

Priya Hays, M.S., Ph.D.

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Summary:

- Freelance Medical Writer for over fifteen years with extensive academic publication record writing, editing and submitting peer-reviewed journal articles and publishing books on personalized medicine, precision oncology, pharmacogenomics, and genomic medicine and presenting abstracts, posters, and presentations at scientific and medical conferences adhering to publisher, journal and conference guidelines.
- Wrote a 745-page monograph on precision medicine, a guidebook for patient advocacy to treat cancer and other diseases, entitled *Advancing Healthcare Through Personalized Medicine, Second Edition*.
- Served as Editor for Cancer Immunotherapies edited collection in the Cancer Treatment and Research series published by Springer Nature.
- Completed three-year Postdoctoral Research Fellowship in Division of Hematology/Oncology, Department of Medicine, Dartmouth Medical School, Hanover, NH from 2005-2008.
- Doctorate in Literature with emphasis on Scientific Writing; Dissertation: *Molecular Biology in Narrative Form*.
- Professional & Experienced Technical Writer with sound experience in writing US-IVD, CE-IVD, and RUO FDA regulatory submissions, label updates, package inserts, user manuals, and procedures for Cepheid suite of products and product launches.
- Cross-functional collaboration with Regulatory, Marketing, Clinical Affairs, Engineering, Virology, Oncology, Research and Development and Product Management under FDA and CE guidance.
- Wrote user manuals, product inserts and quick reference cards on Ion Torrent products using XML/DITA. Wrote library prep user manuals for the Ion Proton and Ion Personal Genome Machine.
- Wrote regulatory compliance materials for vision management instruments using unstructured Adobe FrameMaker 2017, as well as became expert at unstructured Adobe FrameMaker to write documentation on time.
- Created GeneXpert Omni User Manual in XML for mobile device publication, as well as used Adobe FrameMaker, Photoshop and Illustrator as desktop publishing software.
- Used information from various subject matter experts ranging from Mechanical and Systems Engineering, Software Engineering, Electrical Engineering to Regulatory and updated product manuals for launches.
- Wrote Standard Operating Procedures surrounding technical publications processes, as well as solved document management issues that enabled launching on time.
- Highly proficient in conducting Clinical and scientific literature reviews, topic based authoring in DITA/XML using Minimalism, CCMS, XMetaL, unstructured and structured Adobe FrameMaker, Adobe Acrobat, Adobe Photoshop, Adobe Illustrator, InDesign, Visio, SnagIt, MS Paint, MS Word and MS PowerPoint.

Education:

University of California, Santa Cruz, CA **2019**

Certificate, Technical Writing and Communication

UC San Diego- La Jolla, CA **2005**

Doctor of Philosophy (Ph.D.) Literature

University of California - Davis, CA **1999**

Masters of Science in Genetics

Dartmouth College- Hanover, NH

Bachelor of Arts *cum laude*

Double-major in Biochemistry and Comparative Literature

Elections

California State East Bay Continuing Education Big Data Program Advisory Council Member 2021

American College of Medical Genetics 2019

Affiliate Member

Society for Immunotherapy of Cancer 2019

Member

American Society of Clinical Oncology
Allied Physician/Doctoral Scientist

2018

CONTINUING EDUCATION CREDITS

- 47 American College of Medical Genetics and Genomics CME Credits
- 47 American Society for Clinical Laboratory Science (ASCLS) Professional Acknowledgment for Continuing Education (P.A.C.E.®) Credits
- PeerView CME Credits
- Navigating the Complexities of Biomarker Testing in the Expanding Field of Precision Immuno-Oncology: Latest Evidence, Current Challenges, and Practical Guidance for Pathologists; September 9, 2020
- Perspectives on Innovative Treatment for B-Cell Malignancies: The Convergence of Precision Medicine with Groundbreaking Therapeutics; August 11, 2020
- How I Think, How I Treat: Understanding Innovation in Multiple Myeloma—New Models for Attacking Disease Across the Clinical Spectrum; July 1, 2020
- Patient Stories from the HCC CaseBook: Expert Guidance on Optimizing Outcomes and Care With Newly Available and Emerging Therapies; June 30, 2020
- Everything You Need to Know About Biomarkers, Immunotherapies, Combinations, and Other Emerging Approaches for Lung Cancer; June 25, 2020
- Transforming Modern Care in AML: Clinical Solutions with Novel Agents for Diverse Patient Populations; June 24, 2020
- Moving in Leaps and Bounds Towards Expanded Precision Treatment of HER2- or HER3- Driven Breast, Gastrointestinal, Lung and Other Cancers: Current Challenges, Opportunities for Improvement, and Practical Considerations; June 23, 2020

