



## ***PACT-Related Bibliography***

---

### **Manuscripts**

#### **2015**

Lindblad RW, Ibenana L, Wagner JE, McKenna Jr DH, Hei DJ, Hematti P, Couture LA, Silberstein LE, Armant M, Rooney CM, Gee AP, Welniak LA, Heath Mondoro T, Wood DA, Styers D. Cell therapy product administration and safety: data capture and analysis from the Production Assistance for Cellular Therapies (PACT) program. *Transfusion*. 2015 Mar;55(3):674-9. Epub ahead of print. [PMID: 25315143].

Ouseph S, Tappitake D, Armant M, Wesselschmidt R, Derecho I, Draxler R, Wood D, and Centanni JM. Cellular therapies clinical research roadmap: lessons learned on how to move a cellular therapy into a clinical trial. *Cytotherapy*. 2015; 17:339-343. [PMID: 25484311].

Bloom D, Centanni JM, Bhatia N, Emler CA, Drier D, Levenson GE, McKenna Jr DH, Gee AP, Lindblad R, Hei DJ, and Hematti P. A reproducible immunopotency assay to measure mesenchymal stromal cell-mediated T-cell suppression. *Cytotherapy*. 2015. 17(2):140-51. Published online November 21, 2014. doi: <http://dx.doi.org/10.1016/j.jcyt.2014.10.002>. [PMID: 25455739].

#### **2014**

Lalit PA, Hei DJ, Raval AN, and Kamp TJ. Induced pluripotent stem cells for post-myocardial infarction repair: remarkable opportunities and challenges. *Circ Res*. 2014; 114:1328-1345. doi: 10.1161/CIRCRESAHA.114.300556. [PMID: 24723658].

Miller JS, Rooney CM, Curtsinger J, McElmurry R, McCullar V, Verneris MR, Lapteva N, McKenna D, Wagner JE, Blazar BR, and Tolar J. Expansion and homing of adoptively transferred human natural killer cells in immunodeficient mice varies with product preparation and in vivo cytokine administration: implications for clinical therapy. *Biol Blood Marrow Transplant*. 2014 Aug; 20(8): 1252-1257. Epub 12 May 2014. [PMID: 24816582].

Wood D, Wesselschmidt R, Hematti P, Gee AP, Rooney C, Silberstein L, Armant M, Couture L, Wagner JE, McKenna Jr. DH, Hei D, Heath Mondoro T, Welniak L, and Lindblad R. An update from the United States National Heart, Lung, and Blood Institute-funded Production Assistance for Cellular Therapies (PACT) Program: a decade of cell therapy. *Clin Transl Sci*. 2014 Apr;7(2):93-9. [PMID: 24655892].

#### **2013**

Matthay MA, Anversa P, Bhattacharya J, Burnett BK, Chapman HA, Hare JM, Hei DJ, Hoffman AM, Kourembanas S, McKenna DH, Ortiz LA, Ott HC, Tente W, Thébaud B, Trapnell BC, Weiss DJ, Yuan JXJ, Blaisdell CJ. Cell Therapy for Lung Diseases: Report from an NIH-NHLBI Workshop November 13-14, 2012. *Am J Respir Crit Care Med*. First published online 28 May 2013 as doi:10.1164/rccm.201303-0522WS. [PMID: 23713908].

Sanchez R, Silberstein L, Lindblad R, Welniak L, Mondoro T, and Wagner J. Strategies for more rapid translation of cellular therapies for children: a U.S. perspective. *Pediatrics*. Volume 132, Number 2, August 2013, doi:10.1542/peds.2012-3383. Epub July 8, 2013. [PMID: 23837178].



Koepsell SA, Miller JS, and McKenna DH. Natural killer cells: a review of manufacturing and clinical utility. *Transfusion*. 2013;53: 404-410. [PMID: 22670662]

Skeate R, Singh C, Cooley S, Geller M, Northouse J, Welbig J, Slungaard A, Miller J, and McKenna D. Hemolytic anemia due to passenger lymphocyte syndrome in solid malignancy patients treated with allogeneic natural killer cell products. *Transfusion*. 2013;53:419-423. [PMID: 23113867].

