Getting Ready for Engineered Cell Therapies: an administrative perspective

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Goal of this Presentation

Discuss an approach to establishing an engineered cell therapy administrative infrastructure

a) To support quality and risk management

b) To engage clinical programs not familiar with cell therapies

c) To adapt certain existing processes that support HSCT
February 2017 – Where are we?

The variety of new non-stem cell products poses an administrative challenge to cancer centers

• Lots of trials
• Lots of complexity and risk
• FDA approvals on immediate horizon
Taxonomy of Cell Therapies

Oncology Related Cell Therapies
- Hematopoietic Stem Cell Transplantation (HSCT) auto or allo
  - Auto
  - URD
  - MRD
  - Haplo
  - UCB

Non-Stem Cell based Cellular Therapy
- Stem Cell Boost
- Minimally Manipulated Lymphocytes
- Modified Lymphocyte Therapies
  - No Genetic Engineering
    - DLI
    - TILs
    - NK Cells
  - Purified T Cell Subsets
  - Antigen Directed CTLs
  - CIKs
  - Genetically Engineered T Cells
    - TCR transduced T cells
    - Suicide Gene Containing T cells
  - CAR T Cells
- Tumor Vaccines
  - Autologous tumor cells plus genetic engineering
  - Antigen Loaded Dendritic Cells
  - Other
- Provenge

Non Oncology Cell Therapy
- Mesenchymal stromal cells
- Manipulated non-hematopoietic stem cells
  - Limbal Stem Cells
  - Induced Pluripotent Stem Cells

Other
- Minimally Manipulated Lymphocytes
- Standard of Care
- Experimental
- Breakthrough

DANA-FARBER CANCER INSTITUTE
Fast uptick in numbers and variety of IEC trials

- Wide range of immune effector cell (IEC) trials
- Transplant plus other cell therapy combination trials
- Transplant replacements
- Solid tumor trials moving forward
At DFCI:

1. Organization not yet ready to establish separate new program
2. Very supportive organizational leadership
3. HSCT program structure available to lean on
4. Experienced leukemia program were early adopters
5. Cellular product manufacturing and processing capability
Approach at DFCI – Build a Strong Transition Plan

1. CMO involved to lead oversight of effort
   • The CMO is not a cell therapy MD – future treatments will go beyond hematologic malignancies

2. Experienced, skilled project manager assigned
   • Key role dedicated to effort
   • Additional PMs added on part-time basis
PM interviewed internal stakeholder and content experts across the care spectrum, disciplines, operational units

- Trial design
- Patient and clinician teaching/staff preparation
- Inpatient/outpatient care
- Communication and scheduling
- Resource capacity
- Quality management
- Financial clearance
- Data reporting
Organizational structure set up to support initiative

**Engineered Cell Therapy Steering Committee**

- **Trial Review Board**
  - Trial review
  - Trial initiation policies

- **Financial Workgroup**
  - Authorization
  - Payer Policy & Reimbursement

- **Cell Collection & Manipulation Workgroup**
  - Logistical review of ongoing and new trials
  - Resource scheduling

- **In/Outpatient Clinical Workgroup**
  - Communication methods, clinician training, clinical care, Epic build, pharmacy
Looked for affinities among variety of new products and treatments

1. Common risks and standards – clinical and financial
2. Standard workflows from pre-trial development through implementation
3. Defined leeway for variation and innovation
4. Start work on operational model to support FDA approval
Guiding principles and working assumptions

**Guiding Principles**

- Patient safety is paramount
- Each trial is unique
- Take advantage of existing processes and functions
- PIs have direct and immediate responsibility for clinical care and management

**Working Assumptions**

- HSCT and Leukemia services and infrastructure will be drawn upon as appropriate
- Care will be localized among select outpatient and inpatient teams to consolidate expertise
- Space, volume, capacity, and resource needs will be reevaluated continuously

Special attention to support disease programs not familiar with cell therapy operations
Trial Review Board

1. Meets as needed (every 2-3 months)
2. Investigators present trials for input and approval
3. Planning discussions about capacity, staffing
4. Review outcomes and events
5. Intranet tools developed to support trials

Engineered Cell Therapy Trial Startup Kit

- Trial Activation Workflow
- PowerPoint Template for presenting to the Trial Review Board
- PI and Trial Team Checklist
- Clinical Communication Guidelines
- ECT Epic Toolkit
Cell Collection & Manipulation Workgroup

• Meets every 2 weeks
• Logistics and feasibility of products, scheduling, capacity
• Trial design support relative to products
• Time from collection to infusion is +/- 2 weeks
  - Can collection happen closer to home?
  - NMDP donor centers as possible sites of collections?
• At DFCI a single apheresis scheduling unit was developed for all cell therapies and research across organization – linked to cell processing schedules
In/Outpatient Clinical Workgroup

- Meets weekly – review all active patients
- Clinical pathways, risk management, quality plan
- Dissemination of communication protocols, work flows and procedures across hospital units and clinics, admitting staff, ICU physicians, and pharmacy staff
- Localization on specialized teams
- Order sets and immediate care escalation plan
• Multiple scheduling systems from manufacturers
• New CIBMTR forms
• EHR set-up: order sets, algorithms, documentation templates
• DFCI incorporated IEC into the existing HSCT case management system, Epic interface, and reports
Financial Workgroup: many questions still open

- What CPTs to use?
- Global network contracts? Case rates?
- Product charged to provider as a drug?
- Apheresis included in drug charge?
- How will narrow networks handle this?
- Will these therapies initiate value based payment models?
Other important tasks underway

- Patient and staff education tools
- Review of ethical considerations
- Prepare for FACT accreditation
- Housing for treatments with longer risk periods
Summary - What are the big issues as of now?

**Access**

- Expensive - Not yet clear how financial risk will be shared among payers/networks, providers/hospitals, manufacturers
- Capacity – limited inpatient and apheresis beds; need for patient and caregiver housing
- Limited sites with capability to deliver therapy

**Complexity**

- Logistically complicated in context of high risk
- Clinical teams unfamiliar with cell therapies will need support

It’s time to get ready!
Project Team (does not include everyone involved!)

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