Multimodal management as requirement for the clinical use of anticachexia drugs - a regulatory and a clinical perspective

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PURPOSE OF REVIEW
Multimodal management has been proposed as key to any effective drug intervention in cachexia. This article attempts to reflect on clinical and regulatory considerations of multimodal management treatment as a regulatory requirement in anticachexia drug therapy. To date, no European Union (EU) regulatory guidelines have been published and therefore this review could attempt to present and discuss some central issues to consider when developing an anticachexia drug.

RECENT FINDINGS
The following themes are considered: EU regulatory pathways for drug approval (conditional and exceptional circumstances as well as adaptive licensing); selection criteria for randomized clinical trials allowing the identification and characterization of the population of interest that is an at-risk population with undisputable clinical need; issues related to primary and secondary outcome measures that are adequate to determine the efficacy of the intervention and the approach for the development of clinical biomarkers for cachexia.

SUMMARY
Conversely, the incorporation of multimodal treatment in anticachexia drug therapy is expected to increase the effectiveness of intervention. This aspect is the aspect that appeals to pharmaceutical companies; however, at the same time, this raises regulatory and clinical issues that need to be kept in mind when designing randomised clinical trials.