

How to Find and Participate in a GIST clinical trial

(aka---how to maximize your treatment options)

Gastrointestinal Stromal Tumor (GIST)

- ▶ Rare disease, approximately 6000 new cases of GIST every year
- ▶ Compare to 230,000 new invasive breast CA cases/year and 200,000 new lung CA cases/year
- ▶ GIST studies tend to be opened at fewer sites
 - ▶ OHSU (Portland), Dana Farber (Boston), Fox Chase (Philadelphia), MD Anderson (Houston), Memorial Sloan Kettering (New York)

Where are you coming from?



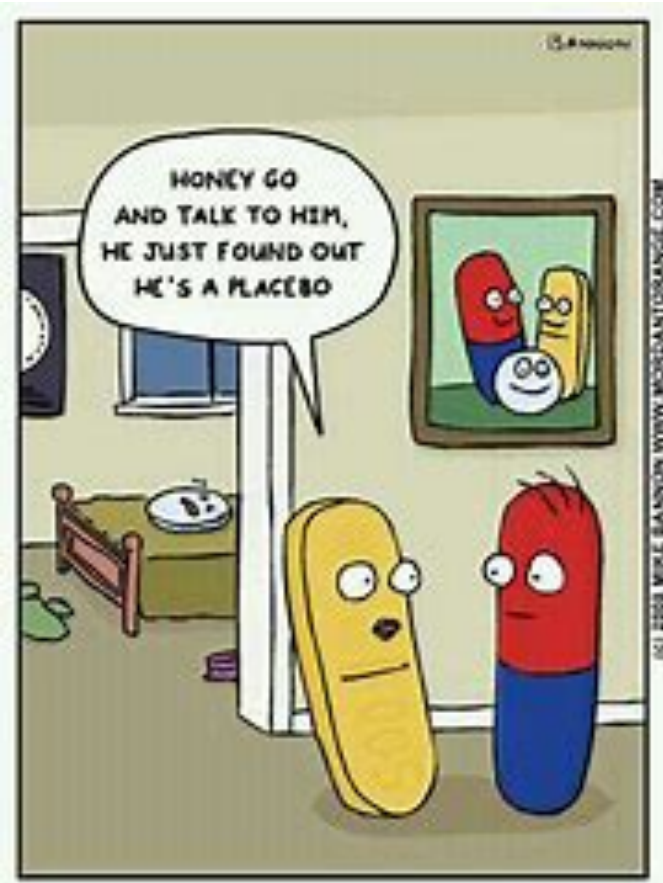
Many of our studies include travel reimbursement (airfare, hotel, food) and sometimes will include a caregiver as well

- ▶ Oregon - 33
- ▶ California - 31
- ▶ Washington - 19
- ▶ Colorado - 6
- ▶ Nebraska - 2
- ▶ Alaska
- ▶ Arkansas
- ▶ Hawaii - 3
- ▶ Idaho - 7
- ▶ New Mexico
- ▶ Illinois
- ▶ Indiana
- ▶ Michigan
- ▶ South Carolina
- ▶ Tennessee
- ▶ Utah
- ▶ Louisiana
- ▶ Montana
- ▶ Texas
- ▶ Virginia
- ▶ Iowa
- ▶ Nigeria
- ▶ Beijing

Drug Development for GIST

- ▶ Gleevec (Imatinib), First line
- ▶ Sutent (Sunitinib), Second line
- ▶ Regorafenib (Stivarga), Third line
- ▶ Current FDA approved drugs (in this order)
- ▶ What next?

I don't want a placebo!



Phases of Clinical Trials

- ▶ **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- ▶ **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- ▶ **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Source: <http://www.nlm.nih.gov/services/ctphases.html>

Phase I Definitions

- ▶ Dose Escalation
- ▶ Dose Expansion

Dose Escalation

- ▶ *The general goal for dose escalation in phase I trials is to safely and quickly find a dose and schedule that can be tested further for safety and efficacy in larger numbers of patients*

Dose Escalation Example

- ▶ 3 + 3 Design
 - ▶ 3 patients 200 mg, wait one month for toxicities-
none
 - ▶ 3 patients 300 mg, wait one month for toxicities-
none
 - ▶ 3 patients, 400 mg, wait one month for toxicities-2
patients with moderate toxicities
 - ▶ Need to add 3 more patients to continue to
evaluate for safety and wait one month for
toxicities
 - IF MORE MODERATE TOXICITIES AT 400mg then
dose would go down to 300 mg for further
testing
 - 300 mg would usually be called the Maximum
Tolerated Dose (MTD)

Dose Expansion

- ▶ Use the MTD (Maximum Tolerated Dose) that was found during dose escalation (ie. 300 mg)
- ▶ Given to more patients (approximately 25-50) to continue evaluating for safety, toxicity and efficacy
- ▶ All patients in this group receive the same dose
- ▶ May still be able to increase or decrease dose from the original starting MTD of 300 mg

What to do BEFORE you need a clinical trial

- ▶ Check with your insurance
 - ▶ Does your insurance allow you to participate?
 - ▶ Myth: Clinical trials do NOT “pay for everything”
 - ▶ As of January 1, 2014, the Affordable Care Act (ACA) includes the requirement that private insurers cover standard of care costs during participation in a clinical trial
 - ▶ At OHSU we will check this for you prior to study participation

