From Field Data to Regulatory Evidence

How AI is bringing the farm, the clinic and the industry closer together

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6th Veterinary Big Data Stakeholder Forum · EMA
· Amsterdam · 10 November 2026

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The evidence already exists

Many species & breeds

Companion animals, livestock, minor species

Many settings

Farms, clinics and households across countries

Real conditions

Comorbidities, varied management, broader populations than trials

Abundant data

Clinic records, labs, farm systems and devices record it every day

We do not lack veterinary data. We lack the ability to connect it, understand it and trust it enough to support decisions.

From field data to evidence

Real-world data

What happens in daily practice: clinical records, lab results, farm and sensor data, pharmacovigilance reports, owner observations.

Real-world evidence

What we can reliably conclude from those data, using a sound, pre-defined scientific method.

The role of AI

A tool that helps collect, clean, connect, analyse and explain the data — faster and at a scale humans cannot.

An AI result is not automatically evidence. Like a lab result, it needs the right sample, a validated method and a qualified person to interpret it.



Animal evidence ≠ human evidence

Species & breeds

Different physiology, metabolism and dosing

Herd vs individual

Decisions often taken at group or farm level

Production systems

Husbandry, economics and climate shape outcomes

Small populations

Minor species and rare conditions

Fragmented ownership

Farmers, vets, labs, device makers, companies

Unconnected data

Free-text records, local coding, closed devices

Source: EMA, Digital technologies and Real-World Evidence (A. Cook), 5th Veterinary Big Data Stakeholder Forum, 2025

AI in plain words: what it can do



It learns

Machine learning: learns patterns from thousands of labelled cases — like a vet student after years of clinics.

e.g. predicting which herds are at risk



It sees

Computer vision: recognises what is in an image or video.

e.g. parasite eggs on a slide, lameness on camera



It hears

Signal analysis: finds patterns in sound and sensor streams.

e.g. pig coughs, heart murmurs, cow activity



It reads

Language AI: understands free text and answers questions in plain language.

e.g. sorting adverse-event reports

AI is only as good as the examples it learned from. Good, well-labelled, representative veterinary data makes good AI — and good evidence.

What AI changes: speed and understanding

Brainstorm faster

Explore literature, past studies and ideas in hours instead of weeks

Develop faster

Build analyses, dashboards and tools with AI assistance

Put in place faster

Move from pilot to routine use with less manual effort

Ingest data faster

Read free-text records, images, sound and sensor streams automatically

Analyse faster

Detect patterns and signals across millions of records

Easier understanding

Ask questions in plain language; get clear summaries and visuals

The biggest change is not one algorithm — it is that the whole cycle from idea to insight becomes much shorter.



1 · Helping owners and farmers

Listening to the barn

Microphones in the barn and AI pick out pig coughs among all other sounds and alert the farmer early to possible respiratory problems.

How it works: the algorithm learned from thousands of recorded barn sounds — much like a stockperson learns to recognise a cough.

24/7 monitoring of activity and rumination

Collars and ear tags track each cow's activity and rumination around the clock and flag cows that need attention — health, heat or nutrition.

How it works: AI learns each cow's normal day; a change from her own baseline triggers an alert.

Pets at home

Activity collars and apps help owners notice changes such as more scratching or less activity, and bring the animal to the vet sooner.

An alert is not a diagnosis: it tells the owner when to call the vet.

Examples describe types of AI tools already used in practice.



2 · Helping veterinarians treat

Samples read by AI

In-clinic analysers read faecal parasites, blood smears, ear cytology and fine-needle aspirates in minutes. In a published study, AI faecal analysis closely matched board-certified parasitologists.

How it works: image-recognition AI trained on thousands of microscope images labelled by specialists.

Hearing what the ear can miss

A digital stethoscope and AI help detect heart murmurs in dogs, trained on thousands of heart-sound recordings annotated by specialists.

In plain words: sensitivity = how many dogs with a murmur it catches; specificity = how many healthy dogs it correctly clears.

Right treatment, right animal

Faster, objective results support targeted treatment — including more responsible antimicrobial use.

AI is a second pair of eyes and ears; the veterinarian confirms and decides.

Examples describe types of AI tools already used in practice. Source: Nagamori et al., Parasit Vectors 2020;13:346.