Skills:

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|--|--|-----------------|
| • Clinical and scientific literature reviews | • Unstructured and structured Adobe FrameMaker | • Visio |
| • Topic Based authoring in DITA/XML using Minimalism | • Adobe Acrobat | • SnagIt |
| • CCMS | • Adobe Photoshop | • MS Paint |
| • XMetaL | • Adobe Illustrator | • MS Word |
| | • InDesign | • MS PowerPoint |

Proficiency in various immunology, molecular biology and biochemistry techniques: Cell/Tissue Culture, Transformations, Transfections, DNA/oligo quantification, Cloning, Subcloning, PCR, Gene amplification, DNA Sequencing, Gel electrophoresis, Plasmid DNA and Genomic DNA purification, DNA ligation and quantification, Chromatin Immunoprecipitation assays, qPCR, Southern blotting, Genotyping, Flow cytometry, Western blotting, Recombinase Mediated Cassette Exchange, ELISA, Chromatin Immunoprecipitation Sequencing, Site-directed Mutagenesis, DNase Assays, HPLC, siRNA techniques and High-throughput genome sequencing

Professional Experience:

Personalis, Menlo Park, CA
Senior Technical Writer

April 2021-March 2022

- Formatted SOPs for the Tech. Transfer team in Process Development to deliver accurate and concise high-quality documentation for NeXT Dx and NeXT Personal products that met required timelines.
- Shadowed Laboratory Operators on various protocols supporting Personalis products
- Submitted Change Orders on documentation control system Compliance Quest.
- Shadowed laboratory procedures to update the Automated Library Preparation, FFPE Extraction, and Automated Enrichment procedures for clarity and accuracy.
- Substantially revised and edited Pfizer Validation Report for AML samples and submitted on CQ.
- Wrote and formatted SOPs and submitted files through Change Orders.

Abbott Corporation, Remote
Contract Technical Writer

November 2020-March 2021

- Wrote and edited manuals using structured authoring Author-it platform

Talis Biomedical Corporation, Menlo Park, CA
Senior Technical Writer

May 2019-October 2020

- Managed documentation team to deliver accurate and concise high-quality documentation that met required timelines.
- Developed documentation infrastructure for Talis.
- Worked with Assay Development, Quality, Regulatory and Engineering to enable well-organized reviews, assemble feedback and implement revisions.
- Set up document version control system with FDA compliance that led to a system of controlled versioning of and centralized system of storage for documents.
- Created Quick Reference Instructions, Package Inserts, and User Guides for Talis suite of products.
- Created Style Guides for the documents the documentation team prepared.

Roche Sequencing Solutions, Santa Clara, CA

Nov 2018-Mar 2019

Technical Writer

- Worked on the Millisect User Manual using Structured FrameMaker.

Applied Materials, Santa Clara, CA

May 2018-Sep 2018

Technical Writer

- Acted as Project Lead for the Preventative Maintenance Service Agreement pilot study.
- Used Microsoft Excel to write Checklists and Procedures for Preventative Maintenance Sym3 Etch Semiconductor tools.
- Interfaced with SMEs such as Engineers and Project Management to verify accuracy and safety of checklists and Procedures.
- Involved in company-wide XML/DITA implementation.

Johnson & Johnson, San Mateo, CA

Jan 2018-Mar 2018

Technical Writer

- Wrote regulatory compliance materials for vision management instruments using unstructured Adobe FrameMaker 2017.

Thermo Fisher Scientific, Fremont, CA

Jul 2017-Dec 2017

Technical Writer

- Created, formatted, revised, edited and finalized GHS Inserts, Instructions for Use, Standard Operating Procedures, Assay Specification Sheets, and Safety Data Sheets for Cascadion CE-IVD Product Launch in 2018 supporting clinical assays.

