



## Themes for the 15<sup>th</sup> EBF Open Symposium

### The Bioanalytical Compass - Navigating to our True North



You can submit an abstract fitting your scientific interest on one or more of below themes – to submit, use [the attached submission form](#) and send to [open@e-b-f.eu](mailto:open@e-b-f.eu) before 20AUG2022 (or navigate to the conference website: <https://bcn.e-b-f.eu/submit-an-abstract/>)

Before you start...good to know::

- We will include **feedback on EBF discussion, recommendations** and upcoming publications in a number of sessions. This includes but is not limited to **Biomarkers, GxP/DI, Nabs, qPCR or Hybrid assays**
- Not all themes may 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. A session will need at least 3 presentations from different organisations to qualify for a stand-alone session
- For most of the sessions, presenting your case studies will be a very valuable cornerstone of the discussions and learning opportunity for the meeting delegates.

Depending on the submitted abstracts we are planning for a **plenary session** for following 4 themes

<b>1. Recent developments and challenges for microsampling</b> <ul style="list-style-type: none"><li>• Why isn't microsampling the norm in our industry?</li><li>• sensitivity challenges due to microsampling, increasingly active compounds with limited exposures</li><li>• Why isn't compliance to 3Rs the norm in our industry?</li><li>• Opportunities and challenges for Patient centric sampling/home sampling</li></ul>	<b>2. Regulatory updates</b> <ul style="list-style-type: none"><li>• Feedback from industry and HA on regulatory trends<ul style="list-style-type: none"><li>◦ A separate track on ICH M10 will be included only if the Guideline is published</li></ul></li><li>• New regulations on the horizon</li><li>• Data Integrity</li><li>• Risk-Based Approach in regulated bioanalysis – the discussion continues</li></ul>
<b>3. Getting more out of an early phase 1 study</b> <ul style="list-style-type: none"><li>• Are regulations slowing us down?</li><li>• The challenges of metabolite quantification or biomarkers analysis.</li><li>• Are tracer studies reviving?</li></ul>	<b>4. Bioanalytical challenges with solid matrices</b> <ul style="list-style-type: none"><li>• What does validation mean for tissues? Does it fit our tick box? - or alternatives to our tick box focussing on the questions asked?</li><li>• Is what we measure the true exposure?</li></ul>

Depending on the submitted abstracts we are planning for a **breakout session** for following 10 themes

<b>5. The wonderful world of immunogenicity – what's next?</b> <ul style="list-style-type: none"><li>• Update on scientific and regulatory challenges and learnings related to ADA, NAbS and the BA toolbox</li></ul>	<b>6. Bioanalytical challenges for C&amp;GT</b> <ul style="list-style-type: none"><li>• Update on Scientific and regulatory challenges and learnings specific for C&amp;GTs</li></ul>
<b>7. New drugs scaffolds increasing the challenges with sensitivity and robustness of LBA/CBA assays</b> <ul style="list-style-type: none"><li>• Update on technology developments</li><li>• When do we go "hybrid" and why? Or why not? An how to evaluate different read outs from different platforms?</li><li>• Singlicate analysis: the norm or the exception – learnings and experiences</li></ul>	<b>8. New drugs scaffolds increasing the challenges with sensitivity and robustness of LC-MS assays</b> <ul style="list-style-type: none"><li>• More robust assays demanding more robust sample preparation</li><li>• Developments in separation technology, incl. chiral separations</li><li>• Solving issues in low pg/mL range for small molecules assays</li><li>• Solving issues for molecules with extreme phys-chem properties</li></ul>
<b>9. Biomarkers</b> <ul style="list-style-type: none"><li>• Are we making progress in bringing the right focus to challenges?</li><li>• Feedback from regulatory interactions on biomarkers assay validation requirements</li></ul>	<b>10. Bridging DMPK and Bioanalysis</b> <ul style="list-style-type: none"><li>• From metabolite identification to metabolite quantification</li><li>• Challenges with BA support for <i>in vitro</i> assays. Do they fit our tick box? – or alternatives to our tick box focussing on the questions asked?</li></ul>
<b>11. What if it goes wrong (building on the 8th YSS)?</b> <ul style="list-style-type: none"><li>• Sharing experience of assays going wrong and how it was solved</li></ul>	<b>12. The e-environment</b> <ul style="list-style-type: none"><li>• Progress on vendor neutral secure data transfers for MS and LBA/CBA data</li></ul>
<b>13. Automation</b> <ul style="list-style-type: none"><li>• Technology update and sharing experience on automation solutions for bioanalysis</li></ul>	<b>14. What if it's neither small nor large?</b> <ul style="list-style-type: none"><li>• Sharing experience on scientific challenges with bioanalysis of peptides and oligonucleotides.</li></ul>

Depending on the submitted abstracts we are planning for a **workshop\*** format for following 3 themes

(\* a workshop format consists of maximum 2 presentations and ½ of the session allowing for round table discussion)

<b>15. Has Covid changed the way we work?</b> <ul style="list-style-type: none"><li>• Sampling and sample logistics</li><li>• Lab workflows and automation</li><li>• Are we ready for the next pandemic?</li></ul>	<b>16. Challenges for the next generation of BA experts</b> <ul style="list-style-type: none"><li>• In search of the talents being able not only to implement new methods and technologies, but also to participate in a (Pharma) project team, knowing how BA can contributing more to a DMPK or ADME package.</li></ul>
<b>17. Bioanalysis for discovery support – is the bar raising?</b> <ul style="list-style-type: none"><li>• Impact of shifting regulations and data integrity requirements on bioanalytical support for discovery (focus encompasses <i>in vivo</i> PK, <i>in vitro</i> studies and PD)</li></ul>	

and, if you cannot choose from above, we invite you to bring ... **Your Burning Platform** ... to our meeting

#### 18. Free theme(s) – Your Burning Platform (for either workshop or oral presentations)

If you have an urgent, exciting or important (non-commercially driven) theme which is not on our list and you want to bring to the meeting, please submit and the EBF will evaluate if there is a potential fit with our meeting and the EBF mission (<https://e-b-f.eu/home-2/>)