3 · Helping the industry

More data, from real conditions

Connected devices and digital diagnostics generate continuous, objective data far beyond what a clinical trial can collect.

Better research questions

Field data show where needs are unmet: which diseases, species, regions and production systems.

Smarter studies

Sensors measure outcomes objectively 24/7 in animal trials, e.g. cough monitoring in swine studies.

Earlier safety insight

AI helps sort and read pharmacovigilance reports and literature, so experts can focus on real signals.

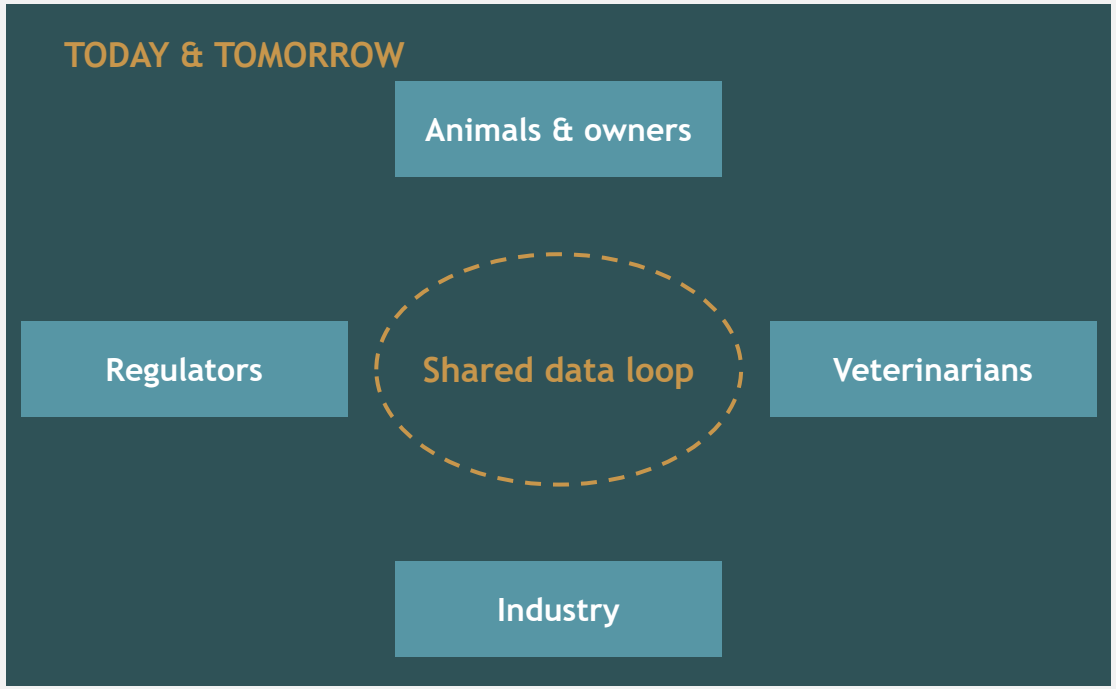
Result: products developed on what really happens in the field — not only on what happens in a study.

Source: EMA, Digital technologies and RWE (A. Cook), 2025

Field and industry are converging

YESTERDAY

- Industry
- Trial
- Authorisation
- Field use
- Occasional report



Yesterday: one-way and slow. **Today:** a continuous loop — what happens on the farm or in the clinic reaches research, safety and regulators within days.

Where field evidence helps regulators

Before authorisation

- How common is the disease?
- Current standard of care
- Which animals to study
- Context for minor species

Benefit-risk assessment

- Is the trial population representative?
- Outcomes in broader populations
- Effects across species & systems
- Supplements, does not replace, trials

After authorisation

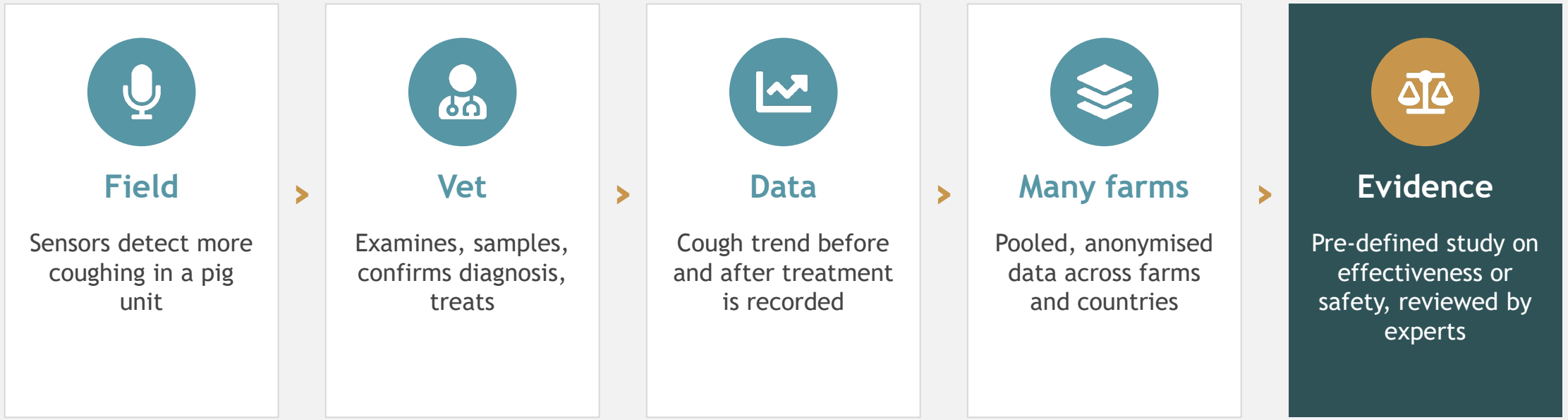
- Earlier safety signals
- Effectiveness in daily practice
- Treatment-failure patterns
- Antimicrobial use & stewardship

Lifecycle & policy

- Label updates
- Long-term outcomes
- Evidence-gap identification
- One Health surveillance

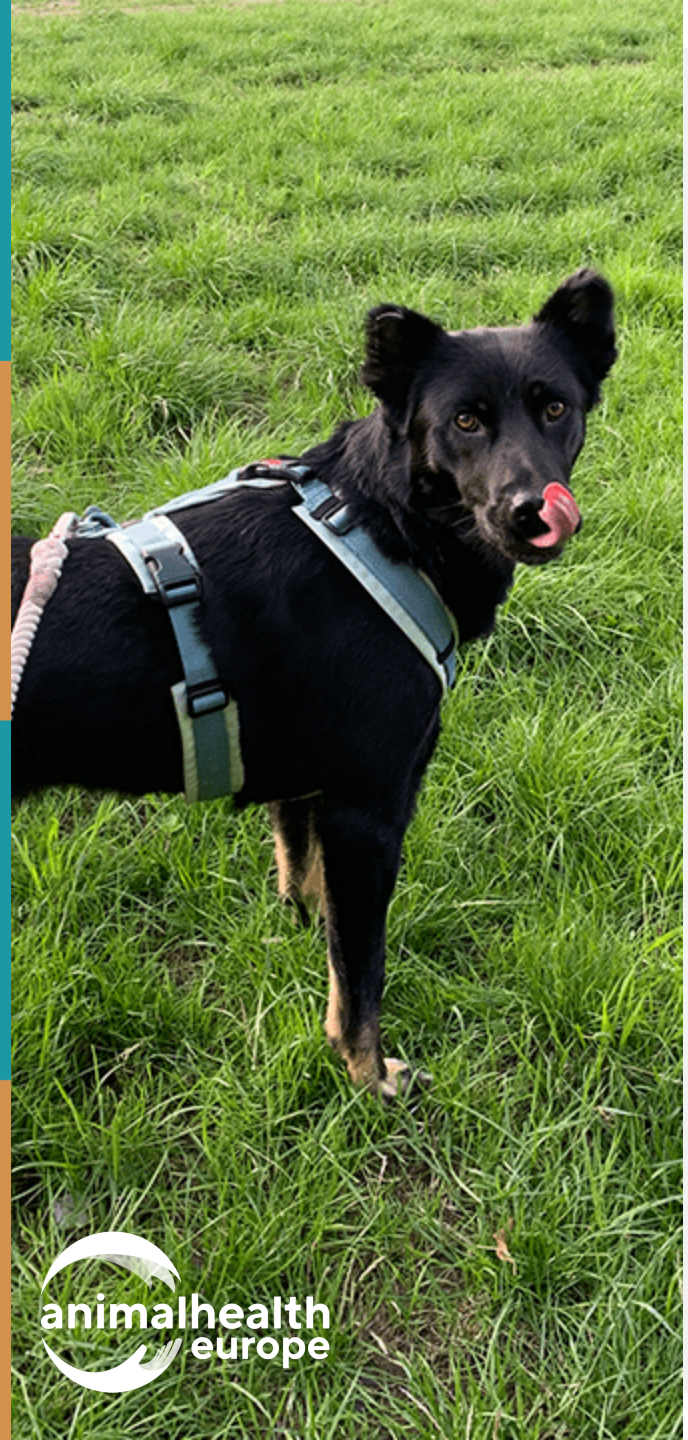
Source: EMA, Real-world evidence (ema.europa.eu)

