

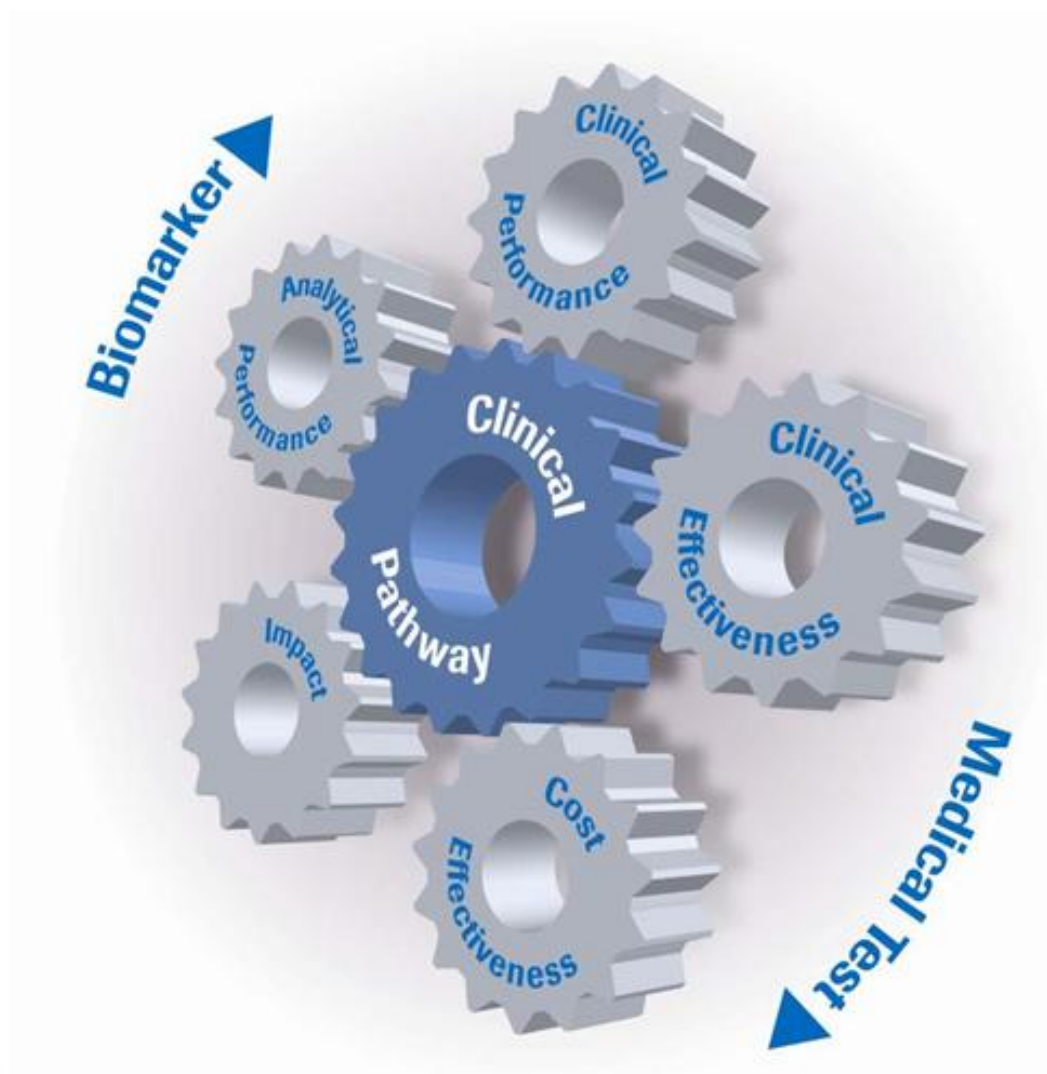


EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

Working Group on Test Evaluation (WG-TE)

Slide deck V 1.0 - November 2017

From biomarker to medical test



WG-TE - Mission

- Our goal: improving health outcomes and health care efficiency with better medical tests
- Our tools: test evaluation framework, unmet clinical needs checklist, adequate study designs ...



WG-TE - Terms of Reference

- Collaboration with epidemiologists, industry and regulatory authorities to set standards for clinical evaluation of new biomarkers and new technologies.
- Development of frameworks and practical tools to support the evaluation of the clinical effectiveness and impact of medical tests.
- Guidance on positioning of clinically relevant biomarkers in clinical pathways and/or clinical guidelines;
- Education and training of all those involved in biomarker development through international courses, webinars, and social media.

WG-TE - Papers published to date

- **Biomarker development targeting unmet clinical needs**
Monaghan P, Lord SJ, St John A, Sandberg S, Cobbaert CM, Lennartz L et al. for the EFLM Working Group on Test Evaluation. Clin Chim Acta 2016;460:211-9
- **Setting analytical performance specifications based on outcome studies – is it possible?**
Horvath AR, Bossuyt PMM, Sandberg S, St John A, Monaghan PJ, Verhagen-Kamerbeek WDJ, et al. on behalf of the joint EFLM Working Group on Test Evaluation (WG-TE) Clin Chem Lab Med 2015;53:841-8
- **From biomarkers to medical tests: The changing landscape of test evaluation**
Horvath AR, Lord SJ, St John A, Sandberg S, Cobbaert CM, Lorenz S, et al. for the Test Evaluation Working Group of the European Federation of Clinical Chemistry Laboratory Medicine. Clin Chim Acta 2014;427:49–57

WG-TE - Forthcoming activities

- Preparation of paper on setting clinical performance standards
- Test evaluation course in Sydney, Australia – March 2018
- Position statement regarding the impact of the IVDR
- Task group on performance specifications based on clinical outcome



WG-TE - Membership

Christa Cobbaert - Chair

Patrick Bossuyt

Cecilia Gelfi

Michael Hausmann

Rita Horvath

Anne Incamps

Lieselotte Lennartz

Sally Lord

Philip Monaghan

Maurice O'Kane

Ralf Roeddiger

Sverre Sandberg

Andrew St John

Wilma Verhagen-

Kamerbeek



Working Group on Test Evaluation (WG-TE)

<https://www.eflm.eu/site/page/a/1158>

