

Celerion ScienceSM: Translating Years of Scientific Insight

Celerion continues its [Celebration of Translating Science into Medicine](#) for over a decade by highlighting the contributions made by our best Celerion Scientists to advances across a variety of drug development fields. Over the past decade, Celerion Scientists have contributed to several in-depth and thought-provoking review articles in fields as diverse as regulation, bioanalysis, biomarkers and safety assessments of drug development.

Our Top 10 Most Insightful Published Review Articles

1. [Rapid and Robust Bioanalytical Assays are Critical for SARS-CoV-2 Therapeutic and Vaccine Development and Beyond](#) by [Sumit Kar](#) & [Rafiqul Islam](#)

This timely commentary describes the fit-for-purpose SARS-CoV-2 assays and their context of use as biomarkers for [COVID-19](#) clinical trials.

About Sumit: Sumit Kar, PhD is Manager, Translational Science and Biomarker Method Development and leads a specialized team of scientists that develop and validate innovative biomarkers for a wide range of therapeutic areas.
2. [Evaluating Cardiac Risk: Exposure Response Analysis in Early Clinical Drug Development](#) by [Julie Grenier](#), [Sabina Paglialunga](#), [Bruce H Morimoto](#) & [Robert M Lester](#)

A detailed summary describing exposure response QT modeling of intensive [ECG data collection](#) for assessing drug QT liability.

About Robert: As Chief Cardiologist and Global Medical Director, Robert M. Lester, MD FACC brings more than 20 years of experience to cardiac safety studies in early clinical drug development.
3. [QT Assessment in Early Drug Development: The Long and the Short of It](#) by [Robert M Lester](#), [Sabina Paglialunga](#) & [Ian A Johnson](#).

A thorough review of the QT interval addressing its discovery, utility as a surface biomarker for ventricular repolarization and role in clinical drug development including [TQT studies](#) and QT modeling.
4. [Clinical Assessment of Hepatic De Novo Lipogenesis in Non-Alcoholic Fatty Liver Disease](#) by [Sabina Paglialunga](#) & [Clayton Dehn](#)

This review explores the role of hepatic de novo lipogenesis (DNL) in the etiology of [nonalcoholic fatty liver disease \(NAFLD\)](#) as well as techniques to assess DNL in clinical trials.

About Sabina: Sabina Paglialunga, PhD is Director, Scientific Affairs is Celerion's metabolic disease subject matter expert and provides scientific and operational support for clinical studies.
5. [Cystatin C Is a More Reliable Biomarker for Determining eGFR to Support Drug Development Studies](#) by [Sumit Kar](#), [Sabina Paglialunga](#) & [Rafiqul Islam](#)

A comprehensive review of the current and future utility of cystatin C as a renal [biomarker](#) in drug development.
6. [Update and Trends on Pharmacokinetic Studies in Patients with Impaired Renal Function: Practical Insight into Application of the FDA and EMA Guidelines](#) by [Sabina Paglialunga](#), [Elliot Offman](#), [Nita Ichhpuranic](#), [Thomas C. Marbury](#), & [Bruce H. Morimoto](#)

Detailed review article on the regulatory and clinical aspects of [renal impairment](#) PK studies including expert commentary.

7. [Review of Drug Development Guidance to Treat Chronic Obstructive Pulmonary Disease: US and EU Perspectives](#) by [Aernout van Haarst](#), Lorcan McGarvey & Sabina Paglialunga
Comprehensive summary of [chronic obstructive pulmonary disease \(COPD\)](#) regulatory guidance, drugs in development, study endpoints and biomarkers with expert opinion.
About Aernout: Aernout van Haarst, PhD is Director, Scientific Affairs and has 25 years of experience in clinical drug development. In his current role, he provides scientific support for respiratory and vaccine clinical trials.

8. [A Fatty World: Exploring Racial Disparity in NAFLD/NASH](#) by [Sharon H Jaycox](#)
Insight into the role of genetic variants and polymorphism in nonalcoholic fatty liver (NAFLD) and [nonalcoholic steatohepatitis \(NASH\)](#) progression.
About Sharon: Sharon H Jaycox, MHA is Metabolic and Pharmacodynamic Specialist and is a strong advocate for diabetes research and diversity in clinical trials.

9. [Quantitative Analysis of Bisphosphonates in Biological Samples](#) by Veniamin N Lapko, Patrick S Miller, Curtis E Sheldon, Ridha Nachi, [Chris J Kafonek](#)
A methodological review of on-column derivatization for bisphosphate drug [bioanalysis](#).
About Chris: Chris J Kafonek is Manager, Method Development in Lincoln, NE where she leads a team of talented bioanalytical analysts.

10. [Saliva: a Reliable Sample Matrix in Bioanalytics](#) by [Michael Gröschl](#)
This review describes the physiology of saliva formation, the types of compounds found in this matrix, and expert advice for collection, storage and [bioanalytical](#) methods.
About Michael: Michael Gröschl, PhD is Associate Director Bioanalytical Laboratory in Zurich, Switzerland. He is an endocrinologist with more than 60 scientific publications and specialized in assay development for uncommon biological matrices.