

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

**June 1, 2020**

Date of Report (Date of earliest event reported)

**MARKER THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-37939**

(Commission File Number)

**45-4497941**

(IRS Employer Identification No.)

**3200 Southwest Freeway  
Suite 2240**

**Houston, Texas**

(Address of principal executive offices)

**77027**

(Zip Code)

**(713) 400-6400**

Registrant's telephone number, including area code

**N/A**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	MRKR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On June 1, 2020, Marker Therapeutics, Inc. (the “**Company**”) hosted a live webcast featuring Brandon G. Smaglo, M.D., FACP, lead investigator and Associate Professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, Houston, Texas, and the Company’s senior management to discuss interim results from an investigator-sponsored clinical trial led by Baylor College of Medicine evaluating the Company’s MultiTAA therapy for the treatment of patients with pancreatic adenocarcinoma. A copy of the slides presented during the webcast is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today’s date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Company presentation, dated June 1, 2020</u></a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Marker Therapeutics, Inc.**

Dated: June 1, 2020

By: /s/ Anthony Kim  
Anthony Kim  
*Chief Financial Officer*

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# **Phase 1 Trial in Pancreatic Adenocarcinoma (TACTOPS)**

JUNE 1, 2020



**MARKER**  
THERAPEUTICS

## FORWARD LOOKING STATEMENTS

This presentation includes forward-looking statements. All statements contained in this presentation other than statements of historical facts, including statements regarding future results of operations and financial position of Marker Therapeutics, Inc. ("Marker," "we," "us," "our" or the "Company"), our business strategy and plans, our research, development and regulatory activities and expectations relating to our non-engineered multi-tumor antigen specific T cell therapies, the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases and the timing and success of our clinical trials, as well as clinical trials conducted by our collaborators, are forward-looking statements. The words "anticipate," "believe," "continue," "estimate," "expect," "intend," "may," "will" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, clinical development, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. We are under no duty to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this presentation.



# 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

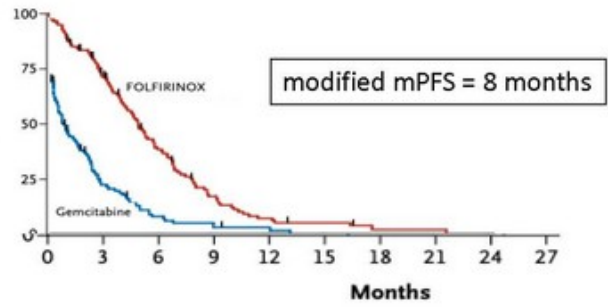
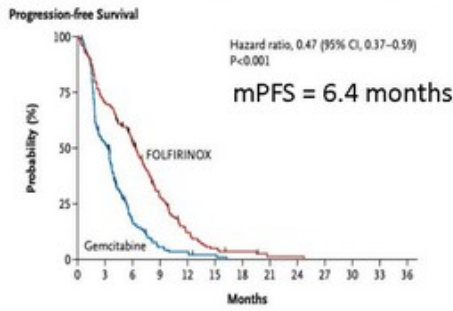
- SOC for front-line unresectable pancreatic cancer: Chemotherapy (FOLFIRINOX or Gemcitabine/nab-paclitaxel)
- Less than **20%** of patients are candidates for surgery (resectable) because cancer has usually spread by the time of diagnosis



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

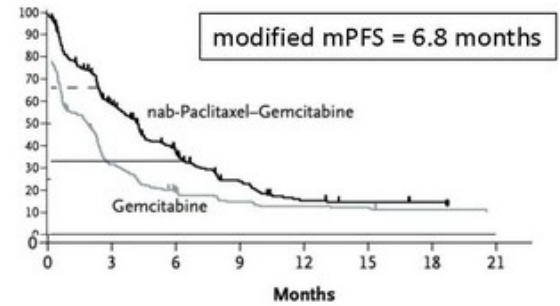
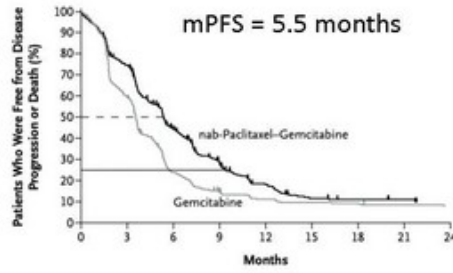
We commissioned an outside statistician to analyze the expected PFS for patients consistent with the eligibility of BCM Ph1 TACTOPS study by removing patients who progressed during the first 3 months of chemotherapy alone

FOLFIRINOX  
(ACCORD study)



Expected PFS  
based on Baylor  
Ph1 Eligibility

Nab-Paclitaxel-Gemcitabine  
(MPACT study)



# 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







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**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*

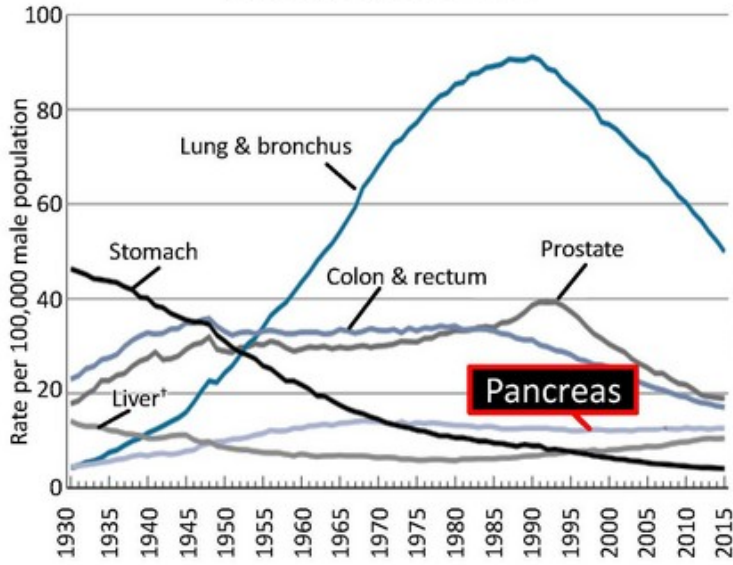
*TACTOPS study conducted by Baylor College of Medicine*

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)

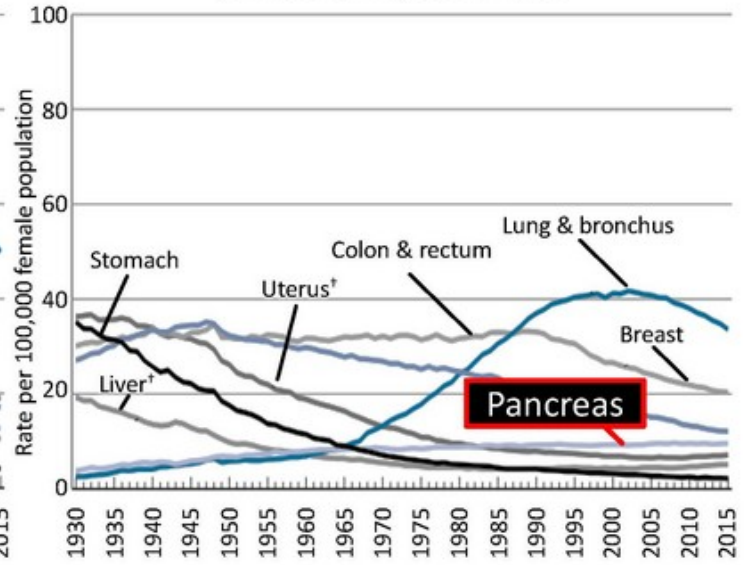
Brandon G Smaglo, MD, FACP

# Pancreatic Cancer Mortality

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



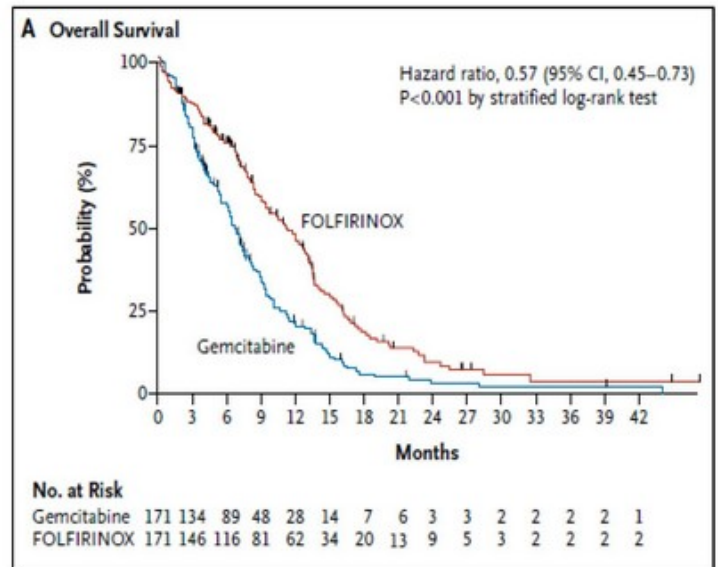
Trends in Age-adjusted Cancer Death Rates, **Females**, US, 1930-2015



