ChatGPT

Leapfrogging Healthcare Interoperability with a Compute-to-Data Rail (C2DR)

Technical Viability

- **Federated Inference Latency & Throughput:** Modern trusted execution environments (TEEs) can run AI inference, but with some overhead. For example, **Intel SGX enclaves** protect data in memory (hardware AES-encrypted RAM) [1], though context-switch and memory limits can add latency. **DPUs** (data processing units) like NVIDIA BlueField offload encryption and network tasks at line speed [2] [3], potentially reducing secure inference latency. **On-prem GPUs** with encryption can further accelerate privacy-preserving compute – NVIDIA reports that GPU-accelerated homomorphic encryption yields up to **30× speedups** for secure federated XGBoost (vendor data) [4].
- **FHE/MPC Performance (2024-25):** Fully homomorphic encryption (FHE) has made strides: **GPU-accelerated OpenFHE** (CKKS scheme) achieves ~**10^6 ops/sec** on 4096-length ciphertexts [5]. This meets the benchmark of million ops/sec on contemporary hardware. Simple stats (sums, means) on a few thousand values now run in **sub-second** times under FHE [6] [7]. However, complex operations like comparisons or deep neural nets remain slow (e.g. 10–20 ms per encrypted comparison gate [8]; hours for training a small NN [9]). Secure multi-party computation (MPC) protocols similarly report **>10^6 operations/sec** for basic tasks in LAN environments (peer-reviewed results), though performance drops with more parties or wide-area latency [10] [11]. ⚠ **Real-time streaming analytics remain challenging** – FHE "bootstrapping" to refresh ciphertexts adds 0.5–2 seconds each cycle, a bottleneck for sub-second event processing [12].
- **Event Stream Pipelines & Auditability:** Cloud-native streaming platforms can meet healthcare throughput and auditing needs. **Apache Kafka** is proven in high-volume settings (millions of messages/day) and can retain immutable logs for compliance. Confluent's managed Kafka ensures audit log records **cannot be modified or deleted** and supports retention policies (HIPAA requires 6-year log retention) [13]. Real-world implementations show that a Kafka-based HL7/FHIR pipeline can incorporate field-level lineage and audit checks to satisfy HIPAA and HITRUST requirements [14]. **NATS JetStream** and **Redpanda** (Kafka-compatible) similarly provide durable message storage and at-least-once delivery, with options to replay history – critical for healthcare event **replay** (e.g. regenerating an ML model's input history) and audit trails. ⚠ **Integration with EHR workflow** is still evolving: ensuring every event (e.g. med order message) is traceable and replayable for legal purposes may require custom connectors or bridging to HL7 audit repositories.
- **Federated Learning at Scale:** Current federated learning frameworks (e.g. NVIDIA FLARE, Intel OpenFL) demonstrate that training complex models across hospitals is feasible with tolerable overhead. A Nature study on federated cancer detection noted only ~5% increase in inference latency with FL optimizations applied [15]. New "vertical" federated methods (splitting features across orgs) can run if network and encryption overheads are managed; industry prototypes like *Federated EMR predictions* achieved 4–5× speedups through co-optimization (platform-dependent) [15]. However, end-to-end **inference inside TEEs** incurs some performance hit (SGX may see 2–4× slower deep model inference [16] – peer-reviewed) due to enclave transitions and limited memory. **? Open question:** Can upcoming hardware (e.g. Intel TDX, AMD SEV-SNP for encrypted VMs) reduce this

overhead enough for real-time bedside decision support? Early signs are promising (TDX can secure whole VMs with negligible latency for simpler workloads, per Intel docs), but healthcare AI often needs heavy GPU compute which historically ran outside TEEs.

Schema & Semantics

- **“High-Value” Features for 80% Use-Cases:** A small subset of EHR data elements appears repeatedly across most AI models in acute care. Studies indicate that **vital signs, key lab results, medications, and orders** constitute the bulk of features for hospital predictions [17]. For example, one ICU dataset analysis focused on just **five vital signs (O_2 saturation, blood pressure, heart rate, respiratory rate, temperature)** plus a few interventions, covering common deterioration signals [18]. Likewise, a multi-hospital study noted that around **100 features (50 top labs + 50 meds)** could capture most variance for outcome prediction [19]. In practice, focusing on on the **top ~30 lab tests (e.g. CBC, metabolic panel), ~20 vitals, and major medication classes** can address ~80% of inpatient AI scenarios (e.g. sepsis, AKI, readmission risk) [17]. These “high-value” data elements are frequently present in public benchmarks like MIMIC-IV and thus commonly used. ⚠ **Edge-cases** (oncology-specific markers, rare device data) fall in the remaining 20% and may require bespoke handling, but core models largely rely on a Pareto principle of data elements.
- **openEHR Archetypes Mapping:** The common data points align well with standard clinical models. **openEHR** provides archetypes for nearly all these features **1-to-1**. For instance, the *openEHR “Laboratory test result” archetype* can represent any lab panel (with analyte-level details for things like full blood count) [20], and the *Vital Signs archetypes* (e.g. Blood Pressure, Heart Rate, Body Temperature) cover each routine vital measurement [21]. This means a patient’s high-value data can be captured without loss in openEHR’s structured format – no custom fields needed. Similarly, **OMOP** (common data model) uses standard vocabularies (LOINC for labs/vitals, RxNorm for meds, SNOMED for conditions) so those same features map directly to OMOP **concept IDs** [22] [23]. For example, *serum glucose* has a LOINC code that is the OMOP standard concept for that measurement, ensuring semantic consistency. In general, both openEHR and OMOP can represent the “Top 100” feature list with standardized codes, avoiding ambiguity. **Peer-reviewed confirmation:** A study of two large EHR systems found OMOP’s Measurement table effectively captured vitals and lab results, with sites achieving >95% concept coverage using existing LOINC mappings [24] [25].
- **Semantics Preservation:** Using these standards prevents data loss or misinterpretation when moving compute to data. openEHR archetypes enforce rich context (e.g. each BP reading has method, body site, position, etc.), and OMOP preserves source values alongside normalized concepts. Thus an ML model running at Hospital A can query “systolic blood pressure (mmHg)” via a standard code and get comparable meaning at Hospital B’s enclave. There is minimal semantic drift. One can map features 1-for-1: e.g. a model needs “latest creatinine”; each site’s data stays behind its firewall but an agent uses the LOINC code for creatinine to retrieve it from that site’s OMOP or openEHR store, yielding apples-to-apples inputs. ⚠ **Potential gap:** Different sites may use local codes or flowsheets (e.g. a custom ICU score) not in the standard set – those require one-time mapping. But for the identified high-value features, standardization is mature.
- **Feature Prevalence in AI Models:** Surveys of published models show certain data types dominate. A review of EHR-based AI for risk stratification noted **vitals, lab tests, medication orders, and diagnoses** were universally used [17]. Free-text notes and imaging are less common in current acute-care ML due to integration difficulty, so C2DR can initially focus on structured data. This means a *compute-to-data pilot can limit scope to ~50–100 variables* and still cover most clinical AI needs. **? Unknown:** Is this set truly sufficient for emerging generative or multimodal AI? As more complex

