Institut national d'excellence en santé et en services sociaux
Québec

PRODUCT NAME:

Pre-submission Meeting Request — Non-Pharmaceutical Innovation

Only one pre-submission meeting per product and per indication is permitted.

This form must be completed **for each pre-submission meeting request.**

The innovator is responsible for providing the requested information relevant to their request. This information will be used by INESSS to assess whether a pre-submission meeting should be held.

If the pre-submission meeting request is accepted, a proposed agenda, the list of participants (maximum of four), any documents identified in the form that have not yet been submitted, and any additional documents required for the meeting must be sent to INESSS 10 working days before the agreed-upon date.

ADMINISTRATIVE COMPONENT	**COMPLETE**	**N/A**
1. ***Pre-submission Meeting Request*** **letter**	☐	
2. ***Pre-submission Meeting Request*** **form**	☐	
3. **Contact person information**	☐	
4. **Health Canada licence, if available** (or expected date)	☐	
5. **Indication requested from Health Canada** (if applicable)	☐	☐
CLINICAL COMPONENT		
1. **Clinical studies and clinical executive summary** (based on available data)	☐	☐
2. **User guide** (or draft guide)	☐	☐
ECONOMIC COMPONENT		
1. **Data and values for the efficiency calculation** (with identification of comparators)	☐	☐
2. **Budget impact** (or, if under development: relevant information on the methodology, data, and assumptions used)	☐	☐
NUMBER AND TYPE OF COPIES		
1 electronic copy	☐	