Myeloid Malignancies
Precision Medicine Initiative

NCI National Clinical Trials Network

NCI MDS Symposium
June 12, 2019

Rich Little
DCTD/NCI
MMPMI: Aims

• Advance therapeutics and improve the health outcomes of Americans with myeloid malignancies through a new collaborative precision medicine model

• Characterization of leukemia biology at the time of relapse, long term remission and refractoriness.
  • Describe and exploit clonal selection related to therapeutic sensitivity and resistance

• Development of a data commons for the longitudinal collection of data on patients through their entire treatment course.
MMPMI: Aims

- Create a clinical trials portfolio and operational model attractive to industry partners and NCTN sites
- Development of an IND structure and CRADAs for the regulatory management of this initiative.
- Develop the careers of young investigators by promoting leadership throughout the clinical trial portfolio and laboratory program.
Myeloid Malignancies PMI Structure

Senior Leadership Council

Agents and Genes Working Group
Laboratory Assays Working Group

Screening Master Protocol
Laboratory Coordinating Committee identifies essential screening tests and specimen banking requirements

Less Fit | More Fit | MDS | Fit/Young

Screening Master Protocol
Assessment of patients at end of protocol therapy, evaluating clonal evolution and characterization for sensitivity and resistance to therapy

Data Commons
Clinical Baskets Working Group

• Chairs of Clinical Working Groups:
  • Older Less Fit Working Group- Laura Michaels (SWOG)
  • Older More Fit Working Group- Geoff Uy (Alliance)
  • MDS Working Group- Olatoyosi Odenike (Alliance)
  • AML & AYA Working Group- Ehab Atallah (EA)

• Chairs are responsible for the organization of committees
• Recording meeting minutes
• Informing the Senior Leadership Council of progress in developing specific clinical trials
• These activities are supported by the coordinating group for each basket
MDS Working Group Members

• Alliance:
  o Pankaj Gupta
  o Coleman Lindsley
  o Toyosi Odenike
  o Vivien Yin
  o Rich Stone

• ECOG
  o Amer Zeidan
  o Steve Gore

• SWOG
  o Hetty Carraway
  o Guillermo Garcia-Manero
  o Rami Komrokji
  o Mikkael Sekeres

• Canada Clinical Trials Group
  o Rena Buckstein
Future Vision

Master
Initial Screening

SWOG
Older Less Fit Basket

Alliance
Older Fit & MDS Basket

ECOG-ACRIN
Younger Adult Basket

COG
AYA Basket

Suite of studies for initial therapy
(induction, consolidation, transplant)

Master
Treatment Failure Assessment and Next Protocol Screening

Suite of studies for first treatment failure and beyond
(novel targets, biologics, genomics-based)

A national resource of annotated specimens and bioinformatics to facilitate understanding treatment failure and overcoming resistance to therapy
Precision Medicine Analysis and Coordination Center

- Working with NCI Center for Bioinformatics and Information Technology to develop an IT infrastructure that will store, retrieve and interpret data across protocols and groups.
- Establish and maintain a controlled-access website for the Network to provide information about the resources available within the Network.
- Develop a web resource for rapid data exchange and electronic communication across the Network.
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  - Soheil Meshinchi
  - Todd Cooper
- BMT CTN
  - Fred Appelbaum
- CCTG
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  - Sarit Assouline
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