SCAR
Standing Committee
on Agricultural Research

European Animal Health
& Welfare Research
COLLABORATIVE WORKING GROUP

SCAR AH&W – SRIA Workshop
Breakout session 1 – Subgroup 3
"Treatments & Vaccines"

Rapporteur: Sven Arnouts

10/11/2022

Who is in this BO-session?

- Rapporteur: Sven Arnouts
  - Business Development Manager at UGent provaxs, Belgium
  - Chair of the expert group for "Vaccines & Treatments"
  - Candidate coordinator of the EUP AH&W

- Participants

SCAR
Standing Committee
on Agricultural Research

European Animal Health
& Welfare Research
COLLABORATIVE WORKING GROUP

Members of the expert group "Vaccines & Treatments"

Vaccines	Treatments	Terrestrial	Fish	Country
	■	■		Belgium
■		■		Belgium
	■	■		Denmark
	■		■	Denmark
	■		■	Italy
■			■	Norway
■		■		Denmark
■		■		France
■		■		Switzerland

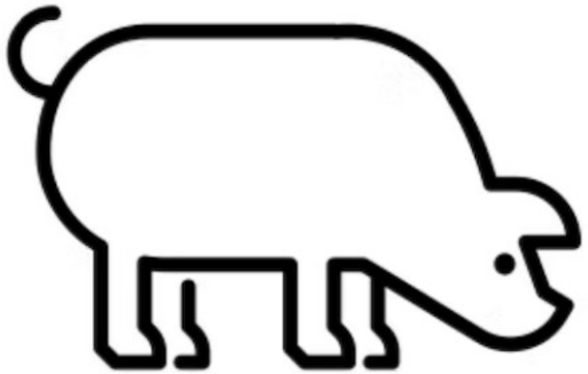
SCAR
Standing Committee
on Agricultural Research

European Animal Health
& Welfare Research
COLLABORATIVE WORKING GROUP

Scope

Stress, hygiene, climate is external to the animal (WG Farm Management)

Farmed/managed animals, terrestrial or aquatic, including bees, as well as companion animals and wildlife when there is a potential threat to public or animal health (livestock)



Effect on vectors (tick, culicoïdes, …)

Delivery: oral, mucosal, injection, aerosol, …

Optimisation of feed/nutrition

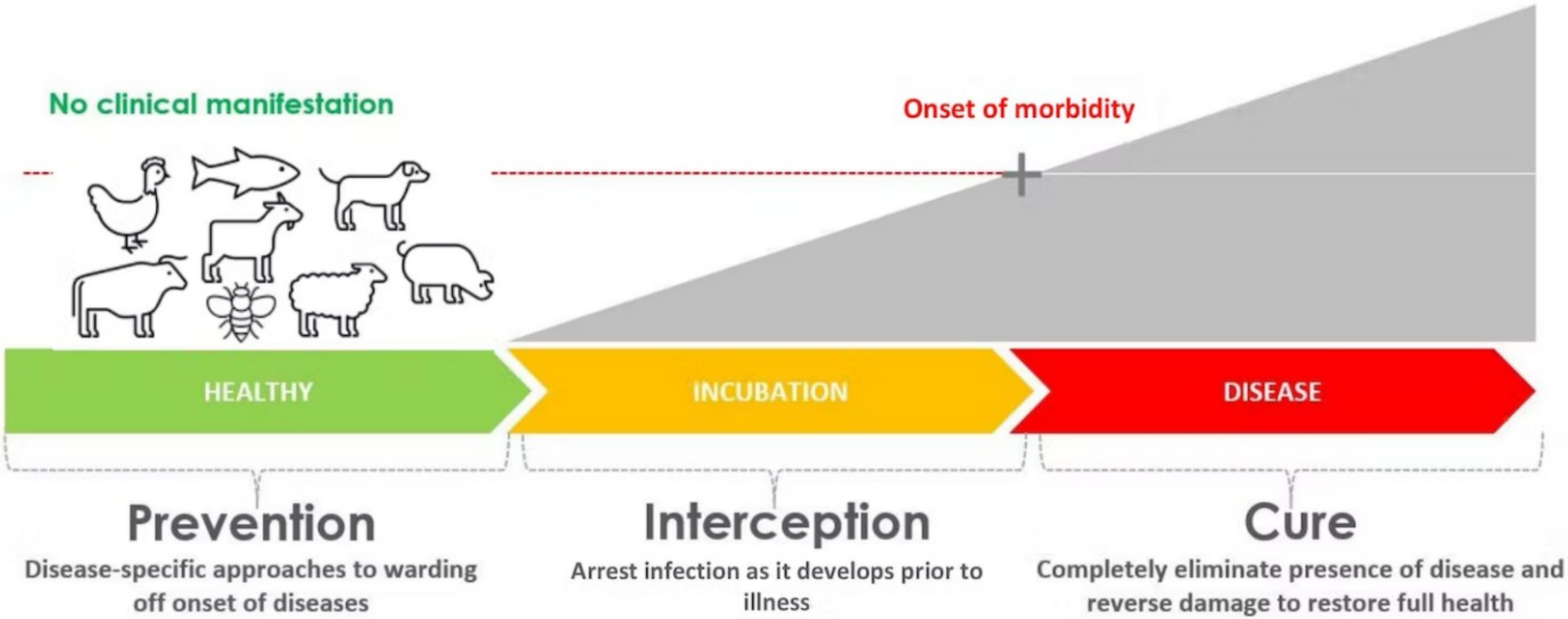
Vaccination and treatment programs using registered/marketed vaccines and therapeutics (WG Farm Management)

(Direct) control of vectors (tick, culicoïdes, mosquitoes) transmitting pathogens within herds

SCAR
Standing Committee on Agricultural Research

European Animal Health & Welfare Research
COLLABORATIVE WORKING GROUP

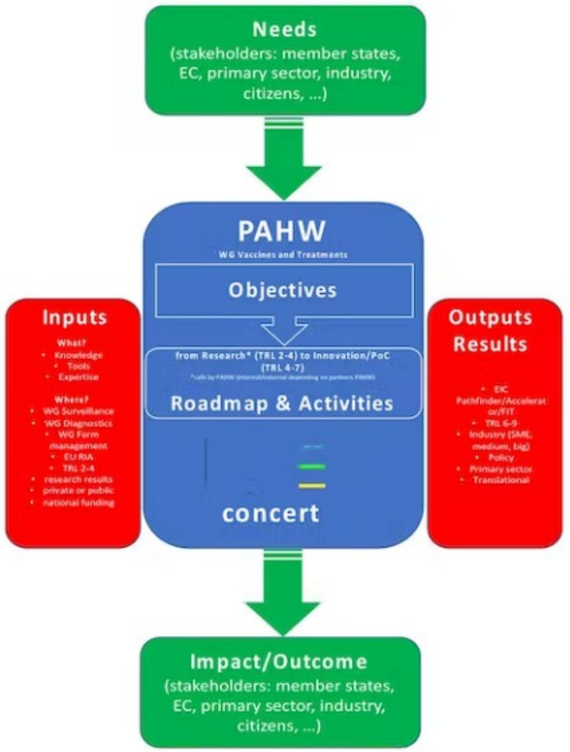
General concept

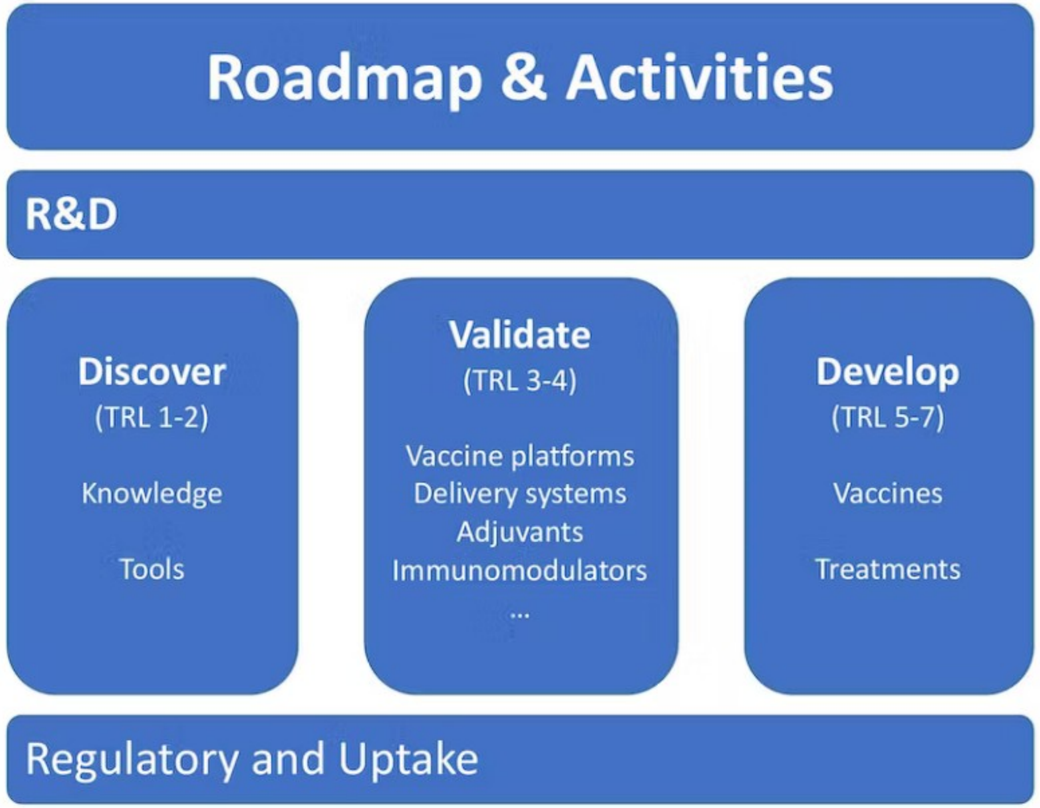


SCAR
Standing Committee on Agricultural Research

European Animal Health & Welfare Research
COLLABORATIVE WORKING GROUP

Needs, Roadmap and Activities





SCAR
Standing Committee on Agricultural Research

European Animal Health & Welfare Research
COLLABORATIVE WORKING GROUP

Part 1: Areas of work

Assess how the EUP AH&W will contribute to a selection of broad areas of work:

- One Health
- Big data
- Social science

SCAR
Standing Committee
on Agricultural Research

One Health

- Special attention to AMR in a broad sense (antibiotics, antiparasitics and antifungals) and prudent use of antimicrobials for humans and animals

- Close collaboration and frequent consultation with EUP working on human infectious diseases (e.g. information on targets for therapeutics or vaccines on pathogens that can emerge and cross species)

- Large international One Health initiatives (e.g. WOAH, WHO, FAO and UNEP)

- Bring the "spotlight" on vaccines also to the field of animal health (CEPI, EVI, …)

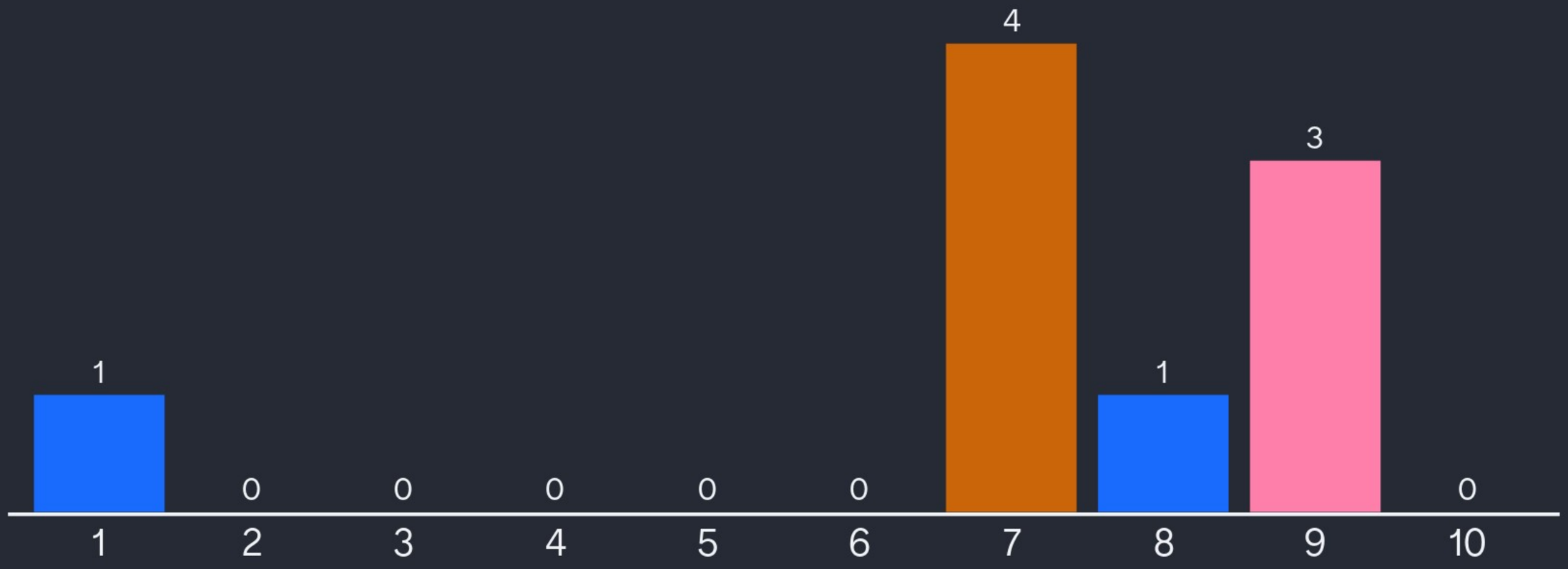
Score these broad areas of work: One health approach

Big data

- Bioinformatics pipelines for analysis of microbiome and pathogen data generated by 16s rRNA gene and metagenomics sequencing
- Collection of data to enable the development of bio-informatics for antigen/epitope prediction, reverse vaccinology, …
- Data on climate to predict risks (parasite load on pasture)

Score these broad areas of work: Big data

Mentimeter



9

Social science

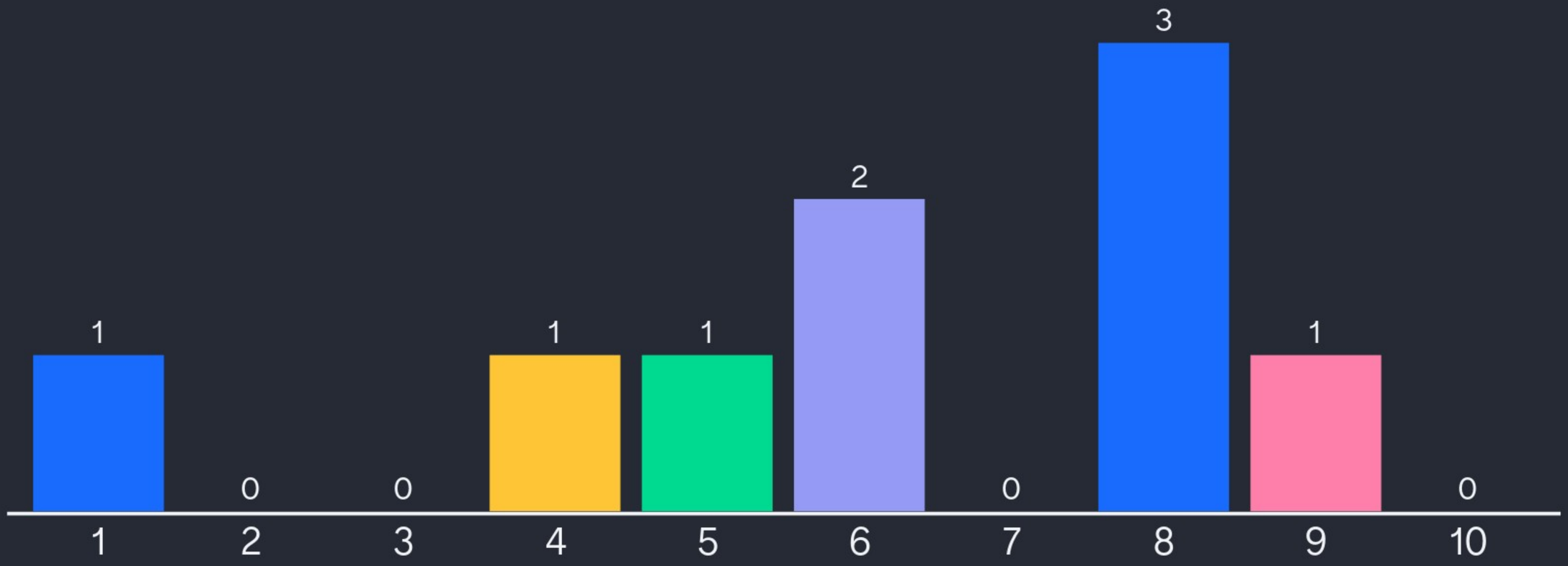
- Interaction with and communication to stakeholders including
  - the primary sector (farmers and veterinarians) and
  - citizens/consumers

