Big Data in Veterinary Medicines Regulation

A Data Landscape Analysis

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Outline

- Who are we
- Why are we doing this?
- What are we doing:
    - Literature search
    - Survey study
    - Metadata catalogue
- Next steps

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Who are we?

This project is **funded by EMA** as part of a contract with Wageningen Research following a public tender procurement process. A link to the awarded contract can be included on the slides – Link: Services - 575628-2021 - TED Tenders Electronic Daily (europa.eu).

"This work is **conducted by Wageningen Research** under the contract no. SC 01 EMA/FWC/2020/46/TDA/L2.01 with the European Medicines Agency and the **opinions expressed are those of Wageningen Research** only and do not represent the European Medicines Agency's official position."

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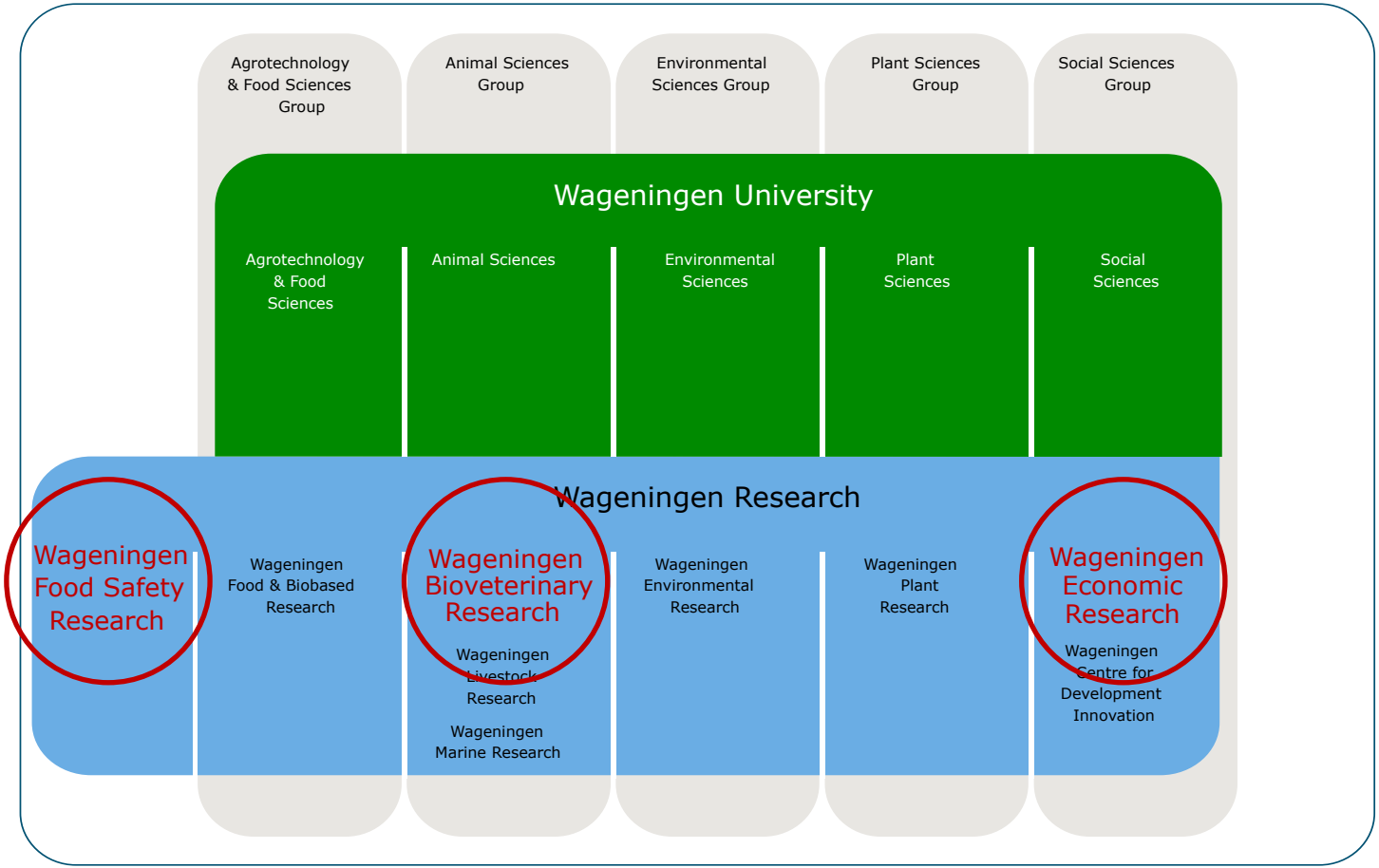

