

STATEMENT OF INVESTIGATOR (Non-US sites only) (See instructions on reverse side)				NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator.
1. NAME AND ADDRESS OF INVESTIGATOR				
Name of Clinical Investigator				
(b) (4), (b) (6)				
Address 1		Address 2		
CTC Clinical Trial Consultants AB, Dag Hammarskjölds väg 10B				
City	State/Province/Region (if applicable)	Country	ZIP or Postal Code	
Uppsala		Sweden	SE - 752 37	
2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select <u>one</u> of the following.) <input checked="" type="checkbox"/> Curriculum Vitae <input type="checkbox"/> Other Statement of Qualifications				
3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED CONTINUATION PAGE FOR ITEM 3				
Name of Medical School, Hospital, or Other Research Facility				
CTC Clinical Trial Consultants AB				
Address 1		Address 2		
Dag Hammarskjölds väg 10B				
City	State/Province/Region (if applicable)	Country	ZIP or Postal Code	
Uppsala		Sweden	SE - 752 37	
4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY CONTINUATION PAGE FOR ITEM 4				
Name of Clinical Laboratory Facility				
ABS Laboratories Limited				
Address 1		Address 2		
BioPark, Broadwater Road				
City	State/Province/Region (if applicable)	Country	ZIP or Postal Code	
Welwyn Garden City		UK	AL7 3AX	
5. NAME AND ADDRESS OF THE ETHICAL COMMITTEE (EC) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) CONTINUATION PAGE FOR ITEM 5				
Name of EC				
Regionala Etikprövningsnämnden i Uppsala				
Address 1		Address 2		
Box 1964				
City	State/Province/Region (if applicable)	Country	ZIP or Postal Code	
Uppsala		Sweden	SE-751 49	
6. NAMES OF SUBINVESTIGATORS (if not applicable, enter "None") CONTINUATION PAGE FOR ITEM 6				
Principal investigator: Erik Rein-Hedin, MD				
Subinvestigator: Fredrik Huss, MD, PhD				
7. NAME AND CODE NUMBER OF THE STUDY PROTOCOL FOR THE STUDY TO BE CONDUCTED BY THE INVESTIGATOR Study Code: SM 18-01. Nicotine plasma concentrations and pharmacokinetics of single doses of non-tobacco-based nicotine pouches (ZYN®) compared with conventional, tobacco-based Swedish snus and American moist snuff among current, daily snus users.				

8. THE FOLLOWING CLINICAL PROTOCOL INFORMATION IS PROVIDED

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the ICH Topic E6 [R2] Guideline for GCP and with the principles that have their origin in the Declaration of Helsinki, national legislation that is set forth in the Directive 2001/20/EC, Directive 2005/28/EC and Directive 2001/83/EC [and the Regulation [EU] No 536/2014 when in force] and the General Data Protection Regulation [EU] 2016/679 or equivalent national and/or local law[s].

I agree to conduct the study(ies) with the relevant, current protocol(s) and will only deviate from the protocol when necessary to necessary to protect the safety, rights or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethical committee (EC) review and approval are met according to local regulations and requirements and as required in the clinical study protocol.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with applicable law and the clinical study protocol. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with the clinical study protocol.

I will ensure that an EC that complies with national and local regulations will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the EC all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without EC approval, except where necessary to eliminate apparent immediate hazards to human subjects.

INSTRUCTIONS FOR COMPLETING STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2 if not already provided.
3. Sign and date below.
4. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR or their designee.
The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

Total amount of pages:

10. DATE (dd/mm/yyyy)

10/12/2019

11. SIGNATURE OF INVESTIGATOR

(b) (6)