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A Patient-Centered Program to Overcome Clinical Trials Accessibility Barriers

Jason Carter Clinical Trials Program

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Background

- Patients who participate in cancer clinical trials often have better outcomes than those who do not. [1]
- Multiple barriers make clinical trials inaccessible to many including:
  - ➢ lack of awareness by providers about available trials
  - ➢ limited clinical trial access across centers
  - ➢ patient misconceptions.[2]

Objectives

- The Jason Carter Clinical Trials Program (JCCTP) was created to:
  - ➢ help people with blood cancers and blood disorders find and join clinical trials

Methods

- Initial literature review was conducted and feedback was gathered from recipients of blood and marrow transplant regarding the gaps in current practice.
- Database and web development experts created a framework for collecting open & enrolling trials published on ClinicalTrials.gov.
- Program planners applied clinical judgment, best practices in health literacy, and knowledge of the patient experience to ensure the program is clinically accurate, easy-to-use, and relevant for patients and families.
- A sustainable process was created, including templates and a style guide, to adapt a high volume of complex clinical information into short descriptions with accuracy.
- User testing was done with BMT recipients to inform ongoing process improvement and ease of use.

JCCTP Components

One-on-one support

- Provided via email and text
- Provided by a master's prepared nurse in the role of Clinical Trial Patient Education Specialist

Online search tool

- 1,200+ clinical trial descriptions written in plain language
- Ability to save search settings and receive proactive notifications about new trials that meet search criteria

Easy-to-read resources

- Patient education resources about the clinical trial process and available options
- Resources can be mailed or printed directly from website

Travel Grant

- Drs. Jeffrey and Isabel Chell Clinical Trials Travel Grant provides patients and families up to $2,000 to cover expenses related to clinical trials (e.g. airfare, hotel, food, transportation)

Guiding Principles

Always use the active voice

Avoid using complex medical terms or define them

Use acronyms with the first use of a complex term, and use it throughout the description

When a study is for children only, write the eligibility and treatment sections in language that speaks to a parent

For important criteria that must be included, indicate that they can ask their doctor if they do not know. For example, as an inclusion criteria, "You have leukemia that is Philadelphia chromosome positive (Ph+). Your doctor can tell you this."

If a word cannot be simplified but must be used, add a pop-up glossary term, such as graft-versus-host disease (GVHD) – POP-UP DEFINITION: When the cells from your donor (the graft) see your body's cells (the host) as different and attack them.

Example: Before

Study to Evaluate Imetelstat (JNJ-63935937) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS)[3]

Brief Summary

The purpose of this study is to evaluate the efficacy and safety of imetelstat in transfusion dependent participants with low or intermediate-1 risk myelodysplastic syndrome (MDS) that is relapsed/refractory to erythropoiesis-stimulating agent (ESA) treatment.

Eligibility Criteria

Inclusion Criteria:

- Man or woman greater than or equal to (>=) 18 years of age
- In Part 1, diagnosis of myelodysplastic syndrome (MDS) according to World Health Organization (WHO) criteria
- International Prognostic Scoring System (IPSS) low Risk or intermediate-1 risk MDS
- Red blood cell (RBC) transfusion dependent, defined as requiring at least 4 RBC units transfused over an 8-week period during the 16 weeks prior to Study Entry; pre-transfusion hemoglobin (Hb) should be less than or equal to 9.0 gram per deciliter (g/dL) to count towards the 4 units total
- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2

Exclusion Criteria:

- Participant has known allergies, hypersensitivity, or intolerance to imetelstat or its excipients
- Participant has received an investigational drug or used an invasive investigational medical device within 30 days prior to Study Entry or is currently enrolled in an investigational study
- Prior treatment with imetelstat
- Have received corticosteroids greater than (>) 30 milligram per day (mg/day) prednisone or equivalent, or growth factor treatment within 4 weeks prior to study entry
- Prior treatment with a hypomethylating agent (example [eg], azacitidine, decitabine); b) Prior treatment with lenalidomide; c) Has received an erythropoiesis-stimulating agent (ESA) or any chemotherapy, immunomodulatory, or immunosuppressive therapy within 4 weeks prior to study entry (8 weeks for long-acting ESAs)

