**The cover letter shall contain the following information:**

1. Identification of the clinical investigation:
   1. Name of the sponsor.
   2. Identification of the investigational site(s) in Norway.
   3. Name and title of the principal investigator at each site.
   4. A list of all the countries where this clinical investigation has been submitted or is planned to be submitted.
   5. CIV-ID number if this has already been generated by a competent authority in another EU/EEA country.
2. Information about any special characteristics of the study population.
3. Information about whether the clinical investigation is a first-in-man study or not.
4. An application to the Regional Committees of Health and Research Ethics (REC) must be submitted at the same time as the application to NOMA. Please provide the REC reference number, or if not available yet, indicate that it will be submitted as soon as it is available.
5. Information about whether the device under investigation is CE-marked or not. If the device is CE-marked, please indicate whether it will be used/investigated within its intended purpose or not.
6. Information on the risk classification of the investigational device and whether it is an invasive device or not. This will determine the route of assessment by NOMA (cf. MDR Article 70.7a and 70.7b).
   1. Explain/justify that the device falls within the definition of a medical device.
   2. Indicate which risk class it belongs to.
   3. Provide the rule(s) that was used to derive the classification and justify why this rule applies to the medical device.
   4. Explain/justify whether the device is invasive or not.

Definitions and classification rules are found in Annex VIII of MDR. Please also take into account any relevant EU-guidance.

1. Indicate whether the device under investigation:
2. is an active or non-active medical device
3. is a stand-alone software
4. has software incorporated
5. uses/involves artifical intelligence
6. comes in direct contact with the human body
7. contains nanomaterials
8. is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives
9. incorporates a substance that can be considered a medicinal substance, including a human blood or plasma derivative