Kite Pharma, Santa Monica, CA

Mar 2017-Jul 2017

Technical/Regulatory Writer

- Edited, revised, and provided scientific content for manuscripts on CAR T-cell therapy and cancer immunotherapeutics and submitted to *Nature Medicine*.
- Created and wrote pre-clinical study reports from CRO data.

Cepheid, Sunnyvale, CA

Dec 2014-Mar 2017

Technical Writer

- Wrote US-IVD, CE-IVD, and RUO FDA regulatory submissions, label updates, package inserts, user manuals, and procedures for Cepheid suite of products and product launches for Technical Publications team with cross-functional collaboration with Regulatory, Marketing, Clinical Affairs, Engineering, Virology, Oncology, Research and Development and Product Management under FDA and CE guidance.
- Project manager for Cepheid product launches on lifecycle documentation.
- Proofread, circulated, edited, assembled, and inspected product submissions.
- Wrote user manual for GeneXpert Dx Instrument Manual by transferring legacy content in FrameMaker into XML (XMetaL).
- Singlehandedly implemented XMetaL software suite for Technical Publications team to enable documentation publishing on phone for GeneXpert Omni product launch.
- Instrumental on the finalization of the urgently required MTB/RIF package insert after speedy FDA clearance.
- Produced Cepheid competitors' technologies market report for distribution to Global Marketing Franchise Leaders.
- Performed usability testing on pre-market Oncology assay and implementing usability studies on Cepheid molecular assays.
- Created GeneXpert Omni User Manual in XML for mobile device publication.
- Used Adobe FrameMaker, Photoshop and Illustrator as desktop publishing software.
- Used Agile to electronically manage documents.
- Received two Make It Happen performance commendations from Marketing and Technical Publications management for XMetaL team training.

- Received Commitment to Action award for performance on the Bladder Cancer CE-IVD product launch that required Photoshop to implement graphics.
- Training in Adobe Illustrator and Adobe Photoshop and applying learning to documentation projects.

Thermo Fisher Scientific, South San Francisco, CA
Technical Writer

Jan 2014-Oct 2014

- Wrote user manuals, product inserts and quick reference cards on Ion Torrent products using XML/DITA. Wrote library prep user manuals for the Ion Proton and Ion Personal Genome Machine.
- Wrote documentation using topic-based structured authoring.
- Used Agile to electronically manage documents.

Hospira, Inc, San Jose, CA
Technical Writer

Jun 2013 - Sept 2013

- Developed technical service manuals for the latest medical device product launches.
- Used information from various subject matter experts ranging from Mechanical and Systems Engineering, Software Engineering, Electrical Engineering to Regulatory and updated product manuals for launches.
- Became expert at unstructured Adobe FrameMaker to write documentation on time.

Affymetrix, Inc, Santa Clara, CA
Sr. Technical Writer

Aug 2012 - May 2013

- Worked with Research and Development, Quality Assurance, and Marketing teams to write end-user documentation, reference cards and brochures for launches around OncoScan, Cytoscan Dx, Axiom 384 and Axiom Target Split products.
- Wrote Standard Operating Procedures surrounding technical publications processes.
- Solved document management issues that enabled launching on time.
- Assisted with 510K FDA regulatory submission for Cytogenetics Division.
- Wrote technical documentation for Nexus for OncoScan software using InDesign.

Amicrobe, Pasadena, CA
Technical Writer

Dec 2011 - Aug 2012

- Wrote technical white papers, NIH and DOD grants on antimicrobials.
- Conducted primary analytical research on cationic antimicrobials to gain knowledge on subjects.

University of California, Los Angeles, Los Angeles, CA
Staff Research Associate

Dec 2010 - Aug 2011

- Worked on molecular biology project involving regulation of adenoviral genes, performing ChIP, ChIP-seq and other experimental techniques.
- Took courses on statistics and statistical analysis at the Luskin School of Public Policy.

Santa Clara University, Santa Clara, CA
Lecturer

Aug 2008 - Sep 2010

- Taught Composition and Rhetoric to undergraduates in a course entitled "Science, Ethics and Society."

