Veterinary novel therapies and technologies

"..to boldly go where no one has gone before.."

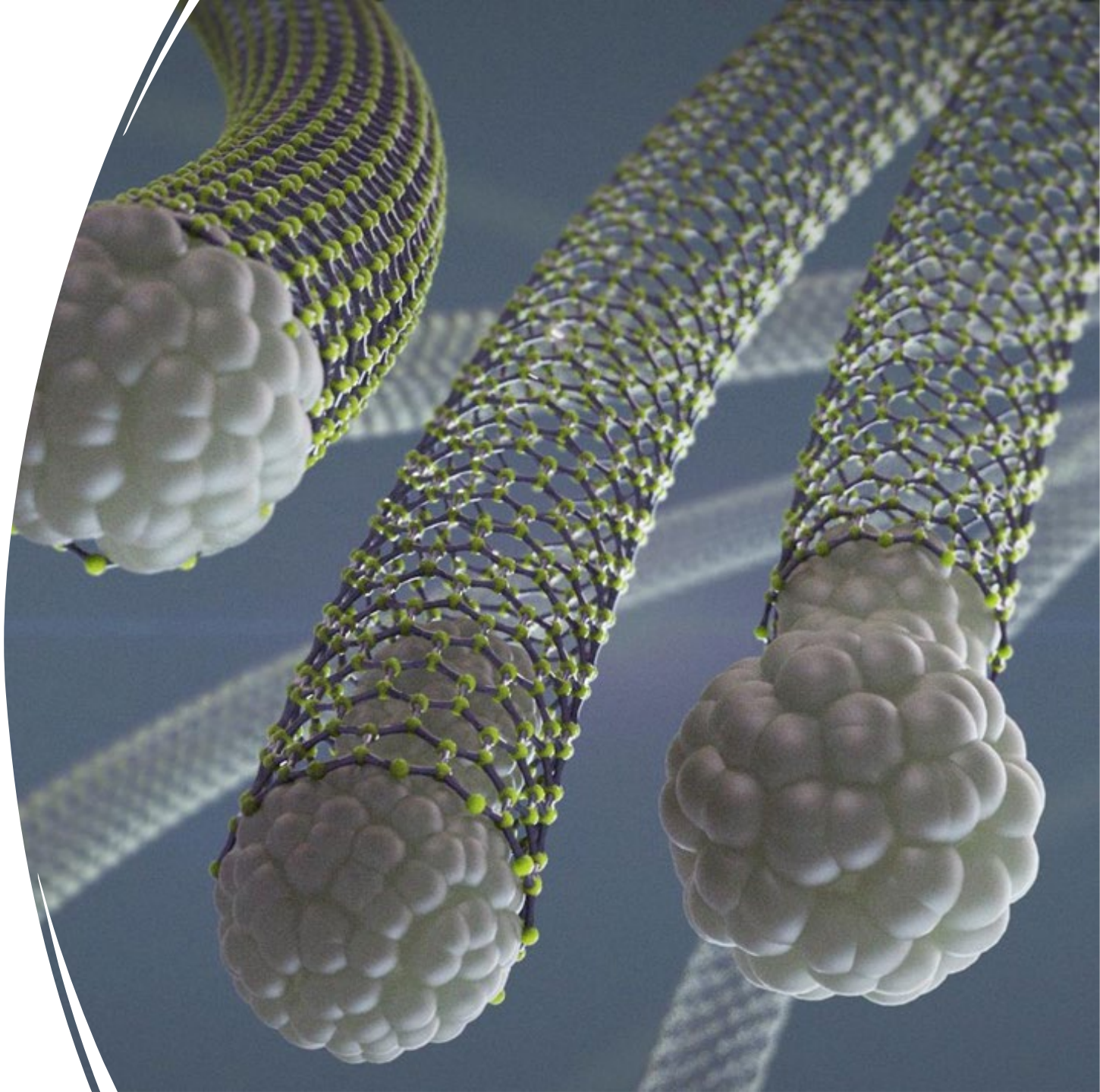
Novel therapies and technologies

- Issued from nanotechnology
- Phage therapy
- Gene therapy
- Regenerative medicine

