

# Paula M. Jacobs, Ph.D.

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## Positions

### **National Cancer Institute, Division of Cancer Treatment & Diagnosis**

Cancer Imaging Program

Expert Advisor, 2018-present

Associate Director, 2012- 2018

Adjunct Investigator, Center for Cancer Research, Molecular Imaging  
Program, 2015-present

Acting Associate Director, 2010 to 2011

Deputy Associate Director, 2009 to 2011

### **SAIC-Frederick, Frederick, MD (Now Leidos Biomedical Research)**

Operations and Technical Support (OTS) Contractor for the National Cancer  
Institute at Frederick

Contracted to: Cancer Imaging Program/DCTD/NCI/ NIH

Director of Regulatory Affairs, 2006-2009

### **Advanced Magnetics, Inc, Cambridge, MA (Now AMAG Pharmaceuticals)**

Pharmaceuticals: MRI Contrast agents, iron therapy; US and International  
Vice President Development, 1986–2005

### **Seragen, Inc., Boston, MA**

Research and Diagnostic Kits: Prostaglandins, cell separation

General Manager—Research Products 1983–1985

Director of Production and Manufacturing Development—1981–1983

### **Clinical Assays (Division of Baxter Travenol), Cambridge MA**

In Vitro Diagnostics: clinical test kits, solid phase immunoassay

Director Of Scientific Operations—1981-1982

Director Of Technical Support—1980-1981

Group Leader, Technical Support—1978-1980

### **Childrens Cancer Research Foundation**

Research Assistant—1968-1970: folate antagonists

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## Post-Doctoral Research

### **Harvard Medical School**

Associate In Radiology—1977-1979

### **Peter Bent Brigham Hospital**

Associate In Radiology—1977-1979

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## **Northeastern University**

Research Associate—1976-1978

## **The Massachusetts Institute Of Technology**

Research Fellow—1975-1976

## **Northeastern University**

Research Associate—1973-1974

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### **Education**

**Ph.D.**, Organic Chemistry

Northeastern University—1973

**M.S.**, Organic Chemistry

Tufts University—1968

**S.B.**, Chemistry

The Massachusetts Institute of Technology—1966

National Merit Scholar

### **Professional Societies**

American Chemical Society

American Association for Cancer Research

American Society of Clinical Oncology

Society of Nuclear Medicine

Radiological Society of North America

Sigma Xi

Inactive:

American Association for the Advancement of Science

American Heart Association

American Roentgen Ray Society

American Society of Nephrology

International Society for Magnetic Resonance Imaging in Medicine

International Society of Nephrology

National Kidney Foundation

New York Academy of Sciences

Society for Molecular Imaging

Royal Chemical Society

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## **Committee Memberships**

Imaging Drug Group, NCI/DCTD 2007-2010  
NEXT Development Committee, NCI/DCTD, 2009-2018  
NEXT Senior Advisory Committee, NCI/DCTD, 2009-present  
NExt Discovery Committee, NCI/DCTD, 2009-2018  
Integrated Canine Data Commons, Steering Committee, NCI/DCTD, 2018-present  
Best Practices Subcommittee of the NCI Integrated Canine Data Commons Steering Committee (ICDC-SC), 2019-present

## **Editorial Boards Reviewer**

Associate Editor, American Journal of Nuclear Medicine and Molecular Imaging  
Nature Reviews Oncology  
Journal of Nuclear Medicine  
Cancer Research  
Clinical Cancer Research  
Radiology  
Annals of Surgery  
Molecular imaging and Biology  
Academic Radiology

## **Awards**

NIH Merit Award, 2011, Leadership  
NIH NLST Award, 2013, Oversight Committee  
NIH Merit Award, 2014, Quantitative Imaging Network Team  
Radiology, Editors Recognition Award, 2016  
NIH Merit Award, 2017, International Partnerships for Beau Biden Moonshot Initiative  
NIH Directors Award, 2018, Interagency Working Group on Medical Imaging

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### Trial Protocols

NCT03206060 17C0087A Lu-177-DOTATATE (Lutathera) in Therapy of Inoperable Pheochromocytoma/Paraganglioma

NCT03181867. 17C0109-18F-DCFPyL PET/CT in High Risk and Recurrent Prostate Cancer

NCT03173924 17C0089 18F-DCFPyL PSMA- Versus 18F-NaF-PET Imaging for Detection of Metastatic Prostate Cancer

NCT02190279. CTEP# 9622 14-C-0140 A Pilot Study of 18F-DCFBC PET/CT in Prostate Cancer. Completed

CTEP #9605 Phase I Study of Ganetespib and Ziv-Aflibercept in Refractory Gastrointestinal Carcinomas, Non-Squamous Non-Small Cell Lung Carcinomas, Urothelial Carcinomas, and Sarcomas

NCT02141490 , NCI 14-C-0107 Evaluation of Ferumoxytol Enhanced MRI for the Detection of Lymph Node Involvement in Genitourinary (Prostate, Bladder and Kidney) Cancers

CTEP # 8826 Clinical Center 11-C-0061 Phase I Trial of Z-Endoxifen in Adults With Refractory Hormone Receptor–Positive Breast Cancer, Desmoid Tumors, Gynecologic Tumors, or Other Hormone Receptor–Positive Solid Tumors

CIP/NCI #: 7832 CC#: 07C0101 A Phase 0 Trial of 111-Indium CHX-A" DTPA trastuzumab Imaging in Cancer. Completed

NCT01296139. 11C0098-CEvaluation of Ferumoxytol enhanced MRI for the detection of lymph node involvement in prostate cancer. Completed

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**PUBLICATIONS & PRESENTATIONS**

As of 5/2019

1. McDonald RJ, Levine D, Weinreb J, Kanal E, Davenport MS, Ellis JH, **Jacobs PM**, Lenkinski RE, Maravilla KR, Prince MR, Rowley HA, Tweedle MF, Kressel HY. Gadolinium Retention: A Research Roadmap from the 2018 NIH/ACR/RSNA Workshop on Gadolinium Chelates. *Radiology*. 2018 Nov;289(2):517-534. doi: 10.1148/radiol.2018181151
2. Jaffray DA, Das S, **Jacobs PM**, Jeraj R, Lambin P. [How Advances in Imaging Will Affect Precision Radiation Oncology](#). *Int J Radiat Oncol Biol Phys*. 2018 Jun 1;101(2):292-298. doi: 10.1016/j.ijrobp.2018.01.047
3. Harmon SA, Bergvall E, Mena E, Shih JH, Adler S, McKinney Y, Mehralivand S, Citrin DE, Couvillon A, Madan R, Gulley J, Mease RC, **Jacobs PM**, Pomper MG, Turkbey B, Choyke PL, Lindenberg ML. [A Prospective Comparison of <sup>18</sup>F-Sodium Fluoride PET/CT and PSMA-targeted <sup>18</sup>F-DCFBC PET/CT in Metastatic Prostate Cancer](#). *J Nucl Med*. 2018
4. Mena E, Lindenberg ML, Shih JH, Adler S, Harmon S, Bergvall E, Citrin D, Dahut W, Ton AT, McKinney Y, Weaver J, Eclarinal P, Forest A, Afari G, Bhattacharyya S, Mease RC, Merino MJ, Pinto P, Wood BJ, **Jacobs P**, Pomper MG, Choyke PL, Turkbey B, [Clinical impact of PSMA-based <sup>18</sup>F-DCFBC PET/CT imaging in patients with biochemically recurrent prostate cancer after primary local therapy](#). *Eur J Nucl Med Mol Imaging*. 2018 Jan;45(1):4-11. doi: 10.1007/s00259-017-3818-x. Epub 2017 Sep 11.
5. Shields AF, **Jacobs P**, Sznol M, Graham MM, Germain R, Lum L, Jaffee E, de Vries EGE, Nimmagadda S, Van den Abbeele AD, Leung D, Wu AM, Sharon E, Shankar LK. [Immune Modulation Therapy and Imaging: Workshop Report](#). *J Nucl Med*. 2017 Aug 17. pii: jnumed.117.195610. doi: 10.2967/jnumed.117.195610. [Epub ahead of print]
6. [Lindenberg L<sup>1</sup>](#), [Adler S<sup>2</sup>](#), [Turkbey IB<sup>1</sup>](#), [Mertan F<sup>1</sup>](#), [Ton A<sup>2</sup>](#), [Do K<sup>3</sup>](#), [Kummar S<sup>4</sup>](#), [Gonzalez EM<sup>1</sup>](#), [Bhattacharyya S<sup>5</sup>](#), [Jacobs PM<sup>6</sup>](#), [Choyke P](#), Dosimetry and first human experience with <sup>89</sup>Zr-panitumumab. *Am J Nucl Med Mol Imaging*. 2017 Sep 1;7(4):195-203. eCollection 2017.
7. [Turkbey B<sup>1</sup>](#), [Mena E](#), [Lindenberg L](#), [Adler S](#), [Bednarova S](#), [Berman R](#), [Ton AT](#), [McKinney Y](#), [Eclarinal P](#), [Hill C](#), [Afari G](#), [Bhattacharyya S](#), [Mease RC](#), [Merino MJ](#), [Jacobs PM](#), [Wood BJ](#), [Pinto PA](#), [Pomper MG](#), [Choyke PL](#). <sup>18</sup>F-DCFBC Prostate-Specific Membrane Antigen-Targeted PET/CT Imaging in Localized Prostate Cancer: Correlation With Multiparametric MRI and Histopathology, *Clin Nucl Med*. 2017 Oct;42(10):735-740. doi: 10.1097/RLU.0000000000001804.
8. Willemieke S. Tummers, Jason M. Warram, Kiranya E. Tipirneni, John Fengler, Paula Jacobs, Lalitha Shankar, Lori Henderson, Betsy Ballard, Brian W. Pogue, Jamey P. Weichert, Michael Bouvet, Jonathan Sorger, Christopher H. Contag, John V. Frangioni, Michael F. Tweedle, James P. Babilion, Sanjiv S. Gambhir and Eben L. Rosenthal, [Regulatory Aspects of Optical Methods](#)

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- [and Exogenous Targets for Cancer Detection](#), Cancer Res April 20 2017 DOI:10.1158/0008-5472.CAN-16-3217
9. Jacobs, PM, " Overview of FDA approval paths optical surgical navigation ", *Proc. SPIE* 10049, Molecular-Guided Surgery: Molecules, Devices, and Applications III, 100490S (February 8, 2017); doi:10.1117/12.2257152; <http://dx.doi.org/10.1117/12.2257152>
  10. Frank I. Lin, E. M. Gonzalez, S. Kummar, K. Do, J. Shih, S. Adler, K. A. Kurdziel, A. Ton. B. Turkbey, P. M. Jacobs, S. Bhattacharyya, A. P. Chen, J. M. Collins, J. H. Doroshov, P. L. Choyke, M. L. Lindenberg, Utility of 18F-fluoroestradiol (18F-FES) PET/CT imaging as a pharmacodynamic marker in patients with refractory estrogen receptor-positive solid tumors receiving Z-endoxifen therapy *Eur J Nucl Med Mol Imaging*. 2017 Mar;44(3):500-508. doi: 10.1007/s00259-016-3561-8
  11. Rieves D and Jacobs P, [The Use of Published Clinical Study to Support the United States Food and Drug Administration Approval of Imaging Agents](#), *J Nucl Med* 2016: J Dec;57(12):2022-2026. online first July 21 2016 as doi: [10.2967/jnumed.116.178814](https://doi.org/10.2967/jnumed.116.178814)
  12. Rosenthal EL, Warram JM, de Boer E, Basilion JP, Biel MA, Bogyo M, Bouvet M, Brigman BE, Colson YL, DeMeester SR, Gurtner GC, Ishizawa T, **Jacobs PM**, Keereweer S, Liao JC, Nguyen QT, Olson JM, Paulsen KD, Rieves D, Sumer BD, Tweedle MF, Vahrmeijer AL, Weichert JP, Wilson BC, Zenn MR, Zinn KR, van Dam GM. [Successful Translation of Fluorescence Navigation During Oncologic Surgery: A Consensus Report](#). *J Nucl Med*. 2016; **57**:144-150
  13. Ellingson BM, Bendszus M, Boxerman J, Barboriak D, Erickson BJ, Smits M, Nelson SJ, Gerstner E, Alexander B, Goldmacher G, Wick W, Vogelbaum M, Weller M, Galanis E, Kalpathy-Cramer J, Shankar L, **Jacobs P**, Pope WB, Yang D, Chung C, Knopp MV, Cha S, van den Bent MJ, Chang S, Yung WK, Cloughesy TF, Wen PY, Gilbert MR; Jumpstarting Brain Tumor Drug Development Coalition Imaging Standardization Steering Committee. [Consensus recommendations for a standardized Brain Tumor Imaging Protocol in clinical trials](#). *Neuro-Oncology* 17(9), 1188–1198, 2015
  14. Fahey F, Zukotynski K, Jadvar H, Capala J; organizing committee, contributors, and participants of the second NCI–SNMMI Workshop on Targeted Radionuclide Therapy. [Proceedings of the Second NCI-SNMMI Workshop on Targeted Radionuclide Therapy](#). *J Nucl Med*. 2015 Jul;56(7):1119-29.
  15. K Do, L Cao, Z Kang, B Turkbey, ML Lindenberg, [A Phase II Study of Sorafenib Combined With Cetuximab in EGFR-Expressing, KRAS-Mutated Metastatic Colorectal Cancer](#). *Clinical Colorectal Cancer*, 2015, Clin Colorectal Cancer. 2015 Mar 7. pii: S1533-0028(15)00036-5. doi: 10.1016/j.clcc.2015.02.007. [Epub ahead of print]
  16. Turkbey B, Agarwal HK, Shih J, Bernardo M, McKinney YL, Daar D, Griffiths GL, Sankineni S, Johnson L, Grant KB, Weaver J, Rais-Bahrami S, Harisinghani M, **Jacobs P**, Dahut W, Merino MJ, Pinto PA, Choyke PL, [A Phase I Dosing Study of Ferumoxytol for MR Lymphography at 3 T in Patients With Prostate Cancer.](#), *AJR* 2015 Jul;205(1):64-9

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17. Sibaprasad Bhattacharyya, Nimit L. Patel, Ling Wei, Lisa A. Riffle, Joseph D. Kalen, G. Craig Hill, Paula M. Jacobs, Kurt R. Zinn and Eben Rosenthal, [Synthesis and biological evaluation of panitumumab-IRDye800 conjugate as a fluorescence imaging probe for EGFR-expressing cancers.](#), Med. Chem. Commun., 2014, 5, 1337
18. Laurence P. Clarke, Robert J. Nordstrom, Huiming Zhang, Pushpa Tandon, Yantian Zhang, George Redmond, Keyvan Farahani, Gary Kelloff, Lori Henderson, Lalitha Shankar, James Deye, Jacek Capala, Paula Jacobs, [The Quantitative Imaging Network: NCI's Historical Perspective and Planned Goals.](#) Translational Oncology 02/2014; 7(1):1-4.
19. Aberle DR, DeMello S, Berg CD, Black WC, Brewer B, Church TR, Clingan KL, Duan F, Fagerstrom RM, Gareen IF, Gatsonis CA, Gierada DS, Jain A, Jones GC, Mahon I, Marcus PM, Rathmell JM, Sicks J; National Lung Screening Trial Research Team, [Results of the two incidence screenings in the National Lung Screening Trial.](#), NEJM, 2013;369:920-31
20. **Bhattacharyya S**, Kurdziel K, Wei L, Riffle L, Kaur G, Hill GC, Jacobs PM, Tatum JL, Doroshow JH, Kalen JD., [Zirconium-89 labeled panitumumab: a potential immuno-PET probe for HER1-expressing carcinomas.](#) Nucl Med Biol. 2013. 40:451–457; <http://dx.doi.org/10.1016/j.nucmedbio.2013.01.007>
21. Farrell BT, Hamilton BE, Dósa E, Rimely E, Nasser M, Gahramanov S, Lacy CA, Frenkel EP, Doolittle ND, Jacobs PM, Neuwelt EA. [Using iron oxide nanoparticles to diagnose CNS inflammatory diseases and PCNSL.](#) Neurology. 2013 Jul 16;81(3):256-63.
22. National Lung Screening Trial Research Team, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, Sicks JD. [Reduced lung-cancer mortality with low-dose computed tomographic screening.](#) N Engl J Med. 2011 Aug 4;365(5):395-409.
23. National Lung Screening Trial Research Team, Aberle DR, Berg CD, Black WC, Church TR, Fagerstrom RM, Galen B, Gareen IF, Gatsonis C, Goldin J, Gohagan JK, Hillman B, Jaffe C, Kramer BS, Lynch D, Marcus PM, Schnall M, Sullivan DC, Sullivan D, Zylak CJ. [The National Lung Screening Trial: overview and study design.](#) Radiology. 2011 Jan;258(1):243-53.
24. Kelloff GJ, Choyke P, Coffey DS; Prostate Cancer Imaging Working Group. [Challenges in clinical prostate cancer: role of imaging.](#) AJR Am J Roentgenol. 2009 Jun;192(6):1455-70.
25. Neuwelt EA, Hamilton BE, Várallyay C, Rooney W, Edelman, Jacobs PM and Watnick S, 'Ultrasmall superparamagnetic iron oxides (USPIO): a future alternative magnetic resonance (MR) contrast agent for patients at risk for nephrogenic systemic fibrosis (NSF)?' Kidney International, 2009, 75, 465–474; doi:10.1038/ki.2008.496; published online 8 October 2008
26. Kelloff GJ, Sullivan DC, Baker H, et al, Workshop on imaging science development for cancer prevention and preemption, Cancer Biomarkers, 2007;3: 1-33
27. Neuwelt EA, Várallyay C, Manninger S, Solymosi D, Haluska M, Hunt MA, Nesbit G, Stevens A, Jerosch-Herold M, Jacobs PM, Hoffman JM, The potential of ferumoxytol nanoparticle

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- magnetic resonance imaging, perfusion, and angiography in central nervous system malignancy: a pilot study. *Neurosurgery* 60:601–612, 2007 (DOI: 10.1227/01.NEU.0000255350.71700.37)
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29. Bourrinet P, Bengele HH, Bonnemain B, Dencausse A, Idee JM, Jacobs PM, Lewis JM, Preclinical Safety And Pharmacokinetic Profile Of Ferumoxtran-10, An Ultrasmall Superparamagnetic Iron Oxide MR-Contrast Agent, *Invest. Radiol*, 2006;41:313–324
30. Muldoon LL, Tratnyek PG, Jacobs PM, Doolittle ND, Christoforidis GA, Frank J, Lindau M, Lockman PR, Manninger S, Qiang Y, Spence AM, Stupp SI, Zhang M, Neuwelt EA. Imaging and nanomedicine for diagnosis and therapy in the central nervous system: report of the eleventh annual Blood-Brain Barrier Disruption Consortium meeting. *AJNR Am J Neuroradiol* 2006;27(3):715-21
31. Yancy AD, Olzinski AR, Hu TC-C, Lenhard SC, Aravindhan K, Gruver SM, Jacobs PM, Willette RM, Jucker M, Differential Uptake of Ferumoxtran-10 and Ferumoxytol, Ultrasmall Superparamagnetic Iron Oxide Contrast Agents in Rabbit: Critical Determinants of Atherosclerotic Plaque Labeling, *J Magn Reson Imaging*. 2005: 21:432–442
32. Spinowitz BS, Schwenk MH, Jacobs PM, Bolton WK, Kaplan MR, Charytan C, and Galler M, The Safety and Efficacy of Ferumoxytol Therapy in Anemic Chronic Kidney Disease Patients. *Kidney Intl.*, 2005: 68: 1801-1807
33. Landry R, Jacobs PM, Davis R, Shenoda M, Bolton WK. Pharmacokinetic Study of Ferumoxytol: A New Iron Replacement Therapy in Normal Subjects and Hemodialysis Patients, *Am J Nephrol* 2005: 25: 400-410
34. Manninger S, Muldoon LL, Nesbit G, Murillo T, Jacobs PM, Neuwelt EA, An exploratory study of ferumoxtran-10 nanoparticles as a blood-brain barrier imaging agent targeting phagocytic cells in CNS inflammatory lesions, *Am J. Neurorad*. 2005: 26:2290-2300
35. Murillo TP, Sandquist C, Jacobs PM, Nesbit G, Manninger S; Neuwelt EA, Imaging Brain Tumors with Ferumoxtran-10, a Nanoparticle Magnetic Resonance Contrast Agent, *Expert Review of Anticancer Therapy*, 2005: 2: 871-882
36. Ersoy H, Jacobs P, Kent CK, Prince MR, Blood Pool MR Angiography of Aortic Stent-Graft Endoleak, *AJR* 2004;182:1181–1186
37. Anzai Y, et. al. Evaluation of Neck and Body Metastases to Nodes with Ferumoxtran 10-enhanced MR Imaging: Phase III Safety and Efficacy Study. *Radiology* 2003; 228:777-788.

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39. Prince MR, Zhang HL, Chabra SG, Jacobs P and Wang Y, A pilot investigation of new superparamagnetic iron oxide (ferumoxytol) as a contrast agent for cardiovascular MRI, *Journal of X-Ray Science and Technology* 11 (2003) 231–240 231
40. Jung C and Jacobs P, Physical and Chemical Properties of Superparamagnetic Iron Oxide MR Contrast Agents: Ferumoxides, Ferumoxtran, Ferumoxsil, *Magnetic Resonance Imaging*, 1995: 13: 661-674
41. Ros PR, Freeny PC, Harms SE, Seltzer SE, Davis PL, Chan TW, Stillman AE, Muroff LR, Runge VM, Nissenbaum MA, Jacobs PM, Hepatic MR Imaging with Ferumoxides: A Multicenter Clinical Trial of the Safety and Efficacy in the Detection of Focal Hepatic Lesions, *Radiology*, 1995: 196:481-488
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43. Josephson L, Lewis J, Jacobs P, Hahn PF, and Stark DD, The Effects of Iron Oxides on Proton Relaxivity, *Magnetic Resonance Imaging*, 1988; 6:647-653
44. Jacobs PM, Separation Methods in Immunoassays, *Ligand Quarterly* 1981;4(4):24
45. Hecht SM, Rupprecht KM, and Jacobs PM, Synthesis of L-Erythro- $\beta$ -Hydroxyhistidine from D-Glucosamine, *J. Amer. Chem. Soc.*, 1979;101:3982-3983
46. Jacobs PM, Sneath RL Jr, Soloway AH, and Dey AS, Protein-Binding Polyhedral Boranes II. DL-S-(10-dimethylsulfidoctahydrodecaborane)methionine, *J. Pharm, Sci.*, 1976;65:604-606.
47. Jacobs PM and Soloway AH, Synthesis of 3,5-Dialkyl-1,2-dioxolanes, *J. Org. Chem.* 1974;39:3427-3429
48. Jacobs PM, and Davis MA, A Novel Synthesis of 2-Selenienylalanine, *J. Org. Chem.*, 1979;44:178-179
49. Jacobs PM, Davis MA, and Norton HA, A Semi-Micro Synthesis of Selenophene, *J. Heterocyclic Chem.*, 1977;14:1115-1116
50. Goodwin HA, Rosenberg IH, Ferez C, Jacobs PM, and Meienhofer J The Synthesis of Biologically Active Pteroyl oligo- $\beta$ -glutamates (Folic Acid Conjugates) , *J. Biol. Chem.* 1972;247:2266-2271,
51. Meienhofer J, Jacobs PM, Goodwin HA, and Rosenberg IH, Synthesis of Hepta- $\gamma$ -L-glutamic Acid by Conventional and Solid Phase Techniques, *J. Org. Chem.*, 1970;35:4137-4140

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52. Johnson BJ, and Jacobs PM, A New Carboxy-protecting Group for Peptide Synthesis and Its Direct Conversion to an Activated Ester suitable for Peptide Formation: 4-(methylthio)phenyl and 4-(Methylsulphonyl)phenyl Esters, Chem. Comm., 1966:73-75
53. Johnson BJ, and Jacobs, The 4-(Methylsulfonyl)phenyl Activated Ester: Susceptibility to Racemization PM, J. Org. Chem., 1968;33:4524-4526

### BOOK CHAPTERS

1. P. M. Jacobs and D. Rieves, "Bringing an Imaging Product into the Clinic," Chapter 4 in *Translational Research in Biophotonics: Four National Cancer Institute Case Studies*, R. J. Nordstrom, Ed., SPIE Press, Bellingham, Washington, pp. 67-81 (2014)
2. Daniel C. Sullivan and Paula M. Jacobs, Cost-Effectiveness Analysis/Economics of Probe Development, in *Molecular Imaging: Principles and Practice*. Weissleder, Ross, Rehemtulla, and Gambhir, ed. 2010, PMPH USA
3. John Pearson, Lawrence Tarbox, Gianluca Paladini, John G. Wolodzko, Paula M. Jacobs, and Zhenghong Lee, "Emerging Radiological Software Standards and Development Technologies: Impact on Clinical Translation and Trials" in *Imaging Tools in Cancer Research and Prevention*, James L. Mulshine and Thomas M. Baer, ed; 2008, Wiley

### Invited Presentations

1. Jacobs, PM, Moving PET Drugs from the Bench to the FDA, 2019 Blood Brain Barrier Meeting, March 2019, Portland, OR
2. Jacobs, PM, Bridging the Gap: Funding and Resources at NCI for Theranostics, Theranostics consensus conference 2018, Bethesda, MD, October 2018
3. Jacobs, PM, The Cancer Imaging Archive TCGA projects: A model for research to individualize treatment care in radiation oncology, 4R symposium, Rutgers University, Feb 2017
4. Jacobs, PM, Overview of FDA approval paths optical surgical navigation, Biophotonics West, January 2017, San Francisco
5. Jacobs, PM, The Cancer Imaging Archive TCGA projects: A model for research to individualize treatment care in radiation oncology, June 2016, Precision Medicine in Radiation Oncology, Bethesda
6. Jacobs, PM, Supply of IND agents to Multicenter Trials, June 2016, SNMMI, San Diego
7. Jacobs, PM, The Cancer Imaging Archive, April 2016, AACR, Boston
8. Jacobs, PM, The NCI (formerly GE) IND for C-13 Pyruvate: A resource for the community. **Fourth International Workshop on Hyperpolarized Carbon-13**, February 2016, Philadelphia



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9. Jacobs, PM, Supply of IND Agents to NCI-sponsored trials by Skilled Academic Sites, ECOG-ACRIN fall meeting, November 2015, Orlando FL
10. Jacobs, PM, The Cancer Imaging Archive, FNIH Biomarker Consortium Cancer Steering Committee Annual Meeting, October 2015, Rockville, MD
11. Jacobs, PM, NCI: New and Current Initiatives that Support Imaging in Precision Medicine, World Congress of Molecular Imaging, September 2015, Honolulu HI
12. Jacobs, PM, New and Current Initiatives that Support Imaging in Precision Medicine: Funding and Resources at NCI for Molecular Imaging Agents, World Congress of Molecular Imaging, September 2015, Honolulu HI
13. Jacobs, PM, Advancing Prostate Cancer Imaging: NCI Perspective, SNMMI Annual Meeting, June 2015 Baltimore MD
14. Jacobs, PM, Funding and Resources at NCI/NIH for Translation of Molecular Imaging Agents, SNMMI Annual Meeting, June 2015 Baltimore MD
15. Jacobs, PM, NCI Resources for Translational Molecular Imaging, 21<sup>st</sup> Blood Brain Barrier Meeting, March 2015 Skamania, WA
16. Jacobs, PM, Getting Your Drug into Early Trials - Clearing the Regulatory Hurdles, 21<sup>st</sup> Blood Brain Barrier Meeting, March 2015 Skamania, WA
17. Jacobs, PM NCI Resources for Translational Molecular Imaging, 3rd Theranostics World Congress on Gallium 68 and PRRT, March 2015, Baltimore, MD
18. Jacobs, PM, Is validation and dissemination of imaging of interest for the NCI?, Definition of a New Paradigm for the Validation and Dissemination of Radiopharmaceuticals: Unmet Needs and Opportunities in Prostate Cancer in Washington, D.C., on February 15-16, 2015
19. Jacobs, PM and Rieves, RD, Obtaining an IND – FDA Regulatory Issues, Fluorescence Guided Surgery Symposium: Clinical Translation of Molecular Imaging for Surgical Navigation, American Society of Image Guided Surgery, Feb 2015, Eden Roc, Miami
20. Jacobs, PM, NCIs Quantitative Imaging Network (QIN): Progress and Impact on Clinical Trials, RSNA, Chicago , Nov 30- Dec 5, 2014
21. Jacobs, PM, Getting your Drug into Early Clinical Trials – Clearing the Regulatory Hurdles, Targeted Radionuclide Therapy, NIH campus, Oct 24-25, 2014
22. Jacobs, PM, The Cancer Imaging Archive, FNIH Biomarker Consortium, Annual Meeting, Rockville, Oct 24, 2014

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23. Jacobs, PM, Clinical Translation of Molecular Imaging: the Role of NCI, International Symposium on Molecular Imaging and Translational Medicine, Beijing, Sept 13-15, 2014
24. Jacobs, PM, Getting your Drug into Early Clinical Trials – Clearing the Regulatory Hurdles, Gordon Research Conference, Metals in Medicine, June 22-25, 2014 Proctor Academy, Andover, NH
25. Jacobs, PM, Session moderator: FDA updates on diagnostic radiopharmaceuticals, SNMMI annual meeting, June 7-11, 2014, St. Louis
26. Jacobs, PM, Supply of IND Agents to ECOG-ACRIN by Skilled Academic Sites, ECOG-ACRIN Spring meeting, Chicago, May 8-10, 2014
27. Jacobs, PM, Translating Imaging Agents into Clinical Trials, University of Wisconsin Radiology Grand Rounds, Madison, WI, April 10, 2014
28. Jacobs, PM, BBB's 20<sup>th</sup> Meeting. Where has imaging been? Where is imaging going?, Blood Brain Barrier Consortium 20<sup>th</sup> annual meeting, Sunriver Oregon, March 19-23, 2014
29. Jacobs, PM, NCIs Quantitative Imaging Network (QIN): Progress and Impact on Clinical Trials, RSNA, Chicago, Dec 1- Dec 6, 2013
30. Jacobs, PM, NCI Resources for Translational Molecular Imaging Research, Advanced Molecular Imaging and Its Clinical Translation, Univ. of Ala Comprehensive Cancer Center, Annual Retreat, Birmingham, Nov 5, 2013
31. Jacobs, PM, Supply of IND Agents, Experimental Imaging Science Committee ECOG-ACRIN Fall Meeting, Hollywood FL Nov 14-16, 2013
32. Jacobs, PM, NCI Resources for Translational Molecular Imaging Research, Advanced Molecular Imaging and Its Clinical Translation, Oct 27-30, 2013
33. Jacobs, PM, NCI Programs in Translational Molecular Imaging Research, NIBIB Workshop on Clinical Translation of Molecular Imaging Probes and Technology Lister Hill Auditorium, National Institutes of Health, Bethesda, MD, August 2, 2013
34. Jacobs, PM, Moderator, FDA and NIH: Critical Concepts for Diagnostic Radiopharmaceutical Research. Society of Nuclear Medicine and Molecular Imaging, June 2013 Vancouver BC
35. Jacobs, PM Overcoming Regulatory Hurdles in Molecular Imaging: The NCI Experience, Society of Nuclear Medicine and Molecular Imaging June 2013 Vancouver BC
36. Jacobs, PM, Translational Molecular Imaging: Promises and Pitfalls, [6th Imaging in Drug Discovery and Development Conference](#), Boston MA **May 8-10, 2013**

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37. Jacobs, PM, Moderator, NCI resources for Imaging Research, AACR Annual Meeting, Washington DC, April 6-10, 2013
38. Jacobs, PM, Facilitating Access to Investigational Imaging Agents, AACR Annual Meeting, Washington DC, April 6-10, 2013
39. Jacobs, PM, Lessons learned: NCI's PET INDs and F-18 NaF NDA, 34<sup>rd</sup> Annual High Country Nuclear Medicine Conference, Vail, CO, March 2013
40. Jacobs, PM, New FDA Guidance: Investigational New Drug Applications (INDs) for Positron Emission Tomography (PET) Drugs, Bio/Pharmaceutical Imaging Forum, December 2012, Philadelphia, PA
41. Jacobs, PM, Translational Molecular Imaging: A View from the NCI, Radiological society of North America (RSNA), November 2012, Chicago, IL
42. Jacobs, PM, The National Cancer Institute's NExT Program, Molecular Imaging: Preclinical and Clinical Advances, Harvard Medical School, October 2012, Boston, MA
43. Jacobs, PM, Overcoming Regulatory Hurdles in Investigational Molecular Imaging: The NCI Experience, ADAPT Congress Session, September 2012, Washington, DC
44. Jacobs, PM, NCI's Initiative in INDs: Update on Investigational Radiopharmaceuticals, Society of Nuclear Medicine and Molecular Imaging, 2012 Annual Meeting, June 2012, Miami Beach, FL
45. Jacobs, PM, NCI Cancer Imaging Program Quantitative Imaging Network (QIN) & Network for Translational Research (NTR), Society of Nuclear Medicine and Molecular Imaging, 2012 Annual Meeting, June 2012, Miami Beach, FL
46. Jacobs, PM, The Role of NIH/NCI in Molecular Imaging Trials. Society of Nuclear Medicine and Molecular Imaging, 2012 Annual Meeting, June 2012, Miami Beach, FL
47. Jacobs, PM, Axelrad J, Yang L, Gelovanni J, Challenges to Translational of Molecular Imaging and Therapy, Panel, 3<sup>rd</sup> Multimodality Cardiovascular Molecular Imaging Symposium, April 2012, Bethesda, MD
48. Jacobs, PM, Alternative Sources of Funding from the National Cancer Institute, 10<sup>th</sup> YHLC Business of Biotechnology, Yale University, March 2012, New Haven CO
49. Jacobs PM, Advances and opportunities in CNS imaging 18th Annual Neuro-Oncology and Blood-Brain Barrier Consortium Meeting, March 2012, Skamania WA
50. Jacobs, PM, Lessons learned: NCI's PET INDs and F-18 NaF NDA, 33<sup>rd</sup> Annual High Country Nuclear Medicine Conference, Steamboat Springs, CO, March 2012

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51. Jacobs, PM, Translating Molecular Imaging into Phase 3 Trials, 5<sup>th</sup> EORTC-NCI-ASCO Annual Meeting on "Molecular Markers in Cancer", Brussels, Belgium, October 2011
52. Jacobs PM, Strategies and Pathways: Translating Molecular Imaging Agents into Phase 3 and Beyond, Society of Nuclear Medicine 2011 Annual Meeting, San Antonio, June 2011
53. Chair: Bioimaging and Other Applications for Disease And Treatment Evaluation; 2010 Second Annual American Society for Nanomedicine Conference – October 14-16 – Potomac, Maryland
54. Moderator: Industry Panel on the logistical and regulatory issues of experimental PET agents; ACRIN Fall meeting, October 3, 2010 in Pentagon City
55. Jacobs, PM, Navigating the Regulatory Shoals: Transitioning Your Imaging Agent to the Clinic, Society of Nuclear Medicine 2010 Annual Meeting, Salt Lake City, June 2010
56. Jacobs, PM, Lessons learned: NCI's FLT F-18 IND and F-18 NaF NDA, Two Topic Imaging Workshop: Standards For Imaging Endpoints And Manufacturing Of PET Radiopharmaceutical Products In Clinical Trials, Bethesda, MD
57. Jacobs, PM, Accessing NCI Resources: Imaging Agent Development, NCI Translational Science Meeting, November, 2009, Vienna, VA.
58. Jacobs, PM, What is an IND and How Does It Affect ACRIN Clinical Trials, ACRIN 2009 Fall Meeting, Pentagon City, VA, October 2009
59. Jacobs, PM, The NCI Cancer Imaging Program: Developing imaging tools for drug development, American Association for Cancer Research, 100<sup>th</sup> Annual Meeting, Denver, CO, April 2009
60. Jacobs, PM, CMC Requirements in INDs, Society of Nuclear Medicine 2009 Winter Meeting, Clearwater, Florida, February 2009
61. Jacobs PM, Imaging Probes: Regulatory Guidelines, Availability, and Considerations for Research, ACRIN Fall Meeting, October 2008, Pentagon City VA
62. Jacobs PM, The IND Process: How to get your experimental drug into human trials, Fourteenth Annual Neuro-Oncology and Blood-Brain Barrier Consortium Meeting, March 2008, Skamania WA
63. Jacobs PM, Regulatory Considerations for Trials of Imaging Drugs and Devices: FDA, INDs, IDEs, RDRC, IRBs, DSMBs, CTEP, Radiological Society Of North America Clinical Trials Methodology Workshop, Scottsdale, Arizona January 5-11, 2008
64. Jacobs, PM, What's in an Investigational New Drug Application (IND)? Workshop: Clinical Development of Small Molecules National Cancer Institute, January 2008 Bethesda, Maryland

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65. Jacobs, PM, Economics of Contrast Agent Development, The Molecular Imaging Biomarker Development and Clinical Trials, Clinical Pre-conference at AMI-SMI Joint Meeting September 2007, Providence Rhode Island
66. Jacobs, PM, The IND Process and the Exploratory IND for Molecular Imaging Agent, The Molecular Imaging Biomarker Development and Clinical Trials Clinical Pre-conference at AMI-SMI Joint Meeting September 2007, Providence Rhode Island
67. Jacobs, PM, Nuts and Bolts--You Too Can Prepare an IND, Workshop, Phase 0 Trials in Oncologic Drug Development, Division of Cancer Treatment and Diagnosis, National Cancer Institute, September 5, 2007, Bethesda, MD
68. Jacobs PM, What is an IND and How Does It Affect ACRIN Clinical Trials. Presented to at the American College of Radiology Imaging Network meeting October 5- 7, 2006 Pentagon City, VA
69. Jacobs PM, Use Of Imaging Agents In Pediatric Cancer Management: Regulatory Issues, at the Pediatric Oncology Imaging Frontiers Workshop, Oct 23-24, 2006 Washington, DC
70. Jacobs PM, The IND Process and the Exploratory IND for Molecular Imaging Agents Academy of Molecular Imaging Meeting, March 29, 2006, Orlando FL. Presented in Session: Translational Molecular and Biomarker Development
71. Jacobs PM, Economics of Contrast Agent Development Academy of Molecular Imaging Meeting, March 29, 2006, Orlando FL. Presented in Session: Translational Molecular and Biomarker Development
72. Jacobs, PM, Iron Oxide Drugs: Medical Uses for Rust, Radiology Research Conference, October 14, 2005, U. Mass. Medical School, Worcester, MA. Emphasis on MR imaging uses of iron oxides
73. (Oral Presentation and session moderator). Jacobs, PM, Cell and Molecular Imaging in the CNS, Eleventh Annual Neuro-Oncology and Blood-Brain Barrier Consortium Meeting, March 2005, Portland, OR.
74. Short presentation on the economics of imaging agents at the 6<sup>th</sup> National Forum on Biomedical Imaging in Oncology, April 7-8, 2005, Bethesda, MD. .  
<http://www.cancer.gov/dctd/presentations05.html>
75. Confidential invited lecture September 2000 to FDA: "Iron Oxide Drugs: Medical Uses for Rust." Seminar presented at the FDA at the invitation of a reviewing chemistry group, emphasis on chemistry and manufacturing of nanoparticle iron oxide drugs.

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**PRESENTATIONS**

1. S Kummar, SL Safgren, M Lindenberg, K Kurdziel... 591 Phase I Trial of Z-endoxifen with Estrogen Receptor Imaging in Adults with Refractory Hormone Receptor-positive Breast Cancer, Desmoid Tumors, Gynecologic Tumors, or...- European Journal of Cancer, 2012
2. Neuwelt EA, Hamilton BE, Várallyay CG, Rooney W, Edelman R, Jacobs PM, Watnick S USPIO: A future alternative magnetic resonance contrast agent for patients at risk for nephrogenic systemic fibrosis?, 46th Annual Meeting American Society of Neuroradiology, June 2008, New Orleans
3. Lewis J, Jacobs PM, Frigo T, Lawler D, Miller P, Kausz A, Bengel H, Biodistribution of <sup>59</sup>Fe-Labeled Ferumoxytol into Red Blood Cells Following Intravenous (IV) Administration in Rats, Annual Meeting American Society of Nephrology 40th Annual Meeting and Scientific Exposition, November 2007, San Francisco
4. Li, W, Salanitri J, Dunkle E, Tutton S, Pierchala L, Jacobs P, Prasad PV, Edelman RR, Mr Evaluation of Deep Venous Thrombosis (DVT) of the Lower Extremities using Ferumoxytol. In: Proc. Intl. Soc. Mag. Reson. Med. 2006:14: 517
5. Lewis JM, Jacobs PM, Frigo TB, Evaluation of a New Iron Replacement Therapy, Ferumoxytol: Free Iron, TSAT and Hemoglobin Changes, Third World Congress of Nephrology Singapore, June 2005
6. GreenJarvis BM, Jacobs PM, Lee H, Holburn G, Price R, Lin C, A technique for monitoring extracranial tumor angiogenesis with a MRI blood pool agent, ferumoxytol, Proc Amer Assoc Cancer Res 2005;46:3798
7. Hu TC-C. Bao W, Lenhard SC., Schaeffer TR, Mirabile RC, Jacobs P, Yue T-L, Willette RN, Jucker BM. In Vivo Monitoring of Inflammatory Cell Mobilization to Heart Following Myocardial Infarction, In: Proc. Intl. Soc. Mag. Reson. Med. 11 (2004) 2733
8. Spinowitz BS, Schwenk MH, Jacobs P, Bolton WK., Kaplan MR, Finkelstein FO, Comparison of Two Intravenous Ferumoxytol Dosing Regimens With Oral Iron Therapy in Anemic Hemodialysis (HD) Patients Presented at The National Kidney Foundation Annual Meeting 2004, Chicago, IL
9. Yancy D, Olzinski, A. Hu T. C-C, Lenhard SC, Aravindhyan K, Jacobs P, Willette RN, Jucker BM, Quantitative Assessment of Ultrasmall Superparamagnetic Iron Oxide (USPIO) Contrast Agent Uptake in Atherosclerotic Plaque by MRI, In: Proc. Intl. Soc. Mag. Reson. Med. 11 (2004) 1919
10. Arai T, Caffarelli AD, Greve JM, Jacobs PM, Robbins RC, McConnell MV, Yang PC, In Vivo Magnetic Resonance Imaging of Inflammation in Myocardial Infarct Mouse Model. 3rd Annual Meeting of the Society for Molecular Imaging, September 2004, St. Louis.

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11. Jacobs PM, Lewis JM, Frigo T, Bleomycin Detectable Iron and Percent Transferrin Saturation In Patients Receiving Either Ferumoxytol, Iron Gluconate, and Iron Sucrose J. Am. Soc Nephrol 15 (2004), 546A
12. Jacobs PM, Landry R, Davis R, Bolton W, Safety and Pharmacokinetics of Ferumoxytol In Iron Replacement Therapy In Hemodialysis Patients Receiving Erythropoietin, J Am Soc Nephrol 2003: 14:27A
13. Lewis JM, Jacobs PM and Frigo TB, Comparison of Free Iron in Ferumoxytol with Other Iron Therapeutics, J Am Soc Nephrol 2003: 14: 771 A
14. Spinowitz BS, Schwenk MH, Jacobs P, Bolton WK, Kaplan M, Charytan C, Galler M, Safety and Efficacy of Ferumoxytol Therapy in Anemic, Iron Deficient Chronic Kidney Disease Patients, J Am Soc Nephrol 2003:14: 772A
15. Buist R, Sun, X Wells J, McCutcheon K, Jacobs P, Peeling J, Yong VW Utility of USPIO's in spinal cord MRI in a murine model of EAE, Proc. Intl. Soc. Mag. Reson. Med., 2003:10:2317, Toronto July 2003
16. Jacobs P and Shenoda M, A Phase I Pharmacokinetics and Safety Study Of Ferumoxytol, a New Intravenous Iron Therapy, J Am Soc Nephrol 2003: 14: 770A
17. Ersoy H, Kent C, Jacobs C, Roessel M, Zhang H, Prince M, Detecting Aortic Stent Graft Leak with Blood Pool MRA Using Ferumoxytol. In: RSNA scientific assembly and annual meeting program. Oak Brook, Ill: RSNA 2003: 441VI-p
18. Jacobs P, Shenouda M, A Phase 1 Pharmacokinetics and Safety Study of Ferumoxytol: A New Blood Pool and Macrophage Specific Superparamagnetic Iron Oxide MR Contrast Agent. In: RSNA scientific assembly and annual meeting program. Oak Brook, Ill: RSNA 2003: 441VI-p
19. Benderbous S, Corot C ,Jacobs P, Bonnemain B, Superparamagnetic Agents: Physicochemical Characteristics and Pre-clinical Imaging Evaluations. Acad. Radiol, 1996: 3 Supple 2, S292-294
20. Bonnemain B, Chachuat A, Benderbous S, Jacobs P, Dugit-Gros P. Superparamagnetic Agents: Physicochemical Characteristics and Clinical Applications. 11th Annual Scientific Meeting, ESMRMB 1994;Vienna, April 20-24 (Book of Abstracts):427 n.398
21. Bonnemain B, Chachuat A, Benderbous S, Jacobs P, Dugit-Gros P. Superparamagnetic Agents (USPIO, SPIO) Characteristics and Application in Abdominal MRI. 5th Annual Meeting, ESGR 1994;Taormina, June 1-4 (Book of Abstracts):103.
22. Doucet D, Jacobs P, Engelstad BL. MR Imaging of the Liver with Particulate Agents: Pharmacology of AMI-25. 17th International Congress of Radiology (ICR) 1989;Paris, July 1-8:974 n.288.and Magnetic Resonance Imaging, 1989; 17 (Suppl. 1): 217; 89th Annual Meeting of The American Roentgen Ray Society, 1989; New Orleans, May 7-12: 143 n.126).

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23. Doucet D, Bonnemain B, Stark DD, Engelstad BL, Jacobs P. Produits de Contraste Specifique ou Non dans le Diagnostic des Tumeurs Hepatiques Developpement d'un Agent Particulaire en IRM. 3eme Colloque Imagerie Medicale en Cancerologie 1988;Tokyo, October 3-8:97-105.
24. Jacobs PM, Goodwin HA, Rosenberg IH, and Meienhofer J, Synthesis of Peptide Homologs of Folic Acid, Presented at the 2nd Northeast Regional Meeting of the American Chemical Society, Providence, R. I., 20 October 1970

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