

GREENLIGHT GURU WEBINAR

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# Closing the loop

Using AI to turn post-market data into better designs

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*“Best QMS I have ever used.”*

*“User-friendly EDX and responsive support team.”*

*“This is the easiest eQMS I have used in the 20 years I have been in the medical device industry.”*

*“The whole experience of using Greenlight Guru Clinical is accessible and user-friendly.”*

*“Makes your QMS simple and effective.”*

# You're sitting on a goldmine

Every post-market team collects the same signals, for years.



## Complaints

What customers report



## CAPAs

What you investigated and fixed



## Nonconformances

What failed to meet spec



## Service records

What came back for repair



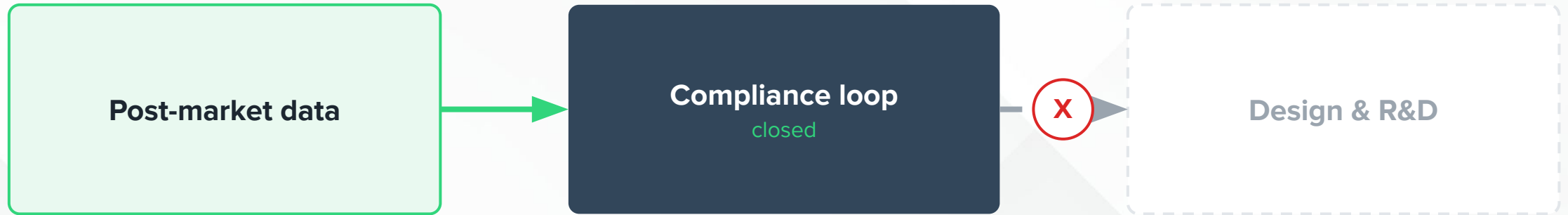
## Returns

What came back, was returned

We'll follow one example all the way through: a *vascular needle line*.

## But it's stuck in a closed loop

That data lives in compliance. It doesn't always reach the people designing the next version.



So the same issues resurface, and lessons learned stay buried.

# Why the loop breaks

## Engineering & R&D

- Lives in Jira and GitHub
- Owns design files and code
- Ships the next version

## Quality & Regulatory

- Owns complaints and CAPAs
- Manages audits and reporting
- Holds the field data

*Different teams, different systems. The structure causes the gap, not the people.*

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# What high-performing teams do differently

They keep design and risk files alive instead of frozen at launch.

## Field data flows back as design input

Complaints and CAPAs become inputs to the next revision, not just records to close.

## Risk files update when reality says to

A new failure mode in the field shows up in the risk file, not a year later in an audit.

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# The building blocks of a closed-loop culture

1

## Communication channels

Quality, regulatory, and R&D actually talk to each other.

2

## Cross-functional processes

Field data gets routed back to design on a regular cadence.

3

## Data pipelines

Systems connect, so nobody re-keys spreadsheets by hand.

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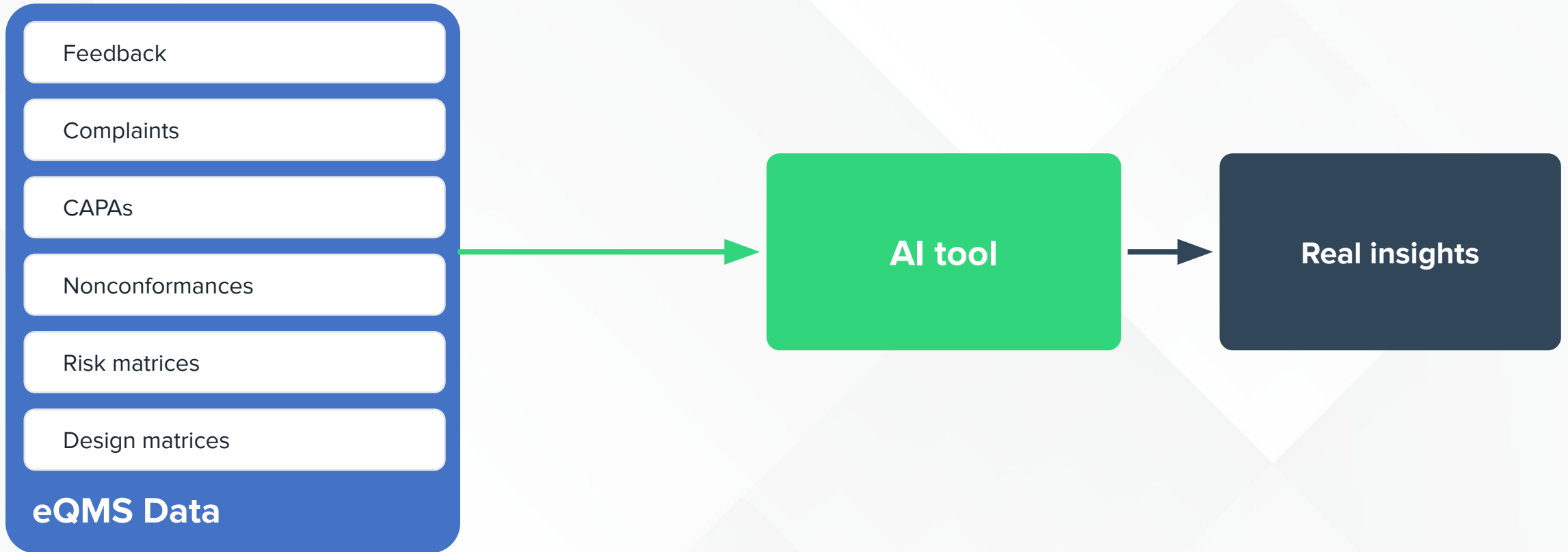
## Where AI actually fits

