Phase 1 Trial in Pancreatic Adenocarcinoma (TACTOPS)

JUNE 1, 2020

MARKER THERAPEUTICS

FORWARD LOOKING STATEMENTS

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Pancreatic Cancer Overview

Pancreatic cancer is the seventh leading cause of global cancer deaths and the third leading cause of cancer death in the U.S.

Prevalence

- In 2017, there were an estimated **78,969** people living with pancreatic cancer in the U.S.
- Estimated new cases in 2020: **57,600**
- Estimated deaths in 2020: **47,050**

Survival Rates

- Local (pancreas): Accounts for **10%** of cases; 5-year survival rate is **37%**
- Regional (lymph nodes): **29%** of cases; 5-year survival rate is **12%**
- Distant (Stage IV or metastatic): More than half of all cases **(53%)** are diagnosed at the distant stage; 5-year survival rate is **3%**
- Overall 5-year survival rate = **10%**

Combination Treatment

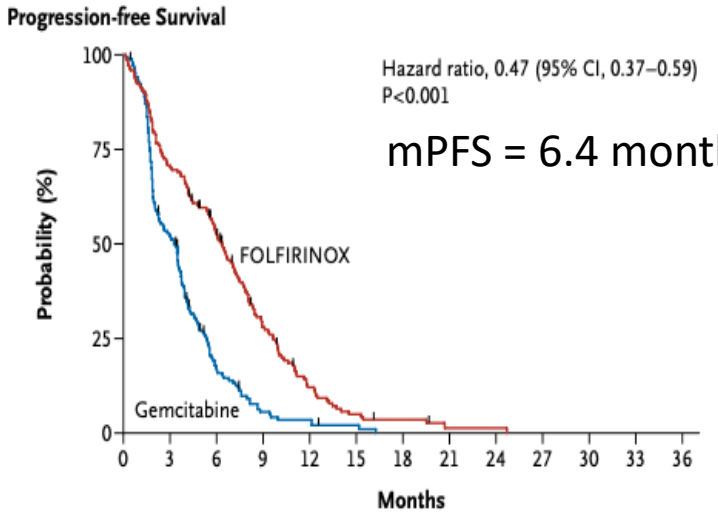
- SOC for front-line unresectable pancreatic cancer: Chemotherapy (FOLFIRINOX or Gemcitabine/nab-paclitaxel)
- Less than **20%** of patients are candidates for surgery (resectable) because cancer has usually spread by the time of diagnosis

Sources: National Cancer Institute, National Institutes of Health, American Cancer Society, Pancreatic Cancer Action Network

Expected PFS in Phase 1 Pancreatic Study at Baylor College of Medicine (BCM)

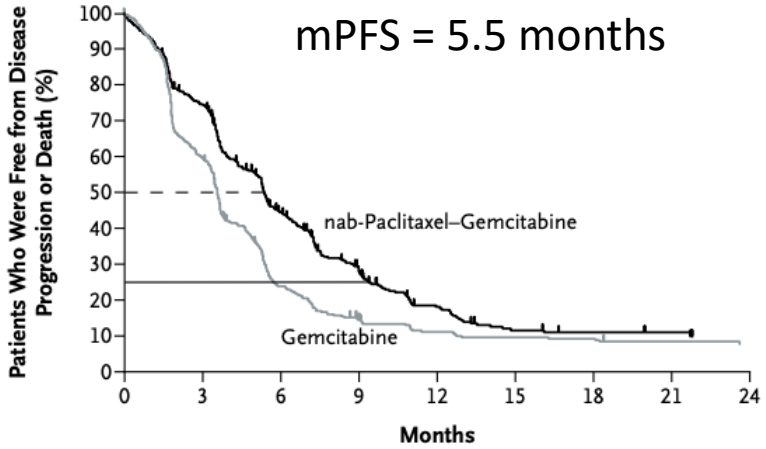
We commissioned an outside statistician to analyze the expected PFS for patients consistent with the eligibility of BCM Ph1 TACTOPS study by removing patients who progressed during the first 3 months of chemotherapy alone

FOLFIRINOX (ACCORD study)



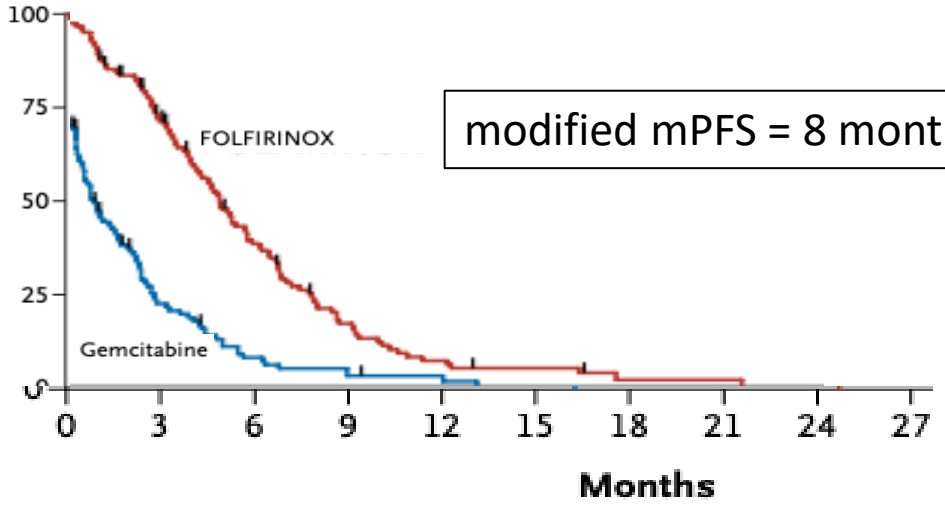
mPFS = 6.4 months

Nab-Paclitaxel-Gemcitabine (MPACT study)

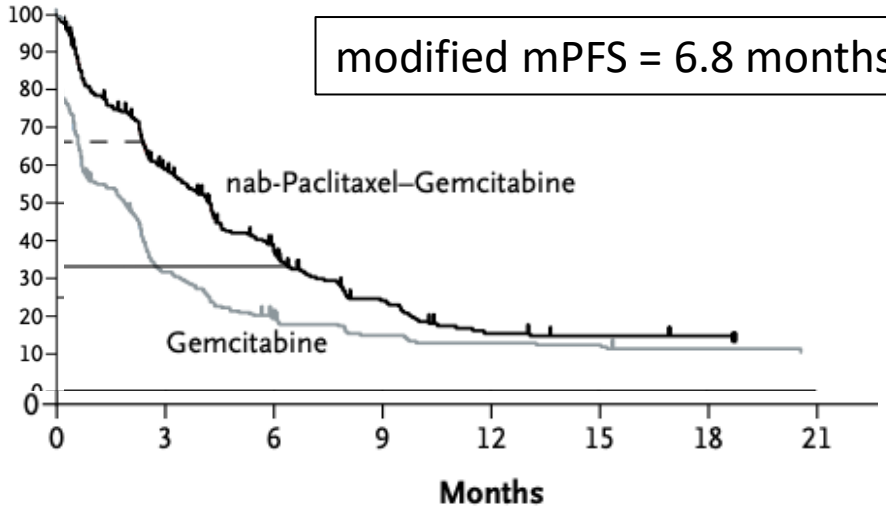


mPFS = 5.5 months

Expected PFS based on Baylor Ph1 Eligibility



modified mPFS = 8 months



modified mPFS = 6.8 months

MultiTAA-Specific T Cell Therapy in First-Line Setting

Demonstrates benefit on top of standard-of-care chemotherapy in patients with advanced and metastatic pancreatic cancer

ASCO 2020 Presentation

"A phase I trial targeting advanced or metastatic pancreatic cancer using a combination of standard chemotherapy and adoptively transferred nonengineered, multiantigen specific T cells in the first-line setting (TACTOPS)"

Observations

- ✓ MultiTAA-specific T cells was well tolerated when administered to patients with advanced pancreatic cancer, along with SOC chemotherapy
- ✓ In some patients, addition of T cells extended duration of first-line therapy, controlled cancer and induced additional tumor responses
- ✓ Clinical benefit correlated with detection of tumor-reactive T cells in patient peripheral blood
- ✓ T cells exhibited activity against targeted antigens and non-targeted TAAs, indicating induction of antigen/epitope spreading
- ✓ No infusion-related systemic- or neuro-toxicity

Brandon G. Smaglo, M.D., FACP

Associate Professor, Department of Gastrointestinal (GI) Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

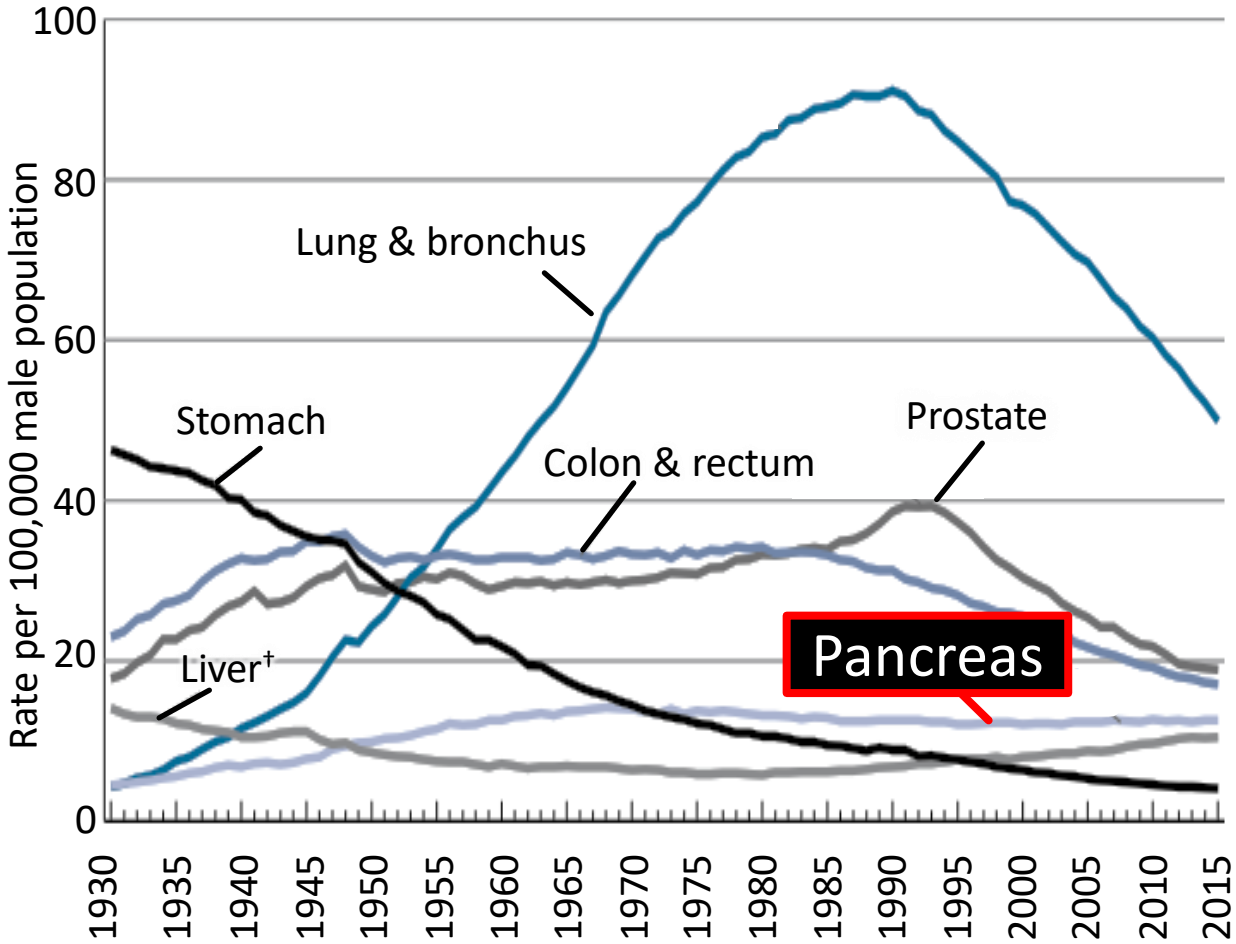
TACTOPS study conducted by Baylor College of Medicine

A Phase I Trial Targeting Advanced or Metastatic Pancreatic Cancer using a Combination of Standard Chemotherapy and Adoptively Transferred Nonengineered, Multiantigen Specific T Cells in the First-Line Setting (TACTOPS)

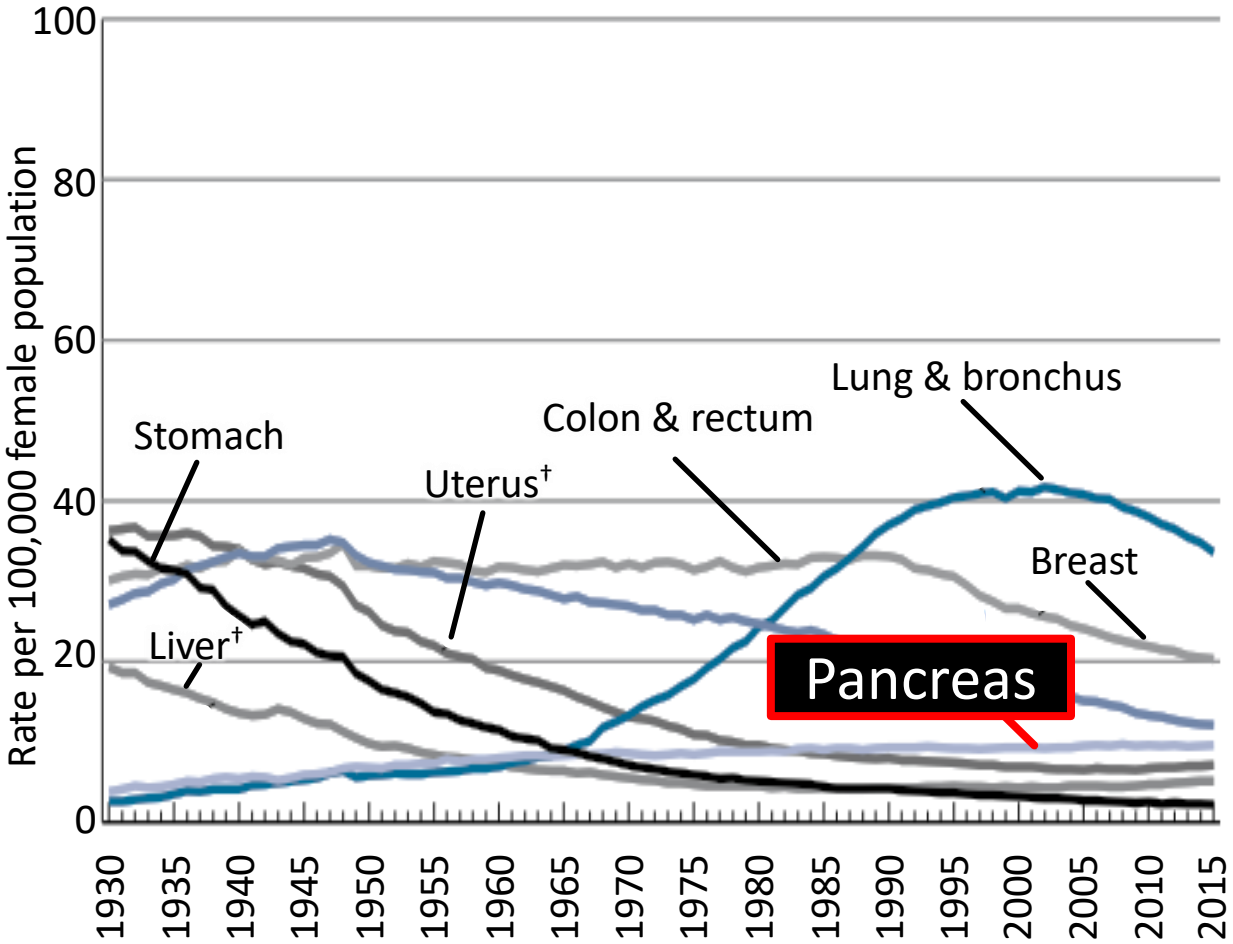
Brandon G Smaglo, MD, FACP

Pancreatic Cancer Mortality

Trends in Age-adjusted Cancer Death Rates, **Males**, US, 1930-2015



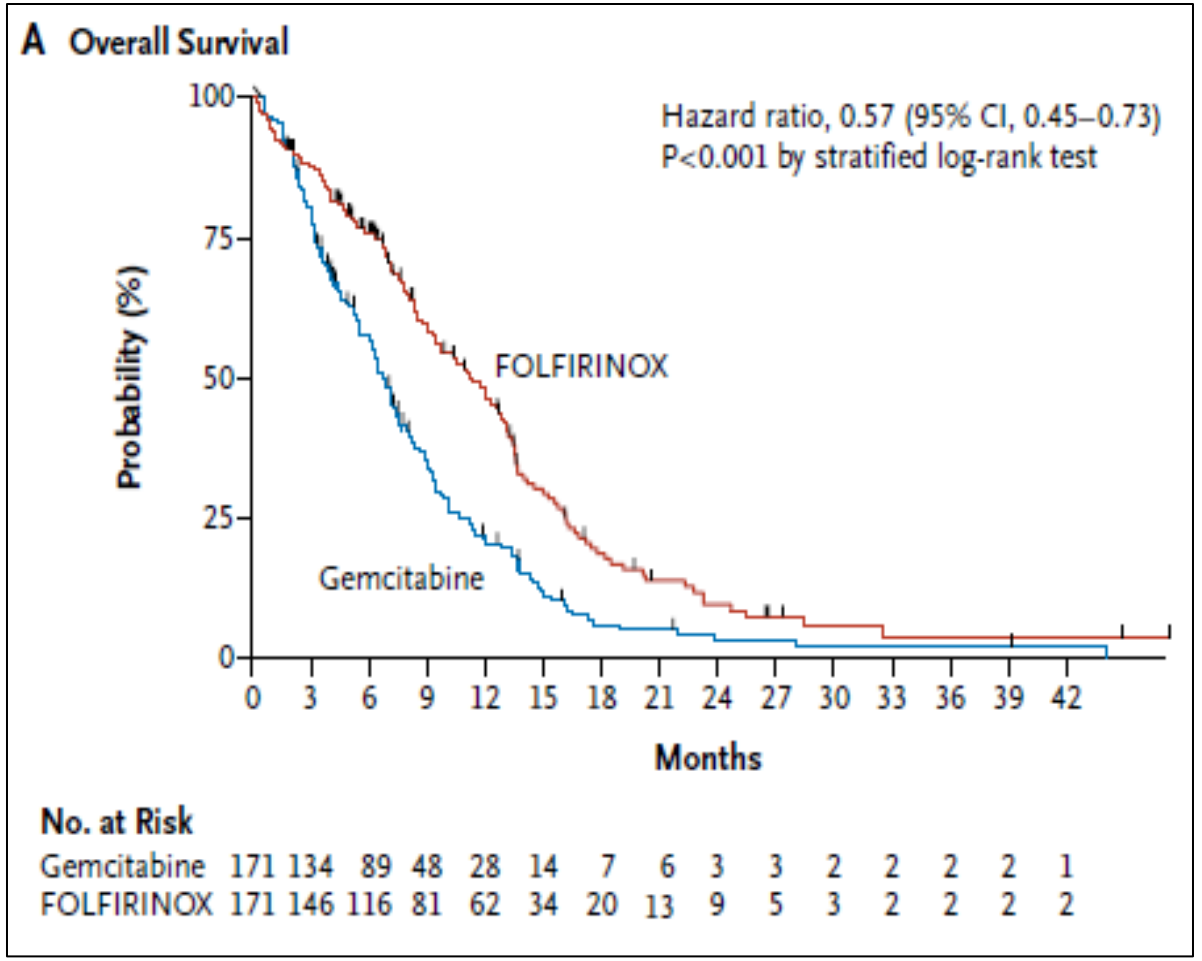
Trends in Age-adjusted Cancer Death Rates, **Females**, US, 1930-2015



American Cancer Society Fact & Figures 2018

ACCORD-11:FOLFIRINOX

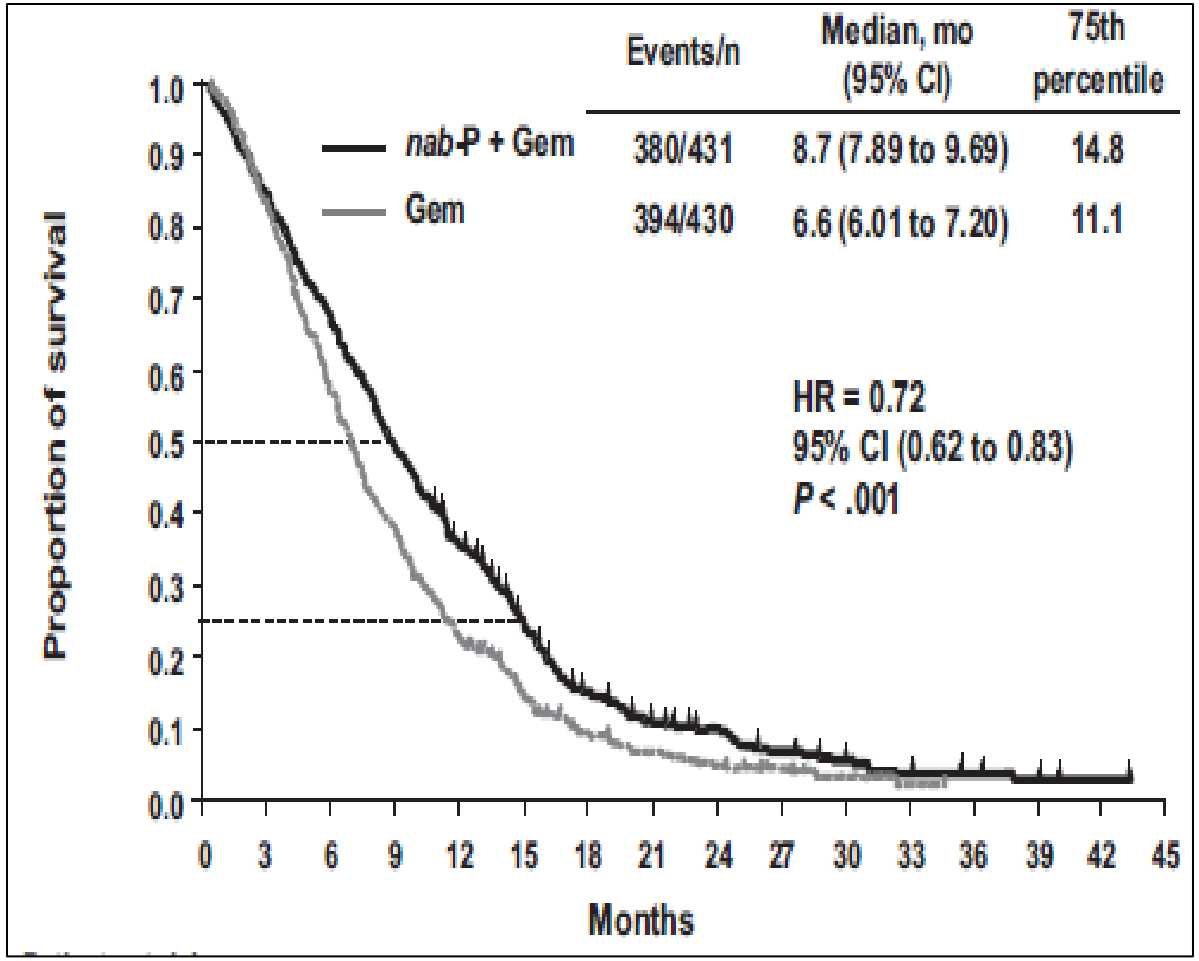
- First line option for metastatic disease
- Toxic
  - Not all patients can tolerate
  - Cannot continue indefinitely
- mOS 11.1 months
- mPFS 6.4 months



Conroy T, et al. N Engl J Med 364:1817; 2011.

MPACT:gemcitabine/nabpaclitaxel

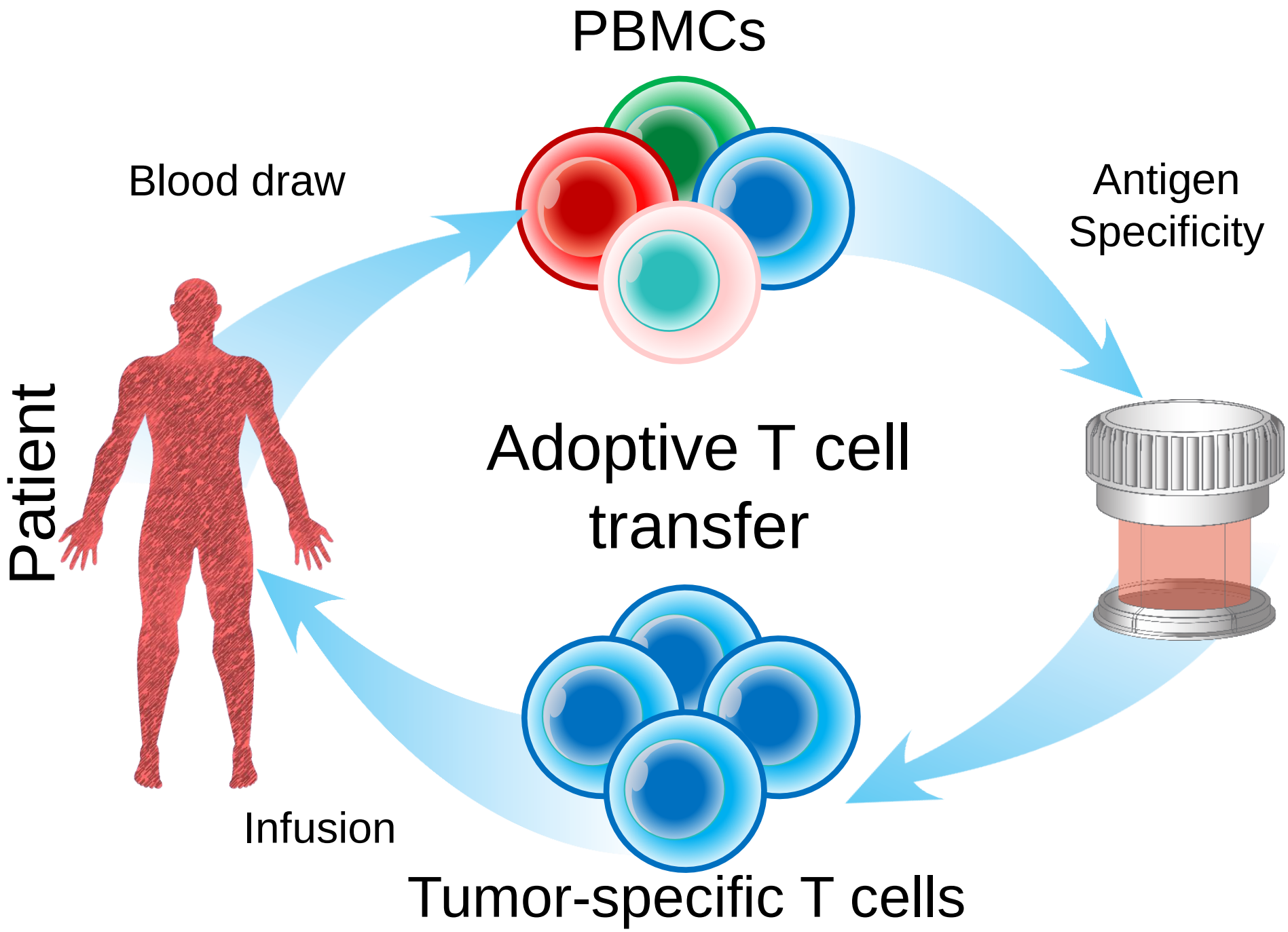
- First line option for metastatic disease
- Thought of as less toxic
- mOS 8.5 months
- mPFS 5.5 months



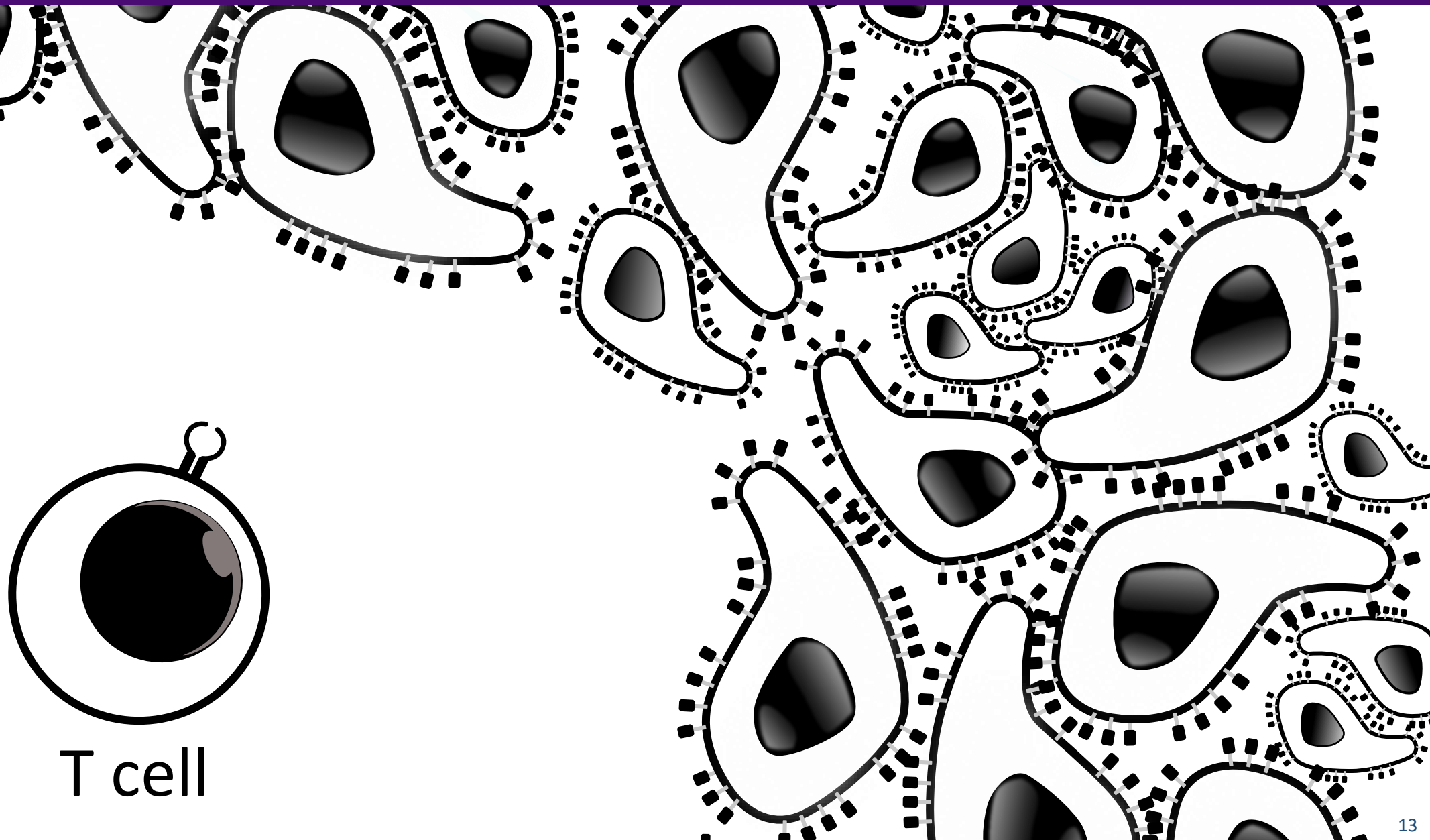
Von Hoff DD, et al. N Engl J Med 369:1691;2013.

