Dried blood spot (DBS) sampling and analysis guideline

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on behalf of the Alternative Sampling Strategies Committee

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Scope of the lecture:
In this interactive session, the final draft of a guideline for therapeutic drug monitoring via dried blood spot (DBS) sampling, developed within the Alternative Sampling Strategies Committee, will be presented. Rather than merely presenting what requirements are imposed or suggested, input from the audience will be asked, via a presentation that will be built up around critical questions.

Learning objectives:
1. Gaining insight into the analytical requirements that should be fulfilled in a DBS method for TDM;
2. Gain knowledge about the clinical criteria that should be fulfilled by DBS-based methods;
3. Gain knowledge to what extent a DBS guideline for TDM differs from conventional guidelines.

Extended abstract:
Sampling *via* dried blood spots (DBS) is increasingly recognized as a potential alternative for conventional venous blood sampling. Currently, major DBS applications include newborn screening for metabolic disorders, epidemiological surveys, toxicology, as well as therapeutic drug monitoring (TDM). Despite the fact that DBS sampling offers many advantages, it is associated with several issues, that need to be dealt with carefully when setting up a method for the quantitative determination of drugs or biomarkers.
When looking into the scientific literature for studies that have utilized DBS, it becomes clear that there is currently no standard on what experiments should be performed exactly in bioanalytical method validation of DBS. In addition, the conclusions on the (potential) clinical validity that are drawn from DBS-based studies diverge widely, with large variations -as well as dangerous misconceptions- in data interpretation. In this context, IATDMCT's alternative sampling strategies committee has decided to formulate a concrete guideline, from method set-up, over analytical validation, to clinical validation, to help researchers from all over the globe to successfully set up and implement DBS-based strategies. During this presentation, the final draft of this guideline will be presented.
Rather than using a '*this is how you should do it*' format, this presentation will be built up around questions, aiming for interaction with and (critical) input from the audience. This may potentially result in further *polishing* of the guideline. Overall, the aim is to offer researchers and clinicians a reference document that should not only maximize the chances of success while setting up a DBS-based strategy, but also maximizes data quality. Especially the latter is important, as the choice to use a DBS-based method should never be at the expense of quality: since data may and will impact patient treatment, the results that are obtained from

DBS should come with the same guarantees as those that would have been obtained with conventional sampling. To move the field forward, it is essential that more high-quality studies are published that demonstrate in a critical way the potential -as well as pitfalls- of DBS sampling for TDM. This is a crucial step for the more widespread acceptance and implementation of DBS-based TDM.