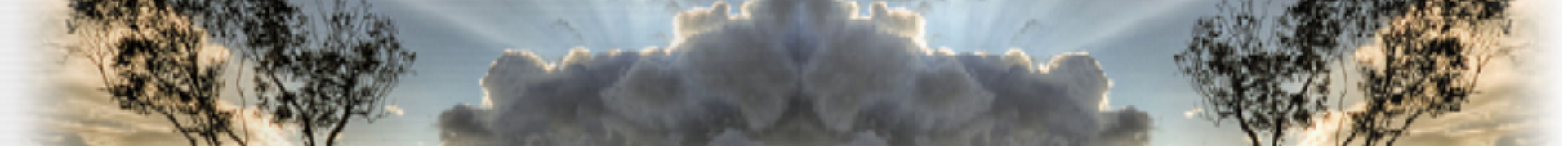

Microsampling: New Devices and Novel Challenges

notes from the meeting

12th EBF Open Symposium
Imagine! A new bioanalytical Earthrise

http://www.e-b-f..eu


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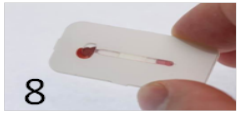
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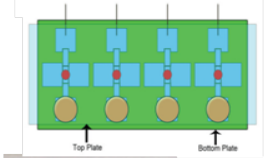

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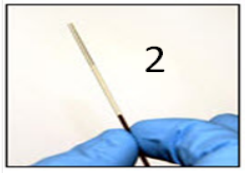
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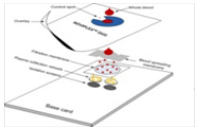
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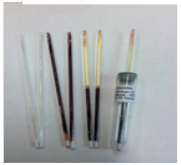
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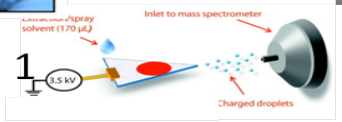

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Home Sampling

2017

Microsampling

2008

What stops us using these devices?

Problems? Why aren't we using these?

- Not practical for serial sampling
  - 10 fingersticks in a row hurts
  - Venous enables repeated sampling
  - Make DBS samples from venous blood
- Bridging from capillary blood to venous blood to plasma?
- Training for use of new techniques/devices
- Price
- Reliability/quality of sample being collected
- Sensitivity requirements (volume of sample)
- Device overload – which to use
- Extra validation steps
- Regulatory guidance not well defined
- No Foolproof device available
- Need consumers to want this approach
- Cost of study is higher
- Extra BA work required
- Recovery over time dried state
- Sample processing reliability (before extraction)
- Ability to use multiple types of samples not established
- Not in my clinical trial syndrome!!! Fear of change/unknown
- Trust of old methods over new methods
- Education on new devices/approaches
- Data not put in context (not one size fits all)
- Device means different things to different people
- Cost benefit of this approach
- Look at the negatives versus the positives
- No magic solution/device
- Still need clinical visit or other samples for some measurements
- Logistics of implementation

Where should we use microsampling?

- Episodic sampling
- Developing world applications (lack of cold chain)
- Remote locations
- TDM
- Easier processing at the clinic (vs plasma)
- Painless sampling needed
- Pediatric studies (small volumes)
- Consumer healthcare testing
- Virtualize a trial across multiple sites
- Connect across different techs (dosing techs), digital biomarkers, time stamps
- Non human studies in the wild
- Anti-doping studies
- Biomarkers
- Alternative sampling location on body
- 3Rs
- Stability in the dried state
- Vulnerable populations (elderly)
- Fear of needles
- Crime scene/roadside sampling
- Transportation
- Adherence monitoring
- Better PK (alternative data points)
- More analyses from same volume
- Patient/Subject convivence
- At home sampling
- Recruitment/retention in trials
- Better for biobanking?
- Nutrition/wellness monitoring

Solutions

- Painless devices to avoid fingersticks
- Serial sampling using venous draw
- Sharing results (easily consumed)
- Plasma separator devices
- Working together, precompetitive space
- Focus on relevant issues
- POC measurements
- Wholistic approach to sample collection and usage
- Get patient input
- Start early with implementation
- Foolproof devices
- Automated workflows (data, samples)
- Alternative matrices
- Develop cost benefit data sets to show the value (or not)
- Ethics can drive adoption
- Well defined unmet need
- No magic bullet device (get over it)
- Take a broader view of technology in clinical studies
- Inform regulators as a group
- Identify champions to support the technology
- Make them cheaper (understand cost benefit)
- Don’t talk yourself out of trying
- Clinical needs to drive the need
- Context of use needs to be defined
- Training material for patients
- Public awareness
- Focus on use cases where most benefit can be gained, most value
- Improved substrates for sample collection (stability, recovery, adsorption)

Contact Information

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