Use of RWD in veterinary regulatory applications

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Content:

Reflections on opportunities to incorporate RWD/RWE as pivotal evidence in veterinary marketing authorization applications.

- Potential uses
- Benefits specific to the veterinary domain

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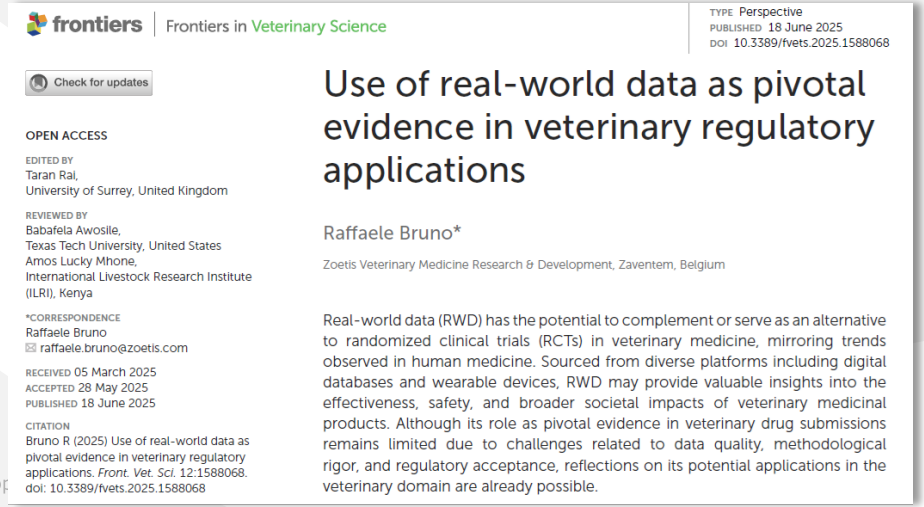

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Use of real-world data as pivotal evidence in veterinary regulatory applications

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Real-world data (RWD) has the potential to complement or serve as an alternative to randomized clinical trials (RCTs) in veterinary medicine, mirroring trends observed in human medicine. Sourced from diverse platforms including digital databases and wearable devices, RWD may provide valuable insights into the effectiveness, safety, and broader societal impacts of veterinary medicinal products. Although its role as pivotal evidence in veterinary drug submissions remains limited due to challenges related to data quality, methodological rigor, and regulatory acceptance, reflections on its potential applications in the veterinary domain are already possible.

Definitions

RWD are often, but not necessarily, 'big data'

Challenges

Acknowledgment of the obstacles in utilizing and gaining acceptance of RWE for supporting new product and claims applications :

- Quality
- Heterogeneity, Lack of standardization
- Representativeness
- Interoperability
- Methodological challenges
- Bias and measurement errors
- …

Challenges described for human medicines also apply to veterinary medicine and may be even greater due to the limited adoption of technology-driven RWD sources

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RWD supporting regulatory approvals of new products or label changes?

1. RWD for Long-term Evaluation of Safety and Effectiveness

Veterinary-specific needs

- Increasing medicalization of chronic conditions in animals

  Long time required to assess positive effects of therapies, including delaying progression of the condition, survival rates etc.

- High costs of long clinical trials

Data collection in the veterinary field

- Electronic health records (EHRs) are not always available
- Human medicine: ***patient***-reported-outcomes → Veterinary: ***owner***-reported-outcomes?


Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

ELSEVIER

Implementation of patient-reported outcome measures in real-world evidence studies: Analysis of ClinicalTrials.gov records (1999–2021)

Konrad Maruszczyk [a,b], Olalekan Lee Aiyegbusi [a,b,c,d,e,*], Victor Roth Cardoso [f], Georgios V. Gkoutos [f], Karin Slater [f], Philip Collis [a,e,g], Thomas Keeley [a,h], Melanie J. Calvert [a,b,c,d,e]

1. RWD for Long-term Evaluation of Safety and Effectiveness

In what circumstances?

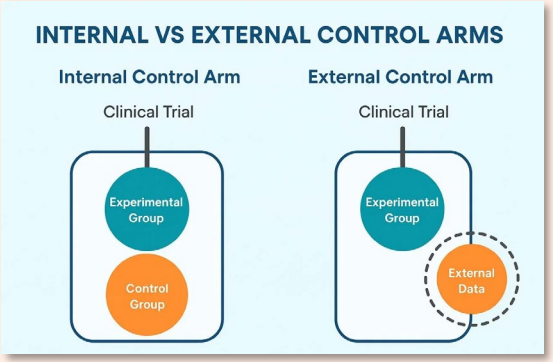
- Post-authorization studies, with less strict monitoring than pre-authorization studies
  - If the parameter is suitable for this type of monitoring
- For certain registration pathways of veterinary medicines (Art 25, novel therapies) the initial dataset can be complemented by '<u>post-authorization measures or *studies*</u>'

Post-authorization studies based on RWD rather than 'traditional' clinical studies?

2. RWD for External Controls

For the same reasons they are needed for human medicines

- When internal control poses ethical or feasibility challenges
- Examples: unethical to withhold life-saving treatments or for rare diseases



Upcoming CHMP Reflection paper may provide guidance also for veterinary medicines?

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2. RWD for External Controls

..and for veterinary-specific contexts

Example: internal controls for prevention of parasitic infections or vector-borne diseases are often not optimal:

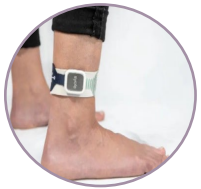
- Negative control: inadequate rescue protocol → ethical concerns
- Negative control: very low infection rates
- Positive control: often 100% prevention for both IVP and CP

Can **external** controls be an alternative?

Examples from procedures assessed by CVMP:
Prevention of parasitic infection: 6% infection in negative group
Prevention of vector-borne-disease: 7.46% in negative group

3. RWD from Wearable Devices

Examples of devices generating ‘big’ data within pivotal clinical trials



Within human clinical trials

EMA qualified a primary endpoint (SV95C*) to assess efficacy in Duchenne Muscular Dystrophy via data collected by wearable device as alternative to the ‘6-minutes walking distance’ (2023)

Within veterinary clinical trials

- Assessment of analgesic efficacy in cats via **activity monitors** on neck **collars**.
- Assessment of alleviation of situational anxiety and fear in dogs triggered by owner departure measured by **activity collars**.

Generated data for the primary variable. Assessed by CVMP in 2018

Generated data to complement owner’s assessment. Assessed by CVMP in 2021

*Stride velocity 95th percentile

3. RWD from Wearable Devices

Examples of devices collecting data outside clinical trials

Activity monitors in companion animals

Detect drinking, eating, sleeping, and activity, or *changes* in pruritic related activity in dogs such as scratching and self-licking.

Biosensors in livestock

Monitoring health and production parameters: body temperature, feeding patterns, milking performance.

3. RWD from Wearable Devices

Veterinary-specific benefits:

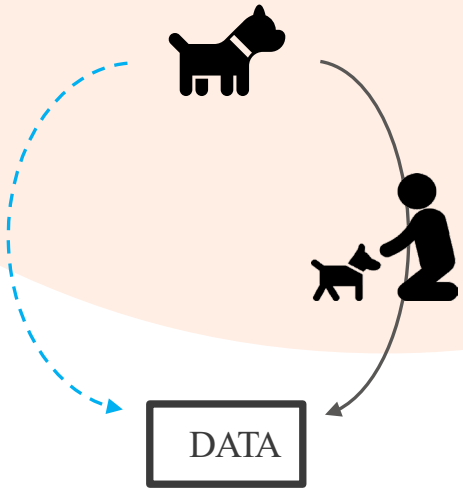
Assessment of treatment effects in therapeutic areas important and/or emerging in veterinary medicine.

- Impact on ambulatory function: pain, inflammation, cardiac issues
- Dermatology: pruritus, licking
- Health-related quality of life

Enhance **objectivity** of measurements

- Reduce reliance on subjective evaluations by veterinarians or owners
- Reduce variability caused by human interpretation
- Reduce the stress-induced bias caused by veterinary examinations

Veterinary patients do not speak!



4. RWD to Measure Effects Beyond the Individual Animal

The **impact** of VMPs extends beyond the individual patients to **broader societal impacts**:

- Human food safety
- Antimicrobial resistance
- Environmental implications

RWE from RWD sources is more likely to support post-authorization label amendments.

Hypothesis: measure trends in antimicrobial use by electronic prescriptions and country-specific databases to support label claim about aid in the reduction of antimicrobial use (vaccines, immunomodulators)

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Conclusions

RWD holds the potential to generate **pivotal** real-world evidence complementing or even replacing traditional study data in veterinary marketing authorization applications

Context of use: initially for post-authorization monitoring or to support new claims to existing products

Some advantages of RWD supporting innovation are **specific** to the veterinary sector

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Thank you for your attention