animalhealth europe
THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Veterinary Big Data stakeholder forum

The way ahead for AnimalhealthEurope

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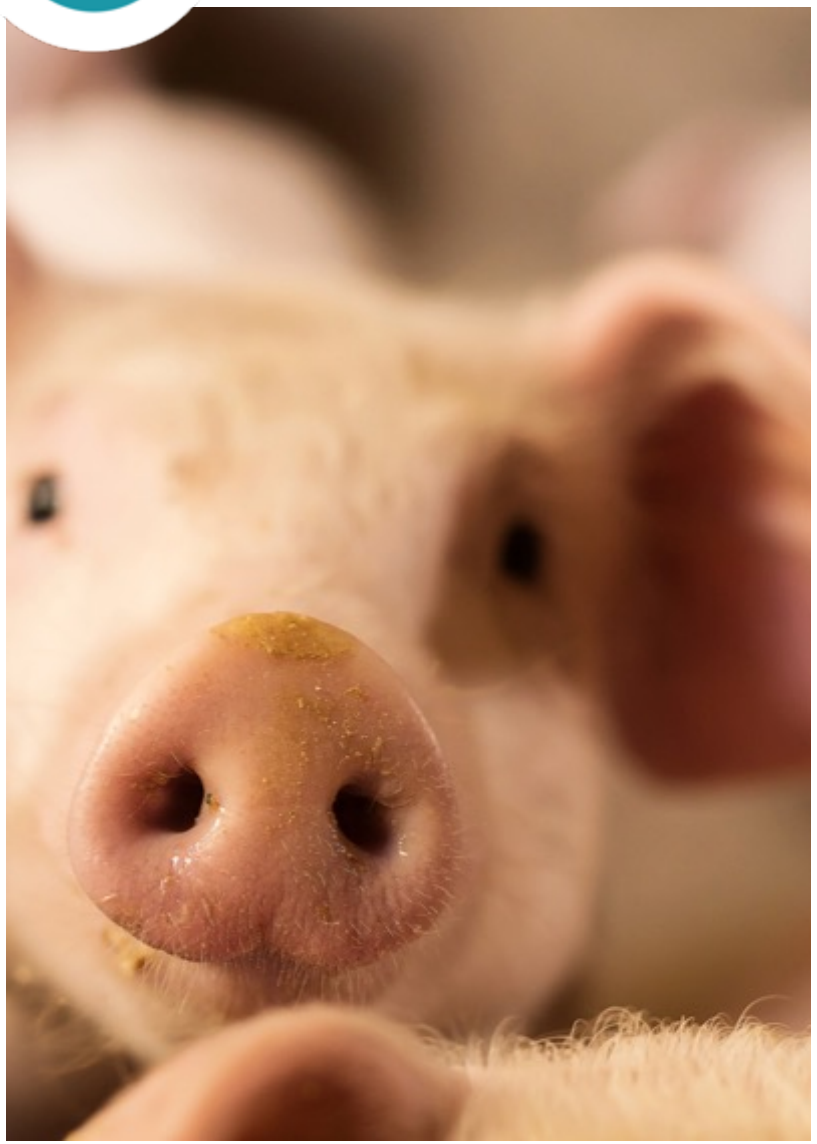
Classic approach to new area



- **Objectives**
  - be clear about what we want to achieve. What is the purpose
- **Infrastructure - what is needed to achieve the objectives**
  - Hardware - databases, inter-operable network;
  - platform to access and analyse EU healthcare data (e.g. DARWIN)
  - Do we need our own animal health data space
  - Software - including guidelines, standards, analytics, AI;
  - EU network capability for big data analysis
- **Operating framework:**
  - policy, rules, guides, committees, controls, regulation, safeguards
  - links to regulation of diagnostics
  - EU vs international

Animal health industry wants to engage

- Digitalization is happening and inevitable; essential we engage
- AnimalhealthEurope policy and strategy development at an early stage. Needs intensive cross-stakeholder collaboration
- Needs to be a win-win - deliver more without adding more burden
- Aim to improve - info, use of resources, accuracy, earlier diagnosis, working lives, animal health
- Support decision making across the product life cycle- MA to PHV (the focus today - but only one area of possibility)
- Fit-For-Future, Fit-For-Purpose, Fit-For-AH sector (cost:benefit)

The simpler we can make things, the more can get done

Policy priorities

- **Assess the Big Data Steering Group workplan July 2020**
  - And how to adapt this to AH: ethics and data governance will need to be different? same Regulatory applications and processes?
- **Challenges to address**
  - Top priority - **data quality** and representativeness; sampling bias and incompleteness of data, context of different data sources; process for data qualification; adopt **common standards** on data quality
  - **Sources of data** and interoperability is key for efficient RWD usage; geographical origin; equitable access
  - harmonisation of **data analysis methods**, standard IT systems; responsibilities for data handling and analysis
  - **Acceptance of evidence**: establishing the evidentiary value and regulatory accessibility of RWD and analytical output
  - Evolution of **regulatory science** to support innovation; keeping up
  - Protecting **confidentiality**; **security** standards for IT systems
  - **Ethical governance** framework; to know where data is kept, how it is used, who is responsible for processing; data ownership; AI ethics
  - Developing **best practice guidance** on all areas
  - **Funding**