RESEARCH MEMORANDUM AND PROPOSAL

Five Minutes and a Reason

Continuous medical device data an AI can actually reason over, assembled from standards that already exist. What Goldman built, what IEEE 11073 over-built, what FHIR left out, and the smallest thing that could work.

Daniel Pettus · 26 August 2026 · aimedagent.net

The argument in six sentences

Federal certification forced every EHR in the country to expose a standard interface, and it worked. Nothing equivalent exists for the devices at the bedside, and after twenty-two years of trying, nothing is coming. The reason is not technical. Every previous attempt asked device manufacturers to change a regulated product for a market that did not exist yet.

This proposal asks them for something much smaller: a read-only endpoint on the gateway they already ship, returning a five-minute summary of what each device reported, plus the reason the numbers look the way they do. Not a stream. Not a sample. A summary, with context.

Alarms bypass it and arrive immediately. The whole thing runs on the unregulated side of a line the 21st Century Cures Act drew in 2016, and can be proven in a public sandbox with synthetic patients before anyone touches a hospital.

And then it stops asking. Rather than wait for a manufacturer to build an endpoint, I build the receiver, publish the schema, and invite them to point a simulator at it. That costs about five dollars a month. If nobody connects, run properly, that is a finding too.

PART 1. THREE ASSUMPTIONS THAT DID NOT SURVIVE CHECKING

This memorandum started from a brief carrying three assumptions that turned out to be wrong. Checking them changed the proposal, which is what checking is for. Anyone working at the front of a field who never has to do this is not at the front of it.

Julian Goldman has not given up

The MD PnP website returns useful content, not a 404, and the program is running. Goldman remains Director of MD PnP and is Medical Director of Biomedical Engineering at Mass General Brigham. He **won the 2026 J.S. Gravenstein Award for Lifetime Achievement** from the Society for Technology in Anesthesia, whose recipient list names him for 2026, and on 12 February 2025 was named principal investigator on an ARPA-H award of up to **$20.8 million**, PARADIGM ICE: Integrated Clinical Environment, building a medical Internet-of-Things platform for mobile rural care on the DocBox Apiary architecture. ECRI announced a collaboration on that work on 13 November 2025.

The confusion is real and it is the program's own fault. There are **two websites**. The old one, mdpnp.org, has a news page whose most recent entry is March 2015; it was superseded by a Mass General-hosted site in 2017 and never retired. The live program is at mdpnp.mgh.harvard.edu. Anyone researching this topic from the first search result will conclude the program is dead. It is not.

The same pattern holds for the code. OpenICE, the program's open-source reference implementation, has commits from **7 May 2026**, and moved to Java 25 in April. Its public website has not been touched since December 2015 and still tells visitors to install Java 8. Part 3 takes the codebase apart properly, because it is the closest thing to a precedent this proposal has and because what is missing from it turned out to matter more than what is in it.

The ecosystem around him, however, is largely gone

This is the part of the brief that was right, and it is worse than "gone silent."

- **ASTM F2761**, the Integrated Clinical Environment standard, was **withdrawn on 16 August 2017**. It was reissued as ANSI/AAMI 2700-1:2019, which is still current, and as of 15 May 2026 the AAMI interoperability working group is seeking members for its reaffirmation. Reaffirmation, not revision. Seven years without a substantive update, and the committee is advertising for participants.
- **The ICE Alliance is dead.** icealliance.org returns HTTP 403 with a 73-byte body. It does not appear among IEEE-ISTO's fourteen current member programs. Its founders' own pages no longer mention it.
- **MD FIRE**, the procurement language that was supposed to create demand, is frozen at version 2.6, January 2018. The current program page promises a cybersecurity update that has been pending for eight and a half years, and provides no download link. The only working download is on the fossil site.
- **The MDICC is gone without leaving a document.** The Medical Device Interoperability Coordinating Council was FDA-convened, and MD PnP describes its purpose as synchronizing the many separate efforts in the field. The West Health paper credits it in the acknowledgements as an open industry forum formed in March 2012, which understates whose idea it was. I could find no charter, no minutes, no roster and no published output. Its last trace is a line in the IHE Patient Care Device committee's October 2013 face-to-face notes: "MDICC removed, replaced with AAMI/UL2800." Seven months after a white paper thanked it, the standards community wrote it out of the roadmap.
- **The Center for Medical Interoperability**, the Nashville hospital-side counterpart funded at roughly six million dollars a year, filed revenue of **$6,171,991 in 2019 and $4,049 in 2024**. Founding-year revenue was $936,686 in 2013 and it peaked above six million for five straight years. The 2024 return reports $4,049 of revenue against $516,086 of expenses and was filed on the small-organization short form. Its domain, medicalinteroperability.org, now returns a 302 to the website of a village hall in Oxfordshire, England, which is what a lapsed domain does. Checked 26 August 2026; it will point somewhere else eventually.

> **The most damning evidence is not that anything failed loudly.** In March 2020 a US federal interagency working group published a review of medical device interoperability which concluded that "even though medical device interoperability has been a focus of government and industry for the past decade, it seems that little progress has been made." That report does not mention ICE, ASTM F2761, AAMI 2700-1, MD PnP or OpenICE anywhere. Neither does a 2024 published account of a German hospital actually building device interoperability, nor a December 2025 industry analyst survey of the whole field. Sixteen years of work, invisible to three independent reviews of its own subject.

The regulatory picture is better than I assumed in one direction and worse in the other

The gateway question resolves favorably, and more strongly than the "Class I, paper submission" framing suggests. Under the 21st Century Cures Act, section 3060, which added section 520(o) to the Food, Drug and Cosmetic Act, software whose function is "transferring, storing, converting formats, or displaying" device data is **excluded from the definition of a device entirely**. Not Class I. Not a device. The corresponding hardware remains Class I under 21 CFR 880.6310, product code OUG, exempt from premarket notification, and FDA has

stated in guidance that it does not intend to enforce even those controls. The regulation was amended on 19 April 2021 to read "a hardware device," conforming it to the Cures Act carve-out.

Quote the whole provision, though, because the second half is the part that binds. The exclusion holds *"unless such function is intended to interpret or analyze"* the device data. Four verbs get the gateway out. One clause can put it back in, and whether computing a minimum and a maximum is analysis is not a question I can answer by reading the statute. I flag it here rather than in a footnote because it is the strongest objection to Principle One below, and it deserves to be raised by me before it is raised by somebody else.

The accessory worry is also unfounded, on two counts. FDA's accessory guidance states that it "does not generally consider articles that do not meet the definition of an accessory as accessories simply because they may be used in conjunction with a device." And since the FDA Reauthorization Act of 2017, classification of an accessory is **statutorily independent of the parent**: FDA shall classify it "based on the risks of the accessory when used as intended … notwithstanding the classification of any other device with which such accessory is intended to be used."

And now the finding that moved the proposal furthest

FDA reissued its ***Clinical Decision Support Software*** final guidance on 29 January 2026. Its supersede line names one document, the version issued 6 January 2026, twenty-three days earlier, and that January version is what displaced the September 2022 guidance most commentary still cites. Two issuances in one month is itself worth noticing. The revision **tightened** the language that matters here. Criterion 1 of the CDS exclusion now describes a signal acquisition system measuring "through continuous, near-continuous, or otherwise *streaming* measurement." That phrase was not in the 2022 text.

Three of the guidance's own worked examples settle the question for any engine of this kind. Examples 20 and 21: software that analyzes five sequential R-R intervals from *Holter monitor data in a patient medical record* is a device function, whether it names atrial fibrillation or merely flags an irregularity and suggests follow-up. Example 24: software that analyzes **hourly** pulse oximetry and heart rate measurements, explicitly "from a patient's EHR," to identify signs of deterioration and alert a clinician is a device function. The stated reason in each case is the same, and in Example 20 FDA says it outright: it analyzes a pattern, "due to the sampling frequency."

There is a competing reading, and it belongs here. At least one FDA regulatory practice reads the 2026 parenthetical as clarification rather than expansion, on the grounds that the 2022 text already spoke of "a continuum between a single sample and a continuous sample." That reading is defensible. It does not change the conclusion, because the worked examples reach the same place under either version, and Example 24 was in the 2022 document too, numbered 25.