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Why are we doing this?

We are drilling for data; there is a big blue ocean out there!

Why are we doing this?

- Because big data has tremendous **potential** to revolutionise animal health and improve the **evidence** available to support **benefit-risk decisions** and facilitate getting better medicines to animals
- The speed of both the development and application of **digital technologies** in animal health is **increasing exponentially**
- The digitalisation of **veterinary diagnostics**, **monitoring** and **predictive technologies** are providing more, better and earlier data
- These data are increasingly being aggregated to build **veterinary intelligence** systems to generate cumulative **knowledge** to enable **better health outcomes**

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This is not unique, neither are the issues

- The wish to **collect**, get **access** to and **combine** big data is all over in society, both in the **private** and **public** sector
- Data is considered as **the new oil**, but only when it has **meaning**
- What happens when I **share** my data:
    - Who will get it, and can it be **used against me**?
    - Will it change the **power balance**, for instance in **supply chains**, but also in the relation of people with the **government**?
    - What's in it for me? Who will get the **benefits**?
- Fortunately, many developments on new **business models**, **ethics**, and **governance** (authentication/authorization, codes of conduct, legislation)

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What: Literature search

Literature search

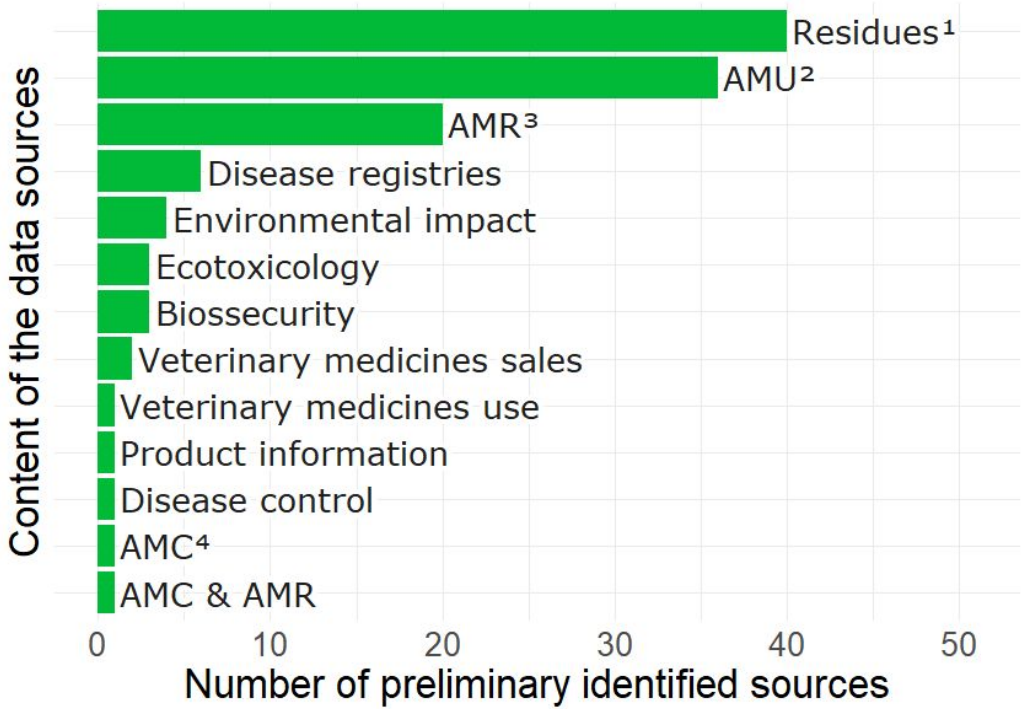
- Can **data sources** on animal health be identified that can be **used to support key regulatory activities** through the life cycle of veterinary medicines including **research and development**, **authorisation** and **post-authorisation** activities

