Summary: Challenges in clinical Lipid(OMICS) studies (Mark Haid)

Clinical OMICs studies can make important contributions to patient stratification and biomarker discovery for human diseases. However, large-scale longitudinal multicenter studies in particular have special requirements in terms of study design, measurement stability, quality assurance (QA) and quality control (QC), as well as data analysis strategies.

Basis for this presentation is our participation as Metabolomics Core Facility in the EU IMI-project "Diabetes ResearCh on Patient StraTification" (DIRECT) [1,2]. The overarching aims of this consortium are to identify biomarkers that address current bottlenecks in diabetes drug development and to develop a stratified medicines approach to treatment of type 2 diabetes (T2D). The consortium comprised more than 24 academic and 5 industry partners across Europe. Between 2012 and 2019, more than 3000 patients were recruited at seven clinical centers and were comprehensively phenotyped using a multitude of OMICS methods, microbiome analyses, MRI-scans, clinical chemistry, anthropometrics, and dietary questionnaires.

This presentation will address issues and pitfalls that were encountered during seven years of work in the DIRECT consortium and will discuss pre-and post-analytical challenges that are relevant for high-throughput LC-MS-based metabolomics/lipidomics analyses of longitudinal multicenter studies.

References:

[1] Koivula, R.W *et al*., Discovery of biomarkers for glycaemic deterioration before and after the onset of type 2 diabetes: rationale and design of the epidemiological studies within the IMI DIRECT Consortium. Diabetologia 57, 1132–1142 (2014)

[2] Koivula, R.W., Forgie, I.M., Kurbasic, A. et al. Discovery of biomarkers for glycaemic deterioration before and after the onset of type 2 diabetes: descriptive characteristics of the epidemiological studies within the IMI DIRECT Consortium. Diabetologia 62, 1601–1615 (2019)