# Global Policy on Expanded Access / Compassionate Use

**INCY.EA.01-1**

*Region: Global*

*Effective Date: March 2021*

This Policy applies to the provision of Incyte investigational products to patients through Expanded Access / Compassionate Use programs. If you have any questions as to the applicability of this Policy, please contact the Global Medical Affairs (GMA) Department at GMAoperations@incyte.com.

**For best user experience**:
- Use Google Chrome when opening Incyte intranet sites and Adobe to read PDF-version of Policy
- Use hyperlinks within Table of Contents and Sections for easier navigation between topics

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# SECTION 1: Introduction

## 1.1 Purpose

Incyte believes that conducting clinical trials for review by regulatory authorities around the world to obtain the necessary approvals provides patients with the optimal mechanism for broad access to medicines as prescribed by qualified healthcare professionals. Incyte recognizes that some patients with serious or immediately life-threatening diseases or conditions may not be eligible for participation in a clinical trial or may not otherwise have other options for potential treatments of their conditions. Subject to appropriate internal review and approval based on the conditions set forth below, Incyte in its discretion may choose to provide patients with access to an unapproved or investigational product outside of a clinical trial setting.

The mechanisms for arranging for therapeutic use of investigational products vary and are subject to applicable law and regulations.

In addition to this Policy, Incyte Representatives must also adhere to other applicable SOPs or procedures, as well as any associated local/regional work instructions for additional details. Decisions to make investigational Incyte products available through Expanded Access programs must be made without commercial influence and must be reviewed and approved as outlined in this Policy and the associated procedures and work instructions. For the purposes of this Policy, Expanded Access / Compassionate Use will be referred to as "Expanded Access".

## 1.2 Scope

This Policy applies to all Incyte employees and contractors, consultants, vendors, agencies, and any other person who is notified that this Policy applies to them (collectively "Incyte Representatives") who have received an inquiry and/or are involved in the evaluation or provision of an investigational Incyte product for Expanded Access.

## 1.3 Definitions

- **Expanded Access:** Providing an unapproved investigational product for a use outside of a clinical trial under the care and supervision of the patient's treating physician. Different vehicles for Expanded Access include (but are not limited to): Single patient/named patient, cohort or protocol-driven, Temporary Authorization for Use (ATU), Recommendation for Temporary Use (RTU), Early Access to Medicines Scheme (EAMS), and other regional or country specific programs as appropriate.

- **Immediately Life Threatening Disease or Condition**: Immediately Life Threatening disease or condition means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. (21 CFR 312.300).

- **Serious Disease or Condition**: Serious Disease or Condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible,

provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. (21 CFR 312.300).

## 1.4 Contact Information / Resources

In the U.S., Expanded Access questions can be directed to Medical Information at Incyte: 1-855-463-3463 or www.incytemi.com. For the European Union and Rest of World, questions can be directed to Global Medical Information via email at: globalmedinfo@incyte.com.

Clinical trial records for an investigational product can be found at www.clinicaltrials.gov by searching for that investigational product.

# SECTION 2: Expanded Access / Compassionate Use

## 2.1 General Requirements

Incyte will consider providing Expanded Access to an investigational product outside of a clinical trial when all of the following criteria are met:

- ✓ The investigational product is under active clinical development by Incyte and is not otherwise available through a commercial channel for the relevant disease and location.
- ✓ Phase 2 safety data is available for the investigational product, and at minimum, plans are being made for Phase 3 (protecting for equipoise).
- ✓ Clinical development of the investigational product is not affected by granting a patient access to the product. For example, Incyte will consider whether safety data reporting obligations stemming from the provision of the Expanded Access could adversely affect a pending marketing authorization application or might otherwise delay marketing approval and ultimately availability to all patients.
- ✓ Granting access to the investigational product would not adversely affect initiation of clinical trials or delay the completion of clinical trials involving the investigational product that could support a regulatory approval of the product or otherwise compromise the potential development of the investigational product.
- ✓ There is sufficient evidence that the investigational product and an appropriate dose may benefit the patient and not raise significant product liability or regulatory risks to Incyte.
- ✓ A formal request is made by the patient's treating physician to Incyte's Medical Information Department, unsolicited by Incyte or any other individual or organization, consistent with local regulatory requirements. If a patient makes the initial inquiry, the patient should be directed to approach their physician to initiate the request if the physician deems it appropriate.
    - The physician must be responsible for the patient's care and understand the risks and potential benefits of the investigational treatment
    - The physician must comply with all regulatory authority requirements and be willing to conduct all necessary medical monitoring, safety reporting and data collection
- ✓ Expanded Access is permitted/approved in the country, region and/or state/ province in which the investigational product will be administered.
- ✓ An adequate supply of the investigational product exists to support both the ongoing clinical trials and approved Expanded Access use, until and if the product becomes commercially available.
- ✗ It is inappropriate to use Expanded Access as a means for providers and patients to "gain experience" with a new drug.
- ✗ Expanded Access programs are not clinical studies and while some data may be collected, the data collection cannot be the primary purpose and must be limited so as to not hinder access to care for patients.