  to facilitate implementation of next generation vaccines/treatments

- Education and training

Score these broad areas of work: Social science

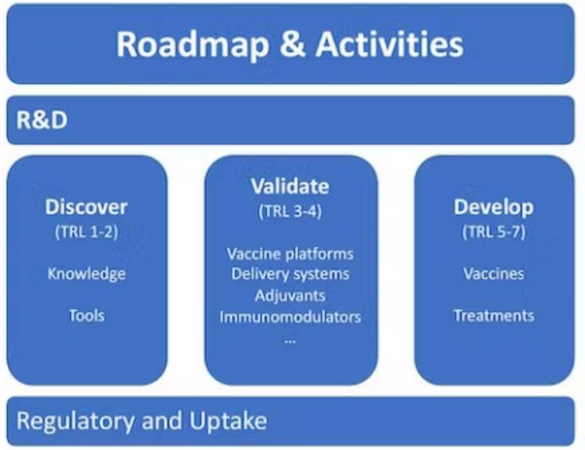
Mentimeter



9

Part 2: Classify a selection of "Research & other needs" of the SRIA

- Discover:
  - Perform basic research (TRL 1-2) to study interactions between pathogens and host microbiome (e.g. pathobiome), and direct or indirect interactions between pathogens (e.g. co-infections), antimicrobial and antiparasitic drugs and host microbiome, mechanisms of anti-microbial (antibiotic and antiparasitic) resistance
  - Develop tools such as
    - experimental farm approaches;
    - in vivo, in vitro and in silico infection models for testing efficacy and safety of new drugs with reduced need for animal testing, new drug-delivery devices, therapeutics including leads for new antimicrobials; and
    - bioinformatic pipelines for analysis of microbiome and pathogen data



- Validate:
  - Build on the results of the Discover phase to develop or improve interventions and treatments and deliver first proof of concept, where appropriate, in collaboration with industry: demonstration of immunogenicity and efficacy in target species; representative (small scale) animal (challenge) model (TRL 3-4)

Technology Readiness Level (TRL)

Veterinary vaccines

Industry		TRL	Description/definition
Pre-development phase - Discovery/Research - Proof of Concept		1	Basic research on vaccine target/review scientific knowledge base, competitive landscape and market potential
		2	Design and formulation of vaccine candidates (experimental vaccines) and clear product profile defined
		3	Demonstration of immunogenicity in non-target/target species
		4a	Proof of Concept: Demonstration of safety in target species
		4b	Proof of Concept: Demonstration of immunogenicity and efficacy (minimum immunizing dose) in target species: representative (small scale) animal (challenge) model
			Selection of vaccine candidate and formulation
Development phase	Early/pre-clinical development	5	Demonstration of animal safety in target and non-target species. Evaluation of user safety, environmental safety and residues.
		6	Demonstration of efficacy in a representative and validated target animal challenge model (if available)
	Late/clinical development	7	Demonstration of safety and/or efficacy evaluated under relevant (field) conditions
Registration phase		8	Final vaccine defined and regulatory dossier completed, ready for MAA (Market Authorisation Application), evaluation, response to questions and approval
Life cycle		9	Vaccine marketed and evaluated in the field (pharmacovigilance)

SCAR
Standing Committee
on Agricultural Research

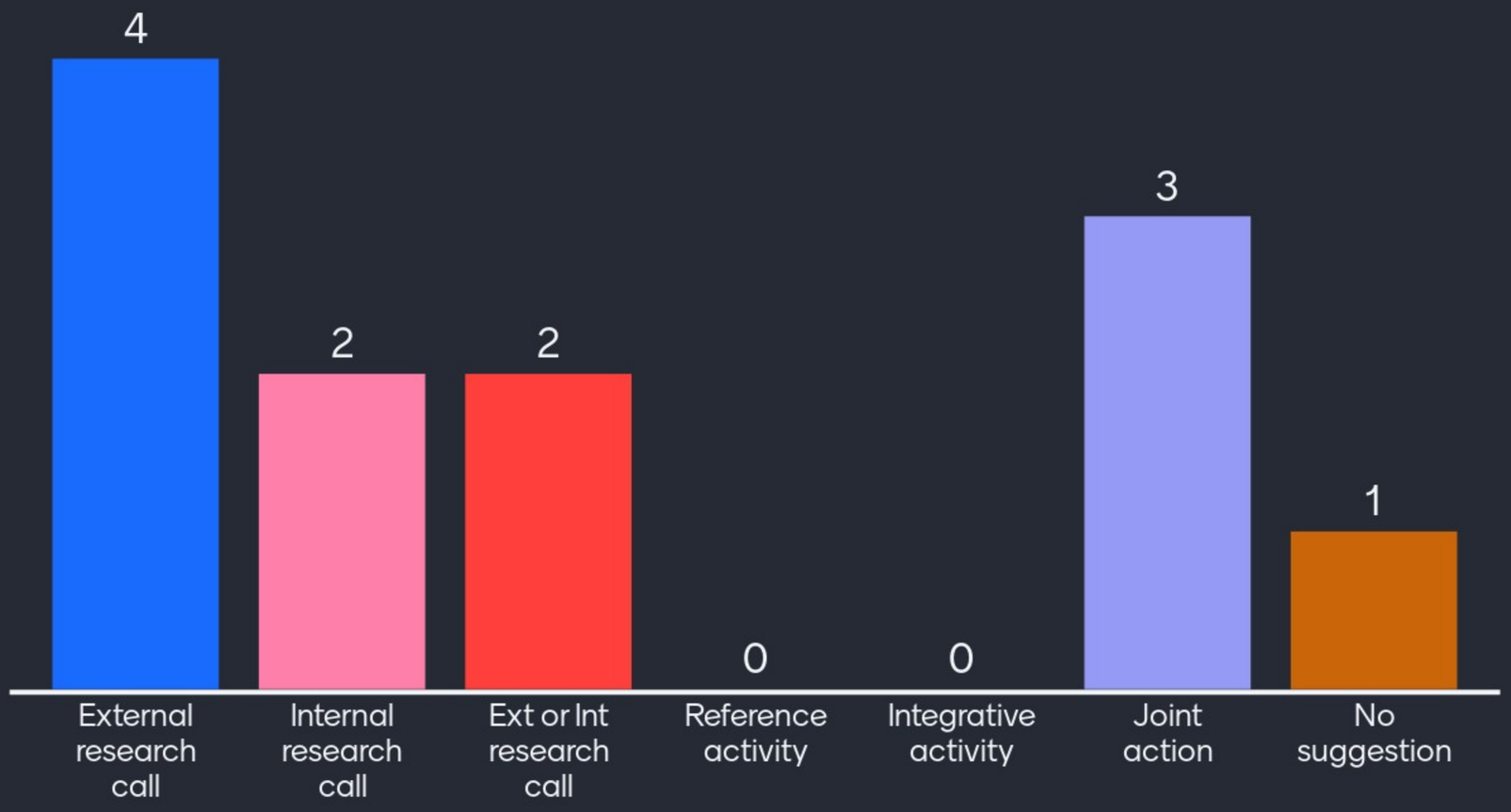
Discover

- Host-pathogen interactions, including interactions between pathogens (e.g. disease complexes and co-infections, with a focus on the modulation of mucosal immunity), between pathogens and host microbiome/health/immune system, and (direct or indirect) interactions between pathogens, antimicrobial/antiparasitic drugs and host microbiome
- Mechanisms of antiparasitic, antifungal, and antiviral resistance
- Investigation of the impact of the reduction of antimicrobials and antibiotic free productions on animal welfare
- Importance and role of different parts of the immune system of farm animals (e.g. antibodies/cellular), including the innate immune capacity of newborn animals and interference between maternal immunity and maturation of the newborn's immune system
- Transmission of pathogens between host species and between wild and farmed animals (especially for fish and for outdoor/free range animal production)
- Vaccine platforms and expression systems (formulation and device and documented overview of existing platforms/expression systems)
- Potency tests to replace in vivo testing (in vitro neutralisation assays ; biomarkers correlated with protection)
- Relevant in vitro (including e.g. organoids, 3R) and in vivo infection models and animal facilities for testing efficacy and safety of antimicrobial, antiviral and antiparasitic drugs/alternatives for antimicrobials

