

Erin Nissen Castelloe, M.D.

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CLINICAL DEVELOPMENT (CLINICAL) AND PHARMACOVIGILANCE (PV)

2023-Present	Clinical and PV (Phase 1/Food Effect)—Small-molecule, selective IKZF2 degrader for solid malignant neoplasms	Australia
2021-Present	Data Monitoring Committee (DMC; Phase 2) Chair—Controlled-release formulation of parathyroid hormone (PTH) for hypoparathyroidism	International
2019-Present	DMC Chair (Phase 2)—Controlled-release formulation of C-type natriuretic peptide (CNP) for achondroplasia	International
2018-Present	Clinical (Phase 1-2)—Small-molecule, anti-inflammatory neuroprotectant for age-related cognitive decline, mild cognitive impairment (MCI), Alzheimer's disease (AD), and AD-related dementias	USA
2018-Present	DMC Chair (Phase 2)—Diazoxide choline controlled-release formulation for hyperphagia in Prader-Willi Syndrome	USA
2022-2023	Clinical (Phase 1-2)—Mitogen-activated extracellular kinase (MEK) inhibitor for susceptible vascular anomalies in children and adults	USA
2020-2023	Clinical & PV (Phase 2)—Glutamate receptor modulator for neuropsychiatric symptoms of 22q11.2 Deletion Syndrome (22qDS)	International
2021-2022	PV (Phase 2-3)—Investigation of electroencephalogram (EEG) as a biomarker of therapeutic efficacy in neuropsychiatric indications	International
2021	PV (Phase 2-3)—Fibroblast growth factor 21 (FGF21) analog for severe hypertriglyceridemia and nonalcoholic steatohepatitis (NASH)	International
2020-2021	PV (Phase 1-2)—Novel therapeutics for rare endocrine diseases and endocrine-related tumors	International
2016-2019	DSMB Member (Phase 2)—Small interfering RNA (siRNA) for Hepatitis B Virus (HBV)	USA
2017-2019	PV (Phase 1-3)—Prodrug and prodrug activator gene therapy for recurrent high-grade glioma	USA
2015-2019	Safety Review Committee Member (Phase 1)—Peptide anti-fungal for invasive Aspergillosis	USA
2017-2018	Clinical & PV (Phases 2-3)—S1P receptor modulator for ulcerative colitis (UC); primary biliary cholangitis (PBC); and autoimmune hepatitis (AIH)	International
2016-2018	Clinical & PV (Phase 1)—Leukotriene synthesis inhibitor for atopic dermatitis	USA
2016-2018	Clinical & PV (Phases 1-2)—Cytochrome <i>bc1</i> complex inhibitor for tuberculosis	International
2015-2016	Independent Research Monitor and Safety Committee Member (Phases 1-2)—siRNA for HBV	International
2007-2016	Clinical & PV (Phases 1-3)—Farnesoid X receptor (FXR) Agonist for PBC; NASH; nonalcoholic fatty liver disease (NAFLD); portal hypertension in advanced alcoholic liver disease; primary sclerosing cholangitis (PSC); biliary atresia (BA); and bile acid diarrhea	International

CLINICAL AND PV**(continued)**

2014-2015	Clinical & PV (Phase 1/Food-Effect)—Protein kinase C (PKC) inhibitor for systemic lupus erythematosus (SLE)	USA
2013-2015	Independent Research Monitor (Phase 1/"Animal Rule")—siRNA for Ebola virus exposure/infection	USA
2012-2015	Clinical & PV (Phases 1-3)—Caspase inhibitor in acute-on-chronic liver failure; alcoholic hepatitis; NAFLD; progressive liver fibrosis after post-orthotopic liver transplant; cirrhosis; and portal hypertension	International
2014	Clinical—Human growth hormone (hGH) for growth hormone deficiency	USA
2013-2014	Clinical (Phase 1)—Leptin for lipodystrophy and weight-loss	USA
2012-2013	PV (Phase 3)—Androgen receptor inhibitor for prostate cancer	International
2012	Clinical (Phase 1/"Animal Rule")—Novel therapeutic for prevention of radiation-induced pulmonary inflammation and fibrosis	USA
2011-2012	DSMB (Phase 2)—Analgesic for post-bunionectomy pain management	EU
2009-2011	PV (Phase 2)—Matrix metalloproteinase (MMP) inhibitor for hepatitis C	USA
2009	Clinical Planning—Novel therapeutic for Type 1 diabetes mellitus	USA
2007-2009	Clinical & PV (Phases 1-2)—Anti-inflammatory oligonucleotide for asthma and allergic rhinitis	Canada
2007	Protocol Development (Phase 2)—Drug-device for acute migraine	USA
2006-2013	PV & US Regulatory Submissions (Phases 2-3)—Peptide neuroprotectant for progressive supranuclear palsy (PSP); mild cognitive impairment; and post-coronary-artery-bypass-graft (CABG) cognitive impairment	International
2006-2009	PV (Phase 3)—Small-molecule therapeutic for SLE Nephritis	International

