Evidilya

GOVERNANCE

Code of Ethics

The standard we hold ourselves
to, every day, on every study.

Edition 2026 · English · Approved by the Board of Directors of Evidilya S.r.l.

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PURPOSE & SCOPE

One standard, shared by everyone who acts in our name.

This Code sets out how Evidilya conducts clinical, scientific and business activity. It builds on the law and on Good Clinical Practice, and it states in plain language the commitments we make to participants, sponsors, colleagues and regulators, everywhere we operate.

Why it matters: a single, written standard means a participant in Milan, Manila or Chicago can expect the same care from us.

Who shares it, the Recipients

Directors, employees, contractors and consultants; investigators, sites and site staff working under our studies; vendors, laboratories, couriers and technology partners in our supply chain; and everyone who represents Evidilya to a sponsor, a regulator, a participant or the public.

Where it applies

Every study, every domain and every engagement model, whether delivered full-service, as FSP, under an ECS™ licence or as a consultative engagement, in every country where the work is performed.

How it works with other rules

Where local law, a sponsor contract or an ethics committee requirement asks for more, we follow the stricter requirement. Where they ask for less, this Code sets the level. Commercial objectives and deadlines are planned around it, never against it.

ICH E6(R3) Good Clinical Practice · Declaration of Helsinki · EU Regulation 536/2014, MDR/IVDR · GDPR (EU 2016/679) · ISO 9001 quality management · EU Directive 2019/1937, whistleblowing

OUR VALUES

Four commitments that decide the close calls.

Most ethical questions in research are not dramatic. They are ordinary decisions made under time pressure. These four values are what we reason with when a rule alone does not settle the answer.

01
People & Research First

The participant comes before the timeline. Dignity, choice and safety are designed into the protocol, not restored afterwards.

02
Scientific integrity

We report what the data shows, in full, and we make our reasoning reconstructable by anyone who audits it.

03
Independence

Sponsors define the question. The evidence defines the answer. We say so openly, in writing, and we keep our interests visible.

04
Accountability

Every conclusion carries a name. Systems accelerate and verify the work; people remain answerable for it.

Evidence reviewed by named people, together.

OUR ETHICAL THESIS

Reach and rigour, held together.

Evidilya exists because science succeeds when it reaches people: hospitals, community clinicians, pharmacies and the home, on one backbone. Greater reach widens who can take part in research, and it raises what research owes them. We design for both at the same time.

Why it matters: the people most often left out of trials are the ones the evidence tends to serve least well.

Equal protection at every touchpoint

A participant at home receives exactly what a participant on a hospital ward receives: informed choice, medical oversight, privacy, dignity and a way to be heard. Convenience is a benefit we engineer for, on top of full protection.

Evidence as a public good

Our studies inform decisions about treatments, devices, foods and care. We treat the credibility of that record as a duty owed to people far beyond the sponsor who funds the work.

Named accountability

Technology can accelerate, verify and audit. Responsibility stays human: every scientific conclusion and every ethical decision carries the name of a person who stands behind it.

Digital reach expands who can take part in research, and keeps intact everything research owes them.

PARTICIPANT PROTECTION

Consent is a conversation we keep having.

Protecting the rights, safety and wellbeing of participants is the first commitment of every Recipient, and it comes ahead of every other provision in this Code.

Why it matters: people give their time, their data and sometimes their bodies to research. Consent is how we keep earning that.

Informed consent and eConsent

Consent is given before any study-specific procedure, in language the participant understands, with time to ask questions and a named contact to ask them of. Identity-verified eConsent meets the same evidential standard as wet ink: comprehension checked, questions answered by a delegated clinician, withdrawal as simple as enrolment.

Additional care where it is needed

Children, people with cognitive impairment, people in acute distress and anyone dependent on the investigator receive additional safeguards, written into the protocol and approved by the competent ethics committee before enrolment.

Direct-to-Participant under supervision

Home visits, at-home sampling, telehealth and pharmacy touchpoints are investigator-supervised and audited exactly like a site visit. Delegation is documented, training is evidenced, and the medical chain of responsibility holds across distance.

Equity of access

Recruitment is designed to include: geography, language, digital literacy and device ownership are planned for. Where a design relies on technology, an alternative pathway keeps participation open to everyone eligible.

Fair reimbursement

Reimbursement covers burden, time and expense. It is proportionate, disclosed to the ethics committee, and set at a level that leaves the decision to take part entirely free.

SCIENTIFIC INTEGRITY

We report what the data shows.

Evidence is valuable because it survives scrutiny. Recipients protect the credibility of the record with the same care whether the finding is commercially welcome or not.

Why it matters: a clinician reading our results will act on them. The record has to be worth acting on.

