



Non sponsored Workshop preceding the 16th OS

One year into ICH M10
Keeping our finger on the pulse

14 November 2023, Hyatt Regency Tower (Barcelona), Spain

Program at a glance

	08:45 – 09:00. Welcome	
09:00	Introduction to GENERAL (G) round tables (ICH Chapters 1,2, 5-9)	
10:00	Coffee break	
11:00	Introduction to CHROM (C) round tables (ICH M10 Chapter 3)	Introduction to LBA (L) round tables (ICH M10 Chapter 4)
12:00	Lunch break	
13:00	Round tables General Themes: <ul style="list-style-type: none"> • Scope interpretation A - primary matrix definition • Scope interpretation B - rare matrix vs. tissues • Scope interpretation C - Defining pivotal studies • Updating historical validations - when, how and why (not)? • Is it allowed to re-analyse positive predose in BE study? • Cross validation - working in the new paradigm 	
14:00	Logistic break – move to Chrom or LBA tables/rooms	
15:00	Round tables CHROM Themes: <ul style="list-style-type: none"> • hybrid assays in ICH M10 - our day-to-day practice • Whole blood stability • Analytes and matrices: focus on urine • Dilution QCs during assay validation & sample analysis • Stock and working solutions stability • Surrogate/rare/preclinical matrix for CHROM 	Round tables LBA Themes: <ul style="list-style-type: none"> • Dilutional Linearity & Parallelism • Singlicate vs duplicate analysis • Surrogate/rare/preclinical matrix for LBA • Chrom. requirements inferring LBA, incl. tissues and blood stability • Dilution QCs during sample analysis
16:00	Coffee break	
17:00	<i>Moderators will consolidate round table discussion learnings for FB sessions</i>	
18:00	FB – General Round Tables	
19:00	FB – CHROM Round Tables	FB – LBA Round Tables

Program details

All presenters will be presenting on behalf of the EBF. The presentations include to the best of our ability the feedback from internal EBF discussions and from the pre-workshop survey

8:45 9:00 Welcome - dynamics of the meeting

Incl. Past current and future challenges for a global BMV Guideline

9:00 10:00 Session 1: Setting the Scene - General items (Plenary)

Feedback from pre-meeting surveys on ICH M10 themes/chapters identified by the EBF and meeting delegates either as introduction to the afternoon GENERAL round tables or limited to session 1

09:00 - 09:15: Scope interpretation - matrix definition - pivotal studies (Philip Timmerman)

09:15 - 09:25: updating historical validations (Lee Goodwin)

09:25 - 09:35: Cross validation - working in the new paradigm (Tsvetelina Ivanova)

09:35 - 09:40: Is it allowed to re-analyse positive predose in BE study? (Tom Verhaeghe)

09:40 - 09:50: ISR, incl. case study from regulatory Feedback (Stuart McDougall)

09:50 - 10:00: Feedback on General items from a recent JBF meeting on ICH M10

10:00 10:30 Coffee break

10:30 12:20 Session 2a: Setting the Scene - Chromatography (Parallel)

Introducing the round tables, incl. feedback from pre-meeting surveys on ICH M10 themes/chapters identified by the EBF and meeting delegates either as introduction to the afternoon CHROM round tables or limited to session 2a

10:30 - 11:00: FB from pre-meeting survey in support of the round tables

- Hybrid assays & ICH M10 (Luca Ferrari)

- Whole blood stability for Chrom (Jörg Faber)

- Focus on urine (Delphine Maux)

- Dilution QCs during validation & sample analysis (Petra Struwe)

- Stock and working solutions stability (Tom Verhaeghe)

11:00 - 11:30: FB from pre-meeting survey for CHROM Themes not selected for round table

- Tissues - how are you interpreting the requirements? (Steve White)

- Choosing the right regression model (Lee Goodwin)

- Matrix effect - special population, haemolysed and lipemic (Enric Bertran)

- Carry over assessment during samples analysis (Petia Milusheva)

- Focus on Metabolites (Philip Timmerman)

11:30 - 11:40: Feedback on General items from a recent JBF meeting on ICH M10

11:40 - 11:50: Stuart Mc Dougall/Lee Goodwin - Surrogate/rare/preclinical matrix for CHROM

11:50 - 12:20: Q&A on themes and additional questions from the survey

10:30 12:00 Session 2b: Setting the Scene - LBA (Parallel)

Introducing the round tables, incl. feedback from pre-meeting surveys on ICH M10 themes/chapters identified by the EBF and meeting delegates either as introduction to the afternoon LBA round tables or limited to session 2b.