Keep Records

- ▶ Date of diagnosis
- ▶ Keep a copy of your pathology report(s) with mutation results
- ▶ Date(s) of surgery and location where surgery was done
- ▶ Previous treatments and dates (be specific)
- ▶ Most recent labs (cbc and chemistries)
- ▶ Most recent CT scan (report and films)
- ▶ Ex. Diagnosed 2012
 - ▶ Gleevec 2012-Dec 2017, stopped for progression
 - ▶ Sutent Dec 2017-Dec 2018, stopped for progression
 - ▶ Regorafenib Jan 2019-March 2019, stopped for hand/foot syndrome

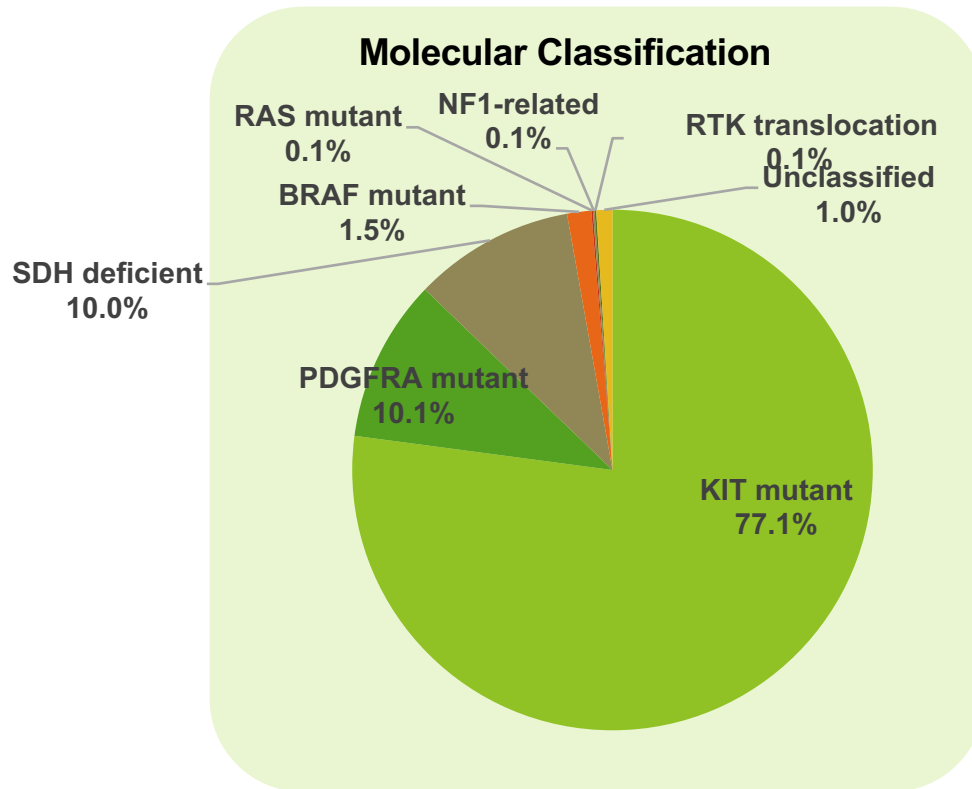
Coordination of Care

- ▶ Important to have an oncologist in your hometown
- ▶ May need to be seen between visits to Oregon:
 - ▶ IV fluids
 - ▶ Blood transfusions
 - ▶ Blood draws
 - ▶ Rash

“Do you know your mutation?”

- ▶ Recommend mutation testing on:
 - ▶ Any GIST with a significant risk of recurrence
 - ▶ Any GIST that has spread (become metastatic)
 - ▶ Any GIST that your doctor is considering treating (ie. if you are going to start taking an oral drug for your GIST, you should have mutation testing done)

GIST Mutations



Knight Diagnostic Laboratories

- ▶ To have mutation testing done on your tissue, please contact Client Services at:
 - ▶ (855) 535-1522

Know Your Mutation

Hello
my name is

Tracy and I have
an Exon 9
mutation

GIST Clinical Trials at OHSU

- ▶ Phase 3 second line study comparing DCC-2618 to Sutent (**Intrigue**, opening within the next 1-2 weeks)
- ▶ Phase 3 third line study comparing BLU-285 to Regorafenib (**Voyager**, BLU aka Avapritinib)-open NOW
- ▶ Compassionate use trial using DCC 2618 for patients who have exhausted all other treatment options-open NOW

How Do I Find a Clinical Trial?

- <https://clinicaltrials.gov/>
 - Voyager (phase 3 BLU vs. Regorafenib for third line)
 - <https://clinicaltrials.gov/ct2/show/NCT03465722?cond=gist&rank=1>
 - Intrigue (phase 3 DCC vs. Sutent for second line)
 - <https://clinicaltrials.gov/ct2/show/NCT03673501?term=intrigue&cond=gist&rank=1>

Be Empowered!



My Superpower?



Sharks!



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