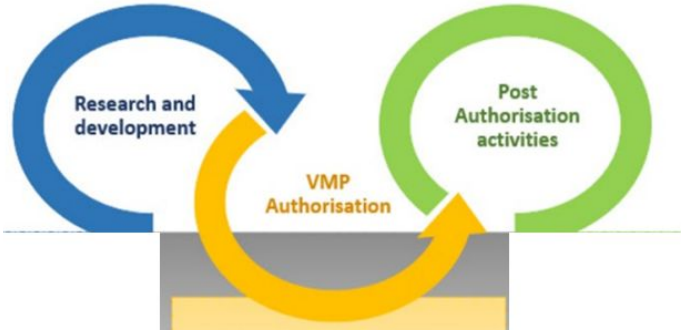
- Specific **queries** developed to search:
  - for **peer-reviewed publications**, in databases e.g. CAB Abstracts, Scopus, Mendeley
  - in statistical **databases** for relevant data sources, e.g. Eurostat, Statista
  - for **reports** published by EMA's sister organizations, e.g. EFSA, EEA, ECHA
  - for **research data in repositories**, e.g., Zenodo

Literature search: preliminary results

- Countries:
  - Total: 121 sources
  - Global: 7 sources
  - Europe: 15 sources
- Searches are ongoing

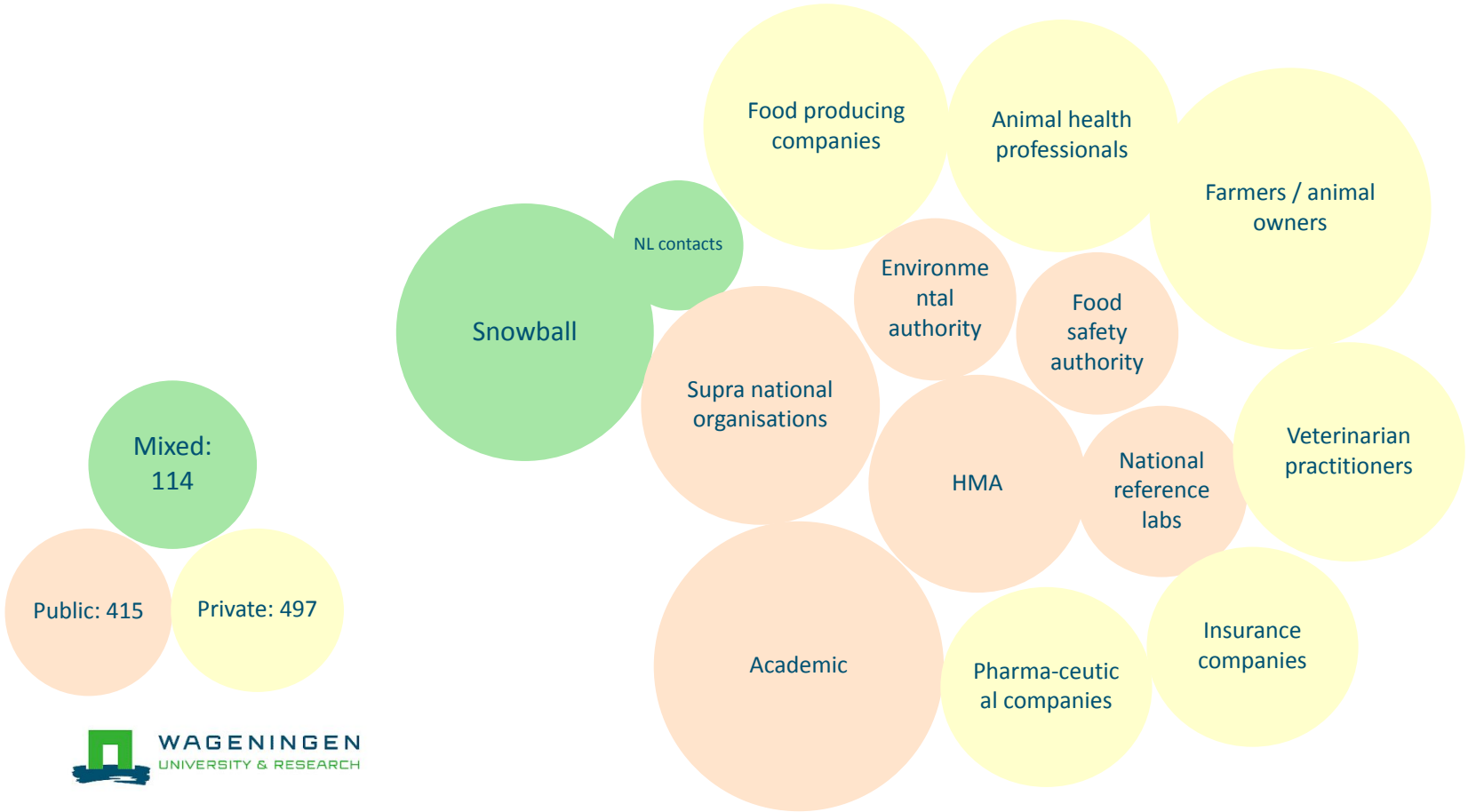
Literature search: preliminary results





Overview of content of the data sources identified preliminary.
[1]Residues in animal and food; [2]AMU: Antimicrobial use; [3]AMC: Antimicrobial consumption; [4]AMR: Antimicrobial resistance

What: Survey



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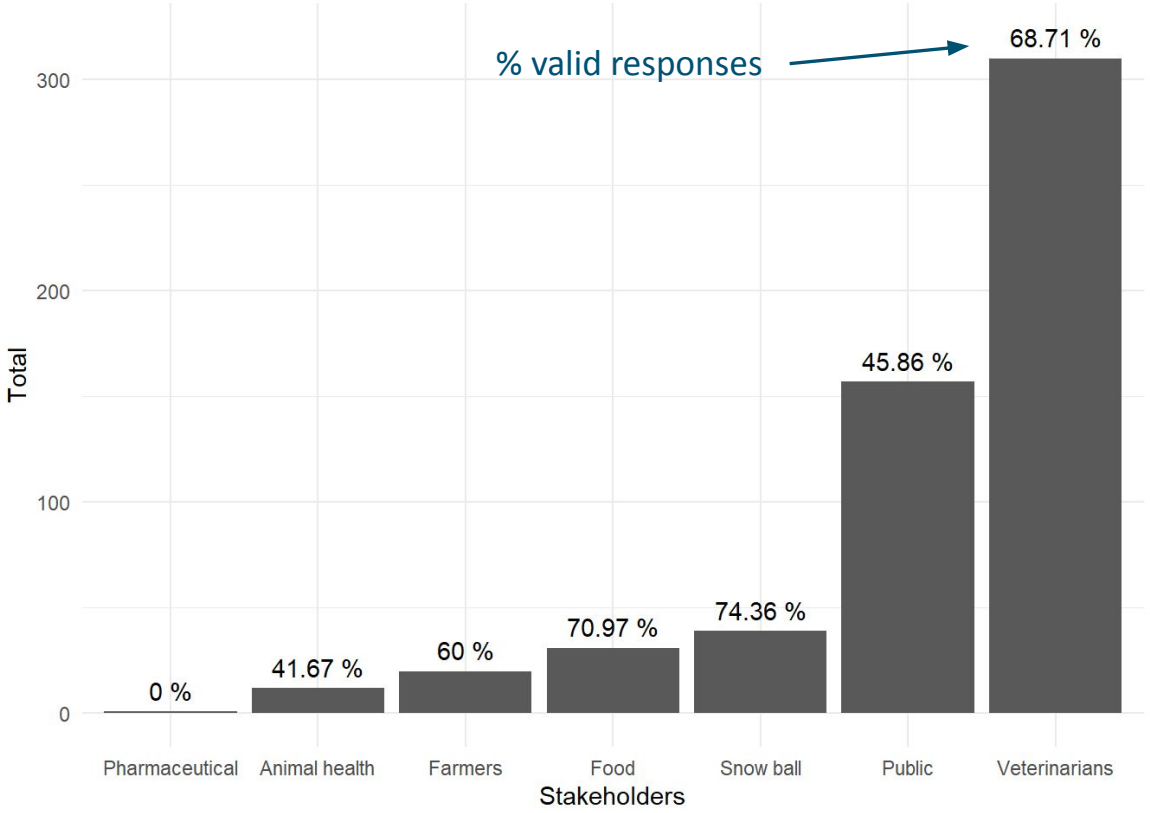
Total number of responses per type of questionnaire



