoid any possible inconvenience to the other institution.

Signatures

For the University of Groningen

The Netherlands,

For Gokula Education Foundation, (Medical) Bengaluru, India

Prof. Jouke de Vries

President of the University

Place, date:

Sri M.R. Sreenivasa Murth

Chief Executive

office of the university

international strategy & relations

International Strategy and Relations T+31(0)50 363 51 33 j.j.ros@rug.nl

PO Box 72 9700 AB Groningen The Netherlands

Savita Ravindra
Department of Physiotherapy,
M.S. Ramaiah Medical College & Hospitals,
MSR Nagar,
MSRIT Post,
Bangalore 560054.

Date

12 December 2018

18/15862

Subject

Memorandum of Understanding between Ramaiah Medical College and the University of Groningen

Dear Prof. Ravindra,

It is with great pleasure that I enclose a signed copy of the renewal of the Memorandum of Understanding between Ramaiah Medical College and the University of Groningen. The agreement has been signed by the President, Prof. Jouke de Vries.

We look forward to the continuation of our valued cooperation.

Yours sincerely,

Mys Robede

Alicja Sobecka

International Strategy & Relations

CLINICAL TRIAL AGREEMENT Protocol # MYL-Her 3001

This Clinical Trial Agreement ("Agreement") between

INC Research UK Limited with registered offices located in the United Kingdom at Riverview, The Meadows Business Park, Station Approach, Blackwater, Camberley, Surrey GU17 9AB, UK, including its affiliates, subsidiaries, and specifically its parent company INC Research, LLC (hereinafter "INC Research")

and

M S Ramaiah Medical College and Hospitals, with a place of business at MSRIT Post, new Bel Road, Bangalore-560054, India ("Institution")

and

Dr.Vinayak V Maka with a place of business at M S Ramaiah Medical College and Hospitals, with a place of business at MSRIT Post, new Bel Road, Bangalore-560054, India ("Principal Investigator")

When signed by all parties, is effective as of date of last signature.

By separate agreement, MYLAN GmbH with a principal place of business at Thurgauerstrasse 40 CH 8050 Zurich, Switzerland ("Sponsor") has engaged INC RESEARCH, LLC, a contract research organization, with a principal place of business in the United States at 3201 Beechleaf Court, Suite 600, Raleigh, NC 27604-1547 USA acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiations and execution of the Agreement and payment administration of grant amounts described hereunder.

Sponsor wishes to support a clinical trial entitled "A MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PARALLEL-GROUP, PHASE III STUDY OF THE EFFICACY AND SAFETY OF HERCULES PLUS TAXANE VERSUS HERCEPTIN® PLUS TAXANE AS FIRST LINE THERAPY IN PATIENTS WITH HER2-POSITIVE METASTATIC BREAST CANCER" ("Protocol") to be conducted at Institution and to involve Trial Subjects ("Trial").

The parties agree as follows:

- 1. <u>Investigators and Research Staff.</u>
 - 1.1 <u>Principal Investigator</u>. The Principal Investigator will be responsible for the direction of the Trial in accordance with applicable Institution policies.
 - 1.2 <u>Subinvestigators and Research Staff</u>. Institution and Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Trial as subinvestigators or research staff.
 - Investigator are responsible to Sponsor for compliance by all Trial personnel with the terms of this Agreement. Institution and Principal Investigator will ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Institution will determine which of the obligations in this Agreement it will delegate to Principal

MYLAN GmbH: MYL-Her 3001 Clinical Trial Agreement

Page 1 of 24

CHATRAPATI CO-OP HSG SOCLITO
PLOT NO. F-3 KODRI COLONY

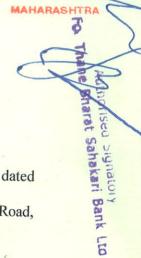
194635

NOV 27 2

In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence a binding Agreement with the expectation that original documents may later be exchanged in good faith.

Agreed to and Accepted:	T.
INSTITUTION	INC RESEARCH UK LIMITED
By: Signature	By: Signature
Dr.D.C.Sundaresh Printed Name	Kirit Sachder Printed Name
PRESIDENT – MSRCRC Title 1:12-2014	Manager, Site Contracts Title 27 NOV 2014
Date	Date
PRINCIPAL INVESTIGATOR By: Signature	
Dr. Vinayak V Maka Printed Name	
Associate prof. Medical Oncology Title	

Date



AMENDMENT #01

(Change in Payee Name)

This Amendment#01 ("Amendment") to the Clinical Trial Research Agreement dated 10th December, 2015 ("Agreement") by and between:

M S RAMAIAH MEDICAL COLLEGE AND HOSPITALS, MSRIT Post, New BEL Road, Bangalore-560054 ("Institution");

SIRO CLINPHARM PVT LTD, Kalpataru Prime, 1st Floor, Unit Nos. 3 and 4, Plot No. D-3, Road No -16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra, India ("CRO") and

MSD Pharmaceuticals Pvt Ltd, 8th floor Platina building, C-59, Block- G, Bandra-Kurla Complex, Bandra-east, Mumbai-400098 ("Sponsor") who has engaged CRO to manage the conduct of the Protocol in terms of the Agreement.