Detailed Description

This is a Phase 2/3, multicenter study of imetelstat that consists of 2 parts. Part 1 is an open-label, single-arm design to assess the efficacy and safety of imetelstat. Approximately 55 participants will be enrolled in Part 1, including the expansion cohort, and be followed-up for safety, hematologic improvement and reduction in transfusion requirement. Part 2 of the study will be initiated if data from Part 1 are supportive of a satisfactory benefit/risk profile. Part 2 is a double-blind, randomized design to compare the efficacy of imetelstat with placebo. Approximately 170 eligible participants will be randomized in a 2:1 ratio to receive either imetelstat or placebo, respectively. Each part of the study will consist of 3 phases: a Screening phase (up to 28 days); a treatment phase; and a post-treatment follow-up phase which will continue until death, lost to follow-up, withdrawal of consent, or the End of the Study (whichever occurs first). The End of the Study is defined as 2 years after the study entry of the last participant or anytime the sponsor terminates the study, whichever comes first.

Readability Assessment:

Gunning-Fog Index: 19.7; Flesch-Kincaid Grade: 17.6,
Flesch Reading Ease Score: 20.3 (Very Difficult - College)

Example: After

A drug, imetelstat (JNJ-63935937), to treat low- or medium-risk myelodysplastic syndrome (MDS) in people who need blood transfusions

Clinical Trial Goal

To find out:

- If imetelstat is safe and works well to prevent the need for blood transfusions for people with MDS

You may be able to join this trial if you:

- Are 18 years old or older
- Have MDS that is low- or medium-risk
- Need to have blood transfusions
- Have not taken imetelstat
- Agree to have other standard tests done to see if you can be in the clinical trial

Tests and Treatments

Imetelstat is a small molecule inhibitor that blocks telomerase. There are 2 parts to this trial: **Phase 2** and **Phase 3**. You will be in Phase 2 or Phase 3, but not both. Which phase you are in depends on when you start the trial.

If you're in **Phase 2**, you'll get imetelstat, given as an intravenous (IV) infusion 1 time each month.

If you're in **Phase 3**, you will be randomized to 1 of 2 groups. You and your doctor won't know which group you're in until the end of the trial. You don't have an equal chance of being in either group. There will be about twice as many people in Group 1 as in Group 2:

- **Group 1** – Imetelstat
- **Group 2** – Placebo

Randomized means doctors will use a computer to assign you to either group. A computer assigns you by chance, like flipping a coin or drawing a name out of a hat. You, your doctor or the clinical trial doctor won't have any control over which group you'll be assigned. This means you won't be able to choose your group.

If you're in **Group 1**, you'll get **imetelstat**, given as an IV infusion 1 time each month.

If you're in **Group 2**, you'll get **placebo** (an IV infusion with no medicine in it), given 1 time each month

You may continue treatment for as long as the clinical trial doctors think it is best for your health. The doctors will check your heath for at least 2 years.

The Food and Drug Administration (FDA) has **not** yet approved imetelstat.

Readability Assessment:

Gunning-Fog Index: 7.1; Flesch-Kincaid Grade: 4.5,
Flesch Reading Ease Score: 87.5 (Easy - Grade 5),

Participation & Evaluation

Since program launch in July 2017*:

- 78 accounts created
- 2,784 searches completed
- Provided 40+ families with one-on-one support
- Satisfaction surveys are given to participants who contact the clinical trial specialist, surveys to assess follow-up actions in development.

*Data from April 2018

Implications

- This framework can be applied to other clinical areas within and outside of oncology to improve the clinical trial search experience for patients.
- This program mitigates some of the barriers experienced by patients and families searching for appropriate clinical trials but barriers remain especially for individuals with limited computer skills.

References

1. Sarkar RR, Matsuno R, Murphy JD. (2016). Pancreatic cancer: Survival in clinical trials versus the real world. *Journal of Clinical Oncology*. 34, 2016 (suppl 4S; abstr 216).

2. Cameron, P., Pond, G. R., Xu, R. Y., Ellis, P. M., & Goffin, J. R. (2013). A comparison of patient knowledge of clinical trials and trialist priorities. *Current Oncology*. 20(3), e193–e205.

3. Study to Evaluate Imetelstat (JNJ-63935937) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS) - Tabular View - ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/record/NCT02598661. Accessed May 1, 2018.

For More Information

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