PREDICARE, a Trial Protocol for Longitudinal Health Vigilance

Intermittent vigilance against longitudinal chronicity, clinical vigilance density as structuring operator, and the conditions of a French institutionalization before default private standardization

The public question is no longer whether a predictive vigilance infrastructure will emerge in the French health system. It is under which doctrine, which institutional architecture, and which contestability regime it will emerge. The absence of public experimentation does not suspend the transformation. It lets the lock-in conditions form under existing law, by accumulation of sensors, cloud infrastructures, models, platforms, and economic vehicles carried by private actors. This article demonstrates, in five hierarchized steps, why the status quo has become an implicit decision with documented cost, and qualifies PREDICARE as an institutional trial protocol allowing France to explicitly test the sustainability conditions before asymmetric industrial lock-in.

I. The Problem: Intermittent Vigilance Against Longitudinal Chronicity

This article does not address AI in healthcare. It does not address platforms. It does not address medical automation. It addresses the **vigilance regime** within which the French health system observes the trajectories of its chronic patients. This preliminary framing is non-negotiable. It conditions the institutional reading of everything that follows.

One notion makes it possible to pose the problem without reducing it to technique. The May 2026 PREDICARE Policy Brief proposes a conceptual operator that must be mobilized immediately: *clinical vigilance density*. It is defined there as "the effective share of a pathological trajectory under observation interpretable by the care system" (PREDICARE Policy Brief, p. 4). The concept is not, at this stage, a calibrated operational metric. It is a doctrinal heuristic intended to structure political discussion. Its interest is threefold. It is intelligible to a public decision-maker. It cuts across clinical, economic and organizational dimensions without privileging any of them. It does not pre-empt any technological solution. It supplies what the public debate most lacks: a transversal measurement operator on which to hierarchize constraints.

Methodological note. The factual coordinates mobilized in this article come, as primary source, from the May 2026 PREDICARE artifacts (Policy Brief v2, Arbitration Note, Clinical

Note v3, Medico-Economic Note v2), which are Twingital Institute working artifacts in the course of publication. Demographic and budgetary data refer to the DREES, INSEE and CNAM publications cited in those artifacts. The list of figures submitted to primary fact-lock before publication is recorded in this version's frontmatter. When a datum belongs to Level 2 signal rather than Level 1 hard fact, the text says so.

Four structural determinants converge in France as of 2026, with none exhausting the explanation. **Medical demography standardized by care needs is declining.** It fell from 331 to 312 physicians per 100,000 inhabitants between 2012 and 2021, and 65 % of general practitioners declared in 2022 that they refused new patients as primary care physician, against 53 % in 2019. **Activity-based pricing**, designed for acute episodes, mechanically rewards hospitalization and penalizes prevention. **The cognitive load of professionals exceeds their longitudinal information-processing capacity**; this saturation is neither a psychological frailty nor a moral defect, it is a physical limit. **Organizational fragmentation** dissociates perimeters between health insurance, regional health agencies, health authorities and care operators, without any actor holding an integrated view of the trajectory.

The epidemiological context converges in the same direction, provided that two distinct measures are not confused. A first, broad measure indicates that nearly two-thirds of reimbursed expenditure is concentrated on chronic pathologies as a whole, with a projection at 75 % by 2035 (estimate from the PREDICARE Policy Brief, to be confirmed against CNAM *Charges et Produits* 2026). A second, more restrictive measure indicates that recognized long-term illnesses represent 67 % of mandatory health-insurance expenditure for 17 % of the insured population. Both measures converge on the same diagnosis, but they do not bear on the same perimeter. To these are added 13.8 million patients in *long-term illness* (ALD, *affection de longue durée*) status as of 1 January 2024, 6.7 million French citizens without a declared primary care physician, and a substantial share of the French population living in a low-density zone according to the indicator used to qualify medical deserts (precise share under DREES primary fact-lock before final publication). These figures fall under Level 1 and are sourced from the PREDICARE artifacts.