WHEREAS the parties hereto are in accord that the Agreement for the conduct of study, V501-125-00 03 A Post Marketing Surveillance to assess the safety of Gardasil in females of 9 to 45 years in routine clinical care.

AND WHEREAS with effect from 01 Feb 2016, M S Ramaiah Medical College and Hospital will be a unit of Gokula Education foundation (Medical), AND ACCORDINGLY the payee name and details are hereby revised and are as follows:

- 1) Payee Name: M S Ramaiah Clinical Research Centre
- 2) Permanent Account Number (PAN #) AAATG1779Q
- 3) Bank Account number:141200301000145
- 4) Name and Address of the Bank: Vijaya Bank, MSRIT branch, MSR Nagar, Bangalore-
- 5) Service Tax No: AAATG1779QST001

It is understood and agreed that all other provisions of the Agreement shall remain in full force and effect.

Upon execution, this Amendment#01 shall form part of the Agreement.

A

Car

M S Ramaiah Medical College and Hospital	SIRO Clinpharm Pvt Ltd.
Sign:	Sign:
Name: Dr Naresh Shetty	
Title: President-M S Ramaiah Clinical Research Centre	Name: Partha Chithyr Title: Heal Clinical Research & CTS
Date: 25 04 16	Date:
Dr. Rajini Uday Sign: Rajini ud ceer	MSD Pharmaceuticals Pvt Ltd. Sign:
Name: Dr. Rajini Uday	Name:
Title: Professor, Dept of OBG Date: 23 04 16	Title: ANIRBAN ROY CHOWDHURY Senior Director-Global Clinical Trial Operations Date:

Jyothi Sharma
04/01/2016

B.

Al.

This Clinical Study Agreement (hereinafter 'Agreement') is made,

BETWEEN

Roche Products (India) Private Limited, an Indian Company, having it's registered office at "The Capital", 15th Floor, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, INDIA, (hereinafter called as "RPIPL", which expression unless repugnant to the context shall mean and include its successors-ininterest and permitted assigns) of the FIRST PART;

M.S.Ramaiah Medical College and Hospitals (hereinafter referred to as "Institution", which expression unless repugnant to the context shall mean and include its successors-in-interest and permitted assigns) of the SECOND PART;

AND

Dr.Nalini Kilara working as Senior Prof.And Head, having his place of business at, M S Ramaiah Medical College and Hospital, New BEL Road, (Gokula extension) MSR Nagar, Bangalore 560094 (hereinafter called as "Principal Investigator or P.I.", which expression unless repugnant to the context shall mean and include his legal heirs, representatives, successors and permitted assigns) of the HIRD PART;

(each a "Party" and collectively "Parties)

WHEREAS, Roche Group has the Intellectual Property Rights in respect of the product -RO4368451) (hereinafter called as "Product")

WHEREAS, RPIPL wishes to engage the P.I., to carry out the research in respect of clinical study titled "A Phase IV, Multicenter, Open-Label, Single-Arm Study Of Pertuzumab (In Combination With Trastuzumab And Docetaxel) In First Line Treatment Of Indian Patients With Her2-Positive Advanced (Metastatic Or Locally Recurrent) Breast Cancer" (hereinafter "The Study") as defined the Protocol No. "ML29282" {'Protocol'};

WHEREAS, the PI and Institution are willing to conduct the Study on the terms and conditions set forthin this Agreement. The P.I. shall conduct the Study at Institution. ("PI and Institution collectively called as Site");

NOW THEREFORE, the Parties hereto have agreed as follows.

EFFECTIVE DATE: This Agreement will become effective on the date of approval of the Study by Drugs Controller General of India or on the date of approval of the Study by the Ethics Committee or on the date on which this Agreement is last signed by the parties, whichever date is later, and shall continue until completion of study or until terminated in accordance with the provision in Clause 14

1. PROTOCOL AND INVESTIGATOR BROCHURE

The scope and nature of the clinical study to be performed under the responsibility of the PL and Institution will be in accordance with Protocol number "ML29282".