Pre-specification

Objectives, endpoints and the statistical analysis plan are fixed before database lock. Post-hoc analyses are welcome, labelled as exploratory, and reported as such.

Complete reporting

Negative, null and unexpected results are reported with the same rigour as positive ones. Publication timing and scope follow the science, and the full result reaches the record.

Authorship and transparency

Authorship follows ICMJE criteria and every contributor is named. Funding, sponsorship and the sponsor's role in design, analysis and reporting are disclosed in every manuscript and presentation. Writing support is acknowledged openly.

Registration and traceability

Interventional studies are registered in a public registry before enrolment. Source data, amendments and analytical decisions stay reconstructable through the audit trail for the full retention period.

Claims the study can carry

Marketing, claim substantiation and scientific communication stay within what the design, the population and the endpoint support. Where a claim needs more evidence, we say what evidence would be needed.

INDEPENDENCE & CONFLICTS OF INTEREST

Independence we can evidence.

Interpretation of evidence stays free of commercial pressure, including our own. Interests are a normal part of professional life; declaring and managing them openly is what keeps judgement trustworthy.

Why it matters: a disclosed interest can be managed. That is the whole point of disclosing it.

Declaration

Recipients declare financial interests, advisory roles, family relationships, equity holdings and anything else a reasonable observer could see as capable of influencing their judgement. Declarations are made on engagement, on change, and at least annually.

Register and management

Declared interests are held in a conflicts register maintained by the ethics owner. Where an interest is material, the individual steps back from the decision, the review is reassigned, and the mitigation is documented.

Scientific independence

Sponsors define the question; the evidence defines the answer. Where a request would shape data interpretation, statistical conclusions or safety assessment, we escalate it promptly and answer in writing.

Investigator and KOL engagement

Advisory boards, speaking engagements and consultancy are contracted for genuine scientific need, at fair market value, with documented deliverables, and are kept entirely separate from enrolment, prescription or opinion.

ANTI-BRIBERY & FAIR BUSINESS

Decisions earned on merit.

We win work on science, delivery and price, and we expect the same of everyone acting in our name. Our anti-bribery standard is absolute: no advantage of any kind is offered, promised, given, requested or accepted to influence a decision, in the public or private sector, with no materiality threshold and no exceptions.

Why it matters: in health research, a bought decision eventually reaches a patient.

One clear line

Recipients never offer or accept anything of value intended to improperly influence a public official, healthcare professional, ethics committee member, sponsor employee or anyone else. Facilitation payments are prohibited, including where local practice tolerates them.

Gifts and hospitality

Modest, occasional, transparent and tied to a legitimate professional purpose, always recorded, never cash or cash equivalents, and always paused during a live tender or negotiation.

Transfers of value

Payments to healthcare professionals and organisations are contracted, justified by genuine need, priced at fair market value and disclosed wherever transparency rules apply.

Fair competition

We compete on merit and respect competitors' confidential information. Price fixing, bid rigging and market allocation have no place in how we grow.

Sanctions, export control and financial crime

Counterparties are screened, and transfers of samples and data follow trade-sanction and export-control rules. We keep our business closed to money laundering and tax evasion.

Accurate books

Every transaction is recorded truthfully in the accounting records, in the period it belongs to, with a description that matches what actually happened.

DATA PROTECTION, SECURITY & AI

Privacy by design, judgement by people.

Participants share intimate information on the understanding that it will be protected and used only for the purpose they agreed to. We treat that understanding as a promise, and we build our systems to keep it.

Why it matters: trust in data protection is what makes people willing to take part at all.

Lawful, minimal, purpose-bound

Personal data is processed on a documented lawful basis, limited to what the scientific question requires, pseudonymised at the earliest practical point, and retained only as long as the protocol and applicable law require.

Data integrity

Records are Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available. Audit trails and electronic signatures stay active, personal and intact throughout the life of the study.

Security

Access is role-based and least-privilege, credentials are personal, devices are encrypted. Suspected incidents are reported the moment they are suspected, and reporting early is always the right call.

Confidentiality

Sponsor protocols, commercial terms, unpublished results and colleague data stay confidential during and after the engagement. Raising a safety risk, a data-integrity concern or unlawful conduct is always permitted and always protected.

Responsible use of AI

AIRA™ and other AI-assisted tools accelerate literature triage, drafting and signal detection. Models used in evidence-relevant work are documented and auditable, inputs are governed, outputs are verified by a qualified person, and clinical, safety and scientific decisions stay with the named human who signs them.

OUR PEOPLE

A place where speaking up is ordinary.

The quality of evidence depends on people who feel safe enough to say what they see. We build the conditions for that deliberately: clear ownership, senior judgement close to the work, and a genuine welcome for questions.

Why it matters: nearly every serious quality issue was visible to somebody early on.

