

Moving forward from the EBF recommendation

Philip Timmerman, on behalf of EBF

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Our interest in DBS

➤ 2008-2009:

- Internal discussion in closed meetings
- Surveys, iterations of surveys

➤ 2010:

- Topic of 1st EBF Focus Meeting: “*Connecting Strategies on Dried Blood Spots*”, Brussels, Belgium
- EBF-recommendation on DBS presented at AAPS Annual meeting, New Orleans (2010) and 3rd EBF Open meeting, Barcelona (2010)

➤ 2011:

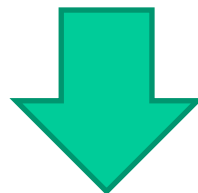
- Recommendation paper on DBS in Bioanalysis (published July 2011, Vol. 3, No. 14, Pages 1567-1575)
- EBF plans to **Focus** on the analytical challenges and science of the DBS technology and to **Refocus** of the added value of DBS in different areas of drug development.

Focus: Open Workshop on DBS in Brussels
(23 June 2011)



EBF – DBS consortium

Refocus: Editorial in Bioanalysis
(Bioanalysis, August 2011, Vol. 3, No. 16, Pages 1787-1789)



Refocus the discussion

Actions from the EBF Editorial

(Next slides)

EBF proposes a 2-tiered approach

- **Reposition DBS discussion in industry**
 - Take a step back to enable enduring value addition of DBS
 - Focus on the business and scientific drivers of DBS
 - What is the question asked?
 - Provide tailored solutions.
 - Continue to connect /be pivot point for disciplines or (with) initiatives with vested interest in DBS (e.g. DMDG, IQ,..)

- **Focus on bioanalytical challenges**
 - Unite and share on solving the scientific and analytical hurdles
 - Based on issues-challenges described in recommendation paper, but open for input
 - Use EBF DBS Consortium as vehicle (next presentations)

Next presentations (Steve et al.)

Reposition DBS discussion in industry - 1

Take step back to enable enduring progress:

– What are the drivers of DBS?

o Scientific

- Smaller sample volume (3R, single animal PK profiles, enable PK in special population, others,...)
- Facilitate Blood PK (instead of / in addition to plasma PK)
- Others...

o Business

- Easier sample logistics in clinical trials
- Cost savings (animals, sample handling)
- Ethical considerations

Is DBS best choice?
Did we consider alternatives?
(smaller plasma volume, wet blood,...)

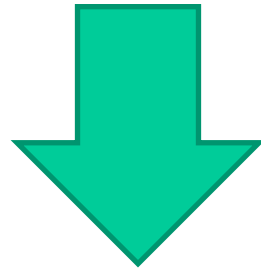
Where can DBS –small volume – Blood PK add value? some examples



Small sample volumes	Scientific drivers	<ul style="list-style-type: none"> • Single animal PK, no/less satellite animals 	<ul style="list-style-type: none"> • Facilitate PK studies in special population
	Business drivers	<ul style="list-style-type: none"> • Ethics (less blood , reduced animal usage) • Cost 	<ul style="list-style-type: none"> • Ethics (less blood, volunteers/patients) • Cost
	Possible hurdles	<ul style="list-style-type: none"> • Limitations of technology (accurate pipetting of micro volumes, sensitivity of analytical equipment) 	

PK in blood (wet blood / DBS)	Scientific drivers	<ul style="list-style-type: none"> • Added value of blood PK, PK/PD 	<ul style="list-style-type: none"> • Added value of blood PK
	Business drivers	<ul style="list-style-type: none"> • Efficiency in vivo screening (wet blood)* 	<ul style="list-style-type: none"> • Less clear • Cost savings in sample shipments (DBS)*
	Possible hurdles	<ul style="list-style-type: none"> • Cost (DBS)* 	<ul style="list-style-type: none"> • Industry has less experience with DBS or blood PK • HA acceptance (challenge DBS > wet blood)* • Cost (DBS)*

* Clarification between brackets specifies if a driver/obstacle is specific for wet blood or DBS



Business & scientific drivers and hurdles are **not necessarily the same** in the different phases of drug development

Reposition DBS discussion in industry - 2

Based on potential of the technology (*e.g. outcome of DBS consortium and industry reporting in peer reviewed literature*):

1. Identify areas where DBS is best choice
 - o Increase focus on DBS and develop strategy to get full benefit from the technology
2. Identify areas where DBS is poor choice
 - o Decrease focus on DBS and develop strategy to get full benefit from alternative solutions.....

.....while keeping abreast with scientific and business drivers mentioned on previous slides

Steve et al. will now provide an update on the EBF DBS Consortium

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