These data do not describe the same thing as a resource crisis. They describe the inadequacy of an episode-based observation regime to trajectories that have become longitudinal, multifactorial, and silent. The French system was historically optimized for the handling of acute events: discrete episodes, short temporalities, localizable causalities, point decisions. Chronicity introduces a different nature of clinical load. Long trajectories, evolving, partially silent, whose deteriorations become visible late. A type-2 diabetic patient followed by a primary care physician is the subject, on average, of four to six annual consultations. The bulk of their physiological trajectory unfolds outside any structured observation field.

A crucial analytical distinction is required. *Human continuity*, the relational quality exercised by caregivers over time, is not *observational continuity*, which is an informational property of the surveillance device. The consultation as a unit of observation remains discrete regardless of the relational quality exercised. The identified problem is not the absence of medical attention. It is the radical discretization of chronic trajectories by the dominant mode of observation.

This discretization produces two clinical phenomena that are well known, customarily treated as distinct, but which are in fact the two states of the same system. *Drift* (*errance*) designates a disorganized over-use of the care system without explicit longitudinal piloting; it is visible in activity indicators. *Fade-out* (*déshérence*) designates a structural under-use, the progressive invisibility of the trajectory; it is silent, invisible in activity indicators. A prolonged drift trajectory tends to tip into fade-out; and fade-out, when it decompensates, produces a new phase of drift in the emergency system. This cumulative dynamic is not an exceptional statistical anomaly. It is the predictable state of a system whose vigilance capacities remain principally organized around discrete contact points. The relative collapse of clinical vigilance density on longitudinal chronic trajectories is not an individual failure of caregivers. It is the structurally expected effect of a regime we have not refounded.

II. The Stake: Lock-In Conditions Form Under Existing Law

The institutional consequence of this inadequacy is rarely named. **The status quo is not a neutral point. It is an implicit decision mode with documented cost.**

The direct cost is measurable. The Weissman method (Weissman, Gatsonis and Epstein, *JAMA* 1992, on Ambulatory Care Sensitive Conditions) places the number of annually avoidable hospital stays in France at 742,474, for an associated envelope between €2 and €3 billion for strictly avoidable stays alone (PREDICARE Policy Brief). The PREDICARE Medico-Economic Note retains a widened range: between 510,000 and 742,000 potentially avoidable hospitalizations, and approximately 4 million potentially avoidable emergency-room visits. The figure of four million emergency-room visits is not to be confused with a primary-care access deficit: it measures the share of visits that would have been avoidable with continuous upstream care, which makes it a specific signature of the intermittent vigilance regime rather than an indicator of general hospital congestion. These figures are neither the result of a local organizational defect, nor the expression of an epidemiological fatality. They are the **economic signature** of a vigilance regime that does not capture the trajectory between clinical contacts.

But direct cost does not exhaust the stake. The absence of a framed public experimentation does not suspend institutional transformation; it lets the conditions of a

private lock-in form *under existing law* (*à droit constant*). Three families of signals, distinct but converging, deserve to be named, without claiming that lock-in is already accomplished or that any single signal is, taken in isolation, conclusive. What makes them significant is their convergence.

These families do not belong to the same register. Some signals are infrastructural, others commercial, still others normative or actuarial. Their interest lies not in their homogeneity but in their convergence toward a single situation: the progressive constitution of vigilance standards outside any French public doctrine.

1. **First family, consumer-grade sensors.** They install themselves into lives without any specific French medical authorization procedure. Cardiac, glycemic, respiratory or neurological monitoring devices marketed directly to patients (Apple Watch, Fitbit, continuous glucose monitors, oximeters, seizure sensors) now constitute an instrumented surface of individual trajectories that grows continuously, without any public institutionalization accompanying it. This surface already produces, and will continue to produce, longitudinal data that no one has framed doctrinally.

2. **Second family, platforms and infrastructures.** A growing share of the health-cloud infrastructures mobilized by telemonitoring industrials relies on North American offerings. Industrial telemonitoring platforms institutionalize themselves under private editors, some of which already operate predictive devices on chronic patient populations. The French reimbursement frameworks for medical telemonitoring (LFSS, ETAPES become standard regime) have accompanied part of this dynamic without framing its institutionalization doctrine. The de facto interoperability standards (HL7 FHIR under HL7 International, SNOMED CT under SNOMED International, LOINC under Regenstrief Institute) have international governance forms whose evolutionary trajectory is not arbitrated in French arenas. When the French debate addresses health data sovereignty, it often fails to signal that a decisive part of technical sovereignty is already being played out in standards whose trajectory largely escapes national public decision. De facto standards then structure the conditions of public action: any French device that wants to interoperate will do so according to those standards, whose governance is not discussed in our arenas.