- Article in Magazine (Dutch Food Companies)

Metadata catalogue for the veterinary domain

Metadata catalogue

- Using the metadata list in human medicines as starting point
- Adjusted to veterinary field where need, keeping the structure as intact as possible to be able to merge data easily in the future
- Criteria to select data sources from the survey and literature research for in-depth metadata description

Metadata list human medicines

- Minerva project EMA
- 442 metadata elements
- Reduced to less than 100
- 60-70% completed f

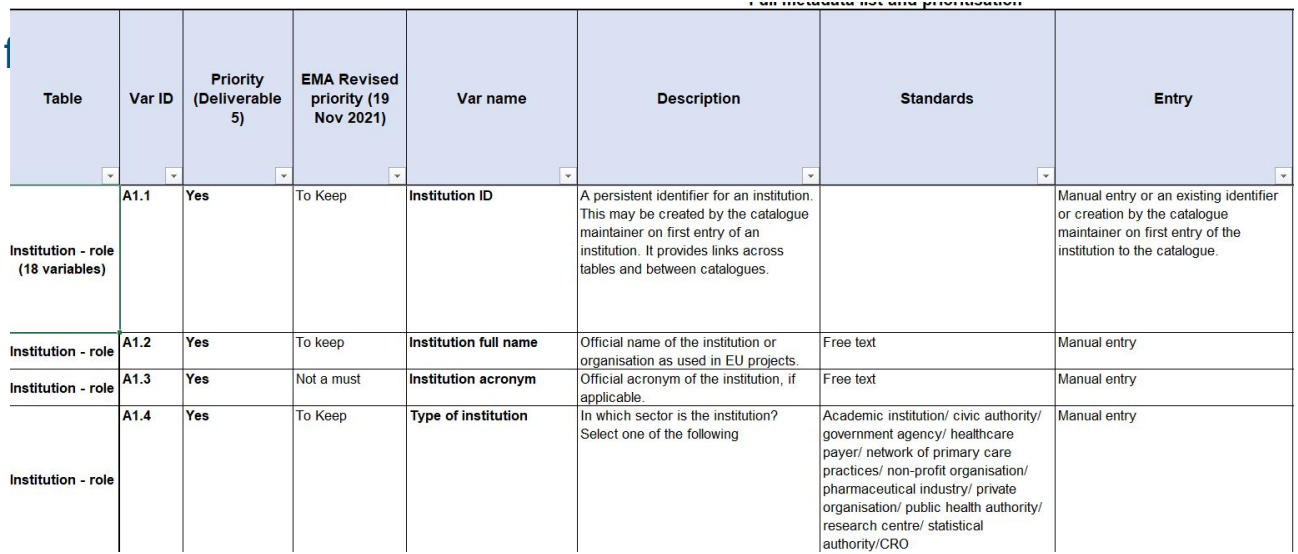


Table	Var ID	Priority (Deliverable 5)	EMA Revised priority (19 Nov 2021)	Var name	Description	Standards	Entry
Institution - role (18 variables)	A1.1	Yes	To Keep	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables and between catalogues.		Manual entry or an existing identifier or creation by the catalogue maintainer on first entry of the institution to the catalogue.
Institution - role	A1.2	Yes	To keep	Institution full name	Official name of the institution or organisation as used in EU projects.	Free text	Manual entry
Institution - role	A1.3	Yes	Not a must	Institution acronym	Official acronym of the institution, if applicable.	Free text	Manual entry
Institution - role	A1.4	Yes	To Keep	Type of institution	In which sector is the institution? Select one of the following	Academic institution/ civic authority/ government agency/ healthcare payer/ network of primary care practices/ non-profit organisation/ pharmaceutical industry/ private organisation/ public health authority/ research centre/ statistical authority/CRO	Manual entry

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Adjusted to the veterinary domain

- Approximately 60 variables need adjustment

Table	Var ID	Priority (Deliverable 5)	EMA Revised priority (19 Nov 2021)	Var name	Description	Keep for Veterinary Catalogue (1=y, 0=n, 2=? or needs adaptation)	Remarks	Proposal for adaptation	Standards	
