Society for Immunotherapy of Cancer

SITC 2026

NOV. 4–8 | PHOENIX

41st Annual Meeting & Pre-Conference Programs

Advance the science, discover breakthroughs and educate the world on cancer immunotherapy.

#SITC26







Clinical and translational evaluation of lifileucel in patients with metastatic undifferentiated pleomorphic sarcoma and dedifferentiated liposarcoma

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Declaration of Interests

1. Principal Investigator (Site PI) for the investigator-initiated trial (IIT) [NCT05607095] on which this presentation is based.

2. Steering Committee Chair for the multicenter Phase II trial [IOV-SAR-201] that will be conducted based on data and findings from the aforementioned IIT for which I will serve in a paid consulting capacity.

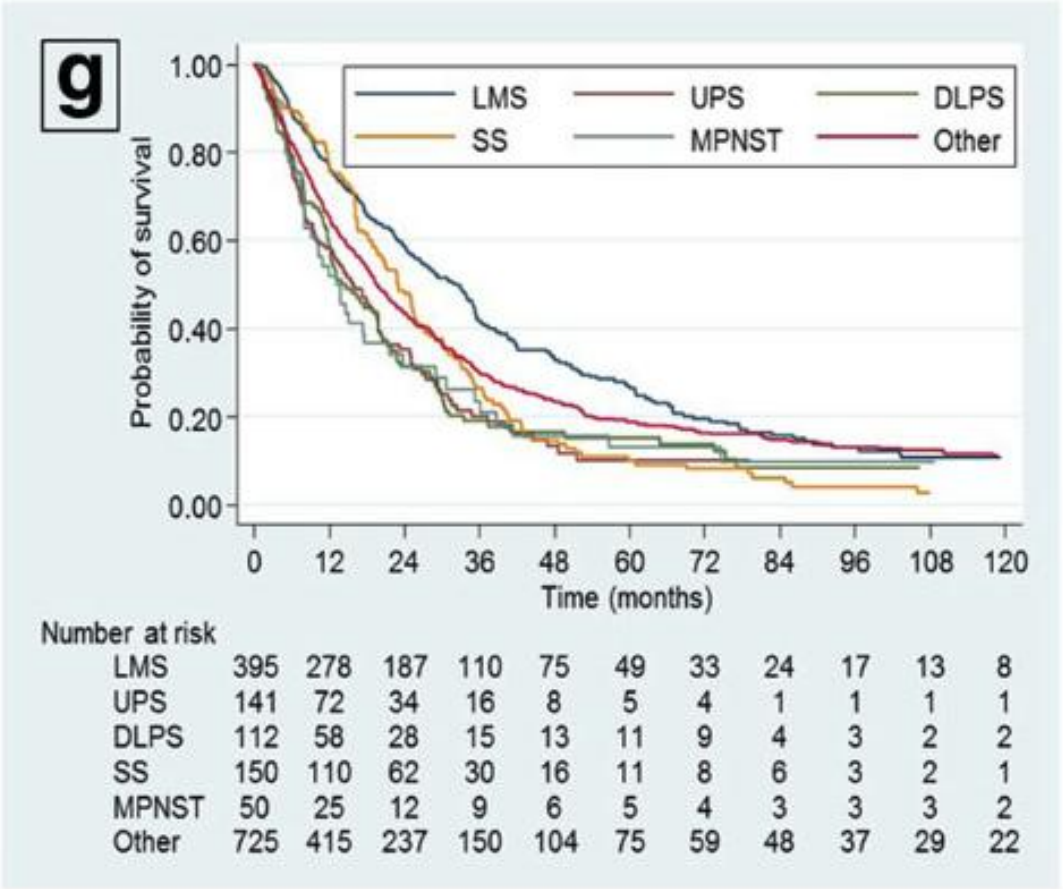
3. Research Funding: Iovance supported the IIT presented in this presentation and is sponsoring the Phase II trial

I have a personal financial interest related to Iovance given the above consulting position. The anticipated dual leadership roles in both the IIT and the Phase II trial represent a potential institutional and scientific conflict of interest.

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UPS and DDLS: New therapies are needed

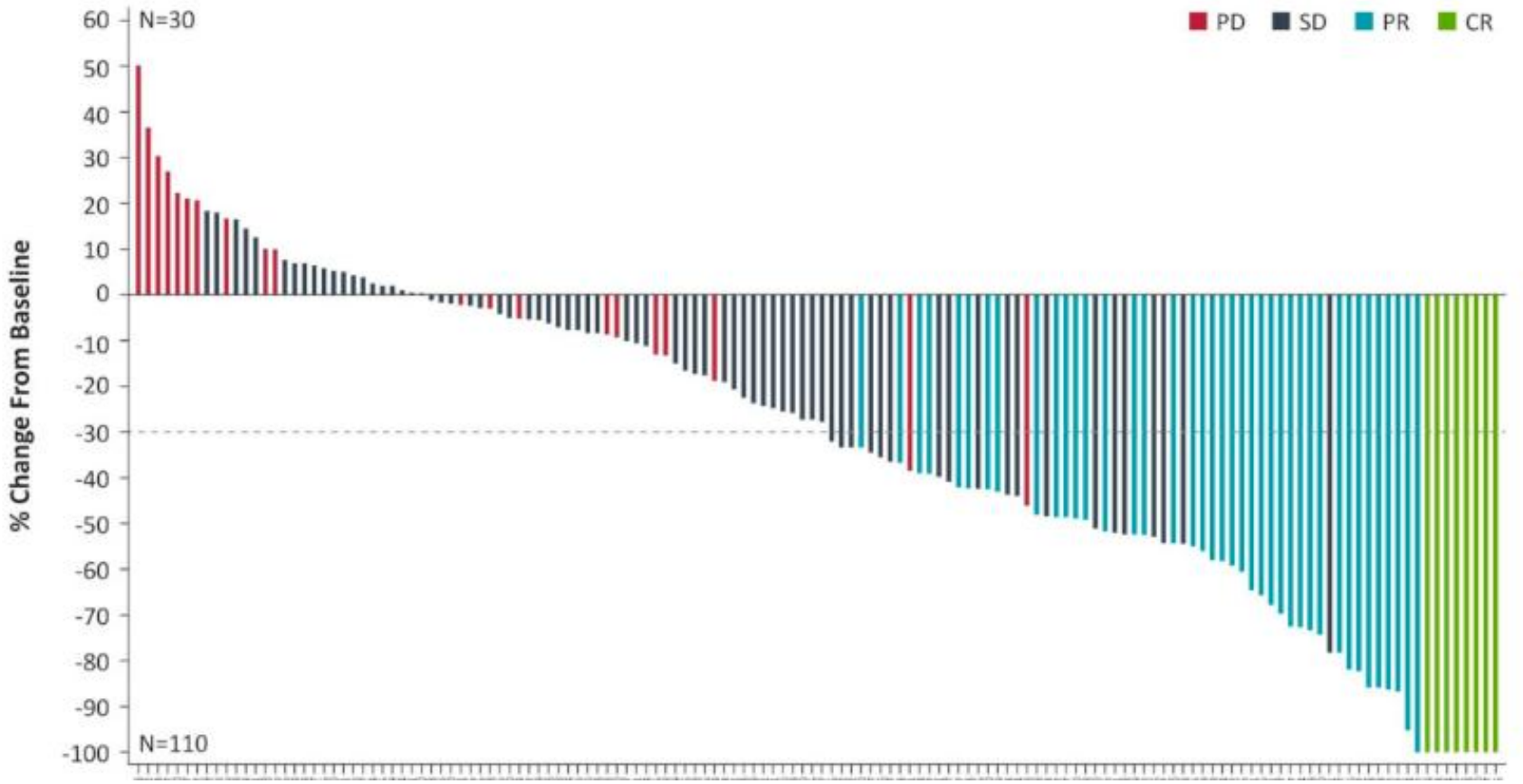
- Median OS for metastatic DDLS and UPS is <2 years (METASARC: Savina et al, BMC Med, 2017)
- Median PFS after 1st line chemotherapy: 5-6 months (Tanaka et al, PLoS One, 2019; GeDDiS: Seddon et al, Lancet Oncol, 2017)