3. **Third family, insurers and actuarial logics.** Several documented public positions of insurers exist, building their own actuarial evaluation devices for AI health risk and instrumented adherence. To these are added corporate-wellness platforms with premium modulation, already deployed in the United States and extending into Europe, which introduce a logic progressively conditioning insurability on continuous observation. None of these positions is today framed by any French public device of doctrinal counterweight.

The convergence of these three families does not establish that lock-in is accomplished. It establishes that **the lock-in conditions are forming under existing law**. This nuance matters. No isolated signal is demonstrative; their juxtaposition is. While French public doctrine waits, private industrial doctrine institutionalizes itself. It is the gap between the two trajectories that defines the risk.

The strategic consequence is precise. The debate no longer concerns the opportunity of predictive vigilance. It concerns the jurisdiction under which it operates. To the absence of framed public experimentation corresponds, under existing law, a progressive transfer of the technical conditions under external standards. The status quo is not a neutral point; it is a point of cumulative degradation. Non-decision is not prudence; it is a default decision whose historical trajectory is known: private industrial standards, actuarial surveillance, asymmetry of access. This is precisely what the PREDICARE Arbitration Note designates as the third structural risk to be politically arbitrated.

III. The Condition: A Governed, Contestable, Financeable Operable Chain

Recognizing the necessity of a predictive vigilance infrastructure is only one step. Recognizing the conditions under which such an infrastructure effectively produces care, rather than a *vigilance theatre*, is another, more demanding step.

A cardinal distinction opens this section. **Observation is not supervision. Supervision is not intervention. Intervention is not clinical improvement.** A vigilance that observes without supervising produces data. A supervision that does not intervene produces anxiety. An intervention that does not improve produces cost without benefit. The complete chain alone is pertinent, and its rupture at any single point reduces the whole to a technological figure without clinical reach.

The operable chain has a single objective. **Increase clinical vigilance density without increasing net cognitive load.** This double constraint is what makes the exercise difficult, and what distinguishes a sustainable infrastructure from a sophisticated yet inoperative device.

The minimal architecture reduces to four cumulative blocks.

1. **The first block is Observe and Qualify.** Capturing the continuous physiological flow through the Internet of Medical Things, and transforming this flow into informative signal via algorithmic instrumentation and explicit thresholds. This operation is the entry into the *partial-continuous regime*. It requires mature IoMT instrumentation and an enforceable, opposable qualification of the model that processes the flow, in the sense posed in Volume 4 of the AI-governance pentalogy. The fourth property of *continuous authority* posed in Volume 5

(opposable evidentiary reconstructibility) finds its direct clinical application here. This reconstructibility supposes at minimum the model version, the inference logs, the execution configuration, the clinical context, the associated human decision, and the trace of post-deployment modifications. **Algorithmic silence becomes opposable in a continuous regime**, which transforms non-intervention into an implicit decision produced by the surveillance system.

2. **The second block is Prioritize and Intervene.** Triaging patients along a temporal triptych of actionability (prediction window, decision window, intervention window) and triggering the effective clinical action. Without synchronization between the three windows, the model predicts into the void. Without available intervention capacity, prioritization becomes operational debt. Operable clinical attention is not a homogeneous resource. It decomposes into clinical attention of interpretation, organizational attention of routing, and logistical attention of intervention-resource mobilization. A relevant alert without action capacity behind it does not produce care; it produces load. And this load degrades exactly what the chain claimed to improve: operable clinical vigilance density.

3. **The third block is Trace and Contest.** Documenting each operation of the chain, and opening the public appeal procedure and patient contestability. The relevant grammar is no longer binary but quaternary: *true alert, false alert, true silence, false silence*. Historical medicine knew how to handle diagnostic error. It does not yet know how to handle the error of algorithmic silence. A sustainable predictive vigilance requires that the patient not only consent, but understand, contest, suspend and discuss the longitudinal interpretations produced about their trajectory. The point consent of a form becomes the continuous consent of a relationship. This point must be stated without attenuation: longitudinal vigilance is legitimate only if the patient remains the interpreter of their trajectory, and not the mere biological support of sensors. Contestability must protect the patient against opacity, but also the clinician against the transformation of signal into implicit order. A device that turned every deviation from the signal into an automatic burden of explanation would transform decision-support into injunction, and would empty clinical responsibility of its interpretive content.

