

Meeting Report – Empower IVD • Globe**Second meeting: Current status and future prospects**

(prepared by Kenneth Goossens on behalf of the Empower Team)

All presentations can be found at <http://www.stt-consulting.com/> (Empower tab).

VENUE

Holiday Inn, Akkerhage 2, 9000 Gent

ORGANISERS

-Dietmar Stöckl, PhD & Linda Thienpont, Prof. Em. (dietmar@stt-consulting.com;
linda.thienpont@ugent.be): Thienpont & Stöckl Wissenschaftliches Consulting GbR
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MODERATORS/SPEAKERS

- Linda Thienpont (LT) – Prof. Em. Ghent University, Thienpont & Stöckl Wissenschaftliches Consulting GbR
- Dietmar Stöckl (DS) – Thienpont & Stöckl Wissenschaftliches Consulting GbR
- Kenneth Goossens (KG) – Ghent University
- Linde De Grande (LDG) – Ghent University
- An-Sofie Decavele (AD) – AZ Sint-Andries Tielt

PARTICIPANTS

The meeting was attended by approximately 55 participants. Most of them were clinical chemists (and coworkers), but also delegates of the IVD industry and LIS providers were present. Most participants were from Belgium, but there were also some attendees from Ireland, Russia, Finland and The Netherlands.

OPENING OF THE MEETING

One of the moderators, i.e., LT, welcomed the meeting attendees and presented the agenda. The goal of the meeting was to provide a status update on the Empower project, present some of the major observations from the Percentiler and Flagger tools, and discuss the future prospects of the project.

1. Status update on the Empower project (KG)

The concept and theoretical background of the Empower project was rehearsed for attendees not yet familiar with the project. For an overall insight in the project, we refer to the previously published reports (available at www.stt-consulting.com) and peer-reviewed manuscripts (see also PowerPoint presentation).

In addition, a status update in terms of participation rate and received attention on both the Master Comparison studies and the Percentiler and Flagger applications was provided. The former study is currently set on hold because the costs are too high to remain descriptive.

2. Implementation of the Percentiler and Flagger in the IFCC C-STFT project (LDG)

The IFCC C-STFT project for standardization of FT4 assays and harmonization of TSH assays – chaired by LT – was introduced to the audience. It was explained that the Percentiler and Flagger tools will be used to monitor the pre- and post-standardization status of the assays and to monitor the impact of the analytical quality or instability of FT4/TSH assays on the daily surrogate medical decision making (or flagging rate). However, to successfully monitor the recalibration status for all manufacturers, more laboratories are needed that send FT4/TSH data to the Percentiler/Flagger.

3. Quality control in a small laboratory - Added value of the Percentiler (AD)

The AZ Sint-Andries hospital laboratory, located in Tielt, was shortly presented in terms of medical activity and quality control. After the introduction, some Percentiler observations were discussed and compared with the findings from IQC, showing how these two quality monitoring tools can jointly be used and complement each other. The examples showed that in small hospital laboratories the population variation can be relatively high; on the other hand, considering that they mostly work with one or few instruments (such as Tielt), small laboratories in the end can benefit from the Percentiler/Flagger tool similarly to bigger hospital laboratories that split up the measurements over several instruments. Data were presented that emphasized the control of the outpatient stratification when the LIS is restructured. In general, the Percentiler was considered to add value to the traditional quality management tools.

4. The Percentiler - the Flagger: mid- to long-term quality monitoring (KG)

Several Percentiler and Flagger observations/applications were discussed. It was explained that participants have password-protected access to their own data and can identify analytes that are problematic for their own laboratory. By comparing their data with the Percentiler limits, they can verify whether their mid- to long-term performance is in concordance with what is currently achievable by state-of-the-art. Peer group problems, however, can be

identified only by the “Empower team”; such problems were summarized in the PowerPoint presentation (manufacturer/peer groups were coded). However, participants were already informed in the past about problems in their own peer group. Interestingly, some laboratories manage to have stable performance also for analytes that are problematic in certain peer groups. The audience proposed to investigate which efforts are behind by, for example, sending out questionnaires about the IQC limits used in these laboratories. DS argued that the Empower team will not do so, because of the high work-load and the difficulty in interpreting the answers. An additional reason was that in his opinion all laboratories know the required tools and have the resources available to improve stability of their assays when deemed necessary.

In addition, the identification of a laboratory bias was addressed. DS explained that small to medium-sized laboratories or those with few outpatient results are limited to the identification of highly significant biases. Nevertheless, the Empower team encourages sample exchange experiments between laboratories when significant biases are suspected. The effect of population variation, and how to deal with it, was shown at the end of the presentation. A comment was made that high population variation possibly could be resolved by using 100 (or so) consecutive results instead of daily medians. DS considered this not advantageous because increasing the “n” in the moving median increases the “n” of the results anyway. DS also expressed the opinion that the basic “working-unit” for a laboratory is “one day”, therefore, the Percentiler and Flagger software are structured for data treatment on a daily basis.

Finally, the Flagger application was introduced to the attendees. The presentation addressed the use and concept of the Flagger limits, peer group comparison, and the Percentiler-Flagger link. Flagger participants will receive a report that addresses the different aspects from the Flagger.

5. Future prospects and conclusion (DS)

The audience expressed the wish to identify the manufacturer’s codes. Currently, DS mentioned that he understood this, but continued that he still hesitated to openly present manufacturer data. His rationale for this is that he still hopes that manufacturers “silently” work together with their customers to resolve problems observed in the Percentiler/the Flagger applications. He stressed that laboratories and manufacturers share responsibilities in problem-prevention and solving. An example for laboratory efforts required are pre-analytical problems for potassium (and LDH, less extent glucose) observed in the Percentiler for several private laboratories.

Finally, the future prospects of the project were discussed. The long-term continuation of the Empower project will depend on financial support, which is mainly sought at the manufacturer side. Last, but not least, it is the strong opinion of DS/LT that the project will

only have a future if it can contribute to an improvement in stability and comparability of IVD measurements.

Final note: if any participant still needs to register his/her RIZIV number, he/she should do so before the end of the year.