



ILSI Europe marker initiative: What makes a marker a valid marker?

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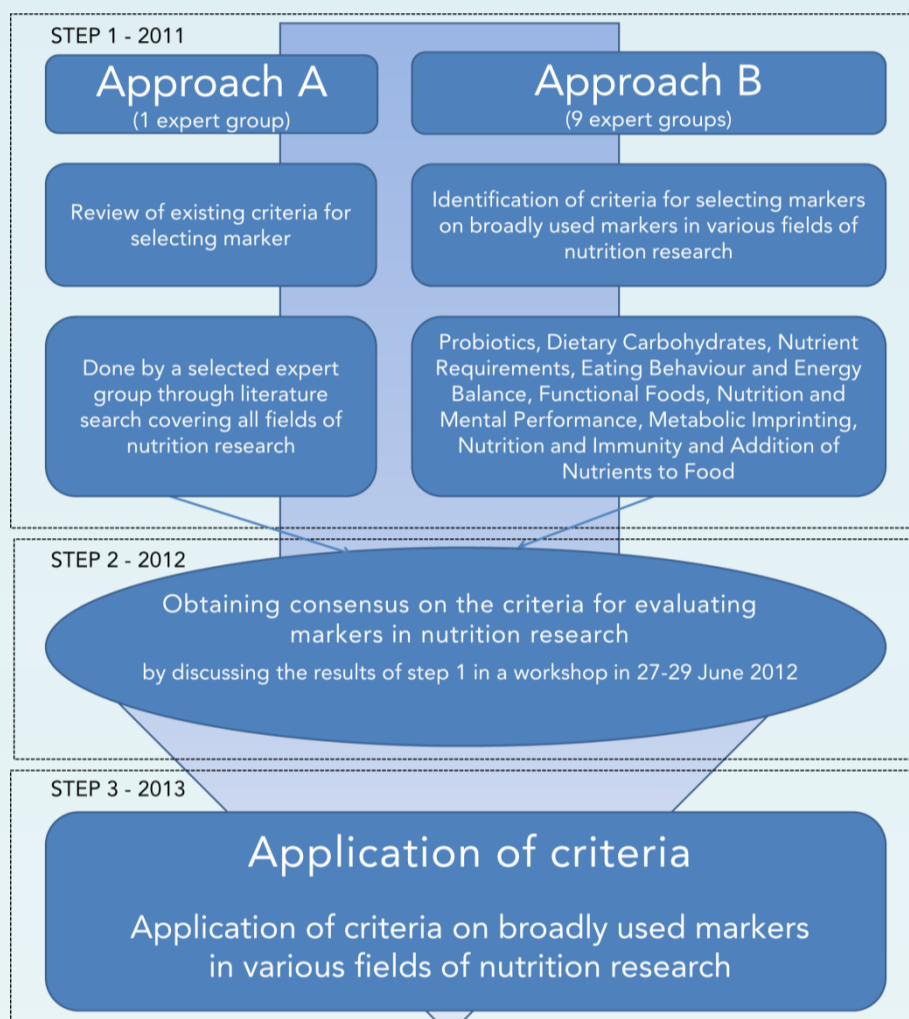
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Background and Objectives:

A research gap has been identified concerning the evaluation of markers used in the field of nutrition research in past and current European projects coordinated by ILSI Europe, like FUFOSE, PASSCLAIM and EURRECA as well as in other international initiatives. The lack of criteria to evaluate these markers makes the comparison of results from various studies difficult, and jeopardizes the future development of evidence-based nutrition. To fill this gap, ILSI Europe started in 2011 a 3-year initiative, called the Marker Initiative in Nutrition Research. The aim of the activity are:

- To obtain consensus on the criteria for evaluating markers in nutrition research
- To initiate the development of guidance on how to use the consensus criteria

Methods:



Results: Approach B

Summary Criteria for the studied marker

Sensitivity: significant changes of the marker during the intervention for the same person, enables detecting people with different level of insulin sensitivity

Gold standard

Existence of a solid body of literature on mechanism of action

Existence of a solid body of cohorts/ studies on which the marker has been tested

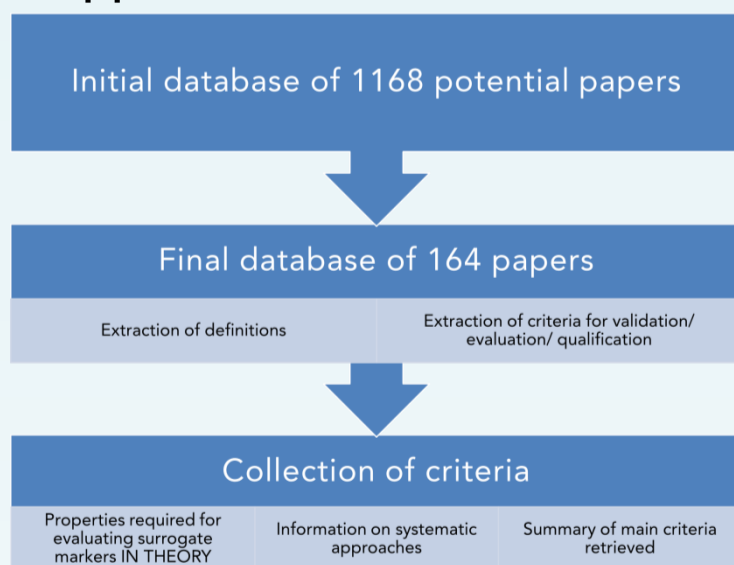
High correlation/association with the endpoint

Known physiological effects

Discussion/Findings:

- Clear lack of a systematic approach for the evaluation of marker;
- Most input from the drug development area;
- Currently, the evaluation is not based on uniform standards or processes but rather on the gradual development of consensus in the scientific community;
- Further develop and dimensionalise criteria identified in the workshop;
- Develop a grading system to assess the validity of a marker;
- Provide a few examples for practical translation.

Results: Approach A



Conclusions:

The identified criteria of the workshop were:

- 1) Analytical aspects
 - i) Method should be validated according to recognised guidelines.
 - ii) This should include for example: robustness, appropriate analytical sensitivity and specificity, reproducibility accuracy, quality assurance, standardization, traceability, stability (quality of the sample).
- 2) Reflect/mark an endpoint
 - i) Significant association between marker and endpoint in a target population
 - ii) Marker changes consistently with a change in the endpoint

Must respond to a dietary intervention

- Any dietary intervention should induce a meaningful change in the marker (meaningful refers to 2.ii)
- Lifestyle changes (which may include changes in the diet) may also include a meaningful (meaningful refers to 2.ii) change in the marker