Institution - role	A1.12	No	Not a must	Medical specialty	Does the institution or member have a medical specialty in any of the following therapeutic/disease areas? Select all that apply.	1	RB: replace with stadndars that are typical for vet domain: pets, production anaimals		Anaesthesia/ Cardiovascular diseases/ Congenital Malformations/ Devices/ Disorders of the central nervous system/ Ear, nose and oropharynx disorders/ Endocrine disorders/ Eye disorders/ Gastrointestinal tract/ Geriatrics/ Gynaecology/ Immunological products and vaccines/ Immunosuppression/ Infectious diseases/ Liver disease/ Malignant disease/ Musculoskeletal and joint diseases/ Neonates/ Nutrition and blood/ Osteoporosis/ Paediatrics/ Poisoning/ Overdose/ Pregnancy/ Psychiatry/ Renal impairment/ Respiratory diseases/ Skin disorders/ Urinary tract disorders/ Other	Ma
Institution - access contracts	**A3.2**	**Yes**	Not a must	**Access permission**	Is permission from an external organization (e.g., a data controller) required for your institute to access (an extract of) the data bank, in order to process the data and publish results of data processing? For example, if approval of a study protocol is needed from an external organization	1	RB: AGV data and permission of data owners		No/ always/ study-dependent	A s for A2.
Data source - underlying	**B1.4**	**Yes**	Not a must	**Data source type**	Type of data source. Select one or more of the following:	2	Revised? RB: Farm data, managemant system, vet practice, test farms, research		Biobank/ administrative claims/ electronic health record/ registry/ other	Ma

Glossary | Overview | **Relevant for vet** | M1 Cat-entry | A1 Ins-role | A2 Ins-data sources | A3 Ins-access contracts | A4 Ins-studies | B1 DS-und

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Next steps

Next steps

- Finalizing the literature research, survey and metadata catalogue
- See if the catalogue works well for entering the findings
- In-depth interviews with a few owners of interesting data sources
- Recommendations on how to move from here
    - With little burden for the data holders / providers
    - With maximum impact for the public task of EMA

Thanks for your attention!

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