EBF

14th EBF Open Symposium

Science – Our Universal Language

All-delegates interactive brain storm and panel discussion on future challenges for the Bioanalytical community

01-03 December, Cyberspace

The value we can bring

Day 1: 24 November 2021

Welcome

Session 1: Biomarkers – Organisational design driving CoU (Plenary)

Session 2: NCE/Chromatography

Session 3: New Modalities

Session 4: Workshop – Remote inspections by Health Authorities – experiences and challenges

Session 5: Workshop – Biomarkers – Organisational design driving CoU

Day 2: 25 November 2021

Session 6: Microsampling – technological developments – patient centric trials

Session 7: Immunogenicity Technology and Applications

Session 8: Biomarker – Technology and applications

Session 9: LBA/CBA – Technical Challenges

Session 10: Immunogenicity – Strategies

Session 11: Protein MS – Applications and EBF update

Session 12: Data

Day 3: 26 November 2021

Session 13: The patient

Session 14: NAb – Strategies and applications

Feedback from Session 4: Remote HA inspections

Feedback from Session 5: Biomarkers – Organisational design driving CoU

Session 15: The future of BA – our ethical responsibility to the community

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Science

Technology

Process

Product

Regulations

The patient

The value we can bring

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Ethical considerations

The patient

The value we can bring

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The patient

Ethical considerations we can contribute to

Is every sample needed?

MVal	Preclinical Studies	Clinical Studies

Ethical considerations we can contribute to

Areas where we can contribute

MVal

Preclinical Studies

Clinical Studies

3R

Miniaturisation

Sampling devices

Ethical considerations we can contribute to

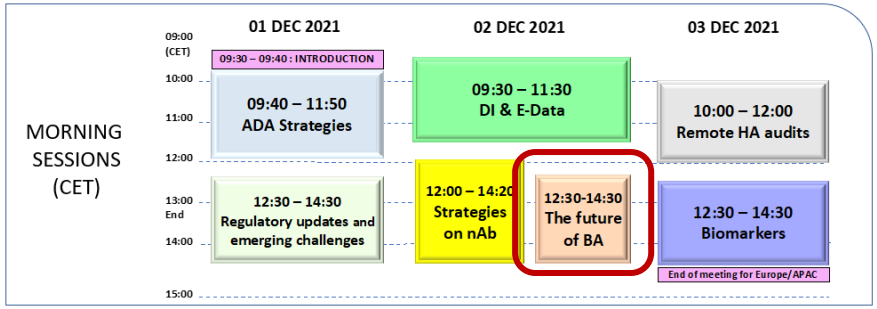
Are we doing enough to prevent non added value work?

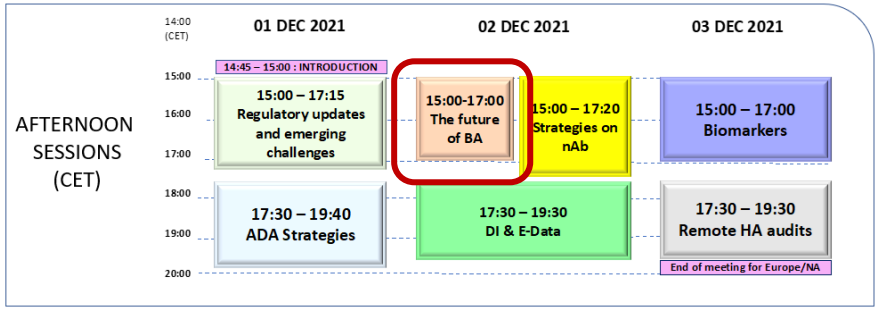
3R	Can we use less animals for BA purposes?
Miniaturisation	Is every clinical sample really needed?
Sampling devices	Can BA contribute to improve animal welfare?
	Can BA contribute to increase patient comfort?

Areas where we are already contributing?

Areas where we can contributing more or better?

And from here…





Get more input in our December meeting

- 200 of you had more time to reflect and add more meat to our ethical bone
- 100 new delegates (December only registrations) can join

If significant, we may **publish** the outcome as a reflection or discussion paper

- Invite our community to promote ethical considerations in their day to day work
- Influence upcoming regulations insufficiently considering 3Rs, developments in sampling technologies or other items we identify

Ethical considerations we can contribute to

Are we doing enough to prevent non added value work?

In the session we landed at 3 areas

Can we use less animals for BA purposes and contribute to improve animal welfare??

Is every clinical sample really needed?

Can BA contribute to increase patient comfort?

Discussion Digest from Barcelona

- **Can we improve animal welfare and reduction of animals? → YES**
  - Overall, increase 3R across the globe
  - Challenge the “I don’t know” or “I don’t care attitude” → create increased awareness – visualise BioA sample consumption per study and validation
  - Suggestions range from “Make surrogate matrix the norm” to “make microsampling the norm”
    - Covid shortages learned us that necessity breaks the law at no scientific expense
    - Other regulated industries can make it work (diagnostics)
  - Kill projects where everybody except 1 team member sees it’s dead earlier

Discussion Digest from Barcelona

- **Is every clinical sample really needed? → NO**
  - "Less" was enough in the past. Are all requests towards "more" today valid?
  - trend for **increased clinical sample** collection, especially for PK and ADA endpoints
    - **PK:** are all necessity for the PK profile as this is neither ethical not sustainable
    - **ADA**: is aligning ADA with PK sampling timepoint leading to unnecessary samples
  - trend for **reduced clinical sample** collection, driven by cost
    - often in smaller organisations with development teams consciously work together on a lean approach .

Discussion Digest from Barcelona

- **Can we contribute to (more) to patient comfort and less samples? → YES**
  - Consider learnings from paediatric sampling technology for other studies
  - Further develop & Promote home sampling
    - sustainability savings includes reduced carbon footprint of everyone having to travel to a site to collect the sample
    - But also, will make the sampling easier will get you more samples?
  - Mixed opinions on the necessity of A & B samples
    - Covid crisis apparently led to more shipments being thawed on the runway. Temporarily?
  - Sampling often driven by lab manual, written without imput from BA and using the standard tubes available from copy/paste
    - Method validation should be done based on sample collection, not the other way around

Ethical considerations we can contribute to

Are we doing enough to prevent non added value work?

Your thoughts or additions

Can we use less animals for BA purposes and contribute to improve animal welfare??

Is every clinical sample really needed?

Can BA contribute to increase patient comfort?

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Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu