Penn Medicine

Cell Therapy and Transplant (CTT) Program

CARs Cruising Down the Highway: From Academic to Community

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Administrative Director

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Biography

20 years in oncology

- 16 in private practice (Cherry Hill, NJ)
  - IT Manager, Practice Administrator, COO, CIO (RCCA)

- 4 with Penn Medicine
  - Integration Executive
  - Current Position: Administrative Director, Cell Therapy and Transplant (CTT)

Education

- BS – Information Technology
- MS – Business Intelligence (Data Analytics)
- MBA

Committees/Consulting/Advisory Boards

- Kite, Novartis, BMS, Iovance, Janssen
- Association of Community Cancer Centers – CAR T in the community setting
- ASTCT (Admin SIG, Liaison to Cell Therapy Committee)

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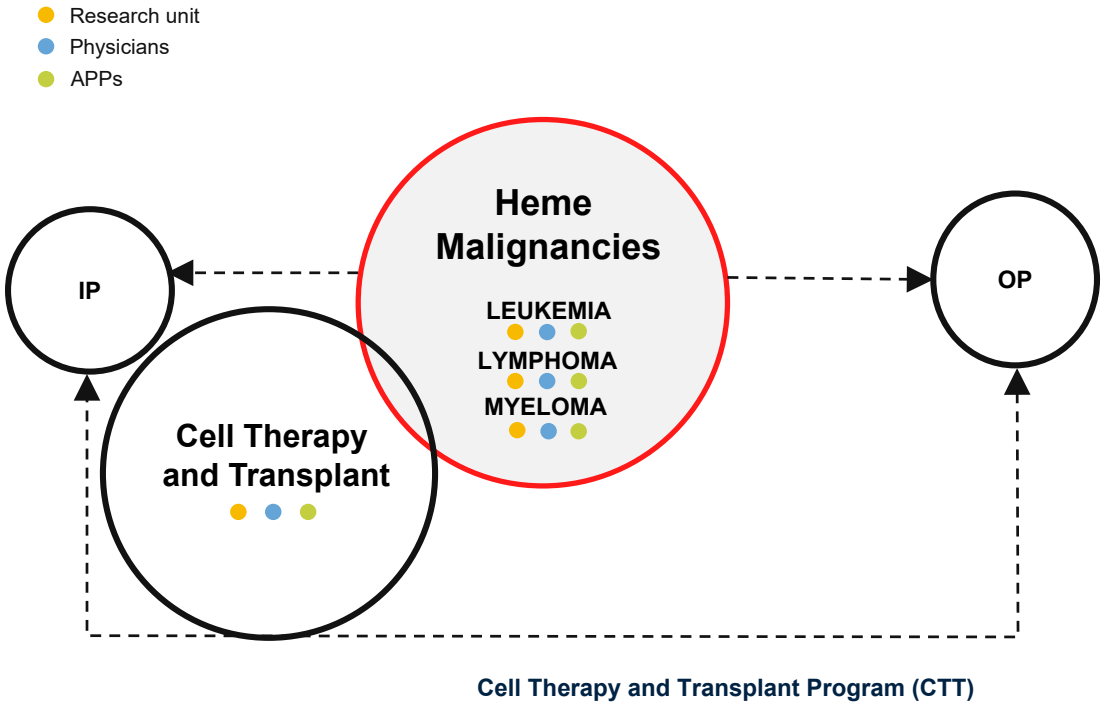
Penn’s Cell Therapy and Transplant Program (CTT)

