CLAIMS

What is claimed is:

1. A method for tracking a cell order during an immunotherapy procedure, the method comprising steps of:

receiving, by a computing device, a cell order request to create transfected T cells for a patient;

generating, by the computing device, a patient-specific identifier associated with the cell order request, the patient-specific identifier comprising a patient identity element, a sales order identifier, and a cell order lot number;

initiating, by the computing device, a process to create transfected T cells for infusion into the patient's bloodstream, the process comprising:

transferring T cells collected from the patient's blood by leukapheresis at a material extraction site to a container that is labeled with the patient-specific identifier,

transmitting the collected T cells to a manufacturing facility,

creating transfected T cells by transfecting the labeled collected T cells with a polynucleotide encoding a chimeric antigen receptor (CAR) or a T cell receptor (TCR) to obtain an immune-oncology agent,

receiving the immune-oncology agent from the manufacturing facility for administration,

wherein a tracking event is recorded for each step of the method, each tracking event including the patient-specific identifier, and

wherein the tracking events comprise a chain of custody of the patient's T cells during the method.

2. The method of claim 1, wherein the transfected T cells are created by transfecting the collected T cells with a polynucleotide encoding a chimeric antigen receptor (CAR), the CAR comprising an antigen binding molecule that specifically binds to a target molecule.

3. The method of claim 2, wherein the antigen binding molecule is a single chain variable fragment.

4. The method of claim 2, wherein the target molecule is a blood borne cancer-associated antigen.

5. The method of claim 2, wherein the target molecule is a viral infection-associated antigen.

6. The method of claim 2, wherein the CAR further comprises at least one costimulatory domain.

7. The method of claim 2, wherein the CAR further comprises at least one activating domain.

8. The method of claim 1, wherein the polynucleotide is a component of a vector.

9. The method of claim 1, wherein the transfected T cells are created by transfecting the collected T cells with a polynucleotide encoding the TCR.

10. The method of claim 9, wherein the TCR binds to a tumor-associated antigen.

11. The method of claim 9, wherein the TCR binds to a viral infection-associated antigen.

12. The method of claim 1, further comprising a step of: receiving a cell order request to create the transfected T cells for the patient.

13. The method of claim 1, wherein the patient-specific identifier comprises a patient identity element, a sales order identifier, a cell order lot number, and wherein the patient identity element comprises a first patient ID associated with the immunotherapy procedure and a second patient ID associated with a facility that administers one or more of: the leukapheresis or administration of the transfected T cells.

14. The method of claim 1, wherein the tracking event is recorded by a computing device for each step.

15. The of claim 14, further comprising steps of:

receiving, by a computing device,

indicia that the transfected T cells have been shipped from a first site after being created; and

receiving indicia that transfected T cells have been received at a second site before administration.

16. The method of claim 14, wherein the computing device stores the tracking events in an ordered sequence.

17. The method of claim 6, wherein the at least one costimulatory domain comprises CD28 or CD8.

18. The method of claim 17, wherein the at least one costimulatory domain comprises a sequence of SEQ ID NO. 2, SEQ ID NO. 4, SEQ ID NO. 6, SEQ ID NO. 8, or SEQ ID NO. 14.

19. The method of claim 7, wherein the at least one activating domain comprises CD3.

20. The method of claim 19, wherein the at least one activating domain comprises a sequence of SEQ ID NO. 10.

21. The method according to claim 1, wherein the CAR comprises: an anti-CD19 scFv, CD8, and 4-1BB; an anti-BCMA scFv and the CD8; the anti-CD19 scFv, CD28, and the 4-1BB; an anti-CD22 scFv and the CD8; the anti-CD19 scFv, the CD28, and EGFRt/19-28z/4-lBBL; an anti-MUC16 scFv and the CD28; an anti-CD 171; an anti-CD123 and the CD28; an anti-BCMA, the CD8, and the 4-IBB; an anti-CD 19 and CD28; an anti-CD19 and the CD8; or the CD28.

22. The method according to claim 1, wherein the CAR comprises a CSF2RA leader sequence, an anti-CD 19 scFv, a Whitlow linker, a CD28 spacer, a CD28 costimulatory domain, and CD3 zeta.

23. The method of claim 22, wherein the CAR comprises a sequence of SEQ ID NO. 147.

24. The method according to claim 1, wherein the CAR comprises a CD8 leader sequence, an anti-CD19 scFv, a Whitlow linker, a CD28T spacer, a CD28 costimulatory domain, and CD3 zeta.

25. The method of claim 24, wherein the CAR comprises a sequence of SEQ ID NO. 149.

26. The method according to claim 1, wherein the CAR comprises a CD8a leader sequence, an anti-CD19 scFv, a Whitlow linker, a CD8a spacer and transmembrane domain, a CD28 costimulatory domain, and CD3 zeta.

27. The method of claim 26, wherein the CAR comprises a sequence of SEQ ID NO. 151.

28. The method according to claim 1, wherein the CAR comprises a CD8 leader sequence, an anti-CLL-1 scFv, a G4S linker, a Minispacer, a CD28T, an intracellular costimulatory region of CD28, and CD3 zeta.

29. The method of claim 28, wherein the CAR comprises a sequence of SEQ ID NO. 155.

30. The method according to claim 1, wherein the CAR comprises a CD8a leader sequence, an anti-BCMA scFv, a Whitlow linker, a CD28T spacer, a CD28 costimulatory domain, and CD3 zeta.

31. The method of claim 30, wherein the CAR comprises a sequence of SEQ ID NO. 157.

32. The method according to claim 1, wherein the TCR comprises an AV38-2 variable alpha chain, a BV7-2 variable beta chain, a murine constant alpha domain, a murine constant beta domain, TRAJ40, Furin-SG SG-P2A, and TRBJ1-3.

33. The method of claim 32, wherein the TCR comprises a sequence of SEQ ID NO. 153.

34. The method according to claim 1, wherein the TCR comprises a TCR beta chain variable region, a TCR beta chain constant region, a P2A peptide with a Furin cleavage site and a linker, a TCR alpha chain variable region, and a TCR alpha chain constant region.

35. The method of claim 34, wherein the TCR comprises a sequence of SEQ ID NO. 159 or SEQ ID NO. 161.