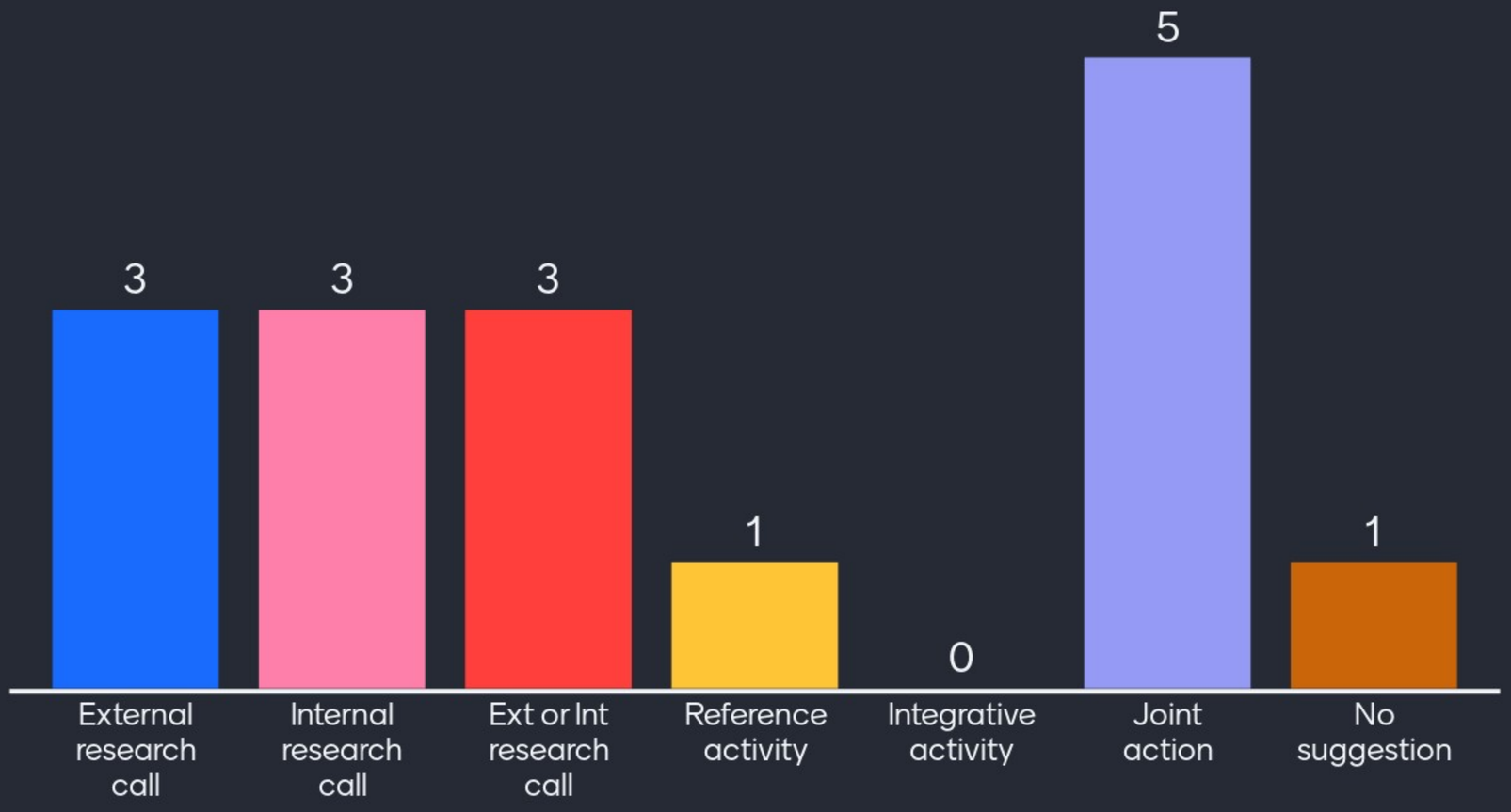
Validate

- Hits/leads of novel antimicrobial, antiviral, and antiparasitic drugs/alternatives with defined therapeutic potential (TRL 2), experimental proof of concept (TRL 3) or validated proof-of-concept and safety (TRL 4)
- Pilot farms to evaluate efficacy of new vaccines (stage between controlled challenge trials on research institutes and field trials on farms ; commercial farms with tools for more precise monitoring of relevant parameters (e.g. water/feed intake per pen, logging of temperature and humidity, animal behaviour, …). This will contribute to EMA's ambition to reduce use of animals in trials and to replace field trials on farm by other studies.

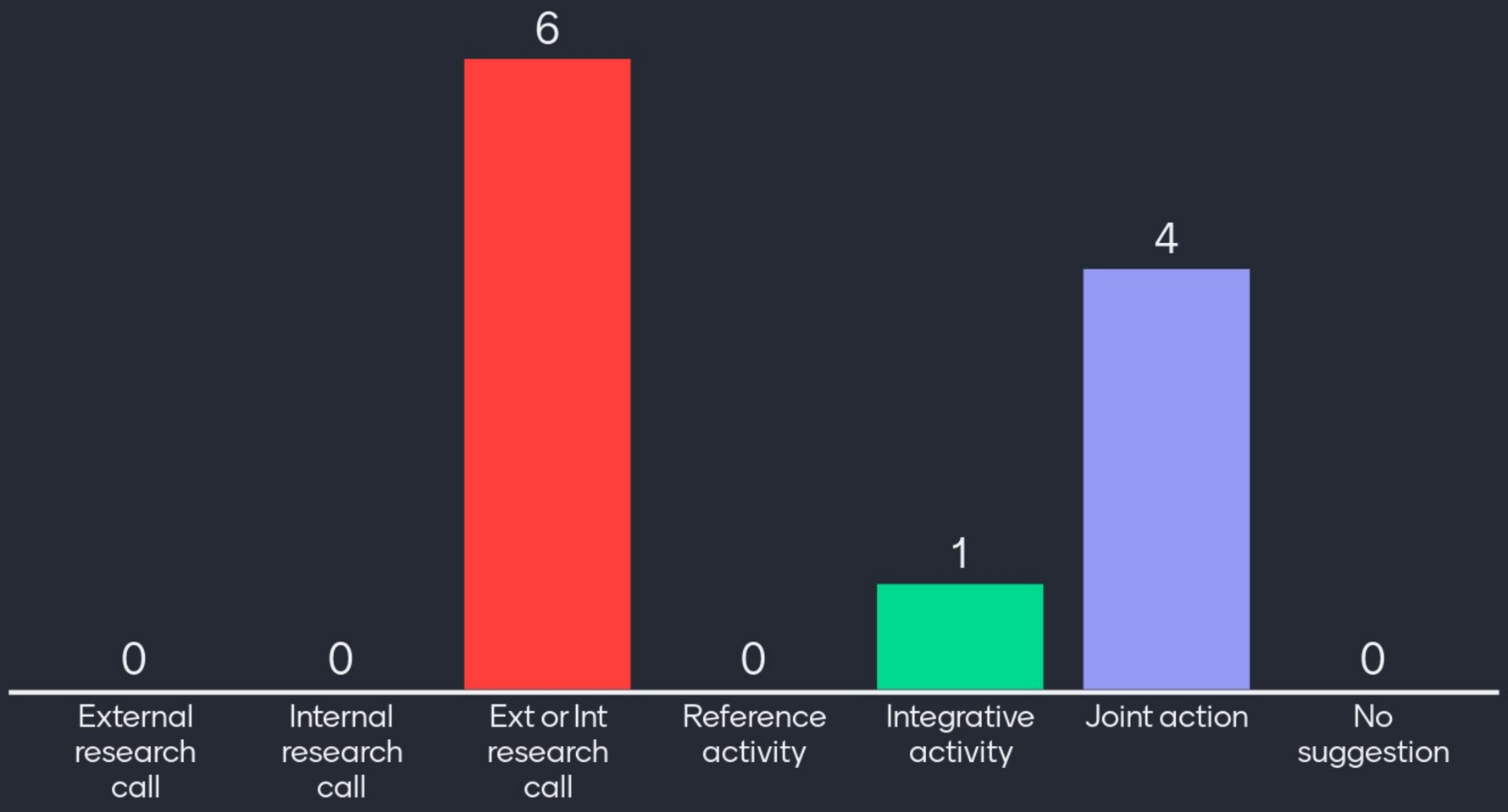
Host-pathogen interactions (triangle pathogen-microbiome-host)



