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Introduction

The path you take when translating a cell therapy from the research lab to the clinic is unlikely to be straightforward. As the range of cell types and tissues being investigated for their therapeutic potential continues to evolve—from immune cells to hematopoietic stem and progenitor cells (HSPCs), to human pluripotent stem cells (hPSCs)—so too are the specific challenges facing researchers. Beyond the need for specialized tools and tissue-specific protocols, developing and testing safe and efficacious cell and gene therapies also involves navigating material qualifications, process validations, and regulatory requirements that can seem as complex as the diseases that researchers are working to treat.

Working with a reliable, supportive supplier can ease the bench-to-clinic journey for your cell therapy in development. Whether you need their recommendations for products and tools that best meet your specific research needs, or assistance with fulfilling regulatory and compliance requirements, an experienced and knowledgeable supplier can be an asset when translating your cell and gene therapy research to the clinic.

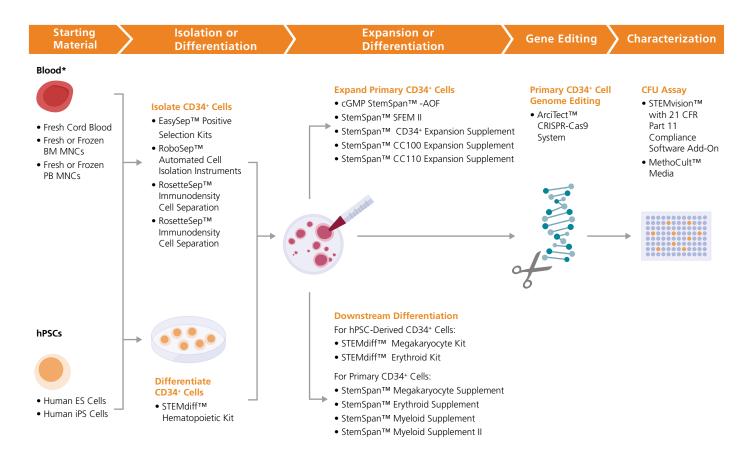
From our specialized products to our expert educational resources and services, STEMCELL Technologies can support your cell therapy development from the research lab to the clinic. Manufactured under a strict quality management system, our high-performance, standardized media and reagents can be used to consistently maintain, activate, expand, or differentiate cells for use in cell and gene therapy research. In addition to helping you build a complete workflow for your research, we also offer customized solutions through our Services for Cell Therapy Program, such as higher compliance product manufacture, regulatory support, and customer documentation.

Explore the sections below for an overview of some of the tools and workflows we have to support your cell therapy research, including products for cell isolation, expansion, gene editing, differentiation, and cell characterization. For detailed or specific information about our product offerings and support, please visit **www.stemcell.com** or contact your STEMCELL sales representative.

Tools for Hematopoietic and Blood-Related Cell Therapy Research

As for all cell therapy research, it is important when working with HSPCs to minimize risk and experimental variability and ensure consistent, reproducible performance and safety. Whether you are looking for reliable sources of CD34⁺ cells, cGMP-manufactured

HSPC culture medium, or efficient gene-editing tools, STEMCELL has products to support every step of your hematopoietic cell and gene therapy research workflow.



^{*}Certain products are only available in select territories.

Figure 1. Example of a Complete Product Workflow for Hematopoietic Cell and Gene Therapy Research

Start with a reliable source of HSPCs by using our fresh or frozen human blood products, including MNCs. CD34* or other cell subsets may be isolated from these samples by using our immunomagnetic EasySep™ cell isolation kits. Alternatively, you may start with our ready-to-use human primary CD34* cells or differentiate CD34* cells from hPSCs using the STEMdiff™ Hematopoietic Kit. Human CD34* cells can be reproducibly expanded or differentiated in serum-free conditions with StemSpan™ media and supplements—such as cGMP, animal origin-free StemSpan™-AOF medium—or with lineage-specific STEMdiff™ kits. Primary cell-derived CD34* cells may be efficiently gene edited using the ArciTect™ CRISPR-Cas9 System. Unmodified and gene-edited CD34* cells can be cultured in MethoCult™ media and analyzed using the STEMvision™ instrument, which is now available with a software add-on for use in high-compliance environments. BM MNCs: bone marrow-derived mononuclear cells, ES Cells: embryonic stem cells, iPS Cells: induced pluripotent stem cells, hPSCs: human pluripotent stem cells, PB MNCs: peripheral blood-derived mononuclear cells.