4. **The fourth block combines four cumulative functions** that must be rigorously distinguished. *Evaluate* publicly measures the real effect on five distinct dimensions (clinical, organizational, medico-economic, attentional, equity). *Redistribute* organizes the return of avoided savings toward the producing territories: the PREDICARE Medico-Economic Note demonstrates that the dissociation between value creation and value capture is the principal lock on preventive financing. The system is technically capable of producing preventive value; it is structurally incapable of capturing it, attributing it, and financing it

within the temporality of its effects. *Govern* ensures the political arbitration instance for thresholds, uses and prioritizations; this function fixes what the device must do and what it forbids itself to do. *Audit* then verifies execution, deviations, effects and drift; this function controls what the device actually does relative to what it should have done. The order *govern then audit* is not incidental. It is an institutionalization requirement: if the same instance governs and audits, the separation of critical functions is abolished and self-regulation becomes the only available horizon.

These four blocks deploy under four transverse conditions that must be posed explicitly.

1. **First transverse condition. The threshold is the central institutional act.** A predictive device always operates on thresholds. The choice of a low threshold multiplies signalings; the choice of a high threshold accepts false negatives. This decision is not technical. Six distinct thresholds must be thought as institutional acts: alert-triggering threshold, priority threshold, intervention threshold, responsibility threshold, reimbursement threshold, threshold of juridical opposability. Without a named public instance for these arbitrations, thresholds are set by default by the technical designers, without mandate or transparency (PREDICARE Policy Brief, first non-delegable arbitration).

2. **Second transverse condition. The temporalities of the clinical system are structurally incompatible.** Six temporalities coexist and do not synchronize. The physiological temporality of degradation is measured in hours or days. The clinical temporality of the consultation, in months. The budgetary temporality of the annuity, in years. The regulatory temporality of guidance, in multi-year cycles. The electoral temporality of the mandate, in five-year terms. The probatory temporality of the clinical trial, in lustra. The difficulty is not only that institutions must act. It is that they must act in a temporality slower than that of the degradation of the trajectories they claim to govern.

3. **Third transverse condition. The institutional separation of critical functions is non-negotiable.** Those who design do not govern alone. Those who operate do not evaluate alone. Those who finance do not define thresholds alone. Those who develop the models do not define uses alone. This separation is not an organizational-chart principle. It is the condition under which a predictive vigilance infrastructure is not reducible to a technology platform managed by its own designers.

4. **Fourth transverse condition. Operational contestability is constitutive.** An operable chain without a public contestation procedure is not an operable chain; it is a proprietary platform operating under public garb.

The complete matrix of the chain reads as ten cumulative links, here grouped into four blocks for readability, in the order that separates *govern* from *audit* as two distinct operations: observe (capture the flow), qualify (transform it into signal), prioritize (temporal triage), intervene (clinical action), trace (document), contest (appeal procedure and patient contestability), evaluate (public measurement), redistribute (return of savings), govern (fixing thresholds, uses, prioritizations), audit (verification of execution, deviations, effects and drift). The failure of a single link breaks the chain. The confusion of two links compromises the institutional legitimacy of the whole.

IV. The Field: PREDICARE as an Institutional Trial Protocol

A framed experimentation alone makes it possible to test the institutionalization conditions of such a regime. PREDICARE constitutes, within the French perimeter, such an experimentation. Its exact doctrinal qualification must be posed at the outset, because it conditions everything that follows.

PREDICARE is not evidence. PREDICARE is a machine for producing admissible evidence. This precision is not authorial coquetry. It fixes the precise epistemic status of the device: it does not claim to demonstrate ex ante the conclusions of the experimentation; it claims to produce, under methodologically defensible and institutionally governed conditions, the evidentiary material from which French institutionalization may be deliberated.

