



Transforming Discoveries into Products: *Maximizing NIH's Levers to Catalyze Technology Transfer*

**Expediting Development of Adoptive Cell Therapy to Address Unmet
Medical Need in Oncology**

Andrew Burke, Ph.D.

Senior Technology Transfer Manager

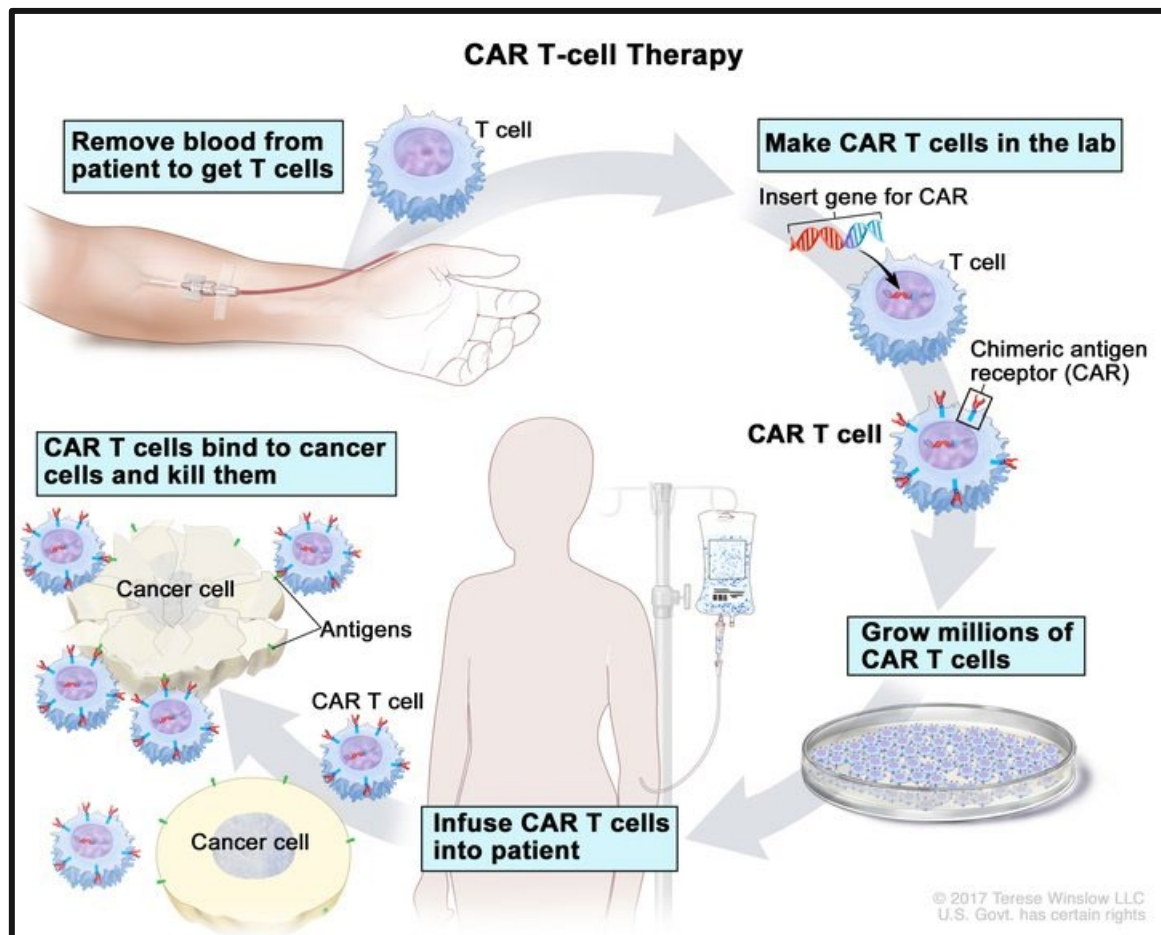
National Cancer Institute

National Institutes of Health



National Institutes of Health
Turning Discovery Into Health

Creating a Living Drug: Adoptive Cell Therapy (ACT)



CAR T-Cell Therapy: NCI Visuals Online (cancer.gov)

ACT Fast Facts

1. 6 FDA-approved CAR-T products for the treatment of certain blood cancers.
2. Significant ongoing research directed at applying ACT in the treatment of common solid cancers (e.g., breast cancer or pancreatic cancer).
3. Key research questions:
 1. Which immune cell to use (T cell, NK Cell)?
 2. Which receptor to use (CAR, TCR) and what should they target?
 3. How should the cell be engineered to express the receptor?
 4. Which cancers are amenable to treatment?

Using the Tools of Tech Transfer to Speed Development

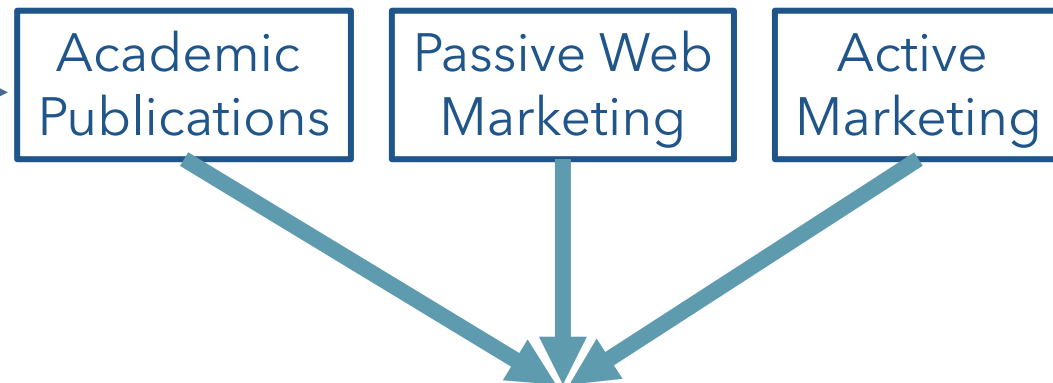
What the NCI Had

1. Large portfolio of isolated TCRs which recognize certain mutated proteins.
 - Widely expressed in cancer cells, but not normal cells.
 - Same mutation(s) found in many patients and many types of cancer.
2. Compelling early clinical data.
3. Robust patent protection.