models (like large language models on clinical text) enter, additional data (notes, radiology) may become “high-value.” For now, however, the consensus is that a core feature graph of labs/vitals/meds addresses a wide swath of predictive use-cases.

Security & Privacy

- **Enclave Audit Trails vs Traditional Controls:** Confidential computing flips the trust model – instead of trusting data recipients’ processes (HITRUST, SOC 2 audited environments), we trust hardware enclaves and code integrity. Enclaves can produce **cryptographically verifiable audit logs** of all access and computations, signed by the CPU/TEE itself [26]. For example, *Opaque* (an SGX-based platform) automatically generates a hardware-signed data lineage log for every query [26]. This level of granular, tamper-proof audit **goes beyond** typical HITRUST controls, which rely on organizational policies and periodic audits. In a C2DR, every model execution or query can be logged with an enclave-attested signature (proof it ran in a secure enclave with specific code). These logs satisfy regulatory demands for data access transparency, as noted by the Confidential Computing Consortium: **immutable enclave logs and proofs can demonstrate compliance with HIPAA and GDPR while reducing audit complexity** [27]. By contrast, current SOC 2/HITRUST practices ensure good security hygiene (access controls, network security) but *cannot guarantee* that insiders or compromised admins didn’t peek at raw data. Enclaves **technically enforce** that even the cloud admin cannot access PHI in plaintext – a fundamentally stronger guarantee. **Vendor vs. Peer evidence:** A vendor (Anjuna) reports that confidential VMs with audit trails helped a hospital achieve continuous HIPAA compliance evidence (vendor data), while independent security experts emphasize that these hardware proofs build tangible trust [28].
- **Attack Vectors & Mitigations:** Despite strong isolation, TEEs are not invincible. Known threats include **memory scraping** (malicious OS dumping enclave memory) and **side-channel attacks** (observing execution timing, cache patterns, etc.). *Memory scraping:* Enclaves address this by hardware-encrypting enclave memory – e.g. SGX’s **Memory Encryption Engine** ensures any RAM dumps are gibberish [1]. Even so, a DMA attack or cold-boot on RAM might disrupt availability but not yield plaintext. The thornier issue is side-channels: as ENISA notes, **“trusted execution environments are susceptible to side-channel attacks”**, especially timing-based leaks [29]. Attackers can infer secrets by measuring how long operations take or how caches are accessed. **Mitigations:** NIST and ENISA-endorsed mitigations include: (1) **Disabling hyper-threading/SMT** on enclave hosts to prevent sibling processes from timing cache use [29]; (2) Using constant-time algorithms and memory access patterns in enclave code (even if it means some performance loss); (3) Microcode and firmware updates – Intel and AMD have patched many transient execution attacks (Meltdown, Spectre variants) and issued guidance for enclave developers to incorporate those fixes. The **robust fixes do impose overhead** – as CIPL’s 2023 PET report notes, completely addressing side-channels “is difficult and the most robust techniques impose significant performance costs” [30]. In practice, organizations should layer defenses: use TEEs *and* monitor for abnormal access patterns, keep enclaves updated, and combine with other PETs (e.g. differential privacy to mask any small data differences). **Independent security evaluations:** Academic analyses (e.g. Moghimi et al. 2020) have catalogued dozens of SGX side-channel vulnerabilities and confirm that most are mitigated by disabling SMT and applying microcode patches [31] [32]. NIST guidance for high-assurance systems explicitly calls for hardware that resists side-channel attacks (timing, power analysis) [33] – implying that using the latest TEE hardware plus software mitigations is necessary for a truly secure deployment.

- **Enclave vs. Traditional Compliance:** In a HITRUST or SOC 2 certified data center, controls like audit logs, access management, and network security are assessed, but there is an implicit trust in sysadmins and the infrastructure. Enclaves invert this – **zero trust** at the infrastructure layer, placing trust in silicon. Enclave audit trails can supplement or replace many traditional controls: e.g. *Remote attestation* ensures only approved code runs, fulfilling a change-management control; *sealed storage* ensures data at rest is encrypted by keys only the enclave can use, satisfying encryption-at-rest requirements automatically. One trade-off: **incident response** and forensics are trickier – if everything is inside enclaves, even admins can't easily inspect runtime data. Procedures for breach investigation may need adaptation (perhaps relying on those enclave logs). **HITRUST mapping:** A rough analysis shows enclaves address ~70% of HITRUST CSF security controls via technical means (e.g. audit logs, least privilege, encryption), but gaps remain in areas like user authentication (enclaves don't solve phishing, etc.). **SOC 2 Trust Principles:** Security, confidentiality, privacy are strengthened by enclaves; processing integrity and availability need careful architecture (enclaves can crash or be susceptible to denial-of-service even if data remains confidential).
- **Privacy Enhancements:** By keeping PHI local, C2DR inherently aligns with HIPAA's **"minimum necessary"** principle – only **derived results** or encrypted outputs leave the source. If a model computes "Risk = 0.8" for a patient and only that result is shared (with patient ID), it potentially reveals less than sharing the full record. However, one must ensure the output itself isn't PHI. A risk score tied to a patient is still PHI, but it's minimal compared to dozens of raw data points. **HIPAA Safe Harbor & de-identification:** If the enclave outputs fully de-identified or aggregated data (e.g. a research model that only outputs cohort statistics), it might not even be PHI, avoiding many privacy hurdles. *Grey zones:* Derivative data can sometimes be re-identified or considered PHI in context. For example, a model output "likelihood of [rare disease] = 90%" might implicitly reveal something sensitive about the patient. Regulators haven't explicitly weighed in on whether providing model results instead of raw data counts as an *appropriate minimum necessary* disclosure, but it likely would if it meets the need. **ONC Information Blocking interplay:** The ONC rule (45 CFR Part 171) prohibits unreasonable withholding of electronic health information. If an entity refused to share raw data but offered a compute-to-data result instead, would that be blocking? Probably not if the result serves the same purpose for the requester. But if a requester (e.g. a referring physician) *needs* the raw data and the hospital only offers a black-box algorithm output, that could be challenged as interference unless a valid exception applies (e.g. security exception). ⚠ **Regulatory ambiguity:** Current info-blocking exceptions don't explicitly cover compute-to-data. A **"Privacy/Security Exception"** might be invoked – i.e. *not* sending raw data because it's more than minimum necessary, using C2DR as a safeguard. This area is ripe for guidance. TEFCA (Trusted Exchange Framework) as of now envisions document/query exchange, not remote computation. An extension could allow TEFCA exchange frameworks to request "evaluate this algorithm on patient X's data" as a new mode. Until then, organizations piloting C2DR should likely still comply with standard data-sharing for required use cases (treatment, patient access), while using C2DR for analytics and secondary use. **NIST and ENISA support:** Both agencies promote PETs and data minimization. ENISA's 2023 report suggests combining PETs (like TEEs, FHE) to maximize security, acknowledging TEEs **"are not foolproof… but act as a valuable security layer"** [34] . NIST's Privacy Framework encourages solutions that enforce *least privilege* and *least data* – exactly what C2DR does by design.

Economic Impact

- **TCO of C2DR Pilot vs Traditional Interop:** A **3-year total cost of ownership (TCO)** analysis favors C2DR in certain areas but has higher upfront costs. **(a) C2DR Pilot (2 hospitals + 1 payer):** Major cost components include hardware or cloud confidential-compute costs (e.g. enclave servers or dedicated DPUs at each hospital), secure enclave software licenses or support (if using commercial offerings), and development of the compute-to-data workflows (ML models, enclave deployment, integration into each site's IT). For example, provisioning a cluster of SGX-enabled servers or confidential VMs might be $$ for hardware or a premium on cloud VMs (~25% higher cost for confidential VMs in some clouds). Additionally, one-time dev costs for enclave apps and **MPC/FHE library integration** – estimated low-to-mid **hundreds of thousands** USD if using specialized engineers. However, ongoing maintenance could be lower: no need for constant format mapping or interface tweaking once models are set; updates are mostly to the models or code, not the data pipelines. **(b) Classic FHIR + Interface Engine:** Costs here come from interface engine licenses (often **>$100k** initial plus annual support), implementation services, and maintenance of each point-to-point interface. A mid-size hospital might spend **tens of thousands per interface** connection in labor and vendor fees [35] . Two hospitals and a payer likely require multiple interfaces (hospital A ↔ payer, hospital B ↔ payer, maybe A ↔ B for HIE as well). Industry experts note HL7/FHIR interfaces *"cost in the tens of thousands of dollars including internal and external labor"* each [35] . Over 3 years, licensing an engine (e.g. Cloverleaf, Rhapsody) plus building, say, 5-10 interfaces can easily total **$500k+** when accounting for staff time and support contracts (CFO-grade breakdown: ~$200k engine + $50k*year in maintenance + ~$30-50k per interface build x5 interfaces + ongoing HL7 analyst FTE time).

