INFORMATION LETTER FOR THE PATIENT

(Version n. 1 - 14/06/2021)

Title of the study: "AISCAF-P – An Innovative Smart Clinic for AF Patients"

Non-profit observational study on the role of the community pharmacist and services pharmacy in the case management of patients suffering from atrial fibrillation and being treated with new generation oral anticoagulants.

Promoter of the study: Raffaele La Regina

Dear Madam, Dear Sir,

You have 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, the purpose it proposes, what such participation will entail for you, the Your rights and responsibilities.

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

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

The study in question, which is not for profit, is promoted by Dr. Raffaele La Regina in collaboration with: Istituto Superiore di Sanità (National Center for Telemedicine and New Assistive Technologies), University of Brescia, Nova Biomedical Italia S.r.l., HTN - Health Telematic Network S.r.l., Centro Studi Federfarma.

The study will be described to you and the content of this information sheet will be discussed with you, a copy of which will be given to you. You will then need to sign a consent form confirming that you have agreed to participate in the study.

Rationale and purpose of the study

We hereby ask for your authorization 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 potential of an innovative Smart Clinic model, based on the network of Territorial Pharmacies, which aims to simplify and facilitate access to the clinical-diagnostic-instrumental services necessary to monitor patients suffering from atrial fibrillation and being treated with anticoagulant drugs new generation oral.

Over the last few years, the National Health Service has witnessed numerous and substantial changes, even more evident if we look at the workload that this system is called to face when it comes to chronic diseases. In fact, if on the one hand the advances in science have led to better outcomes in the treatment of acute pathologies with a consequent increase in the average age of the population and consequently to the increase in the number of people affected by chronic pathologies, even multiple ones, on the other hand the changed socio-economic conditions have led to an increase in the number of elderly and socially fragile subjects. It doesn't take much to understand that these epidemiological and socio-sanitary mutations represent a serious threat to the stability of our health system. To respond to these new needs, the different countries of the world are analyzing and adopting various models of management of chronic diseases. Even if with different methodologies, all the models developed so far place the patient at the center of attention,

in his uniqueness and together with his needs, and aim to provide him with complete assistance, through integration. health and social services.

In this scenario, the role of the pharmacist, historically linked to the dispensing of drugs upon presentation of a medical prescription and to a final control action to ensure the delivery of drugs in total safety, has also evolved over time. To carry out this evolution, new skills were required from the pharmacist, to create what has been defined as a "service pharmacy", through which the pharmacist is recognized the possibility of becoming a strategic figure to meet the changing 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.

Atrial fibrillation is one of the most common cardiac arrhythmias, from which, in Italy, more than a million people are affected and estimates speak of an increase of up to 70% in the coming years. Due to its ability to increase the thrombo-embolic risk, the affected people are subjected to anticoagulant and antiarrhythmic pharmacological interventions in order to protect the patient from highly disabling events such as cerebral stroke or other arterial embolisms. .

However, these pharmacological therapies require a dynamic approach over time, as the choice of active ingredients and the relative dosages depend on the patient's overall health status and for this reason it is important that he adheres to the monitoring plan, prepared by the Doctor. Specialist, so that therapeutic appropriateness is always guaranteed.

The recent epidemiological emergency has highlighted the need to redesign the follow-up paths of these patients in order to reduce interpersonal contacts today and to simplify these paths tomorrow. In fact, nowadays, patients suffering from atrial fibrillation and on anticoagulant therapy must carry out a series of interminable steps to comply with all the activities provided for in their follow-up plan. This, as the National Health System is organized today, therefore, translates into a lose-lose scenario, due to the lack of reconciliation between the diagnostic and therapeutic activities to be carried out and the rhythms of life.

On the basis of this, it is necessary to design follow-up models, which, thanks to the territorial integration of all the care settings and the related health professionals available, allow the patient to be able to enjoy 0 km assistance models, which allow him to carry out the activities provided for in the treatment plans in the simplest and most immediate way possible in order to be able to guarantee in a timely manner the most suitable treatments for your state of health, foreseeing and preventing complications and responding effectively and efficiently to the needs emerging.

