

Expanded Access Policy (ENG/SV)	Policy No:	POL-201-CD
	Version No:	2.0
	Effective date:	01 Mar 2025

Expanded Access Policy

Isofol Medical AB (publ) is a biotech company developing a new drug candidate which is intended primarily for the treatment of metastatic colorectal cancer (mCRC).

The term Expanded Access (sometimes referred to as “Compassionate Use” or “Pre-Approval Access”) is used to describe treatment with an investigational product for a patient with a serious or immediately life-threatening illness when there are no comparable or satisfactory alternative treatments available and the patient is ineligible or unable to participate in a clinical trial.

The following is Isofol Medical AB (publ)’s expanded access policy for investigational drugs that are intended to treat serious diseases.

GENERAL

Isofol Medical AB (publ) believes that investigational drugs should be studied in patients as part of clinical trials designed to obtain data on safety and efficacy, that may be used to support an approval of the product which would lead to subsequent wider availability for patients. At this time, we are unable to provide access to our investigational drug product outside of clinical trials and prior to regulatory approval or commercial availability. Treating physicians and patients interested in learning more about Isofol’s clinical studies can find more information on the company’s website.

CONTACT DETAILS

If you have any questions about our investigational product or Expanded Access Policy, please contact Isofol Medical AB (publ) through the following email address: info@isofolmedical.com.

Responses will be provided approximately within one business week.

As authorized by the 21st Century Cures Act, Isofol Medical AB (publ) may revise this expanded access policy at any time. Additionally, the posting of this policy by Isofol Medical AB (publ) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

You can find additional information about Isofol Medical’s ongoing clinical trials by accessing <https://clinicaltrials.gov>.

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