- Any other therapy considered a nascent field in vet medicine

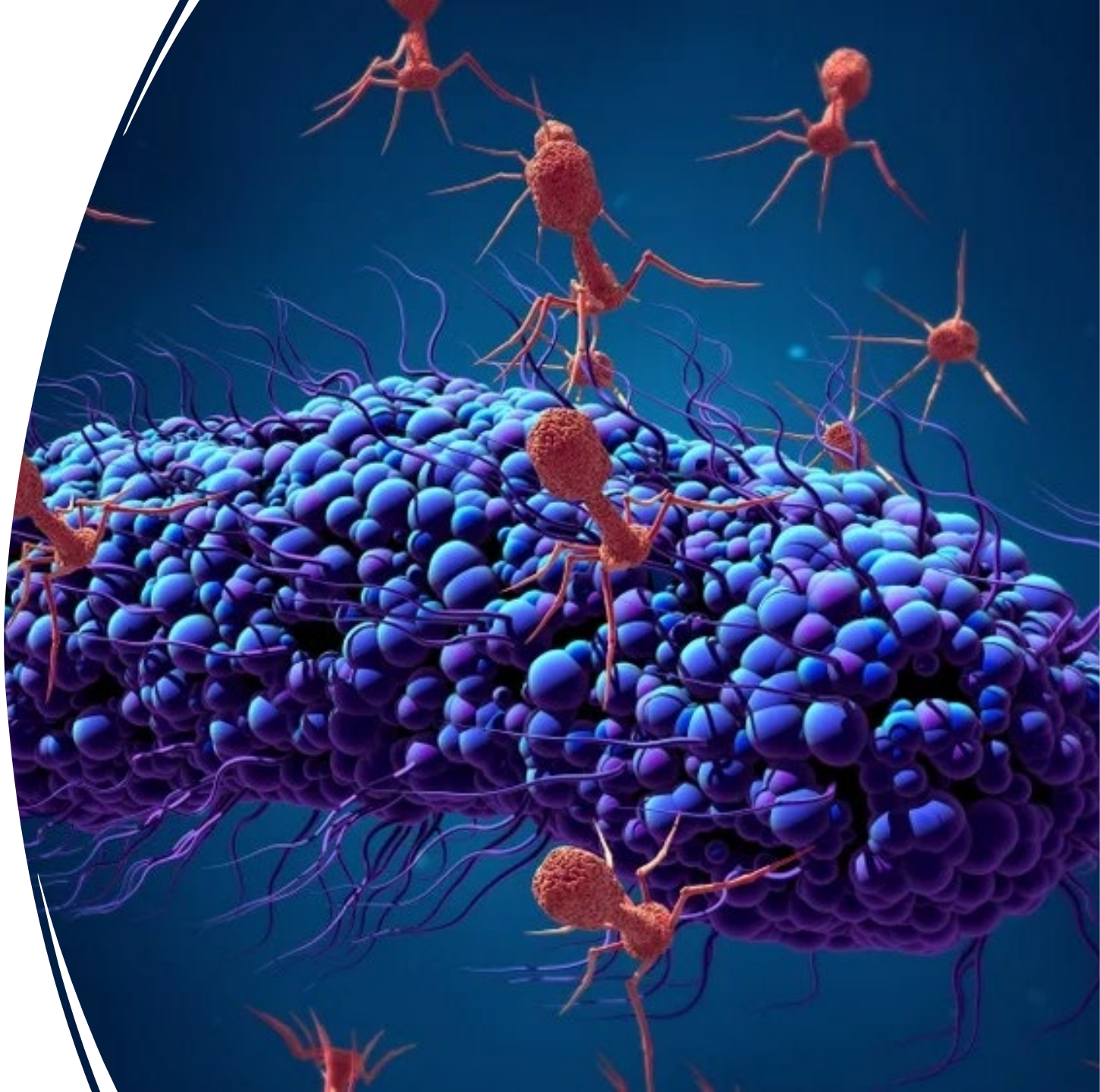
Nanotechnology

- Substances produced at the nanometer scale, with different physical, chemical and/or biological properties because of the nanoscale dimensions.
- Nanoantibiotics. Nanostructures may act synergistically with antibiotics
- Nanoparticles as delivery systems or adjuvants for vaccines (i.e. mRNA vaccines)
- Nanoparticles as targeted drug delivery systems
- Nanosensors, for earlier or more accurate detection of disease or infection



Bacteriophages

- Treatment of humans and animals with some success
- For specific patients and for a limited time. Sometimes wider application is possible.
- Complete cure may not always be the goal: uses include decontamination of the environment or of feed/food, or in conjunction with antibiotics (enhancing the susceptibility of the bacteria).



