Patient Program Information and Informed Consent Form

1. OBJECTIVE OF THE PROGRAM

MyStarCare is a program ("**Program**") that supports patients being prescribed a Sanofi-Aventis South Africa (Pty) Ltd ("Sanofi" or "SANOFI") insulin ("**Medicine**") for the treatment of diabetes, in order to appropriately assist patients in achieving improved management of their diabetes through the use of our Medicine.

The Program is proposed and initiated by Sanofi and, implemented and managed by Sancreed (Pty) Ltd trading as Guidepost, with registered address: 116 Oxford Road, Melrose Estate, Johannesburg, Gauteng, 2196; Registration number 2012/097434/07 ("Guidepost") on behalf of Sanofi.

The Program is defined as a Patient Support Program (PSP) designed to support patients prescribed with Sanofi marketed product, through product and/or disease-oriented support.

2. SUPPORT SERVICES

The Program has been designed to provide you with tailored information and to support your condition, via a panel of services (hereafter designated by "**Support Services**") as below:

- Education and product support for your prescribed Medicine for diabetes, consisting of a face-to-face consultation with a diabetes educator, followed by 4 telephonic consultations spaced over 12 months.
- Some patients may receive only a face-to-face consultation should they require correct injection technique education whilst receiving ongoing diabetes coaching offered by other support programs.
- A series of useful messages at timed intervals in the Program to provide you with video clips and articles addressing topics directly related to the Medicine and diabetes.

Such Support Services may be delivered to you by a variety of channels, including but not limited to being contacted by trained personnel (the "**Educators**") face-to-face, telephonically, by SMS, WhatsApp and/or Email, and administrative personnel of Guidepost as is required from time to time, telephonically, by SMS, WhatsApp and/or Email.

This Program is not and should not be considered as a substitute for visiting and seeking the medical attention of a registered healthcare practitioner. Guidepost and its Educators are not in a position to offer advice or share any medical or other information that would ordinarily form part of your relationship with your healthcare practitioner; their role is limited to offering and performing an educational service which shall not be substituted for medical advice at any time.

3. YOUR PARTICIPATION IN THE PROGRAM

a. Registration and withdrawal

Registration is entirely voluntary and free of charge (and you will not be paid for your participation).

You can withdraw your consent herein and your participation in the Program at any time and without reason by sending an email to: Guidepost at MyStarCare@Guidepost.net. Likewise, SANOFI reserves the right to terminate the Program at any time and for any reason, subject to you being provided with prior notice thereof.

Should you at any time during the course of the Program decide to cease use of the Medicine, your participation in the Program will automatically terminate. Indeed, use of the Medicine is a prerequisite to your participation in the Program. Nonetheless, you are assured that your decision to withdraw from the Program will have no impact whatsoever on your medical surveillance and monitoring by your healthcare practitioner.

Your use of the www.guidepost.net Website and your participation in the Program is subject to the Terms and Conditions as displayed at www.guidepost.net/za/terms.

b. Your Personal Information

"**Personal Information**" and "**Special Personal Information**" have the respective meanings ascribed thereto in the Protection of Personal Information Act 4 of 2013 ("**POPIA**") and includes, but is not limited to, all information that you provide as part of your participation in the Program (including data that you supply as part of the questionnaires, as well as any other medical, pharmacovigilance information (including any adverse event or unexpected reaction regarding your treatment) or other data you may share for the purposes of the Support Services (hereafter together referred to as "**Personal Information**"). This information is processed under the direction of SANOFI, the responsible party.

In order to benefit from the Support Services which comprise the Program, your healthcare practitioner will need to provide SANOFI with your Personal Information as indicated in the below table. SANOFI has appointed Guidepost as its operator to process your Personal Information on our behalf. Upon signing this form, your healthcare practitioner will provide your Personal Information to Guidepost. You will then be contacted by Guidepost whereafter you will need to complete your registration for the Program and the Support Services provided therein. The information uploaded for purposes of registration must be accurate, complete and updated as necessary. SANOFI will not be held liable for any harm suffered by you that may arise as a result of inaccurate, incomplete or outdated registration information. Below is your Personal Information to be collected and processed by Guidepost;

Referring Doctor details:	**Patient's Details:**
Name	Name
Surname	Surname
Practice number	Cell phone number
Location	Diagnosis
General Practitioner	Latest HbA1c reading
Specialty	Fasting blood glucose
	Age
	Referral reason
	Physical address for Face-to-Face Education

As required for the above-mentioned purposes, SANOFI may need to collect and communicate your Personal Information to the following stakeholders as part of the management of the Program: (i) Guidepost, (ii) Guidepost Educators, (iii) Your Doctor/healthcare practitioner, and (iv) health authorities.

SANOFI and each stakeholder acting within the Program undertakes to treat as strictly confidential all Personal Information, which it may obtain from you or relating to the Program whilst providing you with access to the Support Services and to at all times process, disclose and/or store any such information in accordance with POPIA and all other applicable laws. For the avoidance of any doubt, by signing this consent form you hereby consent to the use of your Personal Information by SANOFI for the purposes as set out herein.

Your Personal Information will be held on a database in South Africa, as well as outside South Africa. In an instance where SANOFI transfers your Personal Information outside of South Africa, it has ensured that the parties receiving such Personal Information are bound to the same safeguards and protections as are afforded under POPIA, notwithstanding any applicable data protection law that may apply in such jurisdiction.

SANOFI belongs to a multinational Group. In this context, SANOFI may need to transfer your Personal Information to entities of its Group. SANOFI may also need to share your Personal Information with third parties outside of the SANOFI Group to process your data. As such, and subject to the above, SANOFI shall not disclose Personal Information to any Group entity or third party unless:

(i) Such a Group entity or third party is bound by the same provisions and obligations as those set out in this document; and

(ii) SANOFI has received your prior written consent to disclose such information to the specific Group entity or third party.

SANOFI shall ensure an adequate level of protection of your transferred information in accordance with its own policies which mirror the requirements of POPIA and all other applicable laws.

Once the Program is complete or if you decide to withdraw from the Program, your Personal Information will be deleted as soon as reasonably possible, as it shall not be kept longer than necessary according to the Sanofi Standard Retention policy, unless further retention is necessary to meet legal or regulatory requirements or for the protection of SANOFI's interests.

c. Access rights

In accordance with the rights granted to you by POPIA and the applicable laws, you are entitled

to:

- gain access, by simple request, to your Personal Information and or Special Personal Information held by SANOFI, in which case you may request a copy of your information and/or gain direct access thereto, where possible;
- request that your Personal Information be corrected if such information is inaccurate, incomplete or obsolete;
- procure the deletion of your Personal Information in the specific cases provided for by POPIA and the applicable laws; and
- obtain a limitation on the processing of your Personal Information in the specific cases provided for by POPIA and the applicable laws.
- Lodging a Complaint. You may lodge a complaint with the Information Regulator (South Africa). Contact information for the Information Regulator is: SALU Building, 316 Thabo Sehume Street, Pretoria; Tel 012 406 4818; e-mail: inforeg@justice.gov.za

Should you have any queries concerning the processing of your Personal Information in respect of the Program, kindly contact Guidepost in writing at MyStarCare@Guidepost.net.

d. De-identification and secondary use

As mentioned above, the access to your Personal Information will be strictly limited to the purposes which underline the Program.

This PSP is intended to support the Medicine Risk Management Plan, and SANOFI shall be entitled to share your de-identified Personal Information with local health authorities, where required by the applicable laws.

Guidepost will utilise de-identified Patient Personal Information and derived analytics of this information for marketing, research, and program improvement purposes in perpetuity, in compliance with POPIA.

Kindly note that a separate consent form to utilize your anonymized data for research purposes will be provided to you.

For purposes of Program management and/or the secondary use of your Personal Information beyond the Program as described immediately above, your information will be de-identified and aggregated. This means that all the information that could possibly lead to your personal identification will be removed from the database or de-identified to the extent that said information cannot be re-identified. As such, the information which comprises our secondary use database shall not contain your personal particulars, nor lead to your identification or personal contact.

Save as provided elsewhere in this document, only information in such format (i.e., information with no disclosure of your identity and no information that can lead to your identification) will be shared, without your consent, by Sanofi, companies of the Sanofi Group and/or authorised third parties of Sanofi in the conditions mentioned above.

e. Limitation of Liability

SANOFI (its directors, officers and employees), and/or Guidepost (its directors, officers and employees) shall not be liable to you for any loss or damages that you may suffer or incur as a result of, or in connection with, or arising from any use or disclosure by SANOFI and/or Guidepost of your Personal Information provided to it by you that is inaccurate or otherwise incomplete.

f. Program Contact Details

Guidepost can be contacted by calling or sending a WhatsApp message to 087 2500 431, or sending an SMS to 30602 or an email to mystarcare@guidepost.net

YOUR CONSENT

I am a major adult (i.e. over the age of 18) and hereby consent to participate in / consent to the participation by myself or my minor child / ward in the patient support program as described in paragraph 2 **(SUPPORT SERVICES**).

I have legal capacity to give my informed consent in that I am capable of understanding the legal consequences of my consent and can make decisions about my own healthcare or, as applicable, that of my child / ward.

I consent to my healthcare practitioner providing my (or as applicable that of my minor child / ward) Personal Information and Special Personal Information (as defined above) to the Educator / Guidepost in order to permit my (or my child's / ward's) participation in the Program, for the purposes outlined above. Subject to the limitations detailed in paragraph 3.

I further consent to:

- the collection, processing, disclosure and retention of my (or as applicable my child's / ward's) Personal Information and Special Personal Information by Guidepost;
- the transfer of my (or as applicable my child's / ward's) Personal Information and Special Personal Information to my healthcare practitioner, the Educator / Guidepost, to Sanofi pharmacovigilance, Sanofi medical information and to Sanofi product quality;
- the transfer of my Personal Information and Special Personal Information to third parties within the Republic of South Africa;
- the transfer of my Personal Information and Special Personal Information to third parties outside of the Republic of South Africa, provided that such third parties are subject to same level of data protection as that afforded by POPIA and all other applicable (local) laws;
- the transfer of my Personal Information and Special Personal Information to third parties outside of the Republic of South Africa who are not subject to the same level of data protection, provided that

my information is safeguarded by Sanofi's own policies and third-party agreements which mirror the requirements of POPIA and all other applicable laws;

- not to be notified upon each transfer of my (or as applicable my child's / ward's) Personal Information and/or Special Personal Information to my (or as applicable my child's / ward's) healthcare practitioner, the Educator / Guidepost and to Sanofi pharmacovigilance, Sanofi quality, Sanofi medical information, third parties (both local and outside of the Republic of South Africa), and health authorities as mentioned above; and
- to me and/or my doctor being contacted by Sanofi or its third parties (during and after the termination of the Program or my withdrawal therefrom) for the purpose of being provided with and giving further information on the Medicine's pharmacovigilance, Medicine's quality and Medicine's medical information.

I understand and agree that:

- if my (or as applicable my child's / ward's) Personal Information or Special Personal Information is to be used for any other purpose other than that as set out above in relation to the Program, SANOFI shall be obliged to request and obtain my consent for such processing;
- my (or as applicable my child's / ward's) Personal Information may be transferred to PAREXEL International, DLF Building Tower F, 2nd Floor Chandigarh Technology Park Chandigarh 16010 India and Cognizant Technology Solutions India Pvt. Ltd Candor TechSpace, IT/ITES SEZ, Tower G2, 5th Floor, New Town, Kolkata- 700156 India;
- Sanofi, the Educator and or Guidepost are not in a position nor permitted to offer medical advice or information that ordinarily forms part of the relationship between myself (or as applicable my child / ward) and my (or as applicable my child's / ward's) healthcare practitioner and I may not request or expect Sanofi to do so.

I hereby confirm that I am aware that consent is an ongoing process and am aware of my right to voluntarily revoke consent at any point during the process without repercussions. I am aware that I can revoke consent to the processing of my (or as applicable my child's / ward's) Personal Information and Special Personal Information by means of an email to Guidepost at MyStarCare@Guidepost.net. Upon receipt of such request, Guidepost shall immediately cease the collection and processing of my (or as applicable my child's / ward's) Personal Information and Special Personal Information.

I have read the informed consent, alternatively, if I cannot read this document and/or give my written consent but am able to give an oral form of consent, a third person (the "Witness"), independent and with no conflict of interest either with the healthcare practitioner, the Educator and/or Guidepost, has read to me the full informed consent, and will provide written acceptance with my oral acceptance.

I understand the contents and impact of the informed consent.

I had the chance to ask questions which were answered and have understood the answers provided. I have been given the time to process and discuss the information with others and to decide whether or not to take part in the Program.

This consent is valid from the date of my acceptance by reply text message until the Program's termination or until the withdrawal of participation therefrom. However, should the handling of an adverse event extend beyond the Program's termination and/or the patient's withdrawal, the consent shall be considered valid for the duration of such period.