Among the health professionals available to date, that of the Territorial Pharmacist is little considered, which represents, due to the position in which it is found within the National Health Service, a potential that has not yet been fully exploited. In fact, he could take on the role of case manager (professional who manages one or more cases entrusted to him according to a predetermined path, such as the PDTA, in a defined space-time context) of the patient suffering from atrial fibrillation and in therapy with oral anticoagulants of new generation thanks to the capillarity on the territory, the hourly availability higher than any other territorial health facility, the health skills in its possession and 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 into it and, moreover, being already affiliated with the National Health Service, the conferral of this role would not cause a excessive cost increases, such as that which would result from hiring new staff to achieve the same goals. The involvement of local pharmacists in the case management of these patients could represent the "sustainable" key for de-hospitalization of chronic patients, which has been talked about for some time without being able to find concrete and at the same time not particularly costly solutions, and the gateway to the Service National Healthcare that allows them to monitor their state of health, be supported in their activities and remain connected with all the other actors in the care process.

We hereby therefore ask 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 on the use of self-analysis equipment, underlining that your adhesion DOES NOT involve for you any type of additional therapy with respect 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 study and for any subsequent disclosure in the scientific field, the information relating to you and the diagnostic-therapeutic path that has been prescribed for you.

What happens if you decide not to participate in the study

Your possible adhesion to this research is absolutely free and voluntary, and it is your right to withdraw your consent if necessary, without the need to provide any kind of justification, and without this in any way influencing the treatments that will be possibly in the future pay as much attention as possible.

Confidentiality of personal data

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

All documents relating to the study and, in particular, your personal data, will remain strictly confidential. Both in the analysis and scientific dissemination phase, these data will be presented in an anonymous and aggregate form (i.e. not with individual data but from the overall case history). All people who, for the purposes of carrying out the study and verifying the correctness of its execution, will have access to your personal data and to your original medical documentation (medical record), are required to maintain confidentiality and confidentiality of the information acquired.

Further information

The research protocol that was proposed to you was subjected to the evaluation of the Ethics Committee to which ASL Salerno belongs.

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

Dr. Raffaele La Regina
Telephone number 0975395336

We thank you for your kind attention.

INFORMED CONSENT FORM

(Version n. 1 - 14/06/2021)

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Promoter of the study: Raffaele La Regina

I, the undersigned ……..

(name and surname of the patient)

I declare:

- to have understood and received a copy of the "Patient information letter" (version no. 1 of 14/06/2021), to have received clear and comprehensive information on the conditions of the study and its conduct,
- that Dr. Raffaele La Regina clearly explained the study procedures to me and I had enough time to evaluate and consider my possible 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 participate in the study which will be conducted in the manner that has been illustrated to me.

In this regard, I declare that I am aware that:

- participation in the study is entirely voluntary,
- I am free to withdraw my consent at any time, not to have any explanations in this regard and that all this will not interfere with my future care. In case of withdrawal of the informed consent, no other information will be collected and added to the already existing data,
- the study was approved by the competent Ethics Committee,
- the personal data collected in my medical record could be examined by the Ethics Committee, the Regulatory Authorities, 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 on data confidentiality,
- the consent signed by me is also valid pursuant to Legislative Decree 196/03 "Code relating to the protection of personal data" and the European Regulation 679/2016, and I authorize the inclusion of my data in the databases relating to 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

except (through scientific publications or conferences) in an absolutely anonymous and aggregate form, and in any case the information will be treated without violating the confidentiality of the subject to the extent permitted by law and by regulations in force (among others, Legislative Decree of 30/06/2003, n.196, European Regulation 679/2016 and provisions of the Guarantor for the Protection of Personal Data regarding clinical research). Furthermore, 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 starting 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 and that is: access to my personal data, rectification, opposition for legitimate reasons, portability, by contacting the person who offers me to join this research directly, or through him, to the sponsor of the study (in this case with indication of my patient code).

_____	_____	___ /___ /_____
Patient name / surname in block capitals	*Patient's signature*	*Date of signature*

In the event of the patient's inability to give his or her consent:

_____	_____	___ /___ /_____
Name / surname of the legal representative	*Signature of the legal representative*	*Signing date*

(In the event that a support administrator is designated as the legal representative, the Investigator will take care to verify that the order of assignment by the Tutelary Judge also includes the protection of the health of the administrator)

_____	_____	___ / ___ / _____
Name / surname of the impartial witness	*Signature of the impartial witness*	*Date of signing*

(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 spouse or first degree relative, and not be involved in the clinical trial in any role)

STATEMENT BY THE INVESTIGATOR ENROLLING THE PATIENT

I, the undersigned, declare that I have explained to the patient the nature, purpose and terms of his / her participation in the study, that I have fully answered all the questions posed by the patient. I 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 upon simple notification, and in conscience I believe that these concepts have been understood.

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

_____	_____	___ /___ /_____
Investigator's name / surname in block letters	*Investigator's signature*	*Date of signature*