



**EquiCord-YMAS**  
Advance Therapy

# **Experience of EMA innovation support**



- Advanced Therapies (AT):

Advanced therapy refers to new medical products that use gene therapy, cell therapy, and tissue engineering.

Human  
Cell Therapy  
Gene therapy  
(n= 4)

Vet  
Cell therapy for  
regenerative medicine

# Challenges in Vet AT

1. EU legislation is unclear vs. FDA -> Vet-AT classified as Medicinal products (Faltus et al, 2016)
2. Commercial use of Vet-AT non compliant with the regulation without legislative problems (universities)  
<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm525365.htm>
3. Lack of guidelines and/or regulation for Vet AT

# Regulatory Requirements

---

## 1. Centralized Procedure

- Human: Mandatory
- Vet: Optional scope?

## 2. Difficult classification:

- pharmaceutical product?
- Immunological product?

No guideline



# Specific Issues for Cell-Based products

---

- Identity and purity: Lack of reagents for MUMS
- Tumorigenicity and genomic stability: theoretical risk. Real risk NEVER reported
- Biodistribution and niche: challenging biodistribution trials, even more for large animals
- Immune rejection and persistence: Immunoprivileged? Immunotolerance?
- Potency test: Lack of reagents. Designing a test linked to the therapeutic effect is hard
- Pharmacokinetics: Complex Action Mechanism

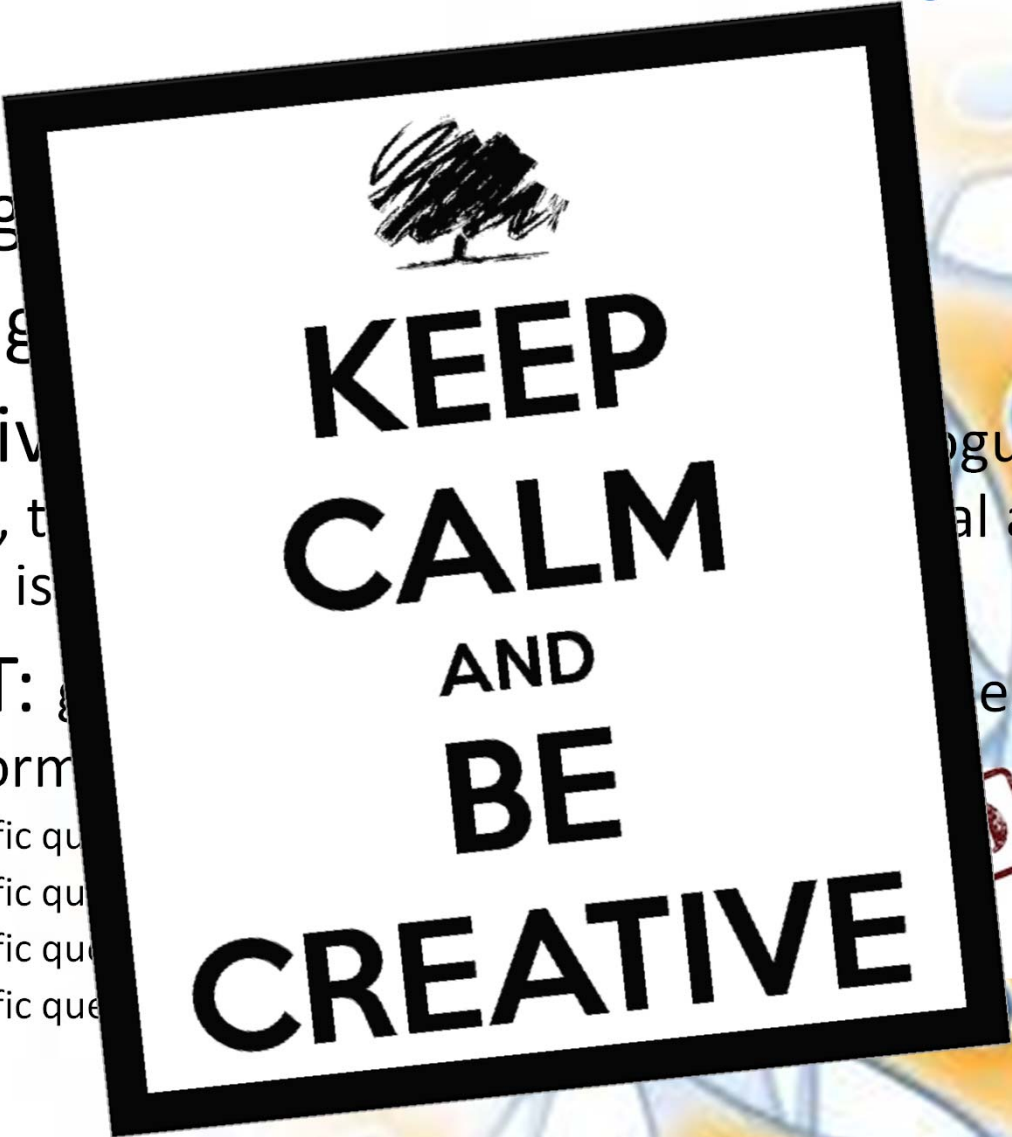
# How to act?



