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Consistency in resecabtagene autoleucel product quality across RESET phase 1/2 clinical trials and manufacturing platforms

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MAY 2026

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Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements.

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Manufacturing CD19-CAR T cell therapies for autoimmune patients

- **Early-phase** clinical studies using CAR T cell therapy across a range of autoimmune diseases (e.g., **systemic lupus erythematosus**, **myositis**, **systemic sclerosis**)[1] have shown significant clinical responses

- **Starting material quality** from **oncology** patients has historically impacted ability to meet dose requirements and relevant **product quality** criteria[2,3]
  - Up to 11% manufacturing failure rate across approved CD19-CAR T cell therapies[4]

- **Cabaletta Bio** has manufactured **rese-cel** (CD19-CAR T cell therapy) for **75 autoimmune patients**[5] across **RESET phase 1/2 clinical trials** and three manufacturing platforms
  - 1 manufacturing failure attributed to patient starting material due to low expression of CD28 on T cells

- Here, we assess whether **autoimmune** patient material is meaningfully different from **healthy** donors by comparing **process consistency** and **product quality** across indications and manufacturing platforms

[1]Muller, Taubmann, Mackensen, Schett, et al. CD19 CAR T-Cell Therapy in Autoimmune Disease — A Case Series with Follow-up. NEJM (2024).
[2]Jo,et al. Risk factors for CAR-T cell manufacturing failure among DLBCL patients: A nationwide survey in Japan. BJHaem (2023).
[3]Dulobdas, et al. Risk factors for CAR T-cell manufacturing failure and patient outcomes in large B-cell lymphoma: a report from the UK National CAR T Panel. Nature (2025).
[4]U.S. Food and Drug Administration. Kymriah (tisagenlecleucel), Breyanzi (lisocabtagene maraleucel), Yescarta (axicabtagene ciloleucel). Prescribing Information.
[5]Manufacturing data available as of March 2026

Rese-cel manufacturing platforms for RESET Phase 1/2 clinical trials

Manufacturing processes share the same sequence of unit operations

Apheresis Collection & Cryopreservation → **Enrichment & Activation** → **Transduction** → **Expansion & Harvest** → **Formulation & Cryopreservation**

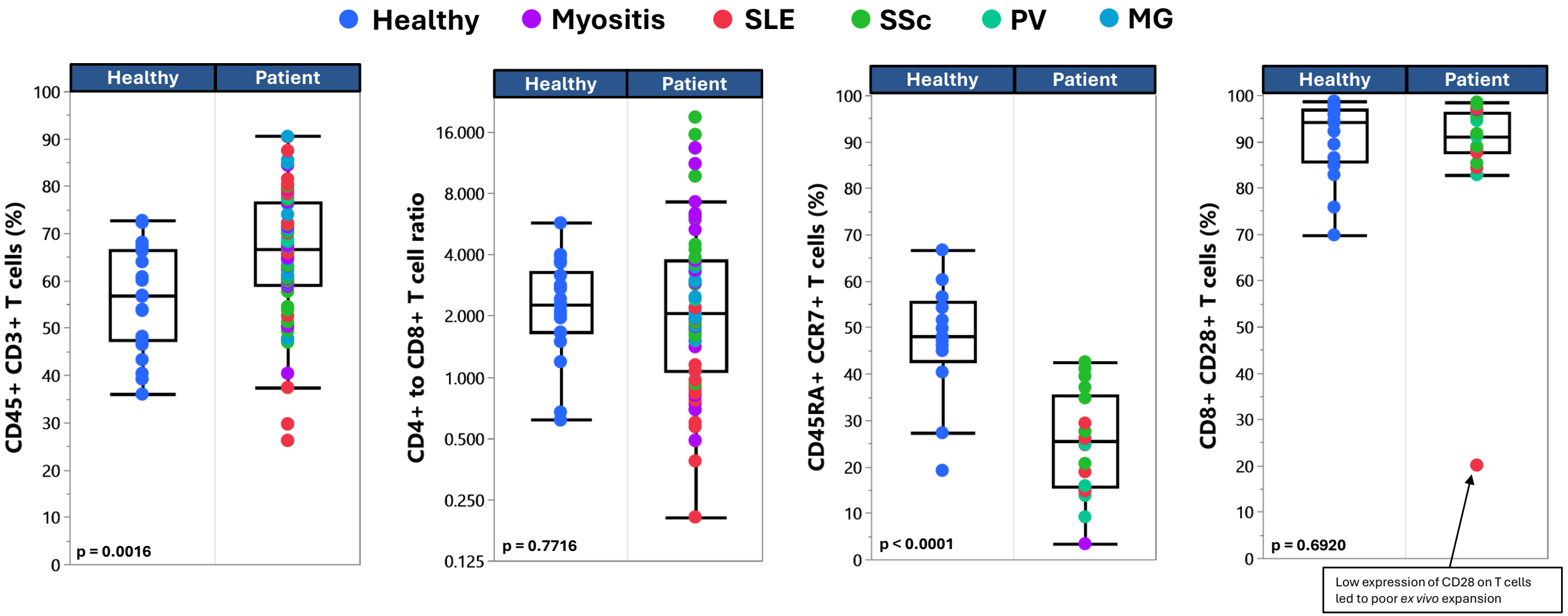
- **Process A:** early phase clinical manufacturing process

- **Process B:** semi-automated manufacturing process to enable commercial launch

- **Process C:** automated manufacturing process to meet future commercial demand

Leukapheresis immunophenotype from healthy and autoimmune patients[1]

No significant differences in CD3+ T cells (%), CD4:CD8 ratio, or CD28 expression[2]
Less naïve T cells in apheresis from autoimmune patients but higher incoming CD3+ T cells (%)

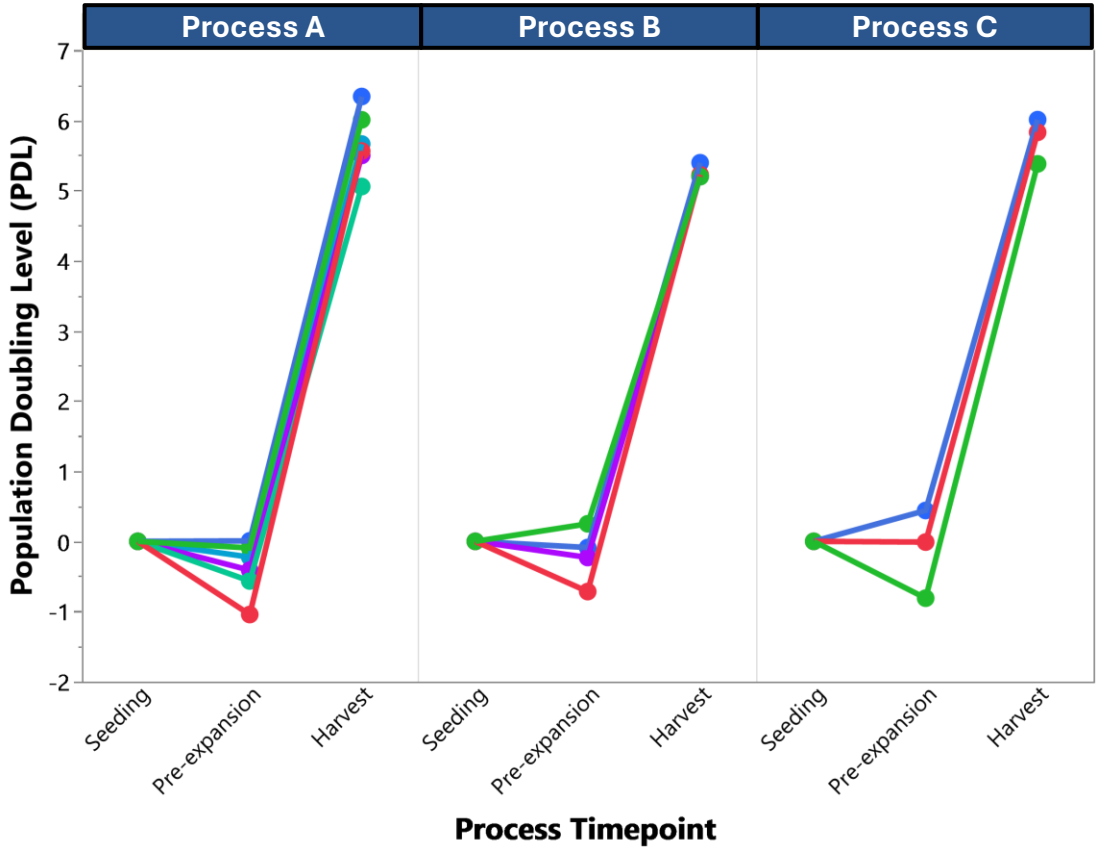


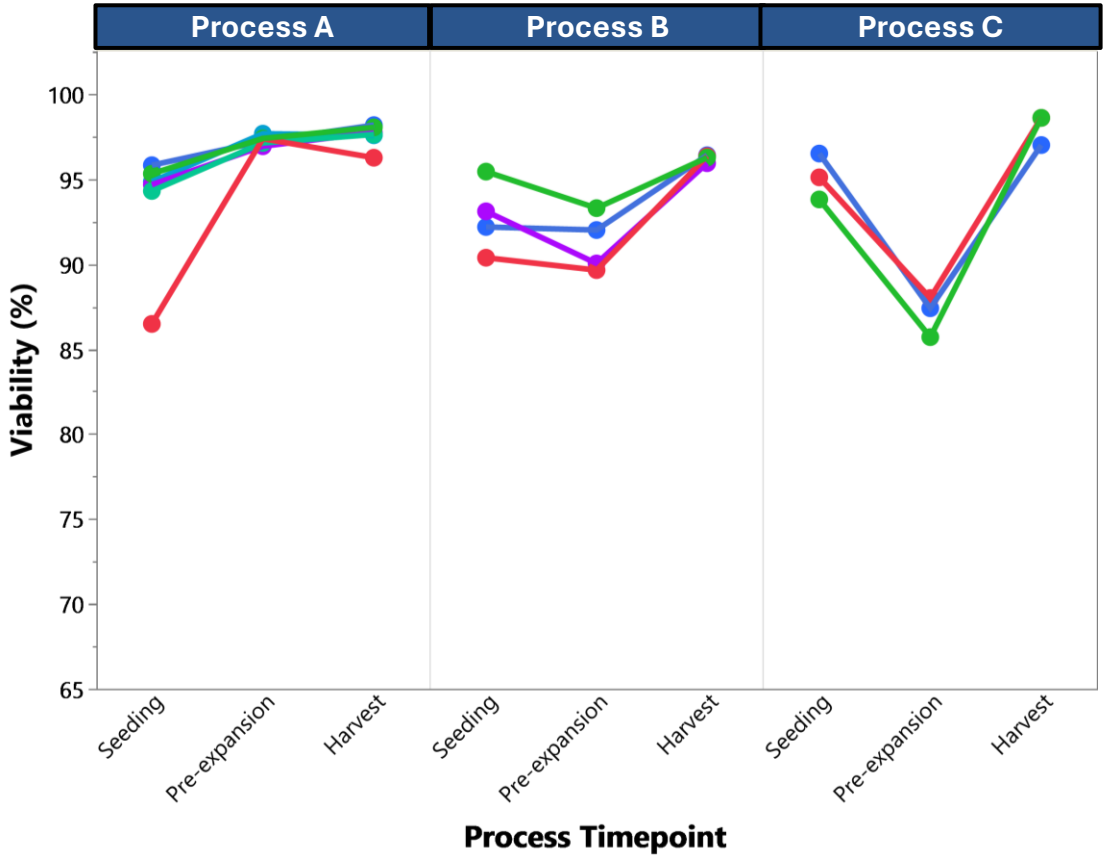
[1]Includes autoimmune patients across RESET Phase 1/2 clinical trials
[2]Characterization data available for limited starting materials
[3]p-values were calculated using the Wilcoxon signed-rank non-parametric test

In-process consistency across RESET[1] indications and manufacturing platforms

Small initial differences in SLE early growth and viability relative to healthy or autoimmune patient material
By end of process, no major differences are observed across indications or platforms

Healthy Myositis SLE SSc PV MG

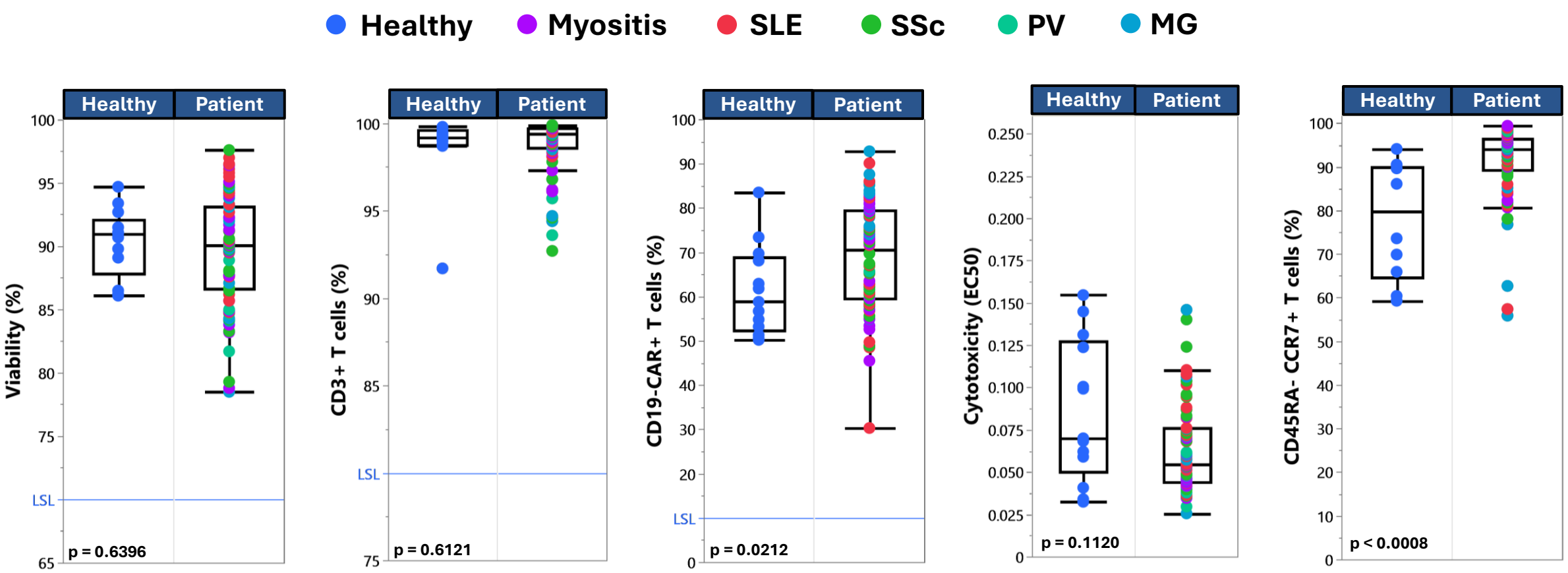




[1]Includes autoimmune patients across RESET Phase 1/2 clinical trials
[2]Seeding, pre-expansion, and harvest correspond to Day 0, 3, and 9 of manufacturing process, respectively

Product quality consistency across RESET[1] indications and manufacturing platforms

All batches exceeded dose requirements except for one patient with low CD28+ expression on T cells



[1]Includes autoimmune patients across RESET Phase 1/2 clinical trials
[2]p-values were calculated using the Wilcoxon signed-rank non-parametric test

Key Takeaways & Future Direction

- **Rese-cel product quality is consistent across RESET indications and manufacturing platforms**
  - Ensures reliable supply of rese-cel for autoimmune patients
  - Supports development of platform processes applicable across patient populations

- **Autoimmune patient material performs similarly to healthy donors**
  - Supports translation of early development and process characterization data from healthy donors to clinical and commercial manufacturing
  - Reduces risk of manufacturing failure and supports expanding to other autoimmune indications

Acknowledgements

- **Manufacturing Science & Technology**
  - Ziad Khalil, Valeria Ramos, Erica Corpuz, Jimmy Perry, Danielle Humbert
- **Analytical Development**
  - Katia Laoubi, Joshua Strong, Katiri Zapolnik, Audra Anastasi, Peter Bokma, Isabella Huber, Wei Li, Julia SantaMaria
- **Process Development**
  - Ming-Tzo Wei, Victoria Stratton

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Backup

Manufacturing failure rate in approved CD19-CAR T cell therapies

Information taken from package insert Section 17 Patient Counseling Information

Approved CD19-CAR T cell Therapies	Manufacturing Failure Rate
KYMRIAH (tisagenlecleucel)	9%
BREYANZI (lisocabtagene maraleucel)	11%
YESCARTA (axicabtagene ciloleucel)	< 1%
TECARTUS (brexucabtagene autoleucel)	4%
AUCATZYL (obecabtagene autoleucel)	4.5%

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