भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2016 ◑

Y 078241

अनु.क्र. 17742 दि. 30/09/2016 मु.शु.रक्कम 500/-

दस्ताचा प्रकार Agreement

दस्त नोंदणी करणार आहेत का? होय / नाही -

मिळकतीचे वर्णन

मुद्रांक विकत घेणाराचे नांव Grape City Research

पत्ता Yerawada Pune 33

दुसऱ्या पक्षकाराचे नांव -

हस्ते व्यक्तीचे नांव व पत्ता Mahesh Patil

Pimple Gurav Pune

स्वाक्षरी

सौ. प्रज्ञा प्र. प्रभु, मुद्राक विक्रेती ला.न. 220995

डांगे चौक, थेरगाव चिंचवड, पुणे 33

परवान्याची मुदत 31/12/2016

मुद्रांक विकत घेणाऱ्याची सही

28 SEP 2016

प्रधान मुद्रांक कार्यालय कोषागार पुणे कार्यालय

Memorandum of Understanding

This Agreement is made on 1st Jul2016, by and between"GRAPECITY RESEARCH SOLUTIONS LLP" a company registered under company act 1956 having its office at Prakash Housing Society, Block no. "GRAPECITY RESEARCH SOLUTIONS LLP"/2,

Thergaon Pune-411033, Maharashtra, INDIA. referred as a party- A**(here in after referred to as the "GRAPECITY RE SEARCH")**

And

MAHATMA GANDHI MISSION's, MEDICAL COLLEGE & HOSPITAL (MGM HOSPITAL), N-6 CIDCO, Aurangabad-431003,Maharashtra, India referred as a party – B**(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties hereto as follows

MGM College & Hospital Aurangabad appoints "GRAPECITY RESEARCH SOLUTIONS LLP" as a Site management organization **for period of 03 years w.e.f 1st Jul 2016 to 1st Jul 2019.**

Obligations of "GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services:

"GRAPECITY RESEARCH SOLUTIONS LLP" is a Clinical Research Organizations and Site Management Organization based in Pune providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities,Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance& Maintenance, and Clinical Research Expertise in India.
"GRAPECITY RESEARCH" is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV clinical trials for new drug & treatment

"GRAPECITY RESEARCH" shall play vital role in getting clinical trials to the hospital / institution from the sponsors and CROs and execute them in institution.

"GRAPECITY RESEARCH" will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

"GRAPECITY RESEARCH" will appoint Project Manager (PM)who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

"GRAPECITY RESEARCH" will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention. Study co-ordination, project management and quality management will be done by **"GRAPECITY RESEARCH".** Study personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

"GRAPECITY RESEARCH" will bear all the administrative cost related to the various activities undertaken by PM, QM or any other staff placed by "GRAPECITY RESEARCH" which includes telecommunication, travel cost, training cost at various centers across India or abroad.

"GRAPECITY RESEARCH" will be conducting /managing all trial(Trials come from "GRAPECITY RESEARCH SOLUTIONS LLP) at the Institution during the tenure of this agreement. This agreement will last for 03 (Three) year and can be renewed further on mutual agreement.

Following activities will be carried outby appointed PM & QM of GRAPECITY RESEARCH SOLUTIONS LLP-

1. Helping study coordinator provided by MGM Hospital Management, for Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement.
2. Helping study coordinator provided by MGM Hospital Management for Preparation for Site selection visit and Site Initiation Visit (SIV)
3. Helping study coordinator provided by MGM Hospital Management, for Communication & Follow up with IRB/IEC Submission and Approval
4. Helping study coordinator provided by MGM Hospital Management, for Accurate and complete documentation of relevant EC documentation
5. Helping study coordinator provided by MGM Hospital Management, for Regulatory Documents Collection

8. Helping study coordinator provided by MGM Hospital Management, for Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous
9. Helping study coordinator provided by MGM Hospital Management, for Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation
10. Helping study coordinator provided by MGM Hospital Management, for Assisting Principal Investigator in administrating ICF and its procedures
11. Helping study coordinator provided by MGM Hospital Management, for Ensure protocol &applicable regulatory guidelines compliance and adherence
12. Helping study coordinator provided by MGM Hospital Management, for Patients pre-screening, screening enrollment and recruitment
13. Helping study coordinator provided by MGM Hospital Management, for Preparing source notes and CRF filling
14. Helping study coordinator provided by MGM Hospital Management, for Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Helping study coordinator provided by MGM Hospital Management, for Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
16. Helping study coordinator provided by MGM Hospital Management, for Managing clinical trial materials(CTM) maintenance, Accountability, distribution and logistics at site
17. Helping study coordinator provided by MGM Hospital Management, for Coordinate all site specific queries-medical, administrative, subject reimbursements and other
18. Helping study coordinator provided by MGM Hospital Management, for Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Helping study coordinator provided by MGM Hospital Management, for Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log

20. Helping study coordinator provided by MGM Hospital Management, for Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Helping study coordinator provided by MGM Hospital Management, for Coordinate with central and local lab for logistics and sample flow
22. Helping study coordinator provided by MGM Hospital Management, for Attend study related meeting as appropriate
23. Helping study coordinator provided by MGM Hospital Management, for Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Helping study coordinator provided by MGM Hospital Management, for Any other required activities during the trials.
25. Helping study coordinator provided by MGM Hospital Management, for Identification of potential database from different therapeutic area of PIs
26. Helping study coordinator provided by MGM Hospital Management, for Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Helping study coordinator provided by MGM Hospital Management, for Other duties as requested by "GRAPECITY RESEARCH" Management
28. For carrying out the above mentioned activities the project manager of "GRAPECITY RESEARCH" will be available at MGM Hospital Management for helping and/or assisting the Principal Investigator and Research Team as and when required and/or before DCGI audit or inspection.

