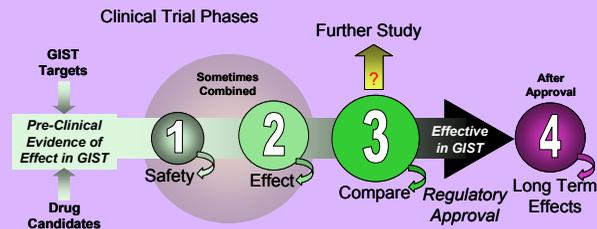


Clinical Trial Phases:



Before it is tested in humans, a new drug must exhibit some effectiveness against GIST in the lab. Candidate drugs from the lab enter clinical trials that are designed to answer fundamental questions about the drug in humans.

Phase 1: Is the drug safe?

- Usually 20-60 patients at one or a few sites
- First use of drug in humans
- Determines whether patient can tolerate the dosage given
- Early patients may not get a therapeutic response because they are on the lowest dosage. Later patients may have increased risk of side effects due to a very high dosage level.

Phase 2: Is the drug effective in treating GIST?

- Usually 100-300 patients at 3-10 sites
- Can be combined with Phase 1

Phase 3: Is the drug better than current standard?

- Compares drug to current standard of treatment for GIST
- Usually 300-1,000 patients at 10-100 sites

Phase 4: Post Approval

- Studies long-term side effects and efficacy

Five-Year GIST Survivors at Life Fest 2006



You do not face GIST alone

The Life Raft Group was formed in 2000 by GIST patients, many of whom were participants in the Phase II trial of STI-571 (Gleevec/Glivec). Many of those patients are still here today because they made the choice to participate. Gleevec is available today because of those first GIST patients who stepped forward. To have GIST is to be a member of a community actively pursuing a cure.

International Patients

Patients outside the United States who try to enter a clinical trial in another country may have a different process to go through than U.S. citizens. To learn more about international access to clinical trials, visit the Global GIST Network at www.globalgist.org.



The Life Raft Group

The LRG is an international patient support organization for people with GIST and their family members. The mission of the Life Raft Group is to ensure the survival of GIST patients while maintaining the quality of their lives. To accomplish this mission the Life Raft Group devotes its efforts to: Information & Support, Treatment Surveillance, Research, Patient Consultation & Assistance, and Advocacy.

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Navigating GIST Clinical Trials



An easy-to-use guide about GIST clinical trials and tips to help you decide which trial to choose

Ensuring that no one has to face GIST alone

GIST stands for gastrointestinal stromal tumor. This pamphlet is intended to answer some of your questions about GIST clinical trials. It is intended to guide those considering options after treatment failure. It is not a substitute for your physician's guidance and care.

Do you need a clinical trial?

If you have GIST progression despite Gleevec and/or Sutent treatment you or your doctor may want to investigate a clinical trial as an option in your treatment plan.

When patients are no longer responding well to standard therapies such as Gleevec and Sutent, they may have the option of entering GIST clinical trials.



GIST patient Marcel Szyszkowski

What are the benefits?

There can be several benefits for GIST patients participating in clinical trials:

- Option to access treatment after standard treatment fails
- Receive treatment at major GIST trial center
- Expanded treatment options
- Help future GIST patients

What are the risks?

- The new drug may not work for you
- Side effects may occur
- Additional testing, time and travel
- Some costs may not be covered by insurance

Informed Consent

Before entering a clinical trial, patients must sign a document called informed consent. Make sure to review it carefully.

Navigation

Understand your role in your care plan

It is important for patients to recognize the responsibility for managing their care. Patients are the ultimate decision makers in their care plan.

Get the proper support

Get a relative, a partner or a friend who can:

- Help you with emotional support
- Be a sounding board
- Be a second pair of ears
- Help with research, billing issues or navigating your treatment plan
- Be your spokesperson or advocate

Get all the information you need

Find out all you can about your GIST:

- Your treatment history
- Current CT/PET scan reports
- Your GIST mutation – In the future, trial drugs may target specific mutations

Use the Life Raft Group (LRG) resources at www.liferaftgroup.org:

- GIST Clinical Trial Listing
- GIST Clinical Trial Map
- Newsletter Clinical Trial reports

The LRG online patient/caregiver community is helpful to find others who have a similar situation as your own. They may have already entered the trial you are considering. They can provide invaluable “insider” feedback. You can join the LRG by going to www.liferaftgroup.org/about_join.html.



Critical Thinking

How to choose a clinical trial

Decide on a set of criteria that are important to you. This will keep you focused. These are examples:

- Proximity to home, job and family
- Sarcoma expertise of physician (GIST belongs to a family of cancers called sarcomas.)
- Potential drug risks and benefits
- Follow-up schedule and options
- Targets a specific mutational type
- Be mindful of the urgency of your situation, but be careful to review trial options

Ask Questions

Learn about trials offered at various locations.

- Which trial offers the best chance of survival?
- What are the chances it will benefit you?
- What are the options if the trial does not work for you?
- If a trial starts at a later date, can you wait until it starts?
- *For phase I trials*, ask your doctor which dosage level may offer the greatest therapeutic response and then ask to be assigned to that group.
- Find out how the trial treatment differs from treatment you have already had.
- Is the trial focused only on GIST patients or a broader group of patients?
- Ask if drug response could be greater if the trial investigators focus only on GIST patients.
- Understand the exclusion criteria. Some trials exclude prior participation in other trials. When choosing between two trials, you may wish to select the one which would exclude you if you were to try and fail the other trial beforehand. This strategy would provide a fallback option if the first trial is not effective.



Critical Thinking (continued)

Taking an active role in your own treatment can be the best approach. Be curious. Have someone with you at appointments to compare notes later. It is okay to be wary of those who presume what you want. Talk to other patients who have already gathered information about GIST and sarcoma trials—they may have the insider track.

Where do you go for GIST clinical trials?

Most GIST clinical trials are conducted at centers of GIST expertise and at major cancer centers around the world. To find a recognized center of GIST expertise, search the directory at the Life Raft Group website (www.liferaftgroup.org). GIST trials can also have local sites at cancer centers throughout the United States.



Will I get the new drug or a placebo?

A placebo is an inactive material with no treatment value. Placebos are not used in Phase I and II trials; they have been used infrequently in GIST Phase III trials. Phase III trials more often compare a new drug to a current standard of treatment.

It is important to find out if the trial uses a placebo. If so, find out if you can crossover to the real drug if you are on the placebo and your disease progresses.

Placebo use is controversial and can affect patient participation. The LRG advises patients to carefully review the trial protocol and informed consent agreements before entering a clinical trial. You always have the right and the option to leave a GIST clinical trial at any time.

