Assessment report Part II – DENMARK

1) ADMINISTRATIVE INFORMATION

EudraCT number	
Member State Concerned	
Title of the study	
Name of sponsors	
IMPs (repeat for PR1, PR2…..)	

Has Part I been submitted prior to the submission of Part II?	Yes ☐ No ☐
If Yes	
Is there already a conclusion on part I?	Yes ☐ No ☐
Is the CT already approved in any member state ?	Yes ☐ No ☐

2) GENERAL INFORMATION

Is the CT a low-interventional trial?[1]	Yes ☐ No ☐
First in man ☐, Phase I ☐, II ☐, III ☐, IV☐ NA☐	
Is the CT a cluster trial[2]	Yes ☐ No ☐
Is the CT intended to be performed in more than one member states?	Yes ☐ No ☐
Does the CT involve more than one site in the concerned member states?	Yes ☐ No ☐
Does the CT include healthy volunteers?	Yes ☐ No ☐
Does the CT include female?	Yes ☐ No ☐
Male?	Yes ☐ No ☐
Age group	
Adults (18-64 years)	Yes ☐ No ☐
Elderly (>= 65 years)	Yes ☐ No ☐
< 18 years	
In Utero	Yes ☐ No ☐
Preterm Newborn Infants (up to gestational age < 37 weeks)	Yes ☐ No ☐

[1] If yes – other demands for damage compensation, cfr. Art. 76
[2] If yes – other demands for informed consent, cfr. Art. 30

Newborns (0-27 days)	Yes ☐ No ☐
Infants and toddlers (28 days - 23 months)	Yes ☐ No ☐
Children (2-11 years)	Yes ☐ No ☐
Adolescents (12-17 years)	Yes ☐ No ☐
Does the CT include vulnerable persons?	
If yes	Yes ☐ No ☐
Minors	
Incapacitated subjects	Yes ☐ No ☐
Pregnant women	Yes ☐ No ☐
Breastfeeding women	Yes ☐ No ☐
Subjects in emergency situations	Yes ☐ No ☐
Other groups If yes specify:	Yes ☐ No ☐ Yes ☐ No ☐
Are there study-specific procedures and/or interventions beyond the drug application?	Yes ☐ No ☐
If yes	
Specify:	

3) INFORMED CONSENT FORM
(Repeat for ICF1, ICR2 ….)

Date/version of Informed Consent Form	
Does the Informed Consent Form contain the correct title of the CT?	Yes ☐ No ☐
Does the Informed Consent Form contain placeholder for the dated signature of the person performing the interview?	Yes ☐ No ☐
Does this placeholder indicate the qualification of the person performing the interview	Yes ☐ No ☐
Does the Informed Consent Form contain a placeholder for	
for the dated signature of the subject	Yes ☐ No ☐ NA ☐
for the dated signature of legally designated representative?	Yes ☐ No ☐ NA ☐
Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained?	Yes ☐ No ☐ NA ☐

Does the subject or the legally designated representative declare that the information is understood?	Yes ☐ No ☐
Additional items may be added according to national requirements	

Conclusion

If all points are addressed Yes): The Inform Consent Form fulfils the conditions in art. 29, 1.

If not

Questions/queries:

4) WRITTEN INFORMATION

Is the Information sheet sufficiently comprehensive, concise, clear, relevant, and understandable to a layperson?	Yes ☐ No ☐
Does the information sheet describe adequately nature, objectives, benefits, implications, risks, and inconveniences, of the clinical trial?	Yes ☐ No ☐
Does the information sheet adequately describe the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification ?	Yes ☐ No ☐
Does the information sheet adequately explain that withdrawal of the informed consent will not affect the results of activities already carried out and the use of data obtained, based on informed consent, before its withdrawal?	Yes ☐ No ☐
Does the information sheet adequately describe the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial?	Yes ☐ No ☐
Does the information sheet adequately describe	
the possible treatment alternatives,	Yes ☐ No ☐
the follow-up measures if the participation of the subject in the clinical trial is discontinued	Yes ☐ No ☐
Post trial treatment options	Yes ☐ No ☐ NA ☐
Does the information sheet provide information about the damage compensation according to national law of concerned member state	
Further detailed points to be filled in at a national level	Yes ☐ No ☐ NA ☐
If NA	
Does the information sheet adequately inform that no particular arrangements for damage compensation are in place	Yes ☐ No ☐
Does the information sheet provide	
the EU trial number	Yes ☐ No ☐
information about the availability of the clinical trial results (that the summary of the results of the clinical trial and a summary presented in terms understandable to a layperson will be made available in the	

EU database)	Yes ☐ No ☐
Does the information sheet provide adequate information about planned personal data collection and processing Does the information sheet provide adequate information about planned collection, storage and future use of biological samples? *Further detailed points must filled in by member states at national level* (in accordance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively)	Yes ☐ No ☐ Yes ☐ No ☐

In the case of a trial with minors. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☐ No ☐
In the case of a trial with incapacitated subjects. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☐ No ☐
In the case of a trial in an emergency situation Are there Informed Consent documents to obtain consent from the subject and/or legally designated representative to continue the participation of the subject in the CT after the intervention?	Yes ☐ No ☐

