



International Alliance for  
Biological Standardization

## 4th Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animal

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### Evolution of a bioinformatics pipeline for adventitious agent detection

High-throughput sequencing offers an unbiased view into the biological composition of a sample, and has found important applications in characterizing the biosphere and its ecology. Such metagenomics approaches have also been leveraged to search for, and simultaneously identify, any potential contaminating viruses or microorganisms in vaccines, biologics, or their intermediates. All of this depends on robust bioinformatics that can reliably assign nucleic acid sequences to their respective taxonomic origin.

A family of approaches can be envisioned for running such an adventitious agent detection pipeline, as outlined in Lambert et. al 2018 (Viruses 10: 528). In this talk, I will describe the evolution of Sanofi's PhylolD™ pipeline, as a concrete instance within this design space. Its architecture is modular, facilitating both development and validation.

Our pipeline development strategy needed to be sensitive to both aspects impacting public health—patient safety and product delivery—in spite of initial uncertainties in the technology. From the practical side, we first focused on utility, then performance, and then automation. Concurrently, we framed our strategy with initial caution and skepticism, then thoughtful risk taking, with the goal of eventual acceptance.

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