Big Data Veterinary workstream

Overview of 2021 deliverables and plan for 2022

EU Big Data Stakeholder Forum 2021 - 7th December 2021

Presenter: Ilaria Del Seppia, Data Scientist – EMA Veterinary Medicines Division

An agency of the European Union

Outlines

Veterinary Big Data Workstream – how we started in 2020

Veterinary Big Data Workstream – Deliverables 2021

The ways ahead - Workplan 2022

Classified as public by the European Medicines Agency

Outlines

Veterinary Big Data Workstream – how we started in 2020

Veterinary Big Data Workstream – Deliverables 2021

The ways ahead - Workplan 2022

Classified as public by the European Medicines Agency

Vet big data: how we started in 2020!

Classified as public by the European Medicines Agency

Vet big data: how we started in 2020!

➔ Analysis and findings on applicability of new digital technologies and RWD availability in Veterinary regulatory domain was performed and shared with BDSG in December 2020

Methodology

- Research in literature on “Big Data/RWD in Veterinary medicine”
- Define regulatory framework and data-legal boundaries
- Analysis of Vet data nature, environment and opportunities
- Set the Veterinary business areas
- Set vision on implementation strategy
- Identify key next steps

Classified as public by the European Medicines Agency

Outlines

Veterinary Big Data Workstream – how we started in 2020

Veterinary Big Data Workstream – Deliverables 2021

The ways ahead - Workplan 2022

Classified as public by the European Medicines Agency

Veterinary Big Data Team – Deliverables 2021 (1)

Feb. 2021

Report to CVMP on Big Data availability and applicability in Veterinary domain

PRELIMINARY IDEA

Classified as public by the European Medicines Agency

Veterinary Big Data Team – Deliverables 2021 (2)

Feb. 2021

Report to CVMP on Big Data availability and applicability in Veterinary domain

Additional expert from BVL joined the Vet Big Data Team

Apr. 2021

PRELIMINARY IDEA

KEY RESOURCES

Classified as public by the European Medicines Agency

Veterinary Big Data Team – Deliverables 2021 (3)

Classified as public by the European Medicines Agency

Summary of the event

- Event run for 1 day and a half
- Organised in 4 sessions
- 8 moderators and 21 speakers
- Average turnout of 300 to 350 attendees
  - ➢ Presentations and videos are available on EMA website

Classified as public by the European Medicines Agency

Key conclusions from the Vet Big Data Stakeholder Forum

1. Current efforts are focused on Reg. EU 2019/6 (VMP-Reg) implementation
2. Big Data is already happening and regulators need to be ready to accept/adsorb digital innovation via participation, cooperation, specialisation and transparency
3. Aspects to be addressed include build data mind-set, establish international cooperation forum, determine data governance, funding and resources
4. EU Veterinary Big Data strategy proposal to be developed across Vet Reg Network

Classified as public by the European Medicines Agency

EU Veterinary Big Data strategy: why now!

- EMRN and the BDSG take leadership in the implementation of new digital technology with important advancements in Human-specific area
- VMP-Reg facilitated new digital systems which will generate increased amounts of data across the EU

➔ It is now to investigate the convergence of traditional systems development with the advancement offered by emerging digital technologies

Classified as public by the European Medicines Agency

Veterinary Big Data Team – Deliverables 2021 (4)

Classified as public by the European Medicines Agency

Draft EU Veterinary Big Data strategy: highlights

Drivers & Benefits: For the Vet Network to absorb and embrace the challenges and opportunities that digital transformation offers continue building on the VMP-Reg goals of increase regulatory systems interoperability, reduce administrative and economic burden and enhance consistency, transparency and responsiveness.

Purpose: Propose ways forward for identifying relevant (regulatory) use cases, existing and additional data sources, critical infrastructures and methods to ensure an innovation-friendly environment for the development of new veterinary treatments for the benefit animal and human health and well-being.

Content and scope: Provide vision and direction for the Vet EU Regulatory Network to set a data framework on how veterinary data resulting from innovative solutions should be managed to support key regulatory activities in the short, medium and long-term phase

