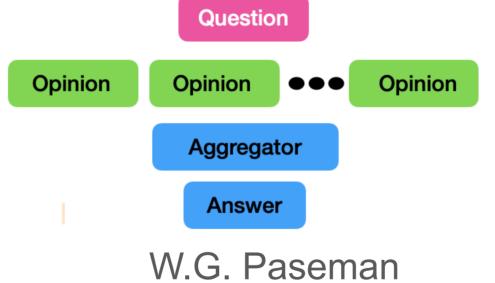
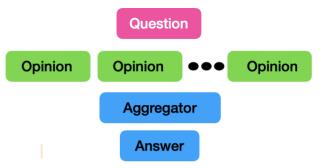
# Helping Patients Navigate Clinical Trials with Al



bill@RareKidneyCancer.org 20250424 Festival of Biologics

# Agenda

- Rare Disease: a Patient's Perspective
  - Success Rate Statistics
  - The Need for Self Advocacy
  - The Process
- A Solution
  - Tumor Boards and Wisdom of Crowds
- Opinions
  - From Machines, From Humans, From Both
- How many Opinions are enough?
- CareGiver Agent Example
  - EVEREST Clinical Trial



### P1RCC – months long PFS

- 1) Standard of Care Small Market for rare diseases (eg p1RCC)
  - 2017 So far, NO improvement in outcome over the last decade. Laurence Albirges
- 2) Clinical Trials Only add single digit months rarekidneycancer.org
  - 2017 "Recommendations for the Management of Rare Kidney Cancers" Median PFS in rare RCC patients
    - for sunitinib and Everolimus groups was 6.1 versus 4.1 mo
    - for ESPN, 8.3 versus 5.6 mo for ASPEN,
    - and 7.2 versus 5.1 mo for RECORD-3.
  - 2023 Cabozantinib, which is a multikinase inhibitor targeting VEGF, MET, and AXL, demonstrated a superior median PFS of
    - 9.0 months, compared to sunitinib with 5.6 months
- 3) So, given these stats and absent a SOC, how do I answer key questions?
  - Should I enroll in clinical trials?
  - What do I take if I progress?

#### Probability of Success<sup>2</sup> by Clinical Trial Phase and Therapeutic Area

	P1 to P2	P2 to P3	P3 to Approval	Overall
Oncology	57.6	32.7	35.5	3.4
Metabolic/Endocrinology	76.2	59.7	51.6	19.6
Cardiovascular	73.3	65.7	62.2	25.5
Central Nervous System	73.2	51.9	51.1	15.0
Autoimmune/Inflammation	69.8	45.7	63.7	15.1
Genitourinary	68.7	57.1	66.5	21.6
Infectious Disease	70.1	58.3	75.3	25.2
Ophthalmology	87.1	60.7	74.9	32.6
Vaccines (Infectious Disease)	76.8	58.2	85.4	33.4
Overall	66.4	48.6	59.0	13.8
Overall (Excluding Oncology)	73.0	55.7	63.6	20.9

Source: Chi Heem Wong, Kien Wei Siah, Andrew W Lo. "Estimation of clinical trial success rates and related parameters." *Biostatistics* 20(2): April 2019, Pages 273-286. Published online: 31 January 2018. DOI: 10.1093/biostatistics/kxx069

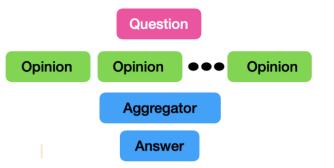
Note: 0.576\*0.327\*0.355=0.067

## Patient's Perspective

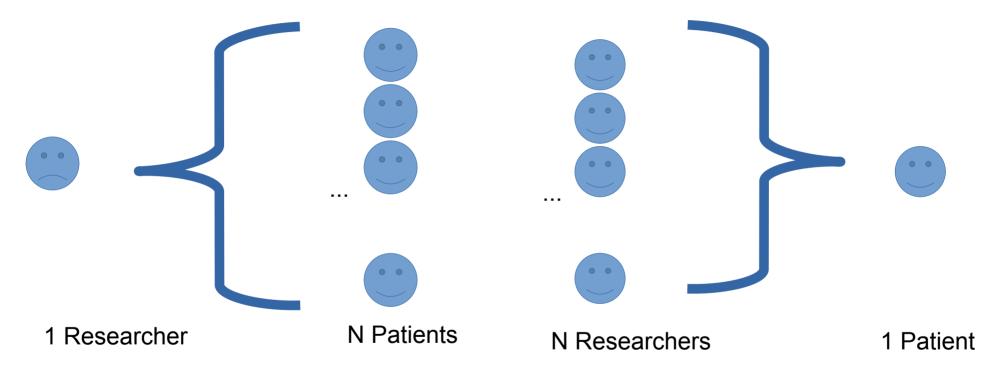
- Success Rate Statistics
  - Standard of Care 30-80%
  - Oncologic Clinical Trials 3.5%
  - Post Clinical Trials < 3.5%
- The Need for Self Advocacy
  - PCP is busy
    - "If you want to know about their trial, talk to them."
  - After their first Trial, the patient is no longer Treatment Naive
  - Patients are responsible for their own care.
- The Process
  - Questions: What questions do I ask, and in what order
  - Opinions: How many people should I ask and where do I find them?
  - Aggregation: How do I weigh their answers?