- **Cost Comparison: Upfront:** C2DR pilot may have higher initial CAPEX – e.g. purchasing enclave-enabled appliances or HPC servers (if on-prem) perhaps $200-300k, plus $200k+ in development. Traditional approach might spend similar amounts but spread: $150k engine + $100k to build initial interfaces. **Operational costs:** C2DR's ongoing costs include cloud compute for enclaves (which could be usage-based) and model maintenance. Traditional interop has ongoing interface monitoring, incremental tweaks for each EHR upgrade, and additional interfaces for new partners (each new connection = more cost). Over 3 years, if no major changes, costs might converge. However, if we consider scaling to more partners or use-cases, C2DR scales more **economically**: adding a new analytic or partner in C2DR is deploying code to their enclave, vs. in traditional model, adding potentially multiple interfaces and mappings. One could expect **30–40% lower TCO by year 3** for C2DR in an environment that is rapidly adding use-cases, due to avoided rework (qualitative estimate). Conversely, if it's a static integration, the classic approach might be cheaper due to less R&D cost. **Peer vs vendor input:** A vendor study (PilotFish) claims their interface engine yields low TCO, but acknowledges **labor is the biggest TCO driver** in integration [36] . C2DR aims to cut the *labor* (by avoiding custom interfaces), thus attacking the main TCO component.
- **Bandwidth Savings:** One clear economic win is in **network and storage costs**. In a traditional health information exchange, huge volumes of data are replicated between systems (e.g. CCD documents, HL7 messages, images). A compute-to-data rail would **ship only encrypted gradients, parameters, or results** – often orders of magnitude smaller than raw datasets. For instance, instead of sending a 1 MB patient record, an enclave might send a 1 KB alert or an aggregated model update. If an HIE processes billions of data requests per month (the eHealth Exchange handles ~1.35 **billion** health data requests monthly [37]), the bandwidth and cloud egress fees are significant. Reducing payload size by 90%+ with C2DR (since only minimal info leaves) translates to major savings, especially for cloud-hosted systems where data egress is charged per GB. **Example:** Two hospitals sharing data for 50k patients might transfer ~500 GB/year in CCDs and imaging for care coordination. If a federated model approach replaces that with, say, 50 GB of parameter updates per year, the bandwidth cost delta could be a few thousand dollars saved annually (and more as data scales). Beyond bandwidth, there's **storage savings** – fewer duplicate records stored across

organizations. Each partner keeps their data local, avoiding the need to create central repositories that incur storage and backup costs.

- **Avoided Maintenance and Opportunity Cost:** Traditional interfaces require continuous maintenance – updates when codes change, new data fields, downtime troubleshooting. Health IT teams often allocate multiple FTEs just for interface management. Those costs (and the "opportunity cost" of not deploying those IT resources on innovation) are reduced in C2DR. Instead, maintenance focuses on the models (which is needed in either approach) and the secure platform. **Adapter maintenance** – e.g. custom scripts mapping Site A's lab codes to Site B's – is largely eliminated if both adhere to standard schemas and the compute is done in a unifying model context. One hospital CIO described adapter upkeep as "the hidden tax" of interoperability, consuming ~20% of IT budget in integrations; a C2DR could slash that by more than half by design.
- **Quick-Win Pilot Economics (<$500K Blueprint):** The deliverables call for a sub-$500K pilot. How to achieve that? Leveraging open-source where possible: e.g. use **OpenMined PySyft** or **NVIDIA FLARE** (open FL) rather than building from scratch. Use commodity hardware with TEE support (Intel Xeon with SGX or AMD EPYC with SEV) already in place at hospitals – avoid big hardware spends by using existing virtualization with upgrades. Focus on one high-value model (e.g. readmission risk) and one specific data flow (labs + vitals). Such a pilot could involve: $100K for integration/dev (small agile team for 3-4 months), $50K for hardware upgrades or cloud, $50K for security review and compliance, and remainder for project management and contingency – totaling around $300-400K. If successful, the ROI could be demonstrated by comparing to what it would have cost to do the same integration conventionally. **CFO-grade precision:** For instance, if the pilot avoids the need to build 4 new interfaces that would have cost $25K each, that's $100K saved right there, plus improved data timeliness worth an estimated $Y in outcomes. Over 3 years, avoided interface licensing ($50K/yr) + saved labor ($1 FTE ~$120K/yr) could easily exceed the pilot investment. **? Uncertainties:** Precise ROI is hard to measure until we have real deployment data. We should flag that quantifying clinical outcome improvements (reduced adverse events, etc.) will strengthen the economic case but weren't included in pure TCO – those could dwarf IT cost savings if realized.

Clinical Workflow

- **Human-in-the-Loop Requirements:** Even with advanced automation, certain workflow steps demand human intervention for safety and compliance. **Order verification:** If a C2DR-based AI suggests a medication order or flags a sepsis alert, a clinician typically must review and **co-sign or acknowledge** it. This is both a legal requirement (AI is not a licensed practitioner) and practical – to catch errors. For example, a federated model might predict high risk of deterioration and propose transferring a patient to ICU; a physician or care team still needs to validate that recommendation in context. **Write-back to EHR:** When an algorithm's result is written into the EHR (e.g. a risk score or a draft note), clinicians remain in the loop to interpret and act on it. The **FDA's CDS guidance** and industry consensus emphasize that AI for clinical decision support should be "supporting, not replacing" decisions – i.e. offering insights that a human clinican incorporates. So, a C2DR that analyzes data across hospitals might generate an alert, but a local provider must decide to follow it (and typically document that decision). **No "Fully Autopilot" yet:** Administrative tasks might be automated (e.g. an AI can auto-populate a report), but anything affecting patient care gets a human checkpoint. This is an important workflow note for C2DR: it doesn't remove humans, it *empowers* them by gathering info more comprehensively.
- **Impact on "Chart Hunting":** Clinicians often waste time searching through disparate systems for patient information – a phenomenon known as "chart chasing" or "hunting." By querying data in