10:30 - 10:40: Dilutional Linearity & Parallelism (Robert Nelson)

10:40 - 10:50: Singlicate vs duplicate analysis (Richard Hughes)

10:50 - 11:00: Surrogate/rare/preclinical matrix for LBA (Gregor Jordan)

11:00 - 11:10: Chrom. requirements infecting LBA, incl. tissues/blood stability (Jo Goodman)

11:10 - 11:20: Dilution QCs during sample analysis (Salvatore Calogero)

11:20 - 11:30: Feedback on LBA from a recent JBF meeting on ICH M10

11:30 - 12:00: Q&A on themes and additional questions from the survey

12:00 13:00 (Lunch Break) (from 12:20 onwards for CHROM)

13:00 16:40 Round Table Discussions ICH M10 themes/chapters identified by the EBF and meeting delegates

13:00 14:30 Round tables General themes

All delegates will get a room number assigned and will need to go to that room. The moderator duos (M) will move from one room to the other every 15 minutes to allow all delegates to provide input

1. Scope interpretation - primary matrix definition - (M: Enric Bertran/Delphine)
2. Scope interpretation - rare matrix vs. tissues - (M: Steve White/Salvatore)
3. Scope interpretation - Defining Pivotal studies definition - (M: Katja Zeiser/Michaela)
4. Updating historical validations - when, how and why (not)? - (M: Lee Goodwin/Robert)
5. Is it allowed to re-analyse positive pre-dose in BE study? - (M: Tom Verhaeghe/Gwenda)
6. Cross validation - working in the new paradigm - (M: Tsvetelina Ivanova/Matthew Barfield)

14:30 14:50 Logistic break - move to LBA and Chrom. Tables /rooms

As we do not know the area the delegates work in (and as per ICH M10, we need to split into CHROM and LBA), all delegates will need to self assign them to a meeting room.

- For CHROM = meeting rooms 1st floor - stair/elevator opposite to Jupiter

- For LBA = meeting rooms @ Auditorium Foyer - escalator opposite to EBF registration desk

The moderator duos (m) will move from one room to the other every 15 minutes to allow all delegates to provide input.

14:50 16:40 Round tables CHROM themes

1. Fitting hybrid assays in ICH M10 - day-to-day practice - (M: Luca Ferrari/Kamil Sklodowski)
2. Whole blood stability - (M: Jörg Faber/Enric Bertran)
3. Analytes and matrices: focus on urine - (M: Delphine Maux/Steve White)
4. Dilution QCs during assay validation & sample analysis - (M: Petra Struwe/Rob Wheller)
5. Stock and working solutions stability - (M: Tom Verhaeghe/Rebecca Sleight)
6. Surrogate/rare/preclinical matrix for CHROM - (M: Stuart McDougall/Lee Goodwin)

14:50 16:40 Round tables LBA themes

1. Dilutional Linearity & Parallelism - (M: Robert Nelson/Katja Zeiser)
2. Singlicate vs duplicate analysis - (M: Richard Hughes/Gwenda Pynaert)
3. Surrogate/rare/preclinical matrix for LBA - (M: Gregor Jordan/Michaela Golob)
4. Chrom. requirements inferring LBA, incl. tissues/blood stability - (M: Jo Goodman/Kyra Cowan)
5. Dilution QCs during sample analysis - (M: Salvatore Calogero/Anna Laurén)

At each of the tables/rooms, EBF moderators host a discussion covering:

- FB from (a) pre-meeting survey(s) from delegates on the theme discussed at round table
- *Ad hoc* questions delegates may still have
- Define (if possible) a (recommended) "way forward", i.e. based on the discussions, how do we recommend interpret and execute the guideline requirement?"
- Where available, share regulatory FB from filings or recent inspections helping harmonisation.

The round table deliverable:

For each of the themes/guideline paragraphs identified for discussion, we will discuss your questions/our experience in small groups (round tables style) with the aim of:

1. Recommending a valid and harmonised path forward on each theme
2. Create awareness and share our worries where the industry already observes different interpretation by regulators and for which industry/regulators need to stay connected
3. Identify ambiguities and provide FB to the (global) regulators so we can resolve these.

Note: for some of the themes or discussions, we will be able to share the discussions and outcome from a recent ICH M10 workshop hosted by the JBF

16:40 17:30 Extended coffee break to allow moderators to consolidate and prepare FB

17:30 18:15 Session 3: FB General themes (Auditorium)

18:20 19:00 Session 4a: FB Chromatography themes (Auditorium)

18:20 19:00 Session 4b: FB LBA themes (Jupiter)

19:00 Adjourn

Organising committee and moderator panel: Luca Ferrari, Matthew Barfield, Kamil Sklodowski (F. Hoffmann- La Roche); Richard Hughes, Robert Wheller, Rebecca Sleight (Resoliant); Stuart McDougall (Quotient Sciences); Mark Jean Gnoth (Bayer); Robert Nelson (Bioagilytix); Salvatore Calogero (Swiss BioQuant); Anna Laurén (NovoNordisk); Gwenda Pynaert (argenx); Petra Struwe (Celerion); Tsvetelina Ivanova, Petia Milusheva (Comac-medical) Tom Verhaeghe (JnJ); Jörg Faber (A&M-labor); Delphine Maux (Syneos Health); Enric Bertran (Moderna); Lee Goodwin, Alexandra Bushy (Labcorp Drug Development); Katja Zeiser, Michaela Golob (Nuvisan); Steve White, (GSK); Kyra Cowan (Merck KGaA); Jo Goodman (AstraZeneca) and Philip Timmerman (EBF)

The workshop is organised by the EBF vzw as non-sponsored non-profit events and is independent from EBF member