American Cancer Society Fact & Figures 2018

# ACCORD-11:FOLFIRINOX

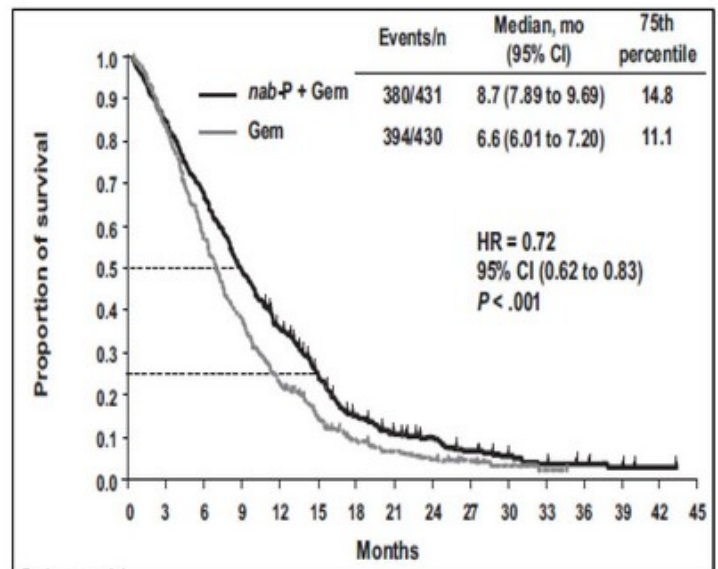
- First line option for metastatic disease
- Toxic
  - Not all patients can tolerate
  - Cannot continue indefinitely
- mOS 11.1 months
- mPFS 6.4 months



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

# MPACT:gemcitabine/nabpaclitaxel

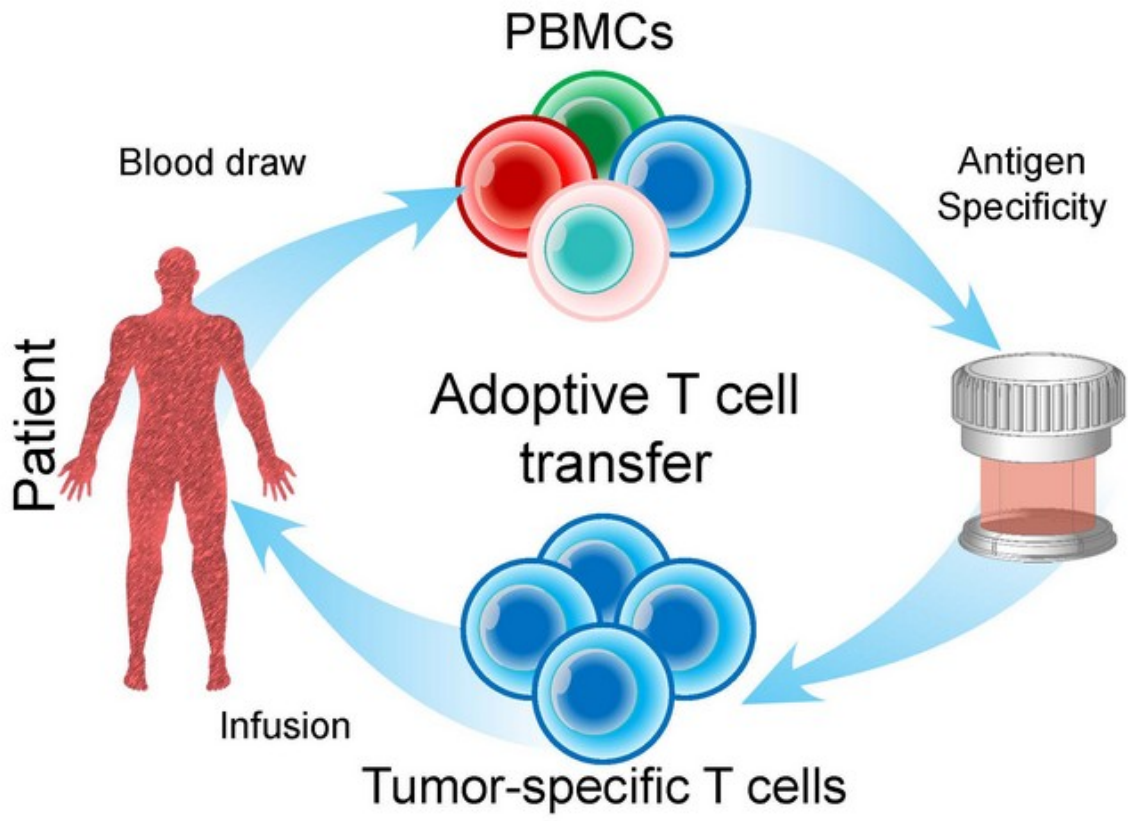
- First line option for metastatic disease
- Thought of as less toxic
- mOS 8.5 months
- mPFS 5.5 months



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

# Pancreatic Cancer: Treatment

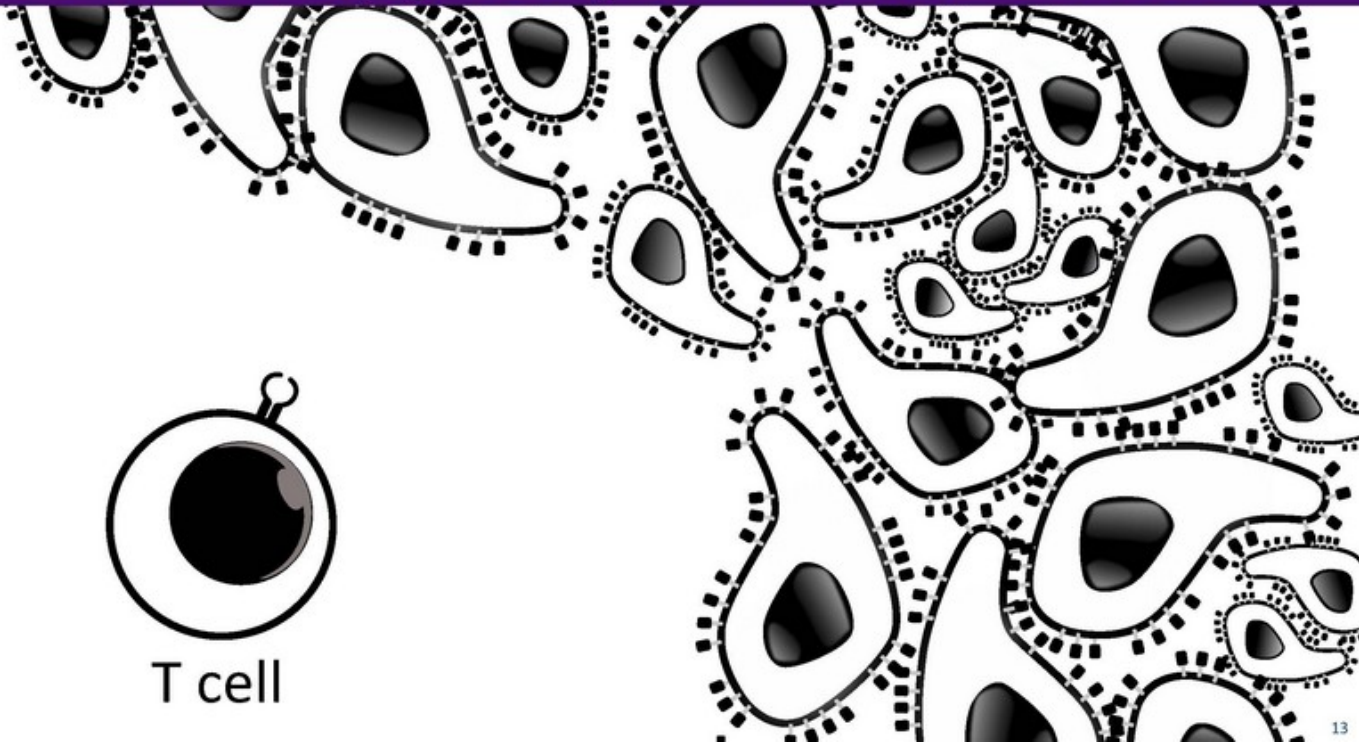
- Combination chemotherapy (FFX or G/A)
  - Non-chemotherapy options very limited
- Side effects
  - Cumulative: fatigue, neuropathy, cytopenias
  - Repetitive: nausea, vomiting, diarrhea
  - Distressing: alopecia, cold-hypersensitivity
- T cell therapy options attractive for exploration