What the NCI Needed

Capable commercial partners able to rapidly translate the NCI's inventions into the clinic.

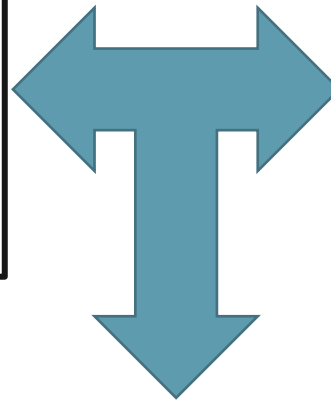
Tech Transfer in Action!



Applying Federal Licensing Statute

Problem

1. Significant unmet medical need;
2. Multiple capable applicants;
3. Requirement for exclusivity.



37 CFR § 404.7

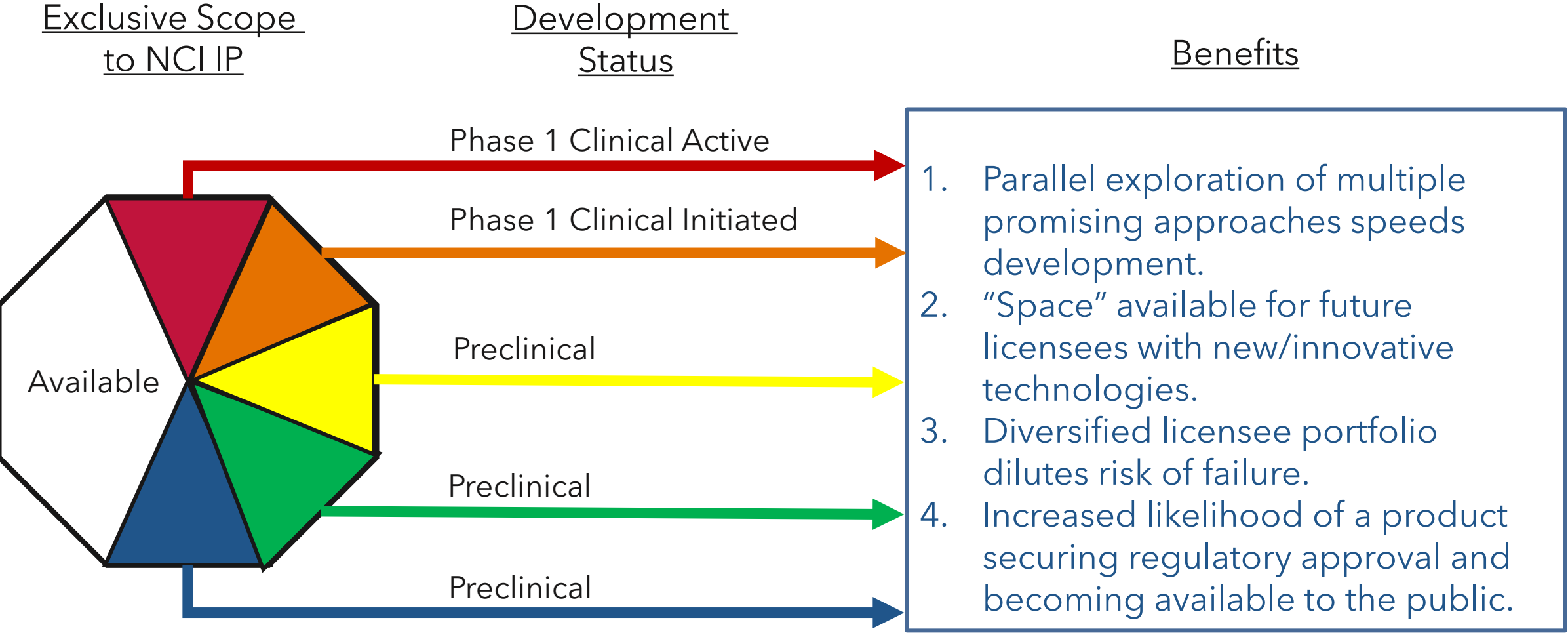
1. Public benefit from license;
2. Exclusivity "reasonable and necessary";
3. Will not "substantially lessen" competition;
4. **Scope "not greater than reasonably necessary".**

Solution

Grant narrow exclusive fields of use tailored to the specific type of cell therapy product each company was well-suited to rapidly develop

Example: Development, manufacture and commercialization of autologous T cell products engineered by transposon-mediated gene transfer to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers.

Maximizing Utilization and Public Benefit



The background features a complex, abstract design. It consists of a dense network of thin, light blue lines connecting various nodes, some of which are small circles or squares. Overlaid on this network are several larger, semi-transparent geometric shapes, including triangles, squares, and circles. A prominent feature is a large, circular, concentric pattern that resembles a stylized sun or a target, composed of multiple rings of varying thicknesses and colors (light blue, white, and pale yellow). The overall color palette is soft and pastel, with shades of light blue, white, and pale yellow. The text 'Thank you!' is centered in a bold, dark blue font.

Thank you!