> **Read that plainly.** A five-minute epoch does not escape the device definition. Neither does reading the values out of the EHR rather than off the wire. Any software that takes a sequence of device measurements and interprets it is a device function, and no sampling interval and no intermediate hop changes that.
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> This is not an argument against the proposal. It is the reason the first artifact has to be a public sandbox running synthetic patients. A sandbox makes no claims about a patient, so it carries no regulatory burden, and it is precisely how Epic, Oracle Health and MEDITECH let outside developers in.

PART 2. WHY THE EHR SIDE WORKED AND THE DEVICE SIDE DID NOT

First, why anyone should care now, when nobody did for twenty-two years

Every argument for device interoperability until roughly 2023 was an argument about people. A clinician would see more, a pharmacist would catch more, a nurse would type less. Those arguments were true and they lost, for the reasons Part 5 sets out.

The argument has changed underneath the field, and not because anyone in the field changed it. Hospitals are now buying software that reasons continuously over a patient, and every such system, whoever builds it, needs the same four things: what was ordered, what was given, what the patient did in response, and when each of those happened. The first two are in the chart and the chart is now reachable. **The second two are only at the bedside.** A reasoning system with access to the entire electronic record and no access to the pump or the monitor can tell you what was intended and not what occurred.

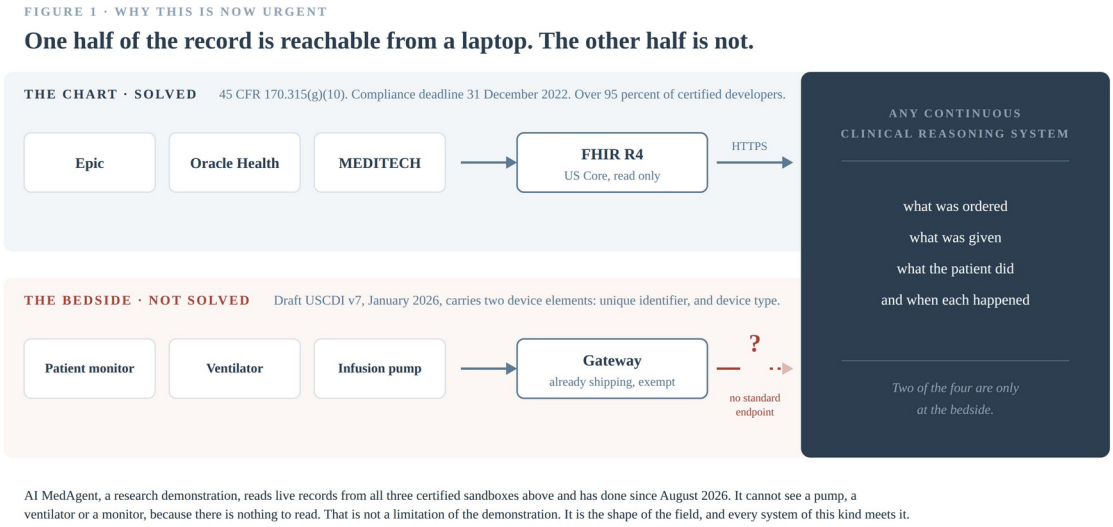

Figure 1. Federal certification solved the top lane in six years. Nothing has solved the bottom one in twenty-two.

I can say this precisely rather than generally, because I built one and ran into the wall. AI MedAgent is a research demonstration of continuous medication oversight. It is not a product, it is not for clinical use, and access is gated by a code because the reasoning calls cost me money per run. Over August 2026 it was connected to live records from three of the largest certified electronic health record vendors: Epic, Oracle Health and MEDITECH.

Getting in was not uniform, and the difference is worth keeping. Epic and Oracle Health took a laptop and an afternoon. MEDITECH took a form, a welcome packet from a support team, an end user license agreement and a wait, and it still cannot be run unattended, because its workspace offers the authorization code grant and not client credentials. But none of the three took money, and none of them required a hospital, a contract or a relationship with a customer, because federal certification had already forced the door open and every one of them publishes a sandbox with synthetic patients in it.

The other half does not exist to connect to. There is no endpoint, anywhere, at any price, that will tell a piece of software what an infusion pump has been doing for the last five minutes in a form it can reason over. Not a hard endpoint, not an expensive endpoint, not a slow endpoint. **There is no endpoint.** The demonstration can read that a physician ordered vancomycin and cannot read whether the pump delivered it, paused, ran at keep-vein-open for forty minutes, or was switched to a secondary line.

> **This is emphatically not a case for one demonstration.** AI MedAgent matters here only as an existence proof, because it is a system that got all the way to the wall and can therefore describe exactly where the wall is. Every serious continuous-reasoning system now being built for critical care will arrive at the same place, and most of them are being built by people with far more money than me. The proposal below is deliberately written so that it is useless to me as a competitive advantage and useful to all of them. If somebody else builds it first and I never touch it again, the point has been made.

There is a peer-reviewed number for this and it belongs in the argument. A 2024 national survey in the *Journal of the American Medical Informatics Association* asked 713 digital health companies about their experience with electronic health record APIs. Of the 141 that answered, **41 percent named the lack of realistic clinical testing data as a substantial barrier**, and 47 percent named high API fees. That is the demand side of this problem, measured, published and peer reviewed, two years before I went looking for it.

The contrast that explains the last two decades

It is tempting to read the last two decades as a failure of engineering. It was not. The engineering was finished years ago and still compiles. What differed was the incentive structure, and the contrast is stark enough to be instructive.

	EHR DATA, 2016 TO 2026	DEVICE DATA, 2004 TO 2026
The lever	A federal certification criterion, 45 CFR 170.315(g)(10), with a compliance deadline of 31 December 2022. Meet it or lose certification.	None. Draft USCDI v7, published January 2026, contains exactly two device data elements: unique device identifier, and device type.
What a vendor had to do	Expose a standard FHIR read API, single patient and bulk. No change to the clinical product.	Change a regulated device, or ship a new one, into a market that did not exist.
Who bore the cost	The vendor, once, at the interface.	The manufacturer, per product, per clearance, with liability attached.
How an outsider got in	A public sandbox with synthetic patients. No hospital, no contract.	A lab in Cambridge, Massachusetts, or a purchase order.
Result	**Over 95 percent** of certified developers compliant. Three of three largest vendors reachable over the open internet from a laptop.	No mandate, no market, no publicly documented adopter of the interoperability standard that survived.

Both columns describe the same country, the same decade, and largely the same hospitals. The difference is one line of federal regulation.

Every serious analysis reaches the same conclusion. The 2020 federal review found that "the current business models of medical device manufacturers and EHR vendors lack enough incentives to drive interoperable or semi-interoperable solutions" and that "many stakeholders see open communication between devices as a threat to their market share." The National Academies' 2018 volume on procuring interoperability found that "medical device vendors lack the market imperative to ensure interoperability, partly because providers bear most of the costs." Goldman himself, in 2013, called it a wicked problem with "little agreement about 'the problem'" and named *turf, proprietary inertia and lack of awareness* as the causes of the standard's failure to spread.

And it has been measured, once, in dollars, by people who then gave up

In March 2013 the West Health Institute in La Jolla published *The Value of Medical Device Interoperability*, putting the annual addressable waste at $36 billion: $17.8 billion in length of stay from delays in information, $12.3 billion in clinician time spent typing numbers a device already knew, $3 billion in redundant testing, $2

billion in avoidable adverse events, and $1.2 billion in the integration and development costs of doing it the hard way. On the day of publication its Chief Medical and Science Officer, Joseph Smith, testified to the House Energy and Commerce Subcommittee on Health, and the paper was entered into the record. FDA still links to it today from its Digital Health Center of Excellence page, described as "the business case for medical device interoperability."

So the economic argument was not merely made. It was quantified, taken to Congress, and adopted by the regulator as the reference. And it failed anyway. The reason is in the same paper, in a figure almost nobody quotes, and it is the most useful table in this memorandum.