## 2.2 Regulatory Obligations

Where Incyte is the regulatory sponsor of the Expanded Access program, the company must confirm it will be able to allocate sufficient resources and headcount to meet ongoing regulatory obligations for the duration of the program – including to follow safety reporting by the supervising investigator or healthcare provider and arrange for independent ethics committee review/ research ethics board, where applicable.

Where the program is sponsored by the patient's physician (e.g., through a named patient program or a treatment use IND), the physician signs an Incyte-approved drug supply agreement with applicable regulatory and liability language.

## 2.3 Review and Approval Requirements

All requests for Expanded Access will be acknowledged and evaluated promptly in a fair and unbiased manner. Incyte or its vendors must never promise the availability of or access to investigational product through Expanded Access programs and must refer Expanded Access inquiries to the Incyte Medical Information Department (see section below "Contact Information and Resources").

The decision to provide investigational product is made by the Chief Medical Officer (CMO) or his/ her approved designee, who must have the requisite skills and experience to make a clinical decision as anticipated by applicable laws and/or regulations. An approved list of CMO designees shall be maintained by Global Medical Affairs.

Decisions shall be based on bona fide medical criteria, and shall not be intended to provide financial assistance to a patient where drug is commercially available or to induce, influence, or reward usage or prescribing of the investigational product or other Incyte products.

Decisions and corresponding rationale, including assessment against Patient Eligibility Requirements, must be documented by the CMO or his/ her approved designee. This documentation shall be maintained by Global Medical Affairs.

## 2.4 Patient Eligibility Requirements

To be eligible for access to an investigational or unlicensed product, a Patient must meet all of the following criteria as determined by the CMO or his/ her approved designee:

- ✔ Have a Serious or Life-Threatening Disease or Condition;
- ✔ Have undergone appropriate standard treatments, such as standard of care, without clinical success or there is no comparable or satisfactory alternative therapy to treat the disease or condition;
- ✔ Is ineligible for participation in any ongoing Incyte-sponsored clinical trial of the investigational product, including lack of access due to geographic limitations, as determined solely by Incyte.
    - Participation in clinical trials is the primary route for providing patient access to investigational product. Expanded Access requests may not be approved if a patient is able to enroll in an ongoing Incyte-sponsored clinical trial.

- ✔ Be informed (or the patient's guardian or caregiver be informed) of the potential risks and benefits of the investigational treatment, provide informed consent and agree to comply with the safety and monitoring requirements defined by Incyte.
    - Patients with exceptional safety risks that have not been sufficiently studied would be excluded.
- ✔ Not otherwise have access to the treatment through legitimate prescribing by a provider or through access in their home country.

If all the above requirements are met, Incyte will consider Expanded Access requests subject to adherence to this Policy, as well as applicable Incyte procedures, work instructions, and laws and regulations.

## 2.5 Other Requirements

Any access to an unapproved, investigational product must comply with the applicable country-specific laws and regulations including medicine importation requirements and approvals from applicable regulatory bodies and applicable Institutional Review Board or Ethics Committee (IRB/IEC). Incyte affiliates create and adhere to country and/or region-specific laws, regulations and procedures regarding Expanded Access Compassionate Use for investigational products including local transparency requirements.

Such procedures and work instructions must be consistent with this Policy.

## 2.6 Responsibility for Compliance

All Incyte Representatives are required to comply with this Policy. Non-compliance may result in disciplinary action up to and including termination of employment. For further information, refer to Incyte's *Code of Business Conduct & Ethics* and *Policy on Reporting & Investigating Allegations of Non-Compliance*.

⚠ Any required deviation from this Policy must be approved in advance by the relevant VP-level department head and Incyte's Compliance Department (compliance@incyte.com).

If you have any questions about the applicability of this Policy, please contact the Compliance Department at compliance@incyte.com.

In addition, Incyte maintains an open environment in which individuals can report, without fear of retaliation, any conduct that may be in violation of this Policy. If you know of a situation that may be a violation of this Policy, please contact your Incyte manager, Compliance, Legal, or Human Resources or report the situation anonymously through the Compliance Helpline (available 24-hours a day, 7-days a week):

- From the United States: 1-855-INCY-411 or 1855-462-9411
- From Switzerland: 0-800-890011, then 855-845-3448
- http://www.incyte.ethicspoint.com