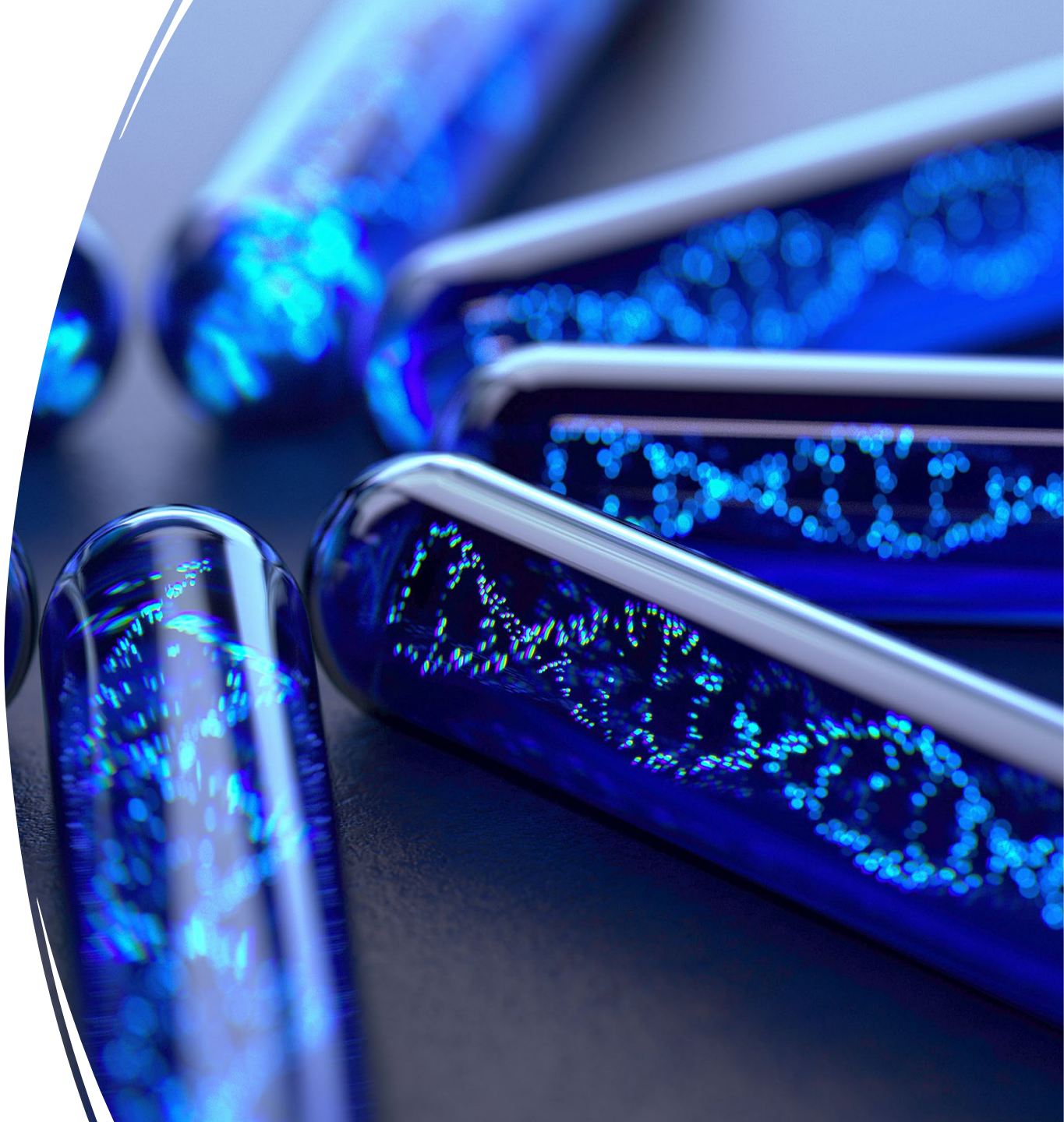
Genetherapy in veterinary medicine

Potential future applications

- inherited diseases (i.e. ocular, metabolic)
- wound healing
- fertility regulation
- chronic diseases (osteoarthritis, diabetes, allergy, renal, ocular)
- cancer
- infectious diseases

