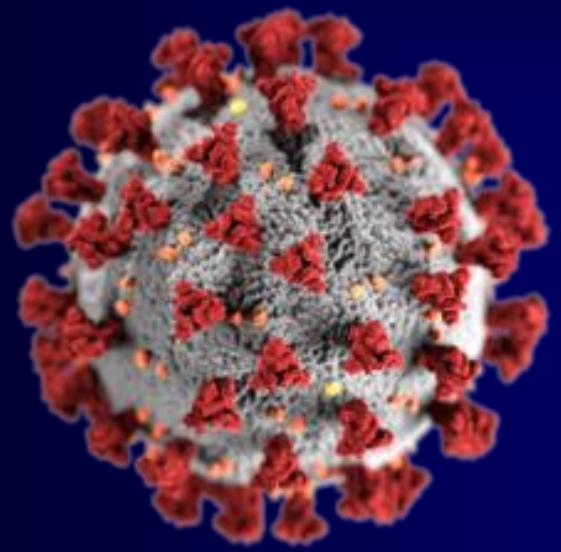
Adenovirus definitions for clinical trials

- Have been ongoing for some time
- Were discussed at the last TAVI Forum meeting in 2019

- After that meeting, two preliminary draft documents were produced.

- Then ……

Covid-19 happened



The discussions ended up in:

- One document for virologic definitions
- One document for possible endpoints/design issures.

Virologic Surrogates in Clinical Trials of Antiviral Drugs for the Treatment or Prevention of Adenoviral Infection in Stem Cell Transplant Recipients: Advantages and Pitfalls

- Laboratory assay challenges
  - Many serotypes
  - Assay variability – many “in house” assays
  - There is a WHO – standard. How to apply it?
  - Sample source

- Predictive value of results for outcome

Challenges in the Design and Conduct of Clinical Trials of Antiviral Drugs for the Prevention or Treatment of Adenoviral Infection in Allogeneic Stem Cell Transplant Recipents

- Definitions
- Unmet medical needs
  - Risk groups
  - No standard therapy available
  - Different risks in different populations
- Types of trials feasible from an ethical points of view

Challenges in the Design and Conduct of Clinical Trials of Antiviral Drugs for the Prevention or Treatment of Adenoviral Infection in Allogeneic Stem Cell Transplant Recipents

- Early phase trials – proof of concept
  - Which patient population to select?
  - Virologic and safety endpoints

- Late phase trials – pivotal studies
  - Which patient population to select
  - Can it be done in children?
  - Which endpoint is acceptable?

Now – Discussion