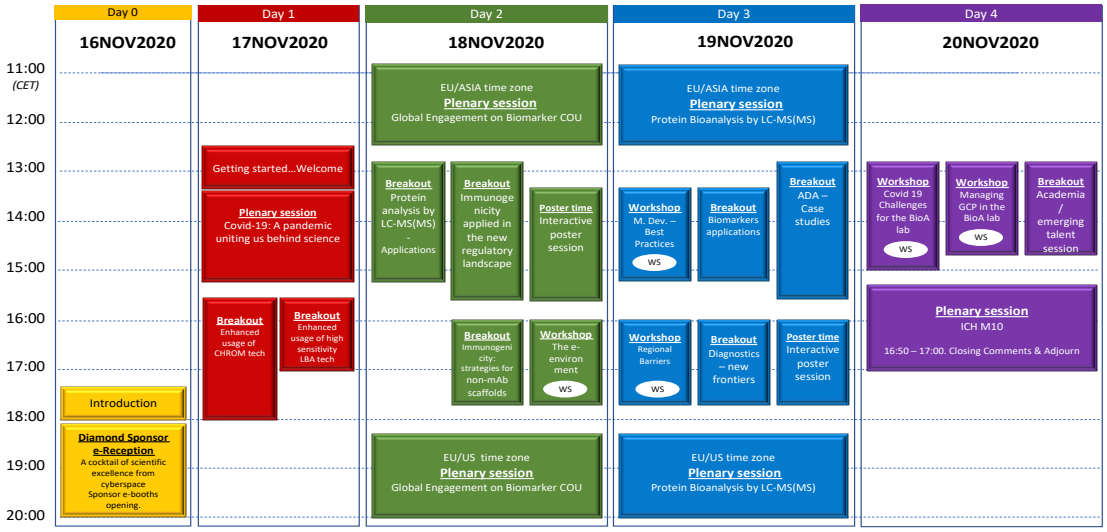
EBF Open Symposium

17 – 20 November 2020

N° 13 From Cyberspace - Staying Connected

13th EBF Open Symposium – Agenda outline



AGENDA AT A GLANCE

Day 0: 16 November 2020

17:15	20:00	Diamond Sponsor Cocktail e-reception

Day 1: 17 November 2020

13:00	13:15	Getting started - Welcome
13:15	15:10	Day 1 - Plenary 1. A Pandemic Uniting us Behind Science
15:30	18:00	Day 1 - Breakout 1. Enhanced usage and recent developments in chromatographic separations (LC-MS and beyond)
15:30	17:00	Day 1 - Breakout 2. Enhanced usage of high sensitivity LBA technologies

Day 2: 18 November 2020

10:45	12:30	EU/ASIA time Zone Plenary Session 1. Global Engagement on Biomarker Context of Use
12:45	15:10	Day 2 - Breakout 1. Protein analysis by LC-MS(MS) - Applications
12:45	15:30	Day 2 - Breakout 2. Immunogenicity applied in the new regulatory landscape (building experience)
13:15	15:30	Day 2 - It's Poster time. Dedicated session 5-min poster pitches
16:00	18:00	Day 2 - Breakout 3. Immunogenicity: strategies for non-mAb scaffolds
16:00	18:00	Day 2 - Workshop 1. The e-environment: towards a vendor neutral secure bi-directional data transfer process

End of Day 2 for EU/Asia

18:15	20:00	EU/NA time Zone Plenary Session 1. Global Engagement on Biomarker Context of Use

Day 3: 19 November 2020

10:45	12:30	EU/ASIA time Zone Plenary Session 2. Protein Bioanalysis by LC-MS(MS)
13:15	15:10	Day 3 - Workshop 1. Best practices in MDEV and communications to drive successful assay transfer between BioA
13:15	15:10	Day 3 - Breakout 1. Applications of Biomarker Assays: success stories and challenges
12:45	15:30	Day 3 - Breakout 2. ADA - Case studies
16:00	17:30	Day 3 - Workshop 2. Regional Barriers and Global Interpretation of Guidelines
16:00	17:30	Day 3 - Breakout 3. Diagnostics and PD decision making in clinical studies: new frontiers
16:00	17:30	Day 3 - It's Poster time. Dedicated session 5-min poster pitches

End of Day 3 for EU/Asia -

18:15	20:00	EU/NA time Zone Plenary Session 2 Protein Bioanalysis by LC-MS(MS)