Key Technologies for HSPC Cell Therapy Research



CD34⁺ Cell Expansion

Reproducibly expand HSPCs in serum-free medium, such as cGMP-manufactured StemSpan[™]-AOF, customizable with CD34⁺ expansion supplements.

www.stemspan.com



Standardized HSPC CFU Assays

Characterize HSPCs in high-compliance environments by using STEMvision™ and MethoCult™ media.

www.stemvision.com



Contract Assay Services

Obtain timely and relevant data for your studies by outsourcing your standard or custom CFU assays to our scientists.

www.contractassay.com

Viral-Safe HSPC Expansion

How would your cultures perform in StemSpan™-AOF, the only truly animal origin-free, cGMP-manufactured HSPC expansion medium? Request an introductory offer and find out.



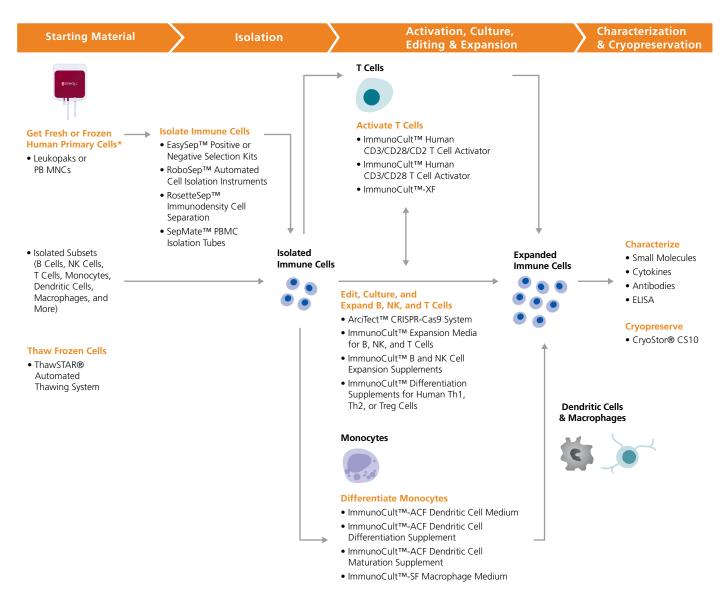
TRY STEMSPAN™-AOF

www.stemcell.com/trystemspan-aof

Immune Cells, Tools, and Reagents for Cell and Gene Therapy Research

Generating high yields of immune cells historically required the use of serum or feeder cells, but this approach can be problematic for immunotherapy development. Although these components facilitate immune cell differentiation and expansion, they can also introduce cell culture variabilities that jeopardize the safety of the therapy in development. Fortunately, serum-free and

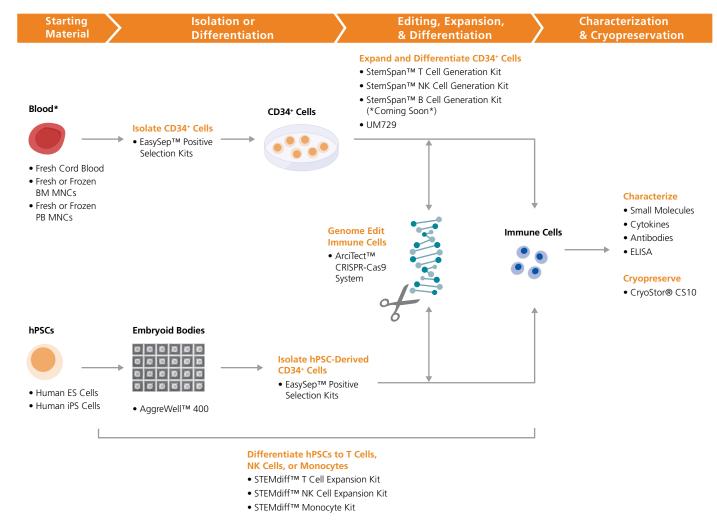
feeder-free methods for generating high yields of immune cells are now available. Depending on your starting material, research application, and type of cell therapy (allogeneic or autologous), there are multiple ways that STEMCELL can support your immune cell generation for downstream cell and gene therapy research applications.



^{*}Certain products are only available in select territories.

Figure 2. Example of a Complete Product Workflow for Generating High Yields of Immune Cells

Start with a reliable source of fresh or frozen human primary cells, available in various formats to fit your needs. With STEMCELL's efficient cell isolation technologies, you can enrich for the cell subsets you need—at small- or large-scale as required. For optimal cell yield and frequency, use serum-free ImmunoCult™ cell culture media and supplements, which are fully compatible with our cell isolation products, to activate, expand, or differentiate cells to use in your downstream applications. ImmunoCult™ may also be used with the ArciTect™ CRISPR-Cas9 System to gene edit immune cells with high efficiency. Expanded cells can be cryopreserved for future use or characterized with our broad porfolio of cell processing and analysis reagents. PB MNCs: peripheral blood-derived mononuclear cells, NK cells: natural killer cells.



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Figure 3. Example Workflow for Generating Immune Cells from CD34⁺ Cells or hPSCs

For researchers developing allogeneic cell therapies, hPSCs and HSPCs can be great options as starting materials. Reliably source HSPCs from our human primary cell products, including fresh cord blood and fresh or frozen mononuclear cells derived from peripheral blood or bone marrow. CD34⁺ cells can be isolated from these samples by using immunomagnetic EasySep™ positive selection kits. The isolated cells may then be immediately expanded or differentiated into immune cells using StemSpan™ media and supplements. For researchers using human ES or iPS cells as their starting material, STEMdiff™ immune kits provide complete, standardized protocols for generating immune cells from hPSCs. Immune cells may be efficiently gene edited using the ArciTect™ CRISPR-Cas9 System, cryopreserved for future use, or characterized with our broad porfolio of cell processing and analysis reagents. BM MNCs: bone marrow-derived mononuclear cells, hES Cells: human embryonic stem cells, hiPS Cells: human induced pluripotent stem cells, PB MNCs: peripheral blood-derived mononuclear cells, NK cell: natural killer cell.

Key Technologies for Immunotherapy Research



Immune Cell Generation

Generate immune cells from either CD34⁺ cells or hPSCs with StemSpan[™] or STEMdiff[™], respectively.

www.stemcell.com/immunecellculture



T Cell Activation

Activate T cells without the use of beads by using ImmunoCult™ T cell activators.

www.stemcell.com/tcellactivation



Immune Cell Expansion

Avoid the use of serum and reproducibly expand immune cells by using ImmunoCult™ media and supplements.

www.stemcell.com/immunecellexpansion

Expand Human T Cells for Use in Clinical Applications

Robustly expand T cells for clinical applications with cGMP-manufactured ImmunoCult™-XF medium, without the need for supplementation with serum or serum derivatives. ImmunoCult™-XF is phenol red-free, xeno-free, and has no added cytokines—providing complete flexibility for your workflow.

This ready-to-use medium is produced according to current GMP guidelines, ensuring the highest quality and consistency for reproducible results.



LEARN MORE

www.stemcell.com/immunocult-xf

Tools for Developing Pluripotent Stem Cell-Derived Cell and Gene Therapies

When developing hPSC-derived cell and gene therapies, it is critical to ensure that your culture workflow will generate human cells that are safe for clinical use. This means considering both product performance and regulatory compliance when selecting your supplier for culture reagents. Addressing both of these requirements, products and reagents from STEMCELL are optimized to yield high-quality cells at each stage of your

workflow and are manufactured under a strict quality management system, enabling you to develop safe and effective hPSC-derived cell and gene therapies. From obtaining or reprogramming your initial hPSC line, through to large-scale cell expansion or differentiation, we have tools to support the full breadth of your hPSC-derived cell therapy research.

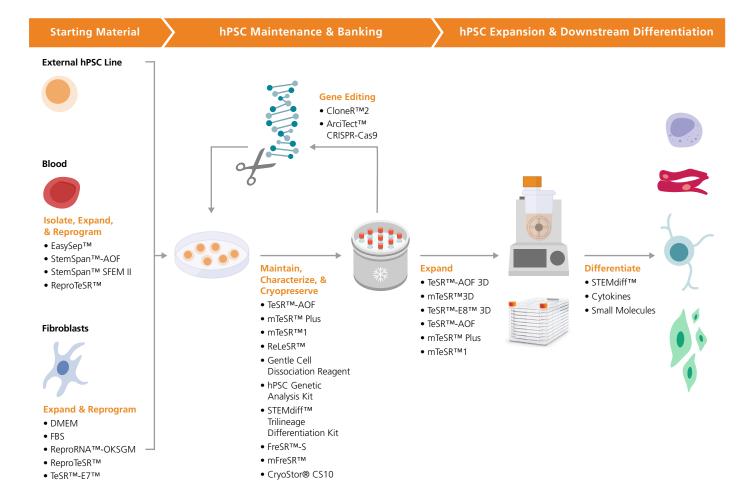


Figure 4. Example of an hPSC-Derived Cell and Gene Therapy Workflow

Whether you are working with a ready-to-use hPSC line or reprogramming iPSCs from isolated human primary cells, STEMCELL has the specialized tools to help you get started. Regardless of their source, hPSCs may be maintained and expanded using our TeSR™ family of feeder-free culture media, available in a variety of formulations to fit your specific culture requirements, format, and scale. Efficiently gene edit your cells with the ArciTect™ CRISPR-Cas9 System, and use CloneR™2 supplement for improved cloning efficiency and survival, even under high-stress conditions. Reproducible and efficient differentiation of multiple hPSC lines to various cell lineages can be achieved with our standardized STEMdiff™ kits and protocols, which are compatible with TeSR™ media. We also offer reagents and services for cryopreserving, banking, and characterizing your cells to ensure hPSC quality. DMEM: Dulbecco's modified eagle medium, FBS: fetal bovine serum.

Key Technologies for hPSC-Derived Cell Therapy Research



Animal Origin-Free hPSC Culture

Reduce risk and obtain more high-quality hPSCs by using TeSR™-AOF medium, manufactured under relevant cGMPs and animal origin-free to the secondary level of manufacturing.

www.stemcell.com/tesr-aof



hPSC Passaging

Easily generate optimally-sized aggregates without scraping, by passaging your hPSCs with enzyme-free ReLeSR™, manufactured under relevant cGMPs.

www.stemcell.com/relesr



hPSC Cryopreservation

Maximize post-thaw cell recovery and viability following cryopreservation at very low temperatures (-70°C to -196°C) with ready-to-use CryoStor® CS10, manufactured under relevant cGMPs.

www.stemcell.com/cryostor-cs10

Animal Origin-Free Maintenance Medium for hPSC Culture

For your hPSC cultures, choose a medium that allows for restricted feeding schedules, enabling you to get more of the cells you need while minimizing the time spent maintaining them. Request a free sample of TeSR™-AOF media.



TESR™-AOF

www.stemcell.com/forms/why-tesr-aof

Human Primary Cells for Cell and Gene Therapy Research

A reliable source of human primary cells ensures continuity in your research and enables you to start experiments according to your schedule, without compromising on quality. Avoid the challenges associated with obtaining human biological material by choosing ready-to-use and ethically sourced fresh or cryopreserved cells* from a supplier you can depend on.



PRIMARY CELLS FROM STEMCELL

Learn more about our primary cell products, get answers to FAQs, and browse our complete product listing.

www.stemcell.com/primarycells

Why Use Human Primary Cells from STEMCELL Technologies?

PHYSIOLOGICALLY RELEVANT. Choose cells that are more physiologically representative of cells in vivo.

ETHICALLY SOURCED. Access donor samples collected using regulatory authority-approved consent forms and protocols.

CUSTOMIZE. Request custom products for non-standard cell types or collections with specific requirements.

FLEXIBLE. Reserve large numbers of cryopreserved cells and start experiments on your schedule with cells you've already tested.

EFFICIENT. Reduce time spent collecting and culturing primary cells.

Key Primary Cell Products for Cell Therapy Research



Fresh or Frozen Leukopaks

Get large numbers of fresh or frozen mononuclear cells from a selection of leukopak sizes. **www.stemcell.com/cells**



Human Cord Blood Cells

Streamline your cell-based assays with ethically sourced, frozen human cord blood CD34⁺ cells. www.stemcell.com/cd34cells-frozen



Human Peripheral Blood Mononuclear Cells

Start experiments at your convenience with ready-to-use, frozen human peripheral blood mononuclear cells.

www.stemcell.com/pbmc-frozen

^{*}Certain products are only available in select territories. Please contact your sales representative or the Product & Scientific Support team at **techsupport@stemcell.com** for further information.

Additional Products to Support Your Cell Therapy Protocols

For a complete listing of products to support your cell therapy research, visit www.stemcell.com.

Media and Reagents	Description	Size	Catalog #
MethoCult™ SF H4636	Serum-free methylcellulose-based medium with recombinant cytokines for hPSC-derived hematopoietic progenitor cells	100 mL	04636
STEMdiff™ Megakaryocyte Kit	Serum-free and feeder-free medium for differentiation of human ES or iPS cells to megakaryocytes and platelets	1 kit	100-0900
mTeSR™ Plus, cGMP	cGMP, stabilized feeder-free maintenance medium for human ES and iPS cells	1 kit	100-0276
MesenCult™-ACF Plus Medium	Animal component-free medium for human mesenchymal stem cells	500 mL	05448
CryoStor® CS10, cGMP	cGMP, animal component-free, defined cryopreservation medium with 10% DMSO	100 mL*	100-1061
BloodStor® 100	Biopreservation reagent for cells and tissues	50 mL*	07951
BloodStor® 55-5	Optimized biopreservation reagent for hematopoietic cells and tissues	16 x 7.2 mL*	07937
HypoThermosol® FRS	Animal component-free, defined hypothermic (2 - 8°C) preservation medium for a range of cell and tissue types	100 mL*	07935

Supplementary Products	Description	Size	Catalog #
PBS-MINI MagDrive Bioreactor	Compact bioreactor with single-use vessels for high-throughput, 3D suspension culture of hPSCs and other cell types	1 Unit	100-1005
ThawSTAR® CFT2 Automated Thawing System	Automated cell thawing system for consistent thawing performance	1 Unit	100-0650
Healthy Control Human iPSC Line, Female, SCTi003-A	Human pluripotent stem cell line, frozen	1 Vial	200-0511
Human Platelet Lysate	Fibrinogen-depleted and xeno-free supplement for the expansion of cells in vitro	50 mL*	200-0360

^{*}Various sizes and formats are available; visit www.stemcell.com to see all options.

Streamline Your Ancillary Material Qualification with Our Services for Cell Therapy Program

A lot goes into choosing the right ancillary materials (also known as raw materials) when working toward an Investigational New Drug (IND) application or Clinical Trial Application (CTA). Developing a robust Chemistry, Manufacturing and Controls (CMC) package, which includes appropriately qualifying all materials for quality, safety, and performance, is critical to your success as you enter the clinic and progress through the clinical phases. STEMCELL's Services for Cell Therapy Program can support the qualification of our products as ancillary materials

by providing extended quality documentation and customized solutions to meet your specific clinical needs.

As of 2022, the Services for Cell Therapy Program has supported over 66 successful INDs/CTAs, including numerous NK and T cell therapy candidates. To learn more about how we can support your preclinical and clinical research needs, visit **www.stemcell.com/sct** or speak with your STEMCELL sales representative.

Try Products That Support Your Cell Therapy Research

Finding products that meet both the needs of researchers and the requirements for cell therapy applications can be challenging. That's why it's crucial to have the right support to help you through all stages of your research. Try our products in your own lab—we offer a range of high-compliance cell culture media and reagents for your cell therapy research.



REQUEST INTRODUCTORY OFFER

www.stemcell.com/try-cgt-products

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MAKE TODAY'S RESEARCH TOMORROW'S CELL THERAPY

Products and Services for Your Research



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