Clinical Study Agreement Version 4.0 dated 27 July 2015 ML29282, Tripartite (RPIPL/ M.S. Ramaiah Medical College & Hospital/ Dr. Nalini Kilara) Page 1 of 12

NSED

IN WITNESS WHEREOF, Parties through their authorized representatives have signed this Agreement.

1. Signed on behalf of Roche Products (India) Pvt. Ltd.

Associate Director - Clinical Operations

Mr. Sachin Bobhate

Senior Manager - Legal and Admin.

II. I hereby agree to the above conditions:

Principal Investigator (P.I.)

Date

Dr.Nalini Kilara

M.S.Ramaiah Medical College and Hospitals

New BEL Road, MSRIT Post

Bangalore -560054

Signed on behalf of M.S.Ramaiah Medical College and Hospitals III.

Authorized signatory from Institution

Name: Dr.D.C.Sundaresh

Designation: President- MSRCRC

CLINICAL TRIAL AGREEMENT

4-DEC-09 THIS AGREEMENT is made and entered into effective as of (hereinafter "Effective Date") by and between BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 having its registered office at 1st floor, "A" Block, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018 (hereinafter "SPONSOR"),

Gokula Metropolis Clinical Research Centre, M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054

a profit corporation in KARNATAKA of Gokula Metropolis Clinical Research Centre, M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054, India (hereinafter "INSTITUTION").

And

Dr. B.S Satyaprakash Prof. & Head, Dept. of gastroenterology, M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054 [Herein referred to as "Principal Investigator"]

RECITALS

WHEREAS, SPONSOR conducts business in the research, development, manufacture and sale of pharmaceutical, nutritional and healthcare products, and

WHEREAS, SPONSOR desires INSTITUTION and Principal Investigator to conduct a clinical trial striction and Principal Investigator to conduct a clinical trial striction and Principal Investigator desires to conduct same, said trial being entitled: and INSTITUTION and Principal Investigator desires to conduct same, said trial being entitled:

Study Title: Randomized, Observational Study of Entecavir to Assess Long-term Outcomes Associated with Nucleoside/Nucleotide Monotherapy for Patients with Chronic HBV Infection: The REALM Study

Protocol Number: AI463-080

(said study, as it may be amended or supplemented from time to time in accordance with this agreement, hereinafter referred to as the "Study") and

WHEREAS, SPONSOR has contracted with PPD PHARMACEUTICAL DEVELOPMENT INDIA PRIVATE LIMITED (hereinafter "CRO") to coordinate and/or perform certain activities required to the conduct of the Study.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set Cortin, INSTITUTION, Principal Investigator and SPONSOR agree as follows:

BMS-Tri-partite CTAg (with Institution & Investigator) (with CRO) India Template dated 15-Dec-2008

緩緩

MATARACTICA

other than performance of the obligations required by the Protocol, as set forth in this Agreement and the Protocol. Principal Investigator and INSTITUTION shall allow only those people directly involved in the conduct of the Study access to the Technology. SPONSOR agrees to provide Principal Investigator with maintenance and repair service for the Technology during the Study. At no time shall Principal Investigator and INSTITUTION attempt to repair, fix or correct any errors or technical problems related to the Technology.

IN WITNESS WHEREOF, Principal Investigator, INSTITUTION and SPONSOR have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

their duly authorized representatives.
GOKULA METROPOLIS CLINICAL RESEARCH CENTRE, M.S.RAMAIAH MEMORIAL HOSPITAL, BANGALORE
By: Shall the
Title: Head of Dynation. Date: 18 Nov 09
Date: 18 Nov 09
Permanent Account Number: AACCP1414
EMENT
Lid. Inta Rd.

In.

AGREEMENT FOR COOPERATION

between

MS Ramaiah Medical College, Bengaluru, India

and

University Medical Center Groningen/Faculty of Medical Sciences, Groningen, the Netherlands

The MS Ramaiah Medical College, Gokula Education Foundation (M), Bangalore represented, by Dr. A.C Ashok, Principal ,Medical College and Dr. S.Kumar, President, Medical Education GEF(M) and the University of Groningen, UMCG/Faculty of Medical Sciences, represented by the President of the University, Prof. Dr. Sibrand Poppema and the Dean of the Faculty of Medical Sciences, Prof. Dr. Folkert Kuipers, now wish to start the exchange of students from the medical, human movement sciences program in an agreement for cooperation.

