Program Co-Leader, Immunology

- Recruited in 2010 from U of Chicago, Illinois
- Research interests focused on developing strategies to promote T cell responses against tumor antigens
- Vice Chair of BMT & Cellular Immunotherapy Dept.
- Research and Medical Director, Clinical Immune Cell Therapy Program
- Chair, Immunotherapy Working Group
- PI of a K23 and former NCI CCITLA Awardee
- Co-led ZUMA-1 Trial, which led to the first FDA approved CAR T therapy for adults
- Over 55 publications

Immunology Program

Jose R Conejo-Garcia, MD, PhD
Frederick Locke, MD
Program Co-Leaders

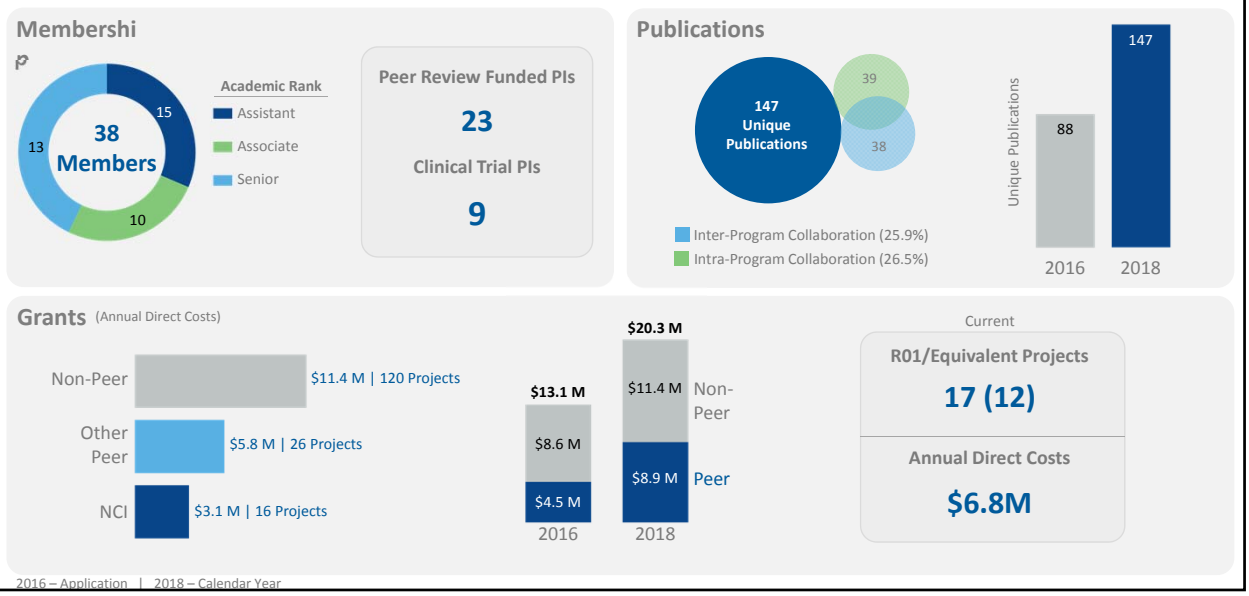
Immunology Program

Goal

To define the basic mechanisms by which tumors evade rejection by the immune system and to develop new strategies to thwart them

Original Aims	Newly proposed Aims (based on EAC recommendation)
1. Advance and translate T-cell therapies for solid tumors and hematologic malignancies	1. To understand molecular and cellular mechanisms to exploit innate and adaptive immunity against cancer.
2. Define molecular and cellular mechanisms to exploit innate and adaptive immunity against cancer	2. To elucidate and target pathways governing effectiveness, resistance and toxicity in anti-cancer immunotherapy.
3. Prevent graft-versus-host disease (GVHD) while sparing graft-versus-leukemia responses after hematopoietic cell transplantation (HCT)	3. To develop and implement anti-cancer cellular therapies

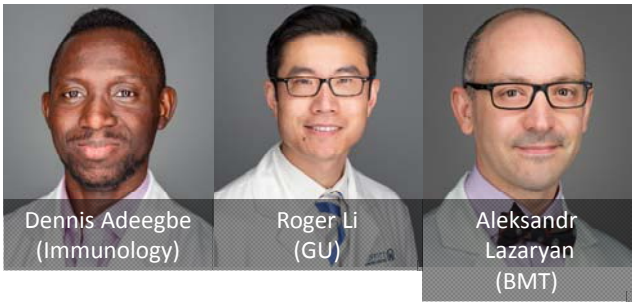
Immunology



Membership (n=38; 23 peer-reviewed funded)

- By Rank
  - Assistant Member 15
  - Associate Member 10
  - Senior Member 13
- By Degree
  - MD or MD/PhD 23
  - PhD 15

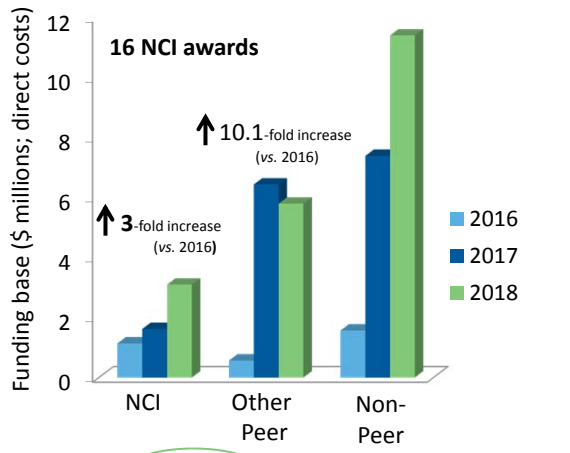
- 4 open recruitment opportunities
- New Members (Recruits)



EAC recommendation: Increase recruitment

- 3 interviews for NIH-funded investigators scheduled in 2019
- Recruitment of new BMT Chair & Malignant Hematology Vice-Chair (Future IMM Members)

Immunology Program Peer-Reviewed Funding (As of December 31, 2018)



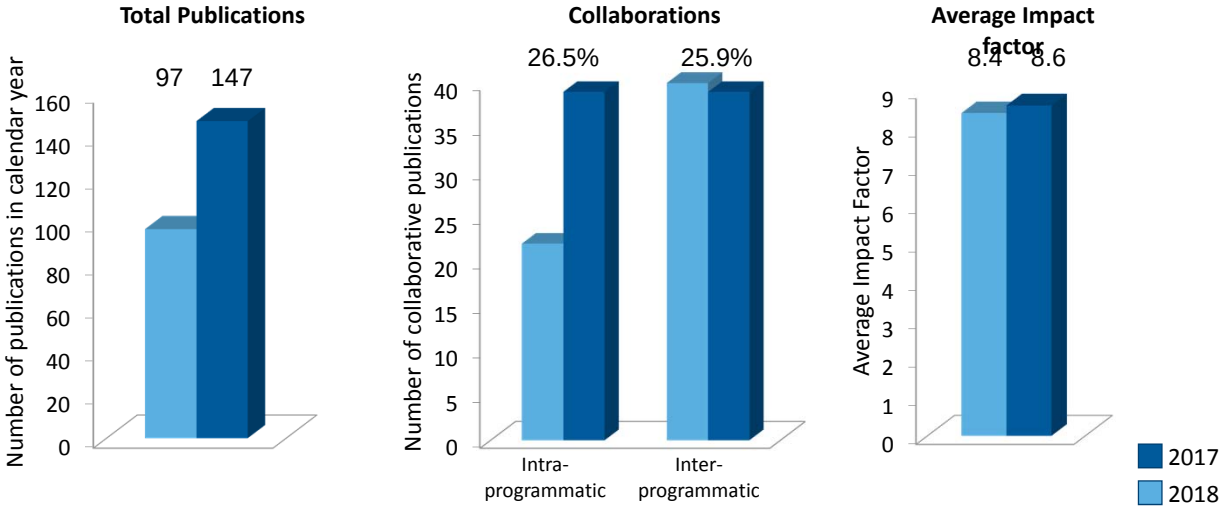
Direct costs: **$20.3 million** → ***1.5-fold*** increase *vs.* 2017

Actions to improve NCI funding (based on EAC recommendations):

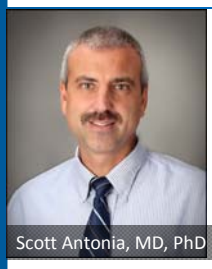
- Mentoring plans & committees for all Assistant Members (scores pending for 3 resubmissions)
- Pilot funding seeds the prospect of securing extramural funding (100K/year)
- New recruits focused on NIH-funded investigators (4 funded candidates scheduled for 2019 Q1)
- New pilot grant funding mechanism for collaborations between members of Cancer Epidemiology & Immunology (2 awards of up to $50K)
- New U54/U01 under preparation for the IOTN RFA (Moonshot) (7 IMM members involved)
- SPOREs (Myeloma submitted, Lung Cancer & Cutaneous pending)

Immunology Program Publications

***NEJM* (2), *Cancer Cell* (2), *Lancet Oncology;* Additional collaborations in *Nature* (2), *Cell* (2), *NEJM* (2)**



Scientific Highlight

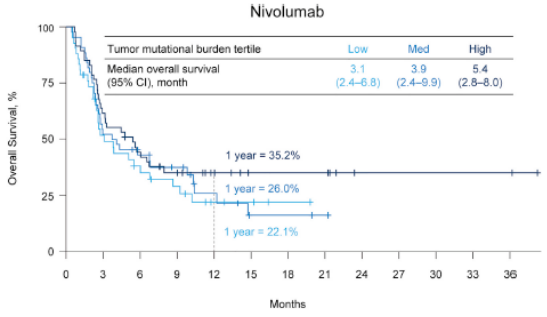


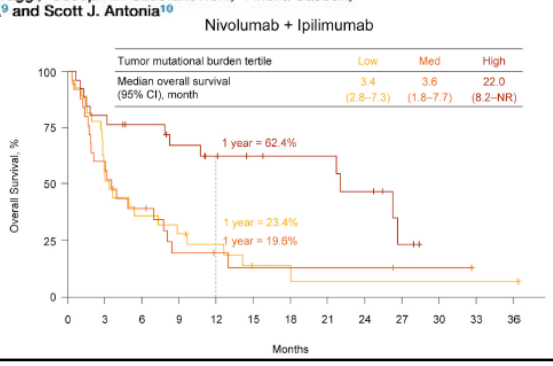
Scott Antonia, MD, PhD

Cancer Cell

Tumor Mutational Burden and Efficacy of Nivolumab Monotherapy and in Combination with Ipilimumab in Small-Cell Lung Cancer

Matthew D. Hellmann,[1,11,12,*] Margaret K. Callahan,[1,11] Mark M. Awad,[2] Emiliano Calvo,[3] Paolo A. Ascierto,[4] Akin Atmaca,[5] Naiyer A. Rizvi,[6] Fred R. Hirsch,[7] Giovanni Selvaggi,[8] Joseph D. Szustakowski,[9] Ariella Sasson,[9] Ryan Golhar,[9] Patrik Vitazka,[9] Han Chang,[9] William J. Geese,[9] and Scott J. Antonia[10]





Immunotherapy Clinical Trials

206 patients accrued onto interventional immunotherapeutic trials in 2018

- **Immunotherapy Working Group (IWG)**
  - Multi-disciplinary forum for industry sponsored CAR T, TILs and TCR studies
  - Platform to foster collaboration aimed at clinical translation
  - **EAC recommendation**: Sets institutional priorities for cellular immunotherapy trials
- **Immune Cell Therapy (ICE-T) Service**
  - Provides clinical care for patients on cellular or other high risk immunotherapies
  - IWG provides determines which trials would be eligible for the service

Moffitt Investigators are Designing & Testing New Cellular Immunotherapies

- New Cellular Immunotherapies*
  - APC lines for expansion of ACT: Marco Davila
  - CAR T for AML: Marco Davila (Atara)
  - gd T cells after Allogeneic Transplant: Marco Davila
  - CAR T for solid tumors: Daniel Abate-Daga
  - CER T cells for FSHR+ ovarian CA: Jose Conejo-Garcia/ Robert Wenham (ITUS)
  - DC vaccines for Breast cancer: Brian Czerniecki
  - DC vaccines for lymphoid cancers: Fred Locke
  - TILs for Sarcoma: John Mullinax
  - TILs for Bladder: Pilon Thomas
  - TILs for Lung cancer: Scott Antonia & Ben Creelan
  - TILs for Melanoma: Amod Sarnaik & Shari Pilon-Thomas
  - Tregs to prevent GVHD: Joseph Pidala
  - TLS for solid tumors: Jim Mulé
- Production Assistance for Cellular Therapy (PACT) projects: Linda Kelley
  - Cell Therapy for MIL Expansion for AML: Marco Davila
  - gd T Cell Purification and Expansion for AML: Marco Davila
  - Phase I Trial of Ex-vivo Expanded Unrelated Donor Regulatory T cells for Prevention of Graft-versus-Host Disease: Joseph Pidala

*Partial list of Moffitt translational investigators with grant funding to develop Cellular Immunotherapies

Cellular Immunotherapy Trials at Moffitt

- Allogene Allo-CAR T for DLBCL
- Kite 107 CAR T for DLBCL 2nd line vs SOC
- Kite 112 CAR T for Front line DLBCL
- Kite 102 CAR T for MCL
- Kite 103 CAR T for ALL
- Kite 106 CAR T + atezo for DLBCL
- Kite 105 CAR T for Follicular Lymphoma
- Novartis CAR T + ibrutinib for r/r DLCBL
- Novartis CAR T for Follicular Lymphoma
- BB/Celgene BCMA P1 CAR T for Myeloma
- BB/Celgene BCMA P2 CAR T for Myeloma
- BB/Celgene BCMA P3 CAR T for Myeloma
- Kite BCMA CAR T for Myeloma
- CEYLAD NKG2D CAR T for AML/MDS
- Iovance TILs for GYN
- Iovance TILs for H&N
- Iovance TILs for Melanoma
- Adaptimmune A3/A6 TCR for Lung
- Adaptimmune NY-ESO-1 TCR Sarcoma
- Adaptimmune NY-ESO-1 TCR Myeloma
- Amgen DLL3 CAR T for SCLC
- Bellicum PSCA CAR T for Pancreatic CA
- Kite MAGE A3/A6 TCR for Solid tumors
- Kite HHV7 TCR for cervical/H&N
- CTEP Nivolumab for relapse post Allo
- CTEP BiTe + revlimid for lymphoma
- CTEP atezo after ACT

*Partial list of Moffitt Cellular Immunotherapy trials accruing or in start up

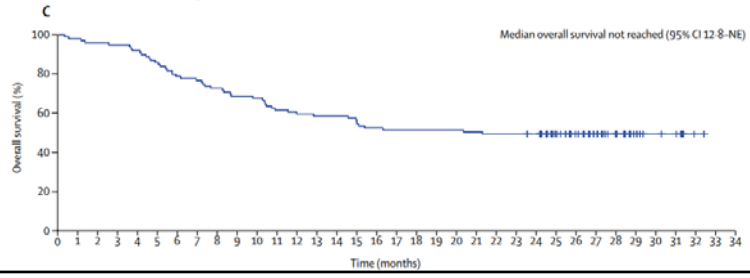
Scientific Highlight


Fred Locke, MD

THE LANCET
Oncology

Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1–2 trial

Frederick L Locke, Armin Ghobadi, Caron A Jacobson, David B Miklos, Lazaros J Lekakis, Olalekan O Oluwole, Yi Lin, Ira Braunschweig, Brian T Hill, John M Timmerman, Abhinav Deol, Patrick M Reagan, Patrick Stiff, Ian W Flinn, Umar Farooq, Andre Goy, Peter A McSweeney, Javier Munoz, Tanya Siddiqi, Julio C Chavez, Alex F Herrera, Nancy L Bartlett, Jeffrey S Wiezorek, Lynn Navale, Allen Xue, Yizhou Jiang, Adrian Bot, John M Rossi, Jenny J Kim, William Y Go, Sattva S Neelapu**



Questions

- Are we in the right track in terms of publications, clinical trials and impact?
- What other actions can we take to improve NCI funding?
- Are the new program specific aims appropriate?