PIVOTAL ASSESSMENT OF THE EFFECTS OF BIOACTIVES ON HEALTH AND WELLBEING. FROM HUMAN GENOMA TO FOOD INDUSTRY

Introduction to the PATHWAY-27 integrated Guidelines for the scientific community

Health claims on food and drink products are evidence-based statements about these products' potential contribution to maintaining health. For a health claim to be authorised by the European Commission, the specific relationship between the food/food constituent and the claimed effect has to be established, based on all robust and scientifically valid data existing. If no or insufficient data are available, it is essential to run well-designed, high-quality human dietary interventions that can contribute to the evidence base. Even if data are available, it is important to be able to judge their validity, e.g. do they come from well-designed randomised controlled trials, and can they thus be used to substantiate a health claim dossier?

The Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority has published a number of documents in relation to health claims, including a scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim. However, low success rates of health claim applications indicate the need for further guidance on the process of scientific substantiation – a need also expressed by industry stakeholders.

Guidelines for the European scientific community were developed within the framework of the EU-funded project PATHWAY-27 and are addressed to scientists from both academia and the food industry. The guidance helps to understand and apply the relevant steps of the health claim substantiation process. These steps include:

1. Thoroughly reviewing the published evidence concerning any putative beneficial physiological effect(s) of the food or food constituent of interest (e.g. a bioactive compound); and
2. Correctly designing, conducting, interpreting, and reporting any necessary human dietary interventions.

The guidance focuses on randomised controlled trials as they are the most rigorous type of interventions to investigate the claimed health effect of a specific food. In this regard, the critical aspects of randomisation, blinding and control are discussed, with hands-on examples from the PATHWAY-27 project of issues that can be encountered when dealing with bioactive compounds and how to solve them. Furthermore, it addresses sample size and data analysis, emphasising the need to involve an experienced (bio)statistician from the outset. Study duration and (non-)compliance are also discussed. As recruitment of study participants can often be a major bottleneck, various recruitment strategies are described. This guidance document also refers to successfully submitted dossiers as well as failed applications and other publically available relevant resources which will help with the appropriate scientific substantiation of health claims.

PATHWAY (FP7-KBBE-2012-6-singlestage) is a collaborative project targeted to SMEs and financed by the EC under the FP7, contract number 311876.

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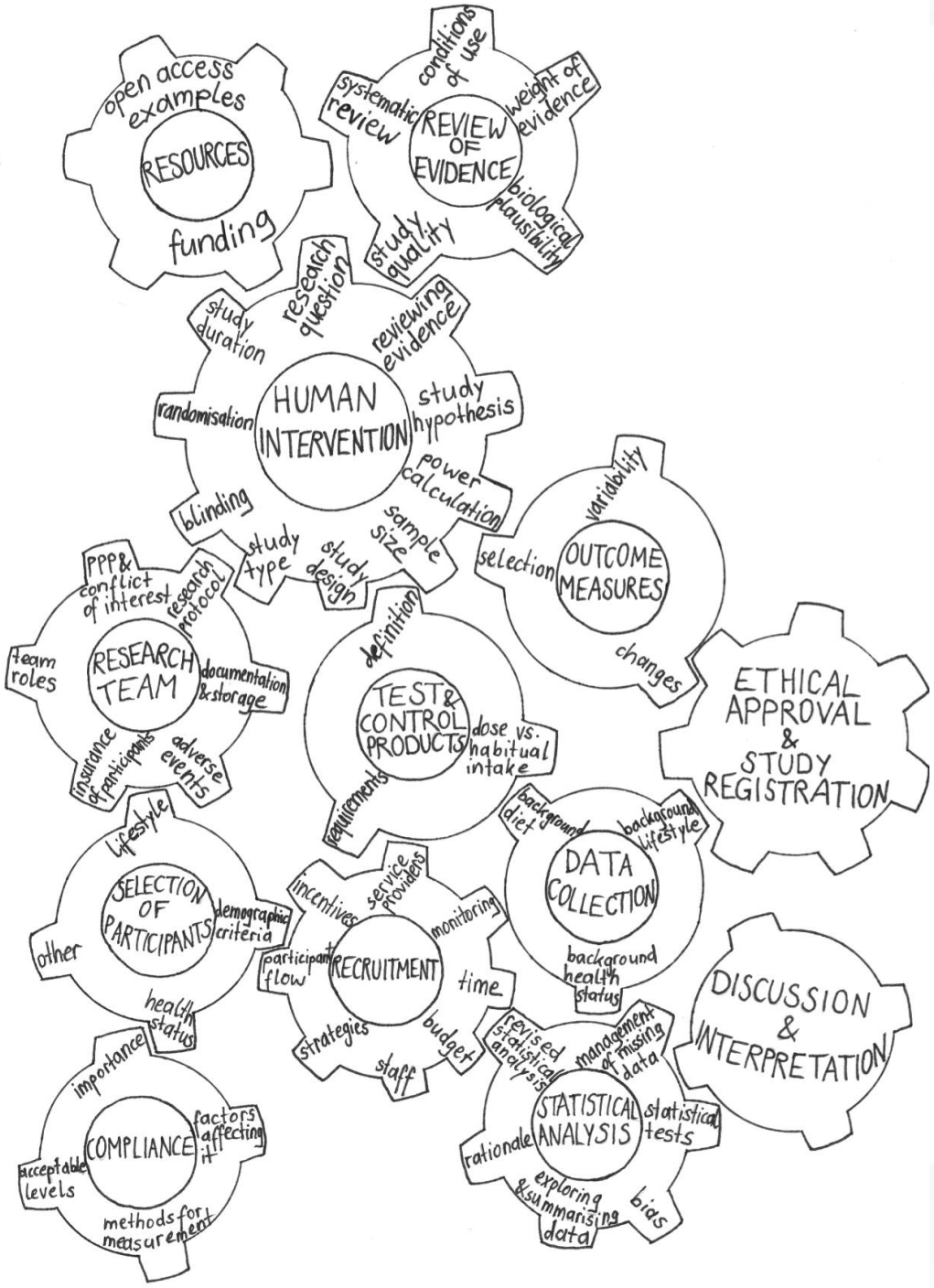
Any applicant of a health claim dossier should bear in mind that each claim is unique and that the scientific evidence required for the substantiation of a health claim will be considered in the context of that specific claim (i.e. the food, the target population, the proposed conditions of use).

This scientific guidance complements separately published guidance for industry with an emphasis on product development.



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The PATHWAY-27 Guidelines are available on the website of PATHWAY-27 (http://pathway27.eu/).

Further information: http://www.pathway27.eu/

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