INSTITUTIONAL REVIEW BOARD

2006-2010	Voting Member— Scripps Clinic Human Subjects Committee	La Jolla, CA
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CLINICAL PRACTICE

2002-2006	Family Medicine Physician—Scripps Clinic	San Diego, CA
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COMPREHENSIVE SEXUALITY EDUCATION

2020-Present	<i>Preparing Positively for Puberty</i> seminar for parents and caregivers—Poway Adult School	Virtual/In-Person Meetings San Diego, CA
2019-Present	<i>Nurturing Sexual Intelligence in Our Children</i> seminar for parents and caregivers—Poway Adult School	Virtual/In-Person Meetings San Diego, CA
2020	<i>Sexuality Across the Lifespan</i> Sponsored by the San Diego Independent Scholars	Virtual Meeting San Diego, CA
2020	<i>Parenting LGBTQIAP2+ Children</i> seminar for parents and caregivers—Poway Adult School	Virtual Meeting San Diego, CA
2020	<i>Suds & Science—LGBTQIAP2+: Welcoming Diversity</i> Sponsored by the Fleet Science Center	Virtual Meeting San Diego, CA
2020	<i>Speaking of Science—Sexuality Across the Lifespan</i> Sponsored by the Fleet Science Center	OASIS Lifelong Learning Center La Mesa, CA
2019	Changing Perspectives: Understanding and Including Intersex, Gender-Diverse, and Sexuality-Diverse Individuals in Our Conversations and Community	Westview HS San Diego, CA
2016-2020	Comprehensive Sexuality Education for 5 th -8 th -grade students	Innovations Academy San Diego, CA
2016-2019	<i>Chatting with Children About Sex</i> seminars for adults who live or work with children	Multiple Locations San Diego, CA

EDUCATION

2002-Present	Continuing Medical Education (CME)— minimum of 150 credit hours every three years	Multiple Locations/Modalities
2019	What Does It Mean to Identify as Transgender or Gender Non-Conforming (TGNC)?	Online—Coursera University of Minnesota
2018	Trans-Youth Care: Comprehensive Approach to the Care of Gender Non-Conforming Children, Transgender Youth, and Young Adults	Oceanside, CA
2017	Positive Prevention Plus: Middle and High School curricula	Azusa, CA
2006-2011	Diploma in Pharmaceutical Medicine curriculum, under direction of A.W. Fox, M.D., Ph.D., FPM	San Diego, CA
1999-2002	Stanford/Sharp Family Practice Residency Program	San Diego, CA
1995-1999	University of Minnesota Medical School, M.D.	Minneapolis, MN
1991-1995	Washington University, A.B., Spanish and Biology	St. Louis, MO

LICENSURE AND CERTIFICATION

2001-Present	Licensure: Medical Board of California (License #A75647)
2002-Present	Board-Certification: American Board of Family Medicine (ABFM)
2000, 1998, 1997	United States Medical Licensing Examinations (USMLE): Step 3, Step 2, Step 1

PUBLICATIONS—BOOK CHAPTERS

- 2015 Morimoto, BH; **Castelloe, EN**; Fox, AW. "Safety Pharmacology in Drug Discovery and Development." *Handbook of Experimental Pharmacology (Vol 229): Principles of Safety Pharmacology*. Ed. Pugsley, MK; Curtis, MJ. Berlin Heidelberg: Springer-Verlag, 2015. 65-80.

PUBLICATIONS—ESSAYS & REVIEWS

- 2019 **Castelloe E**. "Human Rights Violations in Medicine: A-to-Z Action Guide by Dr. Pamela Wible." *Qualitative Research in Medicine & Healthcare* (2019); 3: 139-140, doi:10.4081/qrmh.2019.8635.
- 2017 **Castelloe E**. "Tincture of Time." *Qualitative Research in Medicine & Healthcare* (2017); 1: 103-108, doi:10.4081/qrmh.2017.6925.
- 2017 **Castelloe E**. "Finding Myself in Medicine." *Qualitative Research in Medicine & Healthcare*, (2017); 1:1-5, doi:10.4081/qrmh.2017.6301.