Classified as public by the European Medicines Agency

Outlines

Veterinary Big Data Workstream – how we started in 2020

Veterinary Big Data Workstream – Deliverables 2021

The ways ahead - Workplan 2022

Classified as public by the European Medicines Agency

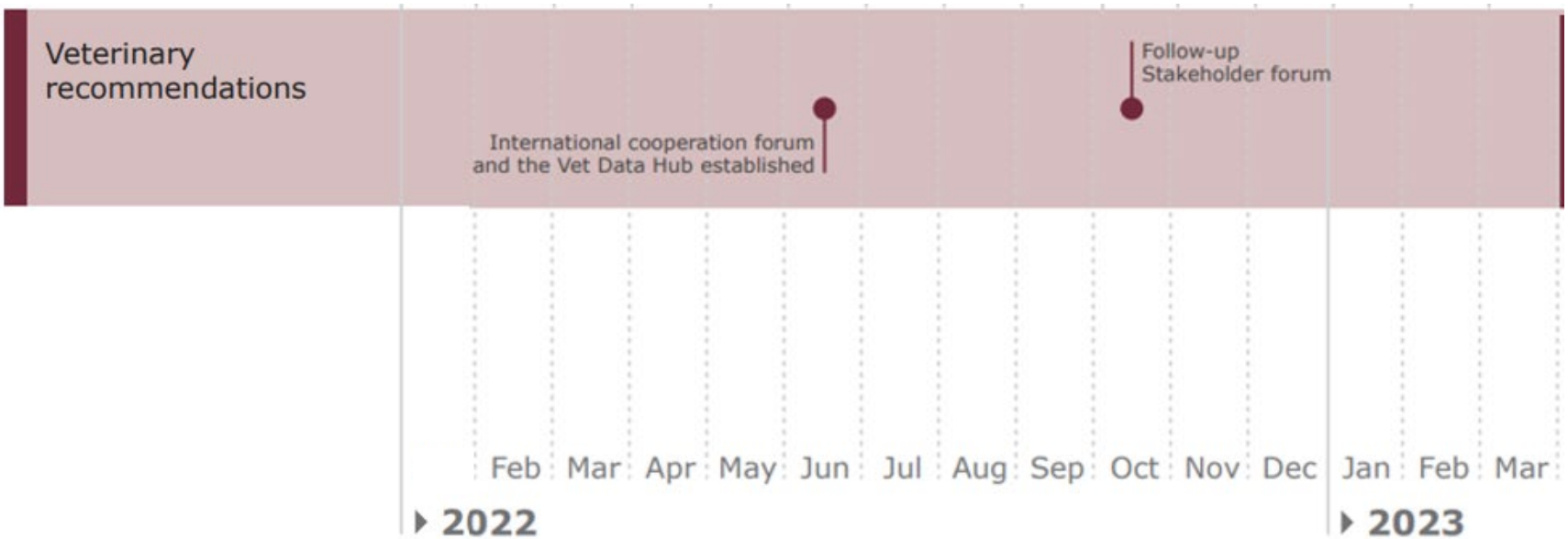
Ways ahead: 2022 workplan activities

EUROPEAN MEDICINES AGENCY

➔ EU Vet Big Data Strategy consultation and adoption by HMA in the course of 2022

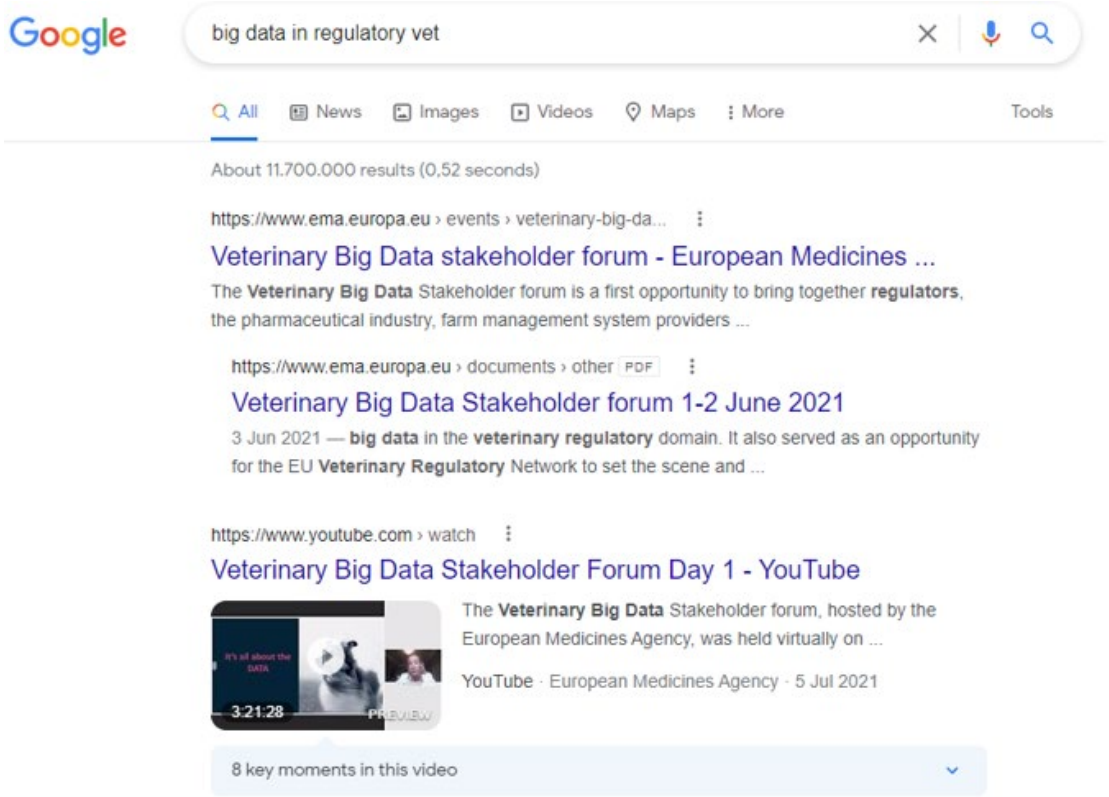
➔ Training curriculum definition to reach all NCAs

➔ Possible thematic workshops with NCAs and stakeholders



Classified as public by the European Medicines Agency

Vet big data end of 2021: where we are today!



Acknowledgement:

- Dr. Sandra Bertulat, *Federal Office of Consumer Protection and Food Safety (BVL) Germany*
- Dr. Céline Simoneit, *Federal Office of Consumer Protection and Food Safety (BVL) Germany*
- Mr. Ricardo Carapeto García, *Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) Spain*
- Dr. Mark Goldammer, *European Medicines Agency (EMA)*

Any questions?

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question vet-bigdata@ema.europa.eu

Follow us on **@EMA_News**