1. GENERAL

- 1.1 The Gokula Education Foundation (Medical) and the University of Groningen agree to collaborate in student exchanges between UMCG/Faculty of Medical Sciences and the MS Ramaiah Medical College.
- 1.2 Competency in English is required for participating students.
- 1.3 Both institutions will identify an educational coordinator/medical staff member at the department involved, responsible for the quality of exchanges.
- 1.4 MS Ramaiah Medical College and UMCG/Faculty of Medical Sciences guarantee that students will work under supervision of a staff member and in case of clerkships students will work under supervision by staff clinicians. Students are not allowed to 'practice medicine' independently from a licensed physician of the host institution.
- 1.5 This agreement will be effective for 5 (five) years from the time of its signing by the authorised signatories of both institutions. The agreement shall be renewed by the written consent of both institutions.

2. EXCHANGE OF STUDENTS

- 2.1 The MS Ramaiah Medical College agrees to receive students of UMCG/Medical Faculty Groningen with a maximum of two (2) students at each time. Each year both parties will make a final agreement about the maximum number of students in one year. In the first year it is expected that this will be 4-6 students.
- 2.2 UMCG/Faculty of Medical Sciences will select interested students as candidates for the exchange. The completed applications of the students shall be sent to the MS Ramaiah Medical College 6 months before the starting date of the exchange for final approval by the MS Ramaiah Medical College.

- 2.3 UMCG/Faculty of Medical Sciences agrees to provide grants for travelling and accommodation for students of the MS Ramaiah Medical College every year, meant for an elective period, international clerkship or participation in the Summer School.
- 2.4 The MS Ramaiah Medical College will select interested students as candidates for the exchange. The completed applications of the students shall be sent to the UMCG/Faculty of Medical Sciences 6 months before the starting date of the exchange for final approval by UMCG/Faculty of Medical Sciences.
- 2.5 Periods of exchange will be between 1-5 months.

3. CONTACTPERSON

Both institutions will identify a liaison coordinator for the cooperation.

4. INFRASTRUCTURE

- 4.1 All visiting students will have equal rights and privileges as enjoyed by students of the host institution.
- 4.2 The host institution will offer the infrastructure needed for hosting the exchange students. This includes the following:
 - a. Assistance in finding accommodation
 - b. Assistance to facilities such as library and internet connection (including e-mail)
 - c. Free access to a Post Exposure Prophylaxis (PEP-HIV) package
 - d. Academic supervision
 - e. Access to equipment and training facilities
 - f. Both institutions will ask the local student union to help visiting students with social activities

5. DUTIES

- 5.1 Students are subject to rules, regulations and disciplines of the host institution in which they are enrolled.
- 5.2 Students will meet all requirements of the host country with regard to immigration.

6. FINANCES

- 6.1 Participating students from both institutions shall pay tuition fees to their home institutions and will not have to pay tuition fees or to the host institution.
- 6.2 UMCG/Faculty of Medical Sciences will provide MS Ramaiah Medical College with grants sufficient (travelling and accommodation) for 2 students, probably around € 2.500 per grant.
- 6.3 No material costs and administrative fees will be charged for the exchange students.

7. INSURANCE

7.1 Students from both institutions shall have appropriate health-, accident- and personal liability insurance as required by the home university.

- 7.2 Students from the UMCG/Faculty of Medical Sciences, under the condition that there is supervision by an appropriate qualified person, have professional liability insurance through the UMCG/Faculty of Medical Sciences for all countries in the world except for USA and Canada.
- 7.3 In case of malpractice, the liable party is the institution where the malpractice took place.

8. EVALUATION

- 8.1 Both institutions agree to monitoring visits every 5 year, starting after 2 years. The protocol for such monitoring visit will be agreed upon in separate monitoring visit protocol.
- 8.2 Students and supervisors involved in the exchange project should participate in the standard evaluations of both institutions.

For the GEF(M)

Date:

Dr. S. Kumar

President Medical Education

President, Medical Education, Gokul Education Foundation New BEL Road, Bangalore - 560 054 For the University of Groningen,

The Netherlands

Date: 7 ()

Prof. Dr. Sibrand Poppema

President of the University

CHONINGEN

For MSR Medical College Date:

For the UMCG/Faculty of Medical Sciences Date:

Principal, MSR Medical College

PRINCIPAL AND DEAN
M.S. Ramarah Medical College
& Teaching Hospital
Bangalore - 560 054.

Prof. Dr. Folkert Kuipers

Dean, Faculty of Medical Sciences.