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### Clinical Trials vs. Tumor Boards (Portfolios)



**Clinical Trial**: one Researcher many Patients

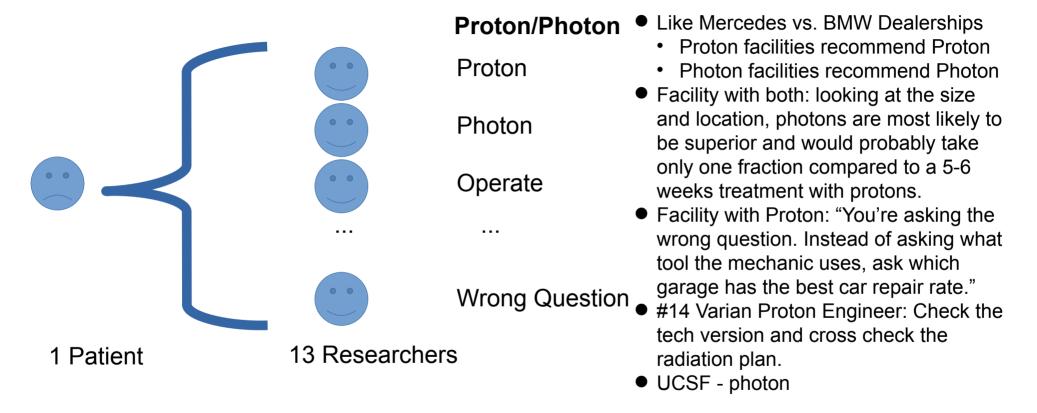
Tumor Board: many Researchers one Patient In essence, each member has a "2<sup>nd</sup> Opinion"

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### A Solution

- Tumor Boards
- Wisdom of Crowds- 2004 James Surowiecki
  - Diversity Each person should have private information.
  - Independence People's opinions are not determined by the opinions of those around them.
  - Decentralization Specialists draw on local knowledge.
  - Aggregation Ability to turn private judgements into a collective decision.
- Automated into a "Caregiver Agent"
  - Formulate a question
  - Solicit opinions
  - Judge and aggregate the opinions using several metrics
  - Provide several answers based on the metrics and aggregation approach

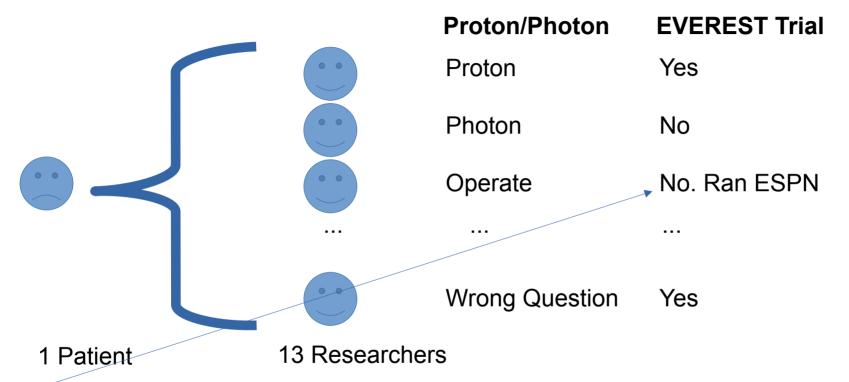
#### Tumor Boards: Which is better Proton or Photon?



- Ensemble Reasoning
  - "The best way to have a good idea is to have lots of ideas." Linus Pauling

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### Tumor Boards: Should I participate in EVEREST



- "I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC. There will be trials w/ **immune checkpoint agents** in the near future but not soon enough to enroll on."
- Note: My EVEREST Clinical Trial Enrollment likely would not have increased overall success rate!!!

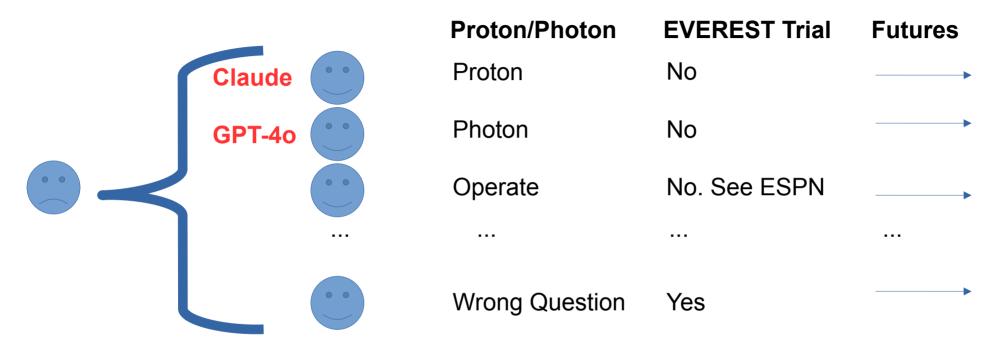
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### To Review...

- EVEREST (adjuvant) Clinical Trial using Everolimus
  - "Everolimus versus sunitinib for patients with metastatic non-clear cell renal cell carcinoma (ESPN): a multicentre, open-label, randomised phase 2 trial"\*\*
  - I asked 13 physicians if I ought participate
    - Yes: 3 ← The first three said yes.
    - No: 5
    - Patient must decide: 5
  - Key Opinion: "I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC. There will be trials with immune checkpoint agents in the near future, but not soon enough to enroll on."
    - i.e. "We tried this out as a first line therapy, and it didn't even slow it down.
- 201406 I declined
- Moderation (Aggregation) Process
  - not "consensus"
  - Gathered independent opinions until someone explained it in a way I found helpful.

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### **Tumor Board Augmentation**

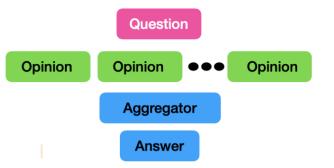


1 Patient

- 13->15 Researchers Welcome Claude and GPT-40 to the Team!
- Ensemble Reasoning
  - "The best way to have a good idea is to have lots of ideas." Linus Pauling
- Note: My Clinical Trial Enrollment in EVEREST likely would not have increased success rate!!! 12

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# ChatGPT on p1RCC

- Question: What adjuvant clinical trial is more promising for papillary RCC and why?
- Answer: The most promising adjuvant clinical trials for papillary renal cell carcinoma (pRCC) are those involving immune checkpoint inhibitors, particularly given the success of these agents in renal cell carcinoma (RCC) overall, including ongoing research in non-clear cell subtypes like pRCC. Here's why:
- 1. Mechanism of Action:
- **Immune checkpoint inhibitors** (e.g., pembrolizumab, nivolumab) work by unleashing the immune system to attack cancer cells. This approach has shown robust efficacy in various cancers, including RCC, by targeting the PD-1/PD-L1 pathway, which tumors use to evade immune detection.
- 2. Clinical Trial Success in RCC:
- **KEYNOTE-564 Trial**: This trial focused on pembrolizumab in high-risk RCC after surgery. The trial demonstrated a significant improvement in disease-free survival compared to placebo. While this trial predominantly involved clear cell RCC, the success of immune checkpoint inhibitors in RCC provides a strong rationale for their use in other subtypes like pRCC.
- **CHECKMATE Trials**: Trials involving nivolumab (with or without ipilimumab) in RCC have shown impressive results, particularly in the metastatic setting, leading to interest in their potential as adjuvant therapies.

# ChatGPT on p1RCC (continued)

- 3. Emerging Evidence in Non-Clear Cell RCC:
- Although most of the robust data comes from trials focused on clear cell RCC, there is growing evidence and ongoing
  trials assessing the efficacy of immune checkpoint inhibitors in non-clear cell RCC, including pRCC. This is particularly
  promising given the challenges of treating non-clear cell subtypes with traditional therapies.
- 4. Limited Efficacy of Alternatives:
- VEGF-Targeted Therapies: Trials like ASSURE and S-TRAC showed limited benefits and significant toxicity with VEGF-targeted agents like sunitinib in the adjuvant setting, particularly in non-clear cell RCC.
- **mTOR Inhibitors**: Evidence from trials like ESPN suggests that mTOR inhibitors like everolimus may be less effective, especially in the first-line setting for metastatic RCC, raising concerns about their utility in the adjuvant setting.

#### Conclusion:

- <u>Adjuvant trials incorporating immune checkpoint inhibitors</u> <u>are currently the most promising for papillary RCC.</u> This is due to the strong evidence of efficacy in RCC overall, the mechanism of action that is effective across different tumor types, and the emerging interest in applying these agents to non-clear cell RCC subtypes. As research progresses, these trials may offer the best chance of reducing recurrence and improving outcomes in patients with papillary RCC.
- 2014 advice: "I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC. There will be trials w/ immune checkpoint agents in the near future but not soon enough to enroll on." 15

# Claude on p1RCC

- Question: What adjuvant clinical trial is more promising for papillary RCC and why?
- When considering adjuvant clinical trials for papillary renal cell carcinoma (pRCC), it's important to note that research in this area is ongoing, and the landscape can change rapidly. However, I can provide some insight into promising directions based on recent research and trials.
- One of the more promising adjuvant clinical trials for papillary RCC is the KEYNOTE-564 trial, which, while not specifically designed for papillary RCC, has shown promising results that may be applicable to this subtype. Here's why it's considered promising:
- 1. Immunotherapy approach: KEYNOTE-564 uses pembrolizumab, an immune checkpoint inhibitor. Immunotherapy has shown promise in various RCC subtypes, including papillary RCC.
- 2. Broad inclusion: While primarily focused on clear cell RCC, the trial included a subset of non-clear cell RCC patients, which encompasses papillary RCC.
- 3. Positive results: The trial showed significant improvement in disease-free survival in the overall population, which is encouraging for potential application to papillary RCC.

# Claude on p1RCC (continued)

- <u>4. Targeted therapy limitations: Traditional targeted therapies like everolimus (used in the EVEREST trial) have shown limited efficacy in papillary RCC, making immunotherapy a potentially more promising approach.</u>
- 5. Molecular basis: Papillary RCC, especially type 2, often has genomic alterations that might make it more responsive to immunotherapy.
- 6. Unmet need: Papillary RCC has historically had fewer treatment options, making any potentially effective adjuvant therapy particularly valuable.
- However, it's crucial to note that while KEYNOTE-564 shows promise, trials specifically designed for papillary RCC are needed. The PAPMET trial, though not an adjuvant trial, has provided valuable insights into treating metastatic papillary RCC, which could inform future adjuvant approaches.
- Other ongoing trials, such as those exploring combinations of immunotherapies or targeted therapies specifically in non-clear cell RCC populations, may also yield promising results for papillary RCC in the adjuvant setting.
- In conclusion, while KEYNOTE-564 shows promise that could extend to papillary RCC, the field is rapidly evolving. The most promising approach may emerge from trials specifically designed for papillary RCC or from further subgroup analyses of broader RCC trials. It's always best to consult with oncologists and keep an eye on the latest clinical trial results for the most up-to-date information.
- 2014 advice: "I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC. There will be trials w/ immune checkpoint agents in the near future but not soon enough to enroll on." 17

### Opinions from People and Machines

Question: What adjuvant clinical trial is more promising for papillary RCC and why?

Toni Choueiri: KEYNOTE-564 Trial: Patients with nonclear cell RCC (e.g. Papillary) were not included.

**ChatGPT: KEYNOTE-564 Trial**: This trial focused on pembrolizumab in high-risk RCC after surgery. The trial demonstrated a significant improvement in disease-free survival compared to placebo. While this trial predominantly involved clear cell RCC, the success of immune checkpoint inhibitors in RCC provides a strong rationale for their use in other subtypes like pRCC.

**Claude.io: KEYNOTE-564** shows promise that could extend to papillary RCC, the field is rapidly evolving.

- Now, the machines did not directly say that KEYNOTE included papillary patients, but it did infer that this trial provided evidence for including them.
- Does it?
- That is a matter for discussion with humans.

### Moderator: Unstructured

- Human tumor board members spend a lot of time explaining their positions to each other
- Can I get an LLM to Moderate the tumor Board?
  - Human Packages: Assistants API, Swarm, Playoff Prompt
- Asking LLM(s) for the Best Approach gives weasel words. E.g.

#### Prompt:

I am considering participation in the EVEREST clinical trail after a full left nephrectomy for a papillary kidney cancer.

I created a "tumor board" of 13 physicians to determine if this is a good idea. Their (numbered) responses are below.

The number is a physician id. This is followed by a "yes" or "no" as to whether I ought participate. Next is the physician "label". Finally, their rationale is included. Given this data, Please act as a tumor board moderator and tell me if I ought participate in the trial. Please include your rationale.

#### Response:....

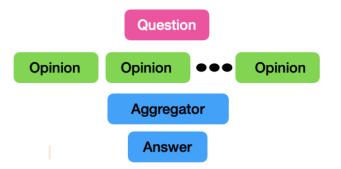
Recommendations: I encourage you to have a detailed discussion with your primary oncologist or a specialist familiar with your case. They can provide personalized guidance taking into account your medical history, current health status, and treatment goals. This conversation will help you make an informed decision that aligns with your values and preferences.

# Moderator: "Playoff"

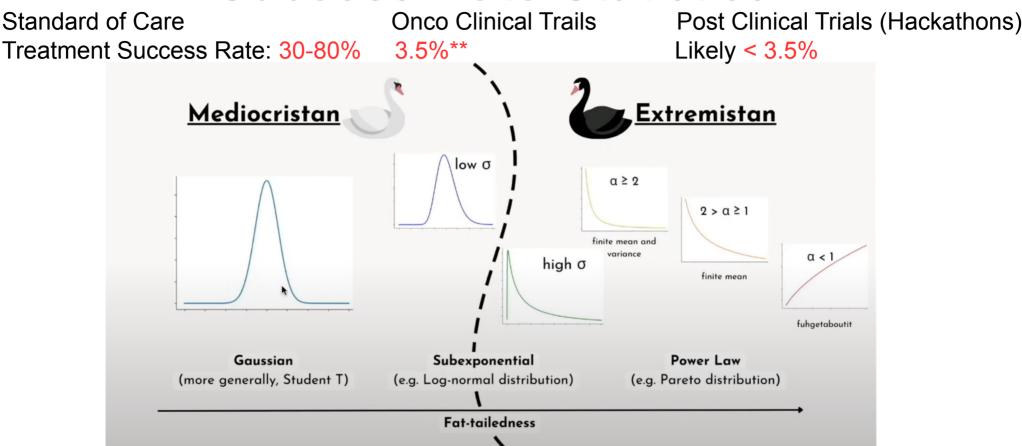
- Prompt: Create a playoff with physicians 1-5 and 7. Pair one of the 3 "yes" physicians with one of 3 "no" physicians into 3 matchups (pairs). Compare each yes/no pair and choose a winner based on how convincing their argument is. If result is unanimous (3 "yes" or 3 "no"), report it. If it is not, create two more playoffs between the minority opinion and each of the majority opinions. Report the results from each step.
- Playoff Results
  - All three matchups were won by the "No" physicians.
  - Unanimous Outcome: The "No" position prevails based on the strength and persuasiveness of the arguments.
- Conclusion: Based on this playoff analysis:
  - Recommendation: The arguments against participating in the EVEREST clinical trial are more compelling among these physicians.
  - Key Factors Influencing the Outcome:
    - Lack of Efficacy Evidence: Past trials like the ESPN trial suggest Everolimus may not be effective for papillary kidney cancer.
    - Safety Concerns: Significant potential side effects, including kidney failure, pose substantial risks.
    - Alternative Options: Waiting for future trials with more promising treatments (e.g., immune checkpoint inhibitors)
      may be advisable.
- Next Steps:
  - Consult Your Oncologist: Discuss these findings with your primary oncologist to consider how they align with your personal health situation.
  - ....

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### **Success Rate Statistics**



<sup>\*\*</sup>American Council on Science and Health <a href="https://www.acsh.org/news/2020/06/11/clinical-trial-success-rates-phase-and-therapeutic-area-14845">https://www.acsh.org/news/2020/06/11/clinical-trial-success-rates-phase-and-therapeutic-area-14845</a>

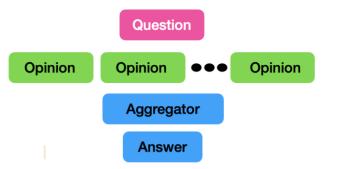
### 2<sup>nd</sup> Opinions, Portfolios & Power Laws

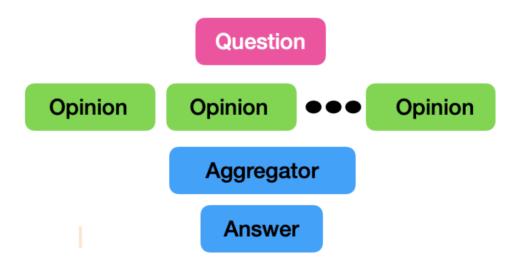
- Cleveland Clinic(\*) second opinions lead to a diagnosis change in 28% of cases. .. initial diagnosis was either incorrect or incomplete for almost one-third of patients. 72% of treatment plans are modified after a second opinion. (So) even if the initial diagnosis is correct, there may be room for improvement in the recommended course of action.
- Linus Pauling: "The best way to have a good idea is to have lots of ideas."
- Personal Finance Here is a Portfolio I created in 1997 for my son and left untouched
  - INTC, CSCO, PYPL, EBAY, MSFT
  - 47%, 103%, 128%, 209%, 2105% ← Change since 1997
- Venture Capital Portfolios https://pitchbook.com/profiles/fund/11170-18F#investments
  - Kleiner IX (formed 1999) 38 investments: 37 OK, #38 was named GOOGLE
    - "Zero to One" (Peter Thiel)
      - "The biggest secret in venture capital is that the best investment in a successful fund equals or outperforms the entire rest of the fund combined."
- Power-law distributions the largest entity is typically bigger, more valuable, or more powerful than all others combined.
- Do "Second Opinions" have a Power Law Distribution?