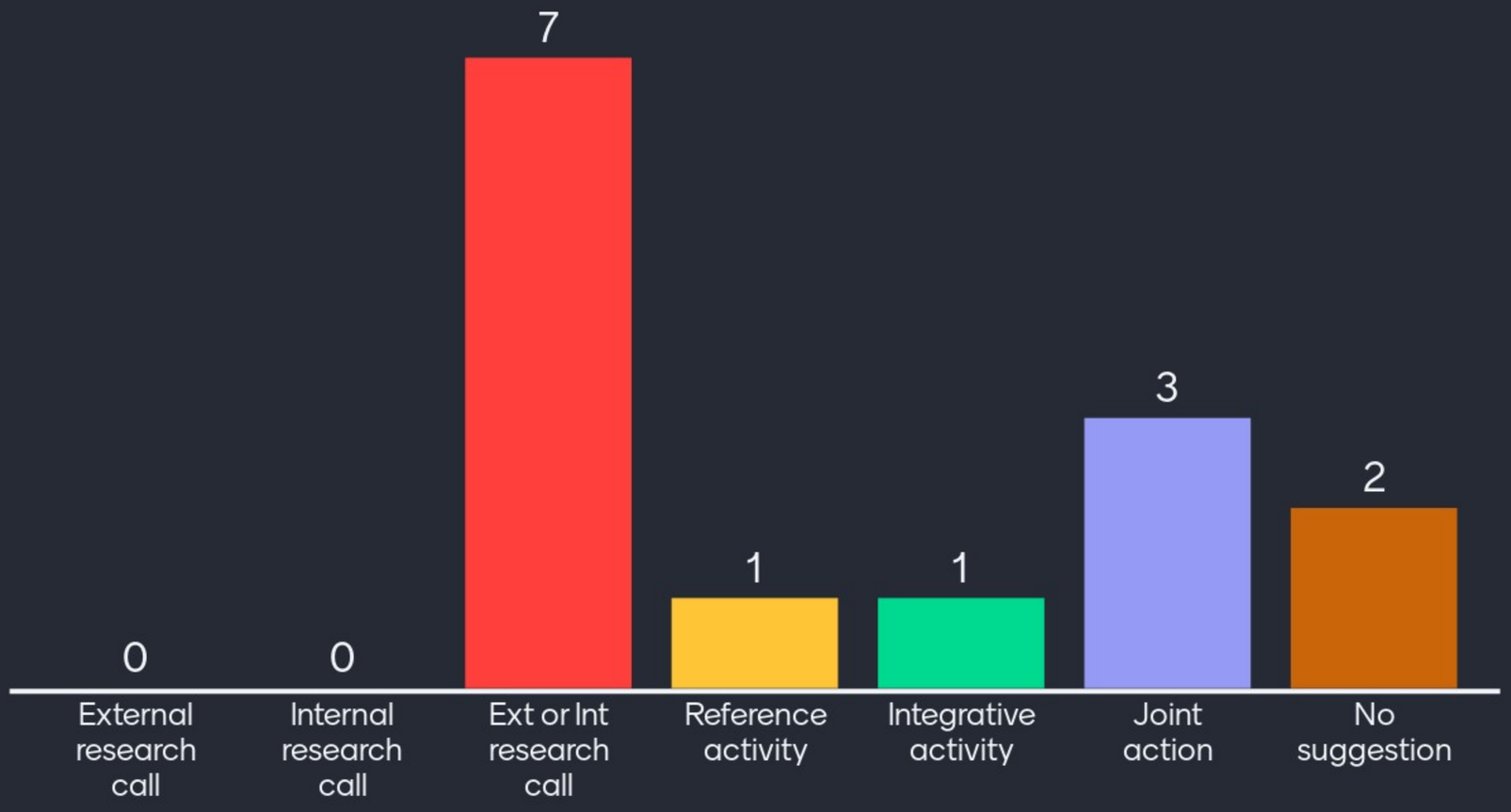
Mechanisms of antiparasitic, antifungal, and antiviral resistance



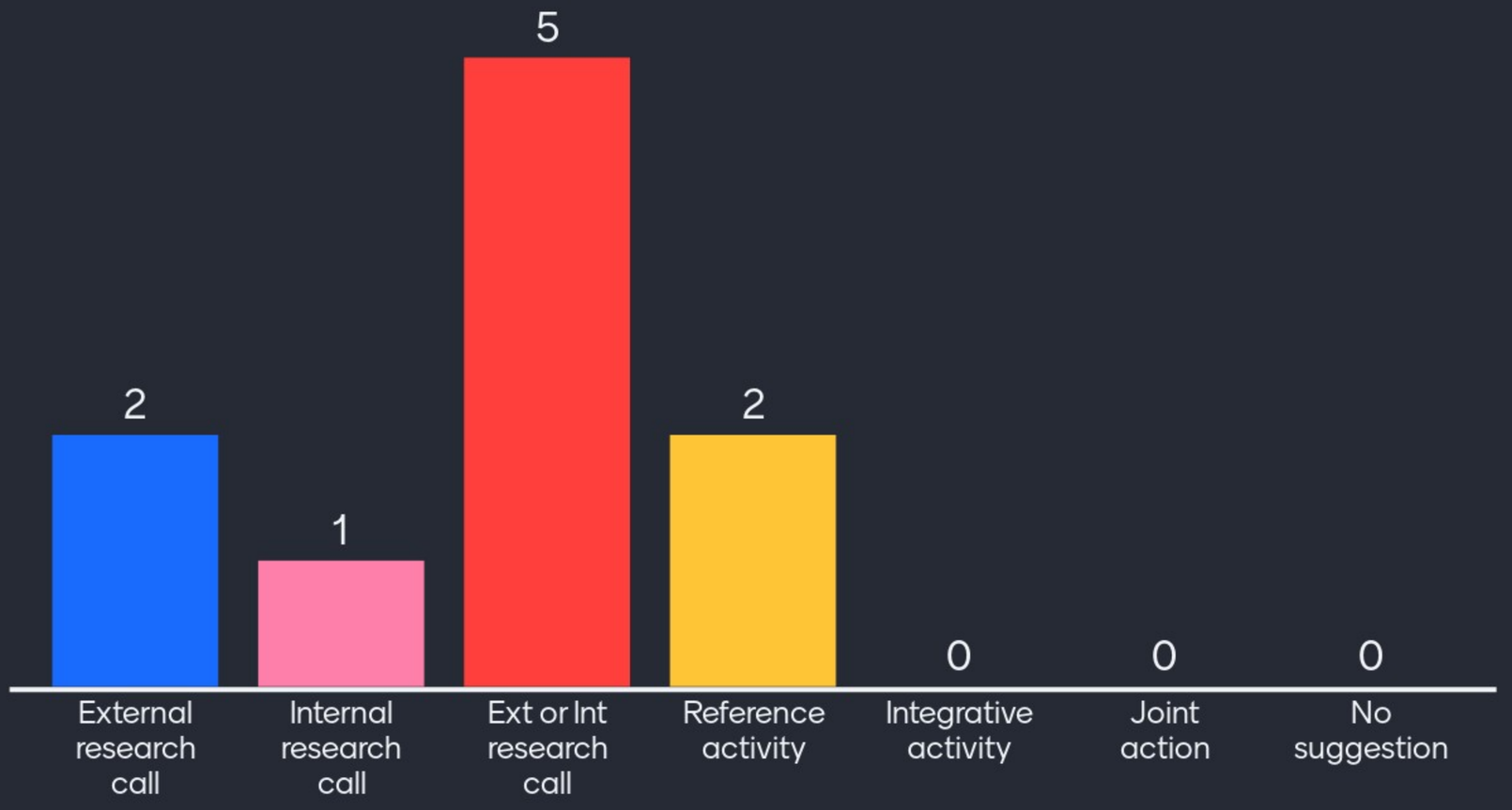
Impact of reduced AM-use on animal welfare



