Bugatti Tank 57C, winner of the 14th and 16th edition of the 24h of Le Mans (1937 and 1939)

Themes for the 16th EBF Open Symposium

Science - Winning the Race

15-17 November 2023, Barcelona, Spain

You can submit an abstract fitting your scientific interest on one or more of below themes – to submit, use this form and send to open@e-b-f.eu before 20AUG2023

The details of what we look for…

Before you start…good to know::

- We will include **feedback on internal EBF discussion**, (upcoming) recommendations or publications in the sessions marked with *.
- Not all below suggested themes will make it to a stand-alone session. There is obvious cross pollination for some themes. Depending on the submitted abstracts, some themes could be combined into 1 session. To qualify as a stand-alone session, we need at least 3 presentations from different organisations.
- For most of the sessions, presenting case studies is the best way to engage with the delegates.
- Below themes may qualify for plenary, breakout sessions or a workshop embedded in the symposium.
- We plan a session in collaboration with the European Immunogenicity Platform (EIP) . The theme is being identified and is not part of this call for abstracts.

24h = 24 themes

The 24 themes for which we welcome your abstract are listed below.

More details are included in the table on page 2.

1. **Progress in Patient Centric Trials ***
2. **Automation & miniaturisation**
3. **Biomarkers/CoU ***
4. **The e-environment ***
5. **The wonderful world of immunogenicity**
6. **The challenges of enantiomeric separations**
7. **How are we dealing with prodrugs in the BA lab**
8. **Challenges with excipients and special formulations for chromatographic assays**
9. **Low CPs – Because we can? ***
10. **Singlicate vs. duplicate analysis ***
11. **Drug tolerance ***
12. **Bioanalytical challenges for CGT ***
13. **Critical Reagents**
14. **Biosimilar Validation concepts**
15. **Bioanalytical challenges with solid matrices ***
16. **One year of ICH M10 – will be separated out as workshop on 14 NOV 2023**
17. **Vaccines**
18. **Technological developments for hybrid assays ***
19. **Regulatory updates**
20. **The next generation of BA experts**
21. **From metabolite ID to metabolite quantification ***
22. **Challenges with BA support for in vitro assays**
23. **CHROM-Clinic**
24. **LBA-Clinic**

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More details on above 24 themes

1/ Progress in Patient Centric Trials * (plenary and/or breakout(s)) • Incl. success stories of application, overcoming logistic issues • A separate session on technology developments	**2/ Automation & miniaturisation** (breakout) • Technology update on automation solutions for bioanalysis • Incl. focus on 384-well methodology giving plate-based assays a boost and how automation can stimulate 3Rs
3/ Biomarkers/CoU * (plenary and/or breakout) • Are we making progress in bringing the right focus to challenges? • Feedback from regulatory interactions on BM assay validation requirements	**4/ The e-environment** * (breakout and/or workshop): • Is the paperless office Utopia or becoming real? • Moving into the cloud – What do BA labs need to know? - Welcoming abstracts on case studies on the implementation of cloud-based approach (if possible, include archiving)
5/ The wonderful world of immunogenicity (breakout) • Welcoming abstracts on themes not covered in 9-14 • Session could focus on (new) technologies.	**6/ The challenges of enantiomeric separations** (breakout) • Must do versus can do • Focus on case studies and regulatory requirements
7/ How are we dealing with prodrugs in the BA lab (breakout) • Must do *versus* Can do • Focus on case studies and regulatory requirements	**8/ Challenges with excipients and special formulations for chromatographic assays** (breakout) • Must do *versus* Can do • Focus on case studies and regulatory requirements
9/ Low CPs – Because we can? * (breakout) • We welcome case studies related to how defining low CPs may be technically possible but scientifically/clinically not/less meaningful	**10/ Singlicate vs. duplicate analysis** * (breakout) • Is industry moving away from duplicate analysis for LBA/CBA platforms • We welcome case studies and regulatory FB during filing
11/ Drug tolerance * (breakout) • We welcome case studies as basis for the discussion • Case studies should focus on Must do *versus* Can do	**12/ Bioanalytical challenges for CGT *** (breakout) • Update on Scientific/regulatory challenges and learnings for C&GTs, including immunogenicity specific to CGT • Assay formats: Technologies and strategies involving PCR, flow cytometry, Elispot, LBA or chromatography • We welcome case studies as basis for the discussion on above
13/ Critical Reagents (CR) (breakout) • Status update on current practices / issues with CR • Includes case studies in tackling CR that did not bridge to previous lots, emerging challenges such as lot to lot variability and stability of CR and regulatory FB.	**14/ Biosimilar Validation concepts** (breakout) • Best strategies to show bioanalytical similarity and approaches for PK assay validation • Updated Immunogenicity strategies/concepts • Regulatory experiences
15/ Bioanalytical challenges with solid matrices * • What does validation mean for tissues? Does it fit our tick box? Is what we measure the true exposure? • Includes a special focus on challenges and needs for oligo's • Depending on the submission content and its relation to ICH M10, the abstracts may move into the ICH M10 workshop.	**16/ One year of ICH M10 → all submissions with focus on experience and case studies will be moved to ICH M10 Workshop** • More info in tab 'ICH M10' of https://bcn.e-b-f.eu • the EBF has decided to separate out the ICH M10 discussion as a separate workshop on the day before the 16th OS.
17/ Vaccines (breakout) • Immunogenicity and biomarkers for vaccines - are the challenges different?	**18/ Technological developments for hybrid assays *** (plenary and/or breakout) • We welcome case studies as basis for the discussion
19/ Regulatory updates (plenary or breakout) • Finger on the pulse of new and/or emerging guidelines impacting the day-to-day work in regulated bioanalysis` • Includes regulations on replacements of animals • Updated IVDR regulations and its (real or assumed) impact on the regulated bioanalytical lab	**20/ The next generation of BA experts** (plenary or breakout) • Possibilities/opportunities for the future generation beyond technological expertise • Connects to the work of the YSS community • enhancing the BA contribution to a DMPK or ADME package.
21/ From metabolite ID to metabolite quantification * (plenary and/or breakout) • Depending on the submission content and its relation to ICH M10, the abstracts may move into the ICH M10 workshop.	**22/ Challenges with BA support for in vitro assays.** (breakout) • Do they fit our tick box – or alternatives to our tick box focussing on the questions asked?
23/ CHROM-Clinic (round table) • Chromatographic assays for small molecules – are all problems solved? If not, bring your case studies to this CHROM-Clinic	**24/ LBA-Clinic** (round table) • If your problem was not covers in any of the above session, bring your case studies to this LBA-Clinic

Scientific Program: Cecilia Arfvidsson (AstraZeneca), Matthew Barfield (F. Hoffmann – La Roche), Kyra Cowan (Merck KGaA), Michaela Golob (Nuvisan), Jo Goodman (AstraZeneca), Anna Laurén (NovoNordisk), Robert Nelson (Labcorp), Steve White (GSK) and Philip Timmerman (EBF) – *potential additions are based on the final programming*

Meeting website and e-mail: https://bcn.e-b-f.eu and open@e-b-f.eu
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