Evidence

When offering a healthcare application to the market, the availability of sufficient clinical evidence is paramount. This requirement is regulated by the ISO 14155 Regulation on Clinical investigation of medical devices for human subjects. The matter of evidence base necessary for applications in the Flemish health and care sector is determined by the relevant regulators in this field. For healthcare applications, this is the Federal ministry for Healthcare to contact, for preventive applications this is the Agency for Health and Care (preventievegezondheidszorg@zorg-en-gezondheid.be).

Below you can find some general rules regarding evidence based:

- The design of your application should be underpinned by an evidence base. This evidence base should include as wide a range of published studies and guidelines as possible (published systematic review or published peer-reviewed primary research study, other). If there is more than one type of evidence please choose the highest category.
- The health app offers concise information about the procedure used to select its content.
- The health app is based on ethical principles and values.