University of Pennsylvania CTT Program

CTT Overview and Purpose

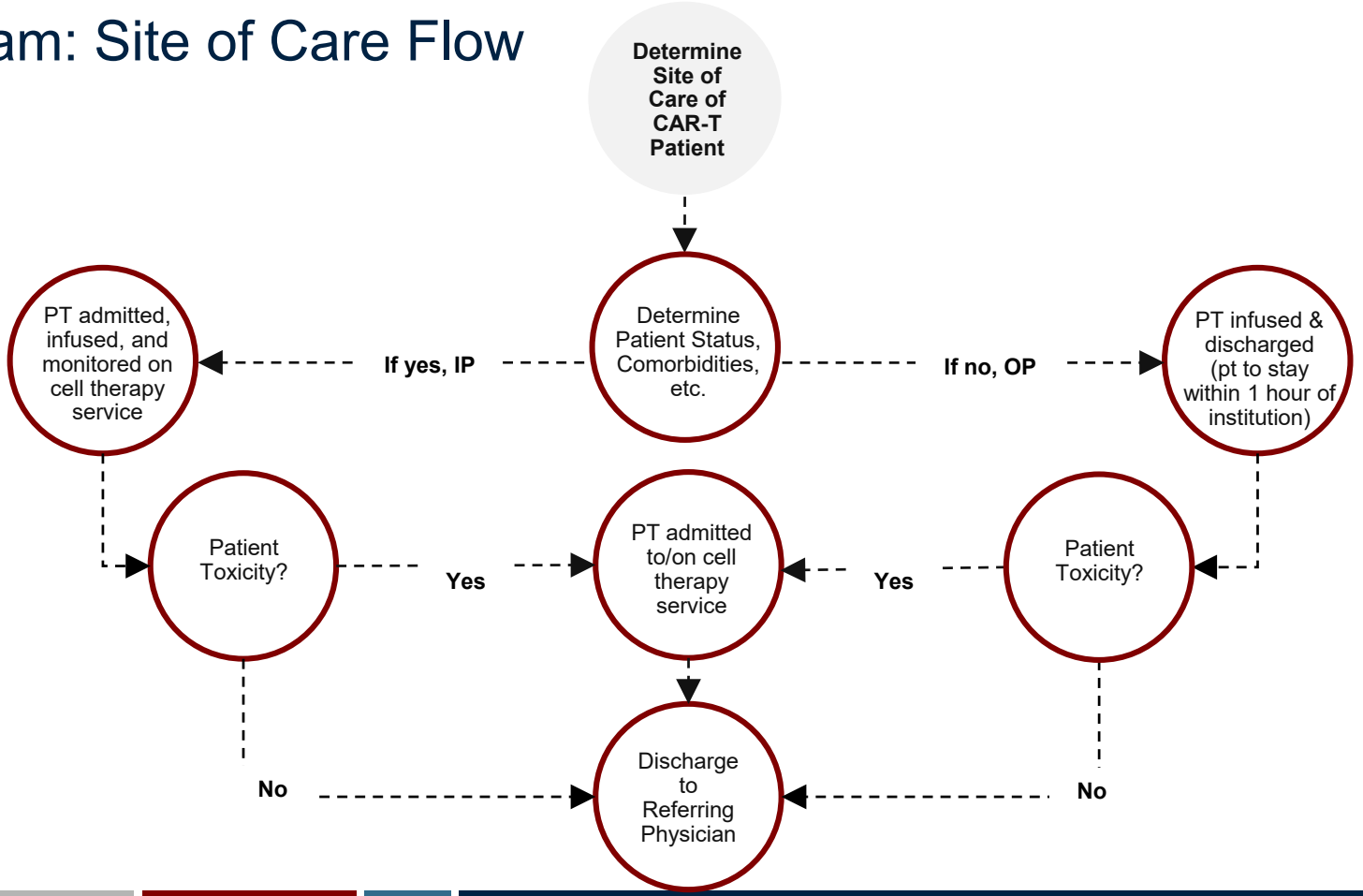
- Manage internal referrals
  - Patients first go to disease group, then are “referred” to CTT
  - **Note:** no external referrals directly to CTT
- Engage pharmaceutical companies as therapies are commercialized
- Interface with hospital leadership about gene/cell therapy
  - finance, operations, reimbursement



Cell Therapy and Transplant Program (CTT)

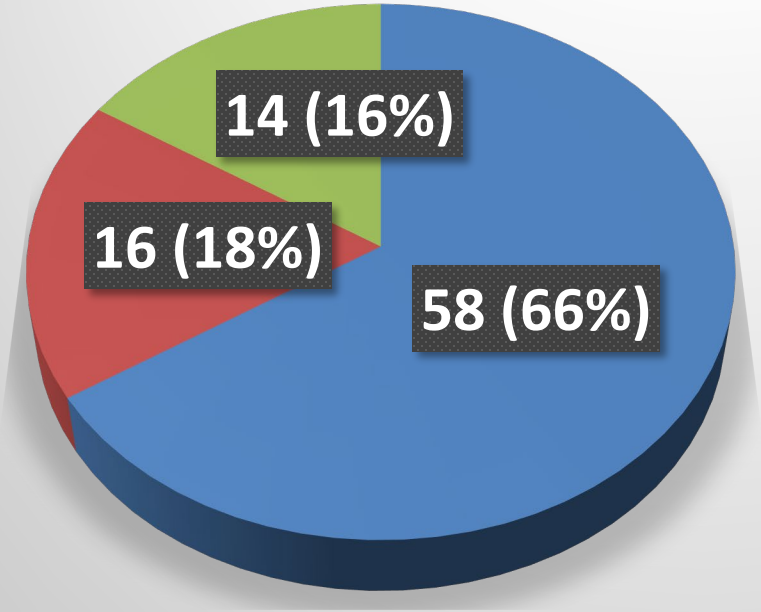
APP, advanced practice provider; CTT, cell therapy and transplant; IP, in patient; OP, outpatient.

Diagram: Site of Care Flow



CAR T, Chimeric Antigen Receptor T-Cell; PT, patient; IP, in patient; OP, outpatient.

Kymriah/EAP Outpatient therapy (2018-2020), n=88



Median Time to Admission = 4 Days Post Infusion

University of Pennsylvania, unpublished data

EAP, Expanded Access Protocol.

Key Points for determining CAR-T Site of Care

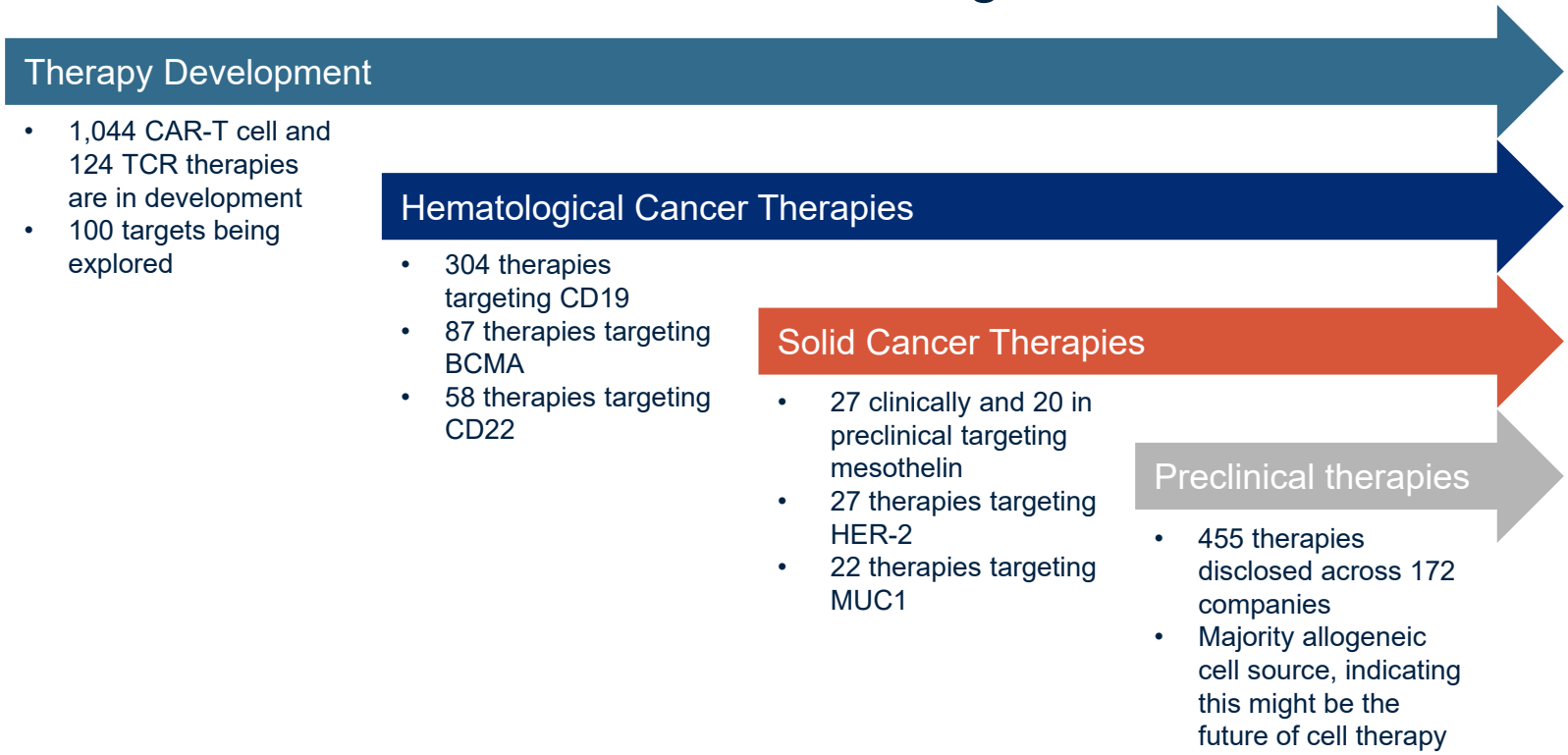
1. Getting a patient ready for treatment
   - Patient selection will determine IP or OP
   - Toxicity onset & site of care
     - **Admit for CRS > 1, any neurotoxicity**
   - Caregiver assessment

2. Post infusion: onset of toxicities
   - How fast do CRS/neurotoxicity occur?
   - Managing side effects in OP setting
     - Some portion of the OP population will need to be admitted within 30 days post infusion

CAR T, Chimeric Antigen Receptor T-Cell; CRS, Cytokine Release; IP, in patient; OP, outpatient.

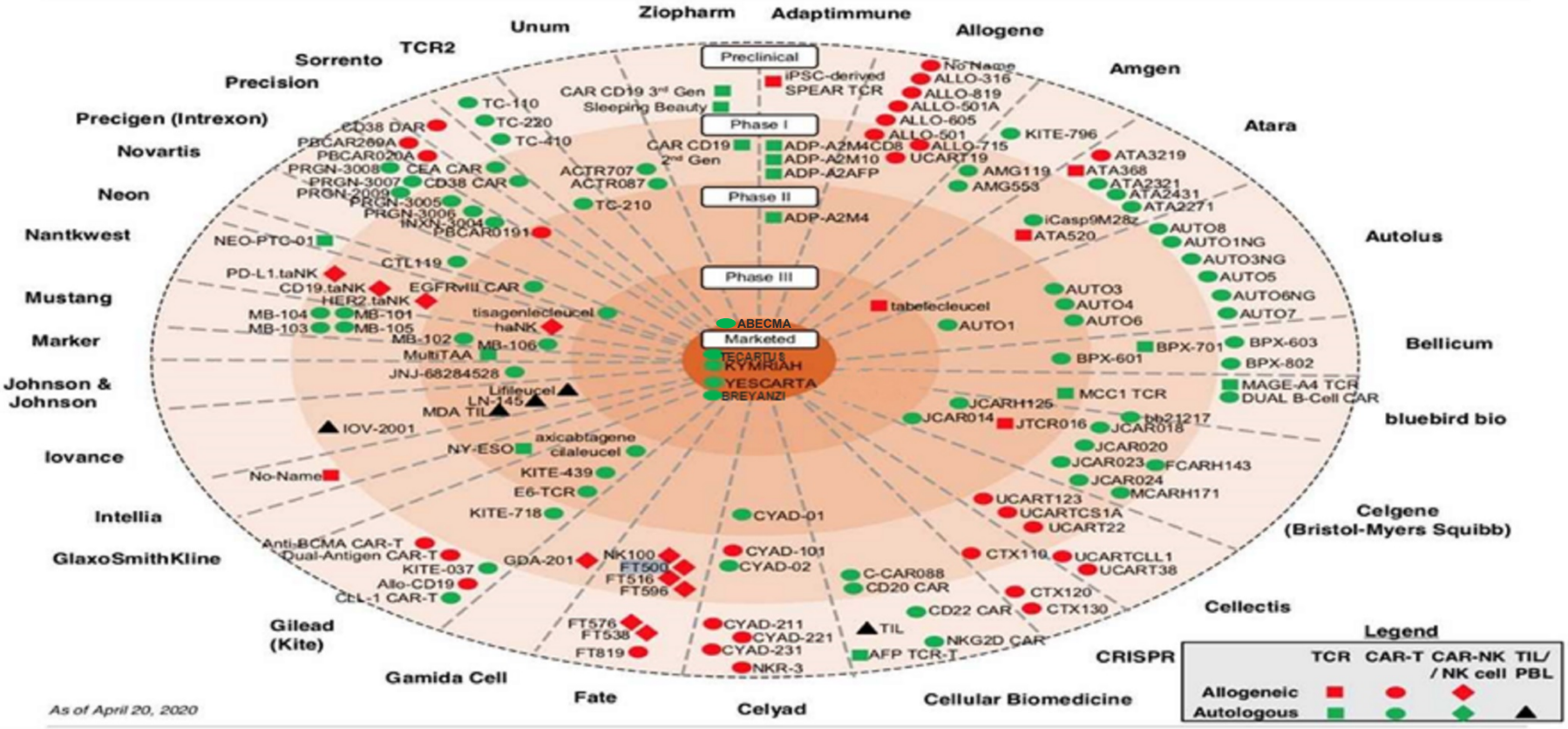
The Cell/Gene Therapy “Tidal Wave”

CAR TCR Summit 2020 – The Coming Tidal Wave



CAR, chimeric antigen receptor; CAR T, Chimeric Antigen Receptor T-Cell; TCR, T-cell receptor.

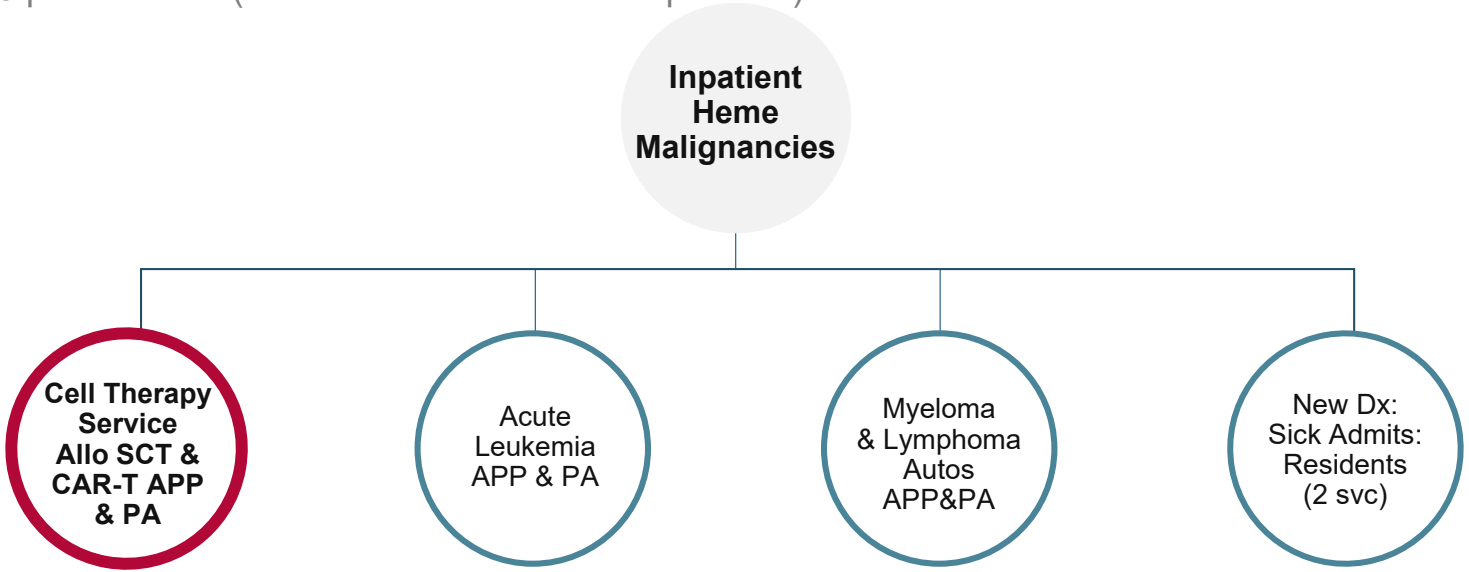
Key Cellular Therapy Assets in Development - Competitive Landscape In Oncology



MIZUHO Source: Mizuho Securities USA *Highest listed phase on Clinicaltrials.gov or as listed on company website. Public companies only on US exchanges

Cell Therapy Service

- Usually, 80-90 patients with heme malignancies in hospital
- Care provided by the Cell Therapy team (manages Allo SCT & CAR-T)
  - 20 patient beds (commercial or clinical trial patients)



*Includes commercial and clinical trial pts (including SOLID tumor patients)

SCT, stem cell transplant; APP, advanced practice provider; PA, physician assistant; IP, in patient; OP, outpatient.

Moving Cell Therapy to the Community

Cell Therapy: A Driving Force for Change

- Cell Therapy (CAR T) as a 2nd line therapy
  - Impact of Bone marrow transplant?
    - Business aspects
    - Clinical aspects
  - Impact to Chemotherapy?
    - Business aspects
    - Clinical aspects

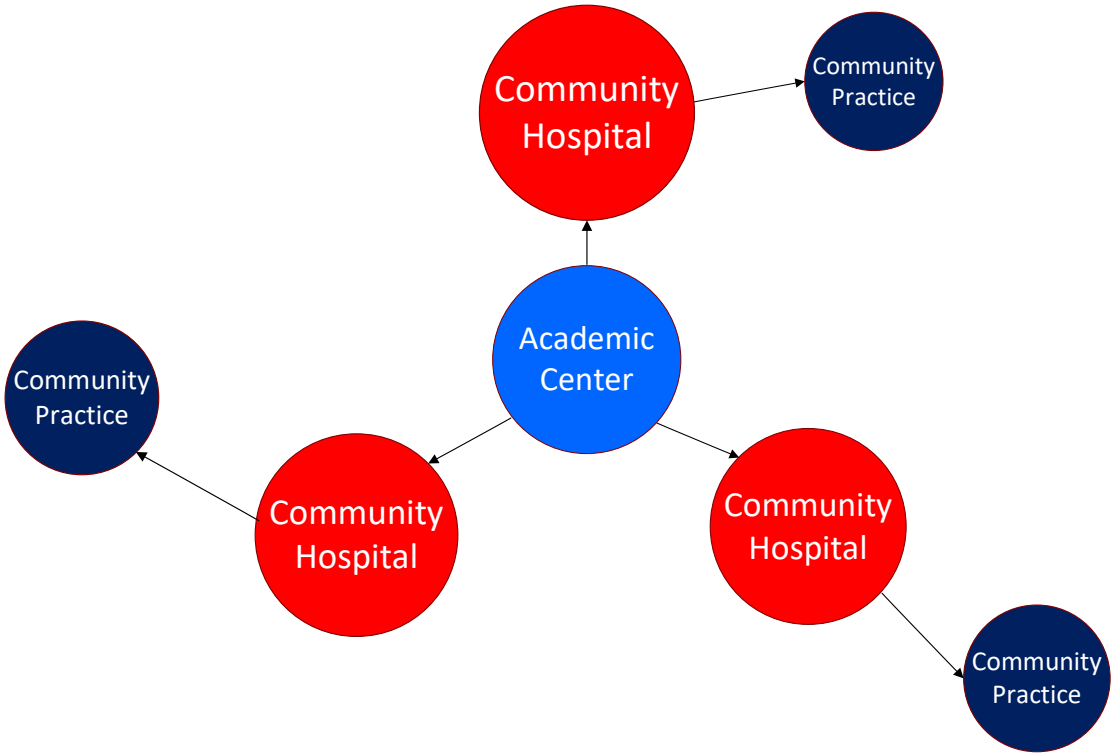
- CAR T during COVID (at Penn)
  - Exclusively treated OP during pandemic (March-August)
    - Curative intent and one treatment allowed the program to continue during pandemic
    - Penn saw volume increases during the pandemic

The potential for disruption in the cell/gene therapy space is the driving force for expansion to the community centers

CAR T, Chimeric Antigen Receptor T-Cell; OP, outpatient.

Hub and Spoke Model

- Some private practices have nearby centers that are certified for cell therapy and can administer in an OP setting and admit (as needed)
- This model fosters continued growth of gene and cell therapy space to locations where access is undeveloped
- Develops hospitals to manage toxicities consistent with REMS guidance from the FDA



REMS, Risk Evaluation and Mitigation Strategy; FDA, Food and Drug Administration; OP, outpatient.

Final Thoughts on Expanding Cell Therapy to Community Groups

- Pharmaceutical companies can help by developing an “onramp” for sites interested in cell therapy with no experience
  - Clinical trials (taking cost of the therapy off the table)
  - Accelerated adoption of cell therapies by a larger pool of centers
  - Q or J codes are considered biologics and typically are reimbursed inclusive of all services to make the drug
    - Apheresis and cryopreservation services (typically paid for on trial)
    - Community hospitals/practices typically operate their business on a lesser margin

- Commercially certified centers can help by educating sites unfamiliar with cell therapies
  - Not all cell therapies are the same
  - Identifying an ideal CAR T candidate
  - Educating on management of toxicities to facilitate OP treatment
  - Risk mitigation strategies to deliver care

Penn Medicine

Special thanks to the Cell Therapy and Transplant team and to our extended family at our first community hospital!