Day 4: 20 November 2020

12:45	15:00	Day 4 - Workshop 1. Covid-19: challenges, experiences and impact on the BA lab
12:45	14:40	Day 4 - Workshop 2. Managing GCP in the BioA lab - learning from the past for a better future
12:45	14:40	Day 4 - Breakout 1. Academia and young scientist: emerging talent for and new perspective on Bioanalysis
15:00	16:50	Day 4 - Plenary session. Feedback on ICH M10 - incl. Q&A
16:50	17:00	Closing remarks - Adjourn

AGENDA DETAILS

Day 0: 16 November 2020

17:15	**20:00**	**Diamond Sponsor Cocktail e-reception**
17:15		Coming online
17:30	17:45	Philip Timmerman, EBF
		Getting started
17:45	20:00	Diamond Sponsor connecting
		Getting to know the scientific/process excellence of our Diamond sponsors and their e-booths
	20:00	Announcement Winner of the Diamond sponsor e-reception teaser
	20:30	Zoom session will be closed by the meeting host

Day 1: 17 November 2020

12:30	**13:00**	**Coming online**
13:00	**13:15**	**Getting started - Welcome**
		Philip Timmerman - EBF
13:15	**15:10**	**Day 1 - Plenary 1**
		A Pandemic Uniting us Behind Science
13:15		Joanne Goodman - on behalf of the EBF
		Bioanalytical solutions in support of the COVID-19 global pandemic
13:30	13:50	Melanie Anderson - MSD, for IQ
		Patient Centric Sampling: How the COVID-19 Pandemic is Shifting the Landscape
13:50	14:10	Else Marie Agger - Novo Nordisk
		SARS-CoV-2 assay development in a bioanalysis laboratory
14:10	14:30	Catherine Vrentas - PPD
		Development and characterization of an MSD-ECL assay for the effective quantitation of anti-SARS-CoV-2 antibodies in human serum
14:30	14:50	Richard Hughes - LGC
		New immunogenicity strategies to meet the needs of a developing pandemic.
14:50	15:10	Sarah Peters - Celerion
		Opening Safely in the Face of a Global Pandemic.
	15:30	Zoom session will be closed by the meeting host
15:30	**18:00**	**Day 1 - Breakout 1**
		Enhanced usage and recent developments in chromatographic separations (LC-MS and beyond)
15:30	15:40	Coming online
15:40	16:00	Aaron Ledvina - Covance
		High-sensitivity workflow for LC-MS based analysis of GalNAc-conjugated oligonucleotides
16:00	16:20	Michael Blackburn - ARCINOVA
		Assessment of fluoride exposure by GCMS: successes achieved and hard lessons learnt
16:20	16:40	Ariane Kahnt - Janssen R&D
		Challenges in the quantitative analysis of Vitamin E TPGS in biological matrices using LC-MS/MS
16:40	17:00	short break
17:00	17:20	Esther van Duijn - TNO
		Metabolic profiling and mass balance studies in pediatric patients using a microtracer approach – a proof of concept
17:20	17:40	Catherine DelGuidice - PPD, in collaboration with Sciex and Virginia Commonwealth University
		Lowering the LC-MS/MS Assay Quantitation Limit to 50 pg/mL for Ranibizumab in Human Plasma after Intravitreal Administration, by Using SCIEX Triple Quad™ 7500 LC-MS/MS System - QTRAP® Ready
17:40	18:00	Nikunj Tanna - Waters
		Advantages of a novel bridged ethyl hybrid surface technology to improve chromatographic efficiency and reduce analyte loss.
	18:20	Zoom session will be closed by the meeting host
15:30	**17:00**	**Day 1 - Breakout 2**
		Enhanced usage of high sensitivity LBA technologies
15:30		Coming online
15:40	16:00	Stephanie Vauleon - F. Hoffmann-La Roche
		Tricky analyte, challenging matrix and a new high sensitivity analytical platform: How to overcome major challenges for a successful biomarker assay validation on the SMCxPRO platform
16:00	16:20	Chris Fox - Gyros Protein Technologies AB
		The efficient generation of pharmacokinetics data using affinity flow-through nanoliter format immunoassays

16:20	16:40	Daniel Creed - LGC *The highs and lows of ultra-sensitive immunoassays: experiences from a CRO's perspective*
16:40	17:00	Daniel Sikkema - Quanterix *The most sensitive immunoassay just got more sensitive: how a 100-fold increase in sensitivity of Simoa was achieved*
	17:20	Zoom session will be closed by the meeting host
		End of Day 1