METASARC: Savina et al, *BMC Med*, 2017

Abbreviations:
Leiomyosarcoma (LMS),
Undifferentiated pleomorphic sarcoma (UPS),
Dedifferentiated liposarcoma (DDLS),
Synovial sarcoma (SS),
Malignant peripheral nerve sheath tumor (MPNST)

Lifileucel is an FDA approved TIL therapy in IO refractory melanoma



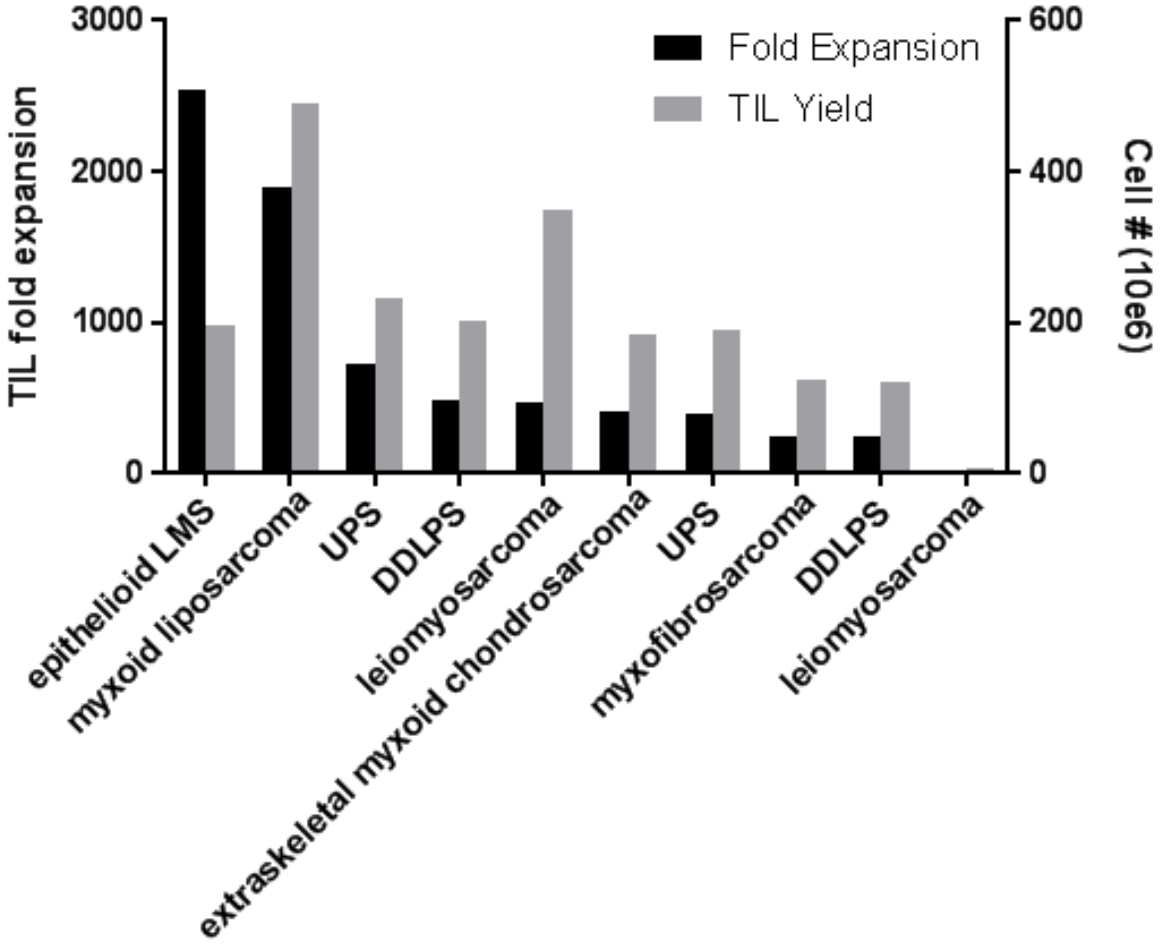
Response Rate: 31.4%
median 3 prior lines of therapy (1-9)

Duration of Response: 36.5 months (5 year)

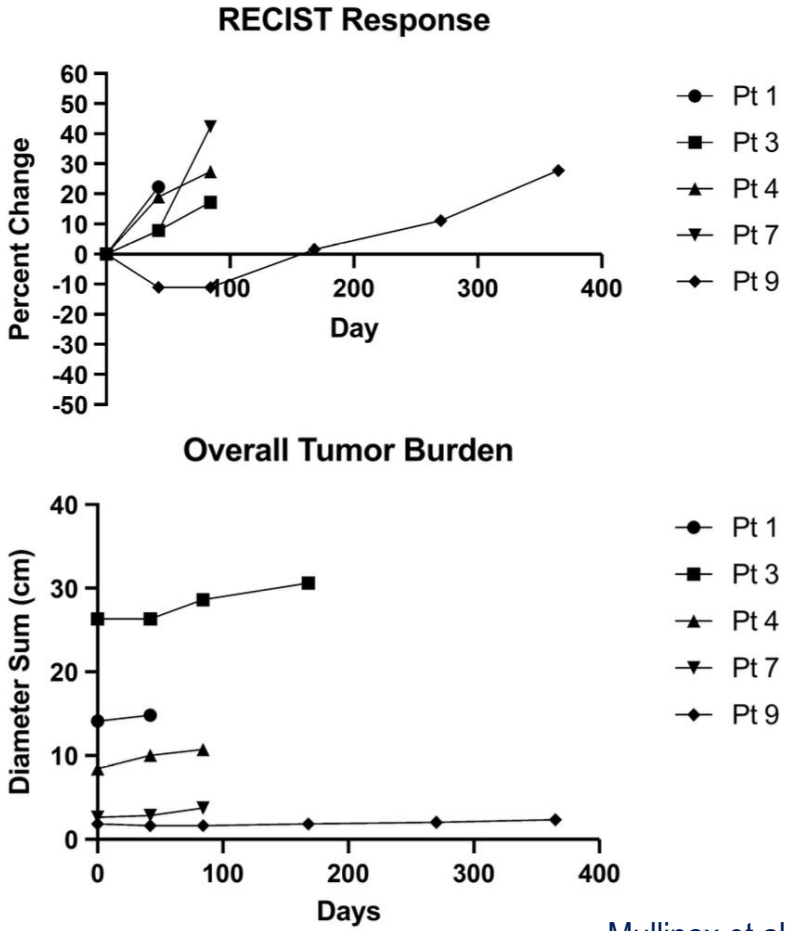
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Chesney et al. *Journal for ImmunoTherapy of Cancer*, 2022
Medina et al. *Journal of Clinical Oncology*, 2025