3R for testing efficacy and safety of new antimicrobial treatments

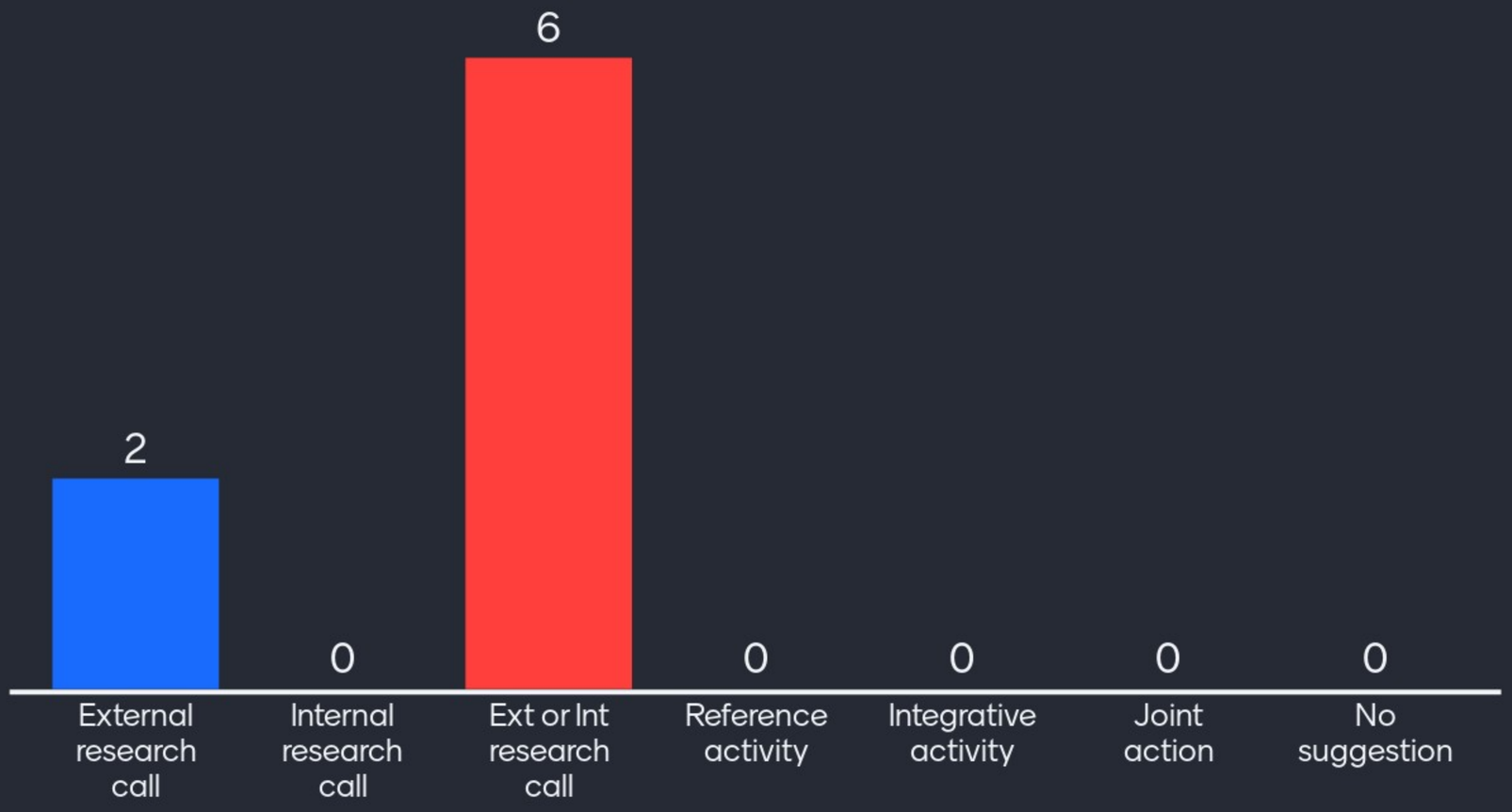


Proof of concept studies (up to TRL4) for novel antimicrobial treatments



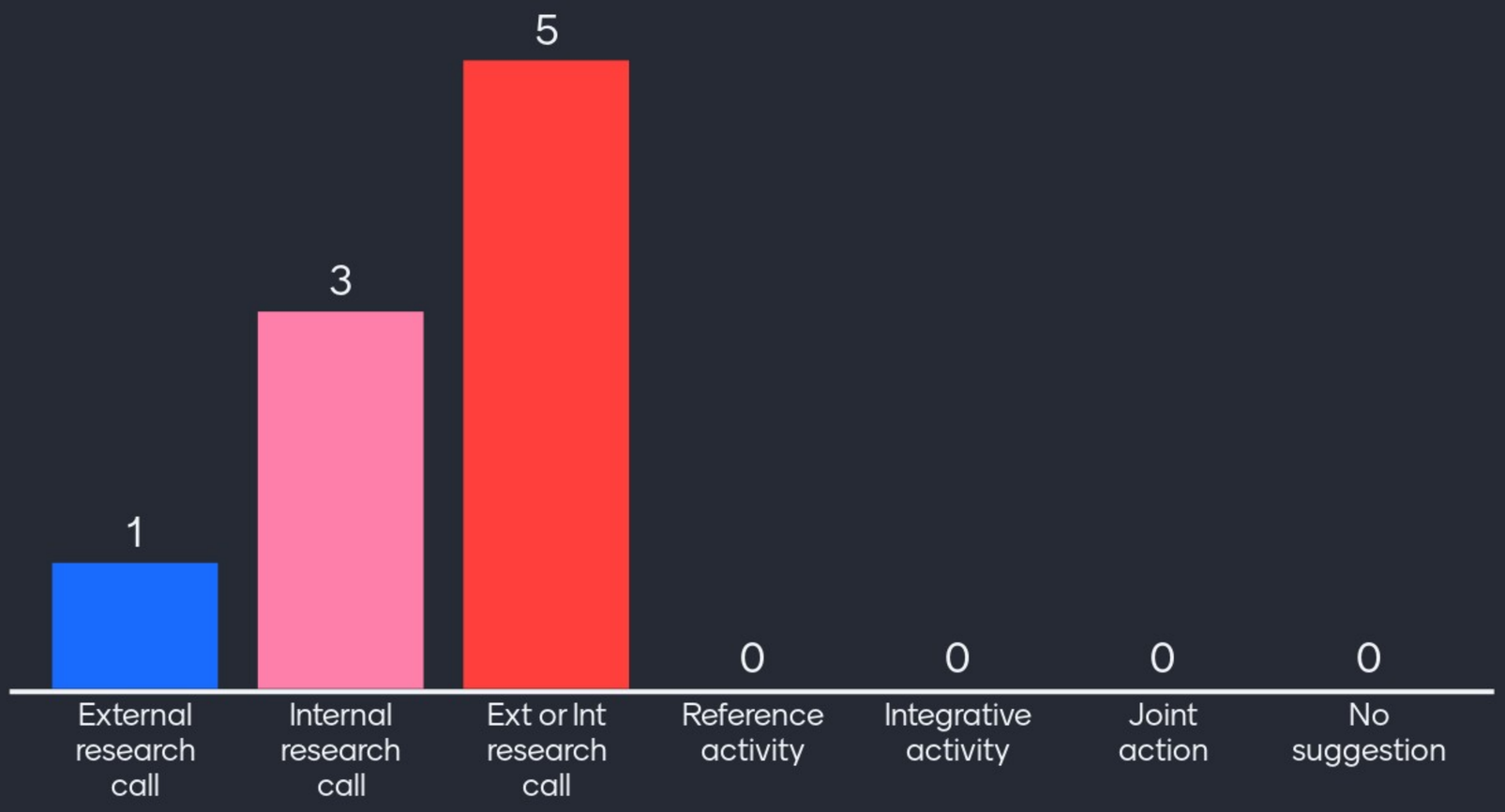
Better understanding of (mucosal) immunity, especially in newborns