CLINICAL TRIAL AGREEMENT

This agreement is made on this 23rd Jan 2014 year(hereinafter 'Effective Date') by and between "NorwichClinical Services" having its principal place of business at Norwich Clinical Services, a company incorporated under Companies Act, 1956 and having its registered office at ACR mansion, No.147/F, 8th main, 3rd block, Koramangala, Bangalore-5600034, (hereinafter referred to as CRO), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the One Part;

AND

"Dr NaliniKilara"havingherprincipal place of businessat M S Ramaiah Curie Centre of oncology, M S Ramaiah Medical College and Hospitals , MSRIT Post, New BEL road, Bangalore - 560054 (Hereinafter referred to as "Principal Investigator" or "P.I"), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the other Part; And

M S Ramalah Medical College and Hospitals, (hereinafter referred to as "Hospital/Institution")
MSRIT Post, New BEL road, Bangalore - 560054

1. BACK GROUND

WHEREAS the purpose of this agreement is for conducting clinical study having Study Title:
"An open label, multicentre, randomized, balanced, two-treatment, two-period, two-sequence, single dose, crossover, oral bioequivalence study of Melphalan Tablets 2 mg of Alvogen Pine Brook., USA compared with that of ALKERAN® (melphalan) Tablets 2 mg of GlaxoSmithKline, USA in adult patients under fasting conditions" in whichMelphalan Tablets 2

mg of Alvogen Pine Brook of Alvogen Pine Brook Inc.10 Bloomfield Avenue, Building B,Pine Brook, NJ 07058Tel.: +1 973 796 3400, Fax: +1 973 796 3439 is compared with that of ALKERAN® (melphalan) Tablets 2 mg of GlaxoSmithKline, USAin patients under fastingconditions,in accordance with Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and ICMR Guideline 2000, on patients as stated in the protocol (hereinafter referred to as the subjects).

- 1.2 The SPONSOR (Alvogen Pine Brook Inc.) is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms;
- 1.3 NORWICHCLINICAL SERVICES (hereinafter referred to as CRO) is a professional clinical research organization in India engaged in the business of undertaking biostudies, Clinical Trial Services and pharmacovigilance servicesin conformance to international standards.
- 1.4 The CROhas represented and warranted to sponsor that it has the necessary skill, experience, expertise and necessary facilities/infrastructure to provide the services contemplated under this agreement.
- 1.5 The CROhas also represented that all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement will be obtained and that all such licenses, authorizations and permissions will be in full force and effect at the time of executing the services outlined in this agreement.
- 1.6 Whereas the CROdesires to enter into agreement with M S Ramaiah Medical College and Hospitals &Dr NaliniKilarato conduct the study in their hospital.
- 1.7 The CROhas agreed to engage Dr NaliniKilarawho is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.
- 1.8 The CROhas agreed to engage M S Ramaiah Medical College and Hospitals& the principal Investigator for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.
- 1.9 Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the M S Ramaiah Medical College and Hospitals& Principal Investigator to CROunder any subsequent individual agreement for specific services to be rendered, referred to as a Specific Protocol
- 1.10 The Project shall be conducted as per the CRO's confidentiality requirements.
- 1.11 M S Ramaiah Medical College and Hospitals & the principal investigator agree that the CRO shall have the right to enter their facility at reasonable times to inspect the facility, and the

Note:

- Hospital stay expenses during the study period will be paid at the end of each period.
- Lab investigation at the time of screening, before the study start and after study completion will be paid by the CRO at actuals only on production of original bills along with the investigator fee.
- Compassionate Medications to each patient will be provided as follows:
 Patient will be provided following medications as per the PI's prescription for each cycleupto a maximum of 6 cycles.
 - a)Melphalan
 - b)Thalidomide
 - c)Prednisolone

An indent form will be submitted by the site prior to each cycle indicating quantity of medication required for patients

Any adverse event experienced by the subject (whether related or unrelated) which necessitates medical treatment, the expenses will be borne by the sponsor.

The following deductions will be made, if applicable:

- Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/institution.
- Any capital expenses for the site incurred by the CRO on behalf of PI will be deducted from the fee
 payable to PI.

For Norwich Clinical Services Private Limited, Bangalore

For Principal Investigator

Dr SaralThangam

Managing Director

Norwich Clinical Services Private Limited.

Dr NaliniKilara

Professor & Head, Dept. of Oncology

Seal:

For Norwich Clinical Services Pvt. Ltd.

