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↳ CLINICAL TRIALS · REAL-WORLD DATA · PHARMA

Clinical trials deserve better *data.*

80%
of trials delayed by data failures

OMOP
CDM mapping out of the box

EHDS
2027-ready from day one

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THE PROBLEM — FOR EVERY TEAM

C-suite: trial delays cost $1M/day

Clin Ops: manual data entry kills timelines

Regulatory: poor data = CRL risk

Clinical data collection is still *broken.*

Patient data sits in hospital EHRs, wearables, lab systems, and paper CRFs — each in a different format, none of them connected. Your clinical operations team spends more time cleaning data than generating evidence.

The molecule works. The data infrastructure doesn't.

WHAT IT COSTS

Every data failure *has a price.*

01 **Months of delay.** Manual data collection and reconciliation across sites adds 6–18 months to average trial timelines. Every month costs millions.

02 **Protocol deviations.** Missing or inconsistent data from EHRs and lab systems forces protocol amendments — the single most expensive event in a trial.

03 **Regulatory rejection.** FDA and EMA require complete, traceable, standards-compliant data. Poor data pipelines are the #1 cause of Complete Response Letters.

04 **Missed real-world evidence.** Wearable and continuous monitoring data that could strengthen your dossier is never collected — because the infrastructure doesn't exist.

WHAT HYDRA MEANS FOR YOUR TEAM

Different teams. *Same answer.*

C-SUITE / VP

Cost & speed

Every month a trial is delayed costs $1–2M in operational expenses alone, before lost revenue. Hydra cuts site activation from weeks to hours and eliminates manual data reconciliation — the single largest cost driver in clinical operations.

MEDICAL AFFAIRS / REGULATORY

Submission quality

Hydra produces CDISC SDTM-compliant data with full audit trails from source — meeting ICH E6(R3) and FDA/EMA expectations. Real-world evidence from EHR and wearable data can strengthen your dossier before submission.

CLINICAL OPERATIONS

Less manual work

Stop transcribing from EHR to CRF. Hydra pulls source data directly from hospital systems — Epic, Cerner, MEDITECH, OpenMRS and more — normalises it, and pushes it into your EDC automatically. Your team focuses on oversight, not data entry.

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We didn't build another EDC system.
We built the data infrastructure layer underneath the trial.

The translation layer that makes every data source — EHR, wearable, lab, device — trial-ready and OMOP-compliant.

HYDRA FOR CLINICAL RESEARCH:

