Document ID and Title	**FRM-MA-009a** **Expanded Access Request Form**
Revision	**01**

Investigational drug expanded access / special access — U.S. FDA (21 CFR Part 312, Subpart I) and Health Canada Special Access Program (Food and Drug Regulations C.08.010–C.08.011)

REGULATORY PATHWAY — select one (determines which Part B to complete)

☐ United States — FDA expanded access (21 CFR Part 312, Subpart I) → complete Part A and Part B-US

☐ Canada — Health Canada Special Access Program (FDR C.08.010–C.08.011) → complete Part A and Part B-CA

INSTRUCTIONS: This form must be completed in full by the requesting physician/practitioner and submitted to Summit at EAP@smmttx.com to initiate the expanded access request process. Incomplete submissions will not be processed. All fields are required unless otherwise indicated. Please type or print legibly. Supporting documentation must accompany this form at the time of submission.

IMPORTANT NOTICE: Submission of this form does not constitute approval of expanded access. All requests are subject to review and approval by Summit's Expanded Access Review Board (EARB) in accordance with [SOP-MA-009]. Summit retains sole and absolute discretion to approve or deny any request. No Investigational Drug will be shipped until all eligibility criteria are confirmed, all required agreements are fully executed, and all regulatory prerequisites are satisfied (including, for Canadian requests, Health Canada's authorization).

FOR INTERNAL USE ONLY

Request Tracking No.:	
Regulatory pathway:	☐ FDA (US) ☐ Health Canada SAP (CA)
Date Received:	
Received By:	
Completeness Med Affairs Review Date:	
Completeness Confirmed (Y/N):	☐ Yes ☐ No
Date Forwarded to EARB Committee:	
EARB Committee Decision:	☐ Approved ☐ Denied ☐ More info requested
Decision Date:	

PART A — Expanded Access Request Details

Complete for ALL requests, regardless of pathway.

Contact and Physician / Practitioner Information

1. Name of requesting physician / practitioner:

2. Degree(s) and medical specialty / board certification(s):

3. Licensure information:

Jurisdiction of licensure (state / province / country):

License number(s):

License expiration date(s):

License status:

☐ Active ☐ Inactive ☐ Suspended ☐ Other (explain):

DEA registration number *(U.S. requests only; not applicable to Health Canada SAP)*:

DEA registration expiration date *(U.S. requests only)*:

4. Clinical expertise and experience relevant to the requested disease or condition:

Include approximate number of patients treated, years of experience, and any relevant subspecialty training or certifications.

5. Name of institution:

6. Physician / institution address *(where drug supply will be delivered, if approved by Summit):*

7. Physician / practitioner phone number:

8. Physician / practitioner email address:

Proposal Information (Please do not include any identifiable patient information.)

9. Name of investigational drug being requested *(the "Investigational Drug")*: *Ivonescimab*

10. Description of patient disease or condition, timeline of prior systemic therapies, and response to prior therapies:

Include relevant clinical history, but do not include patient-identifying information such as name or full date of birth.

11. Rationale for requesting the proposed treatment:

Include available therapeutic options that would ordinarily be tried before the Investigational Drug, or explain why the Investigational Drug is preferable. For Health Canada SAP, confirm that other therapies have failed, are unsuitable, or are unavailable.

12. Description of proposed monitoring procedures, including frequency of response assessments:

Proposal Information (to be provided by Summit)

13. Description of proposed treatment plan (including dose and frequency) and duration of treatment: Ivonescimab 20mg/kg IV every 3 weeks (Q3W). The total maximum duration of ivonescimab treatment is up to 24 months.

14. Planned dose modifications for toxicity (e.g., dose reduction or treatment delay): Dose adjustment of ivonescimab during treatment is not allowed, but delayed administration is allowed for up to 12 weeks (calculated from the time of the last dose).

PART B-US — FDA Physician Attestation & Conditions for Supply

Complete for United States / FDA requests (expanded access under 21 C.F.R. Part 312, Subpart I).

By signing below, I, the requesting physician, attest and agree as follows:

1. I am a physician duly licensed and authorized to practice medicine in the jurisdiction where the Investigational Drug will be administered. I will provide a copy of my CV and medical license.
2. I certify that, to the best of my knowledge, the patient identified in this request meets all eligibility criteria for expanded access as set forth within 21CFR312, including that the patient has a serious or immediately life-threatening disease or condition, no comparable or satisfactory alternative therapy is available, and the potential benefit justifies the potential risks (21 C.F.R. § 312.305(a)).
3. I acknowledge and agree that the Investigational Drug will be supplied solely for use by the patient who is the subject of this request, for no other purpose, and under my direct supervision.
4. I understand and agree that, if this request is approved, I will serve as the sponsor-investigator for the expanded access use under 21 C.F.R. § 312.3(b) and will assume all regulatory obligations of a sponsor-investigator under 21 C.F.R. Part 312, including IND submission and maintenance, IRB oversight, informed consent, safety reporting (including IND safety reports under § 312.32), annual reporting under § 312.33 where the IND continues for one year or more, recordkeeping, and drug accountability.
5. I understand that, to submit my individual-patient expanded access IND to FDA, I require a Letter of Authorization (right of reference) to Summit's IND and supporting data, and I request that Summit provide such authorization (21 C.F.R. § 312.310(a)(3)). I will make the submission to FDA using:

