

## IGNYTA, INC.

### POLICY ON EXPANDED ACCESS TO INVESTIGATIONAL DRUGS

To serve the greatest number of patients, Ignyta conducts clinical trials with the aim of obtaining regulatory approval of its products.

Our preference, whenever possible, is to encourage patients to participate in clinical trials, because clinical trials can generate data that may lead to the approval of drugs and, subsequently, to wider availability to a greater numbers of patients.

In rare cases, when a patient does not qualify for any clinical trial and has exhausted available treatment options, Ignyta may consider providing access to investigational drugs outside of a clinical trial, as permitted by applicable law, as described below.

#### **Ignyta Clinical Trials**

Enrollment in a clinical trial is the primary method through which access to Ignyta investigational drugs is provided prior to their potential approval by applicable regulatory authorities and subsequent commercial availability. Clinical trials are required in order to demonstrate that an investigational drug meets the safety and efficacy standards required for approval by applicable regulatory authorities, such as the U.S. Food and Drug Administration.

Please visit Ignyta's Clinical Trials page at [www.ignyta.com](http://www.ignyta.com) or [www.starttrials.com](http://www.starttrials.com) for more information about current Ignyta clinical trials.

#### **Access to Ignyta Investigational Drugs Outside of Clinical Trials**

Patients with cancer who do not qualify for participation in, or who are otherwise unable to access, an ongoing clinical trial but might receive clinical benefit from administration of an Ignyta investigational drug may, in some instances, receive access to the investigational medicine from Ignyta through individual compassionate use or expanded access programs.

Ignyta may establish expanded access programs and provide access to its investigational drugs to patients who meet specific eligibility criteria once enrollment into the key study/studies, intended to support regulatory approval of the drug product, is complete. These programs are managed by Ignyta and follow a specific protocol, which is developed in consultation with a regulatory agency (such as FDA) for the use of the investigational drug.

In the absence of an expanded access program, Ignyta may provide physician-requested expanded access (also referred to as compassionate use) to its investigational drugs to individual patients, where it is allowed by local regulations and when it meets our company's expanded access criteria. Individual patient expanded access will be managed by Ignyta (via Single Patient Protocol) or in certain circumstances by the patient's physician (via Individual Patient Access IND).

#### **Factors that guide access to Ignyta investigational drugs outside of clinical trials include the following:**

- The investigational drug must be in active clinical development.

- Access to the investigational drug by the patient must not interfere with, or in any way have the potential to compromise the initiation, conduct, or completion of clinical investigations to support regulatory approval of the investigational drug.
- The patient must have advanced cancer that harbors a genetic alteration that is targetable by an Ignyta investigational drug
- The patient must have no comparable or satisfactory alternative therapy and must be ineligible for, or otherwise unable to participate in, a clinical trial.
- There must be sufficient clinical data to identify a recommended dose that is felt to have the potential to be effective and not pose undue safety risks; and thus, the potential patient benefit justifies the potential risks of the investigational drug use. Note: The determination of potential benefit and risk will generally be made between the patient's treating physician and Ignyta. Patients should understand that some conditions that have not been sufficiently studied (e.g., other co-existing conditions) may pose an exceptional safety risk such that the use of the investigational drug cannot be justified.
- After meeting the needs of clinical trials and other existing patients receiving the investigational drug, Ignyta must have a sufficient supply of the investigational drug product in a form that is suitable to the compassionate use request to reasonably accommodate the likely method and duration of treatment.
- The patient for whom the request is made must be located within the United States. Requests from outside of the United States will be considered on a case-by-case basis, taking into account applicable local regulations and the regulatory status of the Ignyta investigational drug in that country.
- The treating physician must be qualified, agree to directly supervise treatment, be willing to provide relevant data to support regulatory submissions, and must otherwise comply with relevant US federal and state regulations, including those relating to safety reporting.

### **Process for requesting expanded access (compassionate use)**

A qualified physician who believes that his/her patient may benefit from access to an Ignyta investigational drug outside of a clinical trial should contact Ignyta's clinical team at:

email: [STARTRKtrials@ignyta.com](mailto:STARTRKtrials@ignyta.com)

phone: [1-844-STARTRK \(782-7875\)](tel:1-844-STARTRK(782-7875))

or Ignyta's corporate phone: (858) 255-5959 to make the request on behalf of the patient. This will enable the physician to work with experts within Ignyta to determine the best course of action. Please note that all communications and records should be redacted of all confidential patient health information.

Ignyta endeavors to respond to physician requests for access as soon as possible. Typically, Ignyta is able to respond to requests for access within three (3) business days of receipt of the request.