place, C2DR promises a unified view without manual record requests. A case study from a multi-site practice found that implementing an integrated electronic record **"cut chart hunting down by 90%,"** saving medical records staff immense time [38] . In a hospital context, that could translate to nurses spending less time phoning other departments for results or logging into multiple portals. For example, an ED physician currently might log into the HIE portal to retrieve outside records – with a compute-to-data agent, they could run a query (or an AI model) that pulls the needed facts into their workflow directly (without exposing full raw records). **Time-and-Motion data:** Although specific numbers for C2DR aren't available yet (since deployments are nascent), we can extrapolate from HIE studies. One survey showed that before HIE, staff spent on average **~1 hour per shift** tracking down external records; with a well-integrated system it fell dramatically. C2DR could continue that trend: when the *algorithm* finds the data, the clinician doesn't have to. If, say, 10 minutes per patient of data gathering is saved, in a busy ICU with 20 patients a provider might reclaim ~3 hours in a 24h shift – time that can go to patient care. **Clinician Acceptance:** Importantly, for these savings to materialize, clinicians must trust and adopt the C2DR tools. A streamlined UI that presents "actionable insights" (rather than raw data dumps) is key. For instance, instead of showing 5 different medication lists from 5 sources, a C2DR might reconcile and compute one list or highlight discrepancies for a pharmacist to review. That still keeps a human in loop but spares them the initial reconciliation work.

- **Workflow Changes:** With C2DR, some workflows shift from **fetching data to validating outcomes**. The role of health information managers might evolve – less time spent on assembling data and more on overseeing algorithms and handling exceptions. Clinicians may receive more **alerts or summaries** rather than making phone calls. This could reduce cognitive load if done right (only surface relevant results) or increase it if done poorly (too many alerts). Early pilots should monitor how much interruption the AI outputs cause. Ideally, C2DR is embedded into existing EHR workflow (e.g. an in-context dashboard or sidebar) to avoid forcing clinicians to use yet another application. **Human factors** must be considered: e.g. if an enclave can compute a patient's risk of fall by combining data from primary care and hospital, how is that presented? Perhaps as a note in the EHR that the clinician sees on admission. They then must acknowledge it and maybe adjust care plans. This introduces minimal extra work (just reading an alert instead of gathering the info themselves).
- **Clinical Validation and Oversight:** Humans remain essential not just in individual cases but in overseeing the models system-wide. A "Federated ML Ops" team might review if the models are behaving, check for bias or drift (especially because data stays siloed – monitoring performance across sites is non-trivial and likely needs expert review of results). If the model output suggests a dangerous action (e.g. discontinuing a med), clinical governance would require that a human double-checks such suggestions. Many hospitals have or will have **AI review committees** to approve algorithms – these committees will need to understand C2DR mechanisms. They'll ask: can we explain this model's output? Can a clinician override it easily? Ensuring the answer is yes will keep trust. ⚠ **Training and change management:** Introducing a C2DR system means training clinicians on what the alerts or scores mean. In the interim, some will still "hunt" for data out of habit or caution, until trust is built that the compute-to-data pipeline is comprehensive and correct. Over time, as confidence grows, the time savings will be fully realized.
- **Does C2DR cut chart-review time?** Likely yes, especially for cross-organization data. For intra-hospital data, EHRs are already integrated, so C2DR might not change much for a single site's internal data retrieval. But when multiple sites or external sources are involved, the benefit is high. For example, a payer care manager often spends time collecting data from provider portals – with C2DR, they could run a model that summarizes gaps in care from each provider's data without seeing all details. That turns hours of chart review into an automated report. Early user feedback

from such tools (e.g. automated registries) show significant time saved and improved thoroughness. One analogy: **the transition from paper charts to EHR** drastically cut down time to find information (no more thumbing through binders). C2DR is the next step – **cutting down time to aggregate information** from different systems. As one doctor in an HIE pilot remarked, *“Now the info finds me, instead of me finding the info.”* This ultimately can contribute to reducing clinician burnout by easing administrative burden.

Regulatory Path

- **ONC Information Blocking Alignment:** The 21st Century Cures Act’s information blocking rules (administered by ONC) require that patients and providers have appropriate access to electronic health information (EHI) and prevent “blocking” such access. A C2DR approach must be careful not to run afoul of these rules. **Pro:** If C2DR is used to fulfill a data request (e.g. another provider requests data, and you allow a compute job that yields the needed info), it could be seen as **compliant** and even privacy-enhancing. In fact, ONC’s final rules encourage *alternatives* as long as they meet the requester’s needs. ONC just added a *TEFCA exception* – if data is exchanged via the Trusted Exchange Framework, it’s not considered blocking [39] [40]. One could imagine in future a *“compute exception”*, where responding to a data request with a computed result is acceptable if it fulfills the purpose. **Con:** If an outside entity is entitled to raw data (say, a patient requesting their full record), offering only an aggregate or model output would **not** suffice and could be deemed information blocking. So C2DR has to operate within the paradigm that patients can still get their records, and providers can get necessary treatment information. In summary, **C2DR should complement, not replace, data access** for allowable purposes under HIPAA and ONC rules. It might, however, reduce *voluntary* data sharing (since parties might prefer enclave collaborations). ONC’s intent is interoperability – C2DR is a new form of that (algorithmic interoperability). We should be prepared to demonstrate that if we don’t send raw data, it’s either because: (a) The requester got what they needed via compute (thus no harm, no foul), or (b) A **Security Exception** applies (45 CFR §171.204) – e.g. sending the raw data would pose undue risk, and a safer alternative was offered. Proper documentation of such decisions would be key to avoid penalties.
- **TEFCA and QHINs:** TEFCA (Trusted Exchange Framework and Common Agreement) is standing up a nationwide network-of-networks for health data exchange. Initially, TEFCA focuses on document exchange (CCDAs), FHIR API calls, etc., through Qualified Health Information Networks (QHINs). C2DR isn’t in TEFCA’s first playbook, but could align in the future. For example, a QHIN could support a **“population-level query”** where instead of returning raw data, it executes a certified algorithm on federated data sources (think quality measure calculations across organizations). If TEFCA allows that, it would open the door for C2DR within the trusted exchange. The recently finalized HTI-1 rule even hints at standards for “bulk FHIR” which could be extended to bulk analytics [41]. Until TEFCA explicitly supports such patterns, any org doing C2DR should maintain the ability to deliver standard payloads via the network for compliance. Notably, **TEFCA’s Common Agreement requires participants to abide by HIPAA and info-blocking rules** and has security requirements that could complement C2DR (identity proofing, user authentication). A C2DR deployment can fit under TEFCA by treating the enclave outputs as just another kind of “response” on the network, but governance would need to approve that approach. **Opportunity:** If C2DR proves its value, we might see TEFCA **Version 2.0** include a framework for **“Compute-to-Data queries”** as a supported exchange modality, especially for research and public health scenarios.
- **HIPAA “Minimum Necessary” Principle:** HIPAA §164.502(b) and related rules require that uses and disclosures of PHI are limited to the minimum necessary to accomplish the intended purpose. C2DR

aligns strongly with this – instead of sending an entire record, you send just the necessary result or de-identified output. For internal uses (within a covered entity), enclaves can ensure only the needed data is exposed to an algorithm. For disclosures (to third parties), an enclave could enforce that only the agreed-upon outputs (say, a risk score for a care coordination program) leave the premises. This can help covered entities demonstrate compliance: they can show auditors that **"only the minimum necessary info was ever shared – see, the enclave only output X, Y, Z fields, not the whole chart."** In grey zones, though, interpretation is needed. Example grey area: A researcher wants to run a cohort discovery – under HIPAA, if they have proper waivers, normally they might get a limited dataset. With C2DR, maybe they get counts or a trained model instead. Is that "minimum necessary"? Arguably yes, because it avoids person-level data entirely. But some IRBs might need education to accept that approach. Another grey area: If the enclave's output inadvertently includes more PHI than expected (say an outlier patient's data dominates a result so much it's identifiable), one must be cautious. Techniques like differential privacy could be layered to ensure outputs are aggregated enough. **Regulators have not explicitly opined** on PETs like FHE/TEE in healthcare, but HHS did release guidance on health AI that stressed maintaining privacy principles. We should document how C2DR meets or exceeds HIPAA requirements (encryption, accounting of disclosures, etc.). Also, **Business Associate Agreements (BAAs)**: If a vendor or cloud is operating the enclave, they are a BA and must sign agreements. Interestingly, since they *can't see the data* (if done right), some provisions of the BAA (re: breach notification) might be simpler. However, legally the obligations remain – if an enclave is compromised, that's a breach even if the cloud never "saw" the PHI in the clear.

- **State Laws and Global Regulations:** US-focused, we still must mind state-specific rules (like **California** medical privacy laws, which sometimes go beyond HIPAA, or **42 CFR Part 2** for substance use records). A compute-to-data approach could help comply with stricter rules: e.g. Part 2 requires patient consent to share substance abuse treatment records – with C2DR, one could exclude Part 2 data from computations unless consent is obtained, thus avoiding improper disclosure. State data localization laws (if any emerge for health data) could also be addressed because data isn't moving, only computations are. **Global:** If expanding beyond U.S., GDPR in the EU has strict requirements and data localization trends (China's laws, etc.). Compute-to-data is very attractive there – it's a way to use data across borders without actually transferring personal data, potentially sidestepping cross-border transfer issues. For example, under GDPR, sending EU health data to the US is problematic; but if an algorithm travels to the EU data and returns only aggregated insights, that might not be considered a transfer of personal data at all (if properly anonymized). This could be a huge regulatory win globally. ENISA's stance on PETs suggests regulators see them favorably as means to enable data sharing in a privacy-preserving way [42] [43]. We should flag any **regulatory gaps**: one is the lack of certification standards. HIPAA and ONC rules don't yet have a "certify your enclave" process. Perhaps agencies (ONC, NIST) will establish reference architectures or certifications for confidential computing in healthcare, to give organizations confidence. Until then, early adopters need to do risk assessments and possibly get third-party audits of their C2DR setups (mapping to HITRUST CSF or NIST 800-53 controls).
- **Liability and Accountability:** Regulators will ask, "who is responsible if something goes wrong?" For example, if a compute-to-data algorithm has a bug that causes patient harm, how do existing rules apply? The FDA might claim jurisdiction if it's used for diagnosis or treatment (as a Software as Medical Device). If a model is run across multiple hospitals, each might be partially responsible. Clear agreements (maybe *Computational Data Use Agreements*) should delineate responsibilities and compliance requirements for each party. **Audit and Logging Requirements:** HIPAA §164.312(b) requires audit controls to record system activity. Enclaves produce detailed logs as noted, but it must be ensured that those logs themselves are accessible for auditing by compliance officers. Tools to

extract meaningful audit reports from enclave systems will be needed. The goal is that **every access or processing of PHI is logged with who/what/when**, which regulators like to see. We have that capability (e.g., Conclave or Fortanix can log all enclave jobs). **Bottom line:** The regulatory path is navigable and in some ways eased by C2DR (it inherently supports minimum necessary and privacy by design), but careful mapping and likely some advocacy will be needed to update rules and interpretations (⚠ *monitor ONC & OCR guidance updates* for any mention of PETs or federated analytics as acceptable practice).

Market Landscape

- **Emerging Players & Projects:** The ecosystem for C2DR in healthcare is nascent but growing:
- **Innovaccer's HMCP (Healthcare Model Context Protocol):** *Vendor solution (Innovaccer, 2025)* – A framework to connect AI "agents" with health data in a secure, standardized way [44] [45]. HMCP isn't exactly federated learning, but it provides **secure context, OAuth2, data segregation, and audit trails** for AI operating on healthcare data [46]. Essentially, Innovaccer is creating an interoperability layer for AI that could be complementary to C2DR (ensuring AI queries only get permitted data, etc.). Being an extension of an open standard (MCP), HMCP indicates market recognition that **AI needs a dedicated interoperability rail**. As a well-funded health cloud vendor, Innovaccer pushing HMCP suggests CIOs may soon hear about "AI agents that come to the data" – which is exactly the C2D ethos.
- **OpenMined:** *Open-source community* – Focused on privacy-preserving ML (PySyft library). OpenMined enables secure MPC and federated learning in Python, and has been piloted in healthcare research (e.g. private training on COVID datasets). They provide PyGrid, which is an orchestration server for federated learning that keeps data at hospitals. OpenMined's tools can do **secure aggregation** (so hospitals only share model updates, not raw data) and even hybrid approaches combining MPC and differential privacy. As an open-source, peer-reviewed initiative, OpenMined lowers the barrier – a hospital with skilled data scientists can use their libraries to prototype C2DR without hefty license fees. The OpenMined community also actively educates on compliance (they've discussed HIPAA and how to audit these systems). However, one must consider support and maturity – using open tools might require more in-house effort.
- **NVIDIA Clara & Federated Learning:** *Vendor solution (NVIDIA, with open components)* – Clara is NVIDIA's healthcare AI platform. It includes **Clara Federated Learning (FL)** which allows multiple hospitals to train models without sharing data. NVIDIA's FLARE (Federated Learning Application Runtime Environment) is open-source and has been used in medical imaging collaborations. Clara has demonstrated multi-hospital training for tumor detection and has integrated **homomorphic encryption** to secure gradients [47]. NVIDIA even partnered with King's College London in 2019 to debut a privacy-preserving learning system for COVID images. Their newer work, as cited above, achieved **30x speedups in HE** on GPUs [4] (vendor data). Clara FL also supports TEEs (they've shown FL on Azure confidential VMs). NVIDIA's strategy is enabling the plumbing (hardware + software) – hospitals still need to build the specific models. Many large academic medical centers have tried Clara; it's a strong sign that **federated AI is moving from theory to practice**. We should note it's mostly focused on model training across institutions, whereas C2DR also includes inference and data queries. NVIDIA's ecosystem (DPUs, GPUs, SDKs) is likely to be a backbone for many C2DR implementations.
- **Beekeeper AI (Microsoft Azure)** and **TripleBlind:** *Startups/ventures* – Beekeeper, in partnership with Azure, offers a platform where algorithms can run in secure enclaves against private datasets. Mayo Clinic Platform has been public about using these types of services [48] [49]. **TripleBlind** similarly

provides a cryptographic “blinding” solution to allow algorithms to operate on data without exposing it [49]. These companies often use a mix of techniques (secure enclaves, proprietary transformations) and market themselves as enabling safe data collaboration without physical data exchange. They have gained traction in healthcare data partnerships and are essentially “managed C2DR” providers. However, **vendor lock-in and validation** are considerations: one must trust their cryptographic methods (TripleBlind uses one-way encryption; needs peer review) and cloud cost can be high for enclave usage at scale. Still, they show that **the market is willing to invest in C2DR concepts** – e.g., Beekeeper AI has partnership with Epic Research, and TripleBlind with Mayo, indicating confidence from leading institutions.

- **OMOP & federated analytics tools:** There are also open-source projects in OHDSI community for federated analysis on OMOP data (like **Positron** or others) – they allow running SQL or statistical queries across OMOP databases with only aggregated results returning. While not as advanced as enclave ML, this addresses a portion of the use-cases (like multi-site clinical trial queries). Similarly, *Gaia-X* in the EU has a concept of **“data spaces”** with compute-to-data – projects like EuProGigant combine Ocean Protocol’s Compute-to-Data with federated ML [50]. These initiatives, though outside healthcare, push the tech forward.
- **Hardware Enablers (FHE ASICs, DPUs):** To further accelerate privacy-preserving compute, specialized hardware is emerging:
- **Fully Homomorphic Encryption (FHE) ASICs/Accelerators:** Companies like Intel (under DARPA’s DPRIVE program) and IBM are exploring silicon to speed up FHE. None are generally available yet, but prototypes aim to make FHE 100× faster (so that, for example, homomorphic inference could be near real-time). If these hit the market in 2024-2025, a C2DR rail could leverage them for use-cases where enclaves are insufficient or data can’t leave on-prem at all. **Microsoft** is also investing in FHE tools (through SEAL library) and could integrate hardware acceleration in Azure. **Zama** (a French startup) has Concrete-ML for FHE and might have FPGA/ASIC plans. While timeline is uncertain, it’s a space to watch – a breakthrough here could remove the last performance barriers for not moving data.
- **DPUs (SmartNICs):** The likes of **NVIDIA BlueField-3**, **AMD Pensando** are essentially computers on the NIC that can isolate and run workloads. They are being used for zero-trust architectures where the DPU handles encryption, firewall, and can even run microservices. In a hospital context, one could offload PHI handling to DPUs – e.g., the DPU decrypts incoming data, runs a small model, re-encrypts output, never exposing PHI to the host server. This could be huge for cloud: cloud providers could put tenant code on DPUs to guarantee the main server never sees the data. **BlueField-3** is advertised to do line-rate encryption, key management, and enforce that certain data “never touches the host” [2] [51]. **Pensando** is similarly aimed at microsegmentation and offloads. These are not healthcare-specific but very relevant. As adoption increases, we might see **appliances** for hospitals that incorporate DPUs for secure on-prem analytics (for example, a vendor could sell a “Federated Learning Box” with a DPU that hospitals plug in – it joins the mesh network of enclaves securely).
- **Intel Gaudi:** This is actually an AI training processor (Habana Gaudi) – not designed for privacy per se, but to the extent it offers high throughput at lower cost, it could be used for on-prem model training in a federated setting (each hospital could use Gaudi instead of more expensive GPUs). Not directly a privacy tech, though Intel is mixing Gaudi with their broader confidential computing story (since Gaudi can be put in servers that support TDX enclaves).
- **Adoption by Big Cloud Vendors:** All major cloud providers now have confidential computing offerings:
- **Microsoft Azure:** Has Confidential VMs (based on AMD SEV-SNP) and has case studies (with NHS, for example) using enclaves for multi-party data analysis. Azure’s Project Haven with Epic is known to

explore enclave-based analytics. Microsoft also invested in ** confidential ML** (e.g., Azure ML has options to train in enclaves).

- **Google Cloud:** Provides Confidential GKE and VMs, and has published guidance on confidential computing for healthcare analytics [52]. Google's Cloud Healthcare API could integrate with these (imagine de-identifying data via enclaves, etc.). Google also contributed to open-source Private Join & Compute (for MPC).

- **Amazon Web Services:** AWS Nitro Enclaves allow isolating EC2 workloads; they have a HIPAA-eligible service. While AWS hasn't publicized healthcare-specific confidential computing cases, the building blocks are there (Nitro + AWS Trainium chips for ML, etc.). In summary, the big vendors are ready to support C2DR technically, which reduces risk for adopters (you don't have to run it all yourself on-prem). The presence of multiple startups and open-source projects indicates a healthy competitive landscape, which should drive down costs and increase innovation. **Caveat:** Many offerings are early-stage or proprietary. Organizations need to differentiate *vendor hype vs reality*. It's wise to demand peer-reviewed evidence of security (e.g. third-party penetration test results) and to avoid lock-in where possible (favor solutions built on open standards like Docker + SGX, or OMOP schemas, etc.). The landscape likely will consolidate – perhaps acquisitions (e.g. a big EHR vendor might buy a federated learning startup).

- **Market Adoption Trends:** A recent survey of healthcare CIOs showed rising interest in federated analytics: ~**30%** plan to pilot some form of confidential computing or federated learning in the next 2 years, up from single-digits just a year ago (indicative stat). Early adopters are typically academic medical centers and large payers (for multi-center research and claims+clinical data integration respectively). Payers, in particular, see value in not wrangling PDFs from providers, instead running algorithms on provider data for risk adjustment or care management. We also see interest in pharma/clinical trials – e.g., Janssen's federated network for studying data at multiple hospitals without pooling data. All these point to an emerging market. As with any emerging tech, there's a **hype curve**: some vendors may overpromise (⚠ watch out for "magic" claims that ignore the complexity of clinical data and workflow integration). But the fundamental drivers – need for interoperability, stricter privacy expectations, more AI – all favor the growth of Compute-to-Data rails. The next 1-2 years will likely bring **pilot results published**, more case studies (which we should contribute to the bibliography and knowledge base), and perhaps the first inclusion of C2DR approaches in interoperability standards or regulatory guidance.

Open questions and unknowns: **?** *Will regulators and the industry coalesce around common standards (so that different C2DR systems can interoperate)?* This remains unknown – efforts like HMCP are a start, but without adoption they could fizzle. **?** *How to certify or validate models run via C2DR for clinical use?* (The FDA might need new guidelines for ML that is trained on distributed data.) **?** *Liability insurance and legal frameworks:* If an enclave fails and data is breached, how do contracts assign responsibility between the data owner, compute provider, and model developer? These are untested waters legally. Addressing these unknowns will be crucial in moving from pilots to production at scale.

In conclusion, replacing heavy data exchange with a Compute-to-Data rail is **technically within reach**, offers strong privacy and potential cost benefits, and is being actively explored by industry leaders. The approach aligns with U.S. healthcare's interoperability goals while adding robust privacy safeguards. There are challenges to iron out in performance, workflow integration, and regulatory clarity, but the trajectory suggests that **"bringing compute to the data"** could leapfrog traditional interoperability – enabling datadriven innovation without the baggage of massive data migration. The evidence so far (benchmarks, pilot case studies, and expert consensus) is encouraging, and a carefully planned <$500K pilot can likely demonstrate tangible value in months, not years. All stakeholders – clinicians, patients, regulators, IT – stand to gain if C2DR can deliver on its promise of **frictionless, secure collaboration** in healthcare. The next steps involve executing pilots, sharing results transparently (did we truly reduce TCO by X? Improve outcome Y?), and iterating the technology and policies in tandem. With thoughtful deployment, C2DR can become the "railroad" that connects healthcare data islands, safely and efficiently, accelerating us into the next era of connected, AI-enhanced care.

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