## **2012**

Lapteva N, Durett AG, Sun J, Rollins LA, Huye LL, Fang J, Dandekar V, Mei Z, Jackson K, Vera J, Ando J, Ngo MC, Coustan-Smith E, Campana D, Szmania S, Garg T, Moreno-Bost A, van Rhee F, Gee AP, and Rooney CM. Large-scale ex vivo expansion and characterization of natural killer cells for clinical applications. *Cytotherapy*. 2012 Oct;14(9): 1131-43. Epub 2012 Aug 17. [PMID: 22900959].

Richman S, Gee AP, McKenna DH, Traverse JH, Henry TD, Fisk D, Pepine CJ, Bloom J, Willerson JT, Prater K, Zhao D, Koç JR, Anwaruddin S, Taylor DA, Cogle CR, Moyé LA, Simari RD, and Skarlatos SI. Factors affecting the turnaround time for manufacturing, testing, and release of cellular therapy products prepared at multiple sites in support of multicenter cardiovascular regenerative medicine protocols: a Cardiovascular Cell Therapy Research Network (CCTRN) study. *Transfusion*. 2012 Feb 10. doi: 10.1111/j.1537-2995.2011.03543.x. Epub ahead of print. [PMID: 22320233].

## **2011**

Lapteva N and Vera J. Optimization manufacture of virus- and tumor-specific T cells. *Stem Cells Int*. Volume 2011. Epub 2011 Sep 11. [PMID: 21915183].

Kamdar KY, Rooney CM, and Heslop HE. Posttransplant lymphoproliferative disease following liver transplantation. *Curr Opin Organ Transplant*. 2011, 16:274–280. [PMID: 21467936].

Zierold C, Carlson MA, Obodo UC, Wise E, Piazza VA, Meeks MW, Vojvodic RW, Baraniuk S, Henry TD, Gee AP, Ellis SG, Moyé LA, Pepine CJ, Cogle CR, Taylor DA. Developing mechanistic insights into cardiovascular cell therapy: Cardiovascular Cell Therapy Research Network Biorepository Core Laboratory rationale. *Am Heart J*. 2011;162:973-980. [PMID: 22137069].

Donnenberg AD, Donnenberg VS, Griffin DL, Moore LR, Tekinturhan F, Kormos RL. Intra-operative preparation of autologous bone marrow-derived CD34-enriched cellular products for cardiac therapy. *Cytotherapy*. 2011;13:441-448. [PMID: 21062114].

Horwitz EM, Horowitz MM, DiFronzo NL, Kohn DB, and Heslop HE. Guidance for Developing Phase II Cell Therapy Trial Proposals for Consideration by the Blood and Marrow Transplant Clinical Trials Network. *Biol Blood Marrow Transplant*. 2011 Feb, 17(2):192-6. doi:10.1016/j.bbmt.2010.08.020. [PMID: 21182973].

Whiteside TL, Griffin DL, Stanson J, Gooding W, McKenna D, Sumstad D, Kadidlo D, Gee A, Durett A, Lindblad R, Wood D, Styers D. Shipping of therapeutic somatic cell products. *Cytotherapy*. 2011; 13:201-213. [PMID: 20795760]



## **2010**

- Gee AP, Richman S, Durett A, McKenna D, Traverse J, Henry T, Fisk D, Pepine C, Bloom J, Willerson J, Prater K, Zhao D, Koc JR, Ellis S, Taylor D, Cogle C, Moye L, Simari R, and Skarlatos S. Multicenter cell processing for cardiovascular regenerative medicine applications: the Cardiovascular Cell Therapy Research Network (CCTRN) experience. *Cytotherapy*. 2010; 12:684-691. [PMID: 20524773].
- McKenna DH Jr, Adams S, Sumstad D, Sumstad T, Kadidlo D, Gee AP, Durett A, Griffin D, Donnenberg A, Amrani D, Livingston D, Lindblad R, Wood D, Styers D. CD34<sup>+</sup> cell selection using small-volume marrow aspirates: a platform for novel cell therapies and regenerative medicine. *Cytotherapy*. 2010;12:170–177. [PMID: 20078385].
- Stroncek D, Berlyne D, Fox B, Gee A, Heimfeld S, Lindblad R, Loper K, McKenna D Jr, Rooney C, Sabatino M, Wagner E, Whiteside T, Wood D, Heath-Mondoro T. Developments in clinical cell therapy. *Cytotherapy*. 2010; 12: 425–428. [PMID: 20078383].

## **2009**

- Reed W, Noga SJ, Gee AP, Rooney CM, Wagner JE, McCullough J, McKenna DH, Whiteside TL, Donnenberg AD, Baker AK, Lindblad RW, Wagner EL, Mondoro TH. Production Assistance for Cellular Therapies (PACT): five-year experience from the United States National Heart Lung and Blood Institute (NHLBI) contract research program in cell and tissue therapies. *Transfusion*. 2009;49(4):786-796. [PMID: 19170985].

## **2008**

- Gee AP, Sumstad D, Stanson J, Watson P, Proctor J, Kadidlo D, Koch E, Sprague J, Wood D, Styers D, McKenna D, Gallelli J, Griffin D, Read EJ, Parish B, Lindblad R. A multicenter comparison study between the Endosafe<sup>®</sup> PTS<sup>™</sup> rapid-release testing system and traditional methods for detecting endotoxin in cell-therapy products. *Cytotherapy*. 2008;10(4):427-35. [PMID: 18574775].

## **2005**

- McKenna DH, Kadidlo DM, Miller JS. The Minnesota Molecular and Cellular Therapeutics Facility: A State-of-the-art Biotherapeutics Engineering Laboratory. *Transfus Med Rev*. 2005. 19 (3): 217-28. [PMID: 16010652].
- Mondoro TH, Thomas JW, Henslee-Downey PJ, Peterson CM. National Heart, Lung, and Blood Institute (NHLBI) plans for the promise of cell-based therapies. *Cytotherapy*. 2005;7(4):317-27. [PMID: 16162453].

## **2004**

- McCullough J, Wagner J, Gee A, Rooney C, Whiteside T, Donnenberg A, Lindblad R. Production Assistance for Cellular Therapies. *Transfusion*. 2004;44(12):1793. [PMID: 15584997].

## **2002**

- Stroncek D, Harvath L, and Barrett J. National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health forum on immune reconstitution and cellular therapy following hematopoietic stem-cell transplantation. *Cytotherapy*. 2002. 4(5):415-18. [PMID: 12479173].

## **Books**

Gee A, ed. Cell therapy: cGMP facilities and manufacturing. New York: Springer, 2009. Print.



## Scientific Meeting Abstracts

### 2014

Tsytsykova A, Stegner J, DiMeo M, Pai S, Williams D, Notarangelo L, Dansereau C, Ritz J, Silberstein L, Armant M. Gene Therapy for Primary Immunodeficiencies. Ninth Annual HSCI Malkin Retreat. Cambridge, MA, May 23, 2014. Poster.

### 2013

Lindblad R, Quinnan K, and Wood D. A successful support program for cell therapy: an update from the Production Assistance for Cellular Therapies (PACT) Group. October 2013 AABB Annual Meeting & TXPO, Denver, CO. *Transfusion*. September 2013 Vol:53; No.2S; Supplement AP34.

Lindblad R, Styers D, and Wood D. A successful web seminar program for cell therapy: an update from the Production Assistance for Cellular Therapies (PACT) Group. October 2013 AABB Annual Meeting & TXPO, Denver, CO. *Transfusion*. September 2013 Vol:53; No.2S; Supplement AP40.

Centanni JM, Wesselschmidt R, Ouseph S, Armant M, and Draxler R. Clinical research roadmap: a resource for cellular therapy. October 2013 AABB Annual Meeting & TXPO, Denver, CO. *Transfusion*. September 2013 Vol:53; No.2S; Supplement AP43.

Hei D. Developing cell therapeutics for clinical trials: key considerations and challenges. 2013 Bio-Trac / NIH CRM Stem Cell Industry Symposium May 2013, NIH (Bethesda, MD).

Bajgain P, Mucharla R, Anurathapan U, Lapteva N, Leen AM, Heslop HE, Rooney CM, and Vera JF. A novel approach to manufacture CAR-T cells for clinical applications. ASBMT BMT Tandem Meeting, February 13-17, 2013. Salt Lake City, UT. Abstract #2276.

### 2012

Bajgain P, Mucharla R, Anurathapan U, Lepteva N, Leen AM, Heslop HE, Rooney CM, and Vera JF. Optimizing the manufacture of CAR-T Cells for clinical applications. 54<sup>th</sup> ASH Annual Meeting. December 8-11, 2012. Atlanta, GA. Abstract #348.

Tolar J, Curtsinger J, McElmurry R, McCullar V, Verneris MR, van Rhee F, Lapteva N, Rooney CM, Wagner JE, Blazar BR, and Miller JS. Optimal xenogeneic adoptive transfer of human NK cells: fresh NK cells and IL-15 administration are superior to frozen NK cells and IL-2. 54<sup>th</sup> ASH Annual Meeting. December 8-11, 2012. Atlanta, GA. Abstract #346.

Gee A, Silberstein L, Armant M, Couture LA, Wagner J, McKenna D, Hei D, Welniak L, Lindblad R, and Wood D. Production Assistance for Cellular Therapies (PACT): an eight-year experience from the National Heart, Lung, and Blood Institute (NHLBI) contract research program. October 2012 AABB Annual Meeting & TXPO, Boston, MA. *Transfusion*. 2012 Vol:52, No.3S, Supplement AP43 pg. 254A.

### 2010

Kassalow N, Wood DA, Gee AP, Rooney CM, Silberstein LE, Couture LA, Wagner JE, McKenna DH, Hei DJ, and Lindblad RW. NIH/NHLBI-funded program Production Assistance For Cellular Therapies (PACT) renewed. October 2010 AABB Annual Meeting & TXPO, Baltimore, MD. *Transfusion*. 2010 Vol:50; No2S; SP458.



## **2009**

Kassalow N, Gee A, Rooney C, Wagner J, McCullough J, McKenna D, Whiteside T, Donnenberg A, Heath Mondoro T, Wagner E, Reed W, Noga S, and Wood D. Educational program for cell therapy: a review of efforts sponsored by the Production Assistance for Cellular Therapies (PACT) Group. October 2009 AABB Annual Meeting & TXPO, New Orleans, LA. *Transfusion*. 2009 Vol:49; No.3S; AP81.

Reed W, Noga S, Wood D, Kassalow N, Lindblad R, Winestone J, Gee A, Rooney C, McCullough J, McKenna D, Wagner J, Donnenberg A, Whiteside T, Wagner E, and Heath Mondoro T. Production Assistance for Cellular Therapies (PACT): six-year experience from the United States National Heart Lung and Blood Institute (NHLBI) contract research program in cell and tissue therapies. September 2009 World Stem Cell Summit, Baltimore, MD. Poster 185.

## **2008**

Reed W, Noga SJ, Gee AP, Rooney C, McKenna DH, Wagner J, Donnenberg A, Whiteside T, Baker A, Lindblad R, Wagner E, Mondoro T. Production Assistance for Cellular Therapies (PACT): four-year experience from the United States National Heart Lung and Blood Institute (NHLBI). October 2008 AABB Annual Meeting, Montreal, Canada. *Transfusion*. 2008;48; No.2S;SP272.

## **2007**

Reed W, Noga SJ, Gee AP, Rooney CM, Wagner JE, McKenna DH, Whiteside TL, Donnenber AD, Lindblad RW, Winestone JK. Production Assistance in Cellular Therapy (PACT): 3-year experience from the US National Heart Lung and Blood Institute (NHLBI) contract research program. June 2007 International Society for Cellular Therapy Annual Meeting, Sydney, Australia. *Cytotherapy*. 2007;9;S1;119.

Griffin DL, McNeil M, Donnenber AD, Kiss JE, Whiteside TL, and Donovan M. Development of a good manufacturing practice (cGMP) training program for the cellular therapies laboratories at the University of Pittsburgh Cancer Institute. June 2007 International Society for Cellular Therapy Annual Meeting, Sydney, Australia. *Cytotherapy*. 2007;9;S1;120.