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

2018-2020

Name of the Collaborating Institute: Sanofi-Synthelabo (India) Private Limited, Mumbai and Covance India Pharmaceutical Services Private Limited, Navi Mumbai, Maharashtra

Name of the Collaborating Department: Yenepoya Medical College Hospital

Activities:

Clinical Trial Project:

Dr. Prabha Adhikari (PI), Professor, YMCH and Sanofi-Synthelabo (India) Private Limited, Mumbai signed a Clinical Trail Agreement to perform study entitled "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function EFC14875Site: 3560028" dated on 26th Jul, 2018.

ATTESTED

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

COVANCE INDIA PHARMACEUTICAL SERVICES PRIVATE LIMITED
Building No. 1, Unit No. 601, Raheja Mindspace
Plot Nos. Gen/2/1/D, Gen/2/1/E & Gen2/1/F at MIDC Trans
Thane Creek Industrial Area, Shiravane, Nerul, Navi Mumbai,
Maharashtra 400706, India.
Tel: +91 (22) 6822 1500; Fax: +91 (22) 6822 1501.
Registered in India | Company No. U74999MH2007PTC172206

19-Nov-2020

To,
Dr. Prabha Adhikari,
Yenepoya Medical College Hospital
University Road, Derlakatte,
Mangalore- 575018, India

Re:	Close-Out Visit - Follow-Up A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function EFC14875 Site: 3560028

Follow up to Close Out Visit: from 11-Nov-2020 to 11-Nov-2020

Dear Dr. Adhikari,

I would like to thank you and your study staff for your time and assistance during the site's remote Close out Visit from **11-Nov-2020 to 11-Nov-2020** for the above-referenced study.

During this visit, I met with the following people:

Attendees		
First Name	**Last name**	**Role**
Prabha	Adhikari	Principal Investigator
Vanamala	Kulal	Study Coordinator
Poojary	Shrijal	Study Coordinator

There were no follow-up items noted as ongoing at this time.

The following is a reminder of what was discussed and accomplished during this final visit:

Study Drug - All study drug was inventoried and has been returned to depo. Copies of all appropriate drug return forms have been left on-site for your records. The return of all the available IMPs is triggered from ALMAC portal by CRA. The IMP box is kept ready at site for pick up by vendor appointed by sponsor/Covance. The vendor will pick-up the IP soon by contacting the site.

Study File Notebook (SFN) - A thorough review and reconciliation of your site's SFN and was completed against the Covance Site Master File. Site confirmed that all the signed ICFs, Patient letter, IMP logs, SUSARs copies, all EC communications and their AoR are filled in a regulatory binder and site binder is up to date. Note all documents were confirmed to be present.

IEC/IRB Notification - Discussed IRB/IEC reporting requirements, including written notification to the IEC/IRB regarding study completion. A copy of the site close out addressed to EC was collected for our files.

Data Queries - All data management items have been finalized. Data base lock is already completed.

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

COVANCE

Study CD - As discussed, you will receive a CD following database release. This CD will contain an archive of your site's data. You will also receive an Acknowledgment of CD for archiving. Please complete this form and follow the return instructions. Please remember that you must retain this CD for 15 years or longer in accordance with local regulation.

Publication Requirements - Discussed requirements as per the protocol and the Clinical Study Agreement.

As a reminder, your ongoing responsibilities as Principal Investigator for this trial are as follows:

Record Retention - All subject notes must be kept for the maximum time period as permitted by the hospital, institution or private practice. Other source documents and study trial file must be retained for fifteen 15 years or longer in accordance with local regulation. Sponsor will maintain the documentation pertaining to the trial as long as the product is on the market and for a minimum of 20 years after the trial has been completed, or in accordance with national regulations, if they require a longer retention period. Please note that you should not destroy any documents without prior written approval by Sponsor.

As informed by you, I have noted that you will archive all study documents for minimum period of 15 years at following location:

- Location: 8th floor, Yenepoya Medical College Hospital, University Road, Deralakatte, Mangalore-575018, India

Regulatory Agency Audits - Please be reminded that if you are contacted regarding a potential Regulatory Agency Audit, you should notify Covance/Sponsor immediately. Access to your archival material will be required if an audit is to be performed.

Financial Disclosure to FDA - Earlier in this trial you were required to complete financial disclosure forms concerning any stake you or your immediate family may have in the outcome of this trial. According to FDA regulations, you must continue to disclose any stake you may have or obtain until one year after the closure of this trial. If you need further information, please consult the financial disclosure form that you completed earlier in this trial.

Affiliation with site - Should your affiliation with Institution change, please notify to Sponsor

Extra Study Supplies –Lab kits are destroyed at the site on 22Oct2020 and nothing is pending.

Site has confirmed that no equipment was provided by CRO/Sponsor. Hence no device to be returned.

Safety report review: PI and EC have reviewed the soft copies of all the safety reports provided by Covance and it's been acknowledged by them. EC has acknowledged all the safety reports from Feb2020 to Jul2020 over an email due to COVID 19 pandemic situation

Final Payment: The payee details mentioned in the CTA was of Vijaya bank, however this bank is officially migrated to Bank of Baroda, hence a new bank account number was issued to the site. Accordingly, site has raised a payee details change notice letter on 13Oct2020 mentioning the corrected account number in which they wanted to have all payments. The payment is processed by the Covance in compliance to that notice letter only. The project team and site team are aware on the same.

The final regular visit payment (including PI grant, SC salary, subject travel fee and institutional overhead) has been paid to site on 22Oct2020. The closeout and archival fee are paid on 04Nov2020. Site has officially confirmed to the CRA via email dated 12Nov2020 that no payment is outstanding now neither from Covance nor from Sanofi and payment file can be closed.

Should you have any questions or concerns regarding the resolution of these outstanding items, please do not hesitate to contact me at 8657566009 or ashik.shaikh@covance.com. Lastly, and most importantly, on behalf of Sponsor and Covance, thank you for your participation and contributions to this clinical trial.

ATTESTED

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

COVANCE

Please file this letter in the correspondence section of the Study Regulatory Binder.

Sincerely,

Ashik Shaikh
Senior Clinical Research Associate
Mobile No: +91 86575 66009
E-mail: ashik.shaikh@covance.com

Copy:
PI- Dr. Prabha Adhikari,
Study Coordinator- Vanamala Kulal
Study Coordinator- Shrijal
Investigator File-Site 3560028

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

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA   2018   TH 914372

4 JUL 2018

PRODUCT CODE:	Sotagliflozin/SAR439954
STUDY CODE:	EFC14875
STUDY NAME:	THE SCORED TRIAL

INVESTIGATOR/INSTITUTION CONTRACT

ATTESTED

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

This Contract (hereinafter "the Contract") is made on this 26th day of July 2018 by and among:

DOCTOR PRABHA ADHIKARI M.R., Professor and HOD of Internal Medicine, having her address at Yenepoya Medical College, University Road, Derlakatte, Mangalore - 575018, Karnataka, India

Hereinafter the "**INVESTIGATOR**",

AND

YENEPOYA MEDICAL COLLEGE, A constituent college of Yenepoya (Deemed to be University), having its address at University Road, Derlakatte, Mangalore - 575018, Karnataka, India represented for the purposes hereof by Dr. G. Shreekumar Menon, Registrar

Hereinafter the "**INSTITUTION**"

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function"(hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin/SAR439954** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled [The SCORED Trial, EFC14875] and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care, and

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Diabetology, and

WHEREAS, Yenepoya Research Centre, is a Constituent Unit of the Yenepoya (Deemed to be University) having its office at University road, Derlakatte, Mangalore 575018, Karnataka and is exclusively involved in research activities at the INSTITUTION and has accordingly provided the SPONSOR a declaration, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ATTESTED

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

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the **INSTITUTION Yenepoya Medical College, A constituent college of Yenepoya (Deemed to be University), University Road, Derlakatte, Mangalore - 575018, Karnataka, India** (hereafter the «Study Site»). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR."

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH– GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR and the INSTITUTION agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 4. TERM.

This Contract is being entered into force from 31st July 2018 ("the Effective Date") and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately 51 (fifty one) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

Dr.Gangadh... K
Yenepoya(Dee... University
Mangalore

5.6 The INVESTIGATOR/INSTITUTION agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (Thirty) Subjects** (the «Subjects »), within **approximately 15 (fifteen) months**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the

Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR and the INSTITUTION of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR and the INSTITUTION, agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION, and shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its

efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com) or any other compliance officer appointed in the future in place of Dr Trivedi. Any changes in the team will be informed to the site. Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR and the INSTITUTION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR and the INSTITUTION shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of

ATTESTED

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

such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or the INSTITUTION to the SPONSOR.

17.4 The INVESTIGATOR and the INSTITUTION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the INSTITUTION for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR and the INSTITUTION upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ATTESTED

Dr.Gangadhara Somayaji K
Registrar
Yenepoya(Deemed to be U
University Road, Deralak
Mangalore- 575 018, Karna

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR and the INSTITUTION represent and warrant that neither the INVESTIGATOR/INSTITUTION nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR and the INSTITUTION shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with INVESTIGATORS and INSTITUTIONS, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR/the INSTITUTION represents and warrants that neither he/she/it nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR and the INSTITUTION further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery

ATTESTED

Dr.Gangadhara Somayaji
Registrar
Yenepoya(Deemed to be Univ
University Road, Deralaka
Mangalore-575 018, Karna

legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR and the INSTITUTION shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

ATTESTED

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

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		NVESTIGATOR	
[Signature]		[Signature]	
[Name]	Dr. Chirag Trivedi	[Name]	Dr. Prabha Adhikari M.R.
[Title]	Clinical Study Unit Director	[Title]	Principal Investigator
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	Y. J. Cama	[Name]	DR. YASHODHAR BHANDARY

INSTITUTION YENEPOYA MEDICAL COLLEGE, YENEPOYA (Deemed University)	
[Signature]	Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore-575 018
[Name]	Dr. G. Shreekumar Menon
[Title]	Registrar
In presence of	
[Signature]	Rekha P.D. 6/8/2018
[Name]	DR. REKHA P.D.

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

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: -

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

   Such amount is divided as follows:

EFC 14875- Per Subject Cost Details			
Visits	Investigator Fees	Site Coordinator Fees*	Subject reimbursement (for travel, meals during site visit)
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500

Close-out visit	14,900	3,100	1,500
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 30 % Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) Sponsor will pay one time lump sum of Rs.4,50,000/- (Rupees Four Lakhs Fifty Thousand only) after the Study Closure to PAYEE for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

9) All the devices or instruments provided by the SPONSOR will be returned to SPONSOR at the time of closeout.

10) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

11) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the Sponsor to the Payee against presentation by the Payee of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

•	Bank Name & Branch:	Vijaya Bank, Yenepoya (Deemed to be University) Branch
•	Bank IFSC	VIJB0001827
•	Account No.:	182701011001151
•	PAYEE:	Yenepoya Research Centre
•	PAN No.:	AAATY1645F
•	GST No.:	29AAATY1645F1ZC

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

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

Annexure 1

YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognised under Sec. 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

TO WHOMSOEVER IT MAY CONCERN

This is to certify/ declare that **Yenepoya Research Centre** is constituent Unit of the **Yenepoya (Deemed to be University).** Yenepoya Research Centre is exclusively involved in research activities and hence all the payments in relation to the research activities shall be done with payee as Yenepoya Research Centre.

The University/ Institution acknowledge the Yenepoya Research Centre as the Payee for the Research related activities.

Finance Officer
Yenepoya University
Mohammad Bava

University Road, Deralakatte, Mangaluru - 575 018.
T : +91 824 220 6000 E : reachus@yenepoya.edu.in www.yenepoya.edu.in

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

जोडपत्र – २

मुद्रांक विक्री नोंदवही अनु.क्रमांक ....१०९९८..... दिनांक .... 9 JUL 2018

दस्ताचा प्रकार ....Agreement........

दस्त नोंदणी करणार आहेत का? :– होय / नाही

मिळकतीचे थोडक्यात वर्णन ....

मुद्रांक विकत घेणा-याचे नाव .... SANOFI-SYNTHELABO (INDIA) PVT. LTD. ....

हस्ते असल्यास त्यांचे नाव, पत्ता ....Albert Tiwade....

सही ....

दुस-या पक्षकाराचे नाव ....Dr. Chirag Trivedi....

मुद्रांक शुल्क रक्कम ....100/-................................

परवानाधारक मुद्रांक विक्रेत्याची सही – (श्री. शंकर साहेबराव यादव) ....

परवाना क्रमांक – १२०१०३१.

मुद्रांक विक्रीचे ठिकाण/पत्ता : जिल्हा सत्र न्यायालय, ठाणे.

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

SANOFI-SYNTHELABO (INDIA) PVT. LTD.
Sanofi House, C.T.S. No. 117-B
L & T Business Park, Saki Vihar Road
Powai, Mumbai – 400072
Tel: 28032000

ATTESTED

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