



ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Saiger	Salma	
Professional Mailing Address			
Street Address: 1210 North Galloway Ave		Other Street Address:	
City: Mesquite	State/Province: Texas	Country: US	Zip/Postal Code: 75149
Email Address:		ssaiger@smsclinicalresearch.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Internal Medicine Residency	2004	Overlook Hospital (affiliate with University of Medicine & Dentistry New Jersey), US	
Internal Medicine Internship	2002	Overlook Hospital (affiliate with University of Medicine & Dentistry New Jersey), US	
MBBS Bachelor of Medicine & Bachelor of Surgery	1998	Dow Medical College, South Asia	
Medical License Number			
M8171	State/Province: Texas	Country: US	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2018	Medical Director/Principal Investigator	SMS Clinical Research, LLC	Mesquite, Texas/US
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2009-Present	President and Medical Director	Salma Mazhar, MD, PA	US
2009-2009	Hospitalist	Methodist Mansfield Hospital	US
2008-2009	Staff Physician	East Texas Medical Center	US
2008-2009	Hospitalist	Flagstaff Medical Center	US
Brief Summary of Relevant Clinical Research Experience:			
Amy Dunn has been under the supervision of the PI as a Sub-I. She is responsible for performing study related procedures and is responsible for making important study-related decisions pertaining to different studies.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		17-JUL-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

11/12/2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Wolf, MD	Thomas	A.
Professional Mailing Address			
Street Address: 350 W 23 rd Street		Other Street Address:	
City: Fremont	State/Province: NE	Country: USA	Zip/Postal Code: 68025
Email Address:	thomaswolf@cctresearch.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	2002	University of Nebraska Medical Center, Omaha, NE USA	
BS-Biology	1997	University of Nebraska, Lincoln, NE USA	
Medical License Number	State/Province	Country	
23824	Nebraska	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2019-Present	Principal Investigator	Methodist Physicians Clinic/CCT Research	NE, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2011-2019	Principal and Sub-Investigator	Synexus Clinical Research US, Inc.	USA
2006-Present	MD	Methodist Physicians Clinic	USA
2008-Present	Volunteer Faculty	University of Nebraska Medical Center	USA
2007-Present	Full Endoscopy Privileges	Methodist Fremont Health Surgical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
Dr. Wolf has over nine years of clinical research experience. He has experience with a variety of indications, including COPD, Vaccines, Type 2 Diabetes, Migraine, and more. For a more complete list of experience, please reference their full CCT CV.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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Document Name: Pfizer CV Wolf

Document ID: 4748

No. Pages: 1

Statement of Testament: I have reviewed and approve the document

Electronic Signature for: Thomas Wolf

Electronically Signed by: TWolf

Date & Time: 15/JUL/2020 4:30 PM CDT

IP Address: 173.20.218.78

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Studdard	Harry	Earl
Professional Mailing Address:			
Street Address 1:100 Memorial Hospital Dr.		Street Address 2: Annex Building, Suite 3-B	
City: Mobile	State/Province: AL	Country:US	Zip/Postal Code:36608
Email Address:		harry.studdard@amrllc.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Residency	1986-1988	University of South Alabama Medical Center, USA	
Internship	1985-1986	University of South Alabama Medical Center, USA	
M.D.	1981-1985	University of South Alabama Medical Center, USA	
B.S. in Biology	1978-1981	University of South Alabama Medical Center, USA	
Medical License Number	State/Province	Country	
MD 11620	AL	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2004	Principal Investigator	Coastal Clinical Research, LLC, An AMR Company	AL, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1997-Present	Physician	Mobile Adult Care Center	USA
1988-1997	Physician	Mobile Health Plan/Primehealth	USA
Brief Summary of Relevant Clinical Research Experience:			
Type II Diabetes, Hypertension, Hyperlipidemia, Hypercholesterolemia, Influenza, DPN, Gout, HIV Device Testing, Smoking Cessation, Cholera Vaccine, Chronic Migraines, Postherpetic Neuralgia, Fibromyalgia, Weight Loss			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		18 MAR 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Rankin	Bruce	G.
Professional Mailing Address:			
Street Address: University Clinical Research-DeLand, LLC d/b/a Accel Research		Other Street Address: 860 Peachwood Drive	
City: DeLand	State/Province: FL	Country: USA	Zip/Postal Code: 32720
Email Address:	brankin@accelclinical.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Fellowship (FACOP)	2013	American College of Osteopathic Family Physicians/USA	
Certified Physician Investigator	2002	Association of Clinical Research Professionals/USA	
Board Certification	1987	American College of Family Practitioners in Osteopathic Medicine and Surgery/USA	
Residency	1987	Southeastern Medical Center/USA	
Internship	1986	Doctors General Hospital/USA	
Doctor of Osteopathic Medicine	1985	Nova Southeastern College of Osteopathic Medicine/USA	
Bachelor of Science in Chemistry	1981	University of Florida/USA	
Medical License Number			
	State/Province	Country	
OS-0006029	Florida	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1998	Medical Director	Accel Research Sites-DeLand Clinical Research Unit	Florida/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1987-Present	Physician	Family Practice of West Volusia	USA
Brief Summary of Relevant Clinical Research Experience:			
Has served as the Medical Director and Investigator at Accel Research Sites since 1998.			
Signature:	 Signed Electronically by: Bruce Rankin - bruce.rankin@fpwv.care 28-May-2020 @ 07:46 AM EDT Reason: Approval		Signature Date: (dd-Mmm-yyyy)
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.2):

Signed electronically by: *Bruce Rankin (bruce.rankin@fpwv.care)*

Date: *28-May-2020 @ 07:47 AM EDT*

Reason: *Approval*

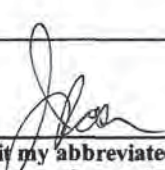
Previous Electronic Signatures:

