Patient Privacy Notice – Early Compassionate Access Program (ECAP) for MaaT013

This privacy notice explains how your personal data are processed in the context of the Early Compassionate Access Program (ECAP) for the medicinal product MaaT013, in accordance with the EU General Data Protection Regulation (GDPR), the French Data Protection Act, and CNIL Deliberation n° 2022-106 of 22 September 2022.

It applies to patients who have received MaaT013 under an Early Compassionate Access Program, whose pseudonymised data are processed for safety monitoring, efficacy follow-up, and regulatory obligations.

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1. Who is responsible for the processing of your data?

MaaT Pharma
70 avenue Tony Garnier, 69007 Lyon, France
Email: **dpo@maat-pharma.com**

MaaT Pharma is the data controller for the pseudonymised data transmitted by hospitals in the context of the Early Compassionate Access Program.

Important:
MaaT Pharma never has access to any directly identifying information about you (such as your full name, contact details, or social security number). This information remains exclusively within your hospital and is never transmitted to MaaT Pharma.

Only pseudonymised data leave the hospital.

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2. What categories of data are processed?

Your directly identifying information (name, surname, date of birth, contact details, etc.) remains exclusively within the hospital in your medical record, under the responsibility of your prescribing physician.

Outside the hospital, only pseudonymised data are transmitted. You are identified only by:

- the first two letters of your surname;
- the first two letters of your first name;
- your age;
- clinical and biological data strictly necessary for safety and efficacy monitoring.

Pseudonymised data may include:

- information on your medical condition in relation to your treatment;
- examination results required for monitoring MaaT013;
- information on adverse events;
- information required for regulatory reporting obligations.

No document transmitted to MaaT Pharma contains data that directly identify you.

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3. For what purposes are your data used?

Your pseudonymised data are used for:

- monitoring the safety and efficacy of MaaT013;
- preparing regulatory reports required by the French National Agency for Medicines and Health Products Safety (ANSM);
- complying with legal obligations relating to pharmacovigilance, traceability, and quality;
- scientific and medical follow-up of the Early Compassionate Access Program;
- providing aggregated information to physicians, pharmacists, and poison control centres when necessary;
- preparing a regulatory dossier for a Marketing Authorisation (MA) for MaaT013, if required, strictly in compliance with GDPR and the CNIL framework.

No automated decision-making is carried out based on your data.

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4. Who has access to your pseudonymised data?

Only authorised personnel bound by strict confidentiality obligations may access your pseudonymised data:

Until 31 December 2025

- **MaaT Pharma**, as the holder of the Early Compassionate Access Authorisation, for safety and efficacy monitoring;
- **Medipha Santé**, acting as pharmaceutical operator, notably for preparing certain mandatory safety reports;
- **Calypse Consulting**, the clinical research organisation managing the eCRF platform and performing quality control where needed.

From 1 January 2026

- **Clinigen**, acting as pharmaceutical operator (excluding pharmacovigilance), responsible for eCRF management, data management, and quality control;
- **Medipha Santé**, which retains full responsibility for **pharmacovigilance**, including case processing and transmission to authorities.

Additionally

- any subcontractor acting on behalf of the above entities, under strict contractual GDPR commitments;
- **service providers, experts, and advisors of MaaT Pharma** involved in the preparation of a Marketing Authorisation (MA) dossier, acting under GDPR-compliant contractual guarantees;
- **ANSM** and the designated **Regional Pharmacovigilance Centre**, for national safety monitoring.

None of these recipients has access to directly identifying data.

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5. What is the legal basis for processing your pseudonymised data?

The processing of your data is based on:

- **Article 6(1)(c) GDPR** – processing necessary for compliance with a legal obligation to which MaaT Pharma is subject;
- **Article 9(2)(i) GDPR** – processing necessary for reasons of public interest in the field of public health, including monitoring the safety and efficacy of medicinal products;
- the French Public Health Code provisions relating to Early Compassionate Access;
- **CNIL Deliberation n° 2022-106**, which establishes the applicable regulatory framework.

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6. Are your data transferred outside the European Economic Area?

If a transfer outside the EEA becomes necessary, it will be carried out strictly in accordance with Chapter V of the GDPR, using:

- an adequacy decision, or
- Standard Contractual Clauses adopted by the European Commission, or
- any other legally required safeguard.

Transferred data remain pseudonymised and do not allow identification.

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7. How long are your data kept?

Retention periods are strictly defined by law and CNIL Deliberation n° 2022-106.

Active database

Your pseudonymised data are kept for up to **two years** after ANSM approves the summary of the final synthesis report required under Article R.5121-74-6 of the French Public Health Code.

Intermediate archive

After this period, data are archived for the **duration of the compassionate access authorisation** and may not be kept beyond **70 years** after:

- the expiration of the Early Compassionate Access Authorisation, or
- the ANSM decision suspending or withdrawing the authorisation.

End of retention

Once these periods expire, data are deleted or fully anonymised.

All retention and archiving are performed under GDPR-compliant security conditions (Article 32 GDPR).

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8. How are your data protected?

Several layers of protection ensure confidentiality and security:

- directly identifying data remain exclusively within the hospital under medical secrecy;
- pseudonymised data only are transmitted outside the hospital;
- access to pseudonymised data is strictly limited to authorised personnel;
- all actors implement GDPR-compliant technical and organisational measures, including:
    - secure electronic platforms (eCRF);
    - encrypted data transfers where necessary;
    - access control and authentication measures;
    - contractual confidentiality obligations;
    - hosting environments compliant with applicable security standards.

MaaT Pharma does not collect or store any directly identifying information.

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9. Can your data be published?

ANSM publishes a summary of the synthesis report assessing the safety and efficacy of MaaT013.

Scientific publications may also be produced based on aggregated, anonymised data.

These publications never contain information allowing your identification.

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10. What are your rights?

Your prescribing physician is your primary contact for exercising your rights.

You may request:

- access to the data concerning you;
- rectification of inaccurate data;
- restriction of processing.

Under French law applicable to Early Compassionate Access Programs:

- you cannot oppose the mandatory pseudonymised data transmission required for the program;

- you cannot request deletion of these data during the legally required retention periods;
- the rights to erasure and portability do not apply;
- you may object to the reuse of your pseudonymised data for research purposes.

Contact details

MaaT Pharma – Data Protection Officer
Email: **dpo@maat-pharma.com**

A response will be provided within one month.

You may also lodge a complaint with the CNIL: **www.cnil.fr**