Mentimeter



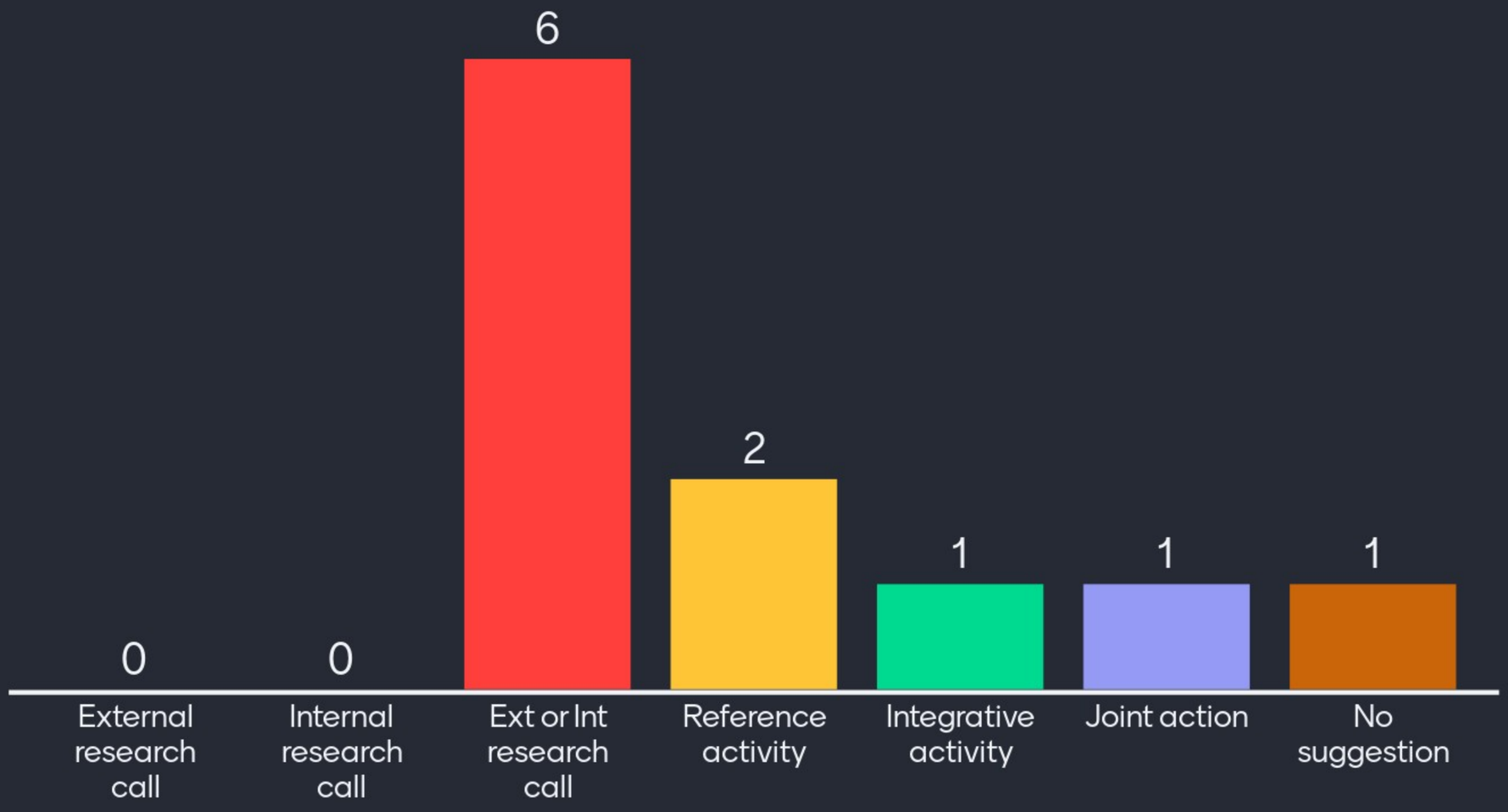
8

Transmission of pathogens between host species including wildlife



Vaccine platforms and expression systems

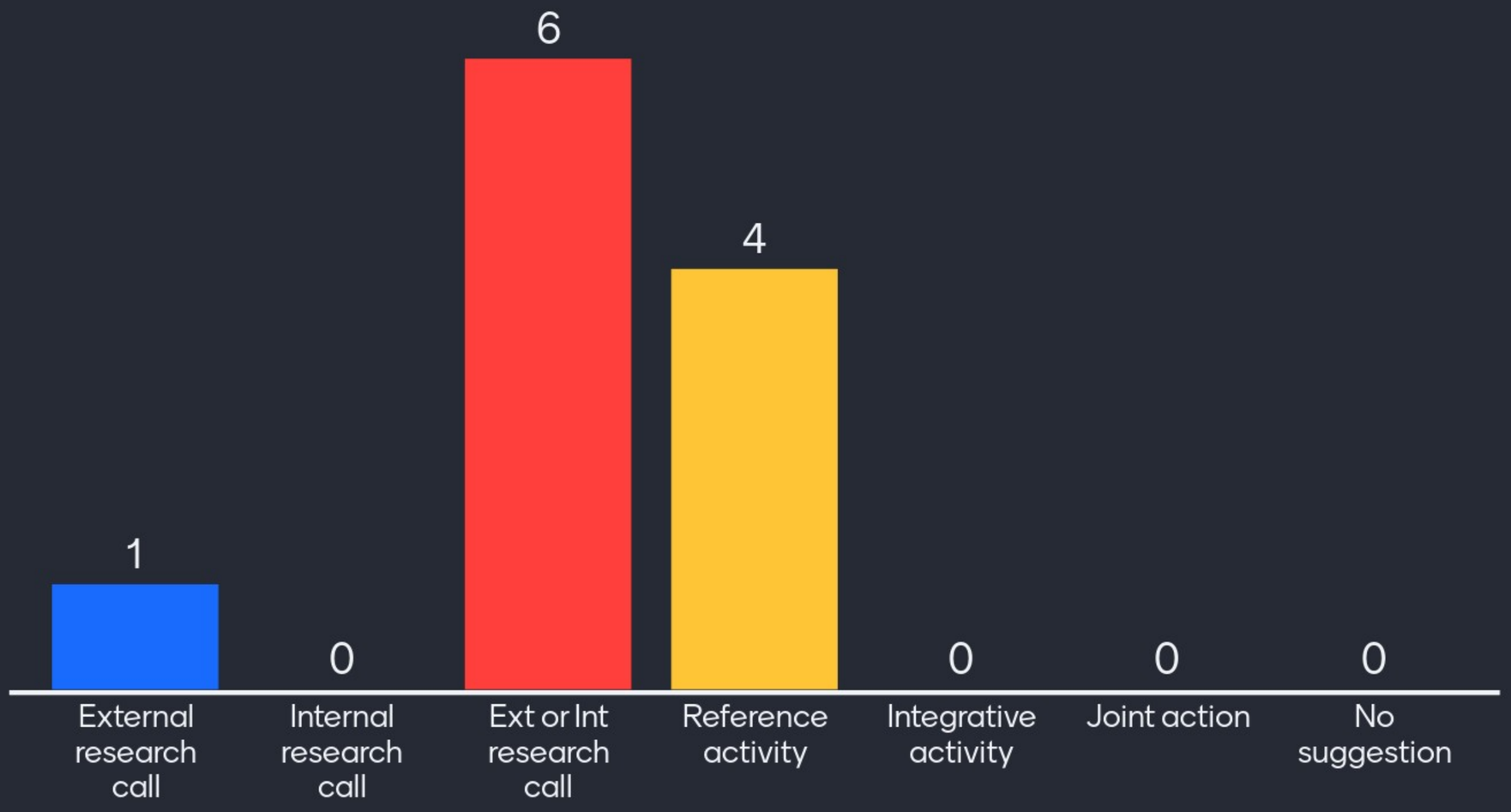
Mentimeter



8

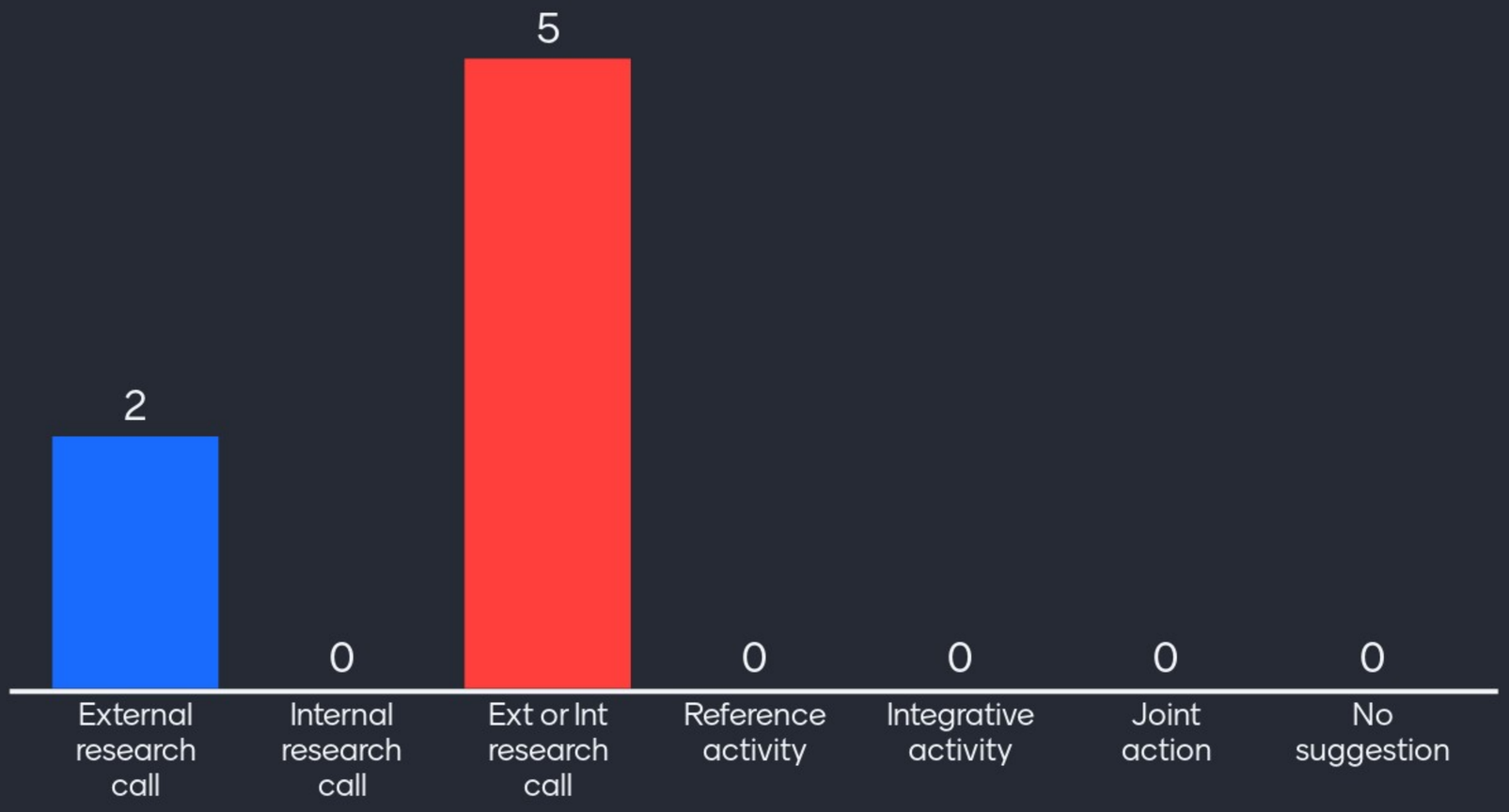
Potency tests that support 3R

Mentimeter



7

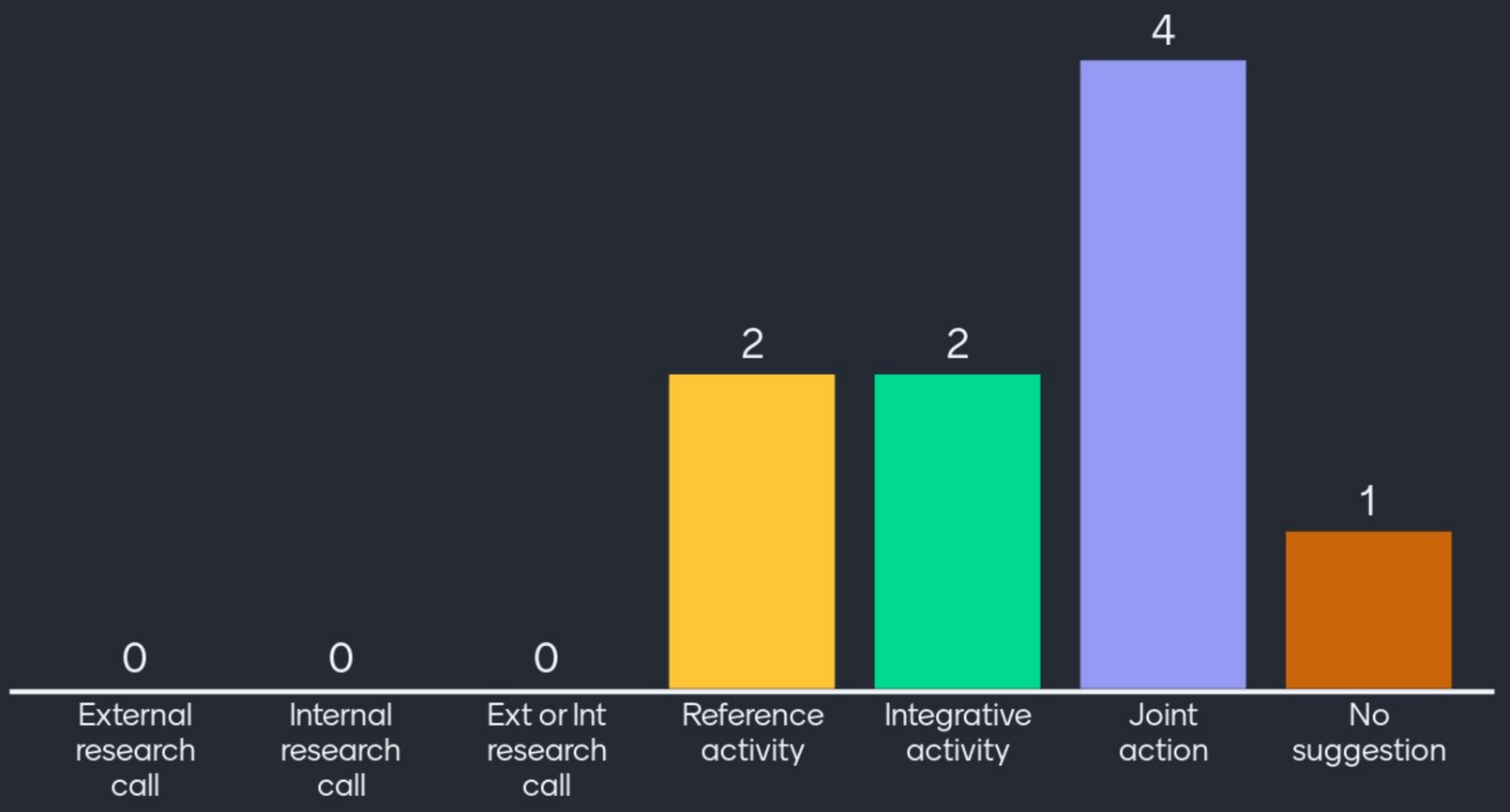
Pilot farms to evaluate effect of vaccines on health and welfare



Uptake

- Preparation of guidelines for registration of alternatives to antibiotics. Therefore also interact with EMA and the workgroups on “Innovation” and “Antimicrobial resistance and other emerging health threats” to participate to EMA’s network strategy for the practical implementation of the Veterinary Regulation (Regulation (EU) 2019/6)

Preparation of guidelines for registration of alternatives to antibiotics.



Wrap up and main conclusions

- Part 1:
  - One Health
  - Big Data
  - Social Sciences
- Part 2:
  - Discover
  - Validate
  - Uptake

Thank you for your attention

SCAR
Standing Committee on Agricultural Research

European Animal Health & Welfare Research
COLLABORATIVE WORKING GROUP