Day 2: 18 November 2020

10:45	**12:30**	**EU/ASIA time Zone Plenary Session 1** **Global Engagement on Biomarker Context of Use**
10:45		Coming online
11:00	11:10	Kyra Cowan - on behalf of the EBF *Introduction into the session*
11:10	11:30	Joanne Goodman - on behalf of the EBF *The 2020 EBF Recommendation on BM Assay Validation - key points to consider when implementing CoU practices*
11:30	11:50	Matthias Sury - Celerion *Biomarker Assay Development and Validation: Failing your Way to Success*
11:50	12:10	Lauren Stevenson - Immunologix Labs *Feedback and reflections from the AAPS PharmSci360 Workshop on CoU*
12:10	12:30	Abbas Bandukwala - CBER-FDA A regulatory perspective
	12:45	Zoom session will be closed by the meeting host
12:45	**15:10**	**Day 2 - Breakout 1** **Protein analysis by LC-MS(MS) - Applications**
12:45		Coming online
13:00	13:20	Nico van de Merbel - PRA-HS *The best of both worlds: developments in hybrid ligand-binding / LC-MS approaches for peptide and protein quantification*
13:20	13:40	Ashley Phillips - LGC *Next Gen Trypsin: Large Molecule LC-MS/MS Bioanalysis Today, Not Tomorrow*
13:40	14:00	Luca Ferrari - F. Hoffmann-La Roche *Therapeutic/biomarker protein quantification in tissues: method development strategies to overcome sensitivity & selectivity issues using hybrid LBA-LCMS*
14:00	14:10	short break
14:10	14:30	Corina Hunger - Sanofi *Validation of a biotherapeutic ligand-binding-LC-MS/MS assay in monkey and mouse serum*
14:30	14:50	Fabrizia Fusetti - QPS *Development and validation of a Trastuzumab/Pertuzumab Hybrid LC-MS assay for clinical development*
14:50	15:10	Eric Niederkofler - Thermo Fischer Scientific *Validation of a Hybrid Assay for the Rapid Quantification of the Biologic, Insulin Degludec*
	15:30	Zoom session will be closed by the meeting host
12:45	**15:30**	**Day 2 - Breakout 2** **Immunogenicity applied in the new regulatory landscape (building experience)**
12:45		Coming online
13:00	13:20	Boris Gorovits - Pfizer *Should we learn more about characteristics of ADA response?*
13:20	13:40	Roland Staack - F. Hoffmann-La Roche *Are immunogenicity assay results really "incomparable"? The critical role of Bioanalysis to bring immunogenicity testing to the next level.*
13:40	14:00	Johannes Stanta - Covance *Singlicate analysis in ADA assays*
14:00	14:10	Short Break
14:10	14:30	Tobias Haslberger - on behalf of the EBF *A Chinese NMPA draft technical guideline on immunogenicity of therapeutic agents: difference and similarities to existing EMA and FDA Guidelines or a new global challenge for harmonisation?*
14:30	14:50	Jacomijn Dijksterhuis - PRA-HS *Different interpretations on new FDA guidance 2019 for ADA validations - a CRO's perspective*
14:50	15:10	João Pedras-Vasconceles - FDA-CDER *Immunogenicity Assessments for Biologics–Current Perspectives from FDA's Office of Biotechnology Products*
15:10	15:30	Q&A / Panel Discussion

