Presenter Disclosures:

- I have no conflicts of interest or disclosures to make.

WRH Cancer Program

Clinical Trials in GU Oncology

How do we choose them?

- The selection process of a clinical trial for a site is intensive; even more so in the last 5 -10 years where clinical research departments no longer have external support or funding; they must be self-sufficient

- Feasibility reviews must include a budget review and cost consideration

- At our centre the oncologists bring forward new clinical trials they wish to open to a Protocol Review Meeting
  - Reviewed and advocated for
  - Trials are prioritized by physicians
  - Further feasibility is done by CT office
- As with most clinical research departments, our limiting factor for the number of studies open is trained staff

How can Physicians and Patients find Trials?

- Clinical Trial participants must be enrolled and treated by an investigator on the trial
- This usually means referring to a centre that has the trial open to recruitment
- You can search for your patient using www.ontario.canadiancancertrials.ca or www.clinicaltrials.gov

NEW SERVICE
CLINICAL TRIALS NAVIGATOR

- There is now a new service, homegrown in Windsor and soon to be available at all Ontario Cancer Centres: the Clinical Trials Navigator
- This is a shift in thinking from getting a patient on a trial at your centre, to getting a patient on any trial anywhere
- Contact information:
  - Youshaa El-Abed, CTN 519-253-3191 x58583
  - clinicaltrialsnavigator@wrh.on.ca

- Most Cancer Centre Research Departments have a website listing their currently recruiting trials
  - Call the Clinical Research Department to confirm trial is open and any details of eligibility (*Our CT Navigator does this step)
  - Ensure referral to that Cancer Program specifies for the trial – best if know which investigator to refer to

General Information for Patients

- There are a lot of initiatives to provide better information for patients to understand Clinical Research

- N2 (Network of Networks) has launched a patient-oriented campaign which includes a website about participating in Clinical Trials
- www.itstartswithme.ca

WRH Cancer Program
GU Trials

- **PCS VI** - Phase III Study of Hypofractionated, Dose Escalation Radiotherapy vs. Conventional Pelvic Radiation Therapy followed by High Dose Rate Brachytherapy Boost for High Risk Adenocarcinoma of the Prostate
- Sponsor: GROUQ – Group of Radiation Oncologists in Urology in Quebec

- Primary Objective: To determine the acute and delayed toxicities of the pelvic IGRT with prostate HDRB boost as compared to the hypofractionation regimen in high-risk prostate cancer patients treated with 3D-CRT or IMRT using IGRT to the prostate and pelvic lymphatic chains, in a randomized fashion.
- **Please remember if you have a patient in this group, to not start them on hormonal therapy as this makes them ineligible for this trial

COMING SOON….
REC.4

- A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)

Patient presents to urologist with clinical stage ≥ T2Nx or TanyN+ RCC requiring nephrectomy; initial interest in trial

- Referral to Med Onc prior to booking surgical date
- Notification to Clinical Trial Team (contact/forms provided)

1 week

Patient consents with Clinical Trials and is Registered to Step 0 (Biopsy Randomization, Arm H or Arm O)

- If biopsy already done within previous 12 months nothing additional required
- If biopsy not done and randomized to Arm H patient proceeds for biopsy

~3 weeks

Eligibility assessments are performed in preparation for Step 1 (Study Randomization)

- Med Onc and Clinical Trials perform baseline eligibility assessments followed by randomization if not screen failed
- e.g. study labwork, QOLs, ECOG, imaging

Randomization to Arm A (neoadjuvant nivolumab + nephrectomy + 9 adjuvant cycles nivolumab)

1 week

Nivolumab 480mg IV x 1 dose

7-28 days

Nephrectomy (radical or partial)

4-10 weeks

Nivolumab 480 mg IV q 4 weeks x 9 doses (to week 40)

Randomization to Arm B (nephrectomy + observation)

< 8 weeks

Nephrectomy (radical or partial)

Observation (to week 40)

Ultimately it has been shown that ALL patients, irrelevant of their personal participation in clinical research, will have better outcomes and live longer when their treating institution runs clinical trials.