WHO BENEFITS FROM DEVICE INTEROPERABILITY	PROVIDERS	PAYERS	PATIENTS	DEVICE VENDORS
$35.3 billion from lack of device interoperability	93%	6%	1%	**0%**
$1.2 billion from lack of common standards	63%	0%	0%	**37%**

West Health Institute, 2013, Figure 9. Percentages as published. The column on the right is the party every proposal for twenty years has asked to do the work.

Ninety-three percent to providers. **Zero to the manufacturers** who were being asked to build it. That is not a failure of persuasion, it is an accounting identity, and no amount of further advocacy was ever going to move it.

The same paper does contain a manufacturer-side number, and it is buried. Device makers were spending an average of **$740,000 per device, per EHR vendor**, to build and test interoperability. Multiply by the six EHR vendors that hold roughly eighty percent of the market and the industry was carrying more than $520 million a year in bilateral integration cost. Against one common interface, West Health estimated the same work at $87 million. That $430 million is the only figure in the document that lands in the pocket of the party being asked to act, and in thirteen years I have never seen it used as the ask.

The design conclusion follows directly. **Any proposal that requires a manufacturer to modify a cleared device will fail, for the same reason every previous one did.** Whatever is asked for has to be small enough that a vendor can say yes without a regulatory submission, a business case, or a board discussion.

PART 3. WHAT ACTUALLY EXISTS TO BUILD ON, AS OF TODAY

This is the inventory. I checked each of these directly rather than relying on the literature, and the status column is what I found, not what the promotional material says.

ARTIFACT	STATUS, VERIFIED AUGUST 2026	USEFUL HERE?
IHE DEV PCD-01 Communicate PCD Data, in the DEC profile	Final Text, DEV Technical Framework Rev 10.0, 4 November 2024. Fifteen years of shipping vendor support. HL7 v2.	**Yes.** The only device interface with a real installed base. The epoch is a summary of exactly this content.
IHE ACM Alert Communication Management	Final Text, Rev 10.0. Transactions PCD-04 through PCD-07.	**Yes.** The alarm channel already exists and is specified. Do not reinvent it.
IHE IPEC Infusion pump events	Final Text since Rev 9.0, 12 December 2019. Required events: Delivery Start, Delivery Stop, Delivery Complete.	**Partly.** No rate change, no secondary-to-primary switchover, no transition to keep-vein-open. The three states a reader most needs are absent and must be inferred.

ARTIFACT	STATUS, VERIFIED AUGUST 2026	USEFUL HERE?
Optimized Message Syntax the 2014 PCD white paper on slow physical layers	Approved as a work item for PCD Cycle 8, 2013 to 2014. Never published as a profile, supplement or white paper in the current framework. Two sibling Cycle 8 items died the same way.	**As precedent.** It proves IHE will entertain a reduced-bandwidth profile, and that entertaining one is not the same as shipping it.
ISO/IEEE 11073 SDC service-oriented device connectivity	Core published: 10207, 20701, 20702, 10700, 10701. The Alert and External Control participant key purposes are still drafts. No certification body, no conformance mark, only an open-source test tool.	**No, not yet.** GE Healthcare joined OR.NET in April 2025 and the coalition is real, but I could not confirm one commercially shipping SDC-enabled product.
HL7 FHIR Point-of-Care Device IG uv-pocd	**Never published.** Four ballots since 2018. Currently 1.0.0-ballot3, in the September 2026 ballot cycle, still built on FHIR R4. Its own publication request says "not yet ready for production use." Zero commits in all of 2024; 130 so far in 2026.	**Yes, as the model.** Its Device hierarchy and its use of SampledData for waveforms are coherent. Build against it, do not cite it as a standard.
IHE SDPi the SDC-to-IHE bridge	v2.4.1, 7 May 2026, Trial Implementation. Actively developed.	**Instructive.** See the finding below.
FHIR DeviceAlert	New resource, present in FHIR R6 ballot, confirmed absent from R5. Owned by the Devices work group, derived from 11073-10201, aligned to IHE ACM.	**Yes.** This is the alarm channel in FHIR form, and it did not exist a year ago.
HL7 Caliper device interoperability FHIR accelerator	Launched early 2026. Technical Director Todd Cooper. Named members include GE HealthCare and Dexcom. Three work areas, the third of which is explicitly AI-enabled devices.	**Yes.** This is the venue. It is nine months old.
West Health Institute 2013 white paper the $36 billion estimate	March 2013. Entered into the record at House Energy and Commerce, 20 March 2013. Still cited by FDA. No published critique, rebuttal or independent replication found in thirteen years. West Health left the field in 2015.	**Yes, and carefully.** The best statement of the value and the only stakeholder split anyone has published. Cite it for the incentive asymmetry, not as a settled number. An unreplicated advocacy estimate is not evidence, however often it is repeated.
eICU Collaborative Research Database	v2.0, 2019. Bedside monitor data captured as one-minute averages, archived as five-minute medians, 12 parameters.	**Yes, as proof.** The five-minute epoch is not a novel interval. It is what the most-used multi-center ICU dataset already stores.
OpenICE the reference implementation of AAMI 2700-1	Alive. Last commit 7 May 2026; Java 25 and Gradle 9 landed 14 April 2026. Last tagged release is v2.0.0, 31 May 2024. 137 stars, 78 forks, 97 open issues, BSD-2. Runs on RTI Connext 7.3 over UDPv4 multicast.	**In parts, and not the parts you would guess.** Harvest the device protocol parsers and the data model. Do not adopt the platform. See below.
MIMIC-IV Waveform Database	Still v0.1.0, 200 records, released July 2022 as a "technical preview" ahead of a v1.0.0 "intended to be released shortly." Four years later there is no v1.0.0.	**Cautionary.** Ten other MIMIC-IV derivatives shipped in that window. The waveform data is the part nobody finished.

> **The single most useful number I found.** IHE's flagship device interoperability profile, SDPi 2.4.1, published May 2026, devotes roughly 3,487 lines of its transaction volume to HL7 version 2 gateway mappings and **13 lines to the FHIR gateway**. Those 13 lines contain no mapping tables at all. They point the reader at a continuous integration build of an implementation guide that has never been published. A ratio of roughly 268 to 1, in a public repository, checkable by anyone.
>
> *That is the state of device data in FHIR in 2026, expressed as a line count.*

OpenICE, examined properly, because it is the closest thing to a precedent

OpenICE is the open-source reference implementation of the Integrated Clinical Environment, built by the MD PnP program under an NIH Quantum award and still promoted on the program's own site. It deserved more than a glance, so I cloned it and read it.

First, the thing the whole field appears to have wrong. **It is not abandoned.** HEAD is commit ea30b5d, 7 May 2026. Java 25 and Gradle 9 landed on 14 April 2026. There are 97 open issues and they read like real users: somebody asking in March 2026 whether it works with an IntelliVue MP network card, somebody else reporting missing invasive blood pressure values. What *is* abandoned is the front door. openice.info is served from a repository whose last commit is 18 December 2015, which is why the public build page still tells you to install the Java 8 JDK and still says the project uses DDS version 5.1. The code moved eleven years and the documentation did not. Anyone who evaluates OpenICE from its website is reading a fossil and will conclude, wrongly, that the project died.

Why none of it can be the transport

OpenICE runs on DDS, specifically RTI Connext 7.3, and every quality-of-service profile in the tree sets the transport mask to UDPv4 alone. Discovery is multicast to 239.255.0.1, with *accept_unknown_peers* set true under a code comment reading "promiscuous for the lab environment." That is an honest description of a laboratory posture and a disqualifying one for anything else.

Which answers the cloud-to-cloud question, and the answer is no. Azure states plainly that virtual networks do not support multicast or broadcast. Google states that VPC networks do not support broadcast or multicast addresses. AWS supports it only through Transit Gateway multicast domains, and its own documentation says multicast routing is not supported over Direct Connect, Site-to-Site VPN, or peering attachments, which means it cannot reach a second cloud even in principle. Making DDS span the public internet requires RTI's Cloud Discovery Service or Real-Time WAN Transport, both separately licensed add-ons, plus NAT traversal and hand-maintained peer lists. That is a fabric to operate, not a file to download.