There are no signatures for any previous versions.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Rosen	Jeffrey	B.
Professional Mailing Address:			
Street Address 1: Clinical Research of South Florida, an AMR company		Street Address 2: 370 Minorca Avenue, 2 nd Floor	
City: Coral Gables	State/Province: Florida	Country: USA	Zip/Postal Code: 33134
Email Address:		Jeffrey.Rosen@amrllc.com	
Academic Qualifications: M.D.			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
M.D.	1979	Downstate Medical Center, State University of New York, USA	
B.A.	1975	Brooklyn College, City University of New York, USA	
Medical License Number	State/Province	Country	
ME40205	Florida	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1985	Principal Investigator/Medical Director/President	Clinical Research of South Florida, an AMR company	Florida/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008-Present	Chief Medical Doctor/Principal Investigator/President	Clinical Research of South Florida, an AMR company	USA
1982-Present	President/Owner/Private Practice Physician	PrimeCare of Coral Gables	USA
Brief Summary of Relevant Clinical Research Experience:			
Broad spectrum of research trials in the Family Practice Arena: Hypertension, Diabetes, Osteoarthritis, Hypogonadism, Hyperlipidemia, Vaccines, ect.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		02/JUN/2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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**CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD)
SUPPORTING DOCUMENT**

Identifier	Version	Title	Effective Date
INV02-INV04- WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020



Full Name:	Last Name Stephens	First Name Michael	Middle Name <i>if applicable</i> A.
Professional Mailing Address:			
Street Address: 1679 Eagle Harbor Parkway, Suite D		Other Street Address:	
City: Fleming Island	State/Province: FL	Country: USA	Zip/Postal Code: 32003
Email Address:		mstephens@encoredocs.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1992	University of Miami School of Medicine	
Medical License Number	State/Province	Country	
ME64230	Florida	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2010	Clinical Investigator	Fleming Island Center for Clinical Research	USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2001-Present	Family Physician	Michael Stephens Family Practice, PA	USA
1995-2010	Medical Director	HCR Heartland Skilled Nursing Facility	
1994-2001	Family Physician	Stephens Family Practice	USA
1994-Present	Medical Director	Moosehaven Retirement Community	USA
1992-1994	Residency	St. Vincent's Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
Dr. Stephens has been a Principal/Sub- Investigator for Fleming Island Center for Clinical Research since 2010. Study experience includes diabetes, hyponatremia, vaccines, women's studies, gastrointestinal studies, cardiovascular diseases, gout, flu, Overactive Bladder, RA, ACS, and arthritis. All trials have been Phases 2-4			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		03 JUN 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Segall	Nathan	
Professional Mailing Address:			
Street Address 1: 175 Country Club Drive		Street Address 2: Building 100, Suite A	
City: Stockbridge	State/Province: GA	Country: USA	Zip/Postal Code: 30281
Email Address:		nsegall@clinicalresearchatlanta.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Doctor of Medicine Degree	1973	University of Alabama/USA	
Internship Internal Medicine	1973-1974	Charity Hospital, LSU Division/ USA	
Resident, Internal Medicine	1975-1977	University of South Alabama/ USA	
Fellowship, Internal Medicine	1977-1979	National Jewish Hospital/ USA	
Medical License Number	State/Province	Country	
020602	GA	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1992	PI/ Sub Investigator	Clinical Research Atlanta	GA/ USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1994-2016	Allergist/Internist	Nathan Segall, MD, PC	USA
1992-1994	Internist	Del Mazo Medical Services	USA
1979-1992	Internist	Atlanta Medical Associates	USA
Brief Summary of Relevant Clinical Research Experience:			
Over 27 years in multi-therapeutic areas, allergy/immunology, cardiovascular, Endocrinology, gastroenterology, pulmonary/respiratory, Vaccine, orthopedics, normal healthy, neurological, dermatology, women's health, and urology.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
			
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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TMF Doc ID
270.01, 272.01

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INV02-INV04-WI-GL02-SD01
Version 1.0, 01-Apr-2019

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ABBREVIATED CURRICULUM VITAE

Full Legal Name:	Last Name	First Name	Middle Name
	Glover	Richard	M.
Professional Mailing Address:			
Street Address 1: Alliance for Multispecialty Research, LLC		Street Address 2: 700 Medical Center Drive, Suite 110	
City: Newton	State/Province: KS	Country: USA	Zip/Postal Code: 67114
Email Address:	richard.glover@amrllc.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Medical Doctorate	1988	University of Kansas School of Medicine	
Bachelor of Science	1980	University of Kansas School of Medicine	
Medical License Number	State/Province	Country	
04-22805	KS	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
02/2017	Sub-I	Alliance for Multispecialty Research, LLC	KS/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2003- 02/2017	Sub-I	Heartland Research Associates, LLC	USA
2005- Present	Physician	Axtell Clinic, PA	USA
1991- 2005	Physician	Axtell Clinic- Broadway	USA
Brief Summary of Relevant Clinical Research Experience:			
Sub-I conducting clinical research Phase II- V in areas including Gastroenterology, Anti-Infective, Auditory, Cardiovascular, Dermatology, Device, Endocrine/Metabolism, Female Health, Hyperlipidemia, Hypertension, Male Health, Musculoskeletal, Neurological, Ophthalmology, Psychiatric, Respiratory, Smoking Cessation, Urogenital, Weight Control, Vaccines.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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Document Name: Richard M. Glover, II, MD Current Sponsor-Specific CVs
"Expires:" 28 May 2022
Document ID: 1030432

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Richard M. Glover, II, MD
Electronically Signed by: richard.glover@amrllc.com
Date and Time of Signature: 28 May 2020 18:24 EDT

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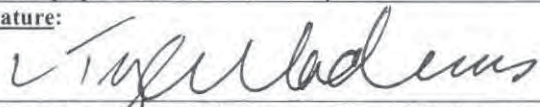
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Matherne	First Name Paul	Middle Name
Professional Mailing Address			
Street Address: 15190 Community Rd.		Other Street Address: Suite 300	
City: Gulfport	State/Province: MS	Country: USA	Zip/Postal Code: 39503
Email Address:	paulmatherne@medpharmics.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BS	1974	LSU	
MD	1978	LSU School of Medicine	
Residency, Family Practice	1981	Earl K. Long Hospital	
Medical License Number	State/Province	Country	
09445	MS	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2016	PI	MedPharmics, LLC	MS, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2016 – Present	PI	MedPharmics, LLC	USA
1991 – 2006	Hyperbaric Medicine & Wound Care	Gulf Coast Medical Center, Director – Chief of Staff (2004)	USA
1984 - Present	Clinical Professor	University of MS Medical School, Jackson, MS	USA
Brief Summary of Relevant Clinical Research Experience:			
Post-Surgical Pain, Phase III; Influenza, Pediatric, Phase III; Influenza, Adult, Phase III; C-Difficile Vaccine, Phase III; RSV Maternal Vaccine, Phase III; Chlamydia Trachomatis, Phase II; Pediatric Meningitis, Phase III; Migraine, Phase II; Migraine, Phase II/III; ; Pediatric Influenza, III; Hot Flash, Phase III;			
Signature: 		Signature Date: (dd-Mmm-yyyy) 13 JUL 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Wadsworth III	Larkin	Tyler
Professional Mailing Address:			
Street Address 1: 711 Old Ballas Road		Street Address 2: Suite 105	
City: St. Louis	State/Province: Missouri	Country: USA	Zip/Postal Code: 63141
Email Address:		ty.wadsworth@sbcglobal.net	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Bachelor of Science, Zoology, Magna Cum Laude	1982	North Carolina State University, Raleigh, NC, USA	
Doctor of Medicine	1986	University of North Carolina School of Medicine, Chapel Hill, NC, USA	
Family Medicine Residency	1986-89	Hennepin County Medical Center, Minneapolis, MN, USA	
Fellowship, Primary Care Sports Medicine	1989-90	Hennepin County Medical Center, Minneapolis, MN, USA	
Medical License Number	State/Province	Country	
103386	Missouri	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2005	Medical Director	Sundance Clinical Research, LLC	Missouri, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2016-present	Attending Physician	St. Louis Medical Clinic	USA
2012-present	Adjunct Associate Professor	Dept of Family Medicine, St. Louis Univ School of Medicine	USA
2005-present	Medical Director	Sundance Clinical Research	USA
1997-present	Attending Physician	Sports Medicine Consultants	USA
Brief Summary of Relevant Clinical Research Experience:			
42 vaccine trials, Phase I-IV, 2005-present		5 OIC, Phase II and III, 2013 - present	
45 Osteoarthritis trials, Phase II-IV, 2005-present		3 Acne, Phase III, 2015 and 2016	
15 Chronic Low Back Pain trails, Phase II-III, 2005-present		2 Non Cancerous Pain, Phase III, 2012 and 2015	
3 cardiovascular trials, Phase III, 2007, 2009, 2010			
5 acute injury trials, Phase III, 2006 - present			
Signature: 		Signature Date: (dd-Mmm-yyyy) 21 MAY 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name	Last Name	First Name	Middle Name
Eder	Frank	Steven	
Professional Information			
Street Address 1: Meridian Clinical Research, LLC		Street Address 2: 1290 Upper Front Street	
City: Binghamton	State/Province: NY	Country: USA	Zip/Postal Code: 13901
E-mail		Phone	
Education			
Degree	Year	Institution	
Doctor of Medicine	1993	State University of New York – Health and Science Center at Brooklyn, USA	
Bachelor of Science	1989	Long Island University, USA	
Residence			
Address	City	Country	
197948-1	New York	USA	
Professional Experience			
Date	Title	Institution	Country
7/2019	Investigator	Meridian Clinical Research, LLC	NY, USA
Employment History			
Date	Title	Institution	Country
1996 to Present	Attending Physician	UHS Primary Care	USA
9/2002 – 7/2019	Investigator	Regional Clinical Research, Inc.	USA
1995 to 1996	Chief Resident	Wilson Memorial Hospital	USA
1993 to 1995	Resident	Wilson Memorial Hospital	USA
Summary			
Conducting Pharmaceutical Clinical Research in the area of out-patient studies for 18 + years with numerous pharmaceutical companies. Has been an Investigator for numerous clinical studies in the areas of migraine, diabetes, stress incontinence, osteoarthritis, hypertension, hyperlipidemia, osteoporosis, GERD, COPD, Flu Vaccines, RSV, meningitis, depression and erectile dysfunction			
Signature		Date	
<p>I will update my CV to reflect the information in this template for inclusion in the ICH-E3 compliant clinical study report. Abbreviated CV's can be no more than 3 pages, do not include attachments or text on reverse pages.</p>			

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Document Name: Frank Steven Eder, MD Sponsor CV 19 May 2020 C4591001
United Medical Associates
Document ID: 1000083

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Frank Steven Eder, MD
Electronically Signed by: frank.eder@nyuhs.org
Date and Time of Signature: 20 May 2020 08:50 EDT

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Bradley	Paul	Simon
Professional Mailing Address:			
Street Address 1: 340 Eisenhower Drive		Street Address 2: Suite 1200	
City: Savannah	State/Province: GA	Country: USA	Zip/Postal Code: 31406
Email Address: pbradley@mcrmed.com			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Bachelor's Degree	1982	Tulane University (USA)	
Doctorate of Medicine	1986	Emory University (USA)	
Internal Medicine	1989	Memorial Medical Center (USA)	
Medical License Number			
30016	Georgia	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2012	Principal Investigator	Meridian Clinical Research, LLC	Georgia (USA)
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
NA	NA	NA	NA
Brief Summary of Relevant Clinical Research Experience:			
75+ Clinical trials including but not limited to RSV Vaccine, Osteoarthritis, Overactive bladder, Influenza Vaccine, Meningococcal Vaccine, Migraine Treatment, Hypertriglyceridemia, C-Diff Vaccinations			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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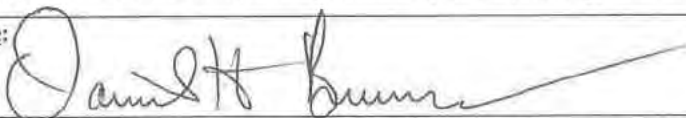
Document Name: Paul Simon Bradley, Md Pfizer One Page Current CV 31 Jan 2019 Expires 01 Jan 2021 Archived
Document ID: 201638

Statement of Testament: I approved the contents of this document
Electronic Signature for: Paul Bradley, MD
Electronically Signed by: pbradley@mcrmed.com
Date and Time of Signature: 01 Feb 2019 09:19 CST

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)



ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Brune	First Name Daniel	Middle Name H
Professional Mailing Address			
Street Address: 4911 N Executive Drive 2 nd Floor			
City: Peoria	State/Province: IL	Country: USA	Zip/Postal Code: 61614
Email Address: dbrunemd@optimalsites.net			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Doctor of Medicine	1985	University of Illinois	
Bachelor of Science	1980	MacMurray College	
Medical License Number	State/Province	Country	
036.073081	Illinois	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2014	Principle Investigator	Optimal Research	Illinois USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2005-2014	Principle Investigator	Accelovance	USA
2000-2005	Principle Investigator	NTouch Research	USA
1992-2000	Principle Investigator	Health Advance Institute	USA
1988-Present	MD	Creve Couer Family Practice	USA
Brief Summary of Relevant Clinical Research Experience:			
Numerous Influenza Vaccines; Zika Vaccine; RSV Vaccines; Transdermal Contraceptive; Pediatric Influenza Vaccine; C. difficile vaccine; COPD; Chronic Constipation; ADPKD; Hypercholesterolemia; Diabetes screening device; Chronic Low back pain; Rosacea; Overactive Bladder; Type 2 Diabetes; Asthma; Meningococcal Diphtheria; Obesity; CMV Vaccine; E. Coli Vaccine, Anthrax Vaccine			
Signature: 		Signature Date: (dd-Mmm-yyyy) 18 MAY 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Donskey	Curtis	N/A
Professional Mailing Address			
Street Address: 10701 East Blvd		Other Street Address:	
City: Cleveland	State/Province: Ohio	Country: United States	Zip/Postal Code: 44106
Email Address:	Curtis.donskey@va.gov		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1990	Medical College of Wisconsin, USA	
Medical License Number	State/Province	Country	
35.068561	OH	United States	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1998	Staff Physician	VA Northeast Ohio Healthcare System	OH, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
N/A	N/A	N/A	N/A
Brief Summary of Relevant Clinical Research Experience:			
Previous experience as PI on several clinical research studies			
Signature:	Curtis J Donskey 402815	Digitally signed by Curtis J Donskey 402815 Date: 2020.07.09 13:28:26 -07'00'	Signature Date: (dd-Mmm-yyyy)
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
<i>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</i>			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Essink	Brandon	James
Professional Mailing Address:			
Street Address 1: 3319 North 107 th Street		Street Address 2:	
City: Omaha	State/Province: Nebraska	Country: USA	Zip/Postal Code: 68134
Email Address:	bessink@mcrmed.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Family Practice Procedural Fellowship	2004	University of Nebraska Medical Center, USA	
Family Practice Residency	2003	University of Nebraska Medical Center, USA	
Doctor of Medicine	2001	University of Nebraska Medical Center, USA	
Bachelor of Science	1997	University of Nebraska – Lincoln, USA	
Medical License Number	State/Province	Country	
22302	Nebraska	USA	
74013	Georgia	USA	
7971	South Dakota	USA	
04-41270	Kansas	USA	
Current Position at Study Site: Principal Investigator			
Start Date	Title	Institution or Company	State/Province & Country
2003-Present	Principal Investigator	Meridian Clinical Research, LLC	NE/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2002-Present	Sub-Investigator	Meridian Clinical Research, LLC	USA
2015-Present	Physician	Bryan Telemedicine	USA
Brief Summary of Relevant Clinical Research Experience:			
Cardiovascular (HTN) Hyperlipidemia – 15		OTC - 10	
Respiratory (COPD) – 12		Restless Legs - 4	
Gastrointestinal (GERD, Constipation, Heartburn) – 15		Osteoporosis - 4	
Vaccine (Adult and Pediatric) – 86		Contraception - 3	
Musculoskeletal (OA, chronic pain, fibromyalgia, IBS) – 17		Genitourinary (OAB, BPH, sexual dysfunction, UTI) - 12	
Dermatologic (herpes labials, psoriasis) – 15		Endocrinology (diabetes, thyroid) - 8	
Migraine - 8			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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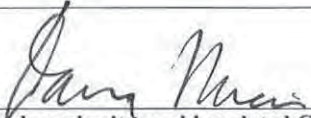
Document Name: Brandon James Essink, MD Version 2.0 16 MAR 2020 Pfizer
One Page Current CV 24 Apr 2020 Expires 24 Apr 2022 Archived
Document ID: 908335

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Brandon Essink
Electronically Signed by: bessink@mcrmed.com
Date and Time of Signature: 24 Apr 2020 15:55 CDT

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)



ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Fried	David	L.
Professional Mailing Address:			
Street Address 1: Omega Medical Research		Street Address 2: 400 Bald Hill Road	
City: Warwick	State/Province: RI	Country: USA	Zip/Postal Code: 02886
Email Address:	dr.fried@omegamedicalresearch.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1989	Emory University, USA	
BS	1985	Dickinson College, USA	
Medical License Number	State/Province	Country	
MD07840	RI	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1996	Medical Director/Principal Investigator	Omega Medical Research	RI, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1997-Present	Clinical Asst. Professor	Brown University	USA
1992-Present	MD-Private Practice	Coastal Medical	USA
Brief Summary of Relevant Clinical Research Experience:			
Principal Investigator of over 340 Clinical Trials for multiple indications since 1996. Became Medical Director of Omega Medical Research in 1999 and oversees all clinical trials at this site. Lead Sub-Investigator for Pediatric, Gastroenterology and Urology trials conducted at Omega Medical Research with other Principal Investigators.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		19 MAY 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Harper	Charles	Harold
Professional Mailing Address			
Street Address 1: 1410 N. 13 th Street		Street Address 2: Suite #5	
City: Norfolk	State/Province: NE	Country: USA	Zip/Postal Code: 68701
Email Address:	charper@mcrmed.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Internal Med Residency	2008	University of Nebraska Medical Center / USA	
Doctor of Medicine	2005	University of Nebraska Medical Center / USA	
Medical License Number	State/Province	Country	
24405	Nebraska	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2015	Investigator	Meridian Clinical Research, LLC	NE / USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2015 - Present	Sub-Investigator	Meridian Clinical Research, LLC	USA
2016 - Present	MD	Norfolk Medical Group	USA
2009-2016	MD	Faith Regional Internal Medicine	USA
Brief Summary of Relevant Clinical Research Experience:			
Healthy Adult Vaccines (Adult and Pediatric) Women's Health (OAB) Dermatologic			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH E3 COMPLIANT CLINICAL STUDY REPORT. MULTI PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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Document Name: Charles Harold Harper, MD Pfizer One Page Current CV 22
Jan 2019 Expires 01 Jan 2021 Archived 01 Jan 2021
Document ID: 196341