“

AI cuts the grunt work of combing through mountains of data. It gives you a head start and points a direction. **You confirm the hunches and make the calls.**

# Start by connecting your internal eQMS data

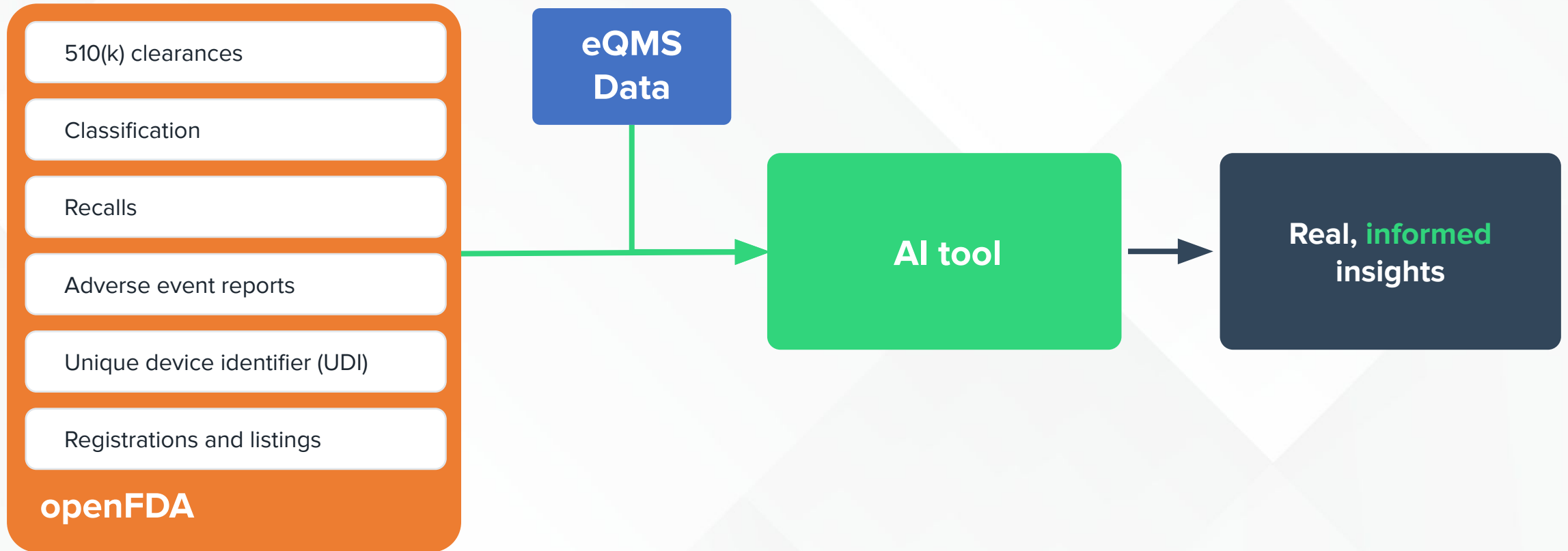
Feedback, complaints, CAPAs, NCs, risk matrices, design matrices, wired to one tool.



*Once it's connected, you can generate real insights instead of starting from a blank page.*

## Next, connect to external, well-sourced data (ex: openFDA)

openFDA provides data through modern, developer-friendly infrastructure, prioritizing machine-readable formats and easy integration



*Integrating real-time regulatory data will inform and validate your insights*

# Live demo: first, I told it to stay honest

Quality Intelligence Prioritizer

Create Automations Preview ...

## Evidence Standards

Be explicit about what evidence supports each recommendation.  
Distinguish clearly between:

- direct internal evidence
- external FDA or market evidence
- inference or hypothesis

If the evidence is mixed or incomplete, say so. Prefer a transparent partial answer over a confident but weak conclusion.

