



Info Day for Veterinary SMEs

- **HorStem**® :
Allogenic Equine Umbilical Cord Mesenchymal Stem Cells for the treatment of equine Osteoarthritis
- The ***first Vet-Advance Therapy medicine*** submitted for centralised MA worldwide
- Three years of an exhausting regulatory process

Pre-Submission activities

Preclinical Research

~ 1 year

Good Manufacturing Practices Manufacturing and Scale-up

~ 2 years

Clinical Phase

- Target Animal Safety
- Exploratory Studies.
- Dose confirmation
- Pivotal Studies

~ 3 years

Dossier Preparation

~ 1 year



- **Regulatory process** in high innovative products may be **long** and **complicated**.
The submission of the dossier is just the first step.
- There are several steps to comply (120-clock stop + 180-clock stop).
- Extraordinary **clock stop**??
- Negative **Opinion**?? **Expert committee**??

- SME companies usually have ***limited resources***.
- ***Time is money*** for any pharmaceutical company but for an SME it is vital, since a delay can put the survival of the company at risk.
- In innovative products, the ***clock stops could be much longer*** than initially expect. New validations and/or new studies may be required.

When things don't go right the first time:

- In innovative products, ***the risk*** that things may not go well ***is higher*** than in conventional products.
- ***SMEs*** working on innovative products ***must be prepared.***
- It is essential to ***reserve human and financial resources*** for the regulatory phase.

- Although many factors are against SMEs, limited resources, pressure from investors, limited experience, etc...
- There is something that makes us great: ***We cannot afford to fail.***
- ***Our survival depends on our success.***
- Therefore, there is nothing left but to roll up your sleeves, work and solve each of the problems that may arise, which will surely do.

- **HorStem®** was the clear example where failure was never an option.
- We had a ***120-clock stop for over a year.***
- On day 208 we had an ***extraordinary clock stop*** that took us 6 months to solve.
- After this, we had to go to an ***experts committee*** who endorsed the safety, quality and efficacy of **HorStem®** .
- After almost three years of the regulatory process, ***we finally got the positive opinion*** of the CVMP with a solid majority of the votes.



**EquiCord,
improving animals lives**

Thank you very much