Potential technologies

viral vectors, naked pDNA, RNA antagonists, CAR-T, CRISPR-Cas

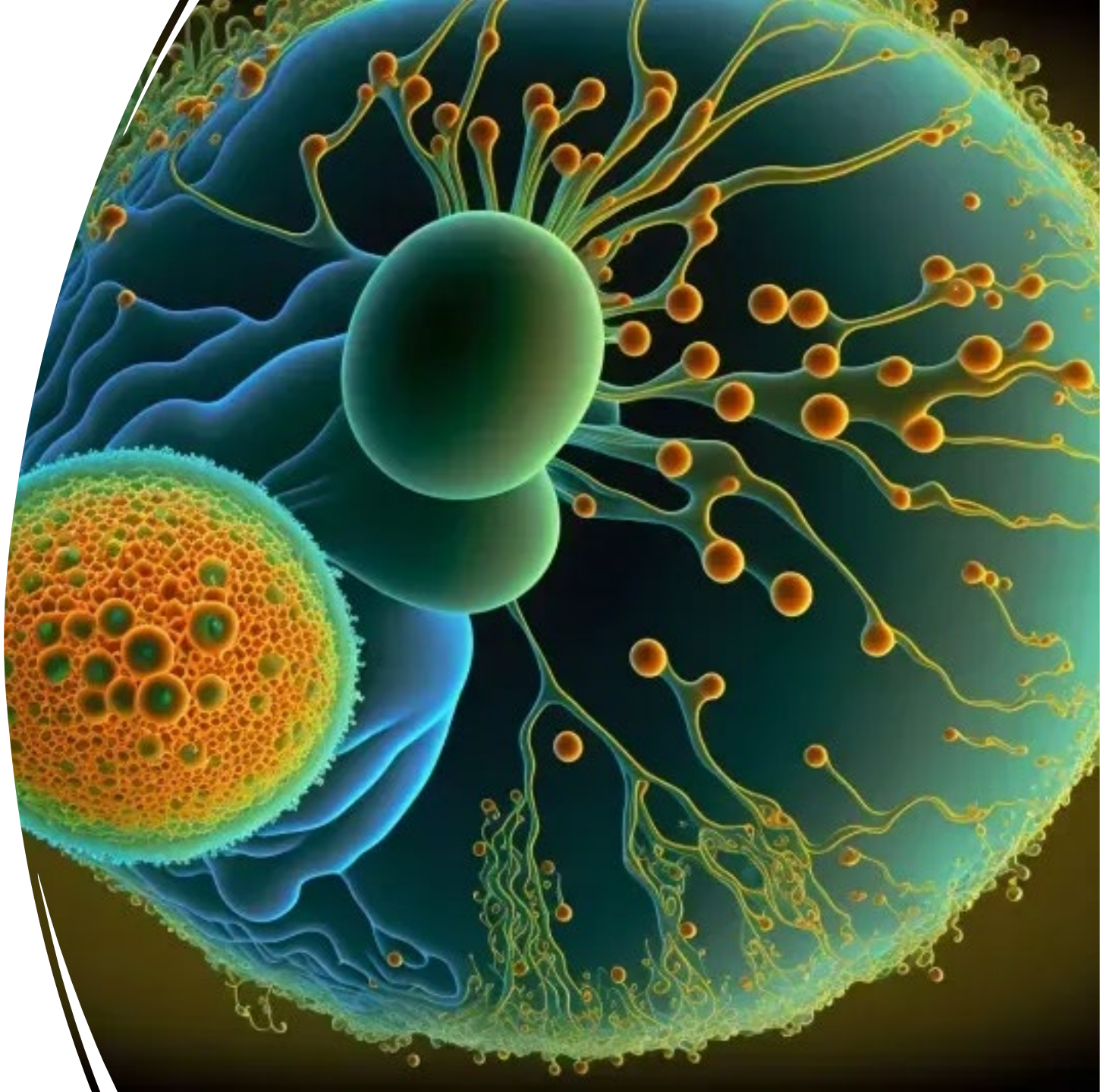


Veterinary regenerative medicine

Applications in osteoarthritis and tendon injury

Potential future applications

- chronic diseases
- Tissue engineering
- Wound healing
- Trauma



Novel Therapies and technologies Working Party

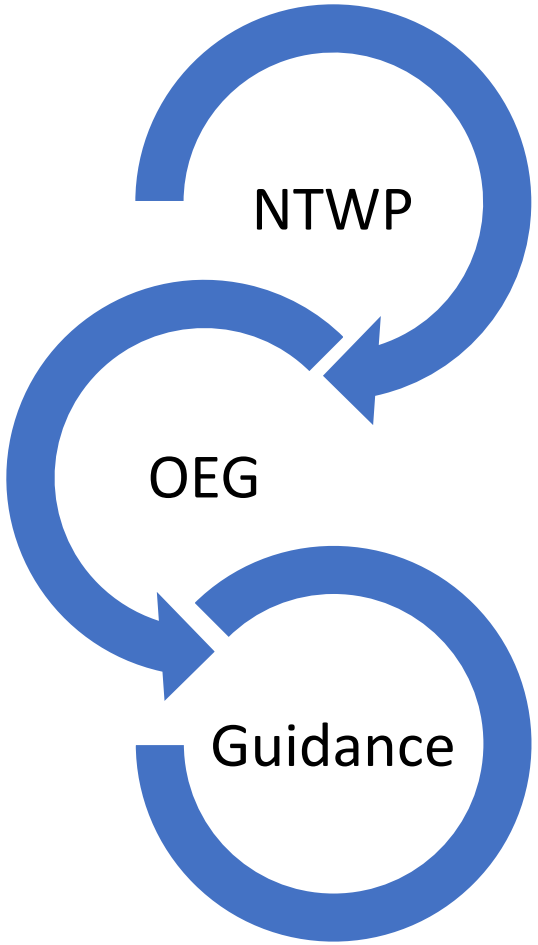
Regulation (EU) 2019/6

“Taking into account the specificities of novel therapy products, specific requirements additional to the standard requirements for evaluation of quality, safety and efficacy may be appropriate.”

“CVMP… shall set up the administrative structures and procedures allowing the development of advice for undertakings ... particularly regarding the development of novel therapy veterinary medicinal products.”

NTWP started april 2021

Novel Therapies and technologies Working Party



Guidelines to be developed (subject, scope, experts, content)
Horizon scanning
Advise on specific topics (to CVMP/other working parties)
Supervise work of the **OEGs**

Operational Expert Groups
(experts in veterinary and human field from academia, institutions, national competent authorities)
OEG for each topic
Coordination with EFSA, EDQM, FDA

