EBF *Alpha to Omega* Events

The Omicron Workshop

Points to Consider on Cut Points

28-29 April 2022 – in Cyberspace

28 April 2022 (all times are in CET = Brussels Time zone)

12:45	**13:00**	**Getting started - Welcome**
		Philip Timmerman - EBF
13:00	**14:00**	**Session 1: Introduction to the meeting and problem statement**
		Jo Goodman - on behalf of the EBF
		Robert Nelson - on behalf of the EBF
		Introduction presentation to introduce the items discussed at the meeting, includes but not limited to: Cut Points (CPs) – what and why; Difference from PK assays (CoU); In study vs. validation CP; Clinical relevance of CPs; regulatory challenges; the changing landscape on ADA and new modalities
14:00	**15:40**	**Session 2: (Strategic) Thoughts to consider**
14:00	14:20	Kyra Cowan, on behalf of the EBF
		Increasing challenges: feedback from discussions in the EBF
14:20	14:40	Nicoline Videbæk, on behalf of the EBF NAb team
		Cut point considerations for Nab assays from the EBF
14:40	15:00	Devangi Mehta, Immunologix Laboratories
		Beyond the Confirmatory Cut point – Reconsidering the value of the confirmatory tier
15:00	15:20	Heather Revell, Labcorp Drug Development
		Assessing specificity of ADA to multi-domain protein therapeutics
15:20	15:40	Panel discussion/ Q&A
15:40	**16:00**	**Break**
16:00	**19:00**	**Session 3 - Case studies *(including a short logistic break)***
16:00	16:20	Sebastien Boridy, Charles River Laboratories
		Overcoming challenges in experimental design for in-study cut-point determination
16:20	16:40	Jenny Valentine, Regeneron
		Population Specific Cut Points in Oncology: Do We Really Need a Different Cut Point for Every Tumor Type?
16:40	17:00	Matt Horsham, LGC
		Where do we draw the line? - Investigating low analytical cutpoints and the impact on in study cut points
17:10	17:30	Brendy Van Butsel, Sanofi
		Applying in-study cut-points in a rare-disease setting
17:30	17:50	Harley Williams (replacing Marleen Lutz), Celerion Switzerland AG
		Challenges in the detection of anti-Filgrastim antibodies facing a low false positive rate
17:50	18:10	Hisanori Hara, Novartis Pharma AG
		A case study of cut point evaluations at early stages of clinical studies and how to provide reliable interim ADA results
18:10	18:30	Mafalda dos Santos Marques Resende, Novo Nordisk
		In-study CP setting in NAb assays - a case study
18:30	**19:00**	**Close out Q&A**
19:00		**Day 1 adjourn**

13:00	**14:40**	**Session 4: Cross validation, general considerations and case studies**
13:00	13:20	Michaela Golob, on behalf of the EBF

		introduction to the session and feedback from discussions in the EBF ADA team
13:20	13:40	Alok Rathi, EMD Serono Cross-Validation of a Neutralizing Antibody Assay Across Global Sites For A Multi Domain Protein
13:40	14:00	Yang Xu, Merck Sharp & Dohme *Experiences and Challenges in Evaluation of ADA Assay Performance with the Same ADA Method Across Multiple Laboratories*
14:00	14:20	Amy Lavelle, on behalf of the AAPS NABH (Neutralizing Antibody Harmonization) sub team *Harmonized Approach to Cross Validations of ADA and Nab Immunoassays*
14:20	14:40	Panel discussion
14:40	**15:00**	**Break**
15:00	**16:00**	**Session 5 - Thinking outside the box-plot**
15:00	15:20	Gregor Jordan, Roche Diagnostics GmbH *Screening assay data transformation – can a Weibull transformation help to achieve the theoretical FPR?*
15:20	15:40	George Walters, LGC *Advantages and Challenges of Automation in Immunogenicity*
15:40	16:00	Atiya Taqui, Gilead Sciences *Random and Fixed Effects Model for Cut Point Determination*
16:00	16:20	Daniel Baltrukonis, Pfizer, Inc. *Simplifying and Automating Anti-Drug Antibody Cut Point Determination*
16:20	16:40	Panel discussion
16:40	**17:00**	**Break**
17:00	**18:00**	**Session 6: Regulatory expectations and challenges, including ISI and closing panel discussion**
17:00	17:20	Johannes Stanta, on behalf of the EBF *Overview of regulatory expectations for cut points for pre-existing Ab*
17:20	17:40	Paul Chamberlain, Immunogenicity Integrated Platform *How to use the Integrated Summary of Immunogenicity (ISI) for effective communication of ADA assay cut point strategy and method life-cycle history to regulators*
17:40	18:00	Close out panel discussion - summarising questions and discussions from the workshop and from questions submitted prior to the workshop
18:00		**Adjourn**