Statement of Testament: I approved the contents of this document
Electronic Signature for: Charles Harper
Electronically Signed by: charper@mcrmed.com
Date and Time of Signature: 23 Jan 2019 10:27 CST

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)



ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Nicola	
Professional Mailing Address:			
Street Address 1: Kaiser Permanente Vaccine Study Center One Kaiser Plaza 16 th Floor		Street Address 2:	
City: Oakland	State/Province: California	Country: United States	Zip/Postal Code: 94612
Email Address: Nicola.klein@kp.org			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1991-1998	New York University School of Medicine, USA	
PhD	1989-1991	New York University School of Medicine, USA	
Medical License Number A69589	State/Province California	Country USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2006	Co-Director Vaccine Study Center	Kaiser Permanente	California, United States
2006	Research Scientist II	Kaiser Permanente	California, United States
2006	Senior Physician	Kaiser Permanente	California, United States
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
n/a			
Brief Summary of Relevant Clinical Research Experience:			
<p>Nicola P. Klein, MD, PhD, is the Director of the Kaiser Permanente Vaccine Study Center, a research group in Oakland, California, since 2006. As a pediatrician vaccine researcher and clinical trial investigator, her research interests include vaccine safety and efficacy, genetic influences on vaccine responses, and vaccine responses among at-risk populations. She is the principal investigator for many ongoing studies of vaccines, biologics, and the epidemiology of infectious diseases, and has published extensively on vaccine safety and effectiveness. In addition, she serves as the Chair of the California Immunization Committee and is the Principal Investigator of the CDC-sponsored Vaccine Safety Datalink (VSD) Project and Clinical Immunization Safety Assessment (CISA) Network. She received her medical degree and doctorate in biochemistry at New York University School of Medicine and completed a residency in pediatric medicine at Lucile Salter Packard Children's Hospital at Stanford University School of Medicine, Palo Alto, CA. She also serves as an adjunct clinical instructor at the Department of Pediatrics at Stanford.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
			
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Tracy	R.
Professional Mailing Address:			
Street Address 1: Alliance for Multispecialty Research, LLC		Street Address 2: 1709 S. Rock Rd.	
City: Wichita	State/Province: KS	Country: USA	Zip/Postal Code: 67207
Email Address:	trak@leinQamrllkdom		
Akademik t ualifikations:			
Degree and/or Certification	Date (@@@@)	Institution and/or Countr@	
Residency	2002	Wichita State University	
Medical Doctorate	1999	University of Kansas School of Medicine	
BA / Chemistry	1995	Tabor College	
Medikal Likense Num) er	State/Provinke	Countr@	
04-28967/ MD	KS	USA	
CurrenbPosition abShud@Site:			
StarbDate	Title	Institution or Compan@	State/Provinke & Countr@
2017	PI	Alliance for Multispecialty Research, LLC (east)	KS/ USA
Previous RelevanbPositions Inkluding Akademik Appoinments:			
Starband End Dales	Title	Institution or Compan@	Countr@
2002- 2017	PI/ Sub- I	Heartland Research Associates, LLC (East)	USA
2003- 2005	Medical Director	Heartland Diabetes Associates, LLC	USA
2001- Present	Family Practice	Family Medicine East, Chartered	USA
Brief Summar@of RelevanbClinikal Researkh Experienke:			
PI conducting clinical research Phase II –V in areas including Gastroenterology, Anti- Infective, Auditory, Cardiovascular, Dermatology, Device, Endocrine/ Metabolism, Female Health, Hyperlipidemia, Hypertension, Male Health, Musculoskeletal, Neurological, Ophthalmology, Psychiatric, Respiratory, Smoking Cessation, Urogenital, Weight Control, Vaccines.			
Signature:		Signature Date: (dd-Mmm- @@@@)	
I will update and resu) mibm@a)) reviated CV if there are khanges and partikularl@if there is an@khange in status which would adversel@affekbthe assessmenbof m@suita) ilib@to kondukt@partikipate in klinikal studiesc			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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Document Name: Tracy R. Klein, MD Current Sponsor-Specific CVs removed additional USA "Expires:" 30 Jun 2022
Document ID: 1111433

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Tracy R. Klein, MD
Electronically Signed by: tracy.klein@amrllc.com
Date and Time of Signature: 30 Jun 2020 14:18 EDT

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)



ABBREVIATED CURRICULUM VITAE TEMPLATE

Full e ga Nm	Last Name Koch	First Name Mark	Middle Name
P: roNf Sri gl Mglsi n Add: Nf			
Street Address: 1307 8th Avenue		Other Street Address: Suite 202	
City: Fort Worth	State/Province: TX	Country: USA	Zip/Postal Code: 76104
Ea gsl Add: Nfm		a g: bbrk@ . N Q. sg: Nf; k@kra	
AkdN sk / uglsokeQri fm			
DN: Nngi d(r: CN QskgQri		Dg(Ny)))S	Ii fQQQri gi d(r: Crui Q)
Doctor of Medicine		1992	University of Texas Health Science Center at San Antonio
Bachelor of Science in Biochemistry		1988	University of Dallas
MNisgl LskN fNe ua vN		pQQP: r. si kN	Crui Q)
J4274		Texas	USA
Cu: :N QPrfsQri gQp(Qd) psQm			
pQ: QDgQ	TsQN	Ii fQQQri r: Cra &gi)	pQQP: r. si kNh Crui Q)
May 2016	Principal Investigator	Ventavia Research Group, LLC	TX, USA
P: N sruf RNN gi QPrfsQri f Ii kludsi n AkdN sk A&&rsi Q N Qm			
pQ: Qri d Ei d DgQf	TsQN	Ii fQQQri r: Cra &gi)	Crui Q)
Oct 2015 – Present	Sub-Investigator	Ventavia Research Group, LLC	USA
Oct 2000 – Present	Physician	JPS Residency Program	USA
Sep 2005 – Present	Physician/Member	JPS Physicians Group	USA
2000 – 2005	Physician	North Texas Affiliated Medical	USA
B: sNpua a g:) roRNN gi QClsi skgl RNNg: k@Ex&N sN kNm			
<p>Trial for Efficacy, Immunogenicity, And Safety Study of Clostridium Difficile Vaccine in Subjects at Risk of C. Difficile Infection; RSV Vaccine with Aluminum in Healthy Third-Trimester Pregnant Women and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in Their Infants; Study to Describe the Safety, Tolerability, And Immunogenicity of a Respiratory Syncytial Virus (RSV) Vaccine in Healthy Adults; Study to Assess the Efficacy, Safety, And Immunogenicity of a Plant-Derived Quadrivalent VLP Influenza Vaccine in Adults 65 Years of Age and Older; A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of A 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults 18 Years of Age and Older; A Phase 3, Randomized, Observer-Blind, Multicenter Study to Evaluate the Efficacy, Immunogenicity and Safety of Seqirus' Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (Qivc) Compared to A Non-Influenza Vaccine When Administrated in Healthy Subjects Aged 6 Months Through 47 Months; A Phase 2b, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of A Respiratory Syncytial Virus (Rsv) Vaccine When Administered Concomitantly with Tetanus, Diphtheria, and Acellular Pertussis Vaccine (Tdap) in Healthy Nonpregnant Women 18 to 40 Years of Age;</p>			
psni gQ: Nm		psni gQ: NDgQmdd-Ma a -)))S	
<p>I wll u&dgQngi d : Nfuva s(Qa) gvv: N sgQd CV so QN Ng: Nk@ri nN gi d &g: (kulg: l) so QN Nsf gi) k@gi nNsi fQQf w@k@wruld gD. NfN) gonkQQNgffNfa N Qroa) fusQvslQ Q kri dukQ&g: Qs&gQnsi kisi skgl fQdsNf</p>			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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Document Name: Mark Koch Pfizer CV Current CV 20 May 2020 Expired 19
May 2021
Document ID: 1006732

