



**Non sponsored Workshop preceding the 16<sup>th</sup> OS**

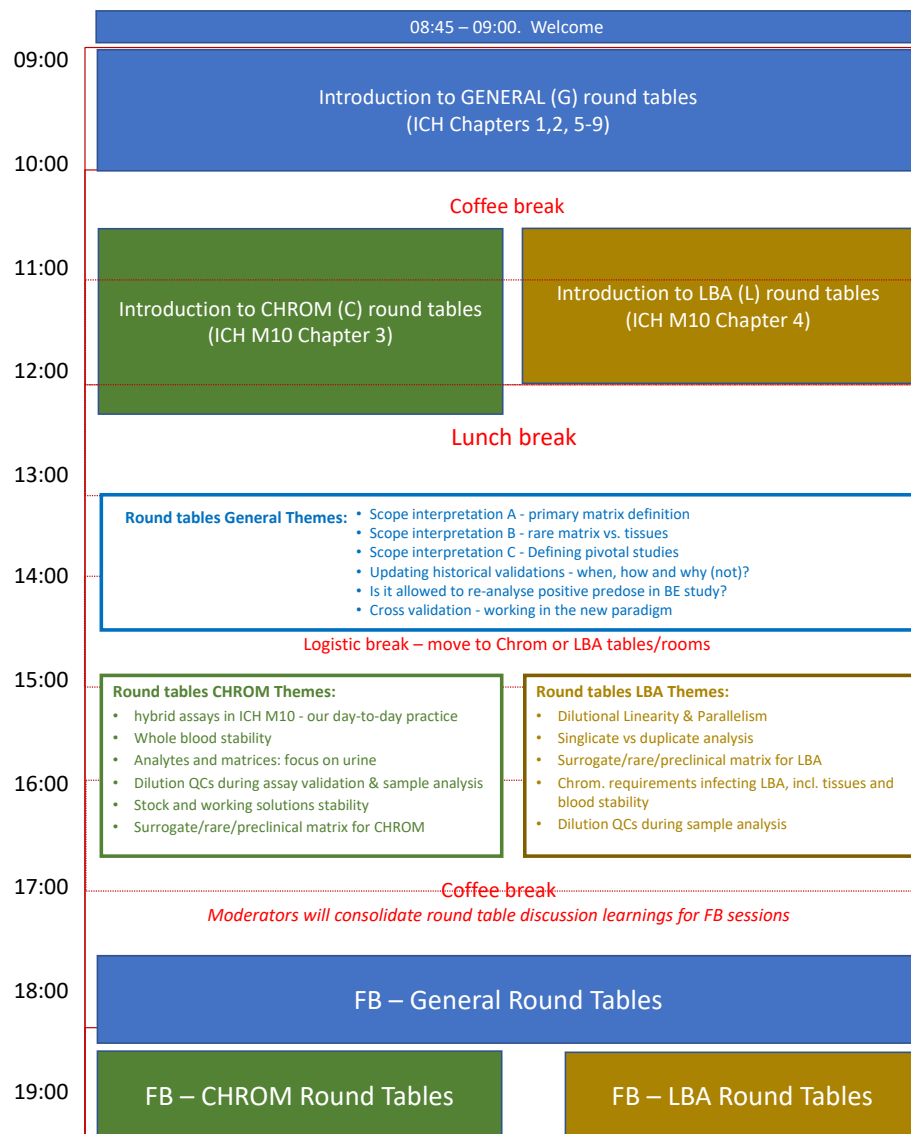
# One year into ICH M10 Keeping our finger on the pulse

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

**Organising committee and moderator panel:**

Luca Ferrari, Matthew Barfield, Kamil Sklodowski (F. Hoffmann- La Roche); Richard Hughes, Robert Wheller, Rebecca Sleight (Resolian); Stuart McDougall (Quotient Sciences); Mark Jean Gnoth (Bayer); Robert Nelson (Bioagilytix); Salvatore Calogero (Swiss BioQuant); Anna Laurén (NovoNordis); 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 companies



## Agenda details

**08:45 09:00 Welcome - dynamics of the meeting**

Incl. Past current and future challenges for a global BMV Guideline - [slides 01. Introduction](#)

**09:00 10:00 Session 1: Setting the Scene - General items (Plenary)**

09:00 - 09:15: Scope interpretation - matrix definition - pivotal studies (Philip Timmerman) - [slides G01FB-0](#)

09:15 - 09:25: updating historical validations (Lee Goodwin) - link to slides: see afternoon session

09:25 - 09:35: Cross validation - working in the new paradigm (Tsvetelina Ivanova) - link to slides: see afternoon session

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

09:40 - 09:50: ISR, incl. case study rom regulatory Feedback (Stuart McDougall) - [slides G05FB](#)

09:50 - 10:00: Feedback on General items from a recent JBF meeting on ICH M10 - [slides G06 JBF G](#)

**10:00 10:30 Coffee break**

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

10:30 - 11:00: FB from pre-meeting survey in support of the round tables - link to slides: see afternoon session

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) - [slides C07](#)

- Choosing the right regression model (Lee Goodwin) - [slides C08](#)

- Matrix effect - special population, haemolysed and lipemic (Enric Bertran) - [slides C09](#)

- Carry over assessment during samples analysis (Petia Milusheva) - [slides C10](#)

- Focus on Metabolites (Philip Timmerman) - [slides C11](#)

11:30 - 11:40: Feedback on General items from a recent JBF meeting on ICH M10 - [slides C12 JBF C](#)

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)**

10:30 - 10:40: Dilutional Linearity & Parallelism (Robert Nelson) - link to slides: see afternoon session

10:40 - 10:50: Singlicate vs duplicate analysis (Richard Hughes) - link to slides: see afternoon session

10:50 - 11:00: Surrogate/rare/preclinical matrix for LBA (Gregor Jordan) - link to slides: see afternoon session

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) - link to slides: see afternoon session

11:20 - 11:30: Feedback on LBA from a recent JBF meeting on ICH M10 - [slides L06 JBF L](#)

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

12:00	13:00	<b>Lunch Break</b>
13:00	16:40	<b>Round Table Discussions ICH M10 themes/chapters identified by the EBF and meeting delegates</b>
13:00	14:30	<p><b><u>Round tables General themes</u></b></p> <ol style="list-style-type: none"> <li>1. Scope interpretation - primary matrix definition - (M: Enric Bertran/Delphine Maux) - <a href="#">slides G01FB-A</a></li> <li>2. Scope interpretation - rare matrix vs. tissues - (M: Steve White/Salvatore) - <a href="#">slides G01FB-B</a></li> <li>3. Scope interpretation - Defining Pivotal studies definition - (M: Katja Zeiser/Michaela Golob) - <a href="#">slides G01FB-C</a></li> <li>4. Updating historical validations - when, how and why (not)? - (M: Lee Goodwin/Robert Nelson) - <a href="#">slides G02FB</a></li> <li>5. Is it allowed to re-analyse positive predose in BE study? - (M: Tom Verhaeghe/Gwenda Pynaert) - <a href="#">slides G03FB</a></li> <li>6. Cross validation - working in the new paradigm - (M: Tsvetelina Ivanova/Matthew Barfield) - <a href="#">slides G04FB</a></li> </ol>
14:30	14:50	<b>Logistic break</b>
14:50	16:40	<p><b><u>Round tables CHROM themes</u></b></p> <ol style="list-style-type: none"> <li>1. Fitting hybrid assays in ICH M10 - day-to-day practice - (M: Luca Ferrari/Kamil Sklodowski) - <a href="#">slides C01FB</a></li> <li>2. Whole blood stability - (M: Jörg Faber/Enric Bertran) - <a href="#">slides C02FB</a></li> <li>3. Analytes and matrices: focus on urine - (M: Delphine Maux/Steve White) - <a href="#">slides C03FB</a></li> <li>4. Dilution QCs during assay validation &amp; sample analysis - (M: Petra Struwe/Rob Wheller) - <a href="#">slides C04FB</a></li> <li>5. Stock and working solutions stability - (M: Tom Verhaeghe/Rebecca Sleight) - <a href="#">slides C05FB</a></li> <li>6. Surrogate/rare/preclinical matrix for CHROM - (M: Stuart McDougall/Lee Goodwin) - <a href="#">slides C06FB</a></li> </ol>
14:50	16:40	<p><b><u>Round tables LBA themes</u></b></p> <ol style="list-style-type: none"> <li>1. Dilutional Linearity &amp; Parallelism - (M: Robert Nelson/Katja Zeiser) - <a href="#">slides L01</a></li> <li>2. Singlicate vs duplicate analysis - (M: Richard Hughes/Gwenda Pynaert) - <a href="#">slides L02FB</a></li> <li>3. Surrogate/rare/preclinical matrix for LBA - (M: Gregor Jordan/Michaela Golob) - <a href="#">slides L03FB</a></li> <li>4. Chrom. requirements infecting LBA, incl. tissues/blood stability - (M: Jo Goodman/Kyra Cowan)</li> <li>5. Dilution QCs during sample analysis - (M: Salvatore Calogero/Anna Laurén) - <a href="#">slides L05FB</a></li> </ol>
16:40	17:30	<b>Coffee Break</b>
17:30	18:15	<b>Session 3: FB General themes (Auditorium)</b>
18:20	19:00	<b>Session 4a: FB Chromatography themes (Auditorium)</b>
18:20	19:00	<b>Session 4b: FB LBA themes (Jupiter)</b>
19:00		<b>Adjourn</b>