And it would be the wrong tool anyway. A five-minute epoch is one message every three hundred seconds, which is 0.0033 hertz. DDS is microsecond-latency real-time middleware with a quality-of-service matrix to match. Using it here is like chartering a freight train to deliver a postcard. An HTTPS POST carrying a FHIR bundle does the same job with no middleware, no discovery, and no license file.

> **The license detail is the one worth pausing on.** The Java source is BSD 2-Clause and permits commercial derivative work. The transport it cannot run without does not. Committed into the repository at two paths is a file named OpenICE_license.dat, issued 3 May 2021 to "Non-Commercial User," whose feature lines read verbatim:
>
> *"Non-commercial license is for academic, research, evaluation and personal use only with OpenICE. USE FOR COMMERCIAL PURPOSES IS PROHIBITED."*
>
> The same lines carry Production=no and ExpiredAction=exit, meaning the participant terminates rather than degrades. The flagship open-source implementation of the medical device interoperability standard ships with a runtime key that forbids production use. That is not a criticism of anyone. It is the clearest single artifact of why twenty-two years of good engineering never reached a hospital that had to buy something.

What is worth taking

Two things, and they are genuinely valuable.

- **The device protocol parsers.** Roughly 280 Java files under devices/ that import no DDS at all. The Philips IntelliVue stack alone is 203 files with zero middleware imports and a build file that depends on a logger and nothing else. Dräger, Puritan Bennett, Oridion, Nonin, Nellcor and Masimo are the same shape. That is the part of this work that takes years of reverse engineering and vendor relationships to reproduce, and it is BSD-2. Note the asymmetry, because it is inconvenient: the monitor and ventilator drivers are clean, and the infusion pump drivers are not. Alaris Asena, Baxter AS50 and Hospira Symbiq live above the line and are welded to DDS.
- **The data model, as a reference rather than a dependency.** Jeff Plourde's ice.idl separates device_time from presentation_time, the device's own clock from the moment the adapter saw the value. That distinction is the difference between a usable record and an unfalsifiable one when clocks drift, and most designs omit it. PCD-E should carry both. Two structures should not be inherited: InfusionStatus is marked deprecated in the file itself, and Alert is a 256-character free text field under a comment admitting it is "a placeholder for something more harmonized."

Two findings from inside the code that change what I would write

The first concerns terminology, and it is the reason Principle Six below refuses to specify code bindings. OpenICE ships rosetta.idl, 1,325 lines, which is as close to a canonical machine-readable nomenclature list as this field has produced in the open. I counted what is actually in it. **659 reference identifiers and not one numeric code**. Every entry maps a name to itself as a string. Worse, the file annotates each term with the annex section it came from, and **344 of the 659 carry an empty citation**. More than half the vocabulary in the reference implementation cannot tell you where it came from. Anyone who has done this work knows why that matters: an MDC term that is almost right still validates.

The second is the one that decided the shape of this proposal. I searched 135,000 lines for any time-windowed aggregation and found none. The only descriptive statistics anywhere are in two files, both quality-assurance screens bound to a JavaFX chart, and their window is a count of the last N samples rather than an interval of time. The export applications write raw samples to CSV, JDBC, Mongo and a Verilog trace format. Not one of them summarizes anything.

> **So the central idea here does not exist in the field's flagship open-source platform.** Not deprecated, not half-built, not present. Twenty-two years of work on moving device data and nobody built the thing that makes it readable at scale. I went looking for prior art expecting to find it and to have to argue for a variation. There is no prior art. That is not a gap this proposal has to work around. It is the argument for it.

PART 4. THE PROPOSAL

Working name: **PCD-E, the device epoch**. Nothing in it is invented. Every element is lifted from something that already works, which is the point. The novelty is in what is left out and in one field nobody currently carries.

Principle one. A summary, not a sample. This is the correction that matters.

The obvious design is to poll each device every five minutes and record what it says. That design has a documented failure mode, and Goldman photographed it in 2016. A patient monitor displayed a low oxygen alarm, **SpO2 84 percent at 14:07**. The anesthesia record for the same patient over the same period shows an unbroken line of normal saturations. The alarm happened, the monitor knew, and the record carries no evidence of it. His caption is two words: sampling error.

A five-minute point sample reproduces that failure exactly. It will miss every transient shorter than the interval, which is most of the events worth reasoning about.

So the epoch carries a **summary of the interval**, not a reading from it. Per metric, per five minutes: the count of samples the device actually took, the minimum and its timestamp, the maximum and its timestamp, the first value, the last value, and the mean. Seven or eight numbers where a 1 Hz stream would have produced three hundred.

Under that scheme Goldman's missing desaturation is not missing. It is a minimum of 84 with a timestamp of 14:07 inside an otherwise unremarkable epoch, and any engine reading the record can see both the excursion and the fact that the patient recovered. **That is roughly a fortyfold reduction in volume that increases rather than decreases what a reader can conclude.**

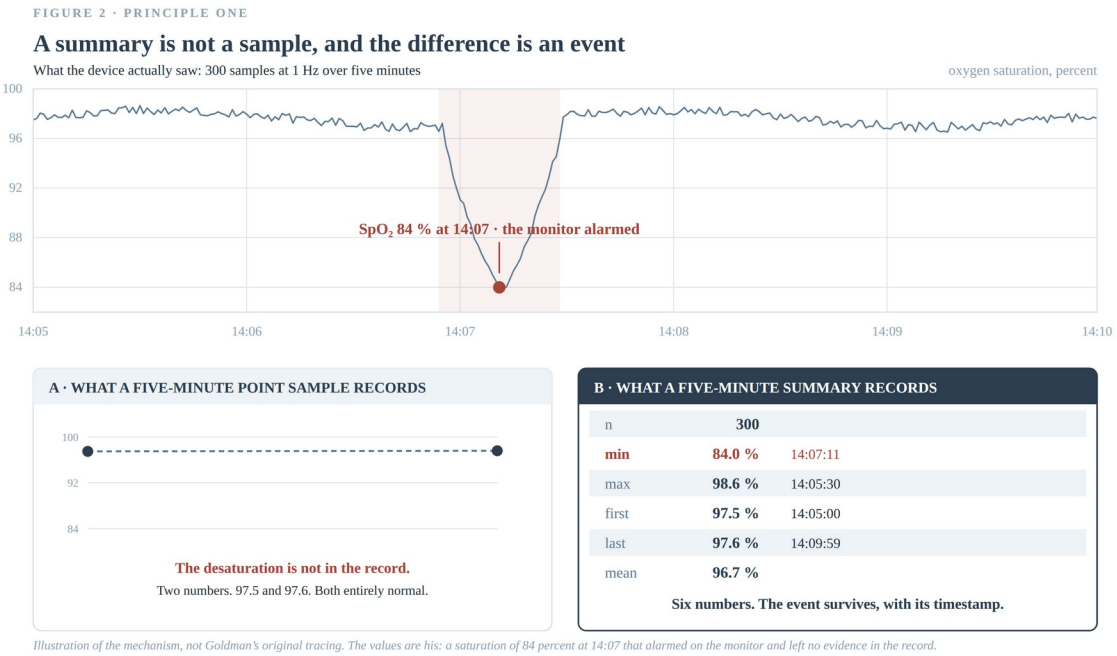

Figure 2. The same five minutes, recorded two ways. The left panel is what a polled point sample preserves. The right panel is what a summary preserves, at a cost of four extra numbers.

This is the "something old" the whole proposal turns on. Trend databases, Holter summaries and eICU have all stored interval statistics rather than raw samples for decades. Nobody has put that shape behind a modern API.

Principle two. Alarms are not epochs and must not wait.

An alarm is not a measurement, it is a request for a human being. It bypasses the epoch entirely and is delivered when it fires. This channel does not need inventing either: IHE ACM has specified it since Final Text, and FHIR now has a **DeviceAlert** resource, new in the R6 ballot, derived from the same 11073 information model and explicitly aligned to ACM.

One discipline borrowed from the alerting literature and from AI MedAgent's own design: alarms carry the alert *and its inactivation*. An alarm with no recorded end is the reason nobody trusts alarm data.

