



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of Pharmacovigilance requirements

EMA Veterinary Medicines Info Day 2024

Presented by James Mount on 14 March 2024
Chair of the CVMP Pharmacovigilance Working Party

An agency of the European Union





Who is the new Chair of Pharmacovigilance Working Party?



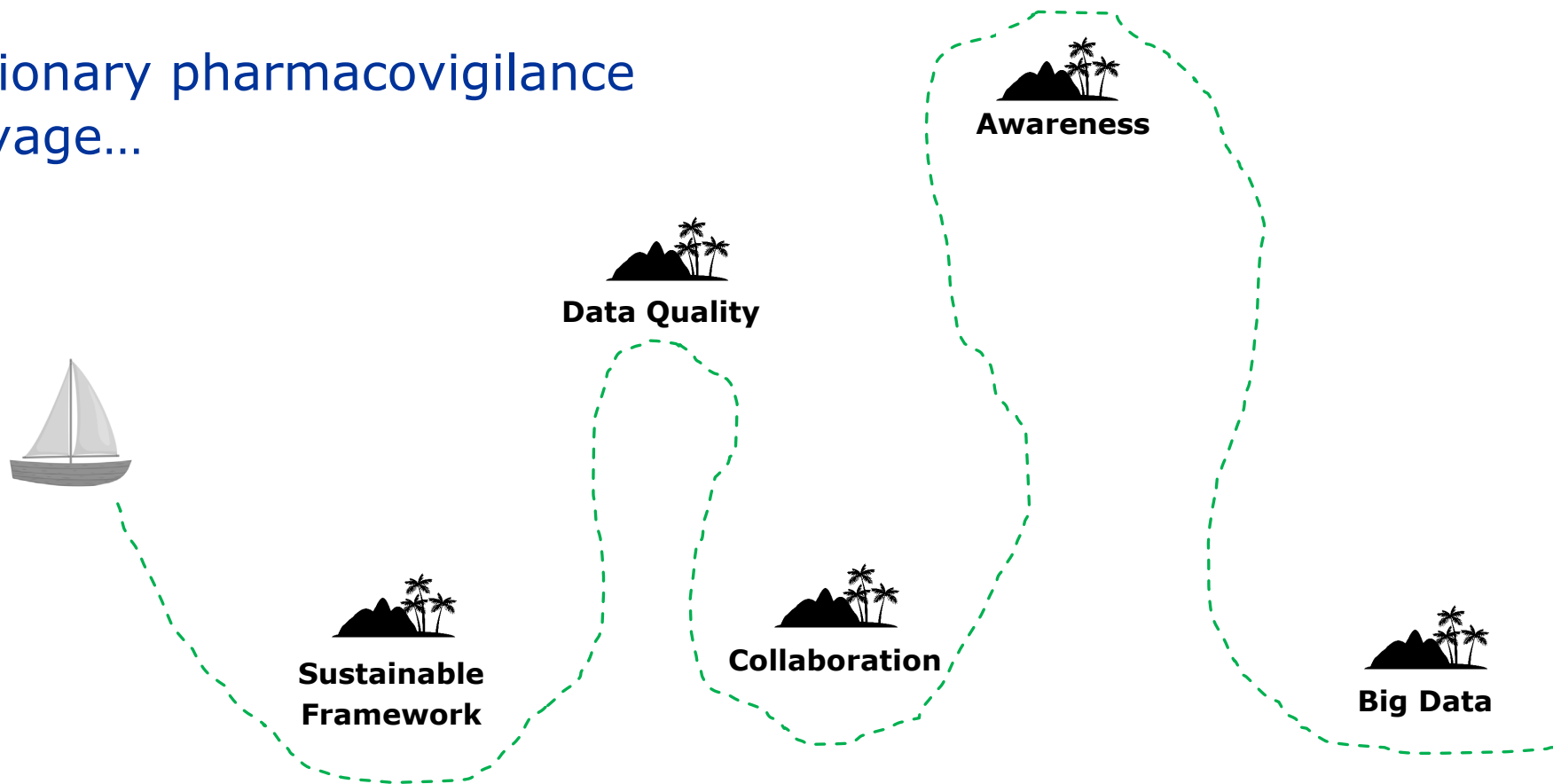
- BVSc - Veterinary Science - 
- BSc - Comparative Pathology - 
- PhD - Cell Biology and Regenerative medicine - 
- Rural mixed clinical practice (UK and Sweden).
- Veterinary Pathologist - 
- Laboratory Animal Veterinarian - 
- Pharmacovigilance assessor - 