Guidance published after approval by CVMP

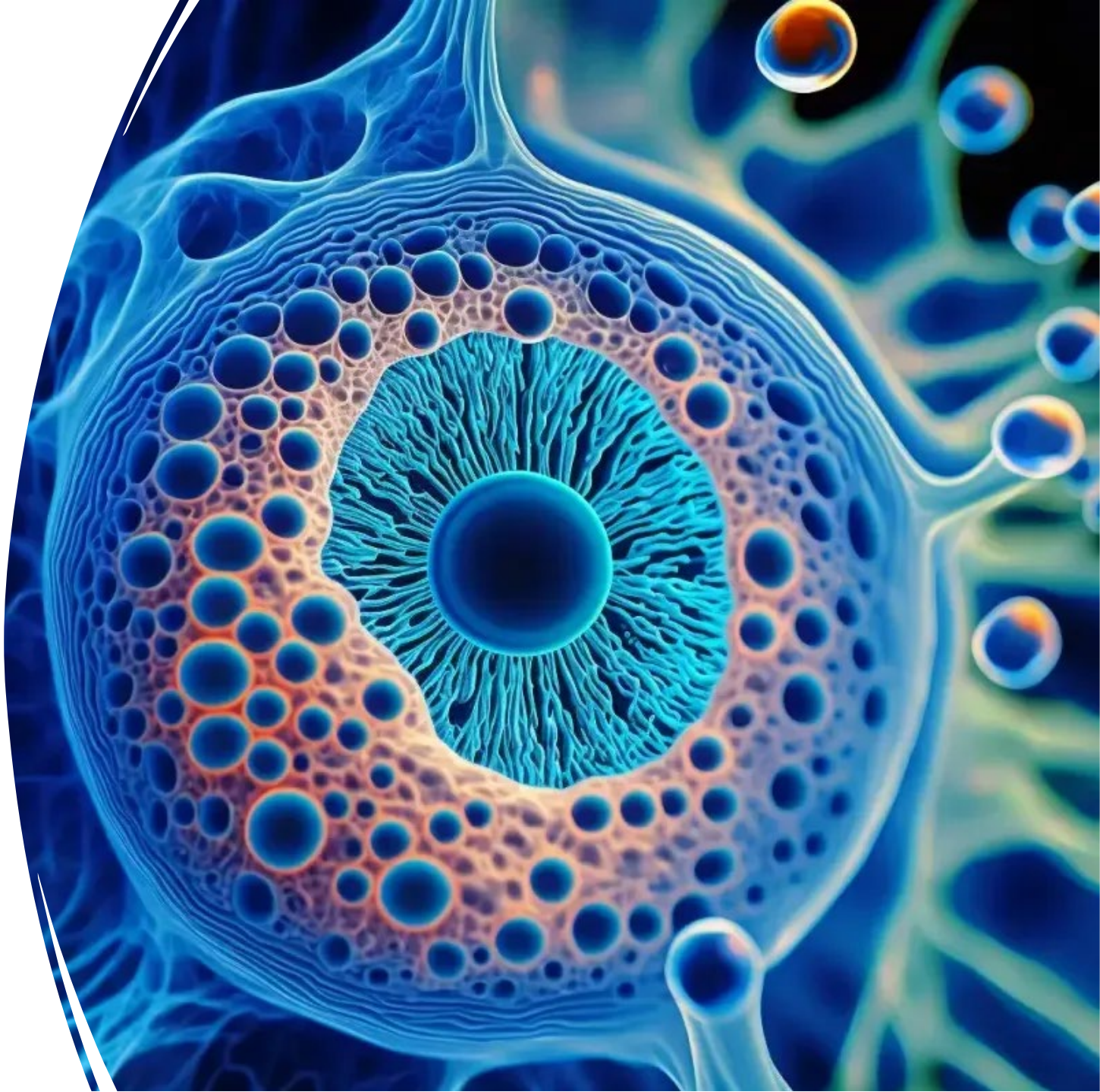
Current/future guidance developed by NTWP

COMMISSION DELEGATED REGULATION (EU) 2021/805, section V, specifies general data requirements for novel therapy products
AND specific requirements for genetherapy products, cell therapy products, phage therapy products, products issued from nanotechnology and RNAi therapy products

- Development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy (published)
- Quality, safety and efficacy of bacteriophages as veterinary medicines (published)
- Safety of products issued from nanotechnology (concept paper under discussion at CVMP)
- Genetherapy? (depending on outcome of horizon scanning)

