NCI PGx Workshop

Bethesda MD

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- Identify infrastructures, resources, and pressing clinical issues, as well as current limitations that need to be addressed to advance cancer pharmacoepidemiology and pharmacogenomics research.

Infrastructure

- Support for training a new generation of scientists trained in epidemiology, pharmacogenomics and clinical therapeutics
  - Not T32 but integrated into multidisciplinary oncology pharmacogenomics research centers.
- Support for collection, transport and extraction of DNA from all trials independent of an individual specific hypothesis.
- Support for highly collaborative multidisciplinary groups to carry out the pharmacoepidemiologic pharmacogenomic research needed outside RPCTs. Access to quality medication and phenotypic outcome data key.
  - Database access with cancer outcomes
  - Toxicity outcomes
  - Highly Granular Medication Data
    - E.g. Marshfield, Regenstrief, Mayo, Vanderbilt, Medco

Resources

- Access to cores able to carry out Next Gen Sequencing
- Support for the final stages of moving tests to clinic

Pressing Clinical Issues

- Economic Consequences of Pharmacogenomic Testing in Different Resource Environments:
  - Need to demonstrate substantial cost savings may be most evident with biologic pharmacogenomics.
- Performance of pharmacogenomic and genetic tests outside the RPCT environment in the real world.

Where we need to go next
An Integrated Approach that Addresses:

- Clinical Practice

Requires Integration of clinical and biomarker data into clinically meaningful, easily communicable "indices" validated in large retrospective datasets or randomized trials
  - E.g. Oncotype Dx™ +
  - Mammoprint™ +
  - CYP2D6, UGT2B7, ER +
  - TPMT +, UGT1A1 +

Requires high sensitivity and specificity:
  - Next Gen Sequencing for relatively rare variants
  - Improved specificity using pattern recognition informatics

Where we need to go next

Clinical Pharmacology in Large Datasets

- Careful characterization of drug effect and toxicity
- Careful medication data collection
- Adherence research and the effects of genomics on adherence

- Integration with Basic pharmacology:

Pathway analysis to identify variants relevant to drug development and most likely worth testing in RPCTs and large datasets.