PREDICARE is a territorial experimentation of predictive vigilance on chronic trajectories at risk of decompensation. The presentation that follows poses the elements of the protocol to be stabilized, subject to ongoing institutional arbitrations, in accordance with the doctrinal discipline that requires implementation grounds to be neither promoted nor concealed.

Clinical perimeter and territory. Population of fragile chronic patients, on target pathologies known for their instrumentable decompensation signature: heart failure, COPD, imbalanced diabetes, other at-risk trajectories to be documented in the stabilized protocol. Deployment territory, working hypothesis subject to arbitration: a territorial scope framed contractually, broad enough to produce a statistically exploitable signal, bounded enough to render evaluation traceable.

Design hypothesis and indicators. Prospective cohort with comparison arm or documented quasi-experimental design; observation duration on the order of 24 to 36 months; longitudinal follow-up between clinical contact points by IoMT instrumentation and algorithmic analysis. Pressed indicators: the nine criteria in the list below, subject to final methodological calibration.

Governance and objective. Target governance: a political arbitration instance for thresholds and uses separated from the operator, an explicit patient contestability device,

independent audit of execution and drift. These elements compose a protocol to be stabilized in the experimental publication. The explicit objective is to increase clinical vigilance density on these trajectories, without a net increase in the cognitive load of the care system, and without displacement of avoided savings toward actors that do not produce the avoidance.

This discipline requires naming, without complacency, what PREDICARE does not yet know how to do. Five authentic limits structure the experimentation.

PREDICARE does not yet know how to demonstrate the clinical effect at scale. The size of initial cohorts remains compatible with a mechanism demonstration, not with a generalization at national scale. The experimentation is precisely the instrument by which this demonstration will be constructed, provided that the success indicators are made explicit upstream and publicly contestable downstream.

PREDICARE does not yet know how to prove its economic model. The principal lock identified by the Medico-Economic Note remains the dissociation between value creation and value capture. The construction of a territorial-return mechanism for avoided savings (a ring-fenced ONDAM line, regional CPOM contracting, HAS-CEESP doctrine adapted to longitudinality) is part and parcel of the experimentation, not its precondition. The medico-economic evidence is built within the experimentation; it does not precede it.

PREDICARE does not yet know how to guarantee city-hospital interoperability at territorial scale. Desynchronization between primary care physician, specialist, hospital, emergency department and platform constitutes the cardinal operational risk. The predictive vigilance regime is less a new medical layer than an interstitial space between city and hospital; and interstices, as usual, are where responsibilities go to die quietly.

PREDICARE does not yet know how to contain the net cognitive load of the clinical system. Any continuous predictive medicine encounters a structural paradox: increasing sensitivity produces alert inflation, increasing specificity raises false negatives. The limiting factor becomes the human capacity to absorb interruptions. The predictive vigilance regime depends less on true prediction than on the capacity to produce cognitively sustainable interruptions.

PREDICARE does not yet know how to ensure territorial equity. Initial deployment in certain territories mechanically creates an asymmetry that will have to be treated institutionally. Without a redistribution mechanism and without a framed extension doctrine, predictive vigilance risks widening, rather than reducing, inequalities of access to care.

Five limits stated without complacency. This statement is the very condition of the experimentation's credibility.

But the PREDICARE ambition exceeds the measurement of clinical effect. The object of PREDICARE is not only to measure whether an alert improves a trajectory. It is to test whether a complete institutional chain can transform a longitudinal vigilance into effective, traceable, contestable, financeable care. This elevation of ambition is the specific contribution. It is not only a matter of producing clinical evidence; it is a matter of producing institutional evidence. The two registers are distinct; the second is more demanding, and it is precisely the second that makes the experimentation politically instructable.

To render this ambition measurable rather than rhetorical, the indicators on which the experimentation will be judged must be named. Nine operational criteria, distinct but cumulative, set the trial.