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Patients Clinical Trials Questions Agents Opinions Moderators

Select Patient

Bill Paseman

#### **Patient History**

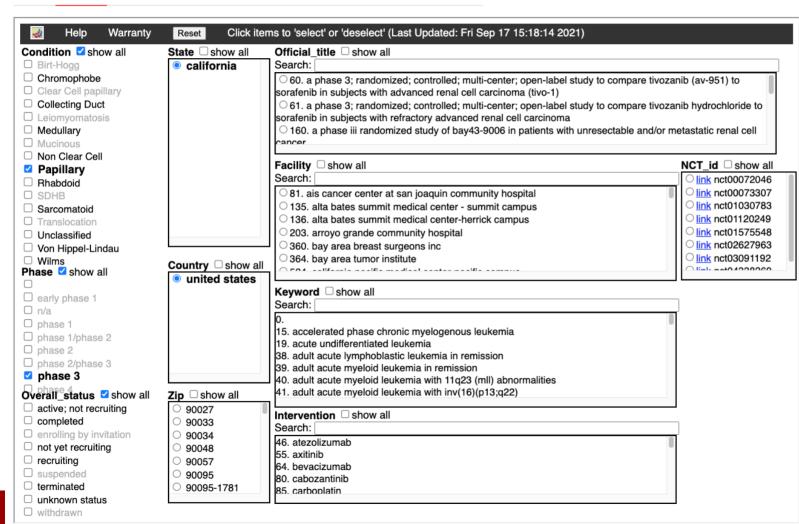
- 19920219 Unable to stand on toes of my left foot. 19860215-19920824
- 11/18/13 (San Jose, Ca) Immunized for trip to India with: Hepatitis A, Hepatitis B, IPV, Influenza, MMR, Tdap, Typhoid Live
- 11/24/13 (Baltimore, Md) DVT Symptoms first appear in left leg.
- 11/27/13 (San Jose, Ca) DVT Diagnosed; Put on Coumadin
- 2/19/14 (Baltimore, Md) DVT Symptoms reappear; Discontinued Coumadin; Put on Heparin
- 2/20/14 RCC (Renal Cell Carcinoma), Brain megioma diagnosed; Discontinued Heparin; Put on Lovenox (Started 2x80mg/day; moved to 1 x 150 mg/day)
- 20140220 Johns Hopkins: Johns Hopkins Hospital <u>Final Reports for all studies</u> page(7) brain tumor size = 1 x 1.2 x 0.8 cm
- 3/17/14 (San Francisco, Ca) IVC Filter In
- 3/24/14 Surgeon's report Total left nephrectomy
- 3/31/14 Pathology Report pT3aN0M0 RCC (stage 3, margins negative), papillary type, 5.6 cm, Fuhrman grade 2, with focal extra capsular extension.
- 4/22/14 IVC Filter Out
- 6/05/14 Chest CT, Abdomen CT clear.
- 6/12/14 DVT diagnosed as chronic.
- 6/16/14 84 days after surgery: Deadline for Everest Trial Participation (Declined. Details here)
- 7/30/14 Discontinued Lovenox, put on Aspirin (81 mg/day)
- 9/29/14 6 month Chest Xray, Abdomen CT scan clear
- 3/12/15 12 month Chest Xray, Abdomen CT scan clear
- 9/01/15 18 month Chest Xray, Abdomen CT scan clear
- 11/21/15 <u>history of My Right Foot</u> "Occlusive thrombus in the superficial greater saphenous vein extending from the knee to the thigh"
- 20151205 UCSF MR Brain with and Without Contrast Findings brain tumor size = 1.0 x 1.3 x 1.1 cm
- 3/14/16 24 month Abdomen CT scan report "Multiple subcentimeter hypoattenuating lesions in the right kidney are too small to characterize but statistically likely represent renal cysts."
- 9/01/16 30 month Abdomen CT scan report "Multiple subcentimeter hypoattenuating lesions in