Pancreatic Cancer: Treatment

- Combination chemotherapy (FFX or G/A)
  - Non-chemotherapy options very limited
- Side effects
  - Cumulative: fatigue, neuropathy, cytopenias
  - Repetitive: nausea, vomiting, diarrhea
  - Distressing: alopecia, cold-hypersensitivity
- T cell therapy options attractive for exploration

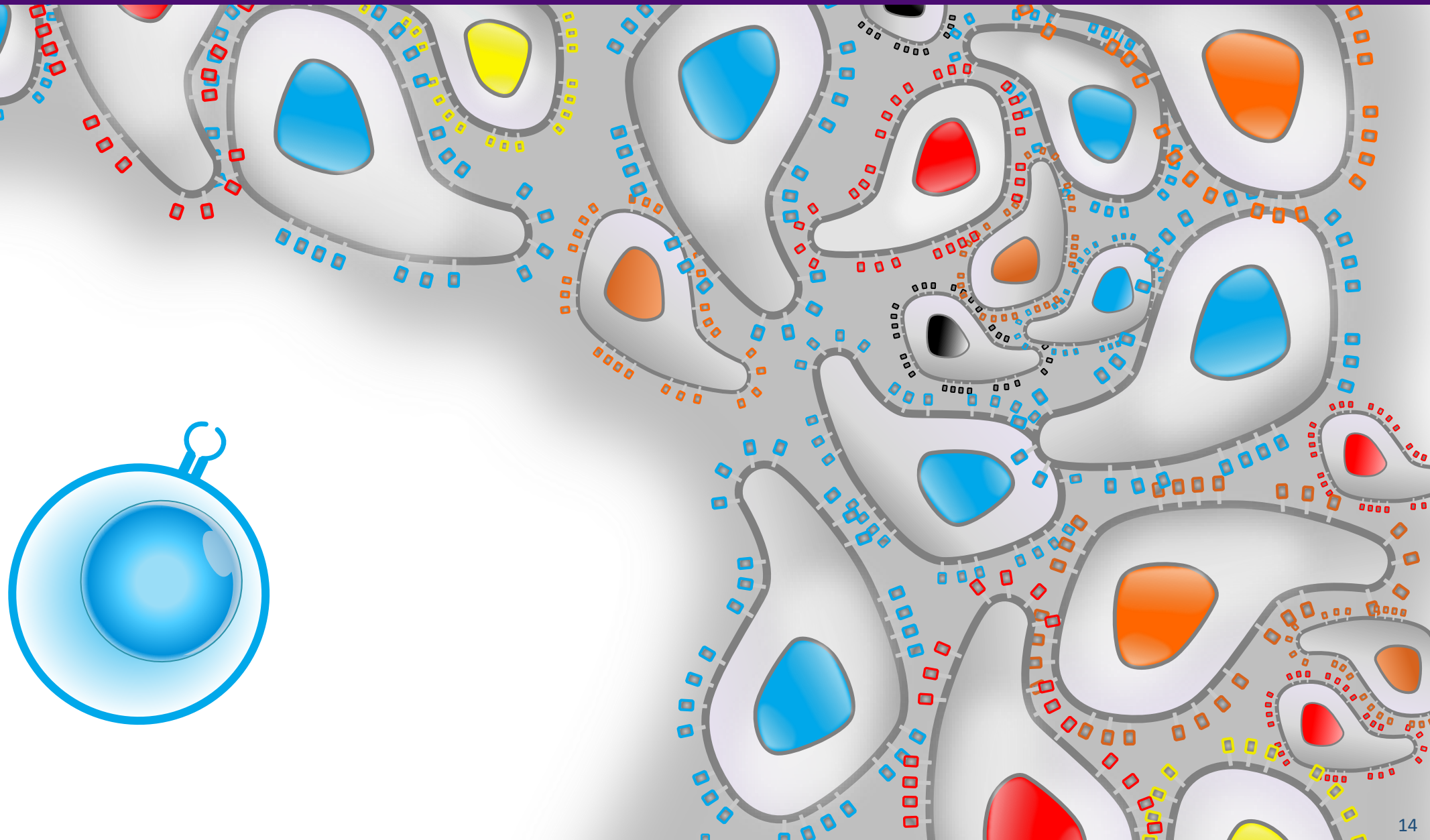

PBMCs
Blood draw
Antigen Specificity
Patient
Adoptive T cell transfer
Infusion
Tumor-specific T cells

T cell therapy for pancreatic cancer

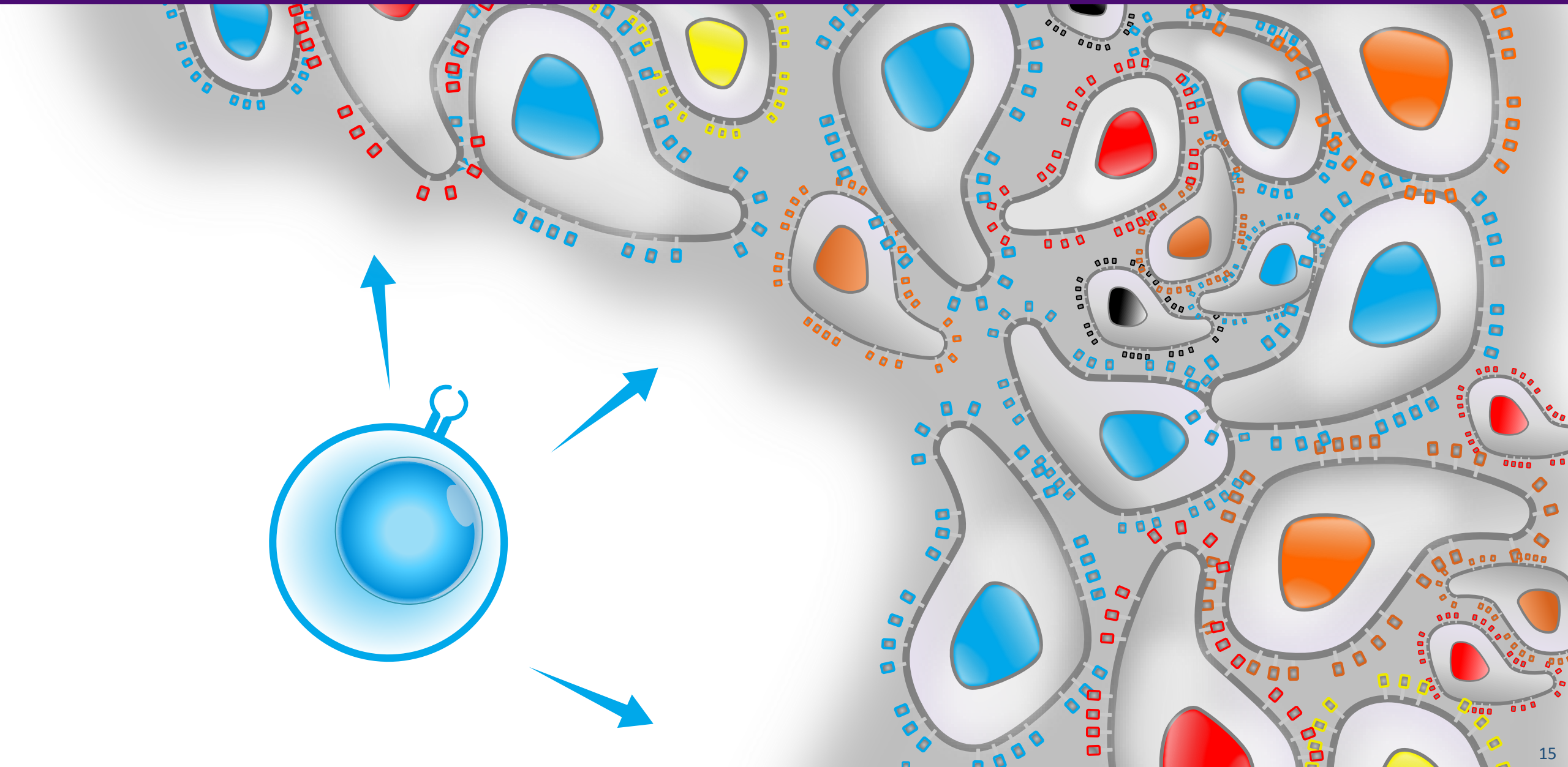


T cell

Challenge: Tumor heterogeneity



Immune Escape

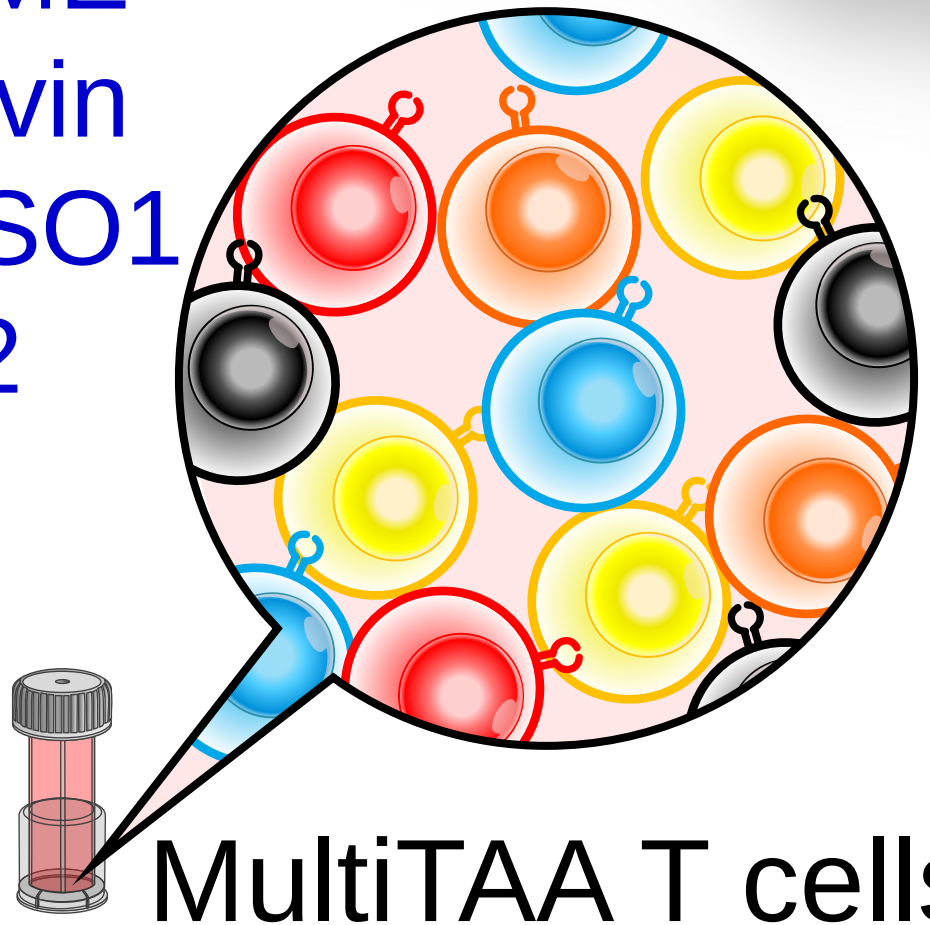


Our approach

- Simultaneously target multiple TAAs
- Target multiple epitopes (CD4 and CD8) within each antigen
- T cells with native T cell receptor specificity (non-engineered)

MultiTAA T cell therapy for PDAC

MAGEA4
PRAME
Survivin
NYESO1
SSX2



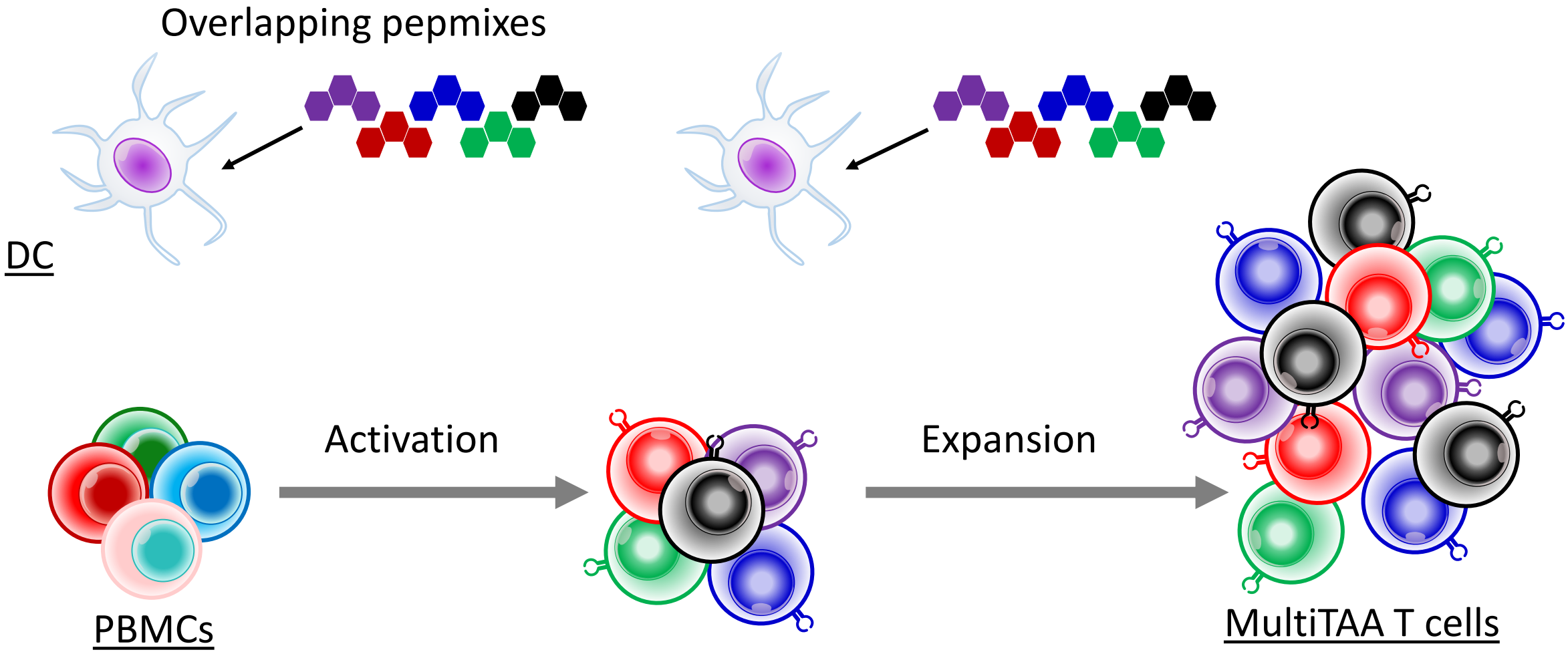
MultiTAA T cells

TAA Expression in PDAC

TAA	Expression in PDAC
Survivin	>75%[1-2]
SSX family	3-30%[3-5]
MAGE-A family	20-86%[3, 5-8]
PRAME	>30%[9]
NY-ESO-1	2-10%[3,5]