Principle three. Carry the reason, not just the number. This is the original part.

Goldman has a second slide, and it is the most valuable thing in the deck. A non-invasive blood pressure cuff and a pulse oximeter are on the same arm. The cuff inflates, blood flow to the finger stops, the oximeter loses its signal and reports a falling saturation. The monitor charts a desaturation that never happened. His caption: **"Inflation metadata could identify BP artifact."**

Every standard in Part 3 would faithfully transmit that false desaturation. None of them carries the one fact that explains it, which is that the cuff on the same limb was inflating at that moment. The data is not wrong because the sampling rate is too low. It is uninterpretable because the context is absent.

So each epoch carries a **context block**: what else the device knew about itself and its neighbors during that interval. Sensor attached or detached. Cuff cycling. Device in service or calibration mode. Patient association changed. Channel switched from primary to secondary. Transition to keep-vein-open. Clock resynchronized.

Note what several of those are. **Rate change, secondary-to-primary switchover and transition to keep-vein-open are precisely the three infusion states that IPEC does not carry** and that a reader currently has to infer from periodic observations. The context block is where they belong, and putting them there costs a gateway nothing, because the pump already told it.

Figure 3. Both records are correct. Both were produced by conforming implementations. One of them can be reasoned over and the other one cannot.

This is not more data. It is different data, and it is the difference between a number and a fact.

Principle four. The epoch declares what it could not see.

Each epoch states which metrics were expected and which arrived. A missing value is explicit and carries a reason: device disconnected, sensor off, patient off the monitor, gateway lost the link. Silence is never returned as normality.

This is the same discipline AI MedAgent already applies to medication screening, where every call states how many of the eight standard classes it was able to perform. A reader that cannot distinguish "normal" from "not measured" will eventually average the two, and the resulting trend line will be handed to a clinician as a fact.

Principle five. It lives on the gateway, and the gateway is not a device.

No device is asked to change. The device talks to the gateway exactly as it does today, over whatever proprietary or PCD-01 path already exists. The gateway aggregates, summarizes and exposes. Under Cures Act 520(o)(1)(D) the transfer, storage, format conversion and display functions of that gateway are **not a device**; the hardware sits at Class I under 21 CFR 880.6310 with stated enforcement discretion.

The line is sharp and it is documented in the market. Dräger registers its Vista Gateway under the medical device data system code and its Infinity Gateway Suite under a Class II physiological monitoring network code. Capsule ships a connectivity platform on the exempt side and *Capsule Surveillance* as a cleared Class II device, because the latter "integrates, analyzes, and displays data … to create clinically relevant alerts." Same vendor, same wires, same data. Adding the interpretation moved it across the line.

PCD-E stays on the exempt side by doing arithmetic and nothing else. Minimum, maximum, mean, count, and passing through what the device already said about itself. **It must not threshold, must not alert, must not interpret.** The moment it does, it is a Class II device and the whole cost argument collapses.

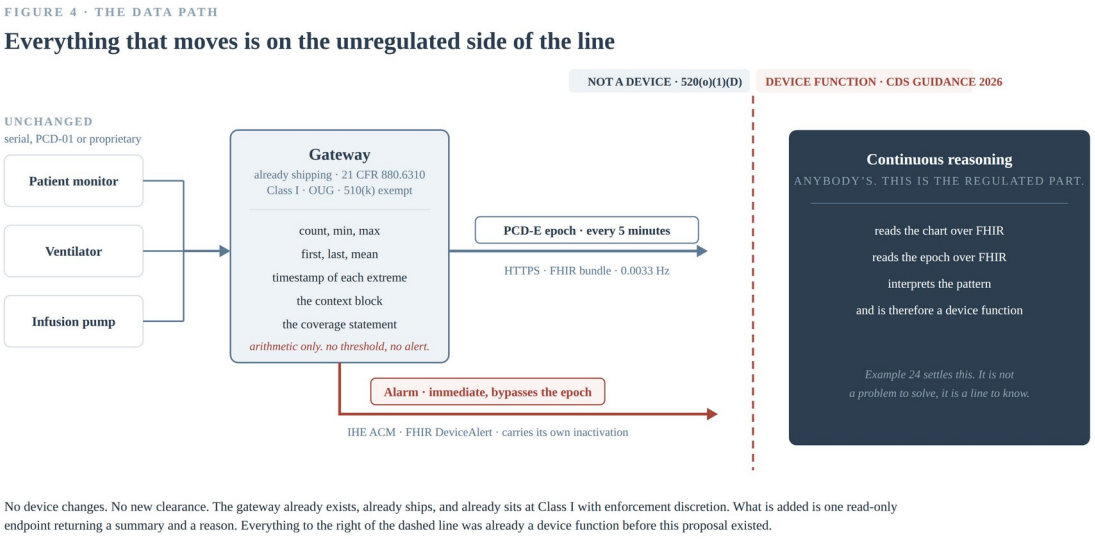

Figure 4. The whole proposal sits to the left of the dashed line. Everything to the right of it was already a device function before this document existed, which is a fact about the reasoning system and not about the interface that feeds it.

Principle six. Prove it in a sandbox before asking anyone for anything.

This is the lesson the EHR side already taught and the device side never learned. Epic, Oracle Health and MEDITECH did not persuade developers by publishing a specification. They published **a sandbox with synthetic patients in it**, and a developer with a laptop could be reading a chart the same afternoon.

So the first deliverable is not a standard. It is a public endpoint serving epoch data for synthetic patients, with a conformance suite and a reference client, on the open internet, no agreement required. It costs nothing to read and nothing to fail against. If it is useful, manufacturers can point their own gateway at the same test suite without touching a cleared product, and without a regulatory submission, because a test endpoint serving invented patients is not a medical device by any reading.

What the sandbox would contain

1. Synthetic patients with physiologically coherent trajectories, generated rather than sampled, so that the record contains real transients at known times and a reader can be scored on whether it found them.
2. At least one deliberately planted artifact per patient, of the cuff-and-oximeter kind, with the context block present, so that a reader can be scored on whether it correctly declined to believe a number.
3. Epochs at five minutes, with a one-minute variant, so the interval itself becomes a testable question rather than an assumption.
4. An alarm stream that fires out of band, including at least one alarm whose corresponding epoch summary looks unremarkable, which is Goldman's 2016 case reproduced deliberately.
5. A published coverage manifest: exactly which metrics the sandbox emits and which it does not, so nobody mistakes absence for normality.

Principle seven. Build the receiving end, and stop asking.

Everything above this line still asks a manufacturer to build something. A smaller something than any previous proposal, on the unregulated side of the line, with no clearance and no clinical claim, but still something. And the entire history in Part 5 says that any ask of a manufacturer, however small, is an ask that does not get answered.

So turn it around. **I build the receiver.** A public endpoint on the open internet, the epoch schema published beside it, an API key available by email, and a standing invitation to every pump, ventilator and monitor manufacturer to point a *simulator* at it. Not a product. Not a hospital. Not a patient. The output of the test rig that already sits on every one of their integration benches. What arrives gets fed to a reasoning engine with a synthetic chart alongside it, and what the engine concludes is published.

The ask collapses from "implement a profile, ratify it, and ship it" to "POST a JSON body to a URL with one header." An engineer can try it on a Friday afternoon without telling anybody, and that last clause is not a joke. Twenty-two years of failure in Part 5 has a common feature nobody names: every available path required a *public commitment*. Join a consortium. Sign the MD FIRE language. Register a system for a Connectathon. Ballot a profile. A test endpoint requires no commitment at all, and it is the only door in this entire field that a curious engineer can walk through alone.

This inversion is not novel, which is the point

FHIR already has a deployed precedent for flipping host and guest, and it is the one this demonstration already speaks. Under CDS Hooks the electronic health record is the *client*, calling out to a decision service hosted by somebody else entirely, and Epic, Oracle Health and MEDITECH all do it in production today. Nobody had to be persuaded that an outside endpoint was acceptable in principle, because that argument was won years ago in the chart half of the record. PCD-E ingest is the same shape pointed at the bedside.