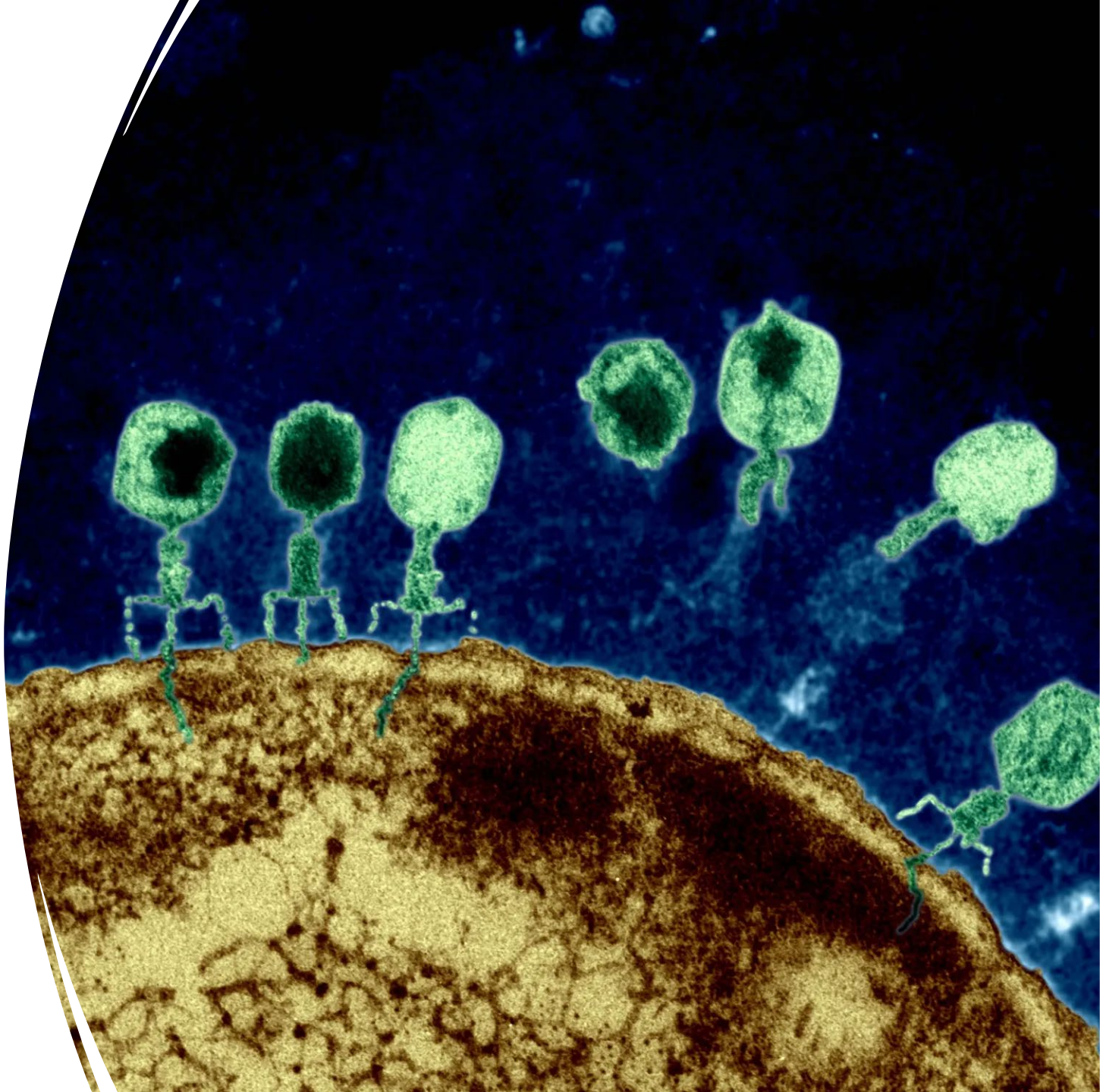
Potency testing of cell-based therapy products

- Consistent functional activity in the recipient needs to be ensured.
- Complex mechanism of action
- Generally not one assay possible
- Start with broader combination of assays, to be used in development
- Use of literature to support mode of action and relate to (surrogate) potency tests
- Demonstrate relation potency test results and clinical efficacy



