

Nutrition/Interventional - MACEDONIA

Competent authority

Contact Details

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Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Competent Authority
National Ethics Committee
Agency for data protection

Regulatory and ethics bodies involved in approval process for trials including patients

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Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

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CA - Registration requirements for clinical trials

Registration mandatory

Registration requirements for clinical trials including patients

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	<p>Registration requirements for clinical trials including healthy participants</p> <p>—</p> <p>Registration requirements for clinical trials including vulnerable population</p> <p>—</p> <p>CA - Submission required to</p> <p>National CA</p> <p>Studies including patients - submission required to</p> <p>—</p> <p>Studies including healthy participants - submission required to</p> <p>—</p> <p>Studies including vulnerable population - submission required to</p> <p>—</p>
Submission Format	<p>Standard application form available</p> <p>Yes</p> <p>Standard application form</p> <p>www.moh.gov.mk</p>
Language of Submission	<p>Language(s) of application</p> <p>Official national language</p> <p>Language(s) of application for trials including patients</p> <p>—</p> <p>Language(s) of application for trials including healthy participants</p> <p>—</p> <p>Language(s) of application for trials including vulnerable population</p> <p>—</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Yes</p> <p>Documents mandatory to be in official national language</p> <p>—</p> <p>Documents mandatory to be in local language of study site</p> <p>—</p> <p>Documents mandatory to be in language of the study participant</p> <p>—</p>
Ethics committee	
Ethical Review – General	<p>Submission for Ethical review mandatory for</p> <p>—</p>

	Submission to CA and EC to be performed in the following order –
Submission Format	Standard application form available Yes Standard application form Standard Application form
Definition	
Nutrition Study	Definition available in national law Yes