	15:50	Zoom session will be closed by the meeting host
13:15	**15:30**	**Day 2 - It's Poster time?**
		Dedicated session on posters
13:15		Coming Online
13:30	15:30	5-minute poster pitch for Scientific posters
15:50		Zoom session will be closed by the meeting host
16:00	**18:00**	**Day 2 - Breakout 3**
		Immunogenicity: strategies for non-mAb scaffolds
16:00		Coming online
16:10	16:30	Bernd Potthoff - Novartis
		A cell based immunogenicity assay to detect antibodies against chimeric antigen receptor
16:30	16:50	Anton Rosenbaum - AstraZeneca
		Immunogenicity Assessment for MEDI7219, an Oral GLP1 Agonist Peptide
16:50	17:10	Nicoline Videbæk - Novo Nordisk
		Improvement of nAb assays with poor sensitivity and drug tolerance – challenges and solutions
17:10	17:30	Anna Laurén - on behalf of the EBF
		EBF consideration for NAb assay development and design with emphasis on matrix, sensitivity and sample pre-treatment
17:30	18:00	Panel discussions
	18:20	Zoom session will be closed by the meeting host
16:00	**18:00**	**Day 2 - Workshop 1**
		The e-environment: towards a vendor neutral secure bi-directional data transfer process
16:00		Coming online
16:10	17:00	Cecilia Arfvidsson - on behalf of the EBF
		Feedback from the EBF - The historical discussions (OS 2018/2019) and interactions with software developers
		Neil Loftus - Shimadzu
		A brief introduction on behalf of software developers on the EBF initiative
		Gidion de Boer - Thermo Scientific and Burkhard Schaefer - Merck
		A vendor-neutral prototype for a secure data transfer - Feedback/proposed solution from the software developer
17:00	17:20	Jason Wakelin-Smith - MHRA
		Feedback from the regulators
17:20	17:40	Burkhard Schaefer - Merck
		Meeting regulatory requirements in long-term storage and processing of HPLC-MS e-data
17:40	18:00	Panel discussions, incl.
		1. Q&A on the implementation of a vendor neutral secure LC/MS-IM bi-directional data transfer process
		2. Feedback from outside EBF on the EBF proposal
		3. Can other areas/platforms benefit form a vendor neutral secure bi-directional data transfer process template?
	18:20	Zoom session will be closed by the meeting host

End of Day 2 for EU/Asia

18:15	**20:00**	**EU/NA time Zone Plenary Session 1**
		Global Engagement on Biomarker Context of Use
18:15		Coming online
18:30	18:40	Joanne Goodman - on behalf of the EBF
		Introduction into the session
18:40	19:00	Kyra Cowan - on behalf of the EBF
		The 2020 EBF Recommendation on BM Assay Validation - key points to consider when implementing CoU practices
19:00	19:20	Matthias Sury - Celerion
		Biomarker Assay Development and Validation: Failing your Way to Success
19:20	19:40	Lauren Stevenson - Immunologix Labs
		Feedback and reflections from the AAPS PharmSci360 Workshop on CoU
19:40	20:00	Abbas Bandukwala - FDA
		A regulatory perspective
	20:20	Zoom session will be closed by the meeting host

Day 3: 19 November 2020

10:45	**12:30**	**EU/ASIA time Zone Plenary Session 2**
		Protein Bioanalysis by LC-MS(MS)
10:45		Coming online

11:00	11:10	Matthew Barfield - on behalf of the EBF Introduction to the session
11:10	12:10	Matthew Barfield - on behalf of the EBF EBF's experiences, discussions and recommendations on Protein Bioanalysis by LC-MS(MS) Kelly Dong - for CBF *Overview of CBF discussion on protein analysis by LC-MS(MS)* Presenter tbc - for JBF *Overview of JBF discussion on protein analysis by LC-MS(MS)* Eric Woolf - MSD *Overview of AAPS discussion on protein analysis by LC-MS(MS)*
12:10	12:30	Panel discussion
	12:45	Zoom session will be closed by the meeting host
13:15	**15:10**	**Day 3 - Workshop 1** **Best practices in method development and communications to drive successful assay transfer between BioA labs**
13:15		Coming online
13:30	13:50	Rachel Green - on behalf of the EBF *A recap of EBF discussions and recommendations on Pharma-CRO partnership best practices for Method Development*
13:50	14:10	Stephanie Cape - Covance *A method development case study highlighting successes and learnings from a CRO – pharma alliance*
14:10	14:30	Lieve Dillen - Janssen R&D Pharma/CRO alliance: what are the keys of success in transfer of assays.
14:30	14:50	Jean-Christophe Genin - F. Hoffmann-La Roche *Successes and learnings: an example from industry*
14:50	15:10	Q&A / panel discussion
	15:30	Zoom session will be closed by the meeting host
13:15	**15:10**	**Day 3 - Breakout 1** **Applications of Biomarker Assays: success stories and challenges**
13:15		Coming online
13:30	13:50	Jade Louber - UCB Biopharma *Implementation of a Fit for Purpose Clinical Biomarker Assay using High-Quality Flow Cytometry*
13:50	14:10	Berthold Lausecker - AZ Biopharma *Method development and validation of an ultra-sensitive LC-MSMS assay for the quantification of estradiol on the basis of an existing assay for ethinylestradiol*
14:10	14:30	Benedicte Brackeva – Ablynx, a Sanofi company Regulatory feedback on context of use biomarker validation for caplacizumab
14:30	14:50	Sebastiaan Bijttebier - Janssen R&D *Development of IP-LC-TQMS methodology as biomarker read-out to quantify tau phosphorylation around T217 in CSF clinical study samples from Alzheimer diseased patients*
14:50	15:10	Robert Nelson - Covance *Making haste, slowly, in bioanalysis of biomarkers*
	15:30	Zoom session will be closed by the meeting host
12:45	**15:10**	**Day 3 Breakout 2** **ADA - Case studies**
12:45		Coming online
13:00	13:20	Susanne Pihl - on behalf of the EBF *EBF feedback for ADA in non-clinical studies focusing on sampling, communication and evaluation of TK/PK*
13:20	13:40	Eugenia Hoffmann - Roche pRED *Impact of drug/anti-drug antibody complexes on drug PK: advanced bioanalysis for a better understanding of immunogenicity*
13:40	14:00	Janett Schwarz - Bioagilytix *ADA/NAB Drug and Target tolerance by SPEAD treatment*
14:00	14:10	Short Break
14:10	14:30	Craig Stovold - AstraZeneca *Assessment of Anti-drug Antibodies to evaluate the immunogenicity in AstraZeneca's leading clinical ASO program using methods that meet regulatory guidance*
14:30	14:50	Gregor Jordan - F. Hoffmann La Roche High drug tolerant immunogenicity testing: Is there space for improvement?
14:50	15:10	Q&A
	15:30	Zoom session will be closed by the meeting host

