

Request for Early Feedback

As a medical expert you have been asked to review the **study summary/synopsis** attached to provide a rapid opinion about the suitability of the study to be conducted in Sweden and feedback on study design.

<i>Study Title</i>	
<i>Study-ID</i>	
<i>Estimated Study Start</i>	
<i>Sponsor</i>	

Please could you review the protocol and answer the questions listed below?

1. Are the requested type(s) of patient populations(s) to be found in Sweden?	
2. a. Please provide an assessment of whether the study is compatible with current Swedish clinical practice/local prescribing practices and expected standards of care. b. Is there a risk that clinical practice/standard of care vary/varies across clinics/regions? c. If yes, please describe.	
3. What is the normal care setting for patients who may be recruited for this study?	
4. a. What do you expect the potential of recruiting patients to be (high, medium, low)? b. If low, why (known competing studies, inclusion/exclusion criteria, and/or other aspects)? c. Are there any issues which may put patients off participating?	

<p>5. What type of sites would be able to participate in the study (e.g. sites relatively new to commercial research, well established research centres, those with a specific patient population or pathway, those with specific expertise, specialist early phase centres, primary care)?</p>	
<p>6. a. Would you anticipate a high level of interest by investigators for this study?</p> <p>b. Are there any sites, to your knowledge, of relevance to contact?</p>	
<p>7. a. Do you have any other recommendations, or comments for consideration by the sponsor at this stage (e.g. key challenges including, clarifications, design, ethical concerns or feasibility issues)?</p> <p>b. If yes, please describe.</p>	
<p>8. <i>(Other critical question)</i></p> <p>.....</p>	
<p>9. If the study is allocated to Sweden, are you interested in participating?</p>	

<p><i>Medical expert/s</i></p>	
<p><i>Place and date</i></p>	