



Clinical Trials – Why Not?

Slightly Radical Thoughts from the Patient and Advocate Perspective

October 11, 2019

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Board Director, International Kidney Cancer Coalition

My COI Disclosure

LIFE	Kidney Cancer
1960	
Localized (14)	1974 Nephrectomy
Metastatic (36)	1996 Surgery x 2
	1999 Surgery
	2004 Surgery
	2006 Nexavar trial
	2007 Surgery
	2009 cMET trial NIH
	2015 SBRT x 1
	2018 Surgery
	2019 Surgery; SBRT x2; OCTANE, InSight studies



COI: \$0 Industry Funding Personally
My COI: Trying to Stay Alive with QoL

Clinical Trials: Walking the Talk...

1. Personally have been on two interventional clinical trials: PMCC; NIH; several genetic studies (GENIUS, INSIGHT, OCTANE)
2. Patient Advocate on NCI Renal Task Force; Patient Advocate Steering Committee at NCI:
 - NCI Renal Task Force: Deb Maskens, Susan Poteat
 - GU Steering Committee: Dena Battle
3. Passionate about moving cancer research forward through clinical trials... and for patients to play an active role in their own healthcare journey

Mantra: “Nothing About Us. Without Us”

Today: Vision of Hope

1. Share patient perspective from clinical trials – lessons learned & “secrets” ...
2. Today’s clinical trials – and Why Not? Accessing tomorrow’s treatments today
3. Beyond today – How WE become part of the pathway to better treatments for all.

Patient Perspective

Lessons learned: Your doctor does not know everything.

1. The Importance of an Expert TEAM Approach for Kidney Cancer:

- Medical experts with various specialties (MDT)
- Great nurse
- Psycho-social support
- GP, family doctor
- Advocate / Patient Organisation
- You.

The most important person on the team is YOU!

- What is your role as the patient?



Patient Perspective



2. The Importance of Shared Decision Making:

This Means:

- You (or your advocate) need to understand:
 - Your individualized diagnosis – subtype, stage, grade, etc
 - The best evidence about various treatment options for that specific diagnosis
 - Clinical trial opportunities you might be eligible for

Together with your doctor(s), you make a decision that is informed and the right decision for YOU.

TIP: “I’m the kind of patient who wants to be involved in making the decisions about treatment...”

TIP: “These are my personal goals and expectations...”

Patient Perspective

3. Your Role as Information Broker: “Everything About You”

Until we all have system-wide electronic records:

- You or your advocate keep track – especially important when crossing institutions, seeing multiple specialists
- Keep a file/binder with everything in one place
- From time to time, summarize timeline...

TIPS:

1. **GATHER:** “Can I have a copy of that please?”
2. **ACCESS:** Patient portals to access what you can online
3. **PREPARE:** Optimize your appointment times:
 - Information you need to share since last visit
 - Questions about now, next steps ahead



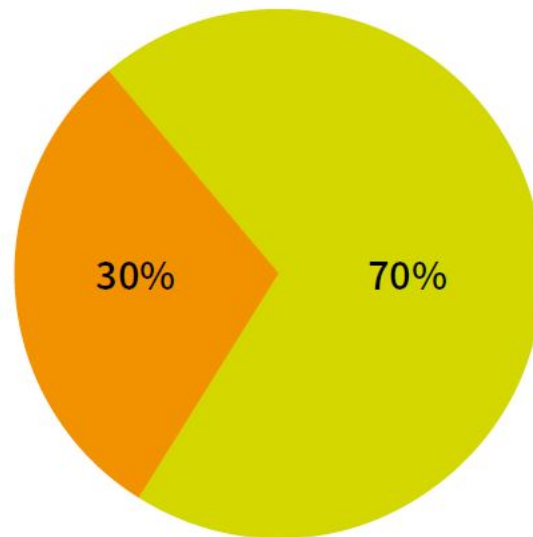
Patient Perspective... re Trials



- Will think about a trial after all other options are exhausted:
- Prefer Approved; “Standard of Care”; FDA Approved!
- Fear placebos, extra tests, procedures, lack of choice
- In U.S: Can mimic trial off-label (!) ...

- Other barriers?
 - Location, convenience close to home
 - Finances \$\$\$
 - Your current physician...?

*IKCC Global
Patient
Survey 2018
n=2000*



70% of patients had never been asked to participate in a clinical trial.

Of those, **89%** said it was fairly likely they would have participated if they had been asked.

45% of these patients were being treated in a major cancer centre and **37%** at a local or community hospital.

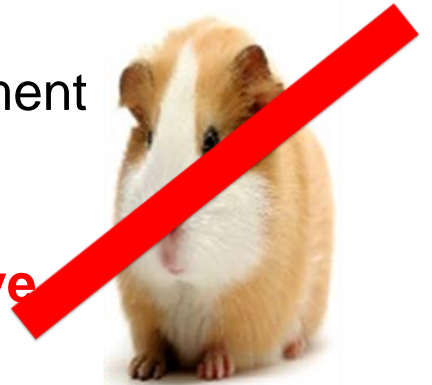
Patient Perspective... Why Trials 1st?

ASK Early: Is a Clinical Trial Right For Me?

Facts:

- Patients treated at centers with clinical trials survive longer!
- Yet, only 3% of patients with cancer in U.S. participate in clinical trials
 - Less than 10% of those from racial or minority populations
- LEAPFROG strategy:
 - Chance to access tomorrow's treatments today
 - A chance to access treatment 5 yrs+
 - ++ Expert team; expert resources; careful management
 - ++ Altruism: help fellow patients

TIP: The earlier you ask, the more options you'll have
Everyone loves a "treatment naïve" patient!



Patient Perspective... Finding Trials

Why is it so hard to FIND a Clinical Trial You Can Participate In?

1. Your doctor(s) may not know about all available options outside of their institution
>250 studies currently recruiting RCC patients in USA alone
2. You can do your own research – or ask for help!
Patient organisations, patient advocates
Websites: clinicaltrials.gov; cancer.gov (NCI)
Services that match patients to trials
- Caution re: company-sponsored sites
3. Eligibility requirements...

Tip: Whenever there's an upcoming treatment decision/change... Periscope UP (look around, evaluate your options)



Questions to Ask About Trials

1. What is the primary Question this trial seeks to answer?
2. What is the Standard of Care outside of the trial?
Is this option one of the arms of the trial?
3. What Phase of the clinical trial is it?
What were the results of the prior phases?
Is it a randomized trial?
4. What are the Side Effects expected from each arm?
5. What will the trial measure? Will it record my QoL?
6. What extra tests/other burdens might I face?
7. What are the risks?

AND: “Why do you think this trial might be a good option for Me? Why Now?”

Patient Perspective... Secrets Shhhh....

- Not all clinical trials are created equal...
- Your Participation is Entirely Voluntary
Means: You can Withdraw at any Time...
- You can negotiate some (not all) aspects (Ask!)
- Trials give you Access, Expert Care & Careful Monitoring
– patient satisfaction with care on trials is very high
- Controversial:
 - Randomized, Double Blinded?
 - Interaction amongst clinical trial participants?

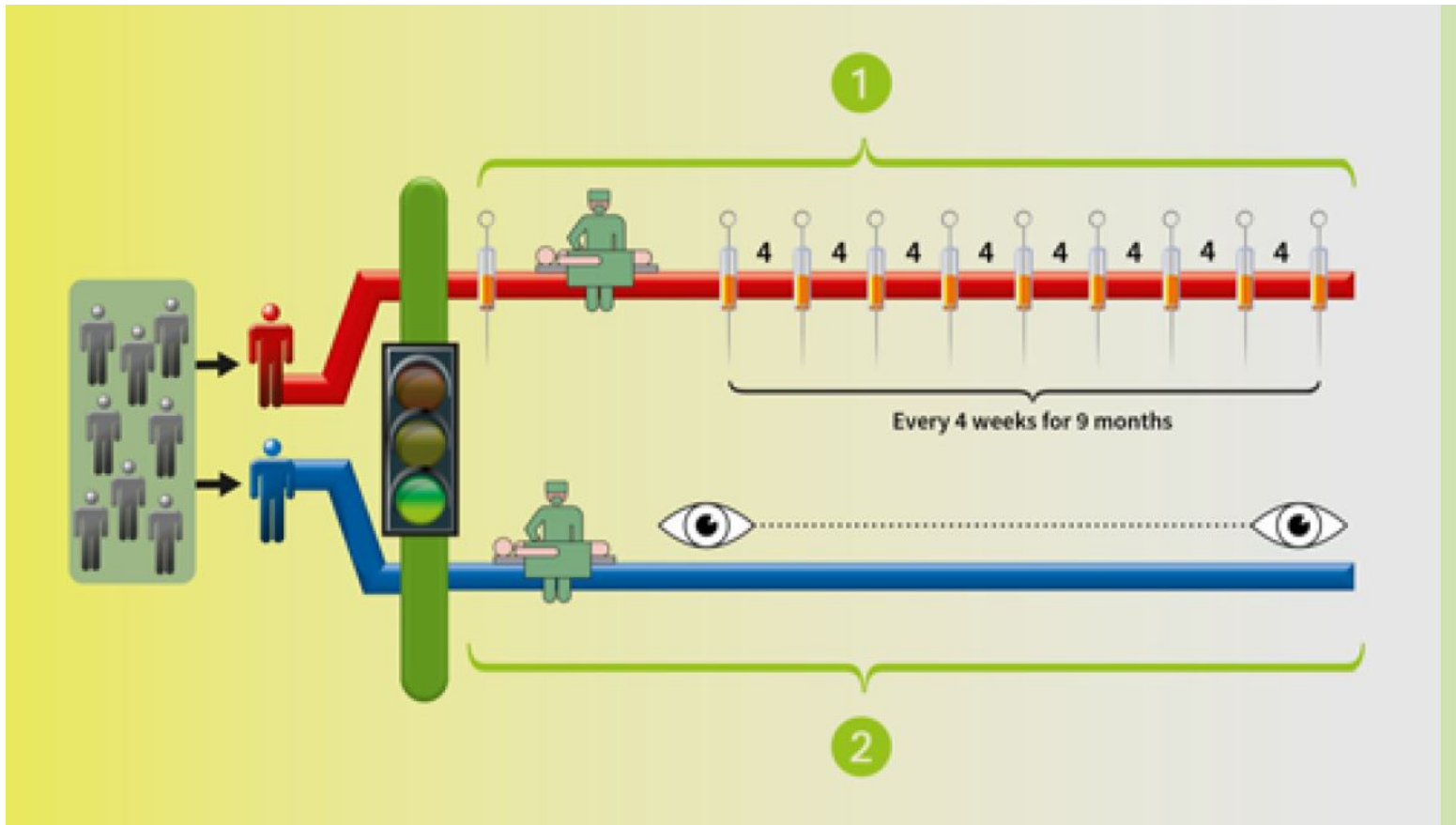
How Can We Work to Make Trials Better for Patients?

Clinical Trial designs with patient input from the beginning
Means we might disagree sometimes:

- Trials find patients automatically (e.g., Rare RCCs)
- Trial design: Patient interests come first
- e.g., No to intravenous placebo (adjuvant)
- Allow cross-over from control arm if progression
- Meaningful Patient Reported (Relevant) Outcomes
- Capture Patient Preferences, all-grade Ses
- No financial burden. Cover travel/incidentals.

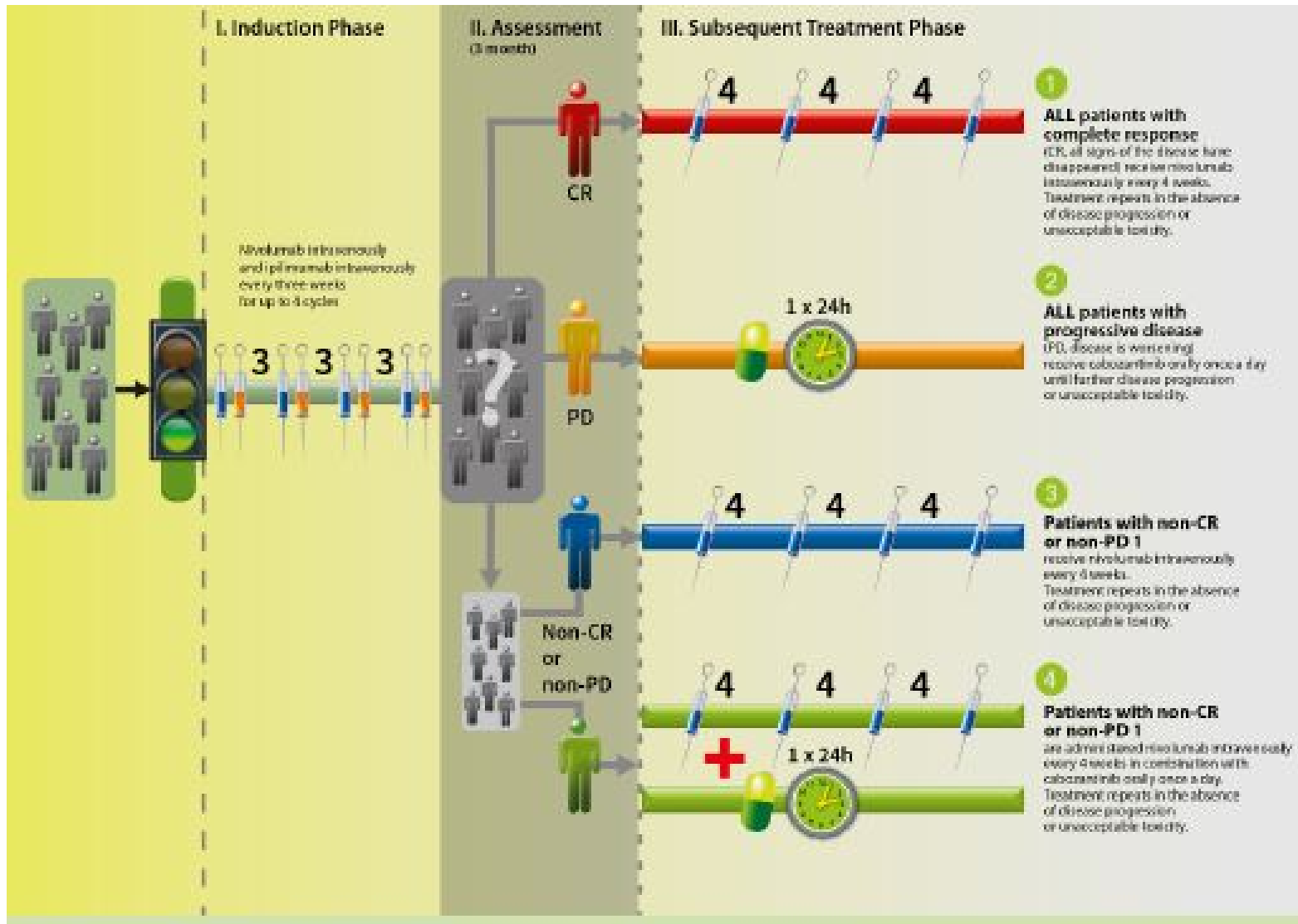
These patients are our HEROES. Make it easy for them to participate as real world human beings.

Example of Phase 3 Clinical Trial at Diagnosis



PROSPER-RCC; Neoadjuvant and Adjuvant IO vs SOC

Example of Phase 3 Trial mRCC 2 Lines



Take-away points for Patients:

- Think of clinical trials at every step of the patient pathway:
 - From 'possible RCC' – Is there a trial for me?
 - More options! Potentially better outcomes.
- Find out about clinical trials beyond your local medical center
 - Can you refer me? *Rare RCCs especially!
- Become part of the movement to improve outcomes for all:
 - Kidney cancer research needs you!
 - Current treatments are not where we need to be
 - Help others; possibly help yourself; leapfrog forward
- How Can We ALL help to champion clinical trials for kidney cancer? It CAN be done!

Inspiration – UK Quadrupled Cancer Trial Participation from 1:26 to 1:6 in 10 years

“With more patients in clinical trials than ever before, we can now look forward to reaping the benefits of new and exciting developments in diagnosing, preventing and treating cancer.

“Importantly, these figures demonstrate the huge enthusiasm and willingness of British people.” **to participate in research that could potentially lead to life-saving new treatments in the future**

NCRI UK; Prof David Cameron Nov 2010

Closing Quote:

“I have learned this one undeniable truth: for all the studied intellect of doctors, and the incredible array of diagnostic testing by which they can refine their hypotheses, **there is no force in medicine more positive and powerful than the self-advocating patient.**”

- Mark A. Lewis, M.D. @marklewismd



Thank you!

- THANK YOU!

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