What it costs, which is the part that should embarrass everybody

Twenty participants sending one bundle per device every five minutes is roughly 173,000 requests a month. On Cloudflare Workers that is the $5 flat monthly plan. On AWS serverless it is under two dollars. On Google Cloud Healthcare API, a managed FHIR store, it is about a dollar twenty. Avoid AWS HealthLake, which bills $0.27 per data store hour whether or not a byte moves, or $197 a month to leave the lights on.

> **Set that against the price of the existing door.** IHE North America Connectathon last published system registration at $8,500 Canadian per system, plus $2,000 Canadian per participant per week, in person, once a year. The infrastructure to run an open device data endpoint for a year costs less than two minutes of that. The reason this was never built is not cost. It has not been cost for at least a decade.

Three design decisions, and the reasoning behind each

- **A plain bearer API key over TLS. Not SMART Backend Services.** The correct standard for server-to-server FHIR authentication is SMART Backend Services, client credentials with a signed JWT assertion, and the specification strongly prefers that the client publish its public keys at a TLS-protected JWKS URL. Read that requirement again. It asks the sender to stand up a public endpoint, which is precisely the "build something" ask that this whole principle exists to remove. Worse, it is a confound: if the endpoint requires JWKS hosting and nobody connects, I cannot tell apathy from friction, and my own result becomes uninterpretable. The specification is published as an optional upgrade path. Nothing is gated behind it.
- **Synthetic only, and never the word "de-identified."** Those are different categories carrying different risk. De-identified means real patient data with the identifiers stripped, which is a compliance question about provenance I could not audit if I wanted to. Data that was never about a person is not protected health information at all, because it is not individually identifiable health information under 45 CFR 164.514(a). Simulator output and Synthea-class generated records. Nothing else, ever.
- **A tripwire at ingest that rejects before it stores.** Any bundle carrying a populated patient name, birth date or identifier, or anything matching a medical record number, is rejected with a 400 and never written to disk or to a log. It is perhaps sixty lines of code and it is the single most important control on the whole endpoint, because the realistic failure mode is not an attack. It is a well-meaning engineer pointing the wrong stream at the URL on a Friday afternoon.

> **One thing this proposal deliberately does not do.** It does not specify terminology bindings. Getting an 11073 nomenclature code almost right is worse than leaving it out, because an almost-right code validates. Terminology mapping is a work item for people with the published tables in front of them, and every code in any eventual specification has to be looked up rather than recalled.

PART 5. WHY THIS MIGHT WORK, AND THE HONEST CASE THAT IT WILL NOT

The case for

- **The ask is smaller than any previous one.** No device change, no new clearance, no clinical claim. A read-only endpoint on a box the vendor already ships and already registers as exempt.
- **The interval is not novel and not arguable.** eICU has archived five-minute medians for a decade. Anyone objecting that five minutes is too coarse is objecting to the dataset their own institution publishes on.
- **There is now a venue, and it is new.** HL7 Caliper launched in early 2026 with Todd Cooper as technical director and "AI-enabled devices" as one of three stated work areas. No such forum existed a year ago.

- **The timing on the implementation guide is unusually good.** The Point-of-Care Device IG is in ballot right now, in the September 2026 cycle, after recording zero commits in all of 2024. It is being actively worked on for the first time in years and it is open for comment.
- **The party that benefits has changed, which is not the same as saying the argument is new.** The tempting version of this claim is that every previous attempt was justified by safety and the economic case was never made. West Health's 2013 paper disposes of that: $36 billion, congressional testimony, an FDA citation that is still live. What was wrong with it was not the argument but the audience. Ninety-three percent of that money accrued to providers and none of it to the manufacturers being asked to build. The change worth betting on is that hospitals are now spending real money on clinical AI, which means the buyer and the beneficiary are for the first time the same party, and that party can put the requirement in a purchase order without asking anyone's permission.

The case against, which deserves to be stated plainly

- **There is still no mandate, and the absence is documented.** Draft USCDI version 7, published January 2026, lists two device data elements: unique device identifier and device type. Nothing in United States regulation obliges anyone to expose continuous device data, and nothing in the draft suggests that is about to change.
- **Congress has tried and failed twice.** The Better Interoperability for Devices Act was introduced in the 117th Congress in September 2022 and again in the 118th in March 2023. It would have required a report to Congress. Not a rule, not a mandate, a report. Neither version became law.
- **The best-funded attempt quit, and it quit after winning the argument.** West Health had philanthropic money, a $36 billion number, a witness chair in front of House Energy and Commerce, and an FDA link. On 4 August 2015 an incoming chief executive announced a single unified strategy called Successful Aging, and the organization's own account of the change lists interoperability among what was being left behind. Today westhealth.org describes an institute "focused on finding evidence-based solutions that lower costs and improve care for older adults," and device interoperability appears nowhere in its nine initiatives. The 2013 paper is still on their server. Every internal link to it is gone. It survives in public mainly because FDA still points at it.
- **Nobody has ever made money from this.** Twenty-two years, more than eighteen million dollars of federal funding into MD PnP alone, a working open-source reference platform, a published standard, and no commercial market. The most likely outcome for any new proposal is that it joins the list.
- **The incumbents have no reason to help.** Philips acquired Capsule for 635 million dollars in 2021. Its platform holds over a thousand device drivers across three thousand facilities and its published interface list is HL7 version 2 and IHE PCD only. An open epoch endpoint makes that asset less defensible, not more.
- **The statutory carve-out may not cover a summary.** Section 520(o)(1)(D) excludes transferring, storing, converting formats and displaying, "unless such function is intended to interpret or analyze." A gateway that computes a minimum, a maximum and a mean is doing arithmetic on device data, and a regulator who wanted to call that analysis would not have to strain. My own reading is that descriptive statistics over a fixed window sit closer to format conversion than to interpretation, since nothing is inferred and nothing is concluded, and the Medical Device Data System regulation turns on whether a system controls or alters device function, which this does not. But that is a reading, not a ruling, and it wants a pre-submission question rather than my confidence.
- **Standards precedent is discouraging.** Optimized Message Syntax was approved as an IHE work item in 2013 and never published. Two sibling device-specialization items approved the same cycle met the same fate. Approval is cheap and publication is not.

> **The honest summary.** The technology worked, the standard was published, the reference implementation still compiles, and twenty-two years later there is no market, because nobody who could have paid for it ever had a reason to. This proposal does not fix that. It lowers the cost of participation to something close to zero and bets that AI is the first reason anyone has had.

PART 6. WHAT TO ACTUALLY DO NEXT

In order, cheapest first. Each step is useful even if the next one never happens.

1. **Write to Caliper first, before anything is published.** This is out of order on purpose. HL7 Caliper launched on 1 January 2026 with GE HealthCare and Dexcom among its founding sponsors, chartered on exactly this problem, and I have found no public test endpoint under it. But "I found none" and "none exists" are different statements, and only one of them is mine to make. One email to caliper@hl7.org settles which. Either they confirm that no such endpoint exists, which puts the finding on the record from the authoritative source, or they invite me in, which is a better outcome than anything else on this list.
2. **Build both halves of the sandbox.** The read half serves synthetic epoch data: five-minute interval summaries, an out-of-band alarm stream, planted artifacts, a published coverage manifest. The write half is the receiver from Principle Seven, with the schema, an API key by email, and the tripwire. Neither requires anyone's permission, and together they are the only artifacts on this list entirely within one person's control.
3. **Comment on the Point-of-Care Device implementation guide ballot.** It is open in the September 2026 cycle. A comment arguing for an interval-summary observation shape and a context block, submitted by someone with forty years of device integration behind them, is cheap to write and lands in front of exactly the right people.
4. **Write to Caliper.** Nine months old, explicitly chartered on AI-enabled devices, technically directed by someone who has been in IEEE 11073 and IHE PCD for decades. The message is one paragraph: here is a running sandbox, here is what it emits, is this the shape you want.
5. **Write to Goldman.** He is not defeated, he has fresh ARPA-H funding for an ICE-based platform, and PARADIGM is about care delivered outside hospitals where bandwidth is genuinely scarce. An epoch summary with a context block is more useful to a rural mobile unit than a waveform stream. He is also, by the evidence, the person most likely to know why this will not work.
6. **Only then consider a formal profile proposal.** IHE DEV, or Caliper, or both. By that point the sandbox is running, the ballot comment is on record and two of the field's principals have either endorsed or demolished the idea. Any of those three outcomes is worth more than a specification written in advance of them.