B. Institution Permits

1. Institution will give the space and required facilities to appointed CRC&"GRAPECITY RESEARCH" in order to perform clinical trials activities under respected PI.
2. Institution will allow "GRAPECITY RESEARCH" and Sponsors of clinical trials to access the facility to verify source documents.
3. Institution will allow "GRAPECITY RESEARCH" to bring Sponsors of clinical trials to meet with SITE representatives at a mutually convenient time.
4. Institution permit all Clinical Trials (The trial which comes for "GRAPECITY RESEARCH") will exclusively manage by "GRAPECITY RESEARCH" only.

C. Term of Agreement

The term of this Agreement shall be for a period of 03 year commencing on the effective date 1th Jul2016. However, this Agreement shall be reviewed annually by both parties.

D. Relationship of the Parties

1. Hospital and "GRAPECITY RESEARCH SOLUTIONS LLP" are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provide in this Agreement.

E. GCP, ICH and CFR Compliance

Institution agrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties hereto recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. "GRAPECITY RESEARCH SOLUTIONS LLP" agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE.

2. Institution shall not disclose to any third party any and all information about new studies received from "GRAPECITY RESEARCH SOLUTIONS LLP"

G. Indemnification

Institution shall indemnify and hold harmless "GRAPECITY RESEARCH SOLUTIONS LLP" against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by Institution, its agents, directors or employees. "GRAPECITY RESEARCH SOLUTIONS LLP" shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by "GRAPECITY RESEARCH SOLUTIONS LLP", its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution, Principal Investigator, "GRAPECITY RESEARCH" and Sponsor and/or CRO will enter into a quadripartite (PI, Institute, Sponsor / CRO & Grapecity research solution LLP) clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through "GRAPECITY RESEARCH SOLUTIONS LLP" and pricing while bidding for the trials shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by "GRAPECITY RESEARCH SOLUTIONS LLP along with Institution for Smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of "GRAPECITY RESEARCH SOLUTIONS LLP.
4. All payment will come to "GRAPECITY RESEARCH" by the sponsors/CRO and

"GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services will be payee for all trial related payment for each trial.

5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. An invoice will be requested from the hospital for study payment and all Study related payments will be done to MGM Medical College &Hospital Aurangabad, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. In case any payment is received by "GRAPECITY RESEARCH" under this MOU from sponsor/CRO then within 15 working days after receipt of such payment "GRAPECITY RESEARCH" shall immediately remit the same to MGM Medical College &Hospital Aurangabad. in case if any payment is made beyond the stipulated period of 15 working days "GRAPECITY RESEARCH" will be liable to remit the same along with an interest of 24% per month.
9. The details of study budget sharing in INR is as follows:
    - Payment per patient from Sponsor/CRO to "GRAPECITY RESEARCH SOLUTIONS LLP": **100%**
    - Payment to Institute/Principal Investigator from "GRAPECITY RESEARCH SOLUTIONS LLP":**65%**.
    - Payment to "GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services: **35%**.
    - Payment to Institute/Hospital from Sponsor/CRO and/or "GRAPECITY RESEARCH" for grants like Lab investigations, Hospitalization etc. will go to "MGM Hospital Management" and same will not be shared. **(Note:** If grants received are more than the as per actual then it will be shared in the ratio of 35 % to Grapecity Research solutions LLP & 65 % to MGM Hospital management**)**.
    - Additional Payment to Institute as Institute Overhead Charges: **20% (Of the investigator Budget, if provided by the Sponsor/CRO) shall be paid to the Hospital/Institute.**
    - If sponsor provide some instrument or pay cheque for instrument purchase for clinical research use, then it should be maintained/ returned back to the sponsor after project completion.OR If Grapecity Research Purchases any instruments for clinical trial use, that will be maintained & remained with Grapecity Research only.
    - Archival of the study documents is responsibility of Hospital/ Institute & should maintain for specific period as per Sponsors policy.

- If coordinator charges are borne by sponsor in such cases grant will go to "MGM Hospital Management" as the payment to coordinators is already the responsibility of "MGM Hospital Management"

(Note: study budget sharing will be revised after one year mutually agreed by both party)

I. Termination of Agreement:

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement:

For good consideration, the undersigned authorizes SMO and it's assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of Aurangabad, MH, India.

MGM Medical College &Hospital Aurangabad

1) Signature: _____

Dean
MGM Medical College,
Aurangabad.

Name:-Dr. rajendra Bohra
Title: - Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date: - 7/10/2016

2) Signature: _____

M.G.M's Medical College M.G.M. Abad

Name:- Dr. Pravin R. Suryawanshi
Title: - Dy. Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date: - 7/10/2016

3) Signature: _____

Name:-Dr. Deepak Bhosle
Title:- Professor & Head Department of Pharmacology
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date: -7/10/2016

"GRAPECITY RESEARCH SOLUTIONS LLP

1) Signature: _____

Name: - Dr. Sushil Chaudhary
Title: -Founder & Director,
"GRAPECITY RESEARCH SOLUTIONS LLP"D/2, PRAKASH HSG SOCIETY, NEAR KALEWADI FATA THERGAON, PUNE411033,
Maharashtra, INDIA

Date: -7/10/2016