Conclusion

If all points are addressed Yes: The written information fulfils the conditions in art. 28 and 29

If not

Questions/queries:

5) PROTECTION OF PERSONAL DATA

Has a statement been submitted by the sponsor or his or her representative that data will be collected and processed in compliance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively	Yes ☐ No ☐
Further detailed points must filled in by member states at national level For example	Yes ☐ No ☐
Are the rules for the collection, storage and future use of biological samples of the subject fulfilled?	Yes ☐ No ☐
Is the procedure to pseudonymise the data correct?	Yes ☐ No ☐
Is it described how long the data will be stored?	Yes ☐ No ☐
Is there a comprehensive description of the aims and scope of data collection?	Yes ☐ No ☐
Is there an indication, whether the data will be transferred to a so called "third party country" with a reduced level of data protection?	Yes ☐ No ☐

Will the subject (or his or her legally designated representative) be asked to consent to the use of his or her data and/or biological samples outside the protocol of the clinical trial for other scientific purposes?	Yes ☐ No ☐
If Yes Will the subject be informed that this consent may be withdrawn at any time by the subject or his or her legally designated representative?	Yes ☐ No ☐

Questions/queries:

6) COMPENSATION

Is there no undue influence, including that of a financial nature, exerted on subjects to participate in the clinical trial	Yes ☐ No ☐
In trials with incapacitated subjects, minors, pregnant or breastfeeding subjects: Are no incentives or financial inducements given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;	Yes ☐ No ☐

Questions/queries:

7) RECRUITMENT

Is the procedure for inclusion of subjects described in detail in the protocol or a separate document	Yes ☐ No ☐
Is clearly described of what the first act of recruitment is?	Yes ☐ No ☐
Is the recruitment of subjects planned to be done through advertisement	Yes ☐ No ☐
	Yes ☐ No ☐
If yes: Have copies of the advertising material been submitted, including any printed materials, and audio or visual recordings.	Yes ☐ No ☐
Has an outline of the procedures proposed for handling responses to the advertisement been submitted?	Yes ☐ No ☐
Have copies of communications used to invite subjects to participate in the clinical trial been submitted?	Yes ☐ No ☐
Have arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial been described?	Yes ☐ No ☐
Does the person performing the interview has the required qualification according to the law of concerned member states	Yes ☐ No ☐
Are the arrangements for recruitment of subjects adequate?	Yes ☐ No ☐

Questions/queries:

8) SUITABILITY OF THE INVESTIGATOR

Is there an informative CV?	Yes ☐ No ☐
Is previous experience obtained from work with clinical trials described?	Yes ☐ No ☐
Is previous experience obtained from work with patient care described?	Yes ☐ No ☐
Have certificates describing adequate ICH/GPV training been submitted?	Yes ☐ No ☐
Has a financial disclosure been submitted?	Yes ☐ No ☐
Have institutional affiliations, that might influence the impartiality of the investigators been presented?	Yes ☐ No ☐
Further detailed points may be filled in by member states at national level	

Conclusion

Reason:

9) SUITABILITY OF THE FACILITIES

Has a list of the planned clinical trial sites with name and position of the principal investigators	Yes ☐ No ☐
and the planned number of subjects at the sites been submitted?	Yes ☐ No ☐
Has a written statement been submitted describing the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product? (issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned)	Yes ☐ No ☐
Does this statement adequately describe	
the suitability of facilities,	Yes ☐ No ☐
the equipment,	Yes ☐ No ☐
the human resources	Yes ☐ No ☐
the expertise of the site,	Yes ☐ No ☐

Conclusion

Reason:

10) PROOF OF INSURANCE COVER OR INDEMNIFICATION

Is the arrangement for damage compensation in accordance to **national law**?	Yes ☐ No ☐
Further detailed points must be filled in at the national level	

Questions/queries:

11) FINANCIAL AND OTHER ARRANGEMENTS

Is there a description confirming adequate financing of the clinical trial is ensured?	Yes ☐ No ☐
Are financial transactions and compensation paid to subjects adequate?	Yes ☐ No ☐
Are financial transactions and compensation paid to the investigator/site for participating in the clinical trial adequate?	Yes ☐ No ☐
Are any other agreement between the sponsor and the site adequate?	Yes ☐ No ☐

Questions/queries:

12) LIST OF QUESTIONS TO THE SPONSOR

13) ASSESMENT OF THE SPONSOR´S RESPONSE

Are all queries resolved?	Yes ☐ No ☐
If not specify:	
.....	

14) FINAL DECISION

The Clinical trial is approvable	☐
The Clinical trial is not approvable	☐
The Clinical trial is approvable subjects to conditions	☐

In case of approval

The approval is valid for the following trial sites and investigators

List of trial sites and investigators

The approval is <u>not</u> valid for the following trial sites and investigators

List of trial sites and investigators

In case of approval subjects to conditions

Conditions:

List of members of the ethic committee participating in the decision