Clinical Trial Design in the Era of Genomic Medicine

Research Advocacy Network
Symposium for Advocates
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Connie Szczepanek, RN, BSN
Patrick Gavin R.Ph.
Grand Rapids Clinical Oncology Program

Conflict of Interest Statement

We have no conflicts of interest to disclose

Grand Rapids Clinical Oncology Program

A Consortium Approach

Funded by a National Cancer Institute CCOP Grant since 1983 and the following

Consortium Members

1. Bronson Battle Creek
2. Mercy Health Muskegon
3. Mercy Health Saint Mary's
4. Michigan State University College of Human Medicine
5. Munson Medical Center
6. Spectrum Health Hospitals
7. Spectrum Health Reed City
8. Van Andel Research Institute
9. West Michigan Cancer Center

Affiliate Member

10. Spectrum Health Big Rapids Hospital

Patient Advisory Board for Clinical Research

Established May 2008

Cancer Clinical Trials…

WE HAVE
Real Answers, Real Options, Real Miracles
Right here in our community!

…Hope for the Future

Grand Rapids Clinical Oncology Program (CCOP)

Clinical Trial Design in the Era of Genomic Medicine

- Historical view of clinical trials
  - Very few drugs to choose from
  - Terrible side effect profiles
    - We didn't have much to help
  - What we had didn't work very well

Clinical Trial Design in the Era of Genomic Medicine

- Trials in the 1990s and early 2000
  - Almost an explosive number of new drugs
  - Much stronger emphasis on helping patients deal with the side effects of the drugs
  - Roll out of many large Phase III trials
  - We saw significant improvement in survival rates of many cancers
    - Leukemia
    - Breast
    - Prostate

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- What is happening today?
  - Drugs are getting to be more patients specific
  - Everything is about DNA
  - Movement from many large Phase III trials to smaller and more focuses phase II trials
  - Patients have moved from being "subjects" to a more involved role of "participant"
  - Patient Reported Outcomes (PROs) and Quality of Life Assessment now becoming more of the norm rather than the exception.

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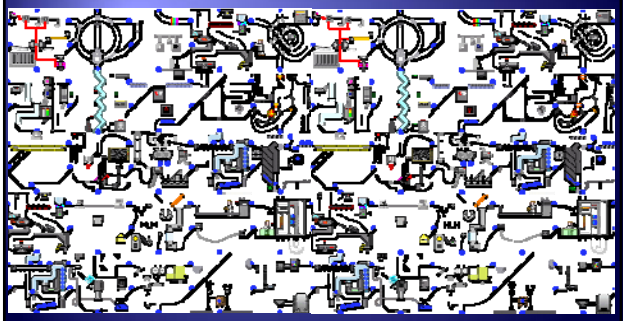
- Tomorrow-The economics of Healthcare
  - How will we fund everything we need to do in the community?
  - How can we make this affordable for the patient?
  - How do we communicate to patients?
    - Revised Informed Consent documents
    - Required publishing of all study results
    - Plain language summaries

Real answers, real options, and real miracles ….
here in our community!

11

Patients adding value



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- How can the Cooperative Group advocates help us?
- 1. Standardization
  - There are no standards between cooperative groups today (forms, formats reports, descriptions)
  - A common look for trial info would help patients as they do their search on clinical trials.gov etc

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- 2. Patient friendly concept information
  - A. What is the trial about?
  - B. What do I need to do to qualify?
  - C. What will be expected of me if I participate? (biopsies, scans etc)
  - D. What should I ask my doctor?
  - E. What will we learn in this trial
  - F. Plain language summaries (*yea* for Deb Collyar!)

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- 3. Patient directed "educational material"
  - IRB ready
  - Handouts for cancer centers, doctors offices, patient gathering replaces
  - Social Media ready information to be posted by trial sites or support groups
  - Pre-written email solicitations

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- 4. A meaningful Accrual Plan
  - Research advocates should be asking questions about the ability of this trial to hit required accrual numbers.
  - Pat's favorite questions to P.I.s
    - "Why would my doctor recommend I participate in this trial?"
    - Why should I participate?
  - Identify why patients won't participate
    - Randomization, invasive tests etc.

Outreach to Patients

www.grcop.org

http://www.lymphomation.org/

www.cisncancer.org

www.allianceforclinicaltrialsinoncology.org