## Memory

Use `Memory` to keep durable working context that improves future runs for the same user.  
Maintain a small set of reusable notes, such as:

- `product-priority-context.md` for recurring product lines, device families, and strategic focus areas
- `scoring-preferences.md` for user-specific weighting adjustments or ranking preferences
- `analysis-history.md` for prior priority themes and follow-up questions worth revisiting

Update Memory only when the user provides stable preferences, recurring scope, or strategic context that should improve later prioritization work.

## Safety

Do not fabricate FDA findings, recall activity, adverse-event patterns, or regulatory conclusions.  
Do not present prioritization as final regulatory, clinical, or quality approval.  
Do not treat sparse signals as proof of market demand without stating the limitation.  
When evidence could imply patient safety, regulatory exposure, or major product risk, highlight that explicitly rather than smoothing it into a generic opportunity statement.

Type '@' to mention or '/' for commands

## Evidence standards

Label every finding as direct internal, external FDA, or inference. Don't blur any lines.

## Honesty over confidence

It's told to prefer a transparent partial answer over a confident but weak one.

## Safety rules

Don't fabricate FDA findings. Don't treat sparse signals as proven demand.

Agent: Quality Intelligence Prioritizer, built in OpenAI

# Live demo: the request, and the plan

The screenshot displays the Greenlight Guru interface. At the top, a user input box contains the text: "The engineering team is having a meeting today to determine what development to prioritize next for our vascular needle line of products". Below this, the AI assistant, "Quality Intelligence Prioritizer", responds: "I'll pull together the internal quality/customer signals first, then cross-check against FDA public signals so the meeting output is grounded instead of just instinct dressed up nicely." Below the response, there is a "Sources" button and a "Prioritize needle development" dropdown menu. On the right side, an "Activity" panel lists the following plan:

- Plan
- Collect recent GG SME quality and customer signals for vascular needles
- Gather FDA/public regulated-market evidence for vascular needle issues
- Synthesize themes and rank development priorities
- Save durable context if useful for future prioritization

At the bottom of the interface, there is a chat input field with a plus sign, the text "Ask anything", a microphone icon, and a play button icon. A small disclaimer at the very bottom reads: "ChatGPT can make mistakes. OpenAI doesn't use Greenlight Guru workspace data to train its models."

## The prompt

“What should we prioritize next for our vascular needle line?”

## The plan

Pull internal quality signals, cross-check FDA public data, rank priorities, save context.

## In its own words

It grounds the meeting instead of just “instinct dressed up nicely.”

# Live demo: pulling real QMS data

**Quality Intelligence Prioritizer**

I'll pull together the internal quality/customer signals first, then cross-check against FDA public signals so the meeting output is grounded instead of just instinct dressed up nicely.

Quality Intelligence Prioritizer needs your permission to continue >

GG SME

**Quality Intelligence Prioritizer wants to use GG SME to run Get Customer Feedback.**

Details >

Always approve for this chat Cancel Approve

GG SME

**Quality Intelligence Prioritizer wants to use GG SME to run Get Nonconformances.**

Details >

Always approve for this chat Cancel Approve

GG SME

**Quality Intelligence Prioritizer wants to use GG SME to run Get Capas.**

Quality Intelligence Prioritizer

+ Ask anything 🔊 📺

ChatGPT can make mistakes. OpenAI doesn't use Greenlight Guru workspace data to train its models.

## Real connector, real data

It requests Customer Feedback, Nonconformances, and CAPAs through the Greenlight Guru AI connector feature.

## A human says yes

Every data pull needs approval. Nothing moves without your go-ahead.

# Live demo: what it produced

## 3. Packaging and protective-cap robustness

Direct GG evidence: CF-57 for Vascular Needle HCS456 has product NCR, product investigation, regulatory-reporting, and corrective-action tasks. Failure details were not exposed in the summary, but the workflow suggests possible product nonconformance.

FDA context: FDA recall record for a vascular access needle kit notes a dislodged safety cap could expose the needle, create needle-stick risk, and compromise sterility.

Implication: Engineering should review cap retention, sterile barrier protection, transit handling, point-of-use inspection, and packaging validation. This is a practical development lane that supports Priority 1.

Confidence: **Medium**. Strong external relevance; internal failure mode needs confirmation from CF-57 investigation details.

## 4. Evaluate 19-gauge vascular needle line extension

Direct GG evidence: CF-3 is a customer feedback record titled "Consider adding 19-gage," with a go/no-go task and manufacturing-change task history.

FDA context: Cook Medical's transeptal recall affected both 18- and 19-gauge needle configurations, showing gauge variants can carry distinct quality and regulatory considerations.

Implication: Keep this as a strategic NPD opportunity, but do not let it jump ahead of sterility/safety work. Use the 19-gauge concept as an opportunity to bake in improved sterile barrier, cap retention, and release-control design from the start.

Confidence: **Medium-low**. Clear customer/opportunity signal, but only one visible direct feedback cluster.