PREDICARE will have to be judged on:

1. **Signal-decision delay**: time elapsed between the production of a qualified signal and the corresponding clinical arbitration.
2. **Decision-intervention delay**: time elapsed between the clinical arbitration and the effective action on the patient trajectory.
3. **Rate of alerts handled within the useful window**: proportion of alerts having given rise to an intervention executed within the relevant temporal window.
4. **Rate of events without prior alert**: proportion of decompensations occurring without any qualified signal within the expected window.
5. **Review of algorithmic silences**: proportion of these no-alert events having undergone a documented review of the model, the threshold, the sensor, the workflow and the clinical context.
6. **Net clinical load**: differential between the cognitive load added by the device and the cognitive load saved on prior observation modes.
7. **Cost per avoided decompensation and cost per stabilized trajectory**, according to a declared and publicly contestable methodology: a dual medico-economic indicator, distinguishing the avoided acute event from the longitudinal trajectory whose stabilization is the very object of the avoidance doctrine.
8. **Impact on non-equipped patients**: documented differential in care access between patients under the device and patients outside the device.
9. **Effectively exercised patient contestation capacity**: number of admissible, processed and traced contestations over the experimentation period.

These nine criteria do not substitute for the five viability dimensions (clinical, organizational, cognitive, medico-economic, democratic). They are their operational

translation, on which the experimentation can be objectively judged and contested. The distinction between indicator 4 and indicator 5 is doctrinally important: the absence of an alert preceding a decompensation is an observable fact; the legitimacy of this absence is a question of methodological investigation, which requires a specific review. Silence thus becomes both measurable as event and qualifiable as judgment, which renders it institutionally opposable.

The conditions of failure must be posed explicitly, mirroring these five dimensions. The thesis would be seriously weakened if no clinically significant improvement were documented within a controlled horizon, if the operable chain did not effectively constitute itself, if alert fatigue clearly increased clinical load, if the medico-economic balance remained durably negative, or if governance concentrated in technical instances without mandate or transparency. At two concurrent failures, the hypothesis demands substantial reformulation. The explicit doctrine of failure is constitutive of the institutional credibility of the experimentation.

Three datable temporal scenarios frame the calendar. The **2026-2027 window** is that of effective launch and first operational evidence. The **2028-2030 window** is that of materialization of the French demographic scissors at its critical inflections. The **2031-2035 window** is that of possible institutionalization, if operational evidence has been produced in 2026-2030, or of a non-recoverable structural lag if it has not been.

V. The Verdict: Explicit Institutionalization or Implicit Institutionalization

Clinical vigilance density on longitudinal chronic trajectories is the operator that measures what the French health system must do. This density will not be substantially increased by adding consultations, nor by injecting resources into an unchanged frame. It will be increased only by a change of vigilance regime, and only on condition that this change does not increase the net cognitive load of the system. This double criterion, increasing vigilance density without degrading net cognitive load, is what a framed experimentation must demonstrate or refute. **No decree will demonstrate it in its place.**

The required political gesture, therefore, is not to authorize or prohibit a predictive vigilance infrastructure. It is to pose, upstream of any deployment, the explicit governance frame within which that infrastructure will be bounded: thresholds, uses, prioritizations, State doctrine. Without this frame, the technical device will deploy regardless. It will simply deploy without mandate or transparency, and its historical trajectory will be that of actuarial surveillance rather than that of a sustainable medical vigilance (PREDICARE Arbitration Note).

The public choice is no longer between prudence and innovation. It is between two forms of institutionalization. The first is explicit, experimental, contestable, bounded by a public doctrine. The second is implicit, industrial, progressive, carried by the actors that already possess the sensors, the data, the models, the infrastructures, and the economic incentives. PREDICARE does not claim to close this choice. It makes it, at last, instructable.

The history of critical vigilance regimes shows, without determinism, a recognizable regularity. Pharmacovigilance took three decades to institute itself as a continuous regime after thalidomide. Aviation safety built its continuity regime by accumulating framed experimentations across several institutional generations. French longitudinal health vigilance will not be decreed any more readily. It will be built either by framed, governed, contestable, evaluated and redistributive experimentations, or by the accumulation of private industrial standards. The 2026-2030 window is not a horizon. It is an institutional calendar.

PREDICARE must not be judged on its capacity to predict more, but on its capacity to increase a clinical vigilance density that is interpretable, actionable, and contestable, without increasing net cognitive load or displacing savings toward actors that do not produce the avoidance. **It is on this condition, and on this condition alone, that an experimentation can claim to instruct a public decision.**