

# Entry into force of the EU Clinical Trials Information System: a missed opportunity

**7 February 2023, Brussels** – The Medical Nutrition International Industry (MNI) regrets that the EU Clinical Trials Information System (CTIS) does not include a mandatory assessment of the nutritional status of the patient during and after the trials.

**As this piece of legislation comes into force, MNI would like to highlight the importance of aiming at an optimal nutritional status of the patient as part of patient’s protection and care during the trial and to allow for the best health outcome at every stage of research.**

Disease-related malnutrition – a condition characterised by inadequate intake of energy, protein, and/or micronutrients as a result of a diverse number of diseases or their treatment – may impact individuals at all stages of life, from infancy to old age. Disease-related malnutrition is linked to:

- Higher complication rate and risk of infections<sup>1,2</sup>
- Prolonged hospital stay and hospital (re)admissions<sup>3,4</sup>
- Reduced independence, poor quality of life<sup>5</sup>
- Increased mortality<sup>5,6,7</sup>

The patient needs to be fed and to be given optimal nutritional care. The European Parliament Report<sup>8</sup> on strengthening Europe in the fight against cancer, published in 2022, pointed out the importance of incorporating clinical nutrition in treatment and research and the ethical implications of that:

*“(…) the results of cancer treatment can be hampered by malnutrition, therefore optimal nutritional care is an essential part of cancer care; calls on the Member States to develop recommendations for **incorporating clinical nutrition into all aspects of cancer care, including treatment, support and research**; considers that, wherever indicated, cancer patients must be provided with clinical nutritional support by a dietitian specialist to be included in the multidisciplinary team; welcomes, therefore, the planned inter-speciality training on nutrition support and calls on the Commission and the Member States to develop minimum standards for continuous training on nutritional care for the multidisciplinary workforce; **recommends that nutrition management be an integral and ethical part***

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<sup>1</sup> Sorensen J, Kondrup J, Prokopowicz J, et al. EuroOOPS: an international, multicentre study to implement nutritional risk screening and evaluate clinical outcome. Clin Nutr 2008; 27(3): 340- 9.

<sup>2</sup> Schneider SM, Veyres P, Pivot X, et al. Malnutrition is an independent factor associated with nosocomial infections. BrJNutr 2004; 92(1): 105-11

<sup>3</sup> The economic cost of hospital malnutrition in Europe; a narrative review - Khalatbari-Soltani, Saman et al. (Clinical Nutrition ESPEN, June 2015, Volume 10, Issue 3, e89 - e94)

<sup>4</sup> Elia M. The cost of malnutrition in England and potential cost savings from nutritional interventions (full report): A report on the cost of disease-related malnutrition in England and a budget impact analysis of implementing the NICE clinical guidelines/quality standard on nutritional support in adults: Malnutrition Action Group of BAPEN and the National Institute for Research Southampton Biomedical Research Centre, 2015.

<sup>5</sup> Elia M, Russell C. Combating Malnutrition: Recommendations for action. Report from the Advisory Group on Malnutrition, Led by BAPEN. Redditch, 2009.

<sup>6</sup> Stratton RJ, Green CJ, Elia M. Disease-related malnutrition: an evidence-based approach to treatment. Wallingford: CABI Publishing; 2003.

<sup>7</sup> Lim SL, Ong KC, Chan YH, et al. Malnutrition and its impact on cost of hospitalization, length of stay, readmission and 3-year mortality. Clin Nutr 2012; 31(3): 345-50.

<sup>8</sup> Report on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy - [link](#)

*of all clinical research involving cancer patients; recommends, furthermore, that proper nutritional support be included in the cancer patients' Charter of Rights".*

Where patients are unable to sufficiently feed themselves, medical nutrition allows them to sustain themselves during treatment, leading to better outcomes<sup>9</sup>. Medical nutrition - to be used under medical supervision - encompasses specialised products for nutritional therapy: oral nutritional supplements and enteral tube feeding (via the gastrointestinal tract) – falling under the EU Food for Special Medical Purposes (FSMPs) Regulation – and parenteral nutrition (intravenous feeding), governed by the pharmaceutical law.

**MNI invites the European Commission, the European Medicines Agency, and the EU Member States to ensure that clinical trials include the assessment of the nutritional status of the participants, which shall be checked prior, during and after the trials. Optimal nutritional care will sustain patients' health and may improve health outcomes.**

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<sup>9</sup> MNI Medical Nutrition in Oncology Value Dossier, Section 4.1.1 - [link](#)