# T cell therapy for pancreatic cancer

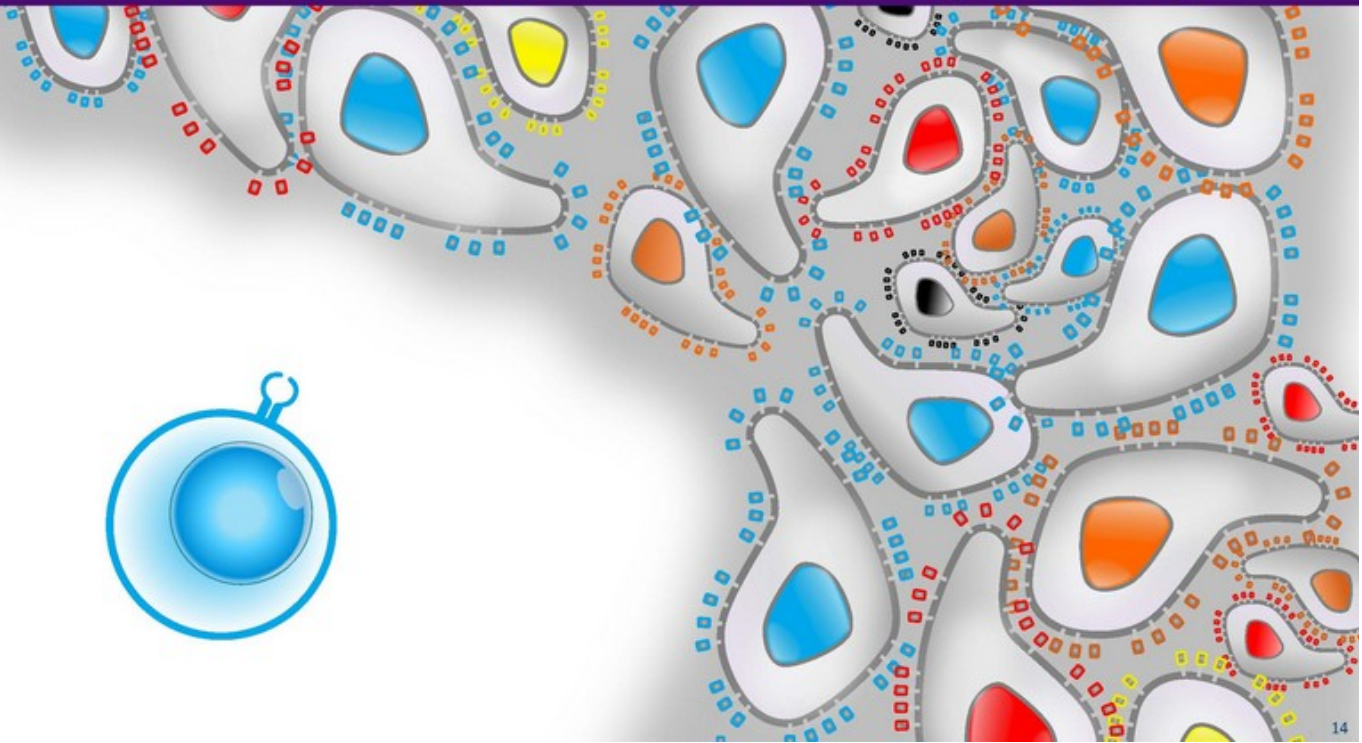


T cell

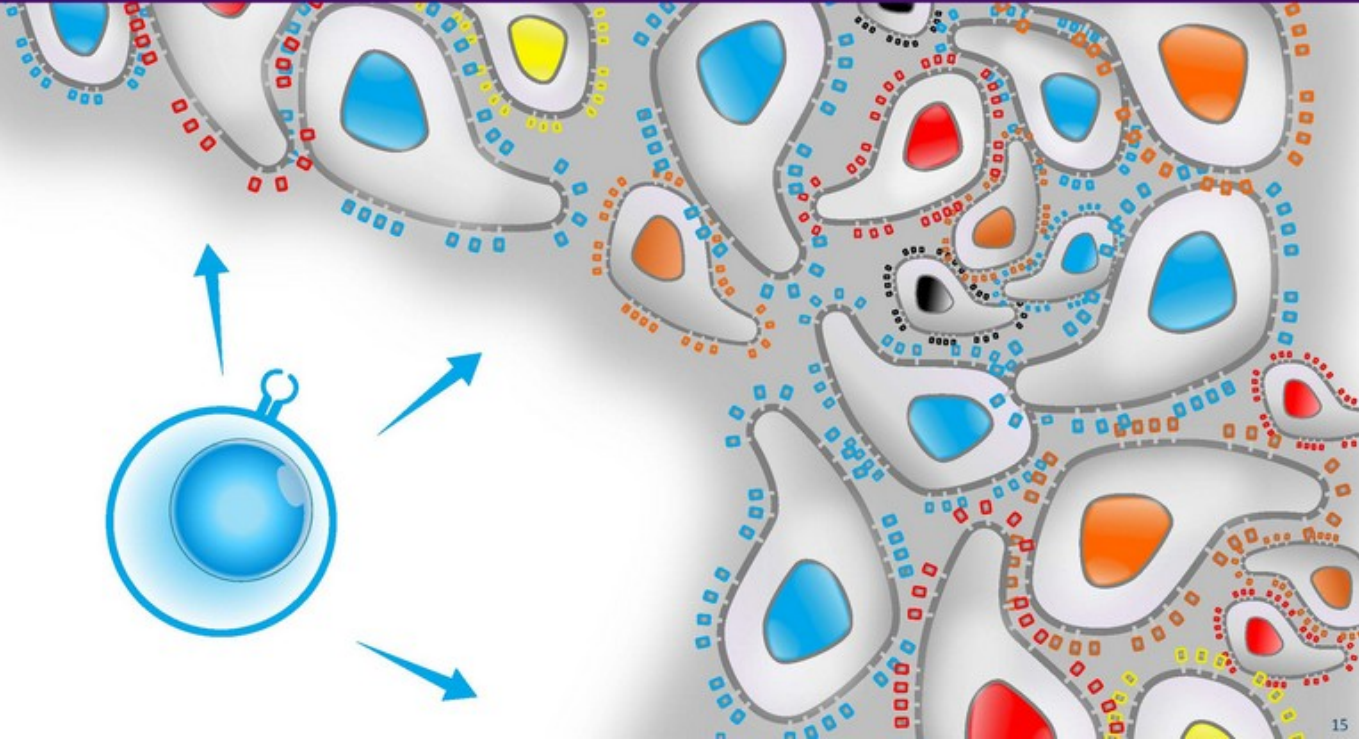




# Challenge: Tumor heterogeneity



# Immune Escape

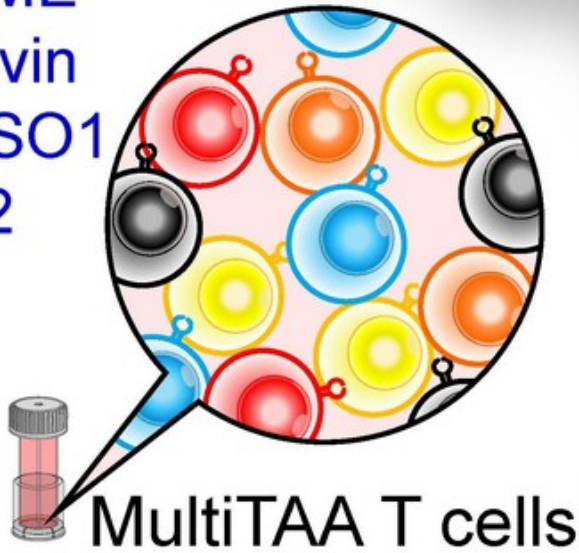


# Our approach

- 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



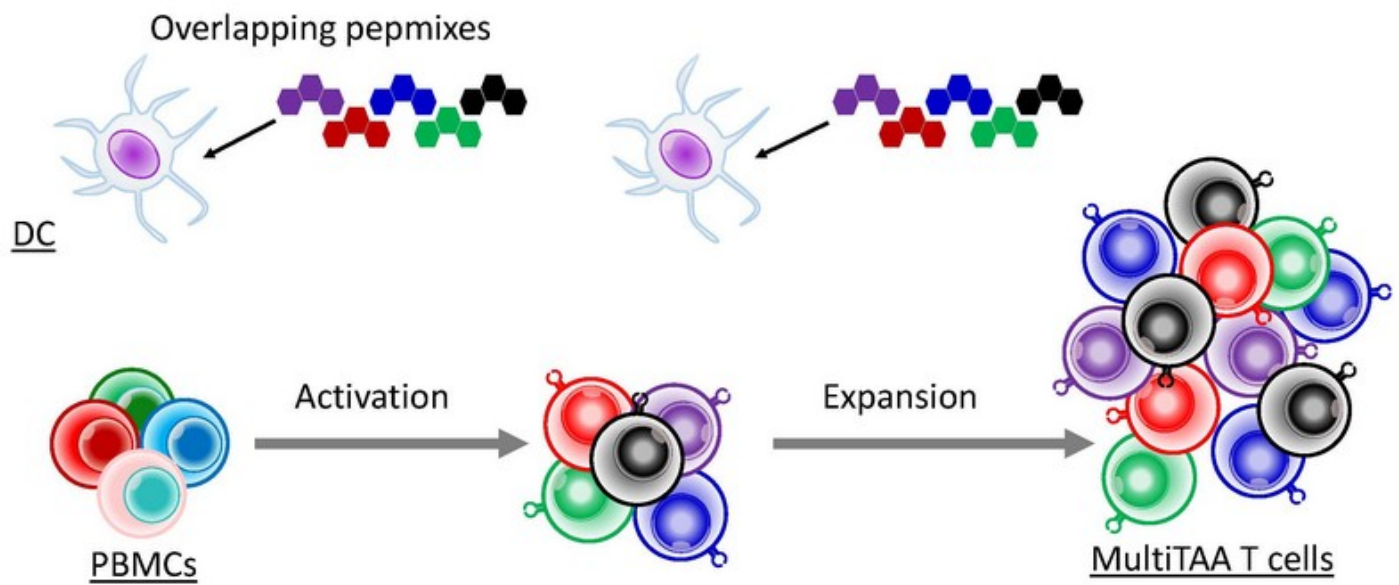
MultiTAA T cells

# TAA Expression in PDAC

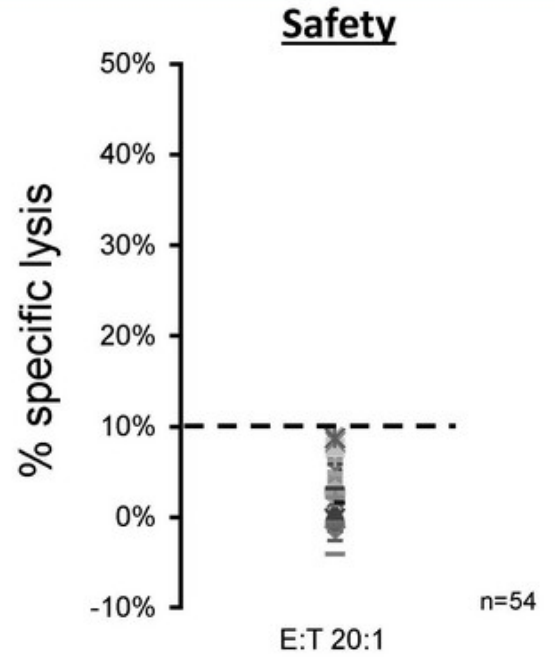
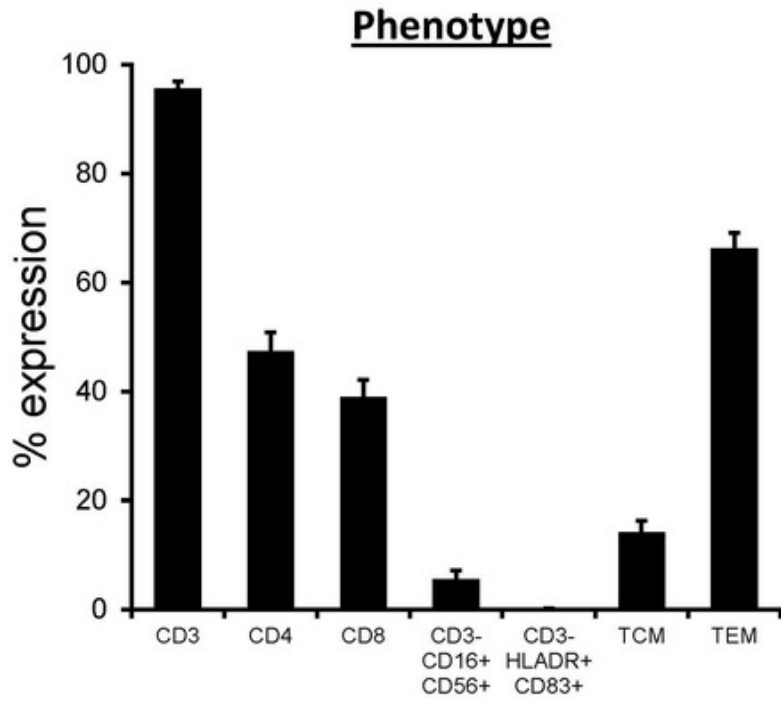
TAA	Expression in PDAC
Survivin	>75% <sup>1-2</sup>
SSX family	3-30% <sup>3-5</sup>
MAGE-A family	20-86% <sup>3, 5-8</sup>
PRAME	>30% <sup>9</sup>
NY-ESO-1	2-10% <sup>3,5</sup>

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

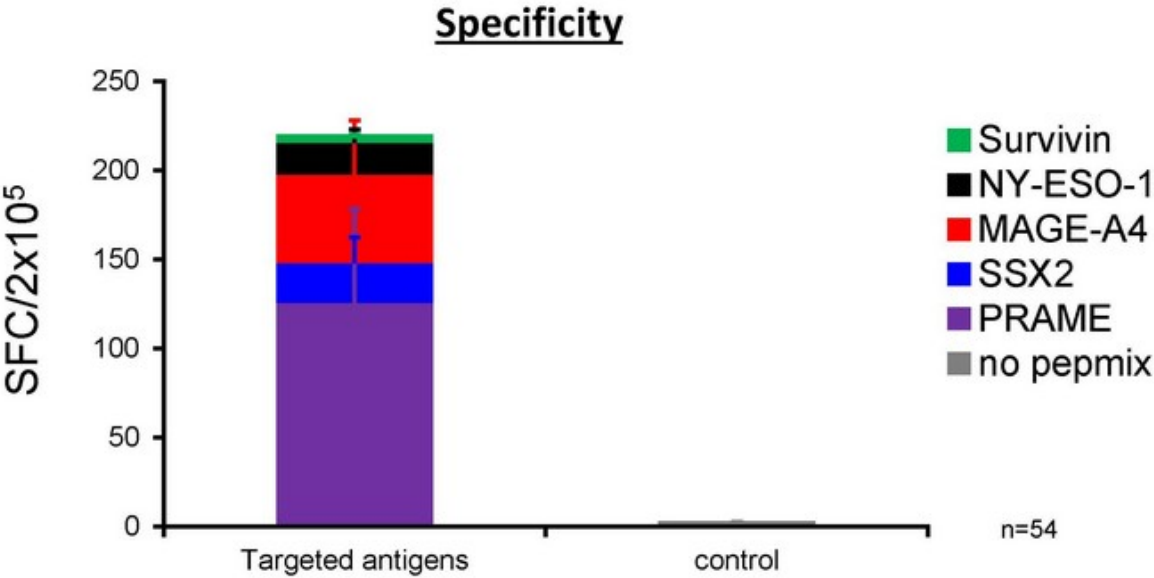
# MultiTAA-T Cell Generation



# Profile of MultiTAA-T cells



# MultiTAA T cell specificity





# Clinical Trial: TACTOPS

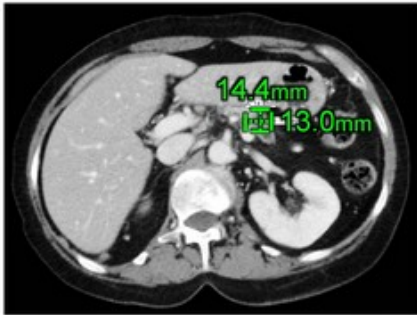
- 6 Infusions, fixed cell dose ( $1 \times 10^7/m^2$ ) - no lymphodepletion
- Receive 3 months chemotherapy
  - Procurement performed and T cells generated
- If cancer controlled after 3 months, start receiving monthly T cell infusions along with ongoing chemotherapy

# 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

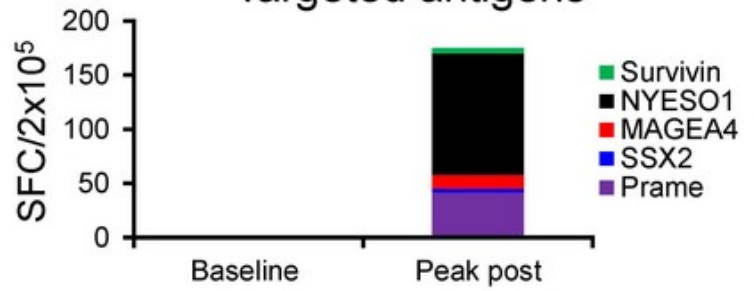
Prior to multiTAA T cells



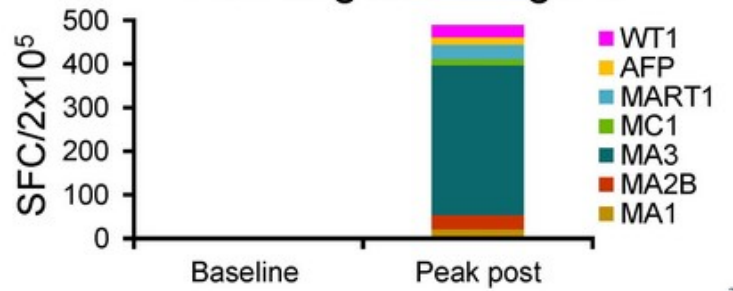
6 months post multiTAA T cells



### Targeted antigens

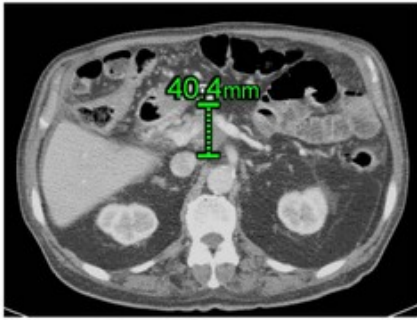


### Non-targeted antigens

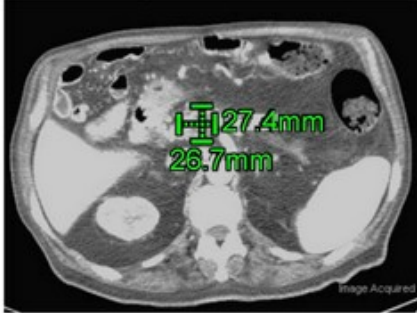


# Clinical response : pt#1

Prior to multiTAA T cells

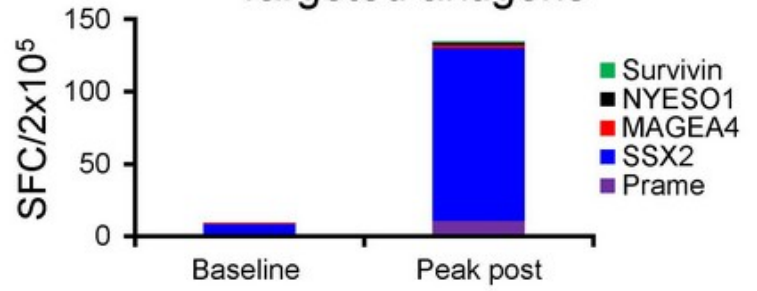


2 months post multiTAA T cells

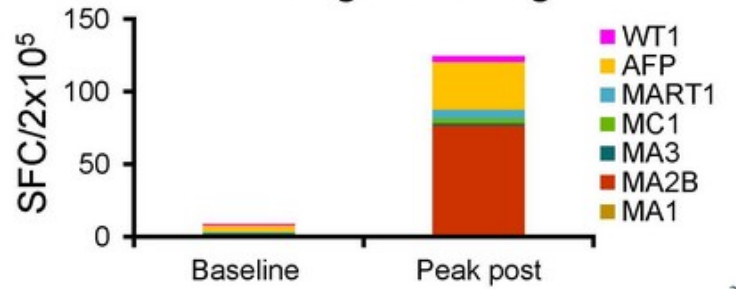


>30%  
reduction  
of index  
lesion

### Targeted antigens



### Non-targeted antigens



# Clinical response : pt#3

Prior to multiTAA T cells

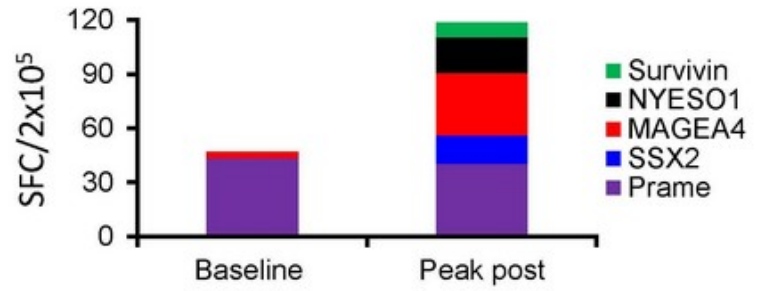


6 months post multiTAA T cells

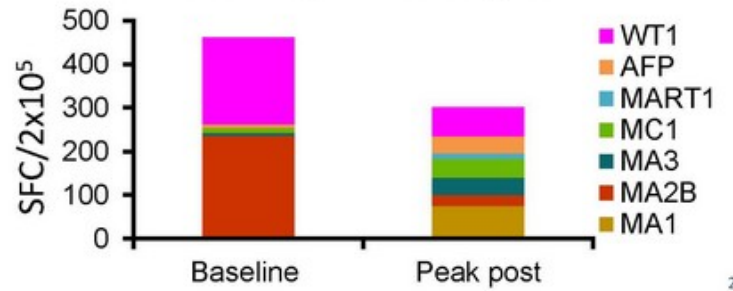


>40%  
reduction  
of index  
lesion

Targeted antigens

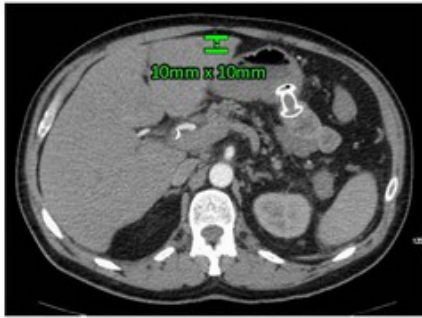


Non-targeted antigens

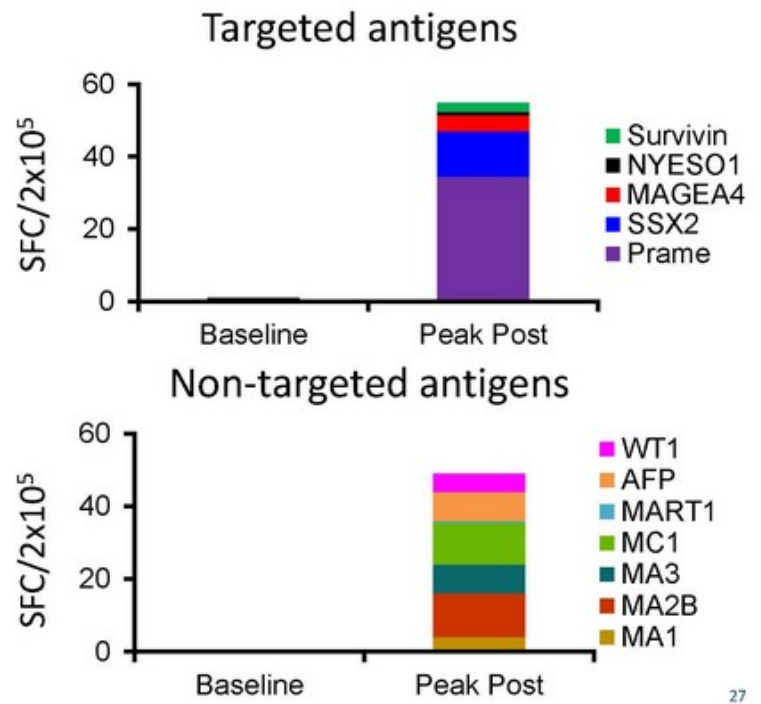


# Clinical response : pt#12

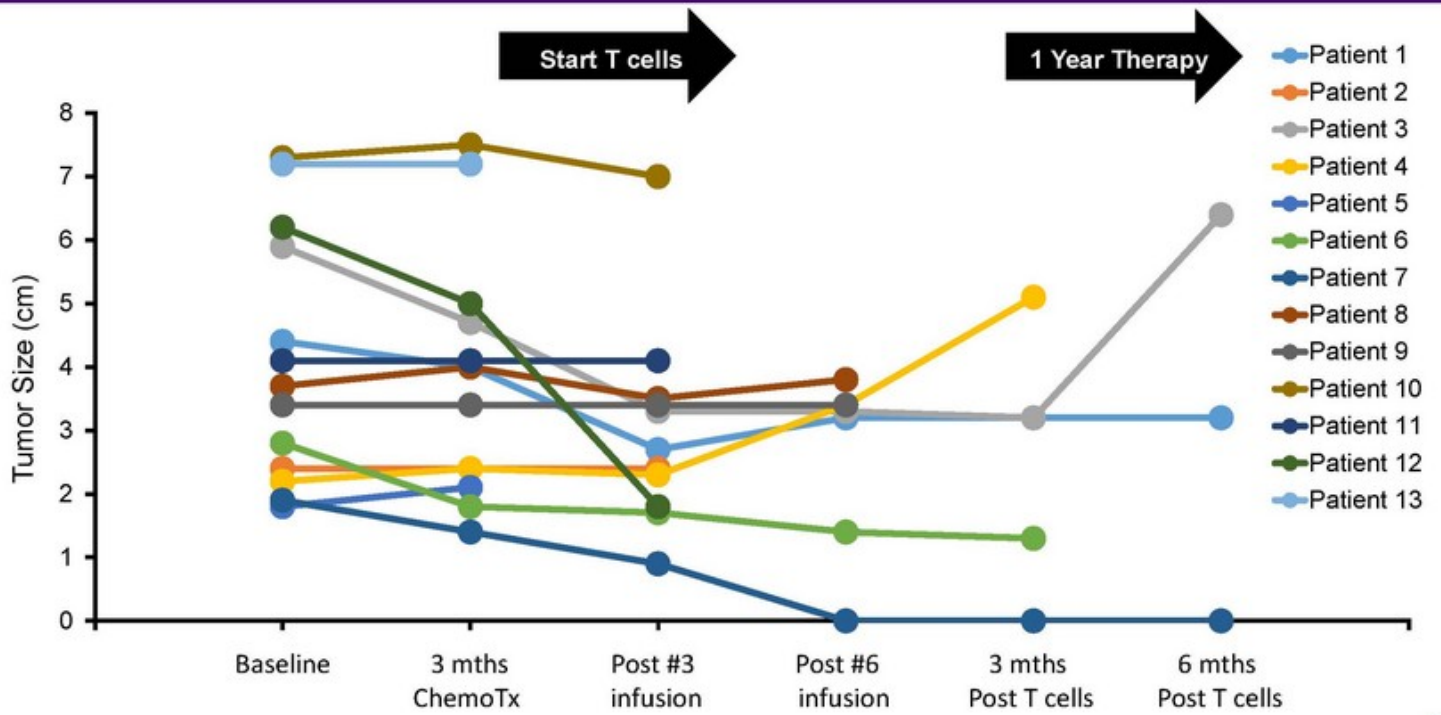
Prior to multiTAA T cells



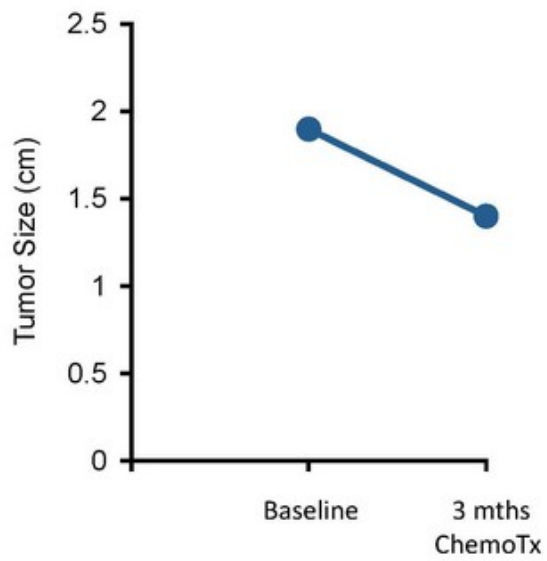
6 months post multiTAA T cells



# Aggregate Tumor Measurements

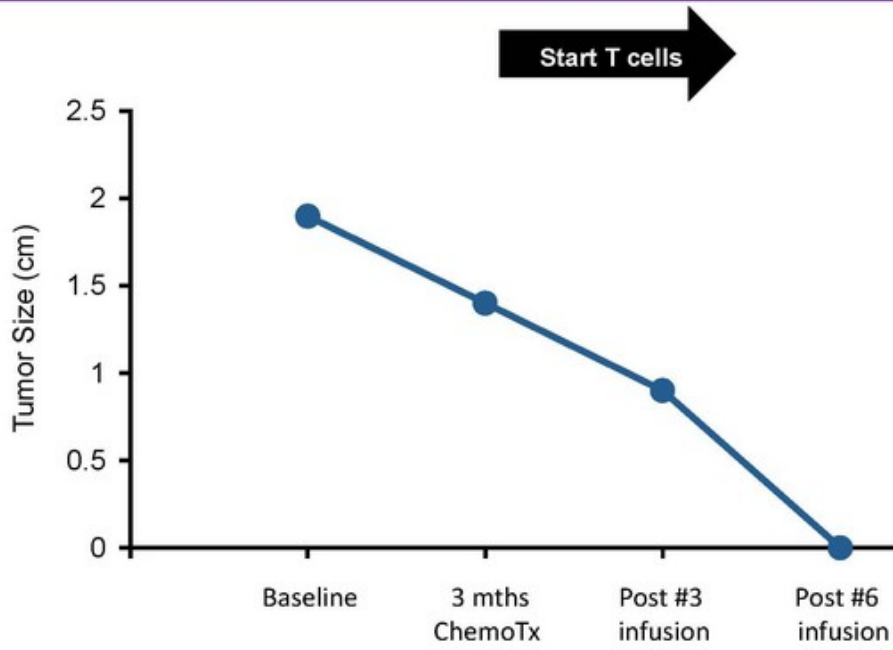


# Radiographic CR : pt#7

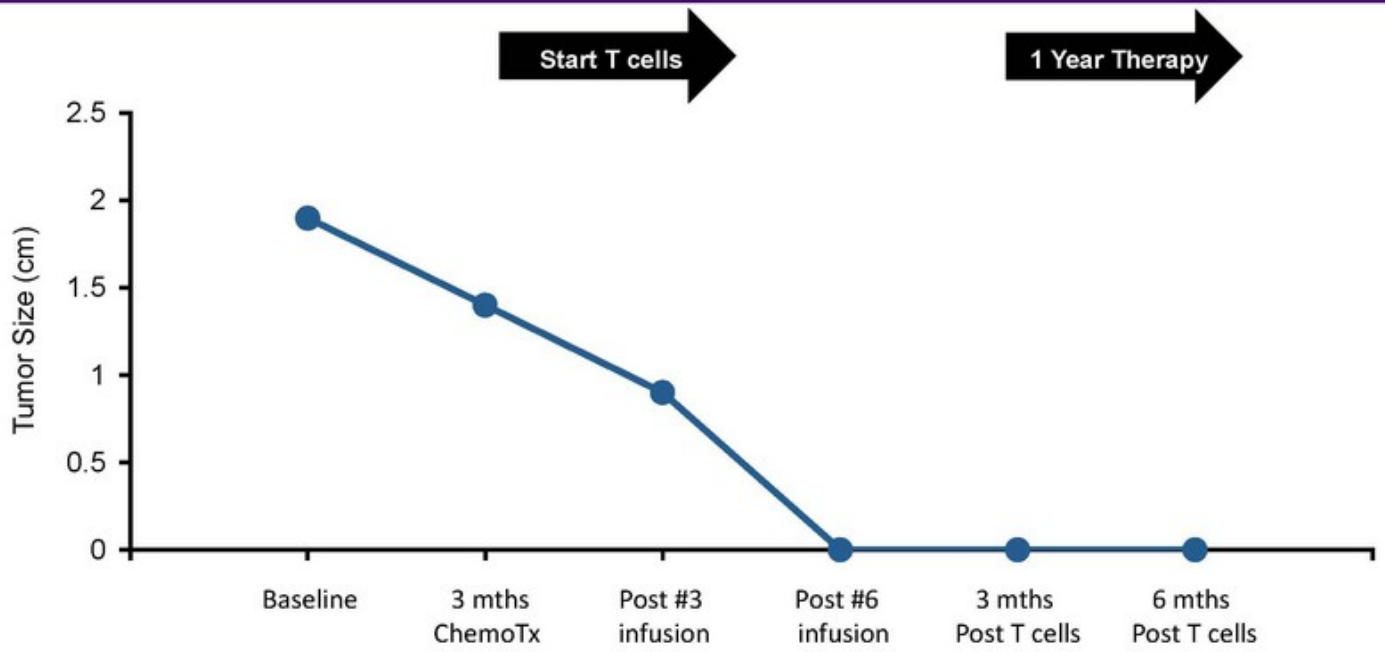




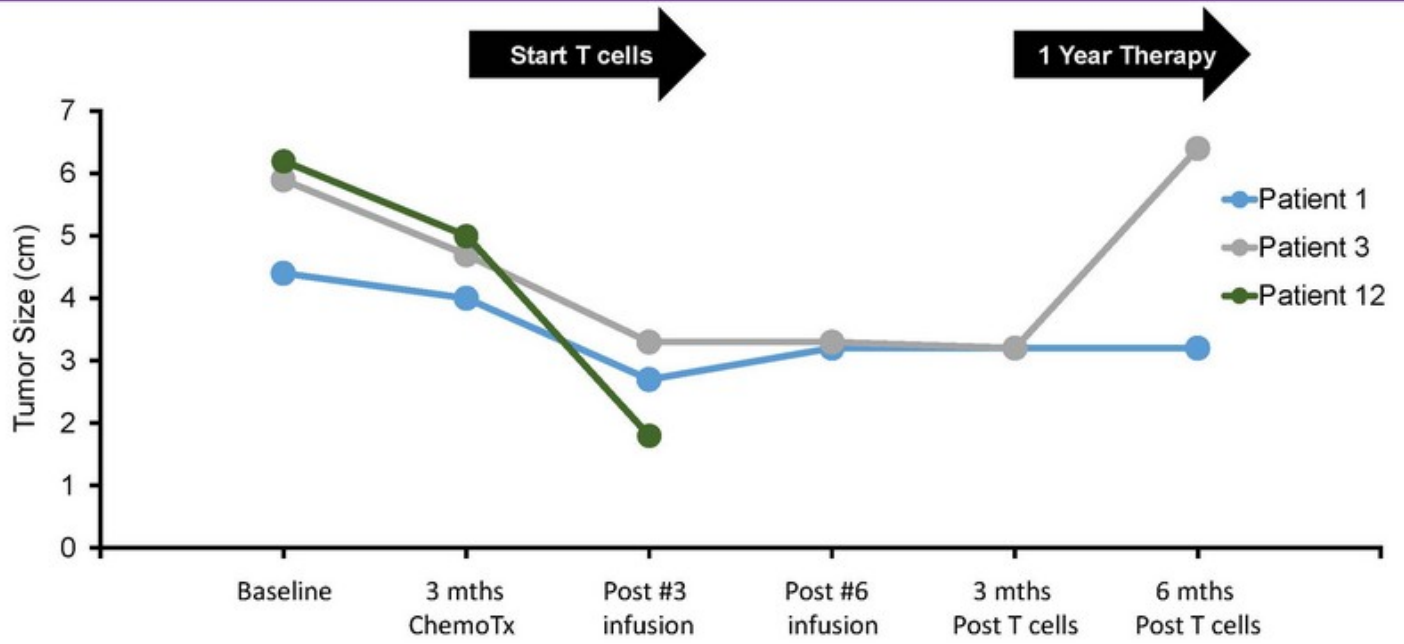
# Radiographic CR : pt#7



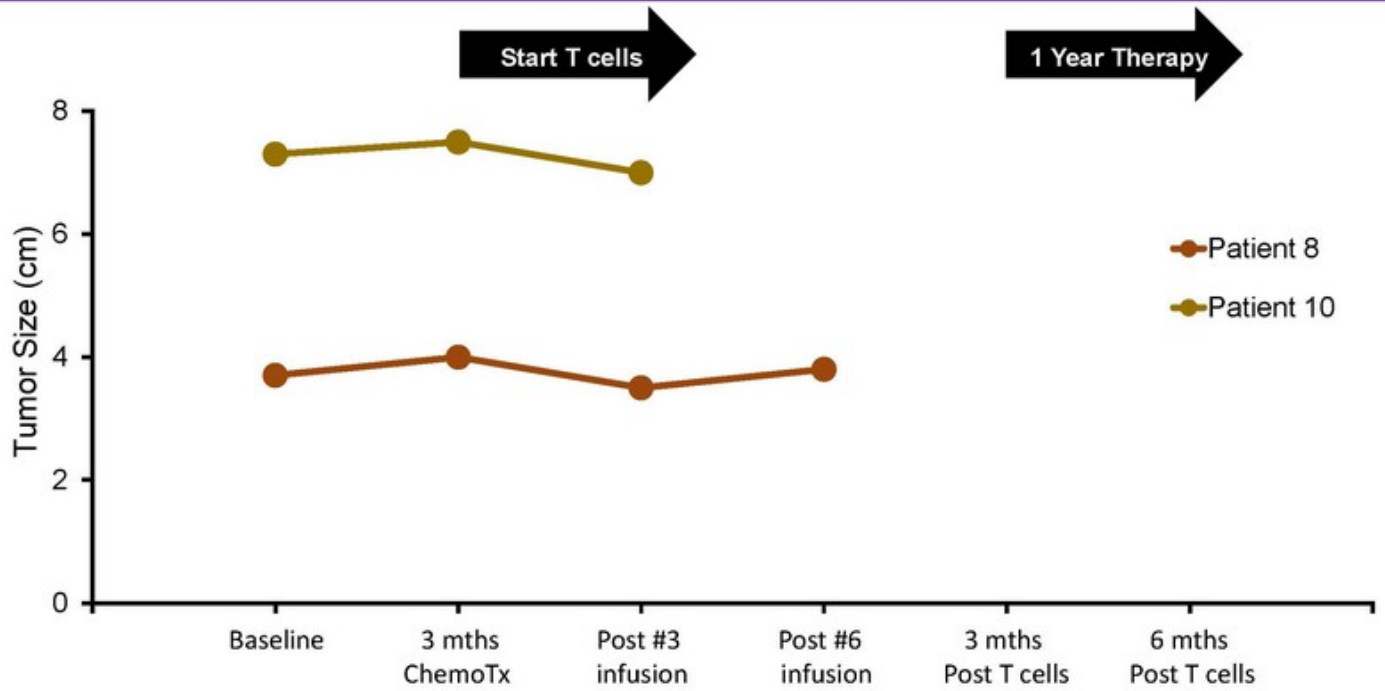
# Radiographic CR : pt#7



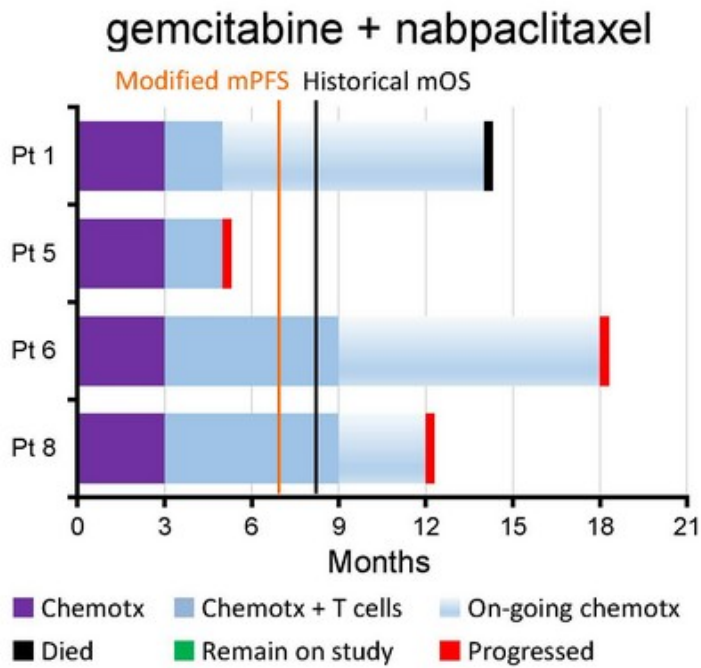
# Enhanced Responses



# Arresting Progression



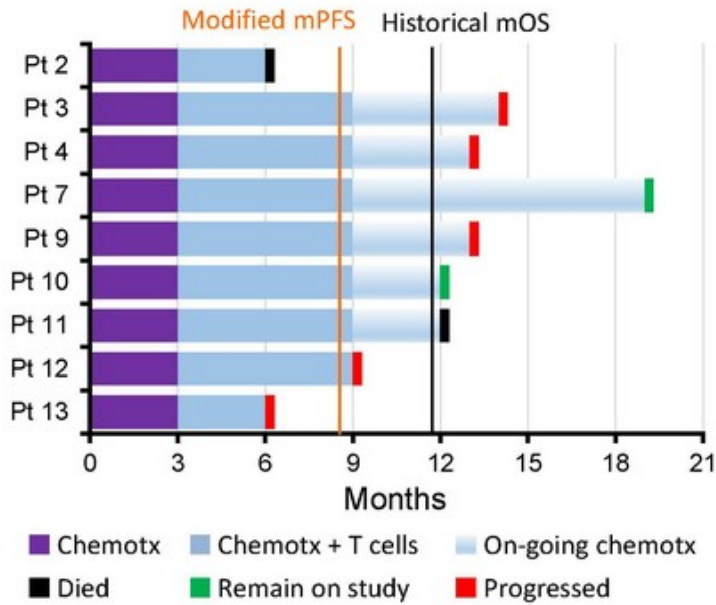
# MultiTAA T cells + Chemo Summary



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

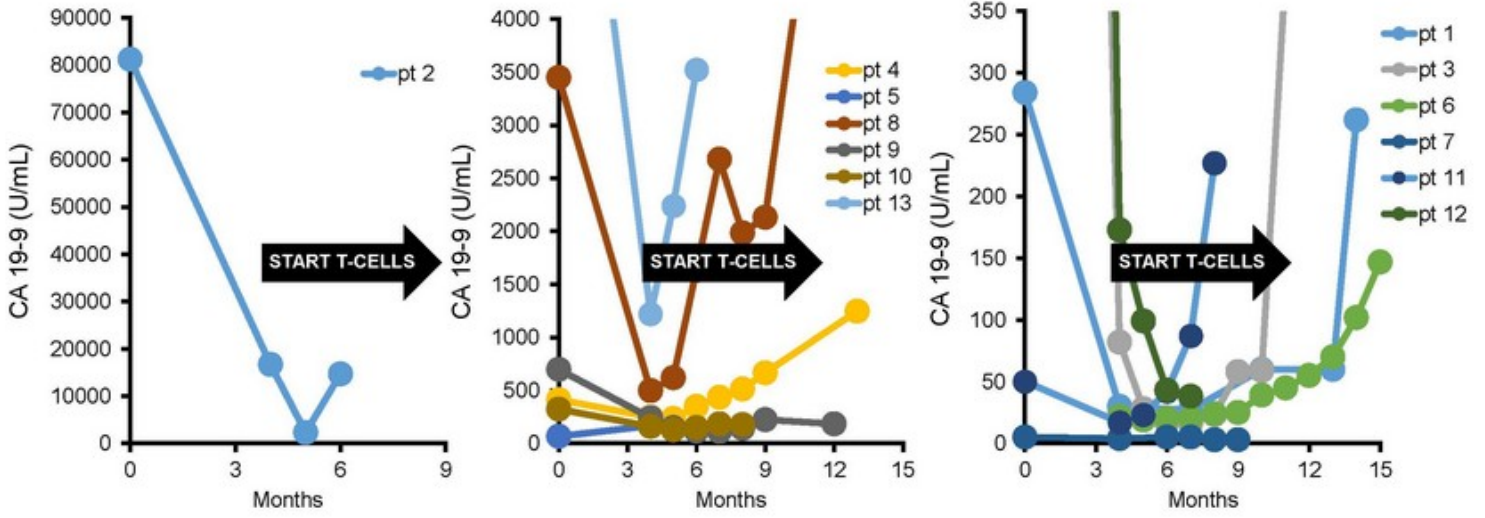
# MultiTAA T cells + Chemo Summary

## FOLFIRINOX



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

# Acknowledgements

## TRL Lab PIs

Ann Leen

Helen Heslop  
Cliona Rooney  
Malcolm Brenner  
Juan Vera

## QA/QC Laboratory

Adrian Gee  
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Natasha Lapteva  
Debbie Lyon  
April Durett  
Suzanne Poole  
Zhuyong Mei  
Crystal Silva-Lentz

## GMP Laboratory

Huimin Zhang  
Birju Mehta

## Clinical Team

Brandon Smaglo  
Yvonne Sada  
Benjamin Musher  
Premal Lulla  
Carlos Ramos  
William Fisher  
George Van Buren

## Clinical Research

Bambi Grilley  
Bridget Medina  
Catherine Robertson

## TRL Laboratory

Ifigeneia Tzannou  
Manik Kuvalekar  
Elizabeth Laval  
Yovana Velasquez  
Wingchi Leung  
Shivani Mukhi  
Tsung-Yen Chang  
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Mohsen Basiri  
Quillan Huang  
Matthew French-Kim  
Pradip Bajgain  
Norihiro Watanabe  
Alejandro Torres Chavez  
Kishore Balasubramanian

**PANCREATIC  
CANCER  
ACTION  
NETWORK**