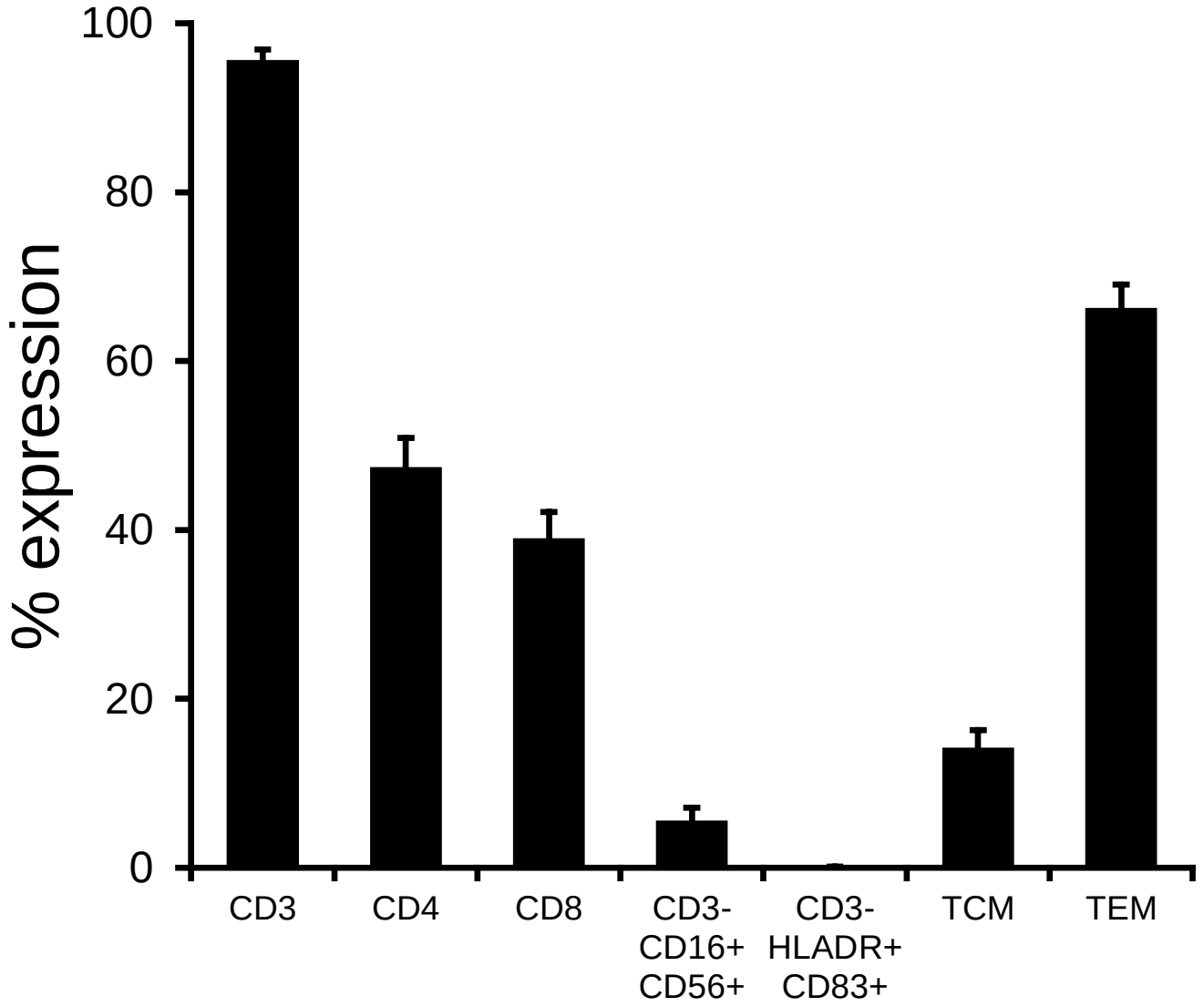
[1] Koido et al, Clin Dev Immunol. 2011, [2] Dodson et al, Immunotherapy 2011, [3] Kubuschok et al, In.t J. Cancer 2004, [4] Abate-Daga et al, PLoS One. 2014, [5] Schmitz-Winnenthal et al, Cancer Letters 2007, [6] Kim et al, Int. J. Cancer 2006, [7] Cogdill et al, Surgery. 2012, [8] Hansel et al, Int J Gastrointest Cancer. 2003, [9] The Human Protein Atlas, www.proteinatlas.org

MultiTAA-T Cell Generation

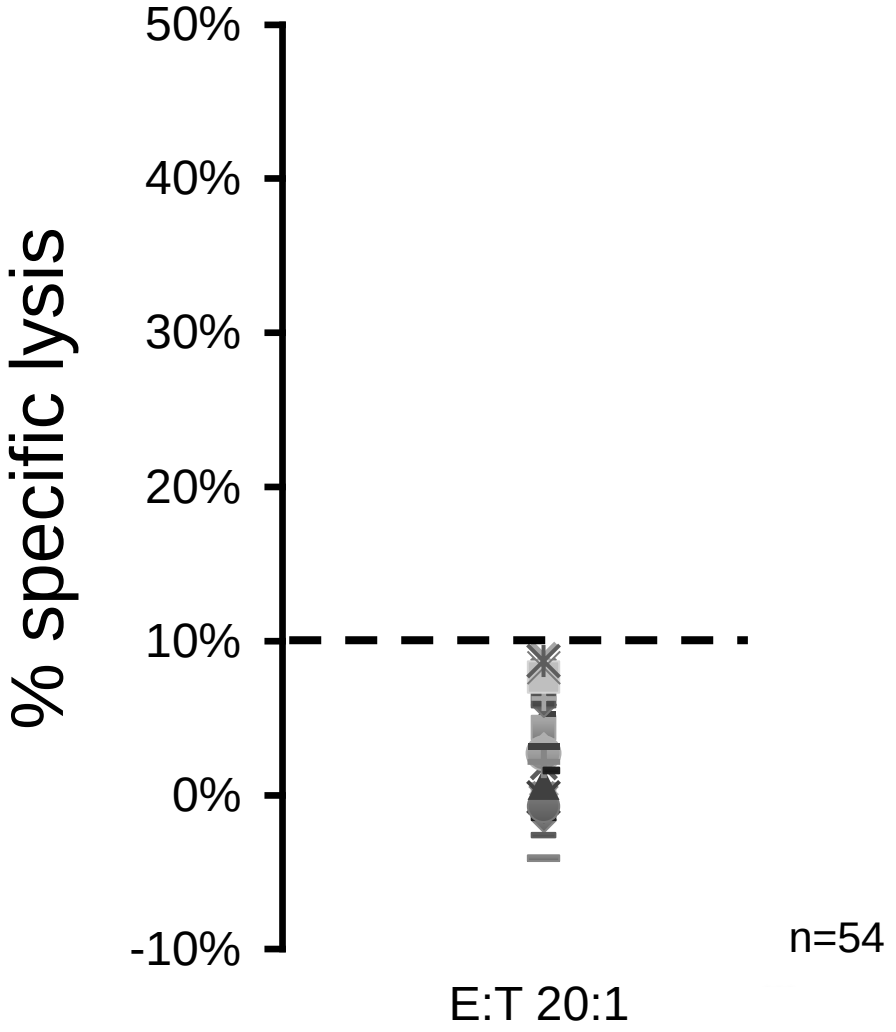


Profile of MultiTAA-T cells

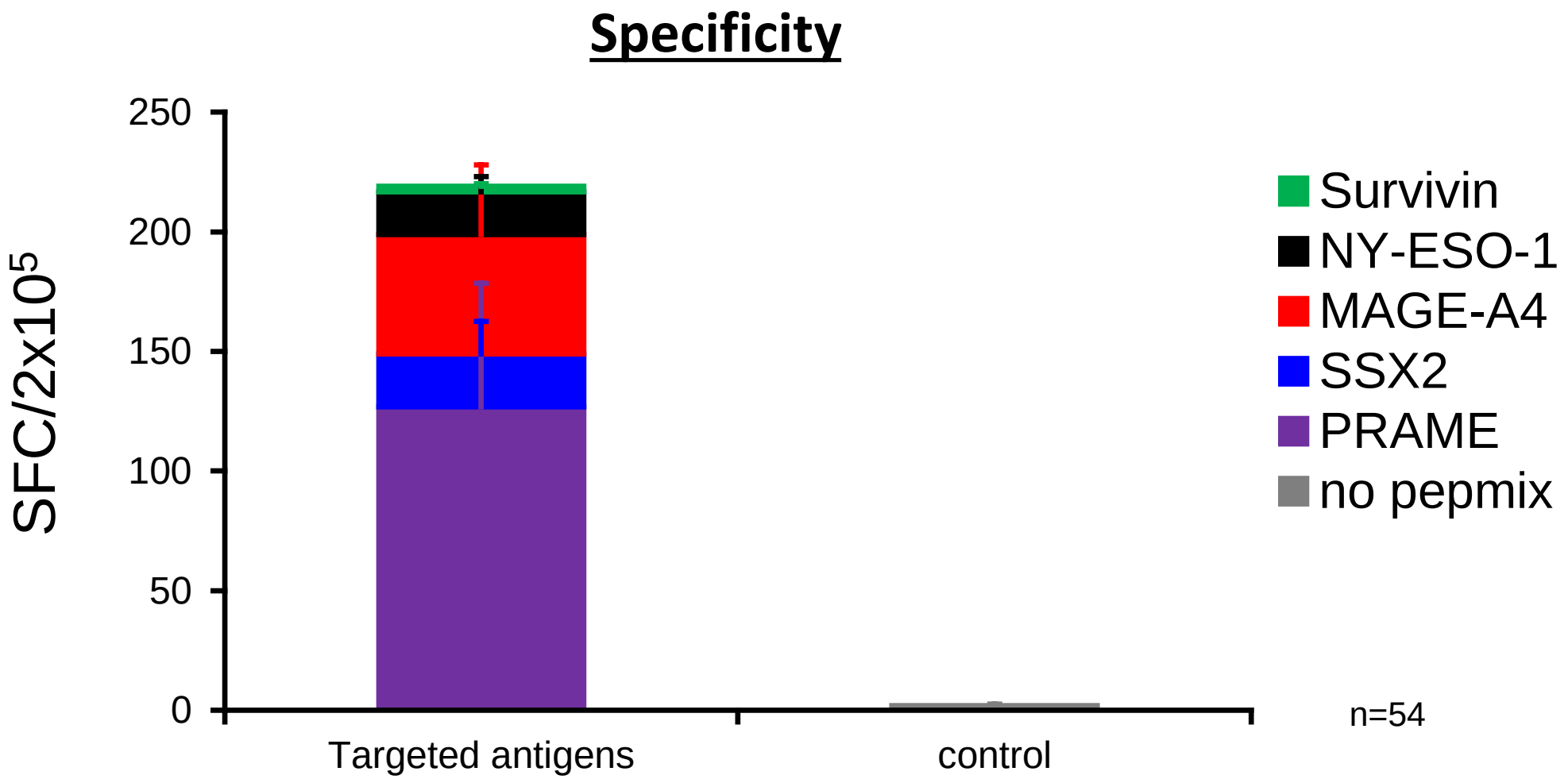
Phenotype



Safety



MultiTAA T cell specificity



Clinical Trial: TACTOPS

- 6 Infusions, fixed cell dose ($1x10^7/m^2$) - no lymphodepletion
- Receive 3months chemotherapy
  - Procurement performed and T cells generated
- If cancer controlled after 3 months, start receiving monthly T cell infusions along with ongoing chemotherapy

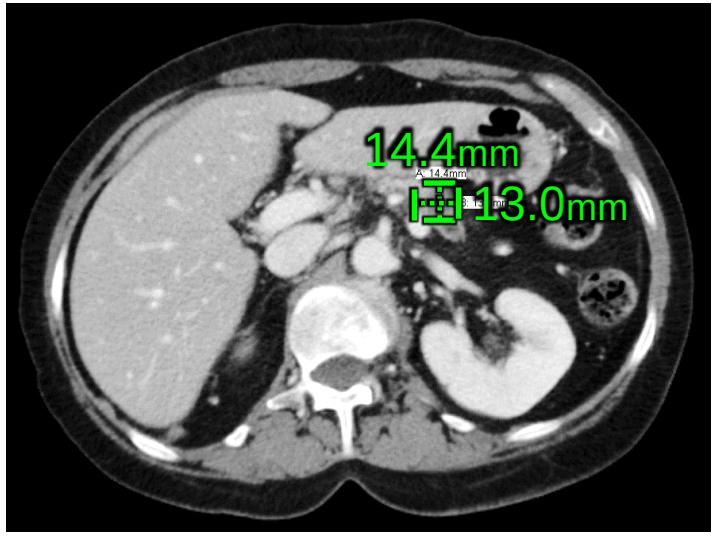
Clinical Trial: TACTOPS

- Primary endpoints – safety, feasibility
- Exploratory – efficacy

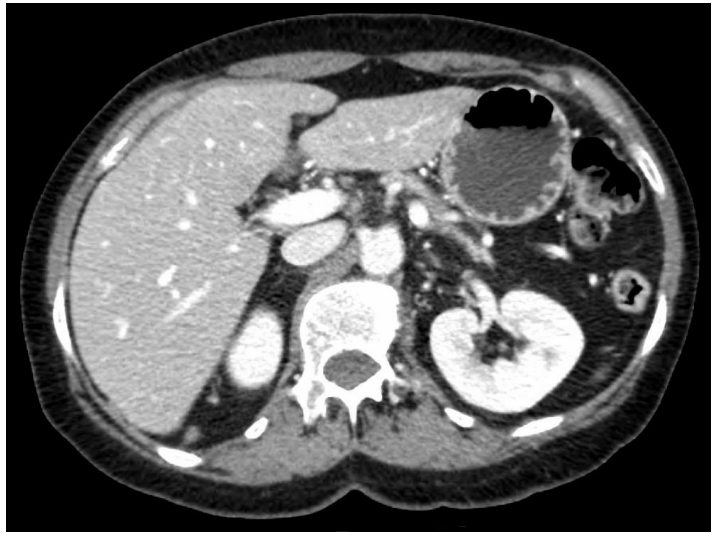
- 13 patients infused
  - Sufficient cells generated for all 6 infusions for 12 patients
  - 2 doses generated for the remaining patient

