

# Incorporating PROs in Long-Term Follow-Up After CAR-T Cell Therapy

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# Disclosure

I have no financial or intellectual conflict to disclose

# CAR-T Cell Late Effects

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- Most patients participating in CAR-T cells trials have only been followed for a relatively short period of time
- The two commercial CAR-T cell products have been only recently approved by the FDA



***Limited data of CAR-T cell late effects is available***

# CAR-T Cell Late Effects

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- Main concerns regarding potential long-term sequelae of CAR-T cells include:
  - Prolonged B cell aplasia with acquired hypogamaglobulinemia
  - Infections
  - Subsequent malignancies
  - New incidence or exacerbation of neurologic or autoimmune disorders

# Long Term Follow-Up after CAR-T Cells Therapy – Objectives

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- Identify and mitigate the long term risks to patients receiving CAR-T cell products
- Capture delayed adverse events

# Long Term Follow-Up after CAR-T Cells Therapy - Challenges

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- Heterogenous patient population
- A variety of CAR-T cell constructs
- In the future - potential heterogenous CAR-T cell targets, which will affect toxicity
- Transition care away from treatment center
- Relapse
- Multiple co-morbidities
- Subsequent exposure to other treatment

# Long Term QOL Assessment After CAR-T Cell Therapy - Challenges

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- No validated instruments for QOL assessment after CAR-T cell therapy
- Lack of uniformity between centers
- Optimal study design is unknown
- Requires significant resources
  - Building questionnaires into electronic forms
  - Follow-up with patients after leaving the treatment center
  - Data collection
  - Data analysis

# FHCRC LTFU After CAR-T Cell - Pilot Study

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- Objective: Feasibility of LTFU after CAR-T cell therapy
- Study population: Patients who enrolled on CAR-T cell clinical trials at the FHCRC
- LTFU plan: yearly follow-up for up to 15 years
- Instruments to be used:
  - Health Care Provider questionnaire
  - Patient Health Status survey
  - PROMIS Global Health
  - PROMIS-29



# CAR-T PROs Current Status

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- Individual centers are exploring strategies to incorporate PROs in CAR-T cell short and long term studies
- A small number of studies are currently ongoing
- Collaborative working group should be established to provide recommendations for:
  - PRO instruments to be used
  - Unified study design
  - Harmonization of data
  - Potential multi center study

# CAR-T PROs Current Status

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- CAR-T PROs are still in development
- Effort should be made to incorporate PROs in CAR-T cell studies
- Awaiting data from ongoing early clinical trials
- Optimal tools to be used are unknown
- Harmonized study design are still lacking
- ***PROs should not be mandated for payer reimbursement of CAR-T cell therapies***