Statement of Testament: I approved the contents of this document
Electronic Signature for: Mark Koch
Electronically Signed by: markkoch@ventaviaresearch.com
Date and Time of Signature: 22 May 2020 15:04 CDT

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**CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD)
SUPPORTING DOCUMENT**

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name Koren	First Name Michael	Middle Name <i>if applicable</i> J.
Professional Mailing Address:			
Street Address: 4085 University Boulevard South, Suite 1		Other Street Address:	
City: Jacksonville	State/Province: FL	Country: USA	Zip/Postal Code: 32216
Email Address:		mkoren@encoredocs.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Internal Medicine/Cardiovascular Disease	2017	National Board of Physicians and Surgeons, USA	
Internal Medicine	2002	American Board of Internal Medicine, USA	
MD	1985	Harvard University Medical School/Massachusetts Institute of Technology	
BA	1981	Brandeis University, USA	
Medical License Number	State/Province	Country	
ME60337	Florida	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1997	CEO/Medical Director	Jacksonville Center for Clinical Research and affiliated sites	FL, USA 32216
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2018-Present	Cardiologist	First Coast Heart & Vascular Center	USA
2000-2018	Cardiologist	Apex Cardiovascular Group	USA
1991-2000	Cardiologist	Jacksonville Cardiovascular Clinic	USA
1988-1991	Cardiologist	New York Hospital Coverage Group	USA
1988-1988	Chief Resident	New York Hospital	USA
1985-1988	Intern/Resident	New York Hospital/Sloan-Kettering Cancer Center/Cornell Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
Dr. Koren has been a Principal Investigator and Sub-Investigator of research studies since 1997. Indications include cardiovascular diseases, hypertension, hypercholesterolemia, hyperlipidaemia, gastrointestinal disease, diabetes, vaccines, hyponatremia, arthritis, autoimmune diseases, panic disorders, women's health, men's health, sleep disorders, and obesity, among others. In recent years, he has served as the international lead principal investigator for several large multiple centered trials including ALLIANCE (a pivotal statin study). ROLE			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

(ranolazine safety study), MENDEL (evolocumab) and OSLER (evolocumab). Dr. Koren has experience working with all age ranges, and has worked on placebo-controlled studies including open label and double-blind trials. He has been actively involved as a principal/sub-investigator of over 800 trials ranging from phases I-IV.

Signature:

Signature Date: (dd-Mmm-yyyy)

28-APR-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file.

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Abbreviated Curriculum Vitae (CV)

First Name: Stephen
Middle Name: Paul
Last Name: Fortmann
Profession: MD
Affiliation Name: Kaiser Permanente Center for Health Research

Address: 3800 North Interstate Avenue

City: Portland

Postal Code: 97227-1098

State/Region/Province: Oregon

Country: USA

Phone: 503-249-3315

Extension:

Fax: 503-331-3096

Email: Stephen.P.Fortmann@kpchr.org

Study Location Name
 (if different):

Address :

City:

Postal Code:

State/Region/Province:

Country:

Phone:

Extension:

Fax:

Email (if different):

EDUCATION

	University	Degree	Year Completed
Stanford University		A.B. (Biology)	1970

MEDICAL EDUCATION

	University	Degree	Year Completed
University of California, San Francisco		M.D.	1974
Santa Clara Valley Medical Center, San Jose California Internship in Medicine and Pediatrics, Residency in Medicine		Intern/Resident	1977
Stanford University School of Medicine, Stanford, California Research Fellow in Cardiovascular Disease Epidemiology and Prevention		Fellow	1979

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Abbreviated Curriculum Vitae (CV)

PROFESSIONAL EXPERIENCE/OTHER RELATED TRAINING		
Institution	Medical Field	Year (Completed)
Kaiser Permanente Center for Health Research Senior Director, Science Programs, Distinguished Investigator and Medical Director		current
Oregon Health and Science University - Portland State University School of Public Health Affiliate Professor		current
Stanford University School of Medicine C.F. Rehnberg Professor in Disease Prevention (Emeritus)		current

Professional License Number: MD157289
State/Region/Province: Oregon Medical Board
Expiration Date: 12/31/2021
Research Area(s) of Interest: Cardiovascular Disease Epidemiology and Prevention; Primary Care
Clinical Trial Phases: I II III IV

List your most Current Clinical Research below:

Therapeutic Area:	Type of Trial	Phase:	Completed	On-Going
Impact of Retail Tobacco Advertising on Youth Smoking, National Cancer Institute.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hawaii Asian and Pacific Islander Diabetes Study (HAPI-D), National Institute of Diabetes and Digestive and Kidney Diseases.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Health and Economic Effects of Light Rail Lines: A Natural Experiment, National Institute of Diabetes and Digestive and Kidney Diseases.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE), National Institute of Diabetes and Digestive and Kidney Diseases.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Cardiovascular Disease Among Asians and Pacific Islanders (CASPER), National Heart, Lung, and Blood Institute.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Evaluating the Implementation of Diabetes Prevention Program in an Integrated Health System, National Institute of Diabetes and Digestive and Kidney Diseases.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Advancing Geriatrics Infrastructure & Network Growth, National Institute on Aging.	None		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Treatment of Hypertension In Adults with ThiazIDES: Pragmatic Trial Pilot Study, National Heart, Lung, and Blood Institute.	None		<input checked="" type="checkbox"/>	<input type="checkbox"/>

GCP Training Documentation (Course Provider/Year Completed): CITI GCP | 12/27/2017

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: Stephen P. Fortmann Date: 21 July 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Randall	William	
Professional Mailing Address			
Street Address: 948 Patterson Road		Other Street Address:	
City: Dayton	State/Province: Ohio	Country: USA	Zip/Postal Code: 45419
Email Address:	(b) (6)		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Specialty Certification, Family Medicine	1991	American Board of Family Medicine, USA	
Doctor of Medicine	1988	University of Cincinnati, USA	
Premedical Studies	1984	University of Dayton, USA	
Medical License Number			
35.059106	State/Province: Ohio	Country: USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
SEP 2010	Principal Investigator	PriMed Clinical Research	OH/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
7/1991- Present	Practicing Family Physician	PriMed Family Practice	USA
7/1988-6/1991	Family Practice Resident	St. Elizabeth Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
I have approximately 11 years of clinical research experience in a variety of indications and developmental phases.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		09 JUN 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Schwartz	Howard	I
Professional Mailing Address:			
Street Address 1: 7261 Sheridan Street		Street Address 2: Suite 210	
City: Hollywood	State/Province: Florida	Country: USA	Zip/Postal Code: 33024
Email Address:		Howard.schwartz@rcatrials.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Doctor of Medicine	1984	University of Miami School of medicine, Miami, USA	
American Board of Internal Medicine	1985	USA	
American Board of Internal Medicine, Gastroenterology	1989	USA	
Medical License Number			
ME47067	Florida	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
12/2017	Chief Medical Officer	Research Centers of America, LLC	Florida, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
06/2018 - Present	President and CEO	Dream Life Recovery	Pennsylvania, USA
06/2017 - Present	President and CEO	Ventre Medical	Oakland Park, USA
01/2016 – 01/2019	Managing Director	Monarch Specialty Group	Miami, USA
07/2015 – 08/2016	Clinical Trial Lead	Miami Cancer Center	Miami, USA
10/1996 – 06/2015	President	Miami Research Associates	Miami, USA
Brief Summary of Relevant Clinical Research Experience:			
Clinical Trial Expert who has worked in the Pharmaceutical industry for the past 20 years conducting over 1000 clinical trials and participating in the commercializing of over 40 products. Participated in the design and execution of Phase 1-3 Trials across multiple areas including Biologics, Vaccines, Oncology, Gastroenterology, Neurology, Rheumatology, Sleep Medicine, Diabetes and Psychiatry.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		13/11/2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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ABBREVIATED CURRICULUM VITAE



Name: Jonathan Paul Wilson, DO
 Professional Title: Investigator
 Organization: PMG Research of Winston-Salem, LLC
 Address1: 1901 S. Hawthorne Road, Suite 306
 Address2: Winston-Salem, NC 27103 **USA**
 E-Mail: jonathan.wilson@pmg-research.com

Main Daytime Phone: 336.768.8062
 24 Hour Phone: 336.768.8062
 Fax: 336.760.2957

VC 14 JUN 2020

AFFILIATIONS

Facility Name	Facility Address
PMG Research of Winston-Salem, LLC	1901 S. Hawthorne Road, Suite 306, Winston-Salem, NC 27103

Education

University/School/Program	Degree/Certificate	Specialty	Year Completed
NorthEast Medical Center, NC USA	Intern/Residency	Family Medicine	2004
Nova Southeastern University College of Osteopathic Medicine, FL – USA	DO	Family Medicine	2001
Nova Southeastern University College of Osteopathic Medicine, FL – USA	Masters	BioMedical Science	1997
University of North Carolina Chapel Hill, NC - USA	BA	NA	1991

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Investigator	PMG Research of Winston-Salem	2006	Current
Private Practice	FairBrook Medical Clinic	2006	2008
Private Practice	Central Carolina Family Physicians	2005	2006

Type of License	License Issuer	Professional License Number	Country	State, Province or Region
Medical	NC State Board	200500132	USA	NC
DEA Schedule 2,2N, 3, 3N, 4, 5	DEA	BW9087619	USA	NC

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ABBREVIATED CURRICULUM VITAE (continued)

Name: Jonathan Paul Wilson, DO



RESEARCH EXPERIENCE

Study Type (Check all that apply):

- Academic
- Industry
- Investigator-Initiated
- Government
- Other / Please Specify:

Clinical Study Phases (Check all that apply) I II III IV

Therapeutic Areas of Expertise:

Therapeutic Area	Therapeutic Area
Family Medicine – All areas	Vaccine
Diabetes	Hypertension
Cholesterol	Osteoarthritis
Obesity	Device

Total Clinical Research Experience: **Total Number of completed studies: 225 +**

Therapeutic Area	Therapeutic Area	Therapeutic Area	Therapeutic Area
Acne	Acute Flu Device	Acute Respiratory	Allergy
Bone Metabolism	C-Diff	COPD	Diabetes/HTN Combo
CV Events Post MI	Cholesterol	Erectile Dysfunction	Erosive Esophagitis
NSAID Associated Ulcers	Flu Vaccine (All types)	Diabetes Mellitus & Type II Diabetes	OA of Hips and Knees
Fatty Liver (NASH)	Heartburn	Herpes Zoster Vaccine	GERD
IBS	Idiopathic Constipation	Crohn's Disease	Ulcerative Colitis
Celiac Disease	Gastroparesis	Pneumonia Vaccine	C-Diff Vaccine
RSV vaccine	dTAP vaccine	Psoriasis	Rosacea
BPH	Birth Control	Nocturia	Prostate Cancer
Overactive Bladder	Hypertension	Rheumatoid Arthritis	Fibromyalgia
Obesity	Weight Loss	Asthma	

Good Clinical Practice (GCP) Training Details:

Training Provider	Title of Training	Date Completed
CITI	GCP	2019

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: Date (DD/MMM/YYYY): 07/JAN/2020

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)

**Dr. Peter John Winkle**

Investigator

Anaheim Clinical Trials, LLC

2441 W. La Palma Avenue, Suite 140

Anaheim, California, United States of America, 92801

Email: pwinkle@act-trials.com

Main/Daytime: (714) 774-7777

Cell/Mobile: (b) (6)

24 Hour: (714) 778-1300

Evening: (949) 295-7809

Fax: (714) 778-0667

AFFILIATIONS

Facility Name (Department Name)	Facility Address	Department Address
Anaheim Clinical Trials, LLC	2441 West La Palma Avenue, Suite 140, Anaheim, California, United States of America, 92801	Not Applicable

EDUCATION

University	Degree/Certificate	Specialty	Year Completed
American Board of Internal Medicine	American Board of Internal Medicine (FACG)	Primary Care (General Practice, Family Practice, Internal Medicine) - Gastroenterology	1995
University of California, Los Angeles	Fellowship	Gastroenterology	1994
American Board of Internal Medicine	American Board of Internal Medicine (FACP)	Primary Care (General Practice, Family Practice, Internal Medicine)	1994
University of Southern California	Medical Degree	Primary Care (General Practice, Family Practice, Internal Medicine)	1989
University of California, Davis	Bachelor of Science	Not Applicable	1984

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Medical Director	Anaheim Clinical Trials, LLC	2011	Present
Investigator	Advanced Clinical Research Institute	2007	2011
Investigator	Associated Gastroenterology Medical Group	2007	2018
Investigator	AGMG Endoscopy Center	2001	Present
Investigator	Orange County Clinical Research	1994	2007

LICENSE DETAILS

Type of License	License Issuer	Professional License Number	Country	State/Province/Region	Expiration Date
Medical Doctor	The Medical Board of California	G70077	United States of America	California	31-Mar-2022
Other	Association of Clinical Research Professionals	None	United States of America	Virginia	30-Nov-2021
Other	United States Department of Justice	BW2564993 / XW2564993	United States of America	California	31-May-2023
Other	United States Department of Justice	RW0442537	United States of America	California	31-May-2023

RESEARCH EXPERIENCE

Study Type: Government;Industry;Academic
Clinical Study Phases: I,II,III,IV
Therapeutic Area of Expertise:

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**Dr. Peter John Winkle**

Investigator

Anaheim Clinical Trials, LLC

2441 W. La Palma Avenue, Suite 140

Anaheim , California , United States of America , 92801

Email: pwinkle@act-trials.com

Main/Daytime: (714) 774-7777

Cell/Mobile: (b) (6)

24 Hour: (714) 778-1300

Evening: (949) 295-7809

Fax: (714) 778-0667

Cardiovascular Diseases; Digestive System Diseases; Endocrine System Diseases; Female Urogenital Diseases and Pregnancy Complications; Immune System Diseases; Musculoskeletal Diseases; Respiratory Tract Diseases; Skin and Connective Tissue Diseases; Vaccines; Virus Diseases

TOTAL CLINICAL RESEARCH EXPERIENCE

Therapeutic Area	Sub Therapeutic Area	Number of Completed Studies	Number of Ongoing Studies
Endocrine System Diseases	Diabetes Mellitus	38	2
Digestive System Diseases	Gastrointestinal Diseases	32	2
Skin and Connective Tissue Diseases	Skin Diseases	18	5
Vaccines	Vaccines	17	3
Immune System Diseases	Autoimmune Diseases	14	0
Respiratory Tract Diseases	Lung Diseases	7	0
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases	6	0
Female Urogenital Diseases and Pregnancy Complications	Pregnancy Complications	6	0
Virus Diseases	Hepatitis, Viral, Human	1	1

GCP TRAINING DETAILS

Course Provider	Course Title	Date Completed (DD- MMM-YYYY)	Status
Pfizer	Good Clinical Practice for Investigational Site Staff - 3.0	24-Jan-2019	Certificate Valid

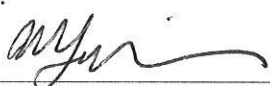

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature:	Dr. Peter John Winkle winklep_5031 03-JUN-2020 20:16:13 GMT Author of CV
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Levin	Michael	L.
Professional Mailing Address			
Street Address: 1022 East Sahara Avenue		Other Street Address:	
City: Las Vegas	State/Province: Nevada	Country: USA	Zip/Postal Code: 89104
Email Address:	<u>mlevin@crcnnv.com</u>		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Clinical and Molecular Genetics Fellowship	1991-1995	Baylor College of Medicine, USA	
Pediatrics Residency	1988-1991	Tulane University School of Medicine, USA	
M.D.	1984-1988	Tulane University School of Medicine, USA	
Medical License Number	State/Province	Country	
7954	Nevada	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
6/2019	Principal Investigator / Sub-Investigator	Wake Research - Clinical Research Center of Nevada, LLC (WR-CRCN, LLC)	Nevada USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2002-Present	Pediatrician	Henderson Pediatrics	USA
2002-2019	Principal Investigator / Sub-Investigator	Clinical Research Center of Nevada	USA
2001-2002	Pediatrician	Foothills Pediatrics	USA
1996-2001	Assistant Professor	University of Nevada School of Medicine	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Pediatrics: MMR/MMRV, RSV, Men ACWY, Pneumococcal, Havrix, Influenza, Epilepsy, ADHD, Weight Loss, Insomnia, Otitis Media, Otitis Externa, Nasal Swabs, Pharyngitis, Strep, Dermatitis, ABC in New Born, Brain Networking Activation</p> <p>Adults: Influenza Vaccines, Shingles Vaccines, Pneumococcal Vaccines, C-Difficile Vaccine, Insomnia, E. Coli Vaccine, Dengue Vaccine, Rabies Vaccine, Anthrax Vaccine, Weight Loss, Post-Op Surgical Pain, Brain Networking Activation, Hepatitis B Vaccine</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
			
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Walter, Jr.	Emmanuel	Benjamin
Professional Mailing Address			
Street Address: 2608 Erwin Road, Suite 210		Other Street Address: 3024 Pickett Road	
City: Durham	State/Province: NC	Country: USA	Zip/Postal Code: 27705
Email Address:		Chip.walