PATIENT INFORMATION LETTER

(Version n. 1 del 01/10/2018)

Study Title: "The community pharmacist and the case management of the tiabetic patient"

Non-profit observational study on the role of the community pharmacist and the "pharmacy of services" in the case management of the diabetic patient.

Study Promoter: Raffaele La Regina

Dear Madam, Dear Sir,

has been proposed to participate in a study that intends to collect some scientific information, and this document aims to inform you about the nature of this project, on the purpose it is proposed, on what will involve such participation, on Your rights and responsibilities.

Please read this information carefully before making a decision about your participation. You will have all the time necessary to decide whether or not to participate in the study.

You can also freely ask any question for clarification and re-propose any question that has not received a clear and complete answer.

The study in question, which is not for profit, is promoted by dr. Raffaele La Regina in collaboration with: Telematic University Pegaso, "Federfarma Campania", "Federfarma Salerno", HTN - Health Telematic Network S.r.l., Biochemical Systems International S.p.a., Next Sight S.r.l.

The study will be described and the contents of this information sheet will be discussed together with you, and a copy will be given to you. He will then have to sign a consent form confirming that he has agreed to participate in the study.

Study rational and purpose

We would like to ask your permission to make available some clinical data concerning you in the context of a clinical-assistance path based on telamedicine tools and self-analysis equipment, in order to carry out a research that aims to evaluate the variation of the adherence index to the PDTA of diabetes, developed by the Campania Region, when the patient is followed by a case manager identified in the local pharmacist and has the ability to perform the checks provided in telemedicine and self-analysis, thanks to the exploitation of the "pharmacy of services".

Over the last few years, the National Health Service has witnessed numerous and substantial changes, even more evident if one looks at the workload that this system is called to face when it comes to chronic diseases. In fact, while the progress of science has led to better outcomes in the treatment of acute diseases resulting in an increase in the average age of the population and consequently to the increase in the number of people suffering from chronic diseases, even multiple, on the other changed socio-economic conditions have led to an increase in the number of elderly and socially fragile individuals. It takes very little to understand that these epidemiological and socio-sanitary mutations pose a serious threat to the stability of our health system. To meet these new needs, the different countries of the world are analyzing and adopting various models of chronic disease management. Even if with different methodologies, all the models developed so far put the patient at the center of attention, in its uniqueness and with its needs, and propose to provide the latter with complete assistance, through the integration of health and social services.

In this scenario, also the role of pharmacist, historically linked to the dispensation of drugs upon presentation of a medical prescription and to a final control action to ensure a delivery of medicines in total safety, over time has evolved. In order to carry on this evolution, new skills have been requested to the pharmacist, to realize what has been defined as a "service pharmacy", through which the pharmacist is recognized the possibility of becoming a strategic figure to meet the changed needs of the population. on the one hand and the National Health System on the other and to support the latter in the transition from a "waiting" medicine to an "initiative" medicine.

Diabetic disease and the resulting chronic complications, today, have a very significant impact on patients and their families, on morbidity and mortality, as well as having a strong economic impact on the health system. Despite this, most of the patients do not carry out what is foreseen by their diagnostic therapeutic assistance (PDTA) due to several reasons such as long waiting times, the need to move to undergo examinations, which is not so easy for young people of working age as well as older people, lack of homogeneity in access to care and in the provision of services and more.

The community pharmacist, therefore, represents, for the position in which it is located within the National Health Service, a potential not yet considered. In fact, it could take on the role of case manager (a professional who manages one or more cases entrusted to him according to a pre-established path, such as PDTA, in a defined space-time context) of the patient suffering from type 2 diabetes mellitus due to the capillarity territory, to the hourly availability superior to any other territorial health structure, to the health skills in its possession and to what it can offer in terms of services within the so-called "service pharmacy". In this scenario, the pharmacist would not replace any of the other actors already present in the multidisciplinary care team but would integrate in the same and, moreover, being already an agreement with the National Health Service, the conferral of this role would not cause a excessive increase in costs, such as that resulting from the hiring of new staff to achieve the same objectives. The involvement of territorial pharmacists in the case management of type 2 diabetic patients could represent the "sustainable" key for the dehospitalization of chronic patients, of which we have been talking for some time without being able to find concrete solutions and at the same time not particularly burdensome.

We are therefore asking for your authorization to use, within the limits and in compliance with current legislation, some clinical data concerning you in the context of a clinical-assistance path based on telemedicine and the use of self-analysis equipment, emphasizing that your membership does not imply for you any kind of additional therapy compared to those that would normally be practiced (so-called "observational" study), but only the possibility for the Promoters to use for research purposes, for the realization of the thesis and for any subsequent disclosure in the scientific field of the information relating to you and to the diagnostic-therapeutic procedure prescribed for you.

What happens if I decide not to participate in the study?

Your eventual adhesion to this research is absolutely free and voluntary, and it is your faculty to eventually withdraw your consent, without need to adduce any kind of justification, and without this can in any way condition the care that will be possibly in the future be given as much care as possible.

Confidentiality of personal data

Pursuant to Legislative Decree 30.06.03 n.196 and the European Regulation 679/2016, we inform you that your personal data collected for scientific research purposes will be processed in full compliance with the above provisions, in order to guarantee the respect of the rights , fundamental

freedoms, as well as the dignity of natural persons, with particular reference to privacy and personal identity.

All documents relating to the study and, in particular, your personal data will remain strictly confidential. Both in the analysis phase and in scientific dissemination, these data will be presented anonymously and in aggregate form (ie not with individual data but with the overall case series). All persons who, for the purposes of carrying out the study and verifying the correct execution of the same, will have access to your personal data and to your original medical documentation (medical records), are held to the confidentiality and confidentiality of the information acquired.

Further information

The research protocol proposed to you has been submitted to the evaluation of the Ethics Committee to which the ASL Salerno belongs.

For further information and communications during the study you can refer to:

Dr. Raffaele La Regina

Telephone number 0975395336

Thank you for your kind attention.

INFORMED CONSENT MODULE

(Version n. 1 del 27/08/2018)

Study Title "The community pharmacist and the case management of the tiabetic patient"

Non-profit observational study on the role of the community pharmacist and the "pharmacy of services" in the case management of the diabetic patient.

Study Promoter: Raffaele La Regina

I, the undersigned, ……..

(*patient name and surname*)

I declare:

- to have understood and to have received a copy of the "Informative letter for the patient" (version n.1 of 14/06/2018), to have received clear and exhaustive information on the conditions of the study and its development,
- that Dr. Raffaele La Regina clearly explained to me the procedures of the study and I had enough time to evaluate and consider my eventual participation in the study. I had the opportunity to ask questions in relation to the study and I am satisfied with the answers obtained.
- to give consent to participation in the study that will be conducted according to the methods that have been explained to me.

In this regard, I declare to be aware that:

- participation in the study is completely voluntary,
- I am free to withdraw consent at any time, not to have explanations about it and that this will not interfere with my future care. In case of withdrawal of the informed consent will not be collected and added other information to existing data,
- the study was approved by the competent Ethical Committee,
- the personal data collected in my medical record could be examined by the Ethics Committee, by the Regulatory Authorities, by the Promoter (and its authorized representatives) and I consent to this examination. Any data collected that concerns me personally must be available (direct access) for Quality Control and Quality Assurance and must be considered confidential in accordance with current legislation regarding data confidentiality,
- the consent signed by me is also valid pursuant to Legislative Decree 196/03 "Code concerning the protection of personal data" and the European Regulation 679/2016, and I authorize the inclusion of my data in the databases concerning the study in question . These data will be processed in a strictly confidential manner and exclusively by competent personnel. I am aware that the data concerning me will always remain confidential and not

made public if not (through publications or scientific conferences) in an absolutely anonymous and aggregate form, and in any case the information will be treated without violating the privacy of the subject to the extent permitted by laws and current regulations (among others, Legislative Decree of 30/06/2003, No. 196, European Regulation 679/2016 and provisions of the Authority for the Protection of Personal Data regarding clinical research). In addition, the data concerning me will be traceable to an identification code and only the doctor who is treating me and the subjects authorized by law will be able to trace my name from this code. I am aware that I will be able to exercise the rights referred to in Articles 16, 18, 20 of the European Regulation 679/2016, namely: access to my personal data, rectification, opposition for legitimate reasons, portability, addressing directly to the doctor who proposes me to join this research, or on its behalf, to the Promoter of the study (in this case with indication of my patient code).

_____	_____	___ /___ /_____
Patient name and surname	*Patient Signature*	*Subscription date*

In the case of incapacity on the part of the patient to grant his consent:

_____	_____	___ /___ /_____
Legal representative name and surname	Legal representative signature	*Subscription date*

(If a support administrator is appointed as legal representative, the Investigator will take care to verify that the custody order by the tutelary judge also includes the protection of the health of the administration)

_____	_____	___ / ___ / _____
Impartian witness name and surname	*Impartial witness signature*	*Subscription date*

(Only if the patient or his Legal Representative is unable to read or write The witness must be able to read and write, not be the patient's first spouse or relative and not be involved in the clinical trial in any role)

DECLARATION OF THE EXPERIMENTATOR THAT ENROLE THE PATIENT

I hereby declare that I have explained to the patient the nature, purpose and terms of his / her adherence to the study, of having answered in a comprehensive manner all the questions posed by the patient. To have illustrated the rights of the patient in terms of protection of personal data, as well as the possibility for the patient to withdraw the consent previously granted behind simple reporting, and in conscience I believe that these concepts have been understood.

I also declare that the patient has freely agreed to adhere to the data collection provided by the study by signing the appropriate consent form, that this form is filed at our research center in accordance with current legislation, and to have delivered a copy to the / to the patient.

_____	_____	___ /___ /_____
Experimentator Name and Surname	*Experimentator Signature*	*Subscription Date*