Expert roles:

- HMA/EMA EU Veterinary Data Hub.
- Pilot - Signal Management Expert Group.
- Informal PhVWP-V / PhV IWG Data Quality subgroup.



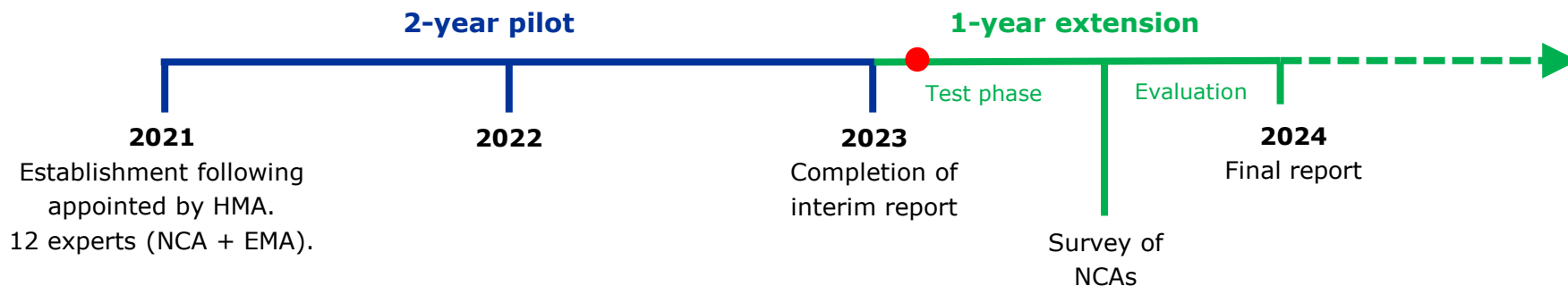
Visionary pharmacovigilance voyage...





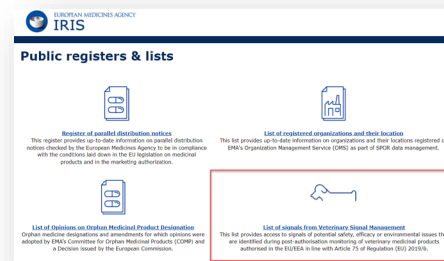
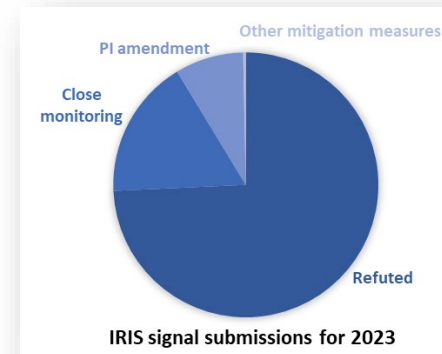
Establishment of a sustainable operational framework

- [Pilot - Signal Management Export Group \(P-SMEG\)](#).
 - Subgroup of PhVWP-V – no formal role; provides advice to PhVWP-V and HMA.
 - Test new processes for work-sharing investigation and evaluation of signals (new risks).
 - Goal: Framework that is required, feasible and sustainable.



Prioritisation and Transparency

- 2023: 311 signal submissions in [IRIS](#) = 'outcomes of signal management'
- Investigation of prioritisation methods:
 - Risk based – new active substance, <5 year since approval.
 - Data driven – active substance, MITs, reporting incidences.
 - Ongoing improvements to data analysis tools.
- Transparency:
 - New risks (Signals): [Public portal of IRIS](#).
 - Adverse event reports: [adrreports.eu](#).