Example: from a barn alert to evidence



AI speeds up every step. Veterinarians remain essential at every step: diagnosis, context and interpretation.

Illustrative scenario — not a description of an existing regulatory submission



Trustworthy AI evidence

Fit-for-purpose data

Contains what the question needs

Transparent method

Protocol, variables and assumptions documented

Validated tools

Tested for the species, setting and outcome

Bias under control

Which animals are missing? e.g. only high-tech farms have sensors

Protected data

Owner, farmer and company data handled securely

Vets & experts decide

AI informs; qualified people decide

Source: EMA, Reflection paper on the use of AI in the medicinal product lifecycle (EMA/CHMP/CVMP/83833/2023)



What is missing today

Discovery

Hard to know which veterinary datasets exist and what they contain

Standards

No common definitions for animals, treatments, outcomes, farm context

Interoperability

Clinic, farm, lab and device data rarely designed to connect

Acceptability

Few worked examples of what regulators accept

Incentives & trust

Data holders need a reason and a safe framework to share

Shared learning

Few controlled spaces to test methods together

Source: HMA-EMA Catalogues of real-world data sources and studies (catalogues.ema.europa.eu)



The ideal future

1. **Discoverable** Every relevant veterinary data source catalogued and described
2. **Connected** Common veterinary data standards; species as a core attribute; One Health links
3. **Secure** Analysis travels to the data; owners' and farmers' data protected
4. **Continuous** Near real-time safety and effectiveness follow-up after authorisation
5. **Qualified AI** Validated tools with a clear regulatory route
6. **Vet-centred** Veterinarians as key contributors and users of the evidence

Outcome: medicines reach animals faster, stay available, and are monitored on real evidence.

How we get there: a phased path

PHASE 1

Map & standardise

- Catalogue veterinary data sources
- Agree core data elements
- Agree rules for data sharing & protection

PHASE 2

Pilot

- One narrow question (e.g. safety signal, antimicrobial use, effectiveness)
- Pre-defined protocol & AI validation
- Regulators, industry, vets, labs, academia

PHASE 3

Scale

- Reusable templates & guidance
- Regulatory route for AI tools
- Shared measures of value

Start small, learn together, then scale — no big-bang change.

Summary: how AI helps at every stage

Farm & home	Clinic	R&D	Assessment	Post-approval
Owners & farmers	Veterinarians	Industry	Regulators	Everyone
AI HELPS BY	AI HELPS BY	AI HELPS BY	AI HELPS BY	AI HELPS BY
Spots early changes in health and behaviour, 24/7	Reads samples and sounds in minutes; supports diagnosis	Finds unmet needs; objective trial endpoints; faster analysis	Structures field data; tests how representative trials are; supports benefit-risk	Sorts safety reports; follows effectiveness and antimicrobial use in practice
Barn sound monitoring, cow collars, pet activity collars	*AI sample analysers, AI stethoscopes*	*Sensor endpoints in field trials*	*Context for minor species and broader populations*	*Earlier, better-targeted safety signals*

One thread runs through every stage: AI speeds up observing, measuring and analysing — veterinarians, experts and regulators interpret and decide.

Three asks

01

Make veterinary field data discoverable and connected

02

Agree what makes AI-supported evidence trustworthy

03

Test it together in focused pilots with veterinarians at the centre

Every day, veterinarians, farmers and owners already generate the evidence. With AI and the right rules, we can turn it into better decisions for animal health, public health and One Health.

Thank you

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