EquiCord-YMAS  
Advance Therapy

- No Vet g
- Human g
- Innovative  
applicants, the  
regulatory is
- ADVENT: g  
answers form

- ☒ Specific qu
- ☒ Specific qu
- ☒ Specific qu
- ☐ Specific qu



**KEEP  
CALM  
AND  
BE  
CREATIVE**

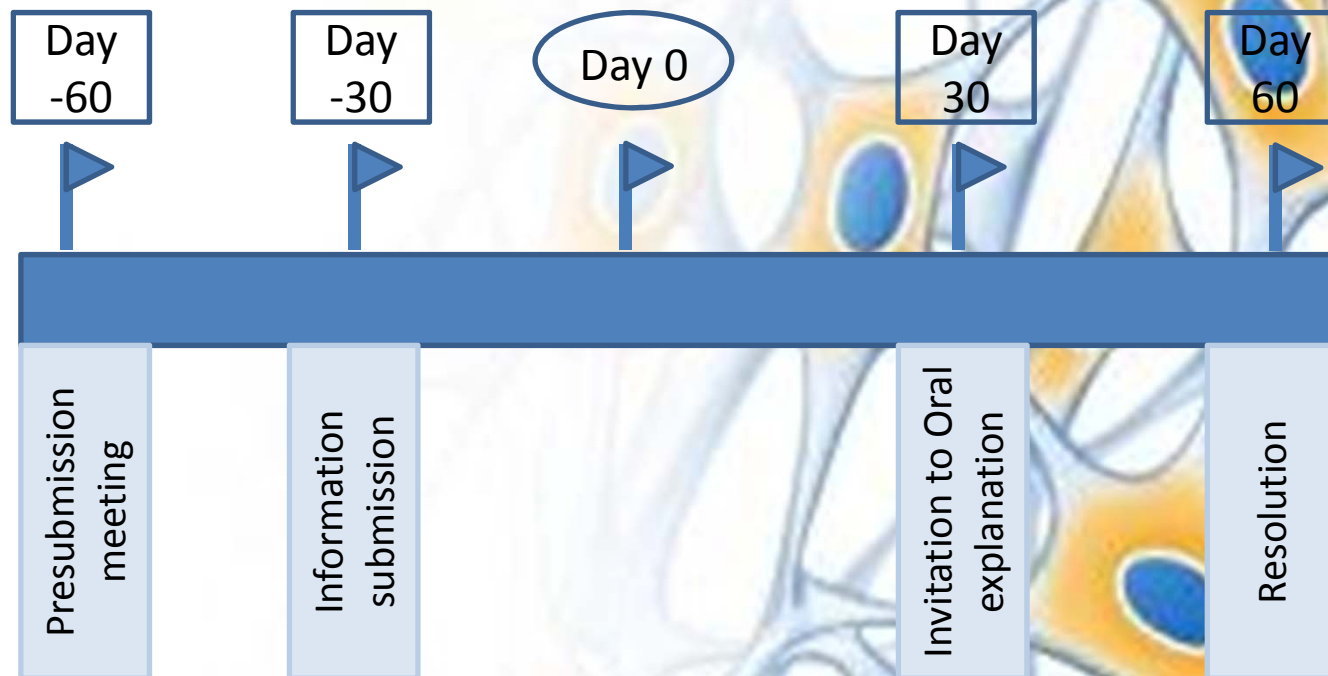
ogue with  
al and

estions and

# Scientific Advice (I):

- Quality, Safety and Efficacy

## Scientific Advice Timetable:



## Scientific Advice (II):

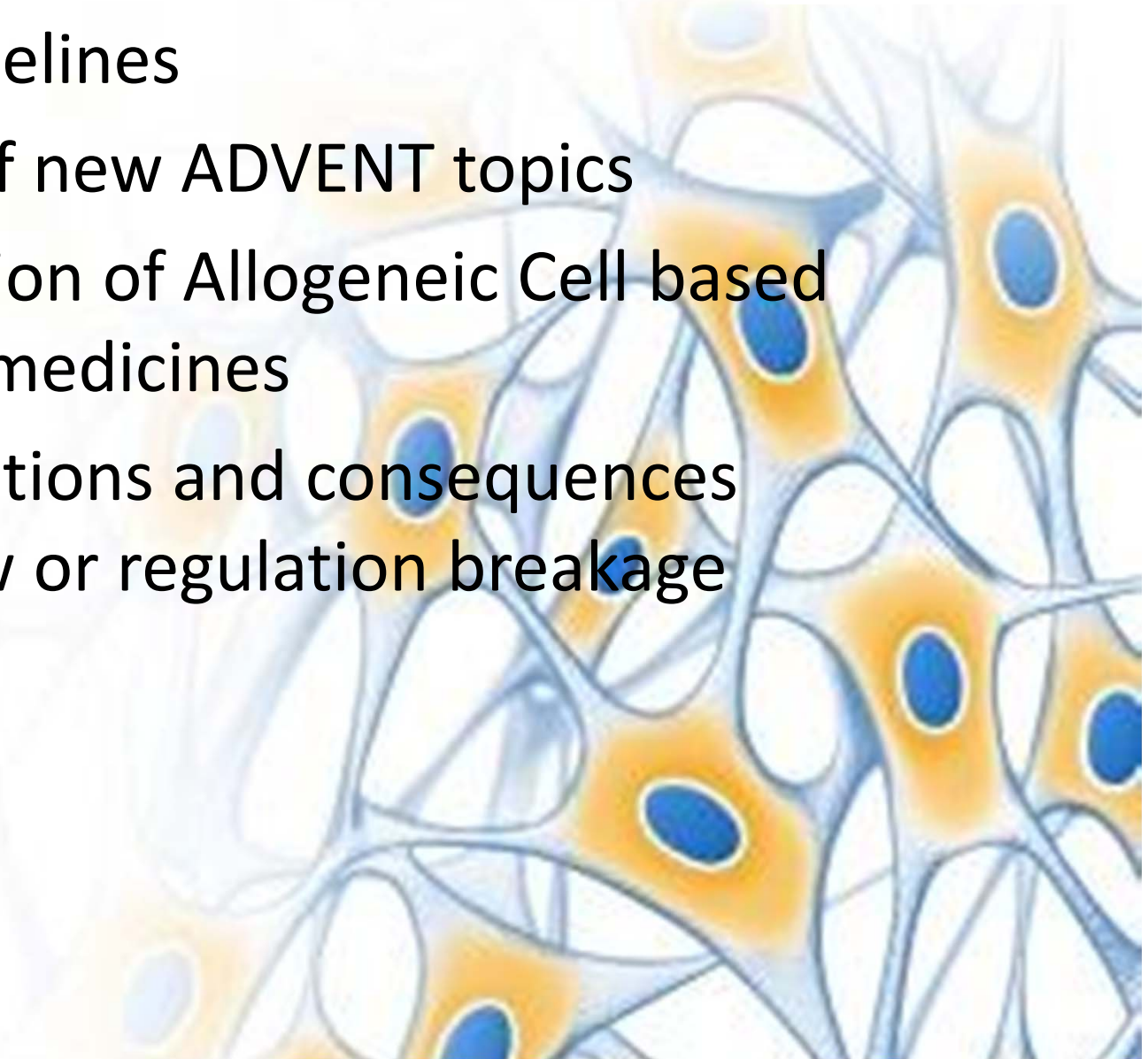
---

- The best option for issues not yet solved by ADVENT
- Great to ensure your creativity is in line with CVMP's opinion
- The applicant raises a specific question and gets a justified response
- The CVMP adopts a clear opinion and response
- NON-VINCULANT but if you stand by it, it is usually respected

# Problems to address in the near Future:

---

- Need of guidelines
- Resolution of new ADVENT topics
- Blunt definition of Allogeneic Cell based products as medicines
- Legal implications and consequences following law or regulation breakage (universities)



Thank  
you very  
much!





**Almudena Pradera Muñoz**  
**Scientific Director**  
**[apradera@equicord.com](mailto:apradera@equicord.com)**