SeaProf. NALINI KILARA, MD DM: A
HOD MEDICAL ONCOLOGY
M.S. Ramaiah Medical Coiloge & Hospital
KMC Rog. No. 15,080

Dr.Saral Thangam Managing Director Version 1.0, 1 July 2013

Page 39 of 39



Ghent University

Reursed MOU 16.11.17 - 16.11.22 DEPARTMENT OF EDUCATIONAL POLICY INTERNATIONAL RELATIONS OFFICE

Prof. Savita Ravindra, Head Physiotherapy Ramaiah Medical College MS Ramaiah Nagar MSRIT Post Bangalore 560054 India Rein Reynebeau/Elisabeth Velle

E Non-Erasmusagreements@ugent.be

T +32 9 264 70 17

F +32 9 264 31 31

Het Pand Onderbergen 1 B-9000 Ghent Belgium

www.ugent.be

DATE PAGE 21 December 2017 1/1

Dear Professor Savita Ravindra,

Herewith you can find one copy of the 'Cooperation Agreement' between Gokula Education Foundation Bangalore and Ghent University, duly signed by our rector for your records.

Kind regards,

Rein Reynebeau/Elisabeth Velle

International Relations Office Ghent University



Cooperation Agreement

between

Gokula Education Foundation (Medical) Bangalore.

Ghent University Faculty of Medicine and Health Sciences

In accordance with a mutual desire to promote international academic, cultural and scientific exchange, Ghent University, Faculty of Medline and Health Sciences (Belgium) and Gokula Education Foundation (Medical) Bangalore. MS Ramaiah Memorial Hospital (India) enter into this Cooperation Agreement.

Both institutions, for the purpose of furthering cooperation through both educational and academic exchanges, hereby affirm their intent to promote such exchanges as will be of mutual benefit to their institutions. Educational and academic exchanges are considered here to include but not be limited to:

- Development of mutually beneficial academic programmes and courses;

- Exchange of academic staff and research assistants for the purpose of teaching and research;

Exchange of students for study and research;

Reciprocal assistance for visiting academic staff and students:

- Exchange of documentation, pedagogical information and research materials.

Both parties decide by mutual consent that all the financial agreements will have to be negotiated and will depend on the availability of funds.

A. Student exchange

Both parties hereby agree that:

- 1. Each Institution may in principle nominate not more than 12 undergraduate or graduate students for exchange each year.
- 2. However, this number may vary in any given year provided a balance of exchanges is attained over the term of the agreement.
- While nominees will normally be accepted for exchange by the host university, the host university reserves the right to review the applications of nominees and make final decisions concerning admission.

4. A selected student may study for a period of 1 to 12 months at the host university.

- 5. Exchange students will not pay examination, matriculation and tuition fees to the host institution, but shall pay these to the home institution as per the usual regulations of the home institution.
- 6. Any academic credit received in the course of the program at the host institution may be transferred to the home institution in accordance with the appropriate regulations of the home institution.
- 7. Each host institution will issue appropriate documents for each accepted nominee for the issuance of a student visa, in accordance with current national laws. It is the responsibility of each individual student to obtain a student visa in their home country in a timely manner.
- 8. The student will provide his or her own health, accident, repatriation and civil liability insurance.

B. Staff exchange

Both parties hereby agree that:

- 1. Both parties agree to support the exchange during each academic year of maximum 2 professors or members of scientific staff from each university.
- 2. However, this number may vary in any given year provided a balance of exchanges is attained over the term of the agreement.
- 3. Each host institution will issue appropriate documents for each visiting staff member for the issuance of a visa, in accordance with current national laws. It is the responsibility of each individual staff member to obtain a visa in their home country in a timely manner.

C. Scientific research

- 1. Details of each research program or research project shall be arranged by mutual consent by the relevant departments, centres, etc, of both parties subject to the approval of the higher authorities of each party.
- 2. Relevant academic materials, technical information including research reports, periodicals, etc. and other information available to each party shall be exchanged between parties.
- 3. All information and/or data that may be exchanged, acquired and shared in connection with the areas of cooperation between both parties pursuant to this Cooperation Agreement shall be treated strictly confidential and shall not under any circumstances be divulged by the receiving party unless and otherwise such information has already been in public domain.
- 4. Any cost and expenses that may be incurred by jointly performing research programs and research activities shall be negotiated and agreed upon to the satisfaction of both parties before starting such programs and activities.

For Ghent University, Prof Hilde Van Waelvelde (Faculty of Medicine and Health Sciences) will be the academic staff member responsible for the Cooperation Agreement. For Gokula Education Foundation (Medical) Bangalore. MS Ramaiah Memorial Hospital (India), this will be Prof

This Cooperation Agreement as well as succeeding plans concerning the concrete proposals of cooperation, shall be effective after approval of the terms of the agreement by the appropriate authorities of the universities. It will remain in effect for a period of 5 years. Thereafter, it will be reviewed and can be amended or renewed as agreed by both parties.

