



Scientific, Regulatory and Technology Challenges in the Development of Oligonucleotide and Peptide Drugs

08-09 June 2023
NH Malaga, Spain

Thu

9:20	9:30		Welcome and aim of the meeting
9:30	11:00		Session 1: Setting the scene
9:30	9:55	A01	<i>Anna Laurén - on behalf of the EBF</i> Peptides aren't neither proteins or small molecules...
9:55	10:20	A02	<i>Cecilia Arfvidsson - on behalf of the EBF</i> Just as oligonucleotides aren't peptides either...
10:20	10:40	A03	<i>Philip Timmerman - EBF</i> Metabolite quantification recommendation - fit for purpose
10:40	11:00		Q&A
11:00	11:30		Coffee break
11:30	12:30		Session 2: Preparing for success = preparing early
11:30	11:50	A04	<i>Mikko Hölttä - AstraZeneca</i> Oligonucleotide bioanalysis in early drug development
11:50	12:10	A05	<i>Mariann Fagernæs Hansen - NovoNordisk</i> PK/PD assay strategy for a therapeutic peptide inhibitor: Meaningful PD marker contra PK and free/total target analyte
12:10	12:30	A06	<i>Davy Guignard- Aptuit (An Evotec Company)</i> Comparison of Quantigene and LCMS technologies for quantification of antisense oligonucleotides in tissue and plasma matrices
12:30	13:40		Lunch break
13:40	15:00		Session 3: More than one way to skin a cat...
13:40	14:00	A07	<i>Robert Nelson - on behalf of the EBF</i> Setting the scene - dealing with tissues and/or non-standard MS approaches
14:00	14:20	A08	<i>Jill Uhlenkamp - Labcorp Drug Development</i> The Pursuit of Robust Quantitation of Oligonucleotides by Hybridization Assays
14:20	14:40	A09	<i>Daniel Schulz-Jander - QPS</i> Quantitation of siRNA's and Metabolites in Plasma, Excreta and Tissues by LC/ToF-MS in Regulated Studies
14:40	15:00	A10	<i>Carrie Vyhlidal - KCAS Bio</i> Quantification of Synthetic DNA Aptamers in Plasma with qPCR

15:00	15:40		Coffee break
15:40	18:00		Session 4: Immunogenicity or what if the cat gives you allergies
15:40	16:00	A11	<i>Jo Goodman - on behalf of the EBF</i> Survey - immunogenicity related to Oligonucleotide and Peptide Drugs - current practices in industry, incl. Risk assessment
16:00	16:20	A12	Chris Jones - AstraZeneca <i>Immunogenicity assessment of incretin mimetics; a review of recently approved molecules with a view to technical, regulatory and strategic considerations</i>
16:20	16:40	A13	<i>Foka Venema - Ardena</i> How to increase assay sensitivity of oligonucleotide Ligand Binding pharmacokinetic assay and how to develop strategies on dealing with ADA challenges of oligonucleotides
16:40	18:00		<i>Breakout round tables on immunogenicity strategies for oligonucleotide and peptide drugs</i> Pre-meeting survey questions and workshop discussions will be the basis for round table

Friday 09-JUN-2023

9:00	10:00		Session 5: Skinning the cat with LC/MS...
9:00	9:20	A14	<i>Emmanuel Njumbe Ediage - Janssen R&D</i> Bioanalytical challenges for analysis of oligonucleotides with LC-MS/MS
9:20	9:40	A15	<i>Alexandra Bushby - Labcorp Drug Development</i> Development of an LC-MS/MS method for GSK3389404, a GalNAc conjugated oligonucleotide and it's non-conjugated metabolite in pre-clinical and clinical studies – challenges and strategies
9:40	10:00	A16	<i>Matthijs Pijnappel - Recipharm</i> Technical challenges in method development for quantification of oligonucleotides by LC-MS in biological samples
10:00	10:40		Coffee break
10:40	11:30		Session 6: Do metabolites quantification strategies need to change?
10:40	11:00	A17	<i>Anna Laurén - on behalf of the EBF</i> Setting the scene: metabolites & oligonucleotide and peptide drugs = a different story
11:00	11:20	A18	<i>Zoltan Timar - Charles River Laboratories</i> High-throughput LC-MS/MS method for therapeutic oligonucleotides
11:20	11:40	A19	<i>Charlotte Hagman - Novartis</i> Leqvio A Novartis Cholesterol-Lowering Drug
11:40	12:00		<i>Anna Laurén - on behalf of the EBF</i> Preparing the session round table metabolites & tissues
13:00	13:20	A21	<i>Luca Ferrari - F. Hoffmann-La Roche</i> Selectivity and sensitivity challenges in the bioanalysis of oligonucleotides and their metabolites
13:20	13:40	A22	<i>Craig Stovold - AstraZeneca</i> Interfacing Bioanalysis and Biotransformation Strategies for Oligonucleotide Therapeutics

13:40	14:00	A23	<i>Solvej Lund Lippert - NovoNordisk</i> siRNA PK hybridisation assay
14:00	15:00	A24	<i>Breakout round tables on metabolite quantification strategies & tissue analysis</i> Pre-meeting survey questions and workshop discussions will be basis for round table
15:00	15:30		Coffee break
15:30	16:30		Close out session - strategising for the future Wrapping up and connecting all dots on strategies for metabolites, tissues, immunogenicity and/or PK/PD for oligonucleotide and peptide drugs
16:30			Adjourn

MEETING ORGANISATION

Anna Laurén (NovoNordisk), Matthew Barfield (F. Hoffmann La Roche), Robert Nelson (BioAgilytix), Jo Goodman (AstraZeneca), Cecilia Arvidsson (AstraZeneca) and Philip Timmerman (EBF)

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