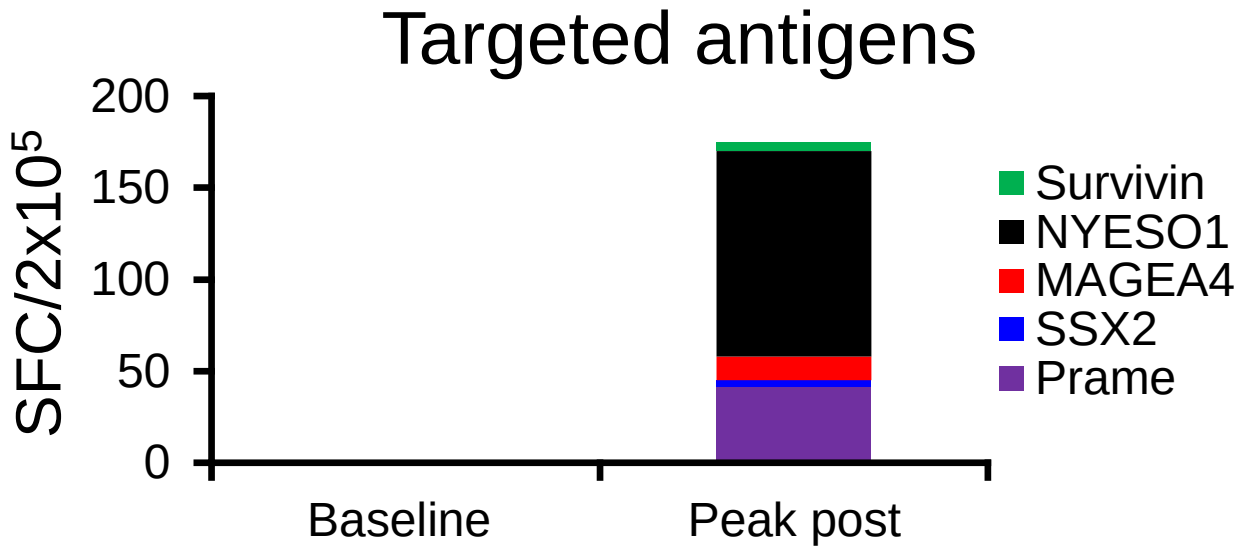
Radiographic CR : pt#7

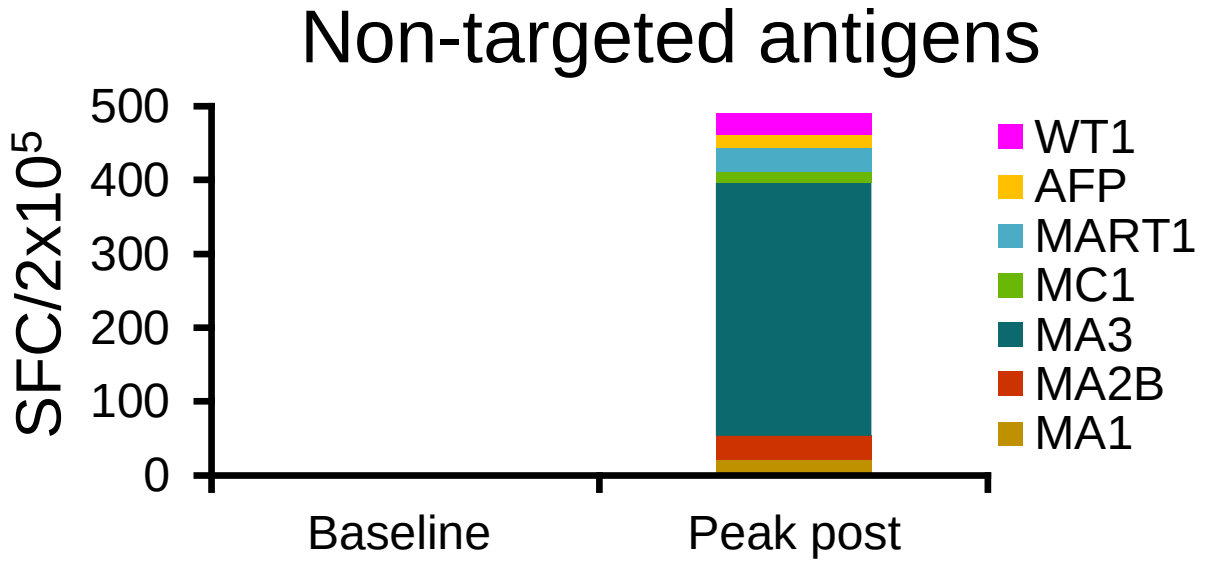
Prior to multiTAA T cells



6 months post multiTAA T cells

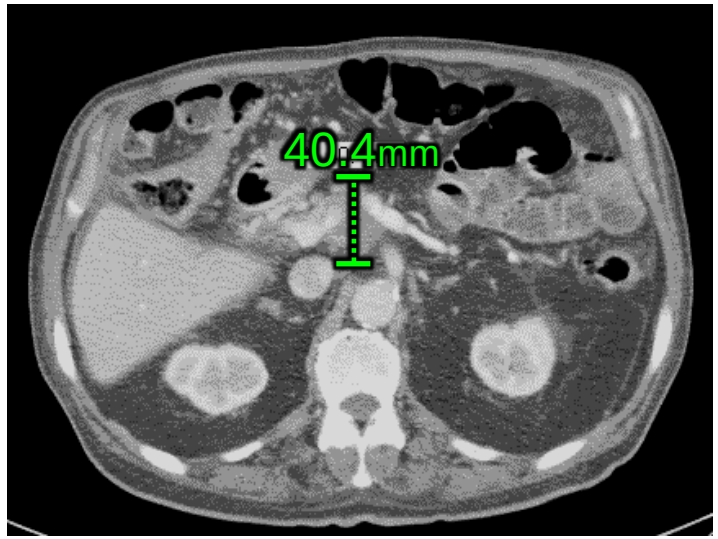




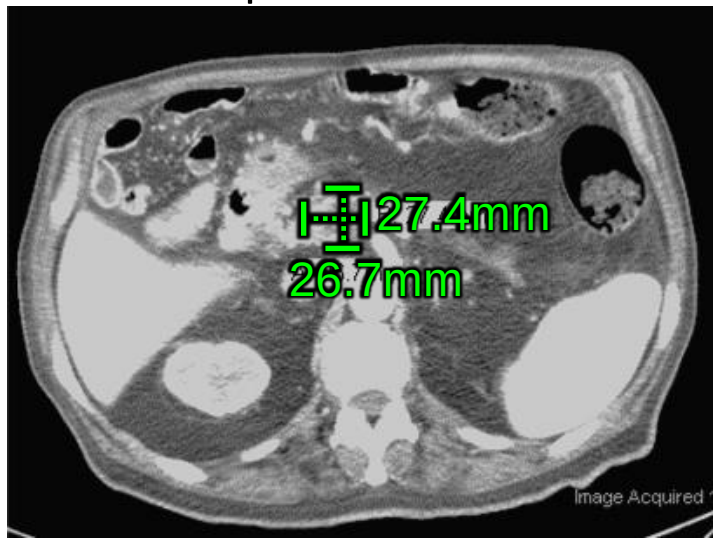


Clinical response : pt#1

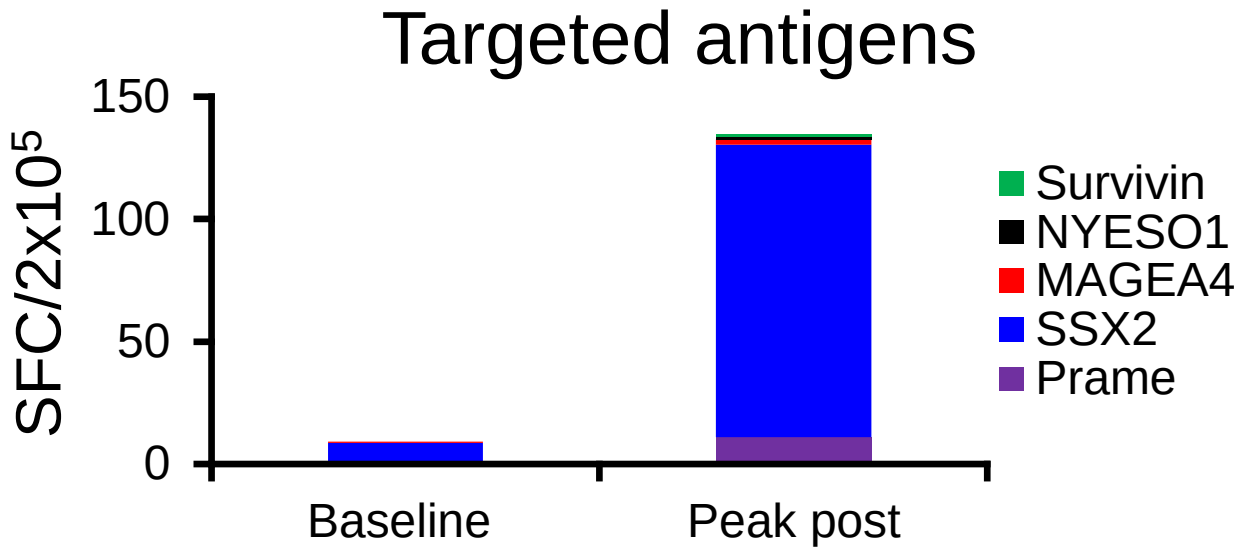
Prior to multiTAA T cells

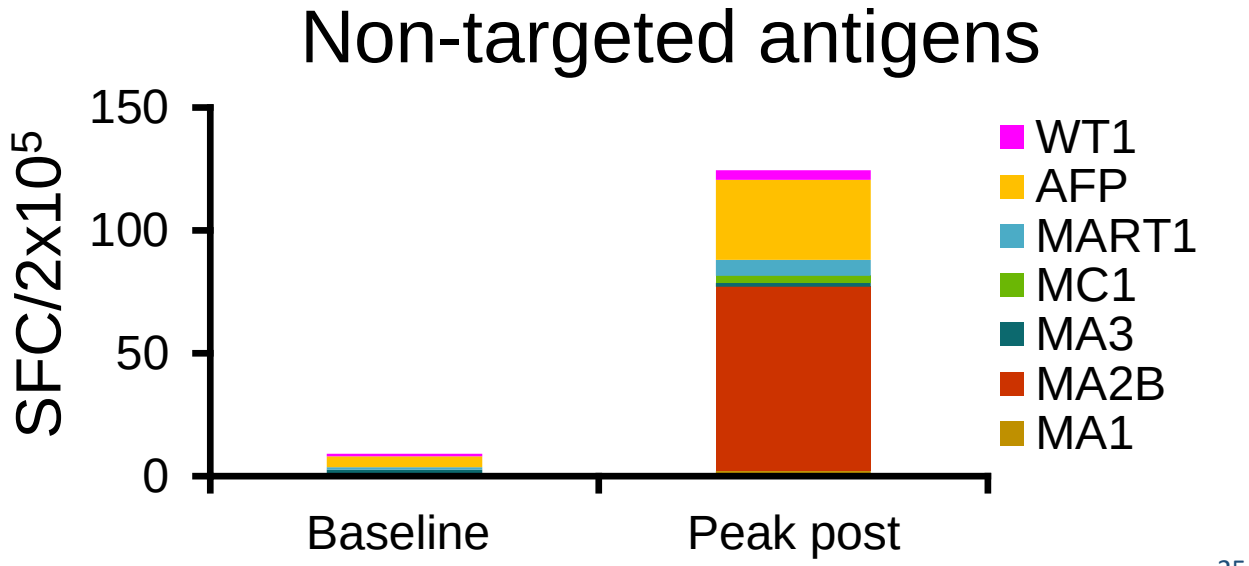


2 months post multiTAA T cells



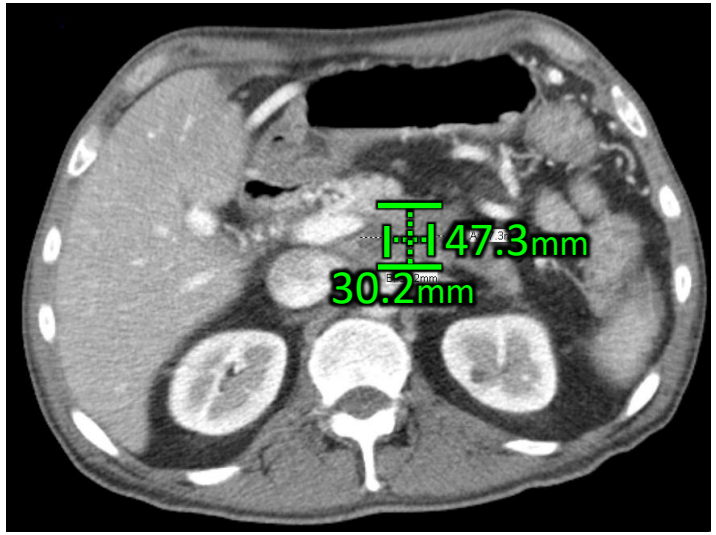
>30% reduction of index lesion



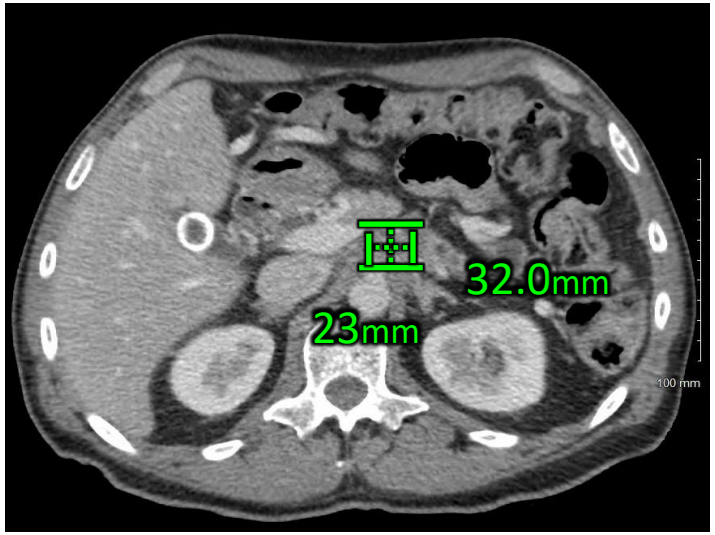


Clinical response : pt#3

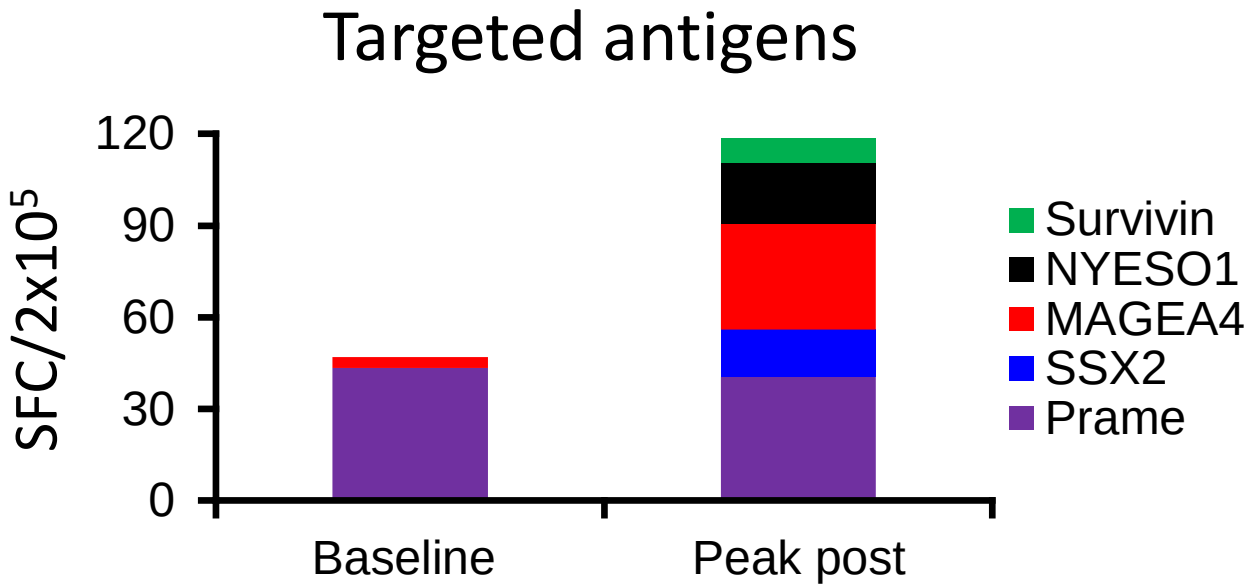
Prior to multiTAA T cells

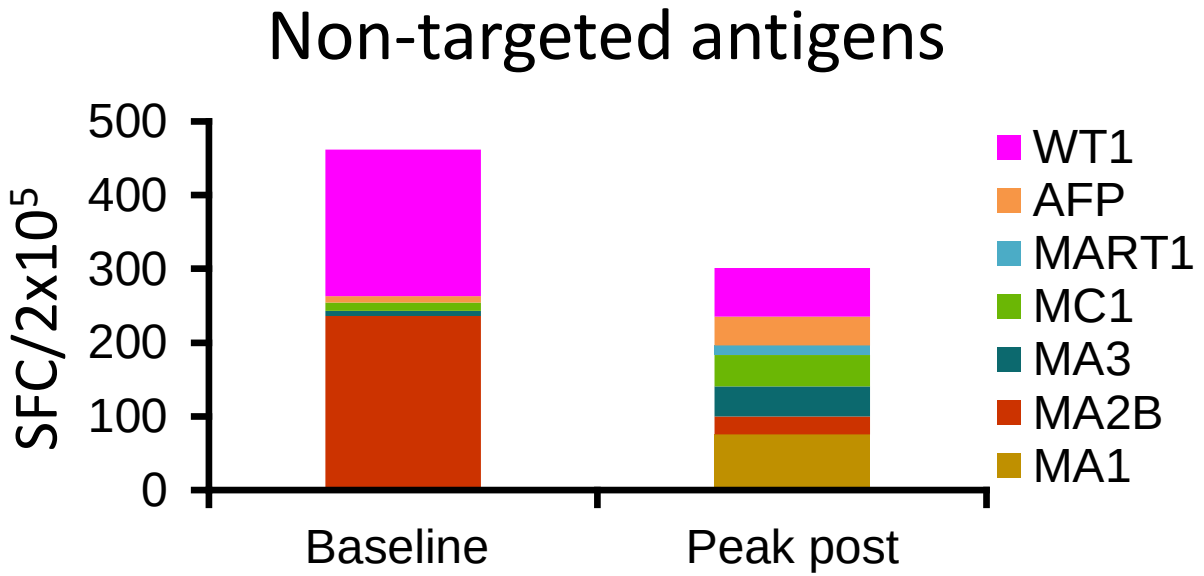