TILs can be expanded from STS and re-infused

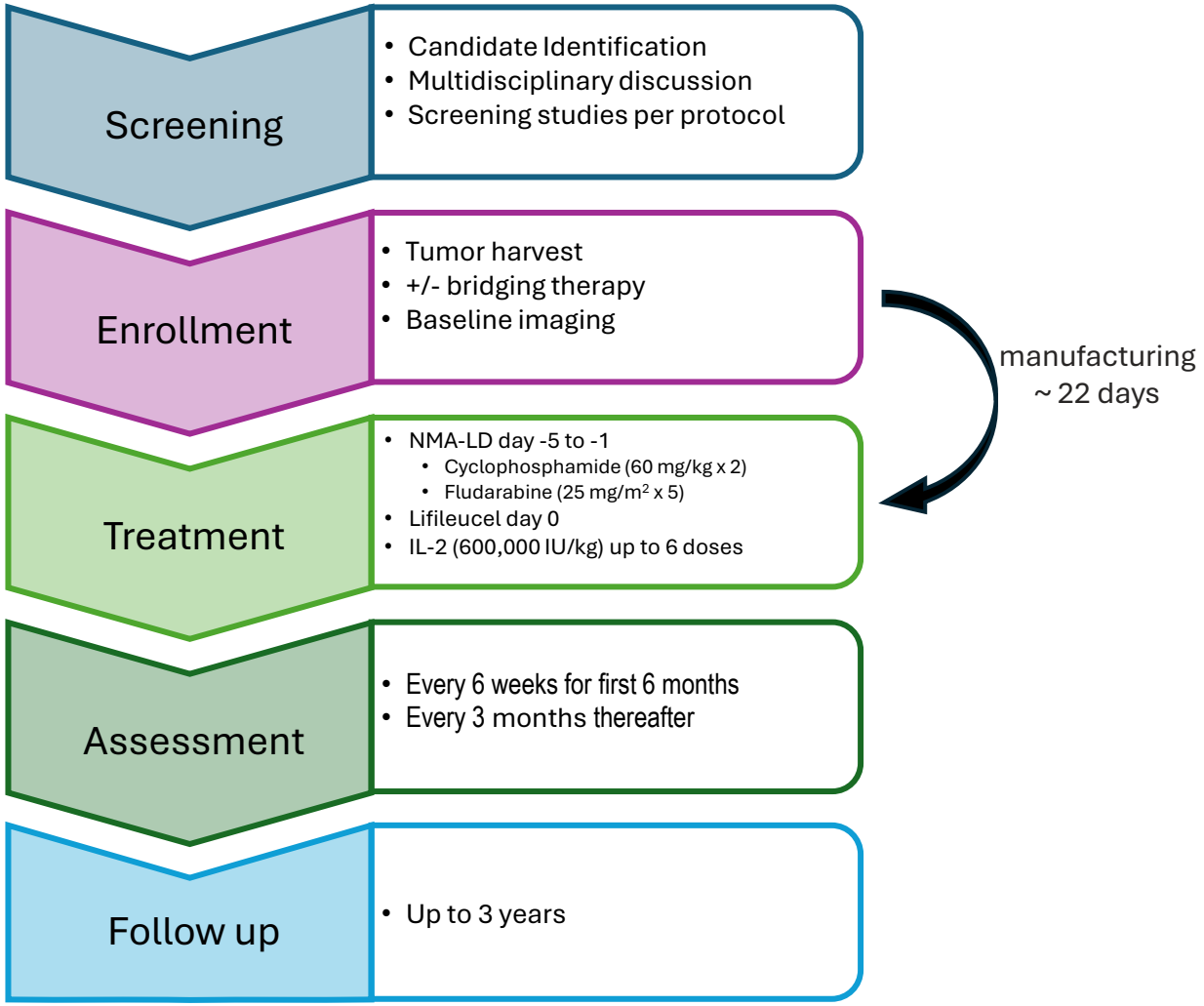


Mullinax et al, *Journal of Immunotherapy*, 2021



Mullinax et al, CTOS, 2023

NCT05607095: TIL (Lifileucel) in DDLS/UPS



10 DDLS/UPS patients:

- Unresectable/metastatic
- ≥1 prior systemic therapy
- ≥1.5 cm lesion for TIL harvest
- target lesion
- adequate organ function and ECOG 0-1

Primary endpoints:

- **Feasibility** - ≥6/10 pts infused with lifileucel
- **Safety** - grade ≥3 TRAE

Secondary endpoints:

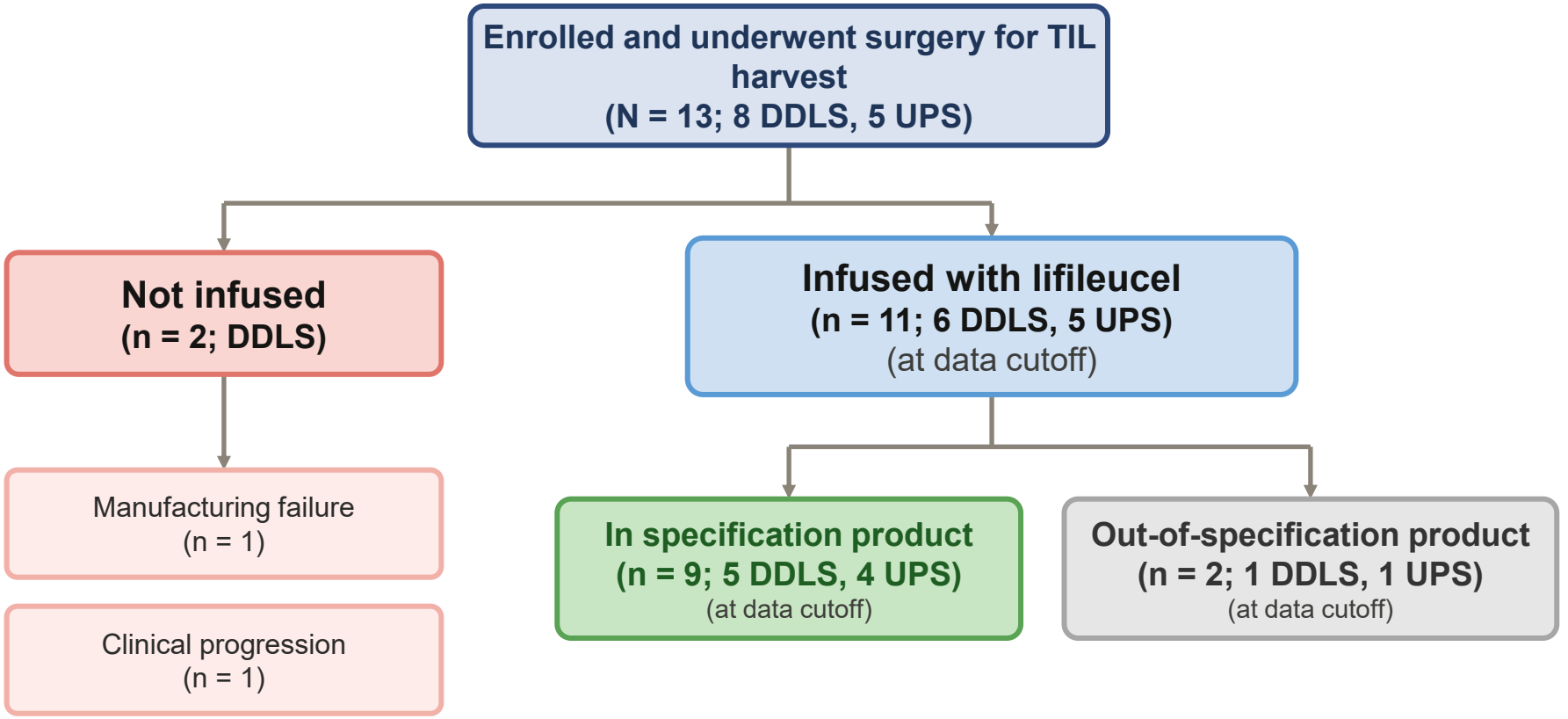
- ORR, DCR, DOR

Exploratory endpoints:

- TIL surgical specimen sequencing
- On treatment biopsy
- Immune monitoring in blood

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TIL (Lifileucel) DDLS/UPS: Feasibility and Safety



Safety (infused patients):

- All patients had grade 4 cytopenias
- Most common grade ≥3 non-hematologic TRAE was febrile neutropenia (40%)
  - 1 pt had grade 4 pulmonary infection and hemorrhage after TIL harvest
- No grade 5 events related to treatment;
  - 1 pt died of disease after progression

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Patient-level data: Updated data cutoff

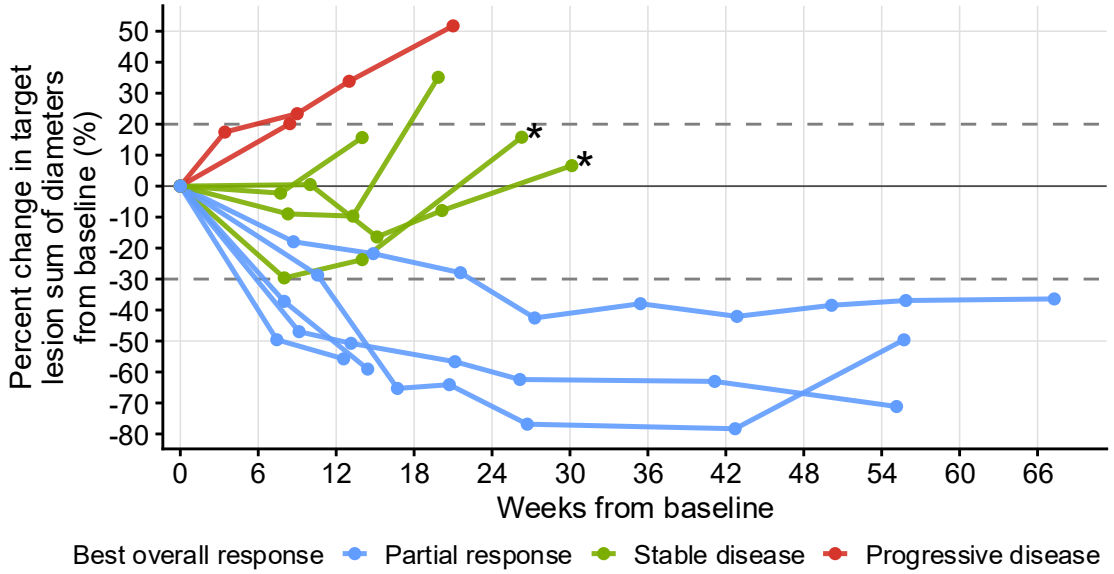
Patient	Age (y)	Sex	Diagnosis	Prior treatment lines (n)	Prior checkpoint inhibitor (Y/N)	Lifileucel infusion (Y/N)	Target SOD (mm)	IL-2 doses (n)	Best overall response	DoR++ (weeks)	DoSD (weeks)
5	**66**	**M**	**UPS**	**7**	**Y**	**Y**	**114.7**	**2**	**PR**	**46**	**55.1**
7	**51**	**M**	**DDLS**	**2**	**N**	**Y**	**115.3**	**2**	**PR**	**39**	**55.7**
2	**43**	**F**	**DDLS**	**2**	**N**	**Y**	**39.0**	**5**	**PR**	**40**	**67.3**
12	**49**	**M**	**UPS**	**2**	**Y**	**Y**	**82.8**	**5**	**PR**	**6.4**	**14.4**
14	**50**	**M**	**UPS**	**7**	**Y**	**Y**	**239.8**	**3**	**PR**	**5.1**	**12.6**
13	45	M	UPS	3	Y	Y	141.0	3	SD		14
4	62	M	DDLS	1	Y	Y	70.3	6	SD		19.9
9	66	M	DDLS	2	N	Y	161.6	2	PD		
10	50	M	DDLS	2	Y	Y	177.6	6	PD		
	* Infused with out of spec product:										
1	60	M	UPS	2	N	Y	96.9	6	SD		26.3
8	66	F	DDLS	1	Y	Y	78.6	6	SD		30.1
	Uninfused product:										
6	61	F	DDLS	3	N	N					
11	58	F	DDLS	4	N	N					

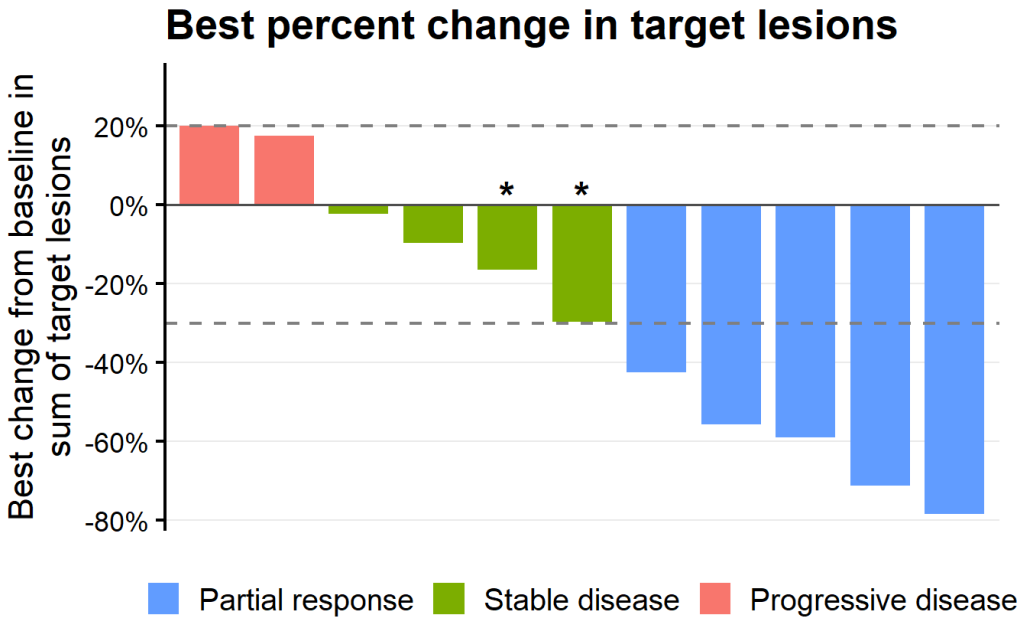
++As of data cutoff date of 30 October 2026, 4/5 PRs were ongoing

Abbreviations: Undifferentiated pleomorphic sarcoma (UPS), Dedifferentiated liposarcoma (DDLS), Stable disease (SD), Partial response (PR), Progressive disease (PD)

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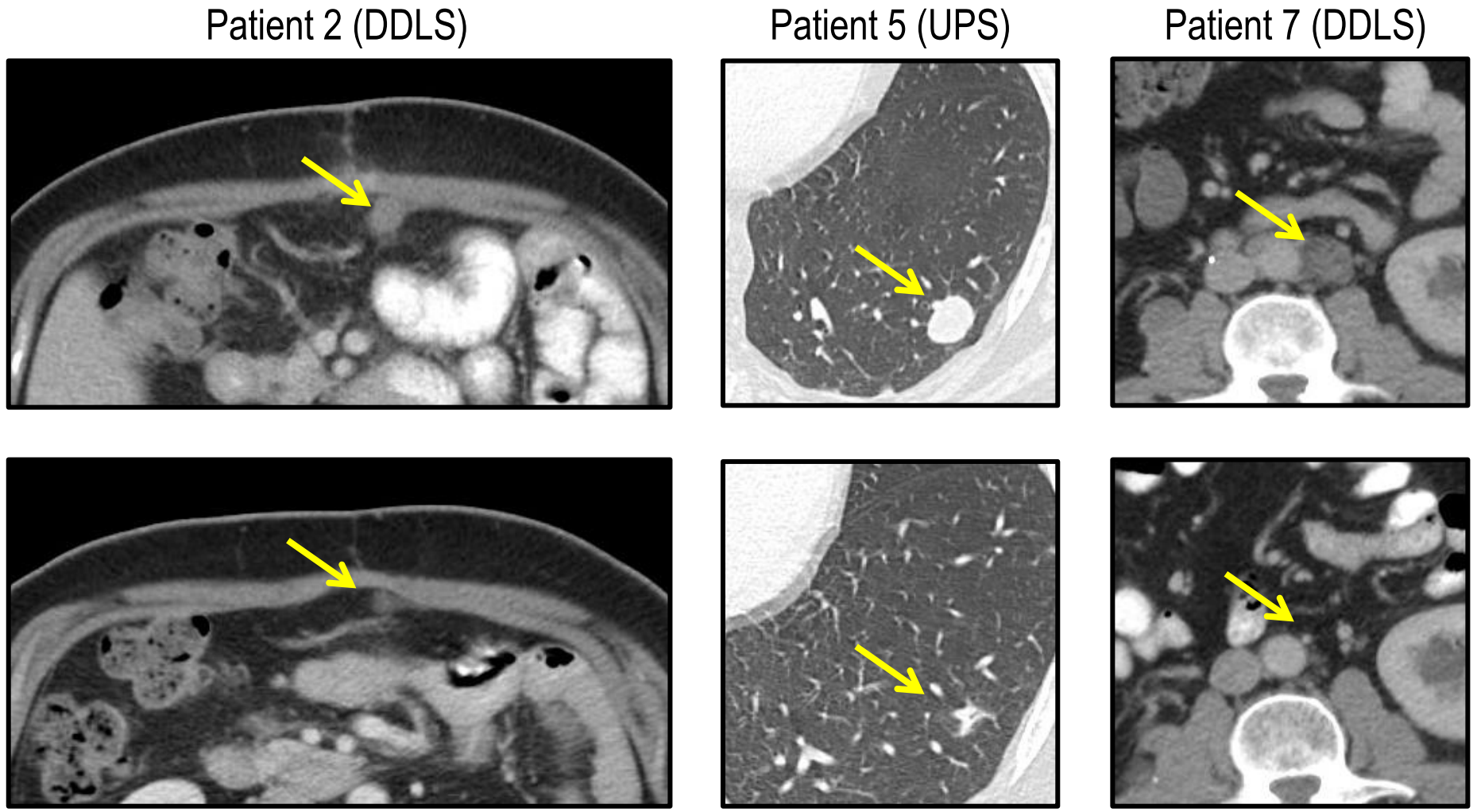
Patient-level data: Updated data cutoff





* Infused with out of spec product

Tumor response



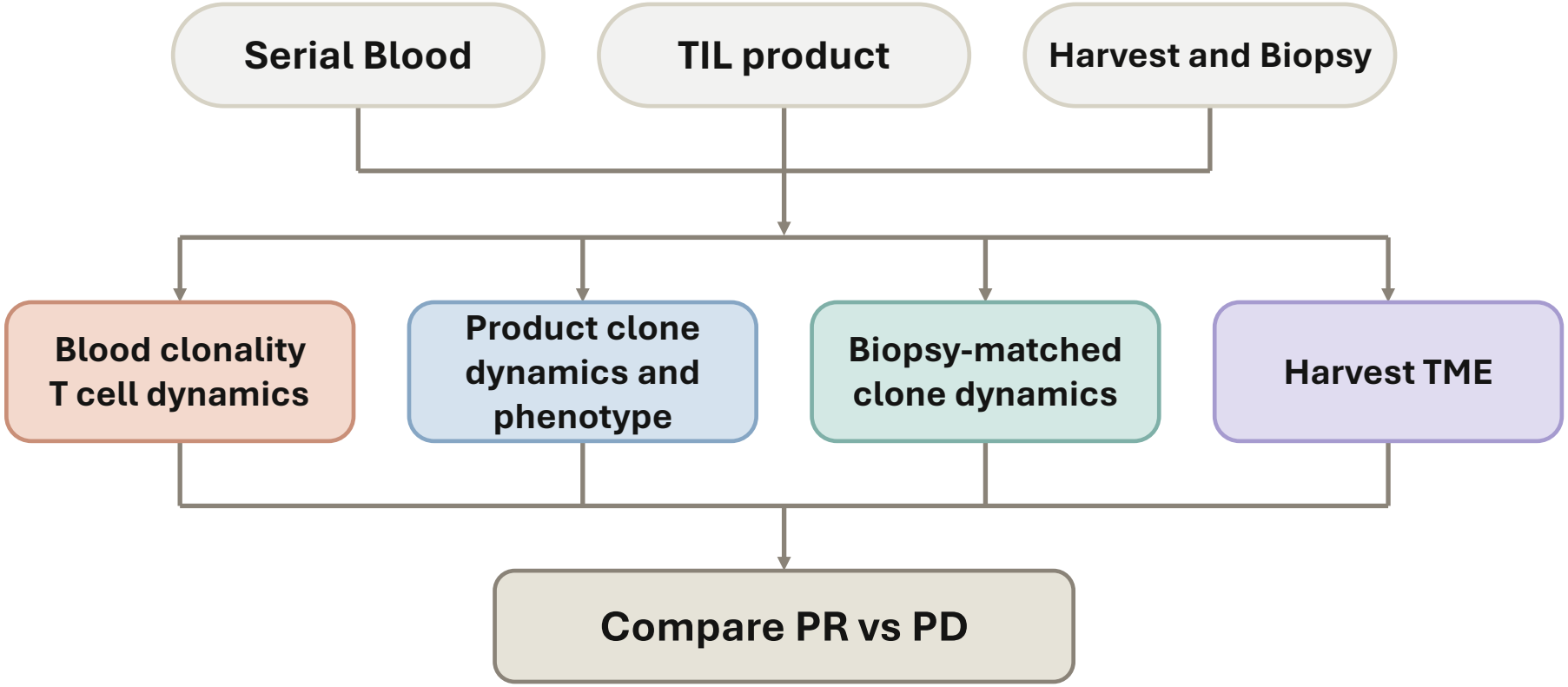
Tumor response

Patient 14 (UPS)

Baseline	6 days post-TIL	~12 weeks post-TIL

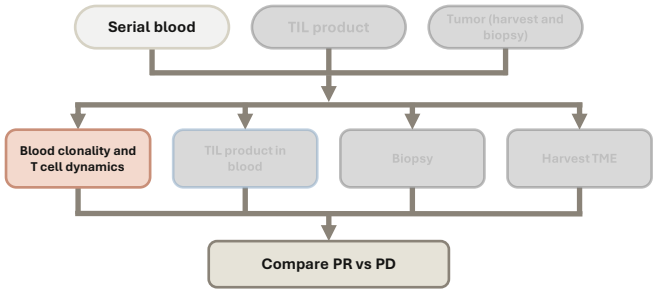


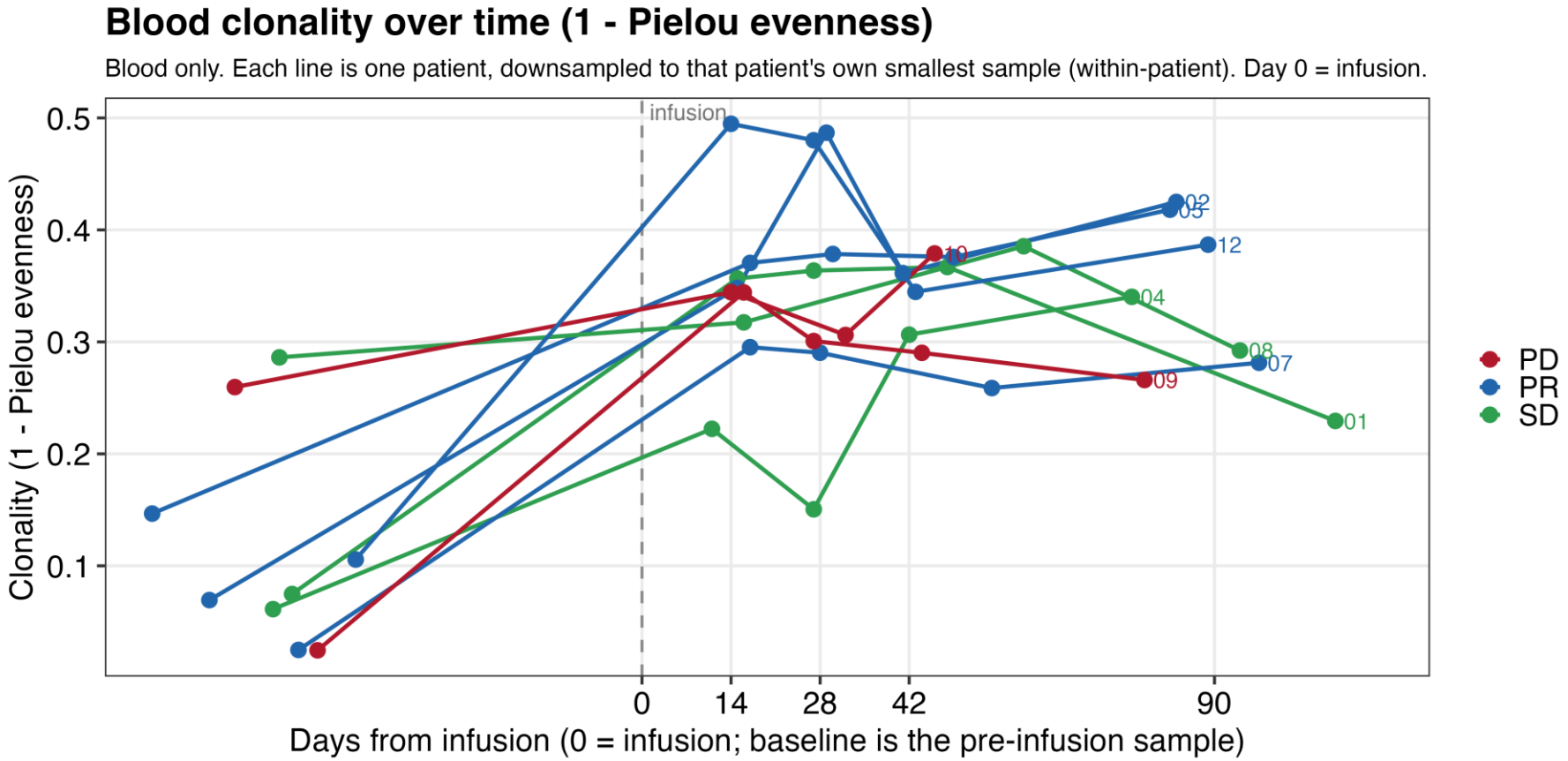
Correlative analysis plan



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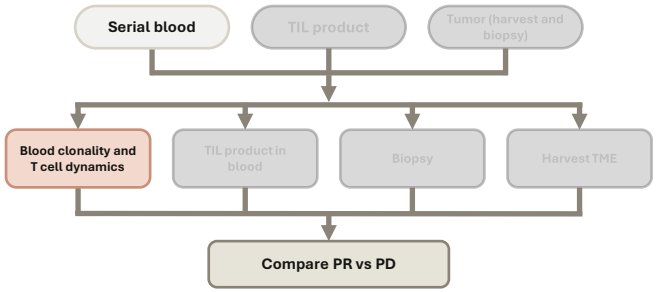
Most patients have increased clonality after TIL

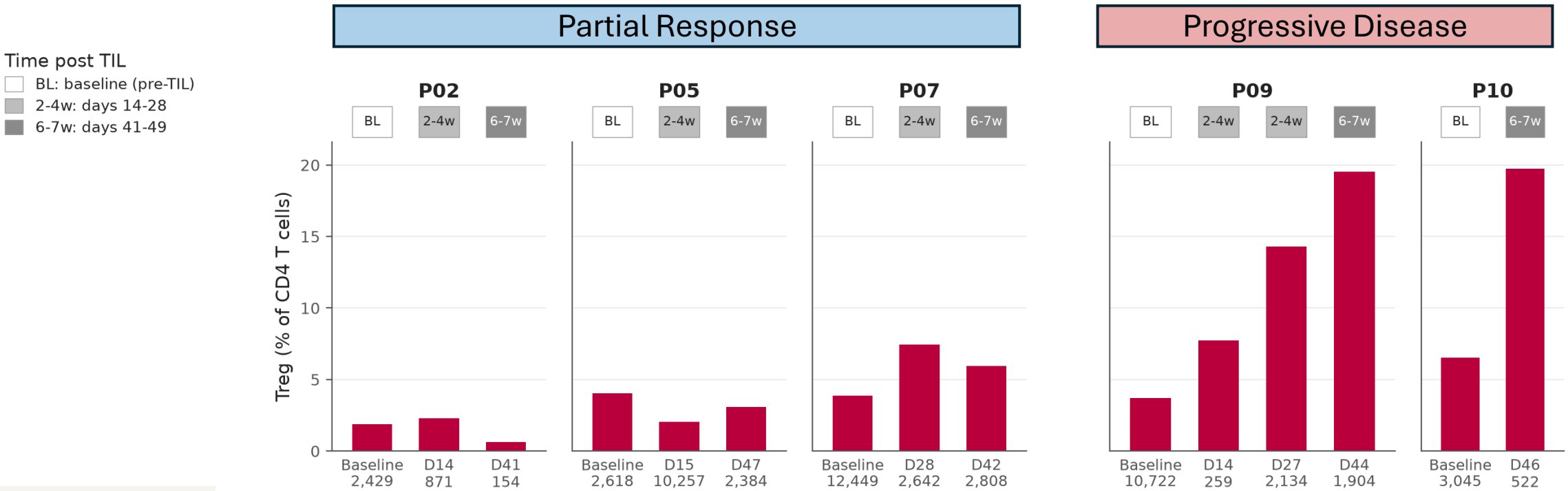




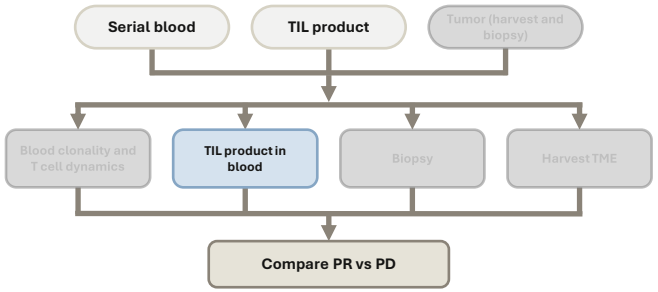
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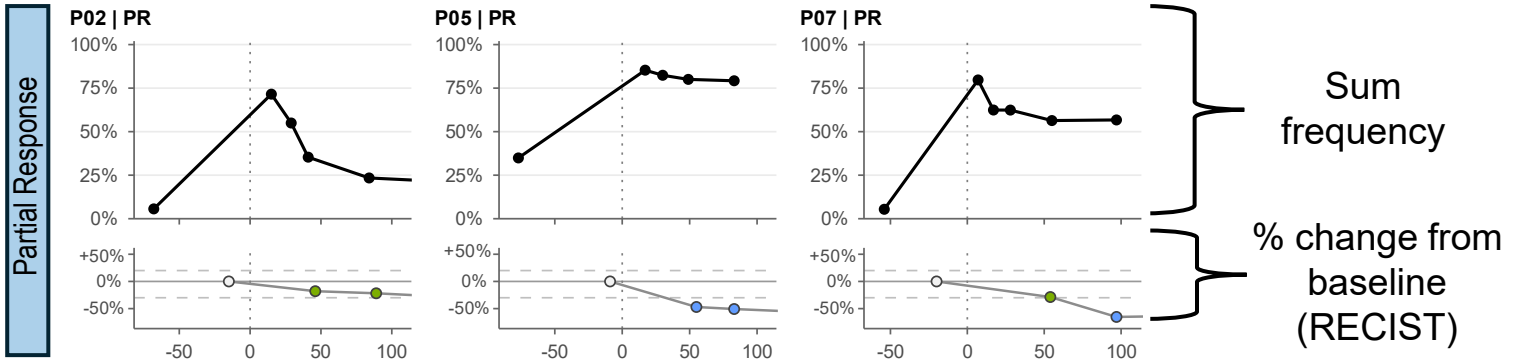
Increased proportion of T regs among CD4 T cells in PD after infusion





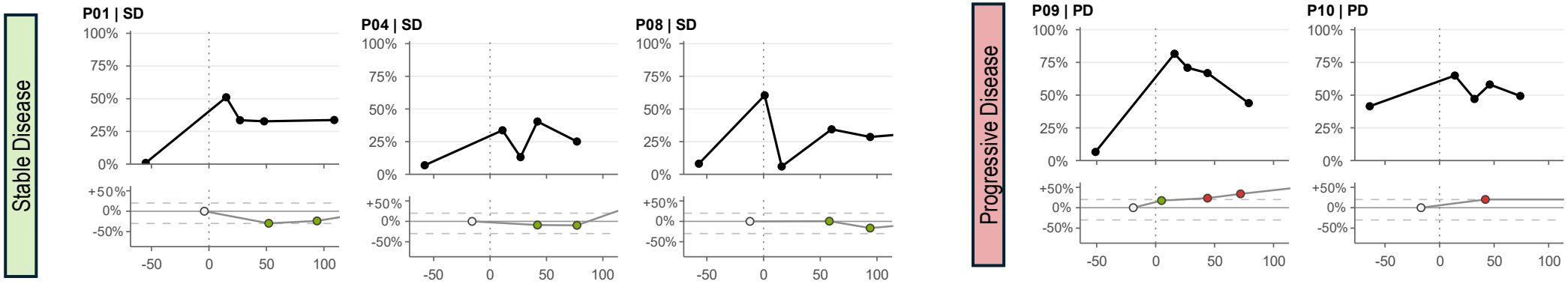
Persistence of TIL product in blood over time





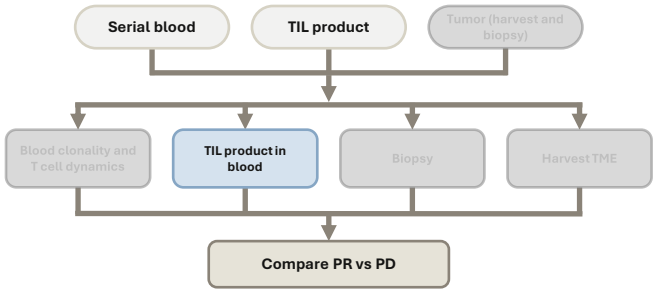
RECIST

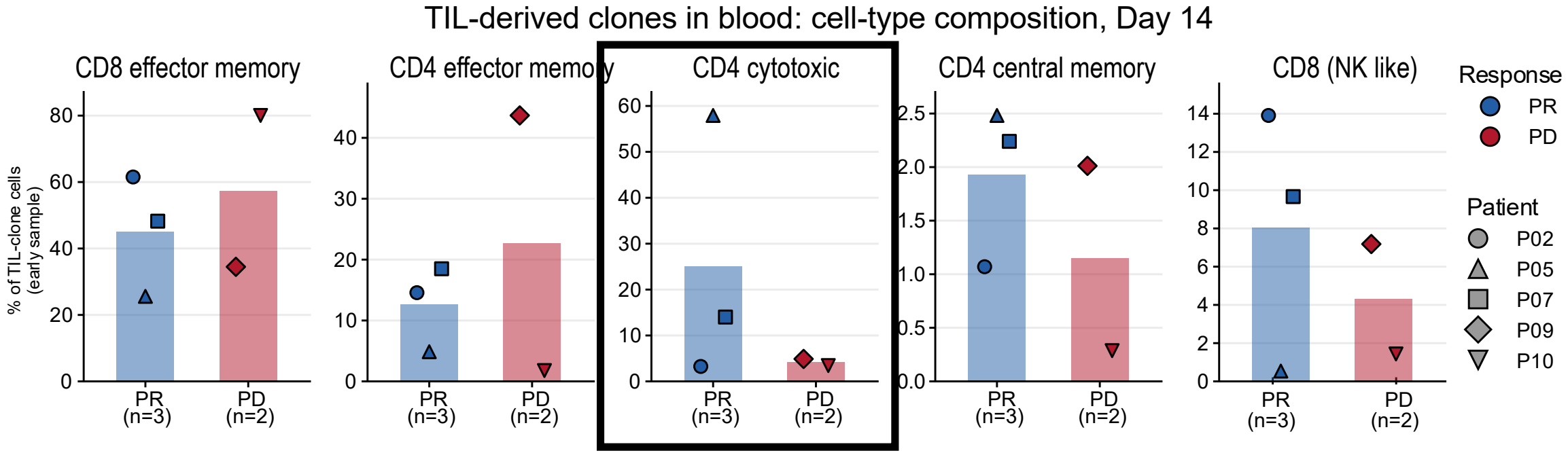
- Partial response
- Stable disease
- Progressive disease
- Baseline scan



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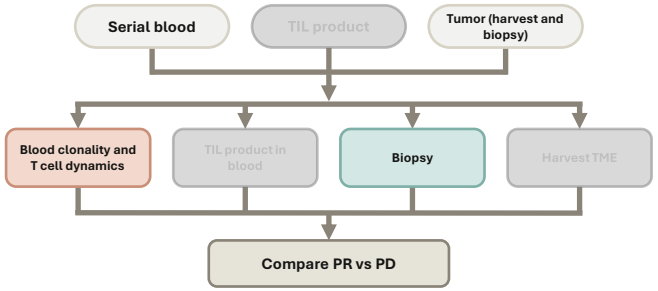
TIL-derived clone phenotypes in blood at day 14

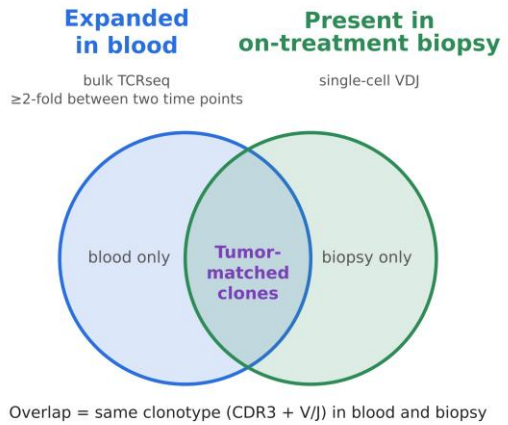


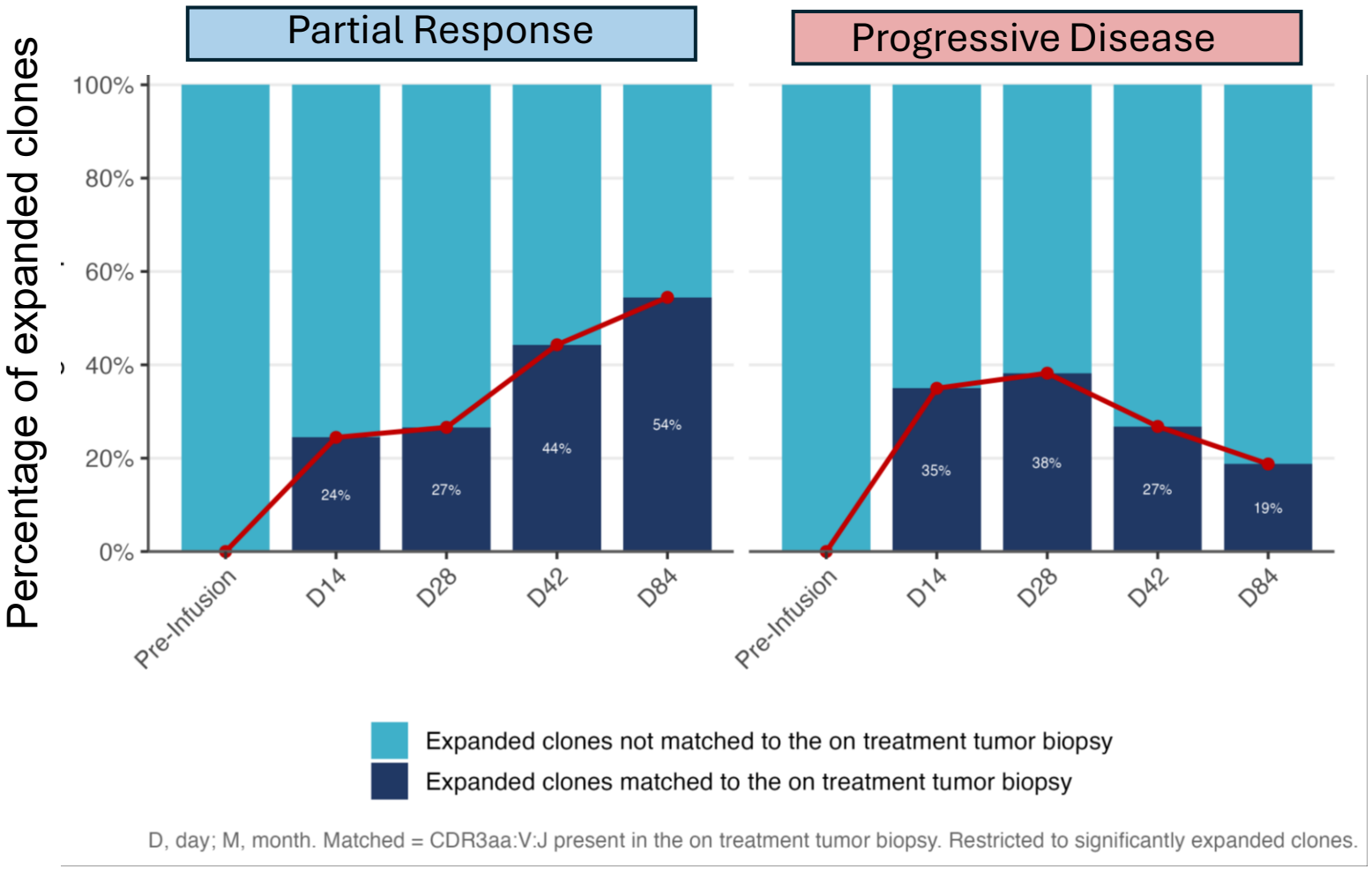


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PR have persistence of expanded biopsy matched clones in blood







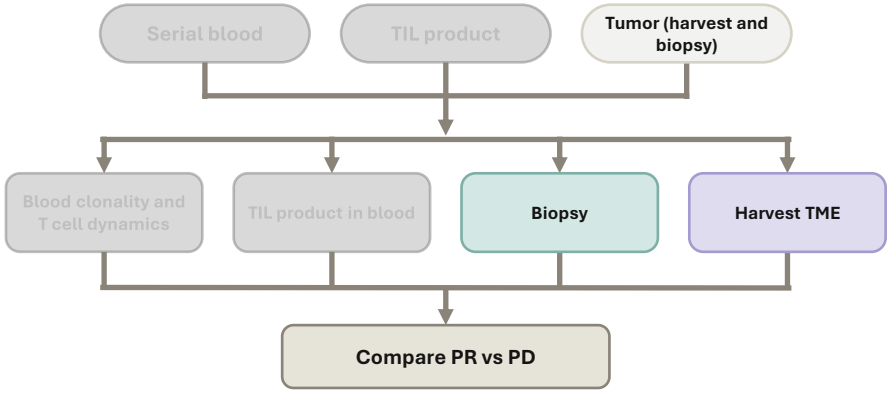
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Conclusions

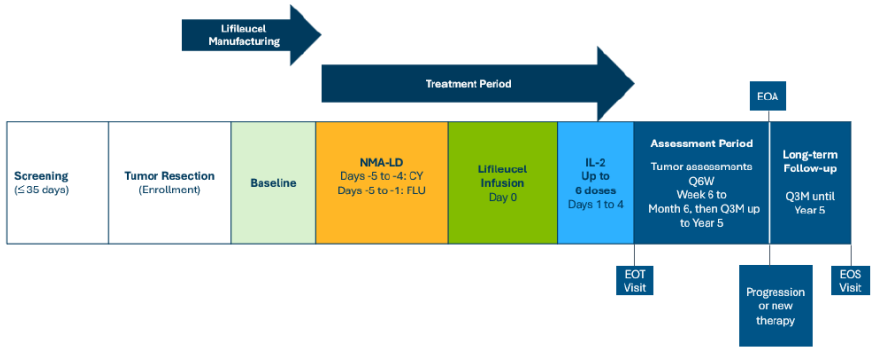
- **TIL therapy is feasible in DDLS and UPS**
  - 11/13 patients infused
  - 9/13 patients infused with in spec product
- **TIL therapy has an expected toxicity profile without treatment related death**
  - Expected self-limiting grade 4 cytopenias and IL-2 toxicity
  - No treatment related deaths
- **TIL therapy has an durable early efficacy signal in DDLS and UPS**
  - ORR (in spec) 5/9
  - ORR (all infused) 5/11
  - Responses are durable
- **Exploratory and descriptive analyses can direct mechanistic hypotheses**
  - Increased clonality after TIL, higher in PR
  - In PR, higher CD4 cytotoxic signal among TIL clones in blood at day 14 and persistent tumor-matched clones
  - Rising circulating Tregs in PD

Future Directions

- **Exploratory:**
  - Tumor tissue single cell/TME analysis
  - Granular phenotypic analysis of TIL over time



- **Clinical:**
  - SARATOGA (IOV-SAR-201), a multicenter phase II study sponsored by Iovance, is now open
    - Formally evaluate efficacy
  - Expansion cohorts to other sarcoma subtypes enrolling



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Acknowledgements

Patients and families

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