Respect and inclusion

Hiring, development, pay and promotion follow capability and contribution. We keep our workplace free of discrimination, harassment, bullying and intimidation, in person and online.

Human rights and labour standards

Employment at Evidilya and along our supply chain is free, fairly paid and freely chosen. Forced labour, child labour and coercive practices are excluded, and working hours and rest follow the higher of applicable law and our own standard.

Health, safety and wellbeing

Field teams, home-visit nurses and laboratory staff work to documented safety procedures, with training, equipment, and the explicit authority to stop an activity they judge unsafe.

Speak-up culture

Concerns raised in good faith are welcomed, investigated and answered. People who report, and people who help an investigation, are protected, whatever the outcome turns out to be.

Senior by default

The person who scopes a study is accountable for how it runs. Experience is not an upsell; it is how we keep judgement close to the work.

SUPPLY CHAIN & THIRD PARTIES

Our standard travels with the work.

A study with reach depends on partners: sites, nurses, couriers, laboratories, pharmacies and technology vendors. Our commitments travel with the work, across every contract boundary.

Why it matters: to a participant, everyone who knocks on the door is Evidilya.

Due diligence before engagement

Third parties are qualified on quality, data protection, security, labour standards and integrity before the first activity, proportionate to the risk they carry.

Shared obligations

Contracts carry this Code or an equivalent standard, including anti-bribery, confidentiality, data protection and the right to audit. Sub-contracting is agreed in writing in advance.

Oversight in life

Performance, deviations and CAPA are monitored through the quality system, with support to improve. Where the standard cannot be met, we end the relationship, whatever the commercial cost.

Sustainable procurement

Environmental and social criteria form part of supplier selection, in line with our sustainability programme.

SUSTAINABILITY & COMMUNITY

Research with a lighter footprint.

Corporate responsibility at Evidilya sits inside the business rather than beside it. It is largely the same decision that makes our studies work: bring the study to the participant instead of moving thousands of people to a site.

Why it matters: the greenest kilometre in a trial is the one nobody has to travel.

Environment

Direct-to-Participant execution removes avoidable participant travel. Electronic source, eConsent and remote monitoring remove paper and monitoring flights. Sample logistics and cold chain are planned for the shortest viable route.

Labour and human rights

Our workforce and our supply chain are held to the standards in this Code, with particular attention to field personnel who work outside our offices.

Ethics

Anti-corruption, scientific integrity, data protection and speak-up are the ethics pillar of our sustainability programme, governed by this Code rather than by a parallel document.

Independently assessed

Evidilya is EcoVadis rated. The assessment covers environment, labour and human rights, ethics and sustainable procurement, and we use it as an external check on progress.

LIVING THE CODE

Four moves that keep this Code real.

A Code becomes real in ordinary moments: a protocol deviation noticed on a Friday, an offer that feels generous, a result that complicates a launch. These are the four moves we expect, and support.

01
Ask early

If a decision would be hard to explain to a participant, an inspector or a colleague, raise it before it is made. Asking is never held against anyone.

02
Disclose openly

Put interests, relationships and pressures on the record. Disclosure protects your judgement as much as the study.

03
Document as you go

Contemporaneous notes are how good decisions stay defensible a year later. Write down the reasoning, not only the outcome.

04
Speak up, and support those who do

Use your manager, the ethics owner or the whistleblowing channel. Backing a colleague who reports is part of the job.

Asking early is always the cheaper conversation.

GOVERNANCE & ACCOUNTABILITY

How we keep this Code alive.

Commitments hold when someone owns them, a channel exists to raise them, and outcomes follow. This Code has all three, with due process at every step.

Why it matters: people trust a standard they can see being applied.

Ownership

The Board of Directors approves this Code. A designated ethics owner maintains it, holds the conflicts register, oversees investigations and reports to the Board at least annually.

Reporting channels

Concerns can be raised with a manager, with the ethics owner, or through the Evidilya whistleblowing channel, which accepts confidential and anonymous reports in line with EU Directive 2019/1937 and its national implementations.

Protection for reporters

People who report in good faith are protected, whatever the outcome of the investigation, and any retaliation is investigated as a breach in its own right.

Investigation

Reports are acknowledged, assessed by people without a conflict in the matter, investigated proportionately and closed with a documented outcome. Confidentiality is maintained as far as the investigation allows.

Consequences, fairly applied

Where the Code is breached, proportionate measures follow, up to termination of employment or contract, and referral to the competent authority where conduct is unlawful. Sponsors and regulators are informed where participant safety or data integrity is affected.

Review

This Code is reviewed at least annually, and whenever regulation, our operating model or an investigation outcome calls for it. The current edition supersedes all previous versions.

GLOBAL OPERATIONS

A EU contract research organisation operating across continents.

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PEOPLE & RESEARCH FIRST™
Evidilya

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