Title: Translating Metagenomics into Clinical Reality

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Abstract: The translation of metagenomic methods into routine use for diagnosis and the development of microbiome-based therapies requires precise taxonomic classification of all microorganisms (bacteria, archaea, viruses, fungi, protists) at strain-level along with characterization of their virulence and pathogenicity traits. The capacity for beneficial effects versus pathogenicity and virulence can vary widely among strains of the same species. And mounting evidence shows that the distinction between commensal and pathogenic lifestyles is strongly influenced by strain - not species-level - variability. With the emerging consensus that the clinically informative and actionable unit in microbiology is a strain, we face the need for validation and standardization of molecular methods, bioinformatics tools and qualified databases that can deliver strain-level resolution. This presentation will highlight class leading bioinformatic approaches that enable multi-kingdom microbial classification with strain-level resolution and quantitatively and present recent studies that assess the accuracy and performance of these approaches. The presentation will further address the importance for “challenges”, controlled cross-platform benchmark studies, for the development and validation of clinical-grade bioinformatics tools and databases and share considerations on how study design can affect the unbiased and controlled validation of these tools. Concluding, we will provide examples for error modes in the metagenomics workflow beyond data analysis and propose strategies for quality control and standardization.