6 months post multiTAA T cells



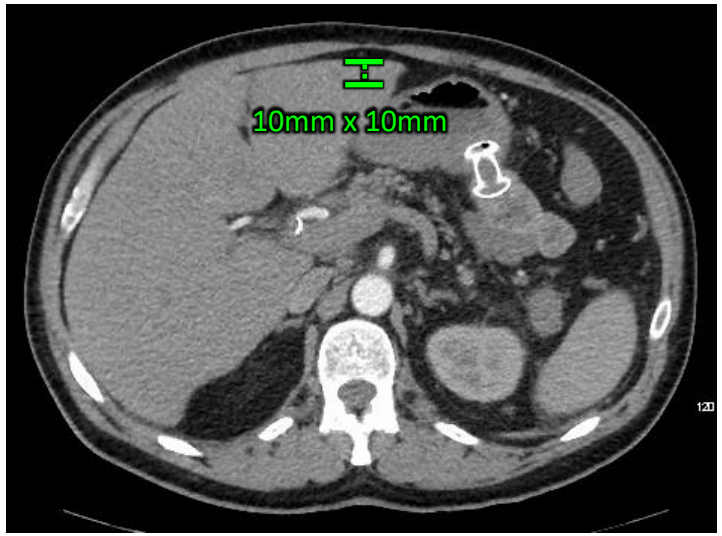
>40% reduction of index lesion



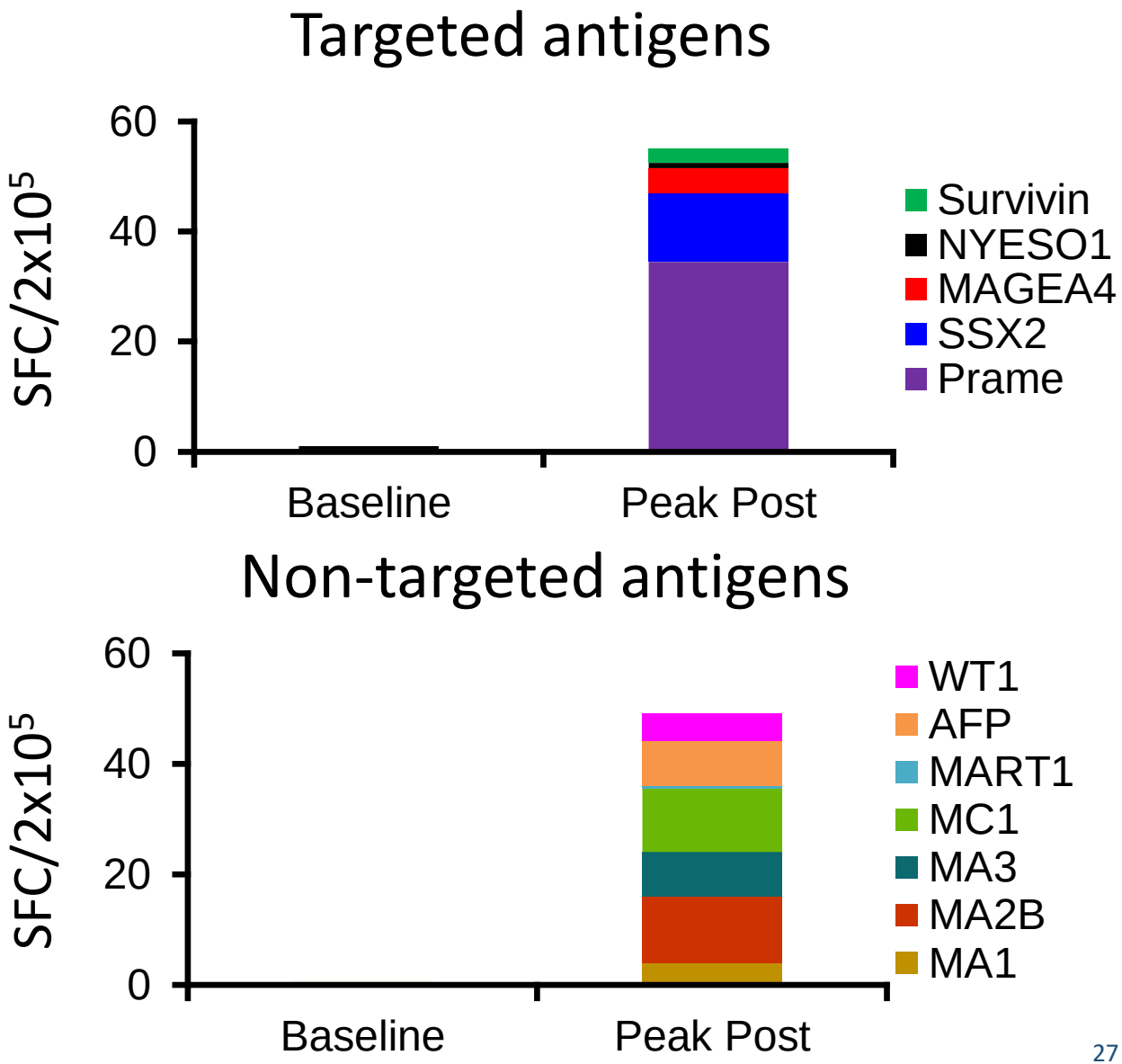


Clinical response : pt#12

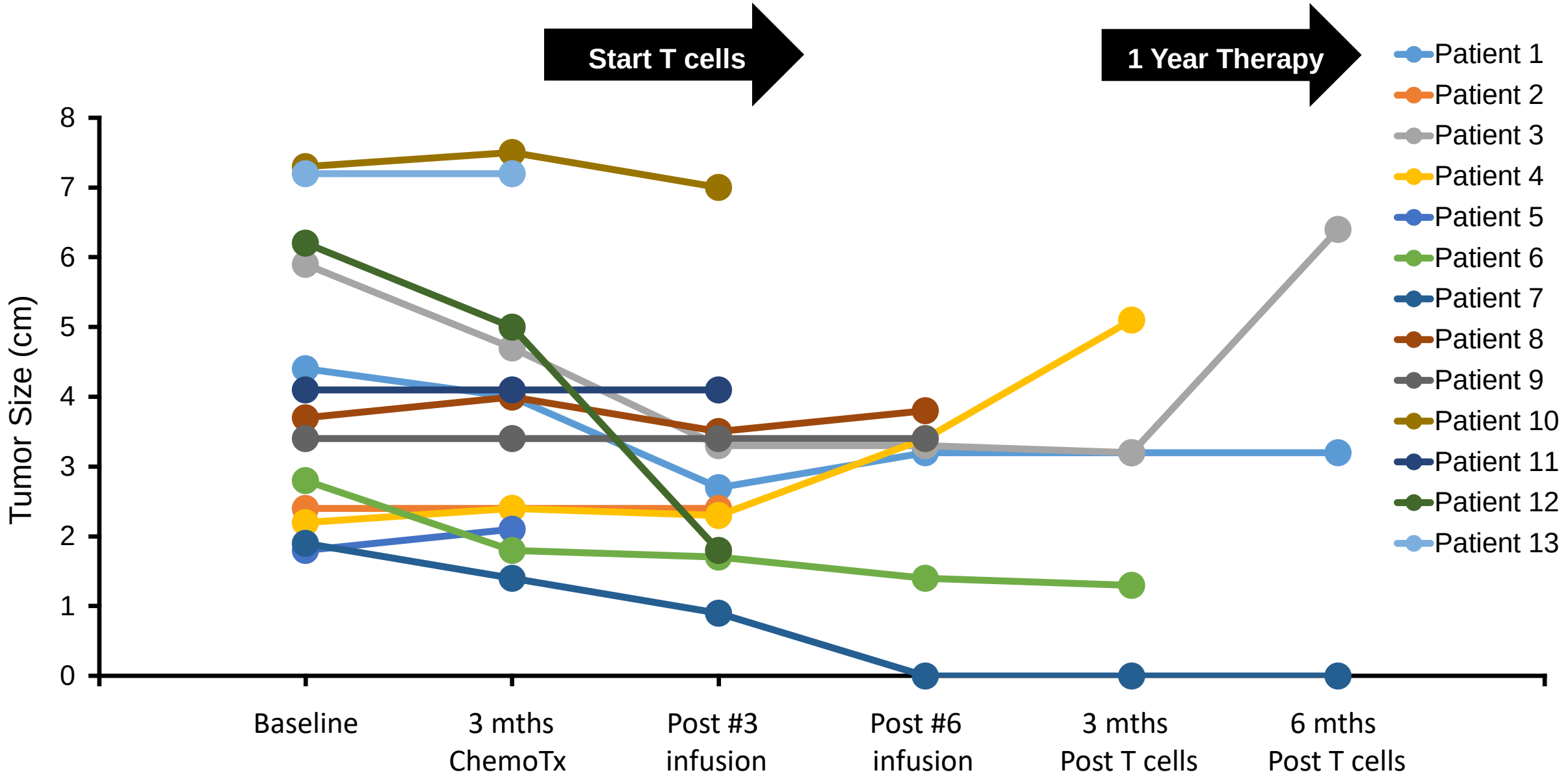
Prior to multiTAA T cells



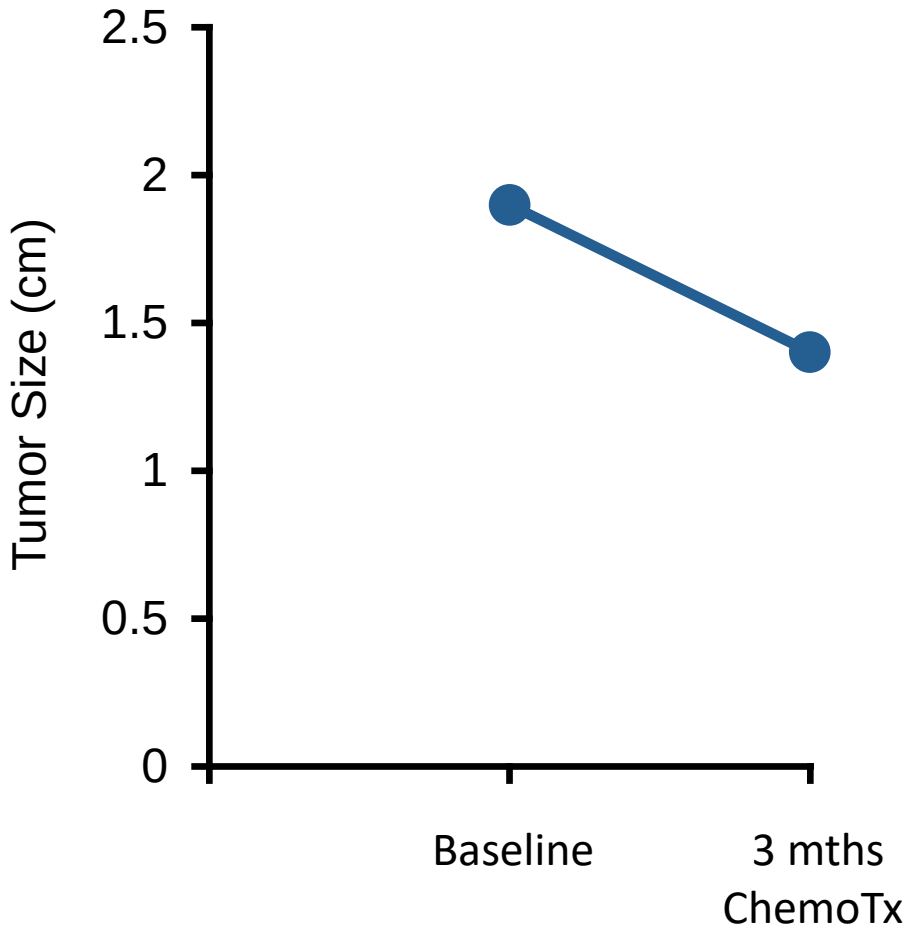
6 months post multiTAA T cells



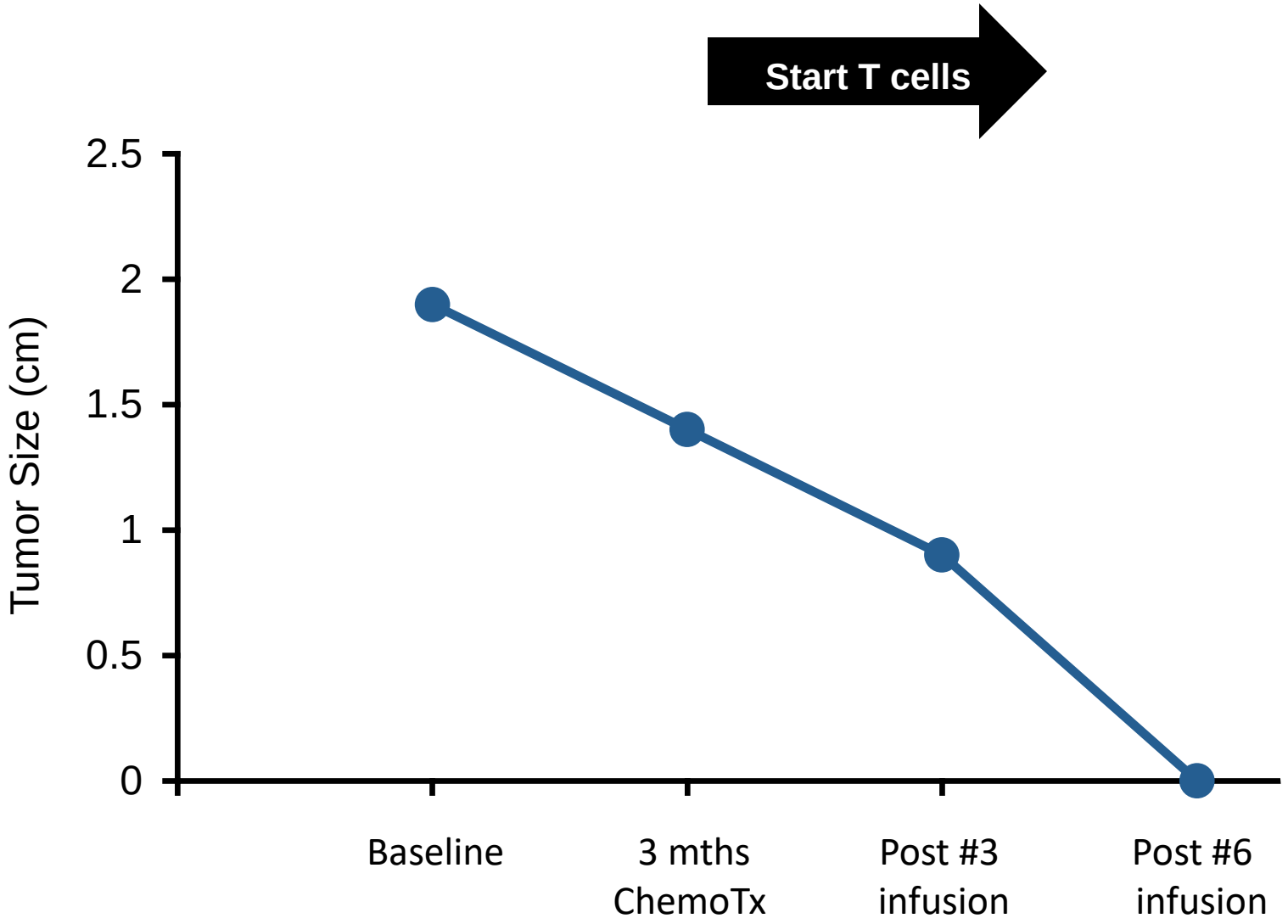
Aggregate Tumor Measurements



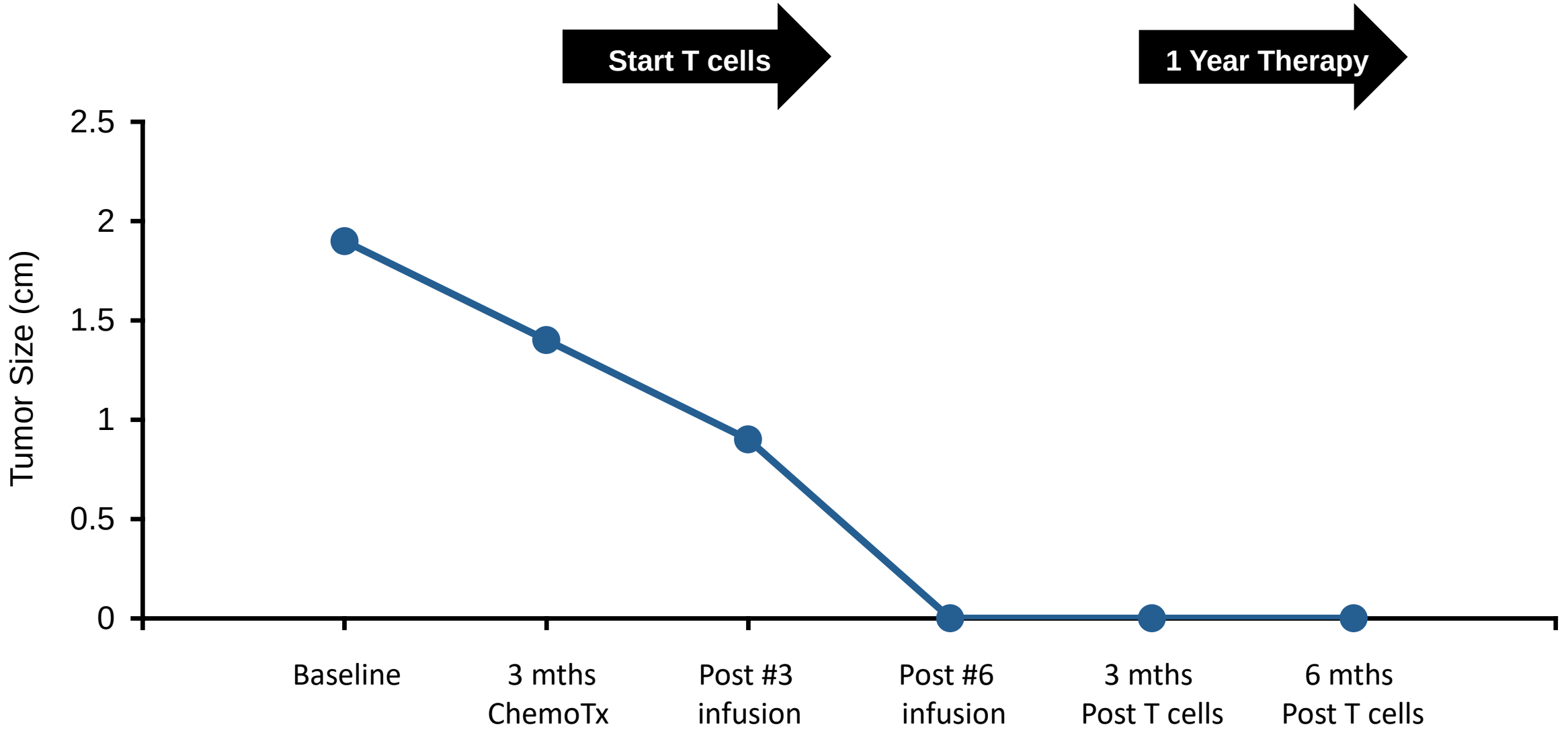
Radiographic CR : pt#7



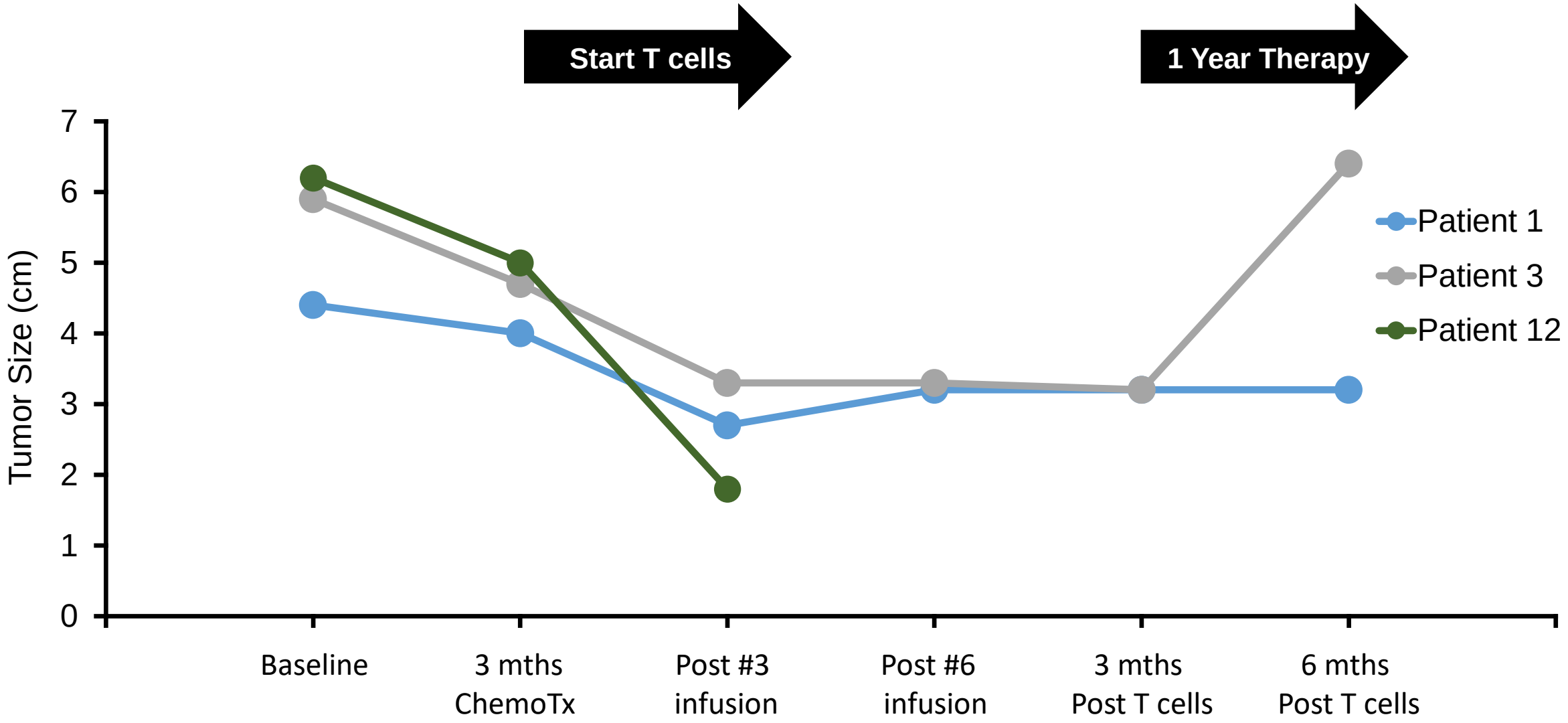
Radiographic CR : pt#7



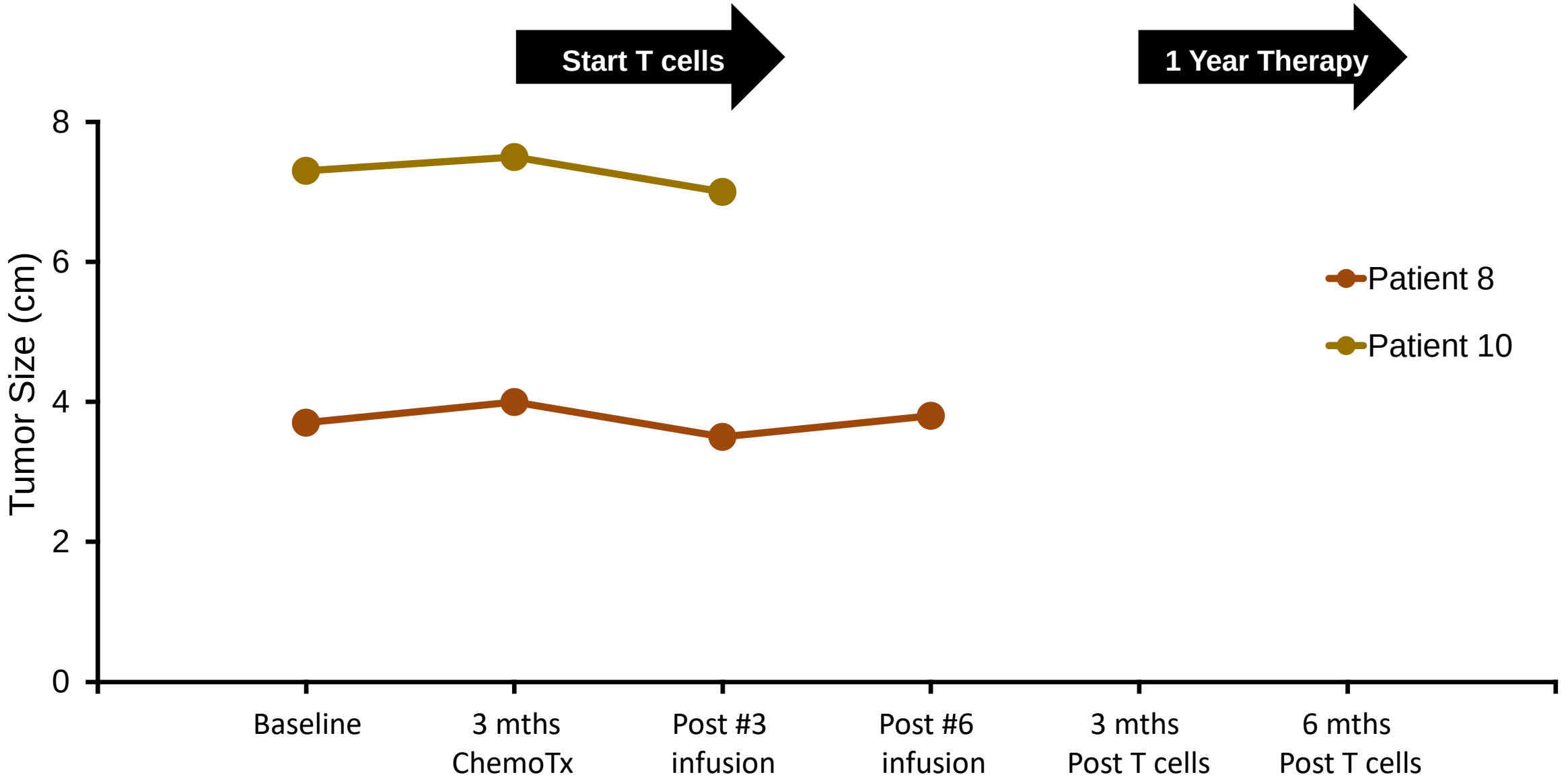
Radiographic CR : pt#7



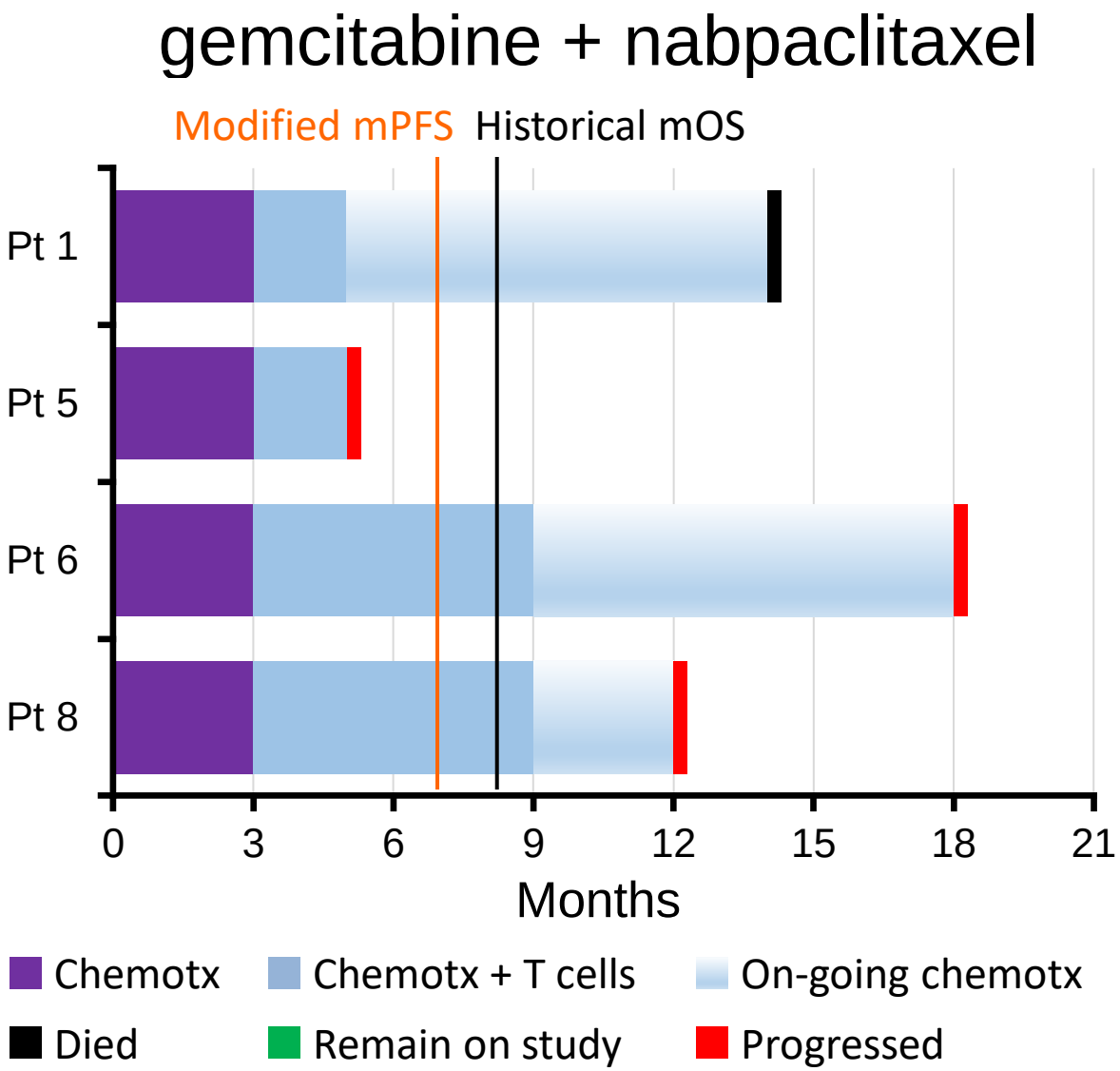
Enhanced Responses



