Enhancing Awareness and Access

Nancy Roach, Fight Colorectal Cancer
Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative (CTTI) or the U.S. Food & Drug Administration (FDA).
Tom Marsilje, PhD aka Dr. Tom
Stage IV

Colon cancer has spread to other parts of the body:

- Distant lymph nodes
- Lung
- Liver
- Abdominal wall
- Ovary

Metastatic cancer
Cancer cells in lymph system
Cancer cells in the blood
Primary cancer
Colon
Promise of Immunotherapy ....

How the Promise of Immunotherapy Is Transforming Oncology

Wall Street Journal, December 4 2014
Search terms:
• Metastatic CRC
• Recruiting
• Not yet recruiting

270 trials total

What about phase 1 trials for solid tumors?
“As a patient, I had no interest in participating in a trial which had both the highest risk of failure as well as limited long-term benefit, even if the experimental therapy worked as designed. I knew that I may only have one shot at a trial, so I wanted to choose that trial wisely and make that potentially single shot count the most!” – Dr. Tom Marsilje
What does that mean?

- **MSS tumors**: Majority of patients (>95%) who have micro-satellite stable tumors (MSS)

- **No trials in China**: at that point, 4-5 years ago, Tom had concerns about listing trials that most people probably wouldn’t be able to access
What does that mean?

- **Highest “potential” chance of benefit:** Chance for a durable response, even if it’s a small chance. Immunotherapy trials* are characterized as highest “potential.”

- **Lowest “potential” chance of trial failure:** Trials can fail due to either safety or lack of efficacy. CRC trials that have advanced to Phase 2 or Phase 3* are characterized as lowest “potential” for failure.

- * means parameters will evolve as science evolves
Hacking for Good: Improving Access to Clinical Trials

By Ben Holtman
Engineering & Product
Curation Process

- Level 1 Curation
  - Research advocate team
    - Is this for stage 4 MSS CRC patients?
    - Is it immunology or phase 2 / phase 3 trial?
    - We now accept trials from China
  - In, Out, or Maybe
Curation process

- Level 2 curation
  - Super advocates with scientific background and scientist support
    - Generally decide questions around potential impact or complex eligibility criteria
  - In or Out, with comments
Impact of curation

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375 trials total vs 270 in CT.gov
Utilization since May 2017

- Over 14,000 users have utilized the tools, amounting to nearly 26,000 unique searches.
- Aside from the United States, the countries with patients using the tool the most are the United Kingdom and China.
- Users spend over two and a half minutes per session and navigate between two and three pages each session.
Tom Marsilje, 1972-2017

I DONT ALWAYS GO TO INFINITY

BUT WHEN I DO I GO BEYOND
Thank you to …

- Maia Walker, the wizard behind the curtain
- FightCRC research advocates who curate
- Flatiron who programmed
- Erika Hanson Brown, the Mayor of Colontown
- Reece Garcia, the FightCRC staff person who juggles (and all the FightCRC staff who believed and helped)
Questions?

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