INFORMATION NOTE

for patients participating in non-interventional research

Evolution of Blood Pressure Classification According to ESC 2024 Guidelines in a Preventive Medicine Cohort: A Cross-Sectional and Retrospective Monocentric Observational Study

Data Controller
Preventive Medicine, Data Science and AI Lab of Zoī SAS (mission-driven company)
50 rue de Paradis, Paris (75010), privacy@zoi.com

Project Leader
Dr. Sylvain Bodard – University Hospital Practitioner
Necker–Enfants malades University Hospital (AP-HP)
Université Paris Cité – Biomedical Imaging Laboratory, INSERM, Sorbonne University
Preventive Medicine, Data Science and AI Lab, Zoī

GENERAL INFORMATION ABOUT THE STUDY

Dear Madam, Sir,

Zoī, as a mission-driven company, is committed to improving health prevention through the development of innovative solutions and the implementation of research projects. Within this framework, your data will be reused for the study entitled:
"Evolution of Blood Pressure Classification According to ESC 2024 Guidelines in a Preventive Medicine Cohort."

The aim of this study is to describe the distribution of blood pressure levels in a population undergoing primary prevention, and to assess the impact of the new European (ESC 2024) recommendations on blood pressure classification. Through the analysis of pseudonymized data, the study seeks to better understand the profiles of individuals reclassified under the new thresholds, and to contribute to a reflection on the relevance of these criteria in a public health approach.

The study is strictly observational, retrospective, and non-interventional. It relies exclusively on data collected during your regular preventive health check-up. No additional procedure will be carried out.

To meet the study's objectives, it is planned to include the data of **2,000 individuals** who underwent a complete preventive health assessment at the **Zoī Vendôme center**, between November 1, 2023, and May 22, 2025. The study is monocentric and relies exclusively on data from this center.

This research received the **favorable opinion of an ethics committee (Adene)** on 26/05/2025, under reference **N° IRB_ADENE_20250602**.
It complies with the **Reference Methodology MR-004 (N° 2236508)**.

Your participation in this research, or your refusal to participate, does not in any way affect your medical care. You may object to participation at any time.

Study timeline

The data concerning you will be analyzed within the framework of a retrospective study on health assessments carried out between **November 1, 2023, and May 22, 2025**.

The objective is to analyze blood pressure classification according to the new European recommendations (ESC 2024), and to compare it with previous classifications, in order to better understand the impact of these changes on early detection of cardiovascular risks.

Planned timeline:

- **August 2025:** Identification of eligible data (available blood pressure values, complete assessment)
- **August 2025:** Extraction of pseudonymized data by Zoī's R&D department
- **September 2025:** Statistical analysis of blood pressure data, description of participant profiles, and comparison between classifications (ESC 2018, ESC 2024, ACC/AHA 2017)
- **October 2025:** Drafting and submission of a scientific article to a peer-reviewed journal

RIGHTS AND INFORMATION CONCERNING YOUR DATA

If you do not object to your participation in this study, your personal data, including health data, will be processed to analyze the study results in light of its objectives.

What data are concerned?

Only the categories of data **strictly necessary for the conduct of this study will be used.** These data come from your preventive health assessment carried out at the Zoī center. **No directly identifying data** (name, surname, address, etc.) will be used.

Reuse of these data complies with the principle of minimization, meaning that only relevant and necessary information will be analyzed. All data are pseudonymized, in line with GDPR and Reference Methodology MR-004.

If your data are to be reused in another study, you will be individually informed by a new, specific information note.

The data used include, in particular:

- Socio-demographic data: age, sex, body mass index (BMI), etc.
- Clinical data: declared medical history, current treatments, results of biological analyses from the health check-up
- Blood pressure data: systolic and diastolic blood pressure values measured during the assessment, according to the center's standardized protocol
- Behavioral risk factors: physical activity, alcohol consumption, smoking

- Health questionnaire data: completed during the preventive assessment, including perceived health status, lifestyle habits, and relevant medical context

How will my data be processed?

Processing is carried out for the **purpose of scientific research in the public interest**. It complies with French (Law No. 78-17 of 6 January 1978 as amended) and European (Regulation (EU) 2016/679 – GDPR) regulations.

- Your data, collected during your Zoī preventive assessment, have been pseudonymized (removal of direct identifiers such as name, surname, date of birth, contact details).
- A double level of pseudonymization is applied:
    - a first identifier at the time of data collection
    - a second identifier when integrated into the secure research environment
- Data are hosted on certified health data servers (HDS), operated by Amazon Web Services EMEA SARL (France region).
- Data will be retained for up to two years after the last scientific publication linked to the study, or until the final report is signed.

No identifying information will ever appear in reports or publications. Results will always be presented in aggregated, anonymous, and strictly non-identifiable form.

Who will have access to your data?

Your pseudonymized data will be accessible only to authorized persons involved in the study, in compliance with GDPR and MR-004:

- Zoī research staff directly involved in the study, within the limits of their duties
- Partner healthcare professionals who may analyze pseudonymized data to complete or validate diagnoses
- Zoī's Data Protection Officer (DPO), in case of a complaint or exercise of rights

All such persons are bound by strict confidentiality obligations.

Your directly identifying data will remain known only to your medical team, professionals involved in your care, persons working under their responsibility, and the DPO if contacted.

What are your rights?

Under GDPR (EU 2016/679) and French law (Law No. 78-17 of 6 January 1978, amended by Law No. 2018-493 of 20 June 2018), you have the following rights:

- Right to information, access, rectification, erasure, and restriction of processing
- Right to object to the processing of your personal data in this study or to its future reuse
- Right to access your full medical record directly or via your referring physician (Article L1111-7 of the French Public Health Code)

If you wish, the overall study results may be communicated to you via your referring physician at the end of the study.

How to exercise your rights?

You may exercise your rights at any time, without justification:

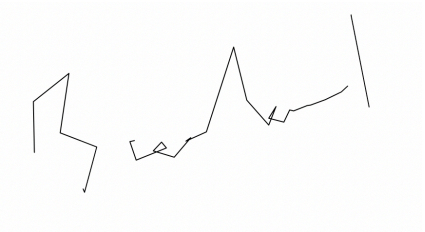
- Through your referring physician
- By contacting Zoï's DPO: **privacy@zoi.com**, Zoï SAS, 50 rue de Paradis, 75010 Paris
- By contacting the project leader or the center's representative (contact details provided in this note)

In case of persistent disagreement or difficulty, you may lodge a complaint with the **French Data Protection Authority (CNIL),** Commission Nationale de l'Informatique et des Libertés (CNIL), 3 Place de Fontenoy, TSA 80715, 75334 Paris Cedex 07.

If you wish to object, you must return the attached form to your study contact at:

Zoï SAS
Data Protection Officer (DPO)
privacy@zoi.com
50 rue de Paradis, Paris (75010), France

Dr. Sylvain Bodard



OBJECTION FORM TO DATA PROCESSING

Title: "Evolution of Blood Pressure Classification According to ESC 2024 Guidelines in a Preventive Medicine Cohort: A Cross-Sectional and Retrospective Monocentric Observational Study – Cross BP"

Zoī SAS
Data Protection Officer (DPO)
privacy@zoi.com
50 rue de Paradis, 75010 Paris, France

I, the undersigned: _____
Born on: __ / __ / ____

Hereby object to the processing of my data and therefore refuse to participate in the study:
"Evolution of Blood Pressure Classification According to ESC 2024 Guidelines in a Preventive Medicine Cohort: A Cross-Sectional and Retrospective Monocentric Observational Study."

I fully understand that my decision will have no effect on my medical care.

Date: _____
Signature: _____