Arresting Progression

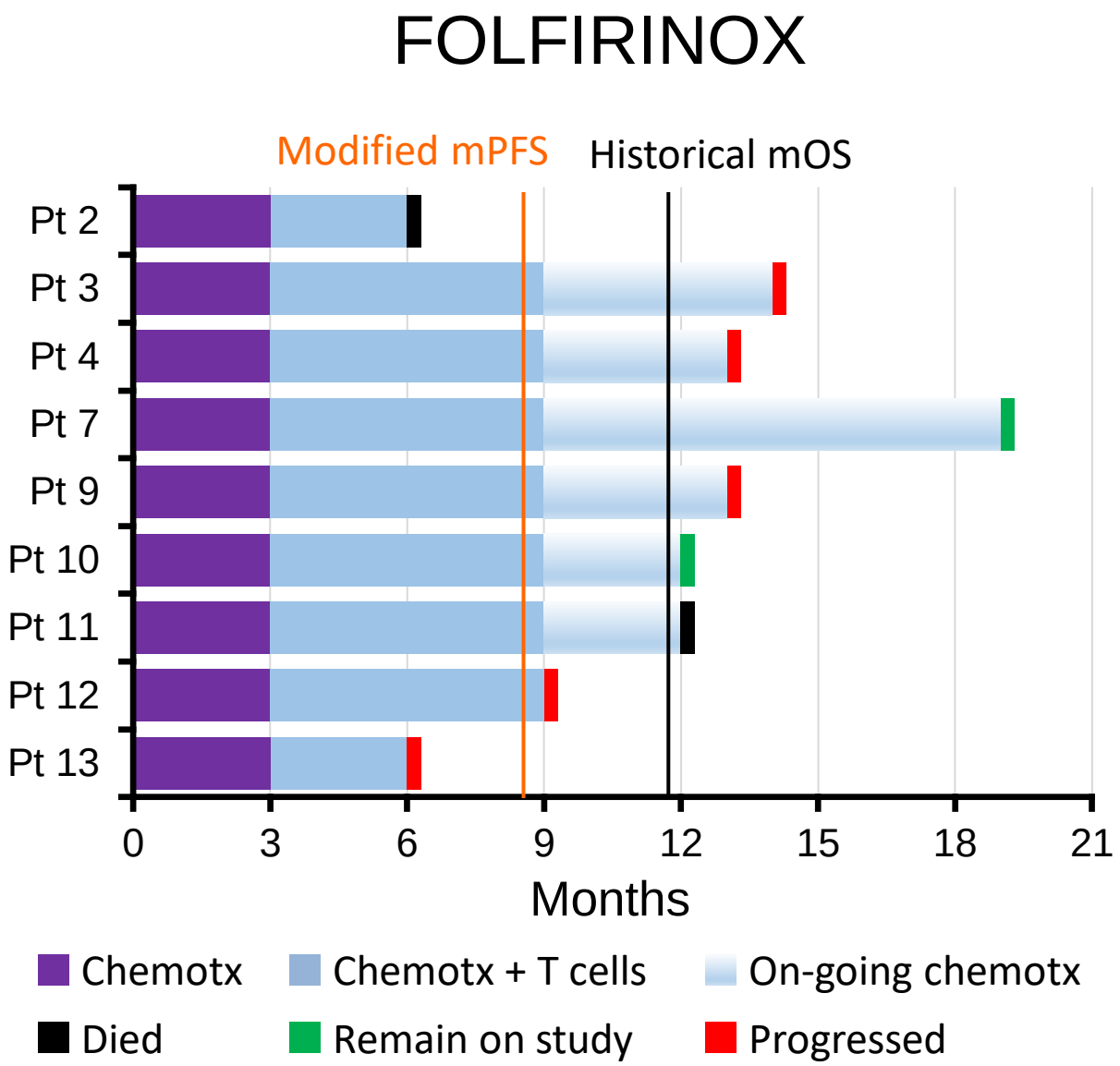


MultiTAA T cells + Chemo Summary



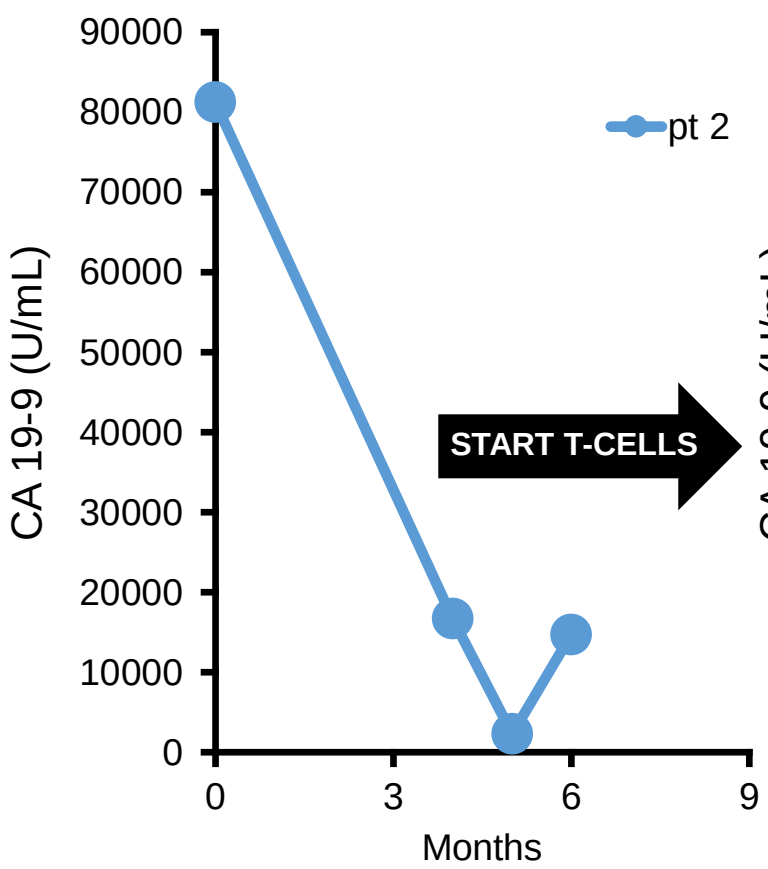
Patient	Best RECIST response on T cell therapy
1	Partial Response
5	Progressive Disease
6	Stable Disease
8	Stable Disease

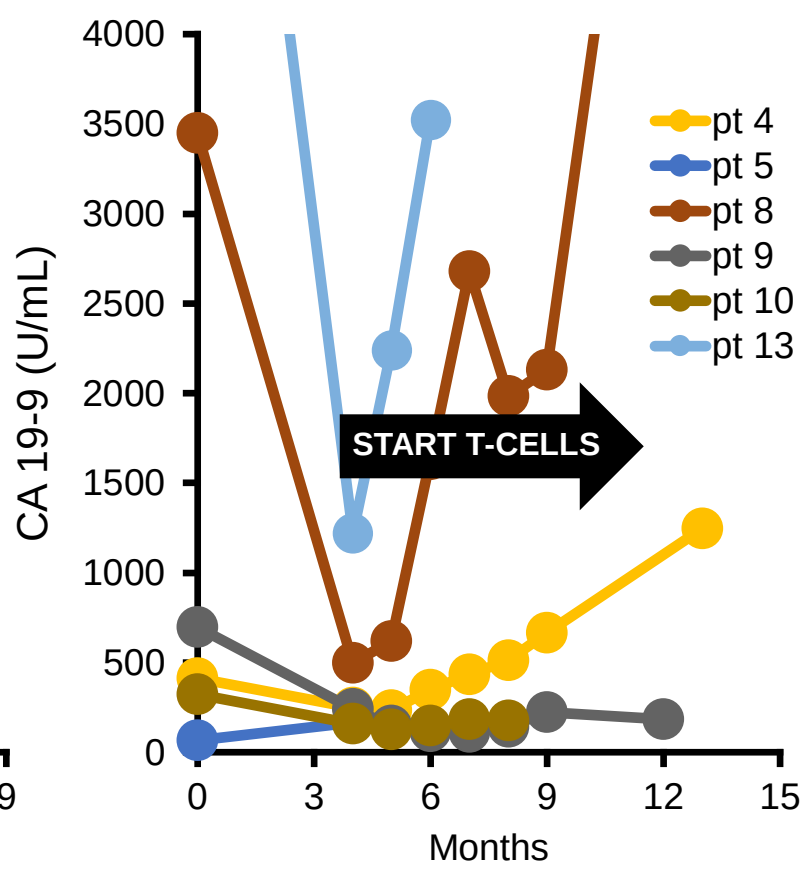
MultiTAA T cells + Chemo Summary

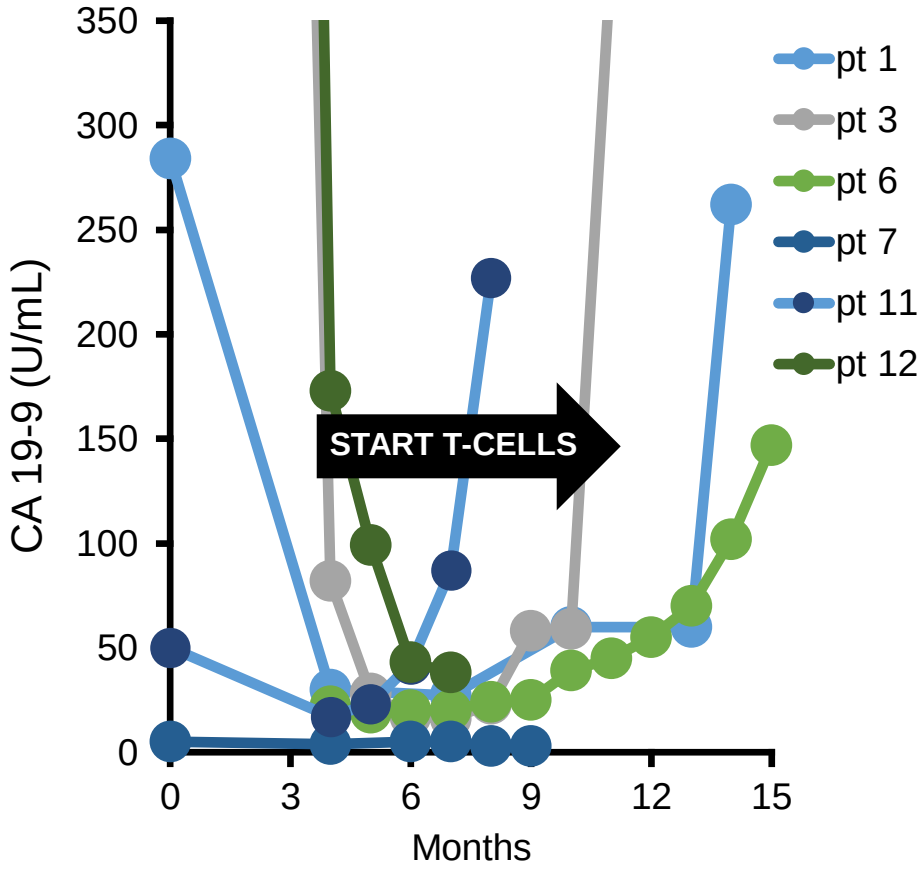


Patient	Best RECIST response on T cell therapy
2	Mixed response
3	Partial Response
4	Stable Disease
7	Radiographic Complete Response
9	Stable Disease
10	Stable Disease
11	Stable Disease
12	Partial Response
13	Progressive Disease

CA 19-9 trends







Treatment Summary

- No additional side effect when adding t-cell therapy
- Durable cancer control with 9/13 patients exceeding historical control of overall survival
- Measurable tumor responses in 4 patients

Conclusions

- Feasible to manufacture multiTAA T cells
- Well tolerated
- Encouraging cancer treatment results
- In vivo expansion of tumor-specific T cells observed
- Antigen spreading

Future

- Encouraging effects seen with chemotherapy
- Explore first line therapy in advanced cancer with earlier t-cell initiation
- Refine which antigens to target

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PANCREATIC CANCER ACTION NETWORK

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