From patient *to dossier.*

REAL-WORLD EHR DATA · WEARABLE INTEGRATION · OMOP CDM · CDISC SDTM · END-TO-END FROM PATIENT TO DOSSIER

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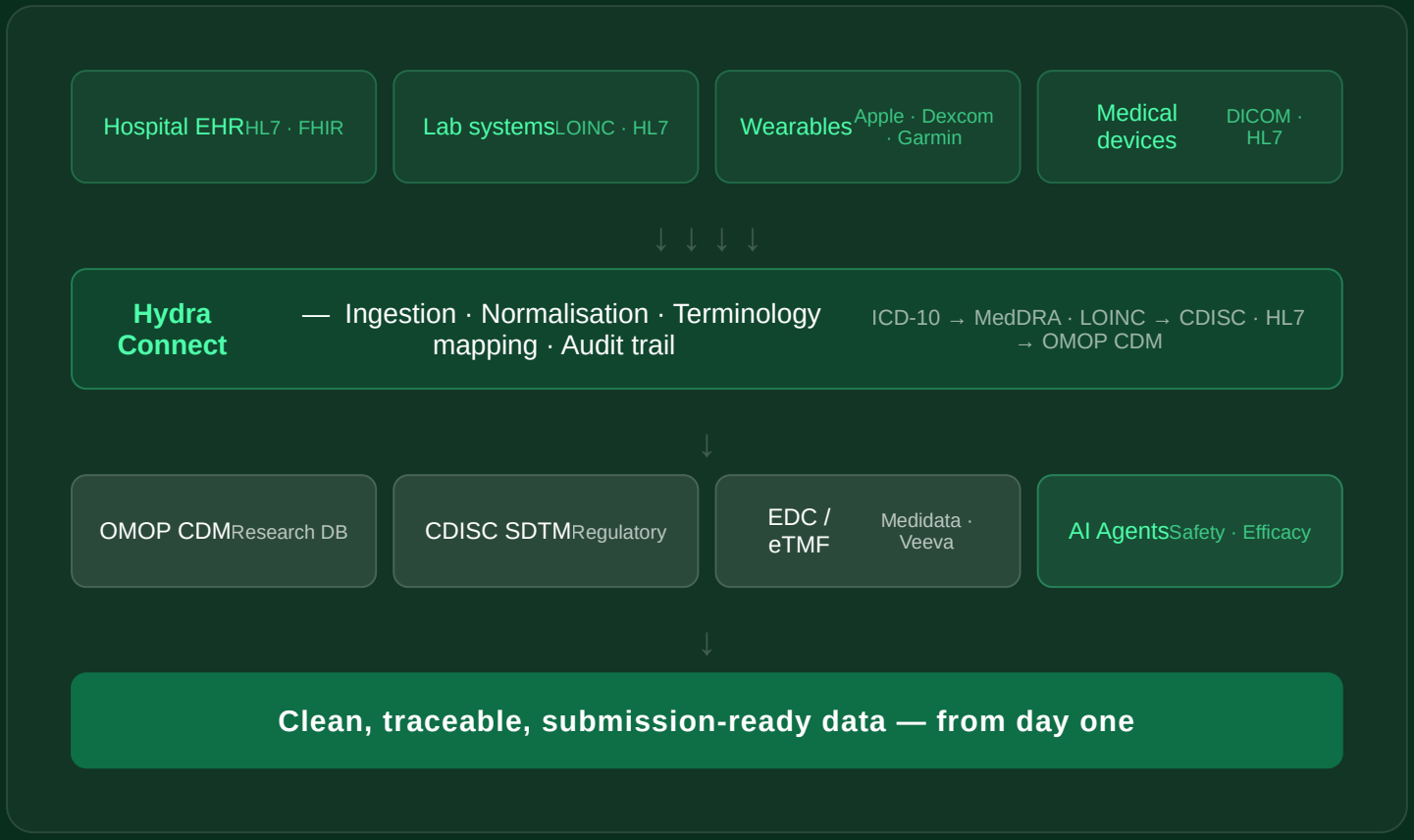
HOW IT WORKS

One pipeline.
Every data source.



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WHAT BECOMES POSSIBLE

Across every *trial type.*

DECENTRALISED TRIALS

Collect real-world data from patients at home — wearables, connected devices, remote lab results — all normalised and mapped to OMOP automatically.

ONCOLOGY TRIALS

Ingest tumour registry data, pathology reports, imaging results, and PROMs from multiple hospital EHRs across sites — unified in one research-grade database.

CARDIOVASCULAR TRIALS

Continuous monitoring data from wearables and implantables mapped to CDISC SDTM — real-world evidence that strengthens your regulatory dossier.

REAL-WORLD STUDIES

Connect to European hospital networks via EHDS-compliant FHIR APIs — accessing anonymised patient populations at scale, without custom integrations per site.

REAL-WORLD EVIDENCE

The EHR is your *largest data source.*

01 **Patient identification at scale.** Query FHIR-connected hospital networks to identify eligible patients across multiple sites — before a site is even activated.

02 **Automated source data verification.** Hydra pulls data directly from EHR source records — eliminating manual transcription to CRF and the errors that come with it.

03 **Post-market surveillance.** Connect to real-world EHR data continuously after approval — building the long-term safety and efficacy evidence regulators increasingly require.

FDA and EMA are moving toward real-world evidence as part of approval packages. Hydra gives you the infrastructure to collect it — today.

REGULATORY COMPLIANCE

Built for *regulators.*

ICH E6 — GCP R3 requires electronic source data to be traceable, attributable, and contemporaneous. Hydra's audit trail meets this standard out of the box.

CDISC — SDTM and ADaM mapping built in. Submit directly from Hydra-normalised data without manual conversion or CRO rework.

GDPR — Pseudonymisation, consent tracking, and data residency controls built in. Compliant across all EU member states from day one.

EHDS — EHDS 2027 mandates standardised cross-border health data access. Hydra connects you to European patient populations before the deadline.

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THE PLATFORM

What you get *from day one.*

50+

CONNECTORS — EHRS, LABS, WEARABLES, DEVICES

OMOP

CDM MAPPING OUT OF THE BOX

Hours

TO CONNECT A NEW SITE NOT WEEKS

EHDS

2027-READY FROM DAY ONE

GDPR · GCP ICH E6(R3) · CDISC SDTM · ISO 27001 · On-premise available

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THE QUESTION

Your molecule works. *Does your data infrastructure?*

The fastest path to approval starts
with the cleanest data pipeline.

See how Hydra works →