



Accelerate your CAR-T cell workflow

From the early steps in exploratory studies to the manufacturing QC process and clinical trials of CAR-T cells, BD Biosciences offers a comprehensive set of single-cell solutions that can help maximise your success.

Looking at **discovery** and **commercialisation**, this brochure explores how these solutions can consolidate your cell therapy projects with flexibility, reproducibility and compliance.



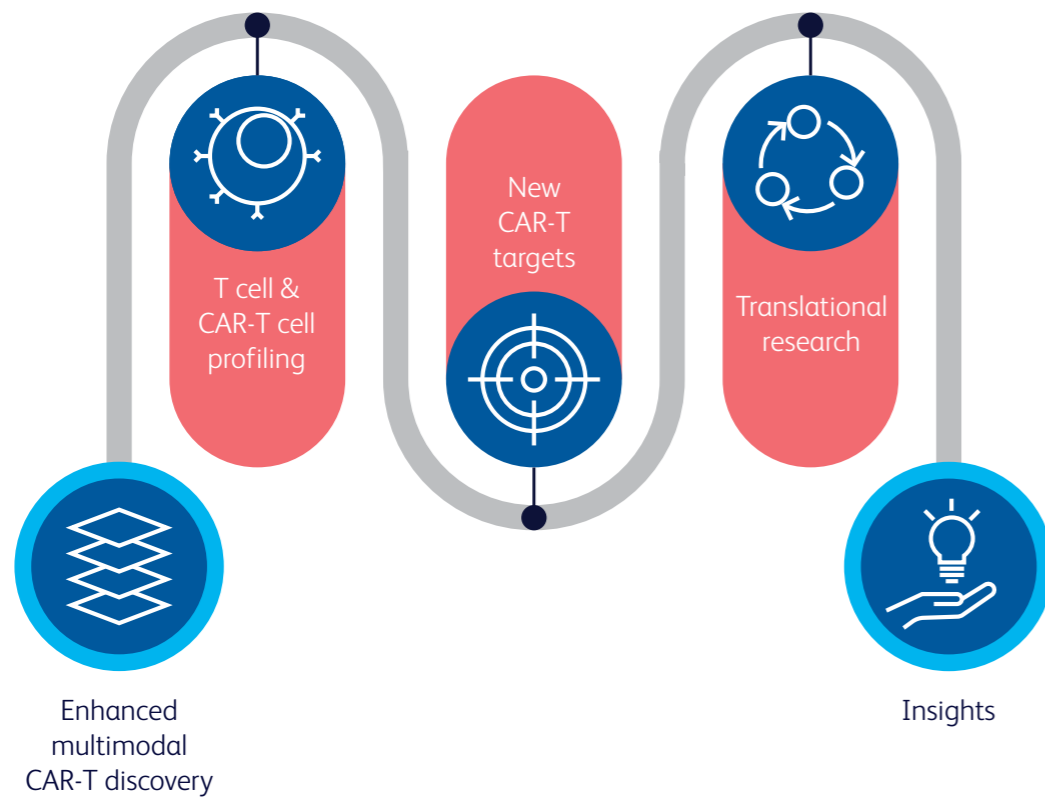
The CAR-T Discovery Suite Workflow

In the early stages of cell and gene therapy research, deep characterisation of starting material to understand the correlation between cell phenotype and function is a critical priority.

Gain deeper insights into the CAR-T product as well as into the patient immune response with our flexible and innovative cell therapy research solutions.

Our solutions enable you to:

- Understand your T cell mechanisms of actions and their interaction with the patient's immune system
- Screen for solid-tumour antigens
- Validate your insights
- Study and monitor



Explore the range of CAR-T Discovery Suite solutions

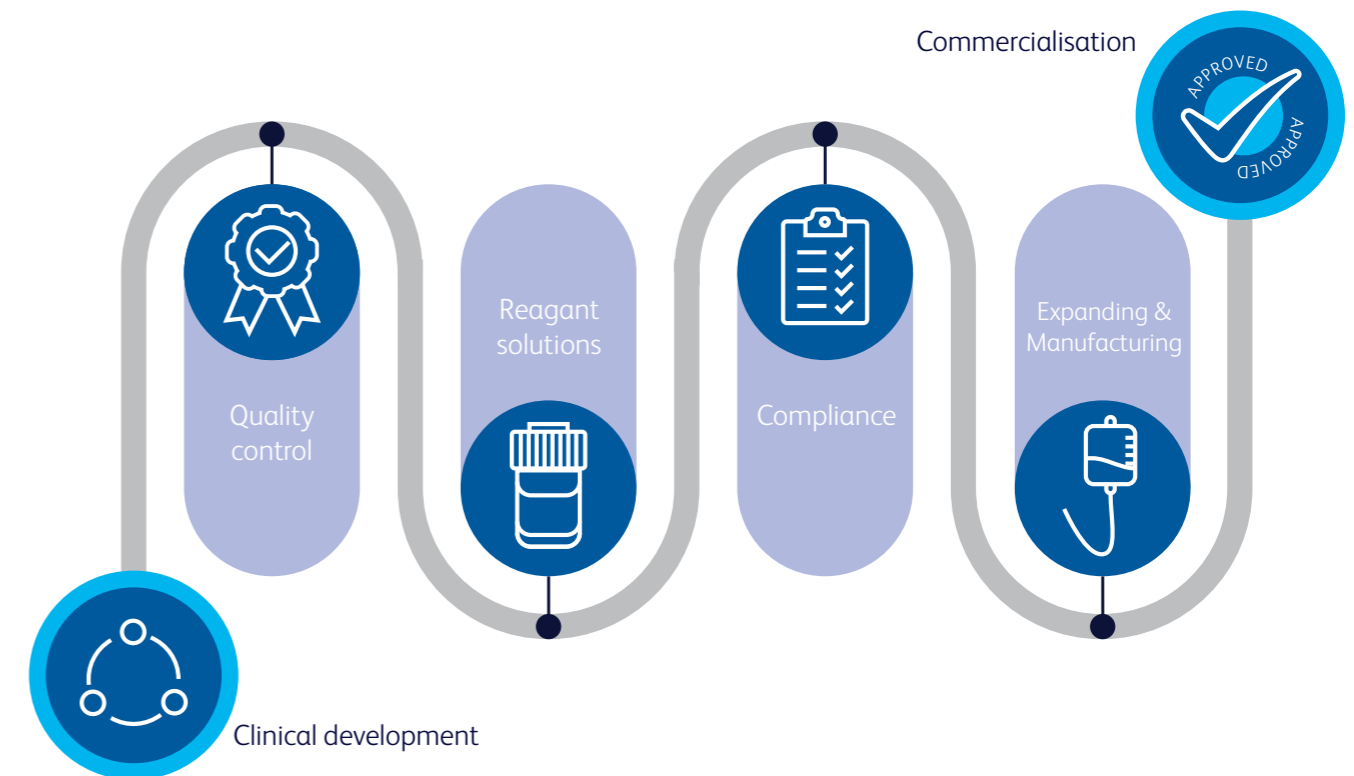
[Visit the website](#) to learn more about the CAR-T Discovery Suite Workflow— including how our single-cell analysis experts can support you with sample preparation and panel design, single-cell analysis and bioinformatics.

The CAR-T Commercialisation Suite Workflow

Flow cytometry is a powerful tool to **characterise cell phenotypes to define critical quality attributes for cell therapy products**, such as cell viability, identity, potency and purity.¹²

In addition, CE-IVD reagent solutions for immune assessment and **minimum residual disease (MRD)** monitoring can support you in generating reproducible, consistent data during clinical trials.

Our **IVDR-compliant* flow cytometer** with integrated automation options and assay portability features facilitates handover steps during clinical development and manufacturing QC.



Discover the full range of BD solutions for cell therapy manufacturing QC and clinical trials

[Visit the website](#) to learn more about the CAR-T Commercialisation Suite Workflow — including how BD experts can support you in setting up robust workflows and panels for clinical trials and manufacturing QC.

*CE-IVDR: in vitro diagnostic medical device CE-marked in compliance with the European In Vitro Diagnostic Medical Device Regulation (EU) 2017/746.

CAR-T Discovery Suite Workflow



Screen for new targets

- By leveraging BD Horizon™ Dri Tumor & Tissue Dissociation Reagent (TTDR) which is designed for gentle and effective dissociation of tumors and tissue for single cell studies.



Understand and monitor

- Take advantage of a broad catalogue of antibodies conjugated with dyes and oligos to understand and monitor CAR-T mechanisms of action by flow cytometry and Single-Cell Multiomic approach.
- Leverage the proteomic and transcriptomic data at single cell level to select new ideal product candidates.



Identify and quantify cell composition and heterogeneity

- To finetune the production process, deep dive into cell phenotype and function by using high dimensional flow cytometry and Single-Cell Multiomics approaches.
- Leverage on the possibility to purify relevant cells based on their immunophenotype or through the innovative CellView™ technology that enables image driven cell sorting.



Assess cell viability and potency

- Quantify target antigen molecules with beads for absolute antigen counting and leverage a selection of reagents to assess viability, activation and cytokine production.
- Qualify CAR-T cell product candidates, predict CAR-T cell product responsiveness, correlate phenotype with function and persistence to discover predictive biomarkers.



Analyse and interpret data

- Leverage on our capacity to design and implement high parameter multicolor panels to help you understanding the interactions between CAR-T cells and the host immune system.
- Use innovative Software FlowJo™ and SeqGeq™ for supervised and unsupervised data analysis of large data sets.

CAR-T Commercialisation Suite Workflow



Manufacturing QC and BD FACSLyric™ Flow Cytometer

- Enabling upscaling and consistency in manufacturing QC across sites with unique assay portability
- Support of 21 CFR part 11 features and maximizing instrument uptime, IQ/OQ procedures
- Automate sample preparation to reduce hands-on time, reduce error prone steps and inter-operator variability.
- Monitor multiple CAR-T cell attributes throughout the manufacturing process (e.g. cell viability, identity, purity, strength)



Clinical trial and MRD

- Next Generation Flow™: CE-IVD solutions for sensitive MRD detection in BCP-ALL and MM. Detection of myeloma cells in patients under anti-CD38 therapy.
- Reproducible analysis of multiparametric MRD data with BD Infinicyt™ software



Clinical trial and Immune phenotyping

- IVDR compliant reagent kits for screening and diagnosis of hematological neoplasia
- IVDR solutions for Immune assessment
- Backbone panels for easier T cell panel design
- Custom reagent solutions including dried reagents for less inter-operator variability.



Companion diagnostics (CDx)

- Partner with BD to develop flow cytometry-based companion diagnostics (CDx) solutions.



Tissue dissociation



Antibody solutions



Cell sorter



SCM



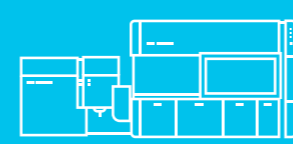
Cell analyser

Sort, screen and validate



Bioinformatics solutions

Bioinformatics



A high-performance CE-IVD flow cytometer



Reproducibility in clinical trials



Bioinformatics solutions

Compliance and data management

"The general challenge facing the industry is the need for standardisation, repeatability, reduction in cost and in the time it takes to set up a panel and analyse the data."

Nicolyn Thompson, Scientist at Cell&Gene Therapy Catapult, UK.

"BD has made significant contributions towards standardisation of process and data analysis through the use of ready-to-use reagents [...], instrument QC with automated compensation and generation of worklists portable between instruments."

Guiseppa Piras, Senior Scientist at Cell & Gene Therapy Catapult, UK.

To learn more about how BD can support you at different stages of discovery and commercialisation, visit our websites on [Cell therapy](#) and [CAR-T therapy solutions](#).

References

1. Sarikonda G. et al. Best practices for the development, analytical validation and clinical implementation of flow cytometric methods for chimeric antigen receptor T cell analyses. *Cytometry*. 2020; 1–13
2. Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell products
<https://www.fda.gov/media/156896/download> (last access 23.01.2022)

Abbreviations:

BCP-ALL: B-Cell Precursor Acute Lymphoblastic Leukemia

MM: Multiple myeloma

MRD: Minimal residual disease SCM: Single Cell Multiomics

Disclaimers:

The BD FACSDuet™ Sample Preparation System and BD FACSLytic™ Flow Cytometer are Class 1 Laser Products.

 BD FACSDuet™ Sample Preparation System and BD FACSLytic™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications, BD Infinicyt™, CYT-BCP-ALL-MRD, CYT-MM-MRD8 and CYT-38F2 are in vitro diagnostic devices bearing a CE mark.

BD Horizon™ Dri Tumor & Tissue Dissociation Reagent (TTDR) is for Research Use Only. Not for use in diagnostic or therapeutic procedures.

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