   ☐ Form FDA 3926

   Summit IND No. (if known): _____
6. I understand that IRB review and approval under 21 C.F.R. Part 56 must be obtained before treatment begins (except as permitted for emergency use). IRB status:

   ☐ Approval obtained — date: _____

   ☐ Pending

   ☐ Requesting waiver of full IRB review under 21 C.F.R. § 56.105 with concurrence of the IRB chair / designated member (per Form FDA 3926)
7. Emergency request? ☐ Yes ☐ No

   If yes, I understand treatment may begin before FDA's written authorization and before IRB approval, provided FDA authorizes the emergency use (21 C.F.R. § 312.310(d)) and the IRB is notified within 5 working days of treatment (21 C.F.R. § 56.104).
8. I acknowledge that expanded access will not be granted unless a fully executed Expanded Access Agreement is in place between Summit and the undersigned (and institution, if applicable). I have reviewed Summit's standard-form Expanded Access Agreement and:

   ☐ have executed it ☐ am prepared to execute it

9. I understand that submission of this form does not guarantee approval of expanded access or supply of the Investigational Drug, that Summit may deny this request in its sole discretion for any reason not prohibited by law, and that such denial is final and not subject to appeal.

10. I certify, with my signature, that I have read, understood, and accept the above terms.

Physician / Practitioner Name:	**Institution Name:**
Signature:	**Date:**

PART B-CA — Health Canada Special Access Program (SAP) Practitioner Attestation & Conditions for Supply

Complete for Canada / Health Canada SAP requests (special access under Food and Drug Regulations C.08.010–C.08.011). This Part replaces Part B-US. The U.S. IND and "sponsor-investigator" framework does not apply in Canada; access is authorized by Health Canada.

By signing below, I, the requesting practitioner, attest and agree as follows:

1. I am a practitioner duly licensed and authorized to practice in the Canadian province or territory where the drug will be administered. I will provide a copy of my CV and medical license.

   Provincial / territorial license no.: _____

2. I am accessing this non-marketed drug for the emergency treatment of a patient under my care in accordance with C.08.010 of the Food and Drug Regulations, and I attest that the patient's condition is serious or life-threatening.

3. I attest that other therapies have been tried and have failed, are unsuitable, or are unavailable for this patient (C.08.010).

4. To the best of my knowledge, the requested drug/indication ☐ is ☐ is not authorized by the U.S. FDA or the European Medicines Agency for the same medical emergency.

5. I am aware that, by accessing this drug through the SAP, the investigational drug is exempt from the provisions of the Food and Drugs Act and Regulations, including those respecting safety, efficacy, and quality.

6. I understand that access is authorized by Health Canada — not by me or by Summit. Summit may supply the drug only after Health Canada issues a Letter of Authorization to the manufacturer (with a copy to me) and only if Summit agrees to provide the drug for this use. I will provide Summit with a copy of the Health Canada authorization before any shipment.

7. I acknowledge that expanded access will not be granted unless a fully executed Expanded Access Agreement is in place between Summit and the undersigned (and institution, if applicable). I have reviewed Summit's standard-form Expanded Access Agreement and:

   ☐ have executed it ☐ am prepared to execute it

8. I understand that submission of this form does not guarantee approval of expanded access or supply of the Investigational Drug, that Summit may deny this request in its sole discretion for any reason not prohibited by law, and that such denial is final and not subject to appeal.

9. I certify, with my signature, that I have read, understood, and accept the above terms.

Physician / Practitioner Name:	**Institution Name:**
Signature:	**Date:**

Information collected on this form may contain personal information about the requesting physician/practitioner and limited patient information. Summit will handle all information submitted in connection with this request in accordance with its Privacy Policy and Applicable Laws — for U.S. requests, including HIPAA and applicable state privacy laws, and for Canadian requests, including PIPEDA, the federal Privacy Act, and applicable provincial health-information privacy laws. Patient-identifiable health information should be limited to what is necessary to evaluate the request. Patient medical records should not be submitted with this form unless specifically requested by Summit. All information submitted will be treated as confidential and used solely to evaluate the expanded access request, fulfill regulatory obligations, and administer the Expanded Access Program.

Electronic submission

After completing the form, click the button below to email it to Summit.
(Requires Adobe Acrobat or Adobe Reader.)

Email Completed Form to Summit