If nobody connects, that is a result, but only if it is run as one

An open endpoint that stays empty is either a finding or an anecdote with a chart, and which one it is gets decided before it opens, not after. There is good precedent for the finding. A 2018 *JAMA Network Open* study had simulated patients telephone 83 top-ranked American hospitals to request their own medical records and documented, hospital by hospital, what actually happened. The 2024 JAMIA survey cited in Part 2 invited 713 digital health companies and followed up with non-respondents **up to fifteen times** to reach a 20 percent response rate. That is the standard. One post on LinkedIn is not an invitation, and a reviewer will say so, in public, and be right.

So: pre-register the protocol before the endpoint opens, with the invitation list, the selection rule, the observation window and the analysis plan timestamped where they cannot be edited afterwards. Record

every invitation like a journalist would, with the name, the channel, the date, the role and the number of follow-ups. Separate the three outcomes that a bare count destroys, which are **declined, silent, and tried and failed**. Publish the endpoint's uptime and a working reference client anyone can run, because otherwise the one-line rebuttal is that the thing was broken and it cannot be disproved. And state in the writeup that every friction excuse was removed in advance: no JWT, no NDA, no participation agreement, no fee, no production system, no real patient.

> **And attack the result before somebody else does.** The obvious competing explanation is probably the true one, and it is more interesting than the one I would be tempted to write. Corporate counsel at a device manufacturer will almost never approve pointing any stream, even a simulator, at an unaffiliated individual's cloud endpoint without a contract in place. If that is what comes back, the finding is not that the industry is apathetic about interoperability. It is that the industry's own legal structure makes lightweight experimentation impossible, and that this is a large part of why interoperability keeps failing.
>
> *That is a better article than the one I set out to write, and it is a different study, because it requires capturing the reason rather than the silence. Which means the invitation has to reach a person who will tell me the reason, and it has to ask for it explicitly. Decide which finding is being tested before the endpoint opens. There is only one chance to run it.*
>
> **A note on what this is not.** This is a proposal for a data interface, not for a clinical system. Nothing in it should be read as suggesting that a five-minute summary is sufficient for closed-loop control, for arrhythmia detection, or for any purpose requiring beat-to-beat fidelity. Those need waveforms and always will. The claim is narrower and, I think, defensible: that a very large class of useful reasoning about where a patient is heading needs interval statistics and context, not samples, and that the absence of an interface carrying interval statistics and context is why that reasoning is not happening.

A NOTE ON JULIAN GOLDMAN

It would be easy to read this memorandum as an obituary for someone else's work. It is not, and I want to be precise about why, because the precision is the compliment.

Goldman was right about the problem in 2004 and the field has produced no better statement of it since. He was right that the unit of interoperability is the *clinical scenario* and not the message. He was right that a device that cannot say what it does not know is more dangerous than one that says nothing. He was right that safety has to be designed at the level of the system rather than the box, which is the whole idea behind an Integrated Clinical Environment and the reason AAMI 2700-1 reads the way it does. The 2016 slide of an oxygen saturation that fell to 84 percent, alarmed on the monitor, and left no trace in the anesthesia record is the single clearest artifact in this entire literature, and everything in Part 4 of this document is downstream of it. Principle One exists because of that slide. Principle Three exists because of the one next to it, the blood pressure cuff inflating on the same arm as the oximeter.

He also built the thing, twice, and kept building it. Twenty-two years, more than eighteen million dollars in federal funding, a published standard, an open-source reference implementation with commits from three months ago, and in February 2025 a new ARPA-H award of up to $20.8 million to do it again for rural mobile care. The people who quit are documented earlier in this memorandum by their tax filings and their lapsed domains. He is not among them.

What did not work was never the vision. It was the ask. Every version of it required a manufacturer to change a cleared product, or a hospital to buy a platform, in service of a benefit that West Health measured and found accrues ninety-three percent to somebody else. This proposal is deliberately smaller than anything

Goldman ever proposed, and smaller is not better. It is just what is left after you subtract everything that has already been tried and has already failed for reasons that had nothing to do with whether it was a good idea.

> *If any of this is worth anything, it is because he spent a career making the case in public and leaving the evidence where somebody else could find it. I found it. That is what the work was for.*

SOURCES

Everything below was checked directly in August 2026 rather than cited from secondary literature. Where a status could not be confirmed, the memorandum says so in the text.

- Goldman JM. "Safe Medical Device Interoperability to Enable Healthcare Transformation." MDIC webinar, 23 February 2016. The source of the sampling-error and blood-pressure-artifact slides, and of the figure of more than $18 million in MD PnP funding since 2004. mdic.org
- Society for Technology in Anesthesia, J.S. Gravenstein Award recipient list. Julian Goldman, MD, FASA, named for 2026. Twenty-five prior recipients listed back to 2000. stahq.org/awards-and-grants/js-gravenstein-award
- ARPA-H award 3396, "PARADIGM ICE: Integrated Clinical Environment." Awardee Massachusetts General Hospital and Harvard Medical School, principal investigator Julian M. Goldman, MD, awarded 12 February 2025, up to $20.8 million, building a plug-and-play environment for interoperable medical devices on the DocBox Apiary platform. arpa-h.gov/explore-funding/awards/3396
- ECRI, "Advancing Rural Health: ECRI Collaborates with Massachusetts General Hospital on ARPA-H Initiative Developing Mobile Medical Units," 13 November 2025. ECRI advises on device selection for security, safety, interoperability and remote capability. home.ecri.org
- West Health Institute, "The Value of Medical Device Interoperability: Improving patient care with more than $30 billion in annual health care savings," March 2013. Source of the $36 billion estimate, the component breakdown, the 93/6/1/0 stakeholder split in Figure 9, and the $740,000 per device per EHR development figure. Still served at westhealth.org and still linked from FDA's Digital Health Center of Excellence page, though no longer reachable from within West Health's own site. westhealth.org
- Joseph M. Smith, MD, PhD, Chief Medical and Science Officer, West Health Institute, written testimony, "Health Information Technologies: How Innovation Benefits Patients," Subcommittee on Health, House Committee on Energy and Commerce, 20 March 2013. The white paper was entered as a supporting document the same day. docs.house.gov
- West Health Institute, current program description, "focused on finding evidence-based solutions that lower costs and improve care for older adults." Nine initiatives listed, none of them device interoperability. The strategy change was announced on 4 August 2015 with a new chief executive. westhealth.org/entities/west-health-institute
- Center for Medical Interoperability, IRS Form 990 series, EIN 46-3191908, via ProPublica Nonprofit Explorer. Revenue $936,686 in 2013, above $6 million from 2016 through 2019, $4,049 in 2024 against $516,086 of expenses, filed on Form 990-EZ on 17 November 2025. projects.propublica.org/nonprofits/organizations/463191908
- IHE Patient Care Device planning and technical committee face-to-face, 8 to 11 October 2013, meeting notes. "MDICC removed, replaced with AAMI/UL2800." The only dated record of the council's removal from the roadmap that I could locate. wiki.ihe.net
- IHE Patient Care Device White Paper, "Optimizing Messages for Slow Physical Layers," Rev. 1.0, Draft for Public Comment, 30 April 2014, Ken Fuchs. Approved as a Cycle 8 work item; never published as a profile. ihe.net
- OpenICE, github.com/mdpnp/mdpnp, BSD 2-Clause. Cloned and read on 26 August 2026. HEAD ea30b5d, committed 7 May 2026; Java 25 and Gradle 9 merged 14 April 2026 as PR #144; latest tagged release v2.0.0, 31 May 2024; 97 open issues. Source of the rosetta.idl count of 659 reference identifiers with 344 empty provenance comments and no numeric codes, of the absence of any time-windowed aggregation in roughly 135,000 lines, and of the DDS-free device protocol modules. github.com/mdpnp/mdpnp
- OpenICE_license.dat, committed in the OpenICE repository at interop-lab/demo-apps/src/main/resources and wis-docker/web_integration_service. Issued 3 May 2021 to "Non-Commercial User." Feature lines RTIDDS, RTISECURITY and RTIRECORD, each carrying "USE FOR COMMERCIAL PURPOSES IS PROHIBITED," Production=no and ExpiredAction=exit. Read directly from the cloned repository. github.com/mdpnp/mdpnp

- openice.info, the OpenICE documentation site, served from github.com/jeffplourde/openice. Last commit 18 December 2015. Still instructs the reader to install the Java 8 JDK and states that the project uses DDS version 5.1. openice.info
- Cloud multicast support. Microsoft: "Multicast and broadcast are not supported" in Azure virtual networks. Google: VPC networks "do not support broadcast or multicast addresses." Amazon: Transit Gateway multicast domains only, and "multicast routing is not supported over Direct Connect, Site-to-Site VPN, peering attachments, or transit gateway Connect attachments." learn.microsoft.com · cloud.google.com · docs.aws.amazon.com
- MD PnP program, OpenICE portfolio page, describing it as "an open-source reference implementation of the Integrated Clinical Environment (ICE) standard as published as AAMI 2700-1," developed under an NIH/NIBIB Quantum award and running on RTI's DDS implementation. mdpnp.mgh.harvard.edu/astra-portfolio/openice
- Barker W, Maisel N, Strawley CE, Israelit GK, Adler-Milstein J, Rosner B. "A national survey of digital health company experiences with electronic health record application programming interfaces." Journal of the American Medical Informatics Association 2024;31(4):866-874. 713 companies invited, 141 responded, 20 percent response rate after up to fifteen follow-ups. 41 percent named lack of realistic clinical testing data a substantial barrier; 47 percent named high API fees. doi:10.1093/jamia/ocae006
- Lye CT, Forman HP, Gao R, et al. "Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records." JAMA Network Open 2018;1(6):e183014. Simulated-patient telephone audit of 83 top-ranked US hospitals. Cited here as the methodological template for an availability audit, not for its findings. doi:10.1001/jamanetworkopen.2018.3014
- HL7 Caliper, "this new implementation community officially launched on January 1, 2026." Founding sponsors include Dexcom and GE HealthCare. Builds on the HL7 Devices work group and the HL7-IHE Gemini Device Interoperability Program. No public test endpoint found as of 26 August 2026, which is a statement about my searching and not a proven absence. hl7.org/caliper
- SMART App Launch, Backend Services, v2.2.0. Client credentials with a signed JWT assertion; RS384 or ES384 required; a TLS-protected JWKS URL is strongly preferred over a static key; access tokens SHOULD NOT exceed 300 seconds. Cited for why it is offered as optional rather than required. hl7.org/fhir/smart-app-launch/backend-services.html
- 45 CFR 164.514(a): information that "does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information." The basis for synthetic-only rather than de-identified. hhs.gov
- Published cloud pricing checked 26 August 2026. Cloudflare Workers paid plan $5.00 per month including 10 million requests. AWS API Gateway HTTP API $1.00 per million requests; AWS Lambda $0.20 per million. AWS HealthLake $0.27 per data store hour, roughly $197 per month before any traffic. Google Cloud Healthcare API storage $0.000328767 per GiB-hour after the first free GiB, requests $0.39 per 100,000 after the first 25,000 free. Azure Health Data Services publishes no figures. cloudflare.com · aws.amazon.com · cloud.google.com
- IHE North America Connectathon Week 2026, 12 to 16 October 2026, George Mason University, Arlington, Virginia. 2026 fees not published; the last published figures, for 2025 in Toronto, were $8,500 CAD per system registered plus $2,000 CAD per participant per week. iheusa.org
- Oracle Health Millennium Platform FHIR R4 API, POST /Observation. VitalSigns, Laboratory and Imaging categories, with System authorization available for backend server-to-server use. Cited because it disproves the convenient claim that certified EHR sandboxes are read-only. docs.oracle.com
- IHE Devices Technical Framework, Rev. 10.0, Final Text, 4 November 2024, Volumes 1 to 3. The domain was renamed from Patient Care Device, which is why transaction identifiers retain the PCD prefix. profiles.ihe.net/DEV
- IHE SDPi, v2.4.1, 7 May 2026, Trial Implementation. The gateway appendix line counts are measurable in the public repository at tag 2.4.1. github.com/IHE/DEV.SDPi
- HL7 FHIR Point-of-Care Device Implementation Guide. Version history and ballot status from the guide's own package-list.json. Currently 1.0.0-ballot3, September 2026 ballot cycle, built on FHIR R4, never published. hl7.org/fhir/uv/pocd
- HL7 Caliper, device interoperability FHIR accelerator. Launched early 2026. Technical Director Todd Cooper. hl7.org/caliper
- 21 U.S.C. 360j(o), added by the 21st Century Cures Act section 3060, Pub. L. 114-255, 13 December 2016. The exclusion is subsection (o)(1)(D), and it runs "for transferring, storing, converting formats, or displaying clinical laboratory test or other device

data and results … unless such function is intended to interpret or analyze" them. The trailing clause is quoted in full in Part 1 because it is the one that binds. uscode.house.gov

- 21 CFR 880.6310, Medical Device Data System. Class I, exempt from premarket notification. Amended 19 April 2021 to apply only to hardware, conforming the regulation to the Cures Act. ecfr.gov
- FDA, "Clinical Decision Support Software," final guidance, issued 29 January 2026. Its supersede line names one predecessor, the version issued 6 January 2026, which in turn displaced the September 2022 guidance. Docket FDA-2017-D-6569. Source of the "continuous, near-continuous, or otherwise streaming" language and of worked examples 20, 21 and 24. The September 2022 text, archived at hhs.gov, carries the same Criterion 1 sentence without the parenthetical, which is how the change was confirmed. fda.gov/media/109618/download
- Hyman, Phelps & McNamara, FDA Law Blog, January 2026, reading the new parenthetical as clarification rather than expansion on the strength of the 2022 "continuum between a single sample and a continuous sample" language. Cited because it is the strongest published counter-reading and the memorandum should not pretend it does not exist. thefdalawblog.com
- FDA, "Medical Device Accessories: Describing Accessories and Classification Pathways," final guidance, 20 December 2017. Independent classification of accessories is statutory, at 21 U.S.C. 360c(f)(6)(A), added by the FDA Reauthorization Act of 2017. fda.gov
- NITRD/HITRD Interagency Working Group, "The Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care," March 2020. Source of the finding that little progress has been made, and notable for mentioning neither ICE nor MD PnP. nitrd.gov
- National Academies of Sciences, Engineering, and Medicine, "Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care," 2018. nap.nationalacademies.org
- ASTM F2761 withdrawal notice, last updated 16 August 2017, no replacement within ASTM. Successor standard ANSI/AAMI 2700-1:2019, in reaffirmation as of the AAMI Standards Monitor of 15 May 2026. store.astm.org
- eICU Collaborative Research Database v2.0, vitalPeriodic table documentation. One-minute averages archived as five-minute medians. eicu.mit.edu
- MIMIC-IV Waveform Database v0.1.0, released 10 July 2022 as a technical preview ahead of a v1.0.0 "intended to be released shortly." Still v0.1.0 with 200 records. physionet.org
- Draft United States Core Data for Interoperability version 7, January 2026. The Medical Devices data class contains two elements. healthit.gov

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Daniel Pettus spent forty years in medical device and health IT leadership at Alaris, CareFusion and BD, contributed to IHE Patient Care Device interoperability standards, and is named on two United States patents with three provisional applications filed on the continuous reasoning method behind AI MedAgent. He writes Inside the Loop at insidetheloopdp.substack.com and is the author of The Technology Was Never the Problem, at pettusbook.com, which is about this subject and how forty years of it actually went. This memorandum is engineering analysis, not clinical guidance. AI MedAgent is a research demonstration. Advisory only. Not a medical device. Not for clinical use.