Information Note on the Processing of Personal Data for the Purposes of the Study "Feasibility and Comparative Study of the Detection of Cardiovascular Calcifications on Thoracic CBCT: A Two-Phase Retrospective Pilot Study"

1. **What is this study conducted by Zoï?**

The study **"Feasibility and Comparative Study of the Detection of Cardiovascular Calcifications on Thoracic CBCT: A Two-Phase Retrospective Pilot Study"** is part of the effort to develop innovative and accessible approaches for the evaluation of cardiovascular risk in preventive medicine.

The aim is to assess the usefulness of **next-generation thoracic ConeBeam CT (CBCT)** in detecting cardiovascular risk factors such as aortic and coronary calcifications, as well as other relevant cardiovascular indicators (aortic diameter, cardiomegaly, i.e. enlarged heart).

The study will proceed in two stages:

- **Phase 1:** Assess the feasibility of detecting calcifications and cardiovascular abnormalities on thoracic CBCT.
- **Phase 2:** For patients who also underwent a standard cardiac CT, compare CBCT results with cardiac CT results (re-reading of pseudonymized scans).

The findings of this feasibility study will lay the groundwork for a larger clinical study aimed at validating next-generation CBCT as a low-radiation, low-cost complementary imaging method for opportunistic cardiovascular screening. Using CBCT in this way could broaden access to cardiovascular risk assessment in non-specialized settings, improving early diagnosis, personalized care pathways, and ultimately, patient health.

This retrospective study will rely exclusively on data from CBCT examinations carried out during health assessments, or from cardiac CT scans that may have been prescribed by your referring physician if medically required. No examination will be performed solely for research purposes.

Conducting this study is considered to be in the public interest, both for the individuals concerned, for healthcare professionals, and for the health system as a whole (Articles 6.f. and 9.2.j of the GDPR).

The study complies with **Deliberation No. 2018-155 of 3 May 2018**, approving the reference methodology (MR-004) for personal data processing in non-interventional health research, studies, and evaluations. It has been registered on the **French Health Data Hub public project directory**: https://www.health-data-hub.fr/projets.

2. **Who is conducting the study?**

The study is conducted under the scientific responsibility of **Dr. Léo Mabit (Radiologist)**.

The data controller, the entity that determines the purposes and means of processing, is **Zoī SAS**. The data are processed within the **Preventive Medicine, Data Science and AI Lab**, Zoī's R&D department specializing in preventive medicine.

For any question or specific request, you may contact Zoī's Data Protection Officer (DPO) at: privacy@zoi.com, or per mail at 50, rue de Paradis, 75010 Paris, France

3. **What data about me will be used for the study? Where do they come from, and how long will they be kept?**

The data used in this study come from your health assessment, your thoracic CBCT examination, and where applicable, your cardiac CT scan performed as part of your medical follow-up.

Only data from adults (18 years and older) who underwent a thoracic CBCT during a health assessment between **1 November 2024 and 22 May 2025** are included in this study.

Only data strictly necessary for the study will be reused.

Categories of pseudonymized data used:

- **Health data from the medical questionnaire:**
  - Demographic data (age, sex, body mass index – BMI)
  - Relevant medical history (cardiovascular risk factors such as hypertension, hypercholesterolemia, diabetes, family history of cardiovascular disease or diabetes)
  - Smoking status
- **Medical imaging data:**
  - Thoracic CBCT: analysis of cardiovascular calcifications, thoracic abnormalities, measurement of aortic diameter, cardiomegaly evaluation, radiation dose
  - For patients included in the comparative phase: cardiac CT data (same analyses as above), performed as part of routine medical follow-up

All processed data are pseudonymized, meaning no directly identifying information is used. Data will be retained by the controller until **two years after publication of the study results**, or, if not published, until the final study report is signed.

4. **Who will have access to my data?**

In accordance with the law, your **pseudonymized personal data**, limited to what is strictly necessary for this research, will be used only by authorized staff at Zoī's Preventive Medicine, Data Science and AI Lab.

This staff is subject to strict confidentiality obligations and cannot identify you, since directly identifying data (such as name, surname, or date of birth) are excluded from the research dataset.

Your data are strictly secured, with encryption and pseudonymization measures to prevent unauthorized access and protect your identity.

To comply with the French Public Health Code (Article L.1111-8), Zoī uses **Amazon Web Services EMEA SARL (France region)** as a certified health data host.

5. **What are my rights regarding the data used in this study?**

In accordance with the GDPR (Regulation (EU) 2016/679) and the French Data Protection Act, you have the following rights:

- **Right of access:** you may request to consult the personal data we hold about you and obtain a copy.
- **Right to object:** you may object to the processing of your data for this study, free of charge, without justification, and at any time, without affecting your preventive health assessment.
- **Right to rectification:** you may request correction of inaccurate or incomplete data concerning you.
- **Right to erasure:** you may request deletion of your data, unless such deletion would make it impossible or seriously compromise the study's objectives.
- **Right to restriction of processing:** you may limit processing in certain circumstances.

To ask questions or exercise your rights, you may contact Zoī's DPO at:
📧 privacy@zoi.com

Please note that the DPO may access your data in order to respond to your request.

You may also exercise these rights through your referring physician.

If you are not satisfied with the response, you may lodge a complaint with the **French Data Protection Authority (CNIL)**.

6. **How can I obtain more information about the study?**

For more information about the study, you may contact the data controller (see section above) or your referring physician.