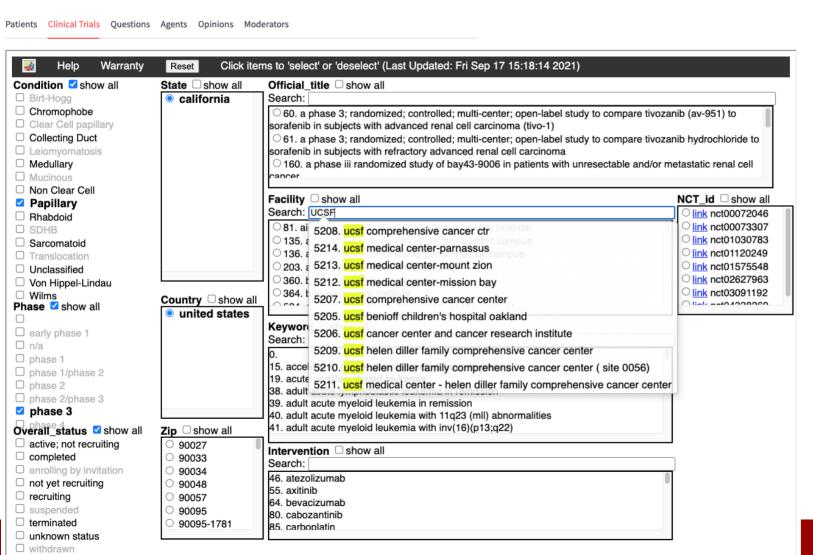
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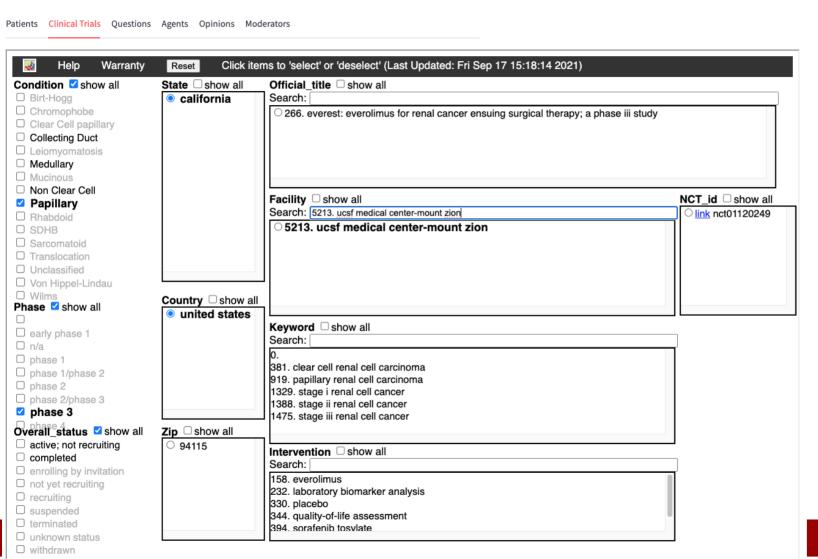
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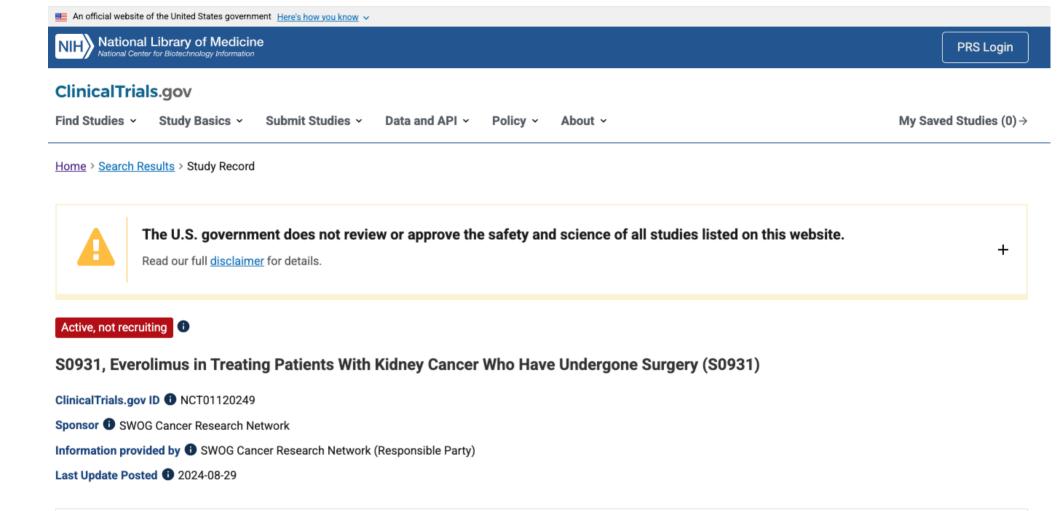
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☐ Clear Cell papillary	○ alabama	carcinoma	
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☐ Leiomyomatosis	O alberta	sorafenib in subjects with advanced renal cell carcinoma (tivo-1)	(20 )
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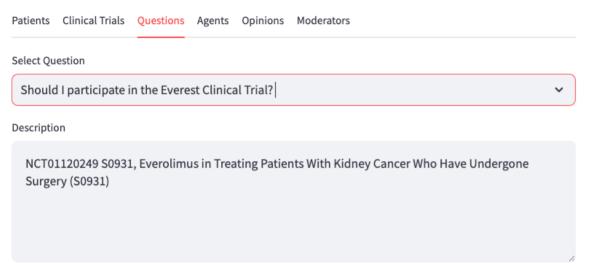