For Ghent University

Prof. Dr. Rik Van de Walle Rector

Date: 05/12/2017

Prof. Dr. Piet Hoebeke

Dean Faculty of Medicine and Health

Sciences

For Gokula Education Foundation (Medical) Bangalore (India)

Chairman

Date: 16-パー(テ

Prof. Dr. Medha Y Rao Principal and Dean

Ramaiah Medical College & Hospitals

Date: 16 (11 /2017

PRINCIPAL AND DEAN
MS. Ramasah Medical College
& Hospital

Bangalore - 560 054



ગુજરાત गुजरात GUJARAT

3 0 JUL 2012

Y 580222

OUINTILES RESEARCH (INDIA) PVT. LTC
B-101-106. Shapath IV,
Opp. Karnavati Club,
Sarkhej - Gandhinagar Road,
Ahmedabad - 380 051, India

CLINICAL TRIAL AGREEMENT

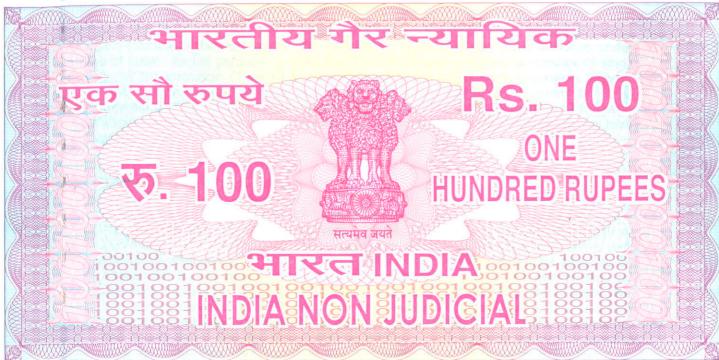
Made between **Dr Nalini Kilara**, having a place of business at M.S. Ramaiah Curie Centre of Oncology, M S Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, Bangalore-560054, Karnataka India (the "Investigator"), **M. S. Ramaiah Medical College and Hospitals** having a place of business at MSRIT Post, New BEL Road, Bangalore-560054, Karnataka, India (the "Institution"), and **Quintiles Research (India) Private Limited**, having a place of business at B-101-106, Shapath IV,Opp. Karnavati Club,Sarkhej-Gandhinagar Road,Ahmedabad - 380 051,Gujarat, India. ("Quintiles") representing the interests of **Dr. Reddy's Laboratories Ltd** (the "Sponsor").

India CTA Template 03 August 2010 [Dr. Reddy's Laboratories, RI-01-002] Dr. Nalini Kilara

SEA.

CONFIDENTIAL

1



गुअरात गुजरात GUJARAT 🚾 🖳

1

 3 0 JUL 2012

Y 580223

QUINTILES RESEARCH (INDIA) PVT. LTC
B-101-106, Shapath IV,
Opp. Karnavati Club,
Sarkhej - Gandhinagar Road,
Ahmedabad - 380 051, India

an 2/2/21

KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	1 100 Calendar Days after Site Initiation Visit	
PRINCIPAL INVESTIGATOR:	Dr. Nalini Kilara an employee of Institution	
SPONSOR:	Dr. Reddy's Laboratories Ltd	
PROTOCOL DATE:	16 Nov 2011	
PROTOCOL TITLE:	A Randomised, Multi-centre, Double-blind, Parallel Group Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety and Efficacy of Two Anti-CD20 Monoclonal Antibodies in Combination with CHOP in Patients with CD20-Positive Diffuse Large B-cell Lymphoma	
PROTOCOL NUMBER:	RI-01-002	

WHEREAS, the Investigator and Institution, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Quintiles requests the Site to undertake such Study;

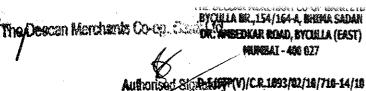
India CTA Template 03 August 2010 [Dr. Reddy's Laboratories, RI-01-002] Dr. Nalini Kilara CONFIDENTIAL

2

ii. Inspect source documents, including but not limited to the hospital/ outpatient/ records, laboratory investigations relevant to the completion of the case report forms & other study related documents.