Data Quality in adverse event reports (AERs)

- Accurate transfer of information in AERs to pharmacovigilance systems.
 - Harmonized data entry and adherence to international coding standards/guidance.
 - Fundamental for optimal detection of new risks (signals).
 - Poor data quality impacts:
 - All stakeholders, including the public (adrreports.eu).
 - Implementation of data mining and AI techniques.
- 2022-23: Regular dialogue with stakeholders.
 - Occasional update to EU guidance.
 - [VICH](#) – harmonized interpretation of GLs between/within VICH regions.



HMA/EMA initiative

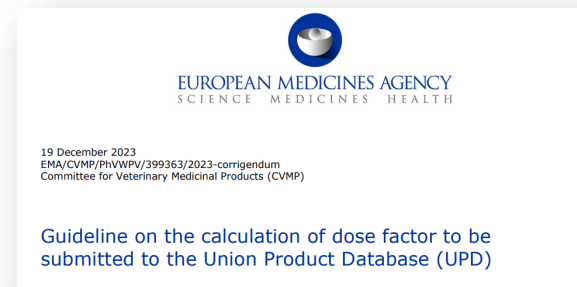
- HMA Big Data steering committee Work Plan 2022-25.
 - 'Data Quality Framework for EU medicines regulation'
 - published 2023 by HMA-EMA joint Big Data Task Force.
 - Next phase: Chapters for specific domains.
 - First chapter: Human and veterinary AE reports arising from all sources.
 - Multi-stakeholder workshop held on 1 March 2024.





Engagement and collaboration with Stakeholders

- Intrinsically a collaborative field.
 - Joint Implementation Group (quarterly), PhVWP- V Interested parties (annually), Ad-hoc engagement (2023).
 - Successful collaboration: Dose factor calculation guidance.
- Regular focused and open discussions.
- Additional guidance for SM.
 - Establish a common understanding and expectations.
 - Update existing guidance (e.g., [VGVP](#)) ± additional (?).
 - Training and consultation/working group (?).





Awareness and education

- NCAs and MAHs are heavily reliant on information provided by vets etc.
- [PhVWPV Work Plan 2024](#).
 1. Establish a promotional and education strategy to encourage adverse event reporting and raise awareness.
 2. Sector-based focus group engagement with veterinarians and healthcare professionals.
- Misconceptions within some veterinary sectors e.g., AE reporting = withdrawal.

EU Initiatives

- PhVWP-V Workshop (January 2024):
 1. Collation of existing national promotional and educational initiatives.
 2. EU proposals for completion under 2024.
- Collaboration with EMA and veterinary organisations e.g., [FVE](#).
- All MSs will benefit from these initiatives.



Federal Office of
Consumer Protection
and Food Safety

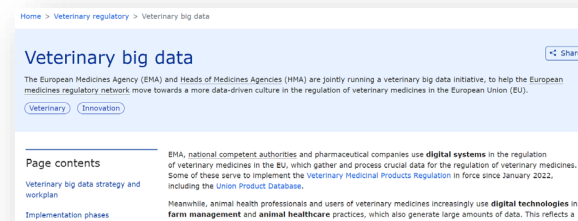


LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY



Veterinary Big Data

- Implementation of data mining and AI techniques.
- Data from other sources – e.g., practice management systems.
- Joint EMA/HMA Veterinary Big Data strategy 2022-27.
 - EU Veterinary Data Hub – network of multidisciplinary experts.
 - Veterinary Big Data Stakeholder forums.
 - Ongoing landscape analysis by Wageningen University.






Operational examples

- Innovations from industry.
- Initiatives from academia – e.g., SAVSNET and VetCompass.
 - Expansion into other regions and diversification into other sectors (equine, production).
 - Passive AE reporting, accurate incidences.
 - Background reference data, climate impact.
 - Scalability of these systems?
 - Alternate languages?

University home > Small Animal Veterinary Surveillance Network (SAVSNET) > Current research > Adverse drug reactions



Adverse drug reactions

The central objective of this project is to explore whether the use of information technology and informatics system, in the form of SAVSNET, can facilitate collection and analysis of pharmacovigilance data and assessment of interventions designed to improve reporting.



We have come a long way...

**...but we have still
some waters to cross.**





Any questions?

Further information

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