FRANCIS COMBES

TALK TITLE

"Regulatory guidelines and imaging of RNA therapeutics for preclinical biodistribution"

ABSTRACT

The success of the messenger RNA-based COVID-19 vaccines of Moderna and Pfizer/BioNTech marks the beginning of a new chapter in modern medicine. However, the rapid rise of mRNA therapeutics has resulted in a regulatory framework that is somewhat lagging. The current guidelines either do not apply, do not mention RNA therapeutics, or do not have widely accepted definitions. The current presentation describes the guidelines for preclinical biodistribution studies of mRNA/siRNA therapeutics and highlights the relevant differences for mRNA vaccines. We also discuss the role of in vivo RNA imaging techniques and other assays to fulfill and/or complement the regulatory requirements. Specifically, quantitative whole-body autoradiography, microautoradiography, mass spectrometry-based assays, hybridization techniques (FISH, bDNA), PCR-based methods, in vivo fluorescence imaging, and in vivo bioluminescence imaging, are discussed. We conclude that this new and rapidly evolving class of medicines demands a multi-layered approach to fully understand its biodistribution and in vivo characteristics.

BIO

Francis Combes obtained a master's degree in Veterinary Medicine at the University of Ghent (Belgium) and received a PhD from the lab of Gene Therapy at the same university. After 2 years of postdoctoral research, he is now a research scientist at SINTEF (a non-profit independent research organization in Norway). Dr. Combes' work focuses on finding novel means of achieving cell-selective delivery and activation of mRNA therapeutics.