PUBLICATIONS—PAPERS

- 2014 Hirschfield GM, Mason A, Luketic V, Lindor K, Gordon S, Mayo M, Kowdley KV, Vincent C, Bodhenheimer Jr. HC, Parés A, Traunder M, Marschall H-U, Adorini L, Sciacca C, Beecher-Jones T, **Castelloe E**, Böhm O, Shapiro D. "Efficacy of Obeticholic Acid in Patients with Primary Biliary Cirrhosis and Inadequate Response to Urosodeoxycholic Acid." *Gastroenterology* (2015), doi: 10.1053/j.gastro.2014.12.005.
- 2013 Mudaliar S, Henry RR, Sanyal AJ, Morrow L, Marschall H-U, Kipnes M, Adorini L, Sciacca C, Clopton P, **Castelloe E**, Dillon P, Pruzanski M, Shapiro D. "Efficacy and Safety of the Farnesoid X Receptor Agonist Obeticholic Acid in Patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease." *Gastroenterology*, 2013; 145: 574-582.
- 2009 **Castelloe E**. "Pregnancy and Lactation Labeling to Improve Drug Safety." *The Monitor*, June 2009, 23(3): 37-39.
- 1998 **Nissen ER**, Melchert PJ, Lewis E. "A Case of Bullous Frostbite Following Recreational Snow-Mobiling." *Cutis*, 63(1): 21-23.
- 1995 Karon BS, **Nissen ER**, Voss J, Thomas DD. "A Continuous Spectrophotometric Assay for Simultaneous Measurement of Calcium Uptake and ATP Hydrolysis in Sarcoplasmic Reticulum." *Analytical Biochemistry*, May 1995, 227(2): 328-333.

PUBLICATIONS—ABSTRACTS

- 2011 Rodriguez-Torres M, Bacon B, Gordon S, Rubin R, Box T, Kugelmas M, Vierling J, Yoffe B, Pockros P, Everson G, Jonas M, Balart L, Bohm O, **Castelloe E**, Huyghe MR, Mento S, Spada A, Fox AW, Chojkier M. Unique Pattern of Virologic Response in Patient with Genotype-1 HCV: A Phase II Study of CTS-1027 in Combination with Peginterferon/Ribavirin (SOC) in Null Responders [abstract]. In: International Liver Congress™ 2011 by EASL; March 20-April 3, 2011; Berlin, Germany; March 30-April 3, 2011. A-343-0028-00549.
- 2011 Chojkier M, Everson G, Muir A, Bacon B, Rodriguez-Torres M, Bennett M, Fried M, Gordon S, Gross J, Nelson D, Balart L, Jonas M, Szabo G, Bloomer J, McCullough A, Nyberg L, Smith C, Bohm O, Fox AW, **Castelloe E**, Huyghe M, Mento S, Spada A. 24-Week Treatment with CTS-1027 in Combination with Ribavirin Reduces HCV-RNA in Treatment Naïve Genotype-1 Patients [abstract]. In: International Liver Congress™ 2011 by EASL; March 20-April 3, 2011; Berlin, Germany; March 30-April 3, 2011. A-343-0028-00562.
- 2011 Kowdley K, Jones D, Luketic V, Chapman R, Burroughs A, Hirschfield G, Poupon R, Schramm C, Vincent C, Rust C, Parés A, Mason A, Sciacca C, Beecher-Jones T, Böhm O, **Castelloe E**, Pruzanski M, Shapiro D, OCA PBC Study Group. An International Study Evaluating the Farnesoid X Receptor Agonist Obeticholic Acid as Monotherapy in PBC [abstract]. In: *Journal of Hepatology*, 2011 (54): S13.
- 2010 Mason A, Luketic V, Lindor K, Hirschfield G, Gordon S, Mayo M, Kowdley K, Parés A, Trauner M, **Castelloe E**, Sciacca C, Beecher-Jones T, Böhm O, Shapiro D, INT-747 PBC Study Group. Farnesoid-X Receptor Agonists: A New Class of Drugs for the Treatment of PBC? An International Study Evaluating the Addition of INT-747 to Ursodeoxycholic Acid [abstract]. In: *Journal of Hepatology*, 2010 (52): S1.

CLINICAL RESEARCH LECTURES

- 2014 Translational Medicine—Safety Pharmacology Society Annual Meeting

PRE-CLINICAL RESEARCH

- 1995-1996 Research Rotation with S. Ramakrishnan, Ph.D., University of MN Medical School, Dept. of Pharmacology. Investigated novel chemotherapeutic techniques for treatment of ovarian cancer.
- 1994 NIH, 3M, & American Heart Association Research Fellowship with D. Thomas, Ph.D., University of MN Medical School, Dept. of Biochemistry. Developed a continuous assay for measurement of calcium uptake in skeletal and cardiac sarcoplasmic reticulum (SR).
- 1993 NIH Research Fellowship with D. Thomas, Ph.D., University of MN Medical School, Dept. of Biochemistry. Correlated molecular dynamics and enzymatic function of Ca-ATPase in skeletal SR.

HONORS

1998	Alpha Omega Alpha
1995	Phi Beta Kappa

MEMBERSHIPS

1999-Present	California Academy of Family Physicians
1997-Present	American Academy of Family Physicians