Dartmouth Medical School, Department of Medicine
Division of Hematology/Oncology

July 2005-July 2008

- Investigated chromatin structure and regulation of human beta-globin gene expression in a biomedical laboratory. Spoke at an oral session at the American Society of Hematology Convention (see Conferences section for title of presentation).
- Wrote two National Human Genome Research Institute-ELSI grants ("Critical Theory and the Human Genome Project", unfunded).
- Conducted research on the mechanism of transcription factor binding in a molecular biology laboratory as part of an effective cross-functional team. I used chromatin immunoprecipitation assays to determine the binding activity of the transcription factor involved in hematopoiesis.
- Advanced my research on healthcare policy, literary theory, medical humanities, bioethics and science studies.
- Attended and led sessions at conferences on literary studies (American Comparative Literature Association; Modernist Studies Association) and published papers in journals on genetics and ethics (New Genetics/New Identities) (see Conferences and Publications section for titles).

- I conducted an anthropological ethnography of the laboratory, leading to insight on ethics in laboratory science and medicine. This led to the publication of my second book, *Science, Cultural Values and Ethics*.
- Conducted field studies of laboratory investigation to develop a theory of scientific practice in the context of literary criticism.

The Scripps Research Institute, La Jolla, CA

Sep 2004 – Dec 2004

Research Specialist

- Performed research on the molecular cloning and expression of genes involved in synthesis and degradation of lysophosphatidic acid, LPA, a molecule important for neural development.

Publications: Books

Cancer Immunotherapies: Solid Tumors and Hematological Malignancies, Ed. Priya Hays, Springer Nature, under contract, upcoming in 2022

Advancing Healthcare Through Personalized Medicine, Second Edition
Springer Nature, September 2021

Advancing Healthcare Through Personalized Medicine, CRC Press/Taylor & Francis, March 12, 2017.

Science, Cultural Values, and Ethics, Science in Society series, Common Ground Publishing, April 2013.

Molecular Biology in Narrative Form: A Study of the Experimental Trajectory of Science, Volume 64 in the Berkeley Insights in Linguistics and Semiotics Series, Peter Lang Publishing, October 2006.

Publications: Peer-Reviewed Articles

“Evidence Basis for Pharmacogenetic Testing in Psychiatry”
Journal of Medical Sciences and Health Research, Vol 5, Issue 3.

“Clinical Development and Therapeutic Applications of Bispecific Antibodies for Hematological Malignancies”
Cancer Immunotherapies: Solid Tumors and Hematological Malignancies, Ed. Priya Hays, Springer Nature, accepted, upcoming in 2022

“Clinical Sequelae of the Novel Coronavirus: Does COVID-19 Infection Predispose Patients to Cancer?”
Preventive Medicine, Epidemiology and Public Health, May 2021, Volume 2, Issue 2

“Challenges for chimeric antigen receptor T cell therapies in the clinical setting: mechanisms of resistance in non-responders”
Biomedical Journal of Scientific and Technical Research, February 2020

“Clinical Care of CAR T-cell Patients and Managing immune-Related Adverse Effects in the Ambulatory and Hospitalized Setting: A Review”
With Deepak Asudani MD, MPH and Caitlin Costello MD
Future Oncology, December 2019.

“Review of Therapeutic Approaches for B-Cell Malignancies with Immune Checkpoint Blockade and Chimeric Antigen Receptor T-Cell Therapies: Development, Benefits, and Limitations”
Journal of Clinical Investigation and Studies, 2019, Vol. 2, pp. 1-6.

“Personalized Medicine: Paradigm Shift or Revolution”
Genetics in Medicine, Official Journal of American College of Medical Genetics, November 2018 online issue.

“Contested Boundaries: How Scientists Deal with Uncertainty and Ambiguity in Language,”
in *Language as a Scientific Tool: Shaping Scientific Language Across Time and National Tradition*; Edited by Miles MacLeod, Rocio G Sumillera, Jan Surman, and Ekaterina Smirnova, 2016, Routledge Studies in Cultural History, pp. 74-88.

“Epistemic Cross-Talk: Why we need—and should desire—interdisciplinarity,”

Interdisciplinary Literary Studies, Vol. 15, No. 2 Fall 2013, pp. 221-239.

"Whence Social Determinants of Health? Effective Personalized Medicine and the 2010 Patient Protection and Affordable Care Act,"

Journal of Clinical Research and Bioethics, 2012, S-5.

"Narratives of Science: Literary Theory and Discovery in Molecular Biology,"

in C.C. Barfoot and Valeria Tinkler (eds.),

Restoring the Mystery to the Rainbow: Literature's Reflections on Science, DQR
Studies in Literature, Vol. 78, pp.429-447.

"Bioeconomy and the Third Industrial Revolution in the Age of Synthetic Life," with

Michael A. Peters, PhD.

Contemporary Readings in Law and Social Justice 2:2 (2010).

"Biocapitalism and the Politics of Life," with Michael A. Peters, PhD.

Geopolitics, History and International Relations 2:2 (2010).

"Nanoselves: NBIC and the Culture of Convergence,"

Bulletin of Science, Technology and Society, 30:2 (2010): 119-129.

"Reception Studies in France: Social Contexts, Reader Interpretation and the Role of

Julia Kristeva,"

L'Esprit Créateur, Special Issue on Reception Studies in France, 49:1

(2009): 111-124. Reprinted in Contemporary Literary Criticism. Ed. Jeffrey W. Hunter.
Vol. 340. Detroit: Gale, 2013.

"The Legitimation of Local Knowledges: Introducing the Postmodern into Laboratory
Science,"

Social Semiotics, 18:4 (2008): 481-491.

"Making Science Accessible: A Semiotics of Scientific Communication,"

with Christopher H. Lowrey, MD, Biosemiotics, 1 (2008): 253-269.

"Genomics, social formations and subjectivity," in Paul Atkinson, Peter Glasner and

Helen Greenslade (eds.) New Genetics, New Identities, London: Routledge Press
(2007): 178-191.

"Targeting GATA-1 to binding sites in nuclear chromatin,"

Blood Cells, Molecules and Diseases, 38(2007).

"Effect of Lead and Cadmium on Erythroid Differentiation in GATA-1 Dependent Gene

Expression," Blood Cells, Molecules and Diseases, 37(2006):164-172.

"A Dialogue on the Scientific Method: Assessing the Foucauldian Method and the Marxist Method,"

Exit 9 The Rutgers Journal of Comparative Literature, VII (2005):15-28.

"Paradigm Shifts and New Worldviews: Kuhn, Laudan and Discovery in Molecular Biology,"

Reconstruction: Online Cultural Studies Journal, 4(2004).

Invited Articles

"Of Dickens and Darwin," TheScientist.com, (2007).

"Yin, meet yang," Point of View, Dartmouth Medicine, (2007): 62.

Conferences/Presentations/Invited Talks

"Spatial Transcriptomics Approaches to Characterizing Childhood Intellectual Disability,"

Poster Presentation, 2022 American College of Medical Genetics and Genomics

Annual Meeting,

Nashville, TN, March 22-26, 2022

“From Older Agents to Newer Generation Treatments: The Development of Targeted Therapies for Lung Cancer,”
Invited Speaker (industry expert) at Pharma R&D Conference,
San Francisco CA, February 22-23, 2022.

“Tumor Agnostic Models in Drug Development for Non-Small Cell Lung Cancer (NSCLC)”
Poster Presentation, 2021 Multidisciplinary Thoracic Cancers Symposium, American Society Thoracic Radiation
Oncology,
December 4-6, 2021

Featured speaker/presenter, Panel Discussant,
2nd Annual Medical Writing Innovation Strategies, Virtual Online session,
June 29-30, 2021.

Advancing Healthcare Through Personalized Medicine
Featured title at 6th Annual LocalLit Faire, Dr. Martin Luther King, Jr., Library, San Jose, CA, December 16, 2018.

“Innovative Tools and Ingenious Systems: ELSI Learned from Writing my Book on Personalized Medicine”
2017 4th Annual ELSI Congress, Jackson Laboratories, Farmington, CT.

“Improving Medication Adherence by Adopting Minimalist Standards”
2016 Pharma and Device Packaging and Labeling Conference, San Mateo, CA.

“Usability Testing on the GeneXpert Bladder Cancer RUO Package Insert”
2016, Cepheid Corporation, Sunnyvale, CA.

“Contested Boundaries: How Scientists Deal with Uncertainty in Language.”
2010 Language as Scientific Tool Conference in Vienna, Austria.

“The Physician as Reader: Ethics and Interpretation in Medicine.”
2010 Society for Literature, Science and Arts Conference in Indianapolis, IN.

“Genomic Variation and Cancer: The Ethical Dimensions of Personalized Medicine.”
2010 Genetics and Ethics in the 21st Century Conference: Genomic Diversity and Health Disparities in Denver,
CO.

“Advancing Stem Cell Research Efforts for Social Benefit.”
2010 Stem Cell World Congress in San Francisco, CA.

“A Unique Ethnography of the Laboratory: Postmodernism, Science Studies and
Ethics.”
2009 International Conference on Science in Society at University of Cambridge, UK.

“The Iterative Process behind Nanoconvergence.”
2008 Society for Literature, Science and the Arts Conference in Charlotte, NC.

“The Paradox of Reading in a Democratic Society.”
2008 South Atlantic Modern Language Association Conference in Louisville, KY.

“Signs and the Generation of Scientific Knowledge in the Laboratory.”
2008 Semiotic Society of America Conference in Houston, Texas.

“Scientific Practice in the Context of Literary Paradigms.”
2007 Society for Philosophy of Science in Practice Conference at University of Twente,
Twente, Netherlands.

“Narrative Approaches to Science.”
2007 International Conference on Narrative at Washington, D.C.

“Specificity Protein 1 Consensus Binding Sequences Flank Many Functional GATA-1
Binding Sites and are Sufficient to Allow GATA-1 Binding to a WGATAR sequence in Nuclear Chromatin.”

2006 American Society of Hematology Convention in Orlando, Florida.

“Integrating Literary Theory and Biomedicine: New Conceptual Approaches.”

Invited speaker for the 2006 Department of Philosophy Colloquium

University of California, Santa Cruz, co-sponsored by the History of Consciousness Department and Feminist Studies.

“Modernist Science and Its Caveats”

Panel Organizer, 2006 Modernist Studies Association Conference in Tulsa, Oklahoma.

“Literary Tropes and Molecular Biology in the Postmodern Era.”

Seminar Organizer, 2006 American Comparative Literature Association Conference at Princeton University.

“Examining the Scientific Method: Science’s Questionable Claims to Lucidity.”

2004 Western Humanities Alliance Conference at the University of California, Santa Cruz.

“An Epistemological Justification for a Poststructuralist Reading of Science.”

2004 Theorizing Methodologies Conference at the University of California, Los Angeles.

“The Effects of Genomics on Social Formations and Subjectivity.”

2004 International Centre for the Economic and Social Aspects of Genomics Conference at the Royal Society, London, England.

“Subverting Semiotics: The Humanist Tradition and Skepticism in the French and Italian Renaissance.”

2004 French and Italian Graduate Student Conference at the University of Texas at Austin.

“Kuhn, Laudan and Discovery in Molecular Biology.”

2003 Society for Social Studies of Science (4S) Conference at Atlanta, GA.

“The Signifier as Discursive Practice: A Post-Structuralist’s View of Science.”

2002 Society for Social Studies of Science (4S) Conference at Milwaukee, WI.

“Translation through Post-Structuralism: A Semiotic and Discursive Analysis of Science.”

2002 Western Humanities Alliance Conference at the University of California, Irvine.

Public Lectures

“Secular Visions of Nanotechnology: The Religious Context.”

Theology and Technology Series, United Methodist Church, Evanston, Illinois, Spring 2008.

“Bioethics and Clinical Research Ethics.” Materials Science and Engineering Department, Northwestern University, Spring 2008.

“Legitimizing Local Knowledges: Introducing the Postmodern into Laboratory Science.”

Department of Comparative Literature, Dartmouth College, Fall 2005.

“Architecture, Art and the External Homunculus.”

Culture, Art and Technology 1C, UC San Diego, Fall 2004.

“Mind-Body Dualism.”

Cognitive Science 11, UC San Diego, Spring 2003.

“Orientalism in the Asian-American Context.”

History 7B, UC San Diego, Winter 2003.

SOCIETY MEMBERSHIPS

- Modern Language Association
- Society for the Study of the Social Studies of Science
- Modernist Studies Association
- Society for the Study of Narrative Literature
- American Comparative Literature Association
- Society for the Philosophy of Science in Practice
- American Society of Hematology
- Semiotic Society of America
- South Atlantic Modern Language Association
- Society for Literature, Science and Arts
- American Society of Clinical Oncology
- Society for Immunotherapy of Cancer
- American College of Medical Genetics and Genomics
- Personalized Medicine Coalition
- Society of Hematology and Oncology