16:00	**17:30**	**Day 3 - Workshop 2**
		Regional Barriers and Global Interpretation of Guidelines
16:00		Coming online
16:10	16:30	Steve White- on behalf of EBF
		Method development documentation; Interpretation of guidelines
16:30	16:50	Cecilia Arfvidsson, - on behalf of EBF
		A recent EBF survey on regional barriers
16:50	17:10	"Matthew Barfield - on behalf of the EBF
		To Ship or Not to Ship – Results from a recent EBF survey exploring the trends in supporting the Bioanalysis of China studies"
17:10	17:30	Q&A
17:50		Zoom session will be closed by the meeting host

16:00	**17:30**	**Day 3 - Breakout 3**
		Diagnostics and PD decision making in clinical studies: new frontiers
16:00		Coming online
16:10	16:30	Anna Laurén - SVAR
		Clia/ISO or BMV for Biomarkers and Diagnostics: two worlds?
16:30	16:50	Yue Huang - AstraZeneca
		Novel Approach to Qualify for Clinical Application a High Throughput HILIC-MRM Method for the Quantification of Human Plasma Phosphatidylinositols
16:50	17:10	Martha Miles - Quanterix
		The Urgency of Diagnostics - Increased Specificity, Increased Sensitivity and Reduced Invasiveness are the Road to the Hallmark Diagnostic
17:10	17:30	Jeffrey Wallin - Gilead
		The TLR7 agonist vesatolimod induces dose-dependent immune responses in HIV controllers
17:50		Zoom session will be closed by the meeting host

16:00	**17:30**	**Day 3 - It's Poster Time Again**
		Dedicated session on posters
16:00		Coming online
16:10	17:30	5-minute poster pitch for Scientific posters
	17:50	Zoom session will be closed by the meeting host

End of Day 3 for EU/Asia

18:15	**20:00**	**EU/NA time Zone Plenary Session 2**
		Protein Bioanalysis by LC-MS(MS)
18:15		Coming online
18:30	18:40	Matthew Barfield - on behalf of the EBF
		Introduction to the session
18:40	19:40	Matthew Barfield - on behalf of the EBF
		EBF's experiences, discussions and recommendations on Protein Bioanalysis by LC-MS(MS)
		Kelly Dong - for CBF
		Overview of CBF discussion on protein analysis by LC-MS(MS)
		Presenter tbc - for JBF
		Overview of JBF discussion on protein analysis by LC-MS(MS)
		Faye Vazvaei - MSD
		Overview of AAPS discussion on protein analysis by LC-MS(MS)
19:40	20:00	Panel discussion
	20:20	Zoom session will be closed by the meeting host