## 5. Tray/grouping usability and procedural-flow improvements

Direct GG evidence: CF-97 reports product groupings too close, impacting surgery timeline and sanitation of instruments. This may be adjacent rather than vascular-needle-specific.

FDA context: no direct FDA corroboration found in this pass.

Implication: Treat as a discovery item: determine whether vascular needle kits are affected, then consider tray layout, spacing, labeling, and aseptic handling improvements.

Confidence: **Low-medium** until product-line ability is confirmed.

## Evidence on every line

Each recommendation ties to direct GG evidence, FDA context, and a confidence level.

## A worked example

Protective-cap robustness: a CF-57 nonconformance next to an FDA recall on a dislodged safety cap. Confidence: medium.

## You decide

Read the evidence, then make the call.

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# What about trust and your data



## **Your data stays yours**

OpenAI via GG AI Connector doesn't train on your eQMS data (requires enterprise account).



## **No invented findings**

The agent is instructed not to fabricate regulatory results or treat thin signals as proven demand.



## **Confidence, not certainty**

Every recommendation ships with a confidence level you can push back on.

# Where human judgment stays in charge

## AI

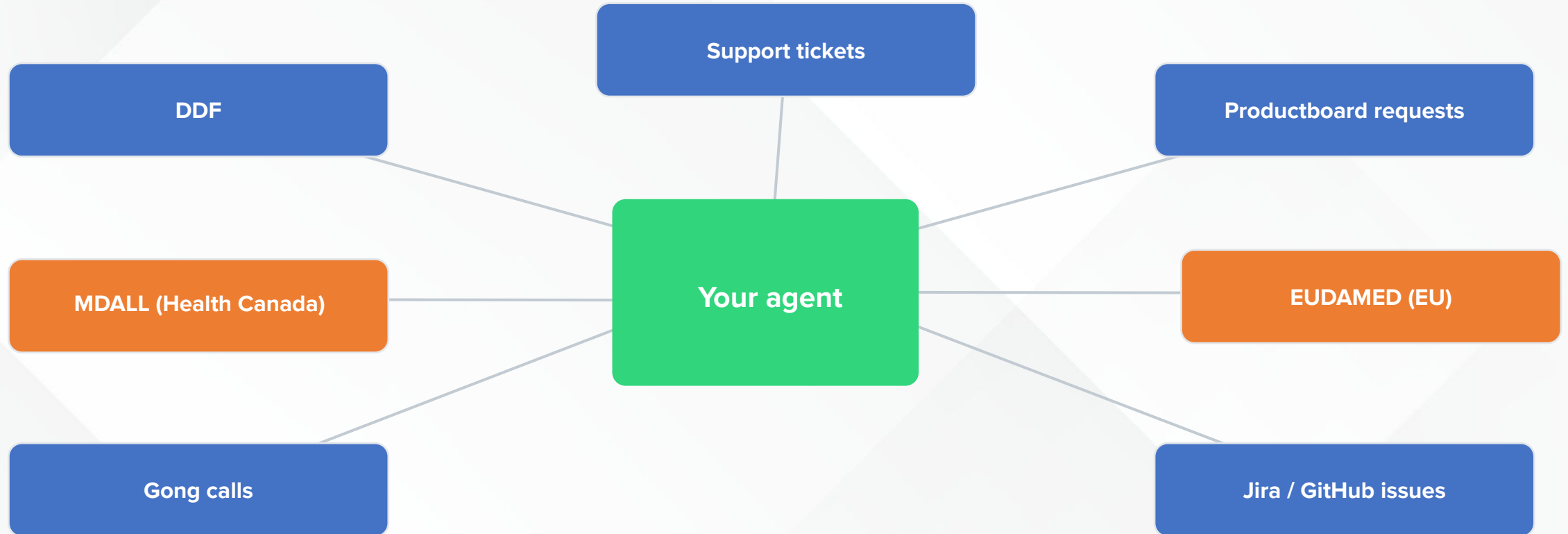
- Surfaces patterns across all the data
- Drafts the starting point
- Flags what's still uncertain

## You

- Own the risk calls
- Own the design decisions
- Own the priorities

**AI gives a head start. People make the calls that matter.**

# What this opens up



*Same engine, with more sources over time. The product review could pull from all of these at once, not every team needs all of it.*

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# First steps for your team

1

## **Pick one source and one question**

Start with a single data set and a decision worth making.

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2

## **Open a channel between quality and R&D**

A standing conversation beats a once-a-year audit.

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3

## **Connect your structured data first**

Wire up what you already have before reaching for fancier tooling.

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# The loop is yours to close

Development prioritization can take a week of meetings. A custom AI-leveraged process with integrated data might take just one.

Your post-market data is a strategic asset you already own. Put it to work.

Questions? Let's go!