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#### **Update/Create Question**

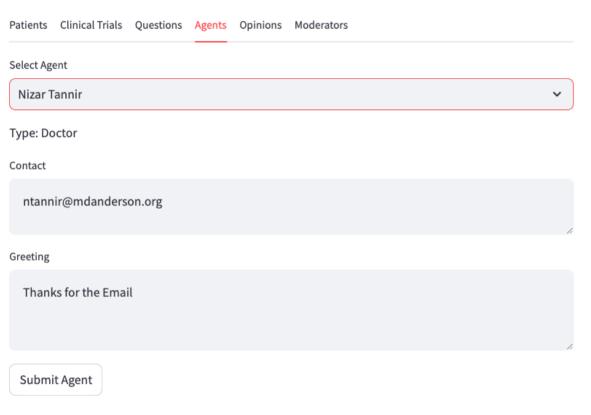
Question Text

Should I participate in the Everest Clinical Trial?

**Question Description** 

NCT01120249 S0931, Everolimus in Treating Patients With Kidney Cancer Who Have Undergone Surgery (S0931)

Submit Question



Patients Clinical Trials Questions Agents Opinions Moderators

Select Opinion

Should I participate in the Everest Clinical Trial? | ntannir@mdanderson.org | I do not recomme...

Opinion

I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC. There will be trials w/ immune checkpoint agents in the near future but not soon enough to enroll

on.

#### **Update/Create Opinion**

Opinion

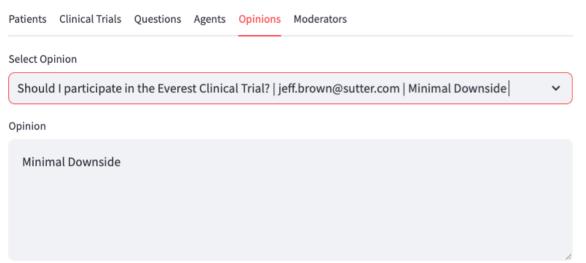
Should I participate in the Everest Clinical Trial? | ntannir@mdanderson.org | I do not recommend any ac

Opinion Description

I do not recommend any adjuvant trial w/ mTOR inhibitors or VEGF targeted agents for papillary RCC.

There will be trials w/ immune checkpoint agents in the near future but not soon enough to enroll on.

Submit Opinion



#### **Update/Create Opinion**

**Submit Opinion** 

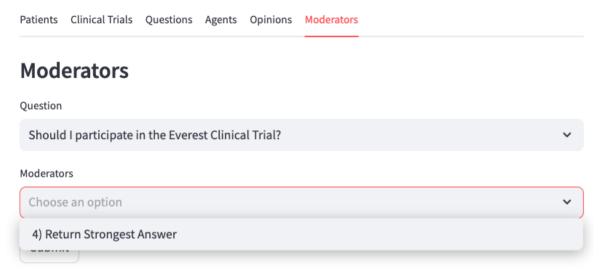
Opinion

Should I participate in the Everest Clinical Trial? | jeff.brown@sutter.com | Minimal Downside

Opinion Description

Minimal Downside

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Patients Clinical Trials Questions Agents Opinions Moderators

#### **Moderators**

Question

Should I participate in the Everest Clinical Trial?

#### Moderators

4) Return Strong... ×







#### **Opinions**

	Moderator 4	Answer	ID	Argument
0	No	Yes	Sutter	"Minimal Downside"
1	No	Yes	Stanford	"If you are eligible always a good idea to partake on trials"
2	No	Yes	Davis	"No cons other than ending up in the placebo arm or having to deal w
3	No	No	Los Gatos	"Kidney cancer has had no successful treatment (e.g. radiation, chem
4	No	No	MD Anderson	Nizar Tannir: "I do not recommend any adjuvant trial w/ mTOR inhibit

#### **Answers**

	Moderator	Answer	IDs	Argument
0	4	No	MD Anderson	Nizar Tannir: "I do not recommend any adjuvant trial w/ mTOR inhibitor

### **Final Word**

"If you work on frequent cancers, do randomized trials! If you work on rare cancers—find friends!"

Olson, TA, Schneider, DT, Brecht, IB, et al.

If you want to help improve rare disease treatment options, contact

Bill (bill@rarekidneycancer.org)
Pete (pete@researchtothepeople.org)

### Could we automate this?

- Alexander's Disease https://www.youtube.com/watch?v=tAP1eZYEuKA
- Castleman's Disease https://cdcn.org/leadership-team/david-fajgenbaum/
- ADNP https://adnpkids-researchfoundation.org/bedrosian-sermone.html
- NF2 https://www.linkedin.com/in/onnofaber/

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