Day 4: 20 November 2020

12:45	**15:00**	**Day 4 - Workshop 1**
		Covid-19: challenges, experiences and impact on the BA lab
12:45		Coming online
13:00	13:20	Anna Laurén - on behalf of the EBF
		The Tale of the Virus and Sample: Considerations from Expert Groups
13:20	13:40	Michael Wright- LGC
		Bad Blood? An Evolving Tale of Risk Within a COVID-19 World
13:40	14:00	Scott Summerfield - GlaxoSmithKline
		Lab set up challenges and UK regional requirements ?
14:00	14:20	Guillaume Couffe - Covance Central labs
		Running Clinical Trials with agility during COVID-19 pandemic

14:20	14:40	Amy Lavelle - PPD
		COVID in North America: impact on the bioanalytical and drug development community
14:40	15:00	Q&A and panel discussion
	15:00	Zoom session will be closed by the meeting host immediattly after the Q&A
12:45	**14:40**	**Day 4 - Workshop 2**
		Managing GCP in the BioA lab - learning from the past for a better future
12:45		Coming online
13:00	13:20	Tom Verhaeghe - on behalf of the EBF
		Feedback from EBF Survey - sharing experiences of GCP inspections
13:20	13:40	Philip Timmerman - EBF
		GCP - From challenges into opportunities
13:40	14:00	Tsvetelina Ivanova - on behalf of the EBF
		Towards and EBF recommendation of sustainable GLP compliance in the BA lab
14:00	14:20	Jason Wakelin-Smith - MHRA
		Feedback from the regulators
14:20	14:40	Q&A and panel discussion
	15:00	Zoom session will be closed by the meeting host
12:45	**14:40**	**Day 4 - Breakout 1**
		Academia and young scientist: emerging talent for and new perspective on Bioanalysis
12:45		Coming online
13:00	13:20	2020 BRSA - winner: Sooraj Baijnath, University of KwaZulu-Natal (South Africa)
		Technological advances in mass spectrometry imaging driving preclinical drug discovery
13:20	13:40	Connor Walker - on behalf of the EBF-YSS
		Feedback from the 6th YSS Science Café - A Sustainable Future
13:40	14:00	Robert Stewart - Covance
		Investigating generic PK methods of quantifying human monoclonal antibodies in pre-clinical species by LC-MS and ligand-binding assays.
14:00	14:20	Salvatore Calogero - Swiss BioQuant
		The rise of "non-standard" techniques in regulated environment
14:20	14:40	Rebecca Paterson (Charles River Laboratories)
		Antibody Drug Conjugate Bioanalysis – An opportunity for LBA and LC-MS Synergy?
	15:00	Zoom session will be closed by the meeting host
15:00	**16:50**	**Day 4 Plenary session**
		Feedback on ICH M10 - incl. Q&A
15:00		Coming online
15:20	16:00	Jo Goodman - AstraZeneca
		A status update on ICH M10
		Philip Timmerman - EBF
		A draft Guideline is a draft Guideline
		ICH M10 Public Consultation - the Essence of our Comments
		Steve White - on behalf of the EBF
		Scope of the Guideline and Chromatographic assays
		Jean-Mark Gnoth - on behalf of the EBF
		Surrogate matrix - a recent survey from the EBF
		Michaela Golob - on behalf of the EBF
		Ligand Binding Assays and Endogenous
		Tom Verhaeghe - on behalf of the EBF
		ISR and Documentation, incl a recent survey on FDA documentation
16:00	16:20	Dulcyane Mendes - Anvisa
		ICH M10 GUIDANCE adoption by ANVISA
		Feedback from the regulators with focus on ANVISA
16:20	16:50	Q&A from audience (live and chat) and pre-meeting survey to registered delegates
16:50	**17:00**	**Closing remarks - Adjourn**
	18:00	Zoom session will be closed by the meeting host

EBF

Meeting Organisation

Jo Goodman (AstraZeneca), Steve White (GlaxoSmithKline), Tobias Haslberger (Abbvie), Michaela Golob (Nuvisan), Robert Nelson (Covance), Arno Kromminga (BioAgilytix), Sunetha Diaram (Covance), Kyra Cowan (Merck KGaA), Anna Laurén (SVAR), Cecilia Arfvidsson (AstraZeneca), Stuart McDougall (Arcinova), Tom Verhaeghe (Janssen R&D), Matthew Barfield (Roche) and Philip Timmerman (EBF)