NUTRIACTIS® ZOOM SEPTEMBER 2021





THE SCIENTIFIC RESEARCH

Document produced in the framework of the partnership between

BNP Paribas Cardif and CHU Rouen-Normandie

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In **September 2021**, Professor Déchelotte and his team launched the first phase of the **NutriActis® research program** among BNP Paribas Cardif employees in France. The aim of this scientific research is to optimise the screening and care of eating disorders and obesity. This first phase gives you the opportunity, if desired, to benefit from a videoconsultation with an health professional to screen for eating disorders and obesity. For this, all you have to do is send us an email to nutriactis.consultation@chu-rouen.fr.

In order to make you more familiar with the field of research, NutriActis Zoom #4 is dedicated to the explanation of the basics of scientific research and, more particularly, clinical research.

What's the scientific research?

Scientific research includes all actions carried out with the aim of producing and developing scientific knowledge. This scientific knowledge can include various forms, such as articles, reports, patents, oral communications, or be integrated into the development of new tools or devices. There are two main types of scientific research: biomedical research, which includes basic research and clinical research, and social sciences and humanities research.

Scientific research:

Biomedical research:

Basic research: involves laboratory work, based on an initial hypothesis, on an experimental model (cells, mice, etc.) with the aim of understanding certain biological mechanisms and leading, among other things, to the creation of a drug or a therapy.

Clinical research: includes studies carried out on humans, with a view to evaluating a therapy, whether medicinal or not, a public health action or a diagnostic tool on a sample of people randomly selected or selected according to different criteria. It is a prospective research, which involves the follow-up of patients or healthy volunteers.

Social sciences and humanities research:

includes many disciplines that aim to explain processes that are not biophysical, but rather human influences, social facts, environment and humans behaviors; always with the individual at the centre of research concerns.

Focus on clinical research:

When the basic studies are successful, they are followed by a **clinical research protocol**, which may allow, among other things:

- the assessment of a new drug, a medical device or an innovative therapy
- the identification of molecular or cellular mechanisms involved in diseases
- the identification of genetic or environmental risk factors
- the comparison of several diagnostic or therapeutic approaches

Clinical research in France is governed by the Jardé law of 2012, and is separated into 3 types, depending on the nature of the intervention provided by the protocol and the level of risks and constraints for the subject:

Clinical research:

Interventional research

(category 1 or RIPH 1)

This involves an intervention that is not without risk to the subject and is not justified by the usual care. It mainly concerns research on drugs, or concerning certain surgical procedures, medical devices, or cellular or genic therapies

Interventional research with minimal risks and constraints

(category 2 or RIPH 2)

They may include minimally invasive procedures or acts, the list of which is established by an official order. This research is essentially aimed at comparing/assessing procedures, combinations of procedures or patient care strategies that are already validated and routinely used.

Non-interventional research (category 3 or RIPH 3)

They are without risk and do not alter the care of the patients, and all procedures and products are used in the routine way.

To exist, this research must fulfil certain **regulatory requirements**, in particular obtaining the **favourable opinion of a Committee for the Protection of Individuals (CPP)**, a committee responsible for giving a prior opinion on the conditions for the validity of any research involving the human person, and also the **authorization** of the **National Commission for Information Technology and Civil Liberties (CNIL)** concerning the treatment of the personal data of the participants.

The NutriActis® program in France:

(Full details on the program can be found in the August 2021 newsletter, still available on EchoNet)

- The second phase of the NutriActis® program comes under the RIPH 2 category and aims to improve
 the screening and support in the management of eating disorders and obesity, taking into account the
 latest scientific knowledge and therapeutic approaches available. Also, the results of this research will
 allow, thanks to the analysis of various assessment criteria, to optimise further the screening and care of
 these diseases.
- This program will respect all regulatory requirements. Thus, participants will be asked to sign an information and consent form, and all their personal data will be secured in an accredited health data hosting space.