Investigator and/or Institution may hold and represent other clients, but such work should not conflict with Investigator's and Institution's Services for Quintiles, as mutually determined by Investigator, Institution and Quintiles. Investigator and Institution shall disclose to Quintiles in advance and in writing the specific nature of any potential conflict of interest or personal interest in any proposed services. Investigator and Institution represent and warrant that execution of this Agreement and performance of the services described in this Agreement do not and will not breach any other contractual and/or legal obligations or the applicable policies of any third party (including but not limited to an agreement in the nature of a confidentiality and/or non-disclosure and/or non-competition agreement) and do not require the consent of any other person, or that the proper consent has been obtained.

per consent has been obtained.
WLEDGED AND AGREED BY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED:
Sandre Saisarlin
Director Head Integrated Site Services
India
18 OCT 2012
OWLEDGED AND AGREED BY M. S. RAMAIAH MEDICAL COLLEGE AND TALS:
1 da
Dr D C Sundaresh
President-Clinical Research
21/9/2012
OWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:
htelaro
Dr Nalini Kilara
20 Sep 2012





Clinical Trial Agreement

ARTICLES OF AGREEMENT made at Mumbai, this <u>05</u>th day of <u>feb</u> 2015 BETWEEN:

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai 400 018 (hereinafter referred to as "the Sponsor", which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and assigns) of the First Part;

Dr. Pramila Kalra whose designation is Associate Professor and having her address at M.S. Ramaiah Medical College and Hospitals, New BEL road, MSRIT Post, Bangalore-560054, Karnataka, India (hereinafter referred to as "the Investigator", which expression shall, unless it be repugnant to the context ore meaning thereof, be deemed to mean and include her heirs, executors, administrators and successors) of the Second Part;

AND

M.S. Ramaiah Medical College and Hospitals, New BEL road, MSRIT Post, Bangalore-560054, Karnataka, India (hereinafter referred to as "the Institution", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee and permitted assigns) of the Third Part.

(The Sponsor, Investigator and Institution may be individually referred to as Party and collectively as Parties)

- A) The Sponsor is, inter-alia, engaged in the business of sale and distribution of a wide range of drugs and pharmaceutical products in India;
- B) The Investigator is a qualified medical practitioner inter alia, engaged in medical research and clinical practice of oncology, at the Institution and the Investigator has represented to the Sponsor that it will obtain the approval of the Ethics Committee of the Institution where the study shall be conducted;
- C) The Institution provides infrastructure to perform certain research and studies and is capable of, accustomed to and interested in performing the required tests;
- D) The Sponsor is desirous of conducting the following studies as per protocol Protocol No. CLCl699C2301

 Protocol Title: "A Phase III, multi-center, double-blind, randomized withdrawal study of LCl699 following a 24 week, single-arm, open-label dose titration and treatment period to evaluate the safety and efficacy of LCl699 for the treatment of patients with Cushing's disease" as may be amended from time to time by the Sponsor at its sole discretion (hereinafter referred to as "the Protocols") and has approached the Investigator for the conduct and supervision of the Trial in accordance with the Protocol.
- E) The Investigator has been informed by the Sponsor that prior approval of the Drugs Controller General (India) (DCGI) for its no objection to conducting the Trial has been applied for and will be procured prior to conducting the Trial. The Investigator, on his/her part, irrevocably consents to undertake and conduct the Trial and has agreed to execute this Agreement. It is agreed between the Parties hereto that commencement and conduct of the Trial in terms of this Agreement shall be subject only to the written 'no objection' of the DCGI for the Trial failing which this Agreement shall stand null and void, Sponsor shall have no liability whatsoever towards the Investigator or the Institution. The permission of the DCGI when received shall be Annexed to this Agreement and shall form a part of the Agreement.
- F) On the faith and strength of the aforesaid representations and warranties, the Sponsor has agreed to appoint the Investigator for the conduct and supervision of the Trial in accordance with the Protocol upon and subject to the terms and conditions hereinafter appearing.

NOW THIS AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO as follows:

1 (a) Based on the representations of the Investigator specified in the Recitals (which are incorporated herein by reference), the Sponsor hereby

IN WITNESS WHEREOF the parties hereto have hereunto set and subscribed their hands to these presents, the day and year first hereinabove written.

SIGNED AND DELIVERED for and on)

Novartis Healthcare Private Limited behalf of the within named **Sponsor**,) by the hand of its authorized signatories,) in the presence of:)

Amitable Dube

Amitabh Dube
Date: 03/02/15

Dr. Manish Mistry

Date: 03/2/15

SIGNED AND DELIVERED by the

Within named Investigator,

Dr. Pramila Kalra,

M.S. Ramaiah Medical College and Hospitals,

New BEL road, MSRIT Post,

Bangalore-560054, Karnataka, India

in the presence of:

, PKalua

Date: 5/2/20/5

SIGNED AND DELIVERED for and on behalf of the within named Institution,

Data

5 Feb 2015