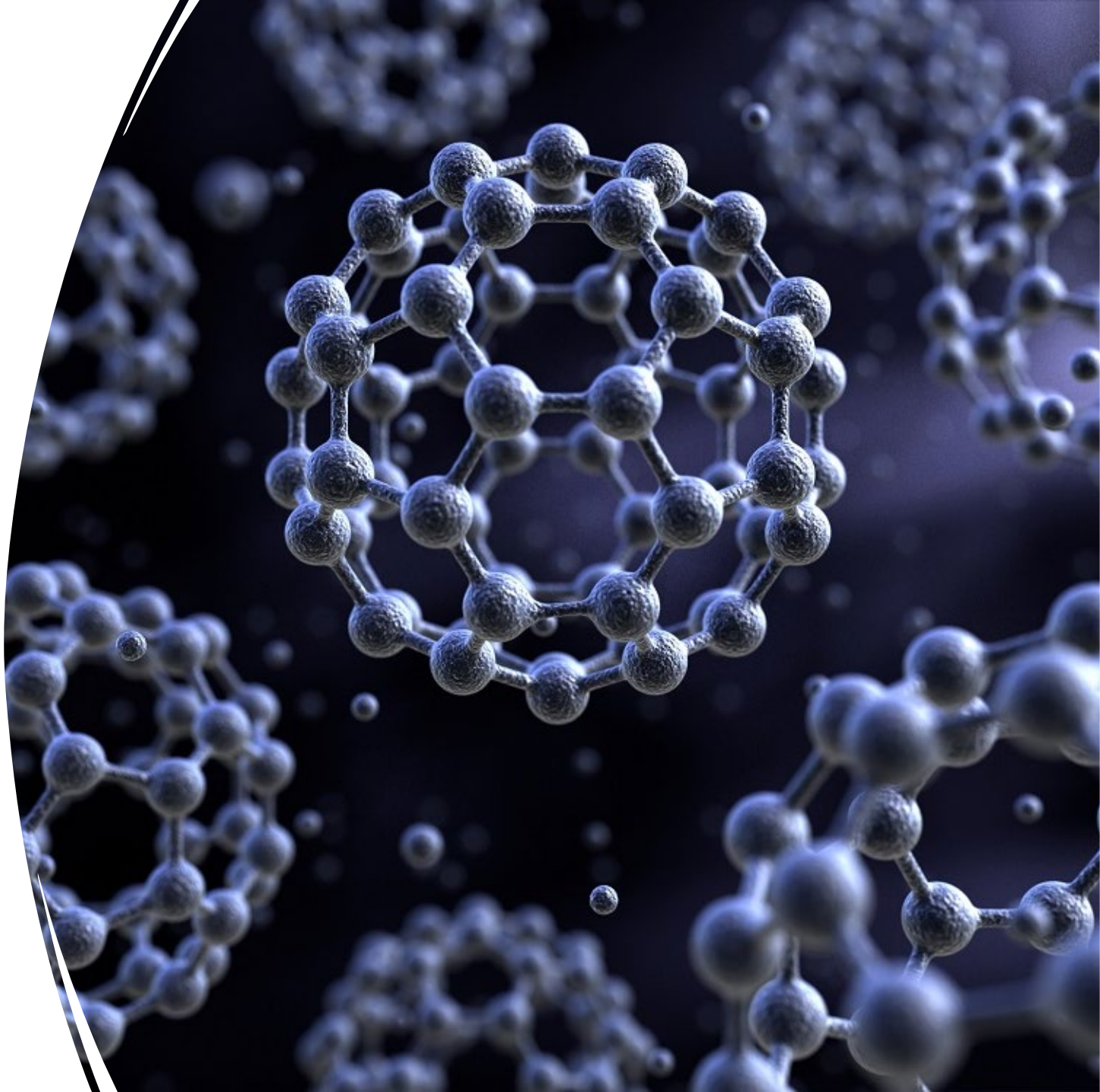
Quality, safety and efficacy of phage products

- Possibility for flexible qualitative and quantitative composition. Somewhat similar to multi-strain dossier, based on phage library
- Characterisation of library phages
- Robustness of manufacturing and controls toward changes in composition
- Safety and efficacy data generated using ‘representative preparations’



safety of products issued from nanotechnology

- Concept paper under discussion at CVMP, expected to be released for consultation Q2 2024
- Aim to include guidance for all VMPs issued from nanotechnology
- Focus on approach to safety testing/safety data (i.e. characterisation of test item, type of additional test)
- Expected to need updating, based on experience



Thank you for your attention!