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Framework for the evaluation of the clinical effectiveness of tests

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The ability of novel medical tests to improve patient outcomes, i.e. a test's clinical effectiveness, is becoming more central in decisions about their regulatory approval for market entry, their clinical use and for policy decisions about reimbursement. Medical tests, however, rarely improve health outcomes directly. Medical tests, used for several different purposes (diagnosis, monitoring, prognosis, etc.), are often part of a more complex clinical pathway, and clinical outcomes follow from subsequent clinical management decisions and actions guided by the test results and patients' symptoms and compliance with and response to therapy.

Ideally, new biomarkers are developed in response to unmet clinical needs. After identifying the link between the new biomarker and the outcomes of a well-defined clinical pathway, the key steps of the test evaluation cycle relate to the assessment of the analytical performance, clinical performance, clinical effectiveness, cost-effectiveness and the broader impact of testing (Figure 1). The Test Evaluation Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine has defined and tightly integrated these components into a dynamic evidence-based framework which clarifies the link and sequence between the various stages of test evaluation and describes the journey of a new biomarker in becoming a medically useful test in the research translation continuum[1].

No new test should be subjected to tedious trials and released to the market if it is unlikely that the test will result in improved clinical actions and measurable outcomes. Therefore, in our framework the clinical purpose and role of testing and the intended application of the biomarker in a well-defined clinical pathway drive all stages of the test evaluation cycle and the most appropriate study designs that have the potential to provide the highest level of evidence as proofs. The framework is supplemented with a toolbox for the assessment of clinical needs[2], and offers methodology for setting analytical[3] and clinical performance criteria for tests. These tools aim to support the understanding of key stakeholders of the necessary steps to be taken when evaluating a test and to

promote that larger and more costly studies are only initiated if there is prior high-quality evidence of the test's value in terms of improving health outcomes at reasonable costs.

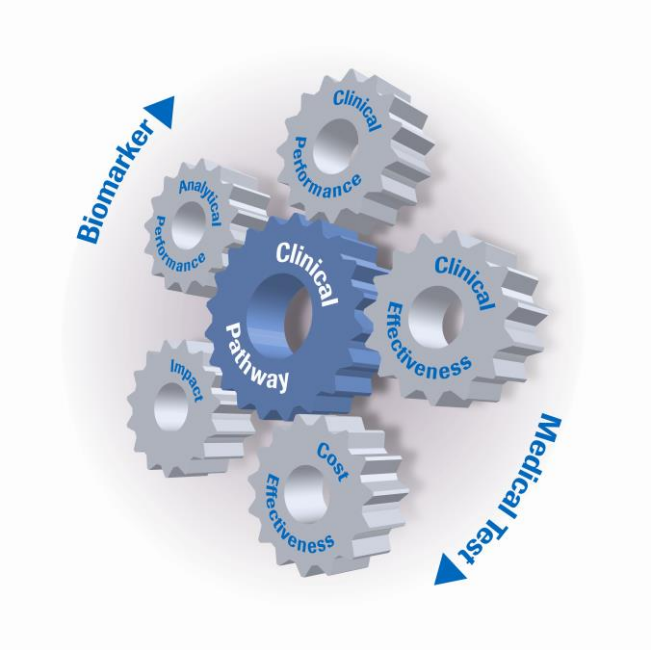

Figure 1: From biomarkers to medically useful tests – the dynamic cycle of test evaluation

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