

Final Business Plan
S3A: Q&As on Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure
Focus on Microsampling
dated 21 May 2014
Endorsed by the ICH Steering Committee on 23 October 2014

1. The issue and its costs

Current ICH S3A Guideline does not fully address the benefit and the use of microsampling. More supportive texts and details in the format of a Q&A document regarding the use of microsampling would encourage the drug developers to reduce animal use in toxicology/pharmacology studies and would also allow for them to discuss the linkage between toxicological effects and drug exposure in each animal whose blood was taken. Some analytical issues of Dried Blood Spot (e.g. homogeneity, stability, reproducibility, etc.) should also be addressed. When the microsampling is appropriately used in animal studies, the number of animals used in such studies can definitely be smaller and consequently the cost of these studies would significantly decline without compromising prediction of human toxicity.

2. Planning

The main deliverable is a harmonised Q&A document of the current S3A Guideline.

The IWG will be comprised of two members nominated by EU, EFPIA, FDA, PhRMA, MHLW, JPMA, Health Canada and Swissmedic. One member can also be nominated by WHO Observer, each Interested Party as well as RHIs, DRAs/DoH (if requested).

The *Step 2 a/b* document will be published for consultation in 1Q 2015.

The *Step 4* document will be finalised in 4Q 2015.

3. The impacts of the project

The facilitation of microsampling techniques by the Q&A document should achieve a beneficial result providing higher quality data combined with reduction and better use of animals. Regulatory authorities will need to agree a clear case not applicable for using microsampling method during the drug development of some particular classes. Otherwise, the topic can be helpful for more profound understanding of animal toxicology and human health.

4. Post-hoc evaluation

When certain amount of study data using microsampling are accumulated after this topic reaches *Step 5* in each region, the IWG may need to evaluate/update an issue(s), if any.