



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

### **Details of the Collaborative Activity**

**2018 to 2020**

**Name of the Collaborating Institute:** Zenith Clinical Services, Kirloskar Colony, 5<sup>th</sup> cross, Basaveshwaranagar, Bangalore

**Name of Collaborating Department:** Yenepoya Medical College Hospital

#### **Clinical Trail Study:**

Dr. Prabha Adhikari M.R. (PI), Dr. Rajendra Chandradas, Ms. Ashra B from Yenepoya Medical College & Hospital and Zenith Clinical Services signed an official MoU to perform study entitled “A multi-center, randomized, 12 week treatment, double blind study to assess the efficacy and safety of QMF149 (150/80 microgram) compared with MF Twistheler (200 microgram) in adult and adolescent patients with asthma” dated 04.04.2018.

**MoU:** An official MoU was signed between the institutes in 2019.

ATTESTED 

Dr.Gangadhara Somayaji K.S.  
Registrar  
Yenepoya(Deemed to be University)  
University Road, Derlakatte  
Mangalore-576 018, Karnataka

# Zenith Clinical Services

# 54/192, Kirloskar Colony, 1 Stage, 5<sup>th</sup> Cross, Basaveshwaranagar, Bangalore – 560 079

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To

08FEB2019

The Medical Superintendent,  
Yenepoya Medical College and Hospital  
Yenepoya University, Deralakatte  
University Road, Mangalore

Subject: Request to provide the ID and access to the study coordinator (clinical research coordinator)

Dear Sir,

We have appointed Ms. Ashra B, as study coordinator (clinical research coordinator) for the study being conducted at Medicine Department, Yenepoya Medical College and Hospital.

The study details are as follows:

Study Title: A multi-center, randomized, 12-week treatment, double-blind study to assess the efficacy and safety of QMF149 (150/80 microgram) compared with MF Twisthaler® (200 microgram) in adult and adolescent patients with asthma.

Principal Investigator: Dr. Prabha Adhikari

Sponsor: Novartis.

I request you to kindly provide the ID and access to the study coordinator (CRC)

Thanking you

Sincerely yours



Dr. Rajendra Chandradas  
Director  
Zenith Clinical Services:  
+91 9448050608  
+91 7892846003

[www.zenithclinicalservices.com](http://www.zenithclinicalservices.com)  
Email: [info@zenithclinicalservices.com](mailto:info@zenithclinicalservices.com)

ATTESTED  


Dr. Gangadhara Somayaji K.S.  
Registrar  
Yenepoya (Deemed to be University)  
University Road, Deralakatte  
Mangalore-575 018, Karnataka  
PH: +91 80 23227029



YRC NAAC 2020 &lt;yrcnaac2020@yenepoya.edu.in&gt;

**Fwd: Ashra CRC Access Request Letter**

1 message

**Aparna Hegde** <aparnahegde@yenepoya.edu.in>  
To: YRC NAAC 2020 <yrcnaac2020@yenepoya.edu.in>

Mon, Jan 11, 2021 at 4:54 PM

FYI

----- Forwarded message -----

From: **Rajendra Chandradas** <rajendra@zenithclinicalservices.com>

Date: Mon, Mar 11, 2019 at 10:57 PM

Subject: Ashra CRC Access Request Letter

To: Deputy Director YRC &lt;dymdirectoryrc@yenepoya.edu.in&gt;

Cc: Aparna Hegde &lt;aparnahegde@yenepoya.edu.in&gt;

Dear Dr Arun B,

Please find the attached letter requesting to provide ID and access to the study coordinator Ashra B.

Thank you and Best Regards

Dr. Rajendra Chandradas

Chief Executive Officer

+919448050608

+917892846003

[www.zenithclinicalservices.com](http://www.zenithclinicalservices.com)

Zenith Clinical Services

--  
Regards,  
Aparna Hegde  
Clinical Research Coordinator  
Yenepoya Research Centre  
Phone: +91 9980 567 147  
Mail: [aparnahegde@yenepoya.edu.in](mailto:aparnahegde@yenepoya.edu.in)

**2 attachments**

image001.png  
20K

**Ashra Access Letter.pdf**  
119K

ATTESTED

A green handwritten signature.  
Dr.Gangadhara Somayaji K.S.  
Registrar  
Yenepoya(Deemed to be University)  
University Road, Derlakatte  
Mangalore- 575 018, Karnataka



YRC NAAC 2020 &lt;yrcaac2020@yenepoya.edu.in&gt;

**Fwd: Ashra CRC Access Request Letter**

1 message

**Aparna Hegde** <aparnahegde@yenepoya.edu.in>  
To: YRC NAAC 2020 <yrcaac2020@yenepoya.edu.in>

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Dr. Rajendra Chandradas

Chief Executive Officer

+919448050608

+917892846003

[www.zenithclinicalservices.com](http://www.zenithclinicalservices.com)

Zenith Clinical Services

--  
Regards,  
Aparna Hegde  
Clinical Research Coordinator  
Yenepoya Research Centre  
Phone: +91 9980 567 147  
Mail: [aparnahegde@yenepoya.edu.in](mailto:aparnahegde@yenepoya.edu.in)

**2 attachments**

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20K

**Ashra Access Letter.pdf**  
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Registrar  
Yenepoya(Deemed to be University)  
University Road, Derlakatte  
Mangalore- 575 018, Karnataka

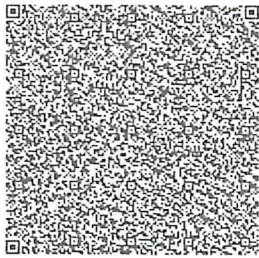
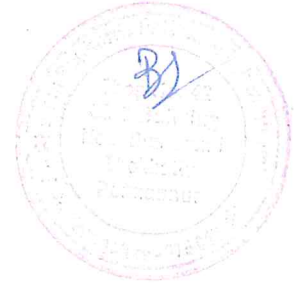


सत्यमेव जयते

# INDIA NON JUDICIAL Government of Karnataka

## e-Stamp

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 Certificate Issued Date : 29-Mar-2018 12:37 PM  
 Account Reference : NONACC (FI)/ kaksfcl08/ THOKOTTU1/ KA-DK  
 Unique Doc. Reference : SUBIN-KAKAKSFCL0810669607930753Q  
 Purchased by : YENEPOYA UNIVERSITY  
 Description of Document : Article 12 Bond  
 Description : AGREEMENT  
 Consideration Price (Rs.) : 0  
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 First Party : YENEPOYA UNIVERSITY  
 Second Party : ZENITH CLINICAL SERVICES  
 Stamp Duty Paid By : YENEPOYA UNIVERSITY  
 Stamp Duty Amount(Rs.) : 100  
 (One Hundred only)



-----Please write or type below this line.-----

### MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding ("MoU") is entered into on the dates and the places hereinafter mentioned:

Page 1 of 5 **ATTESTED**

*Dr. Gangadhara Somayaji K.S.*  
 Registrar  
 Yenepoya (Deemed to be University)  
 University Road, Derlakatte  
 Mangalore - 575 018, Karnataka

*Dr. G. Shree Kumar Menon*  
 Registrar  
 Yenepoya (Deemed to be University)  
 Mangalore 575 018

*Dr. RAJENDRA CHANDRADAS*  
 Director  
 ZENITH CLINICAL SERVICES  
 54/198, Kirloskar Colony, 5th Cross  
 1st Stage, Basayeshwaranagar  
 BENGALURU - 560 079

Statutory Alert  
 1. The authenticity of this Stamp Certificate should be verified at "www.shreestamp.com". Any discrepancy in the details on this Certificate and available on the website renders it invalid.  
 2. The onus of checking the legitimacy is on the users of the certificate.  
 3. In case of any discrepancy please inform the Registrar, both parties.

**BY AND BETWEEN**

Yenepoya Medical College and Hospital, a constituent unit of Yenepoya (Deemed to be University), University Road, Deralakatte, Mangalore - 575018 (hereinafter referred to as the “**Institute**”, which expression shall unless repugnant to the meaning and context thereof be deemed to mean and include its successors in interest and permitted assigns) of the **FIRST PARTY**;

**AND**

Zenith Clinical Services, a Clinical Trial Site Management Company having its office at # 54/192, Kirloskar Colony, 5<sup>th</sup> Cross, 1<sup>st</sup> Stage, Basaveshwaranagar, Bangalore – 560 079 (hereinafter referred to as the “**SMO**”, which expression shall unless repugnant to the meaning and context thereof be deemed to mean and include its successors in interest and permitted assigns) of the **SECOND PARTY**;

**Yenepoya Institute** and the **SMO** shall be individually referred to as “Party” and collectively as “Parties” as the context may so require.

**WHEREAS** the SMO is desirous of facilitating the clinical trial activities that are conducted in the Yenepoya Medical College and Hospital for a Contract Research Organisation (CRO), a pharmaceutical company, a biotechnology company, a medical device company. The scope of SMO’s responsibilities includes:

- Contract
- Submission for Institutional Review Board or Independent Ethics Committee (IRB/IEC)
- Provide Clinical Research Coordinator (CRC) to the study
- Subject Counseling
- Facilitating subject recruitment
- Subject Follow-up
- Informed Consent Form (ICF) translation into vernacular languages
- Site Initiation and trial close-out operations
- Facilitating trial related documents maintenance during the study period
- Assisting in reporting serious adverse events to the sponsor or CRO and the IRB/IEC
- Ensuring Protocol compliance
- Advising & alerting investigators of potential protocol violations
- Advising & alerting investigators of potential ICH-GCP violations


**WHEREAS** the Institute is agreeable to allow the SMO to access the Yenepoya Medical College and Hospital for conducting mutually agreed clinical trials between the parties.


**NOW THIS MOU WITNESSETH:**

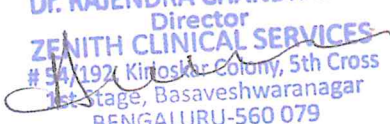
1. The commencement of the study shall be subject to the receipt of an approval from the Investigator and Co-Investigator, Scientific Review Board, Institute’s Medical Ethics Committee – Institutional Review Board. The Parties agree that the Institute’s

Page 2 of 5

**ATTESTED**

  
Dr. Gangadhara Somayaji K.S.  
Registrar  
Yenepoya (Deemed to be University)  
University Road, Deralakatte  
Mangalore- 575 018, Karnataka

  
Dr. G. Shree Kumar Menon  
Registrar  
Yenepoya (Deemed to be University)  
Mangalore 575 018

  
Dr. RAJENDRA CHANDRADAS  
Director  
ZENITH CLINICAL SERVICES  
# 54/192, Kirloskar Colony, 5th Cross  
1st Stage, Basaveshwaranagar  
BENGALURU-560 079

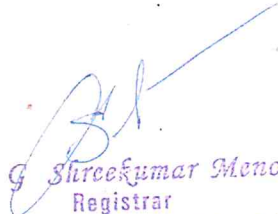
rights and obligations under this MoU are subject to the Institute obtaining the aforesaid approval.


2. The Study Budget is shared as follows:

- a. The budget is shared in the following manner
  - i. Investigators Yenepoya and the Institute Yenepoya Medical College and Hospital (Institute) gets 50% of the budget
  - ii. SMO gets 50% of the budget
  - iii. SMO will recruit and pay the salary to the site CRC
  - iv. SMO will pay subject conveyance for study visits
  - v. SMO will bear lab expenses and other event expenses and the same will be claimed from the CRO.
- b. The above-mentioned Study budget will be directly paid to the Institute or to the SMO by the CRO/Sponsor. If the institute gets the payment then it will pay the SMO as per the payment terms mentioned in the study budget within a week after receiving the payment from the CRO/Sponsor. If SMO gets the payment then it will pay the Institute as per the payment terms mentioned in the study budget within a week after receiving the payment from CRO/Sponsor. Lab expenses and other event expenses received by the Institute from CRO will be completely paid to the SMO and the SMO will bear these expenses.

3. The Institute/Investigators hereby undertakes as follows

- a. Provide the subjects to the study as per the study protocol.
- b. Provide clinical data of the subjects identified in the study cohorts with appropriate consent as per the study protocol requirement.
- c. Conduct study in accordance with the local regulatory requirements.
- d. Management and reporting of Adverse Events (AE's) and Serious Adverse Events (SAE's) if any.
- e. Preparation, maintenance, storage of the study documents during the study period and archiving of the documents as per the applicable regulatory guidelines.
- f. Share the standard operating procedure (SOP's) with the SMO and SMO will keep it confidential and use it only for the purpose of training its staff.

  
Dr. G. Suresh Kumar Menon  
Registrar  
Yenepoya (Deemed to be University)  
Mangalore 575 018

**ATTESTED**  
  
Dr. Gangadhara Somayaji K.S.  
Registrar  
Yenepoya (Deemed to be University)  
University Road, Deralakatte  
Mangalore- 575 018, Karnataka

**Dr. RAJENDRA CHANDRADAS**  
Director  
**ZENITH CLINICAL SERVICES**  
# 54/19F, Kirloskar Colony, 5th Cross  
1st Stage, Basaveshwaranagar  
BENGALURU-560 079

All information shared by the SMO with the Investigators, including the results of the study, shall be treated as confidential information of the SMO/CRO/Sponsor shall not be directly or indirectly disclosed to any third party without the prior written consent of the sponsor/SMO party and shall be handled by that Party in accordance with the terms.

4. Each of the Investigators shall enter into a separate agreement of confidentiality with the Sponsor/CRO prior to the disclosure of confidential information by the SMO.
5. The provisions of this MoU shall remain in effect until it is terminated. The MoU cannot be terminated during an ongoing trial. The MoU can be terminated by one-month notice/mutual consent by either party.
6. The MoU shall be governed by the laws of India, under the exclusive jurisdiction of Courts in Bangalore.
7. Data generated from the subjects will be the Intellectual property of the Sponsor of the study as mentioned in the study protocol.
8. Subject to the terms of this MoU, the Parties agree that the rights and obligations of the Parties hereunder shall be non-exclusive.
9. Length of agreement: This MoU shall remain in force for 3 years and may be extended for additional periods by agreement of parties, unless otherwise expressed by one of the parties and communicated at least three months before the expiry date.

The specific agreements made (for each new study) in the course of this agreement shall be of the agreed length for each case.

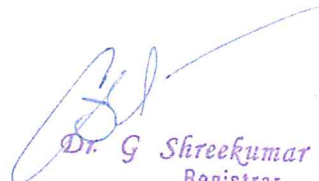

10. This MoU shall insure to the benefit of and shall be binding upon the Parties hereto and their respective successors and assigns but shall not be assignable by any Party except with the written consent of the other Party. In the event of any such assignment with the consent of the other Party, the transferor or assignor shall remain obligated to perform its own obligations and in addition shall be jointly and severally liable for the proper performance of the obligations of the transferee or assignee pursuant to this MoU.
11. Any disputes and differences whatsoever arising under or in connection with the subject matter herein which could not be settled by the Parties through negotiations, after the period of thirty (30) business days from the service of the Notice of Dispute, shall be finally settled by arbitration in accordance with the Arbitration and Conciliation Act, 1996 and all proceedings shall be conducted in English and a daily transcript in English shall be prepared. There shall be three (3) arbitrators, one to be selected by each of the Parties and the third to be selected by the two arbitrators appointed jointly by the Parties, who shall serve as Chairman of the Arbitration Panel. The venue of arbitration shall be in Bangalore, India.

  
Dr. G. Shreeekumar Menon  
Registrar  
Yenepoya (Deemed to be University)  
Mangalore 575 018

**ATTESTED**  
  
Dr. Gangadhara Somayaji K.S.  
Registrar  
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University Road, Deralakatte  
Mangalore- 575 018, Karnataka  
Dr. RAJENDRA CHANDRADAS  
Director  
ZENITH CLINICAL SERVICES  
# 54/192, Kirloskar Colony, 5th Cross  
1st Stage, Basaveshwaranagar  
BENGALURU-560 079



**HEAD OF THE INSTITUTES SIGNATURE PAGE**

<p><b>SIGNED FOR AND ON BEHALF OF THE INSTITUTE:</b></p> <p>Signature: </p> <p>Name: <b>Dr. G Shree Kumar Menon</b> Registrar Yenepoya (Deemed to be University) Mangalore 575 018</p> <p>Designation:</p> <p>Place:</p> <p>Date: <b>04-04-2018</b></p>	<p><b>SIGNED FOR AND ON BEHALF OF ZENITH CLINICAL SERVICES BY:</b></p> <p>Signature: </p> <p>Name: <b>Dr. RAJENDRA CHANDRADAS</b> Director ZENITH CLINICAL SERVICES # 54/197, Kihoskar Colony, 5th Cross 1st Stage, Basaveshwaranagar BENGALURU-560 079</p> <p>Designation: <b>Director</b></p> <p>Place: <b>Mangalore</b></p> <p>Date: <b>04-Apr-2018</b></p>
<p><b>Witness</b></p> <p>Signature:</p> <p>Name:</p> <p>Date:</p>	<p><b>Witness</b></p> <p>Signature:</p> <p>Name:</p> <p>Date:</p>

**ATTESTED**

**Dr. Gangadhara Somayaji K.S.**  
 Registrar  
 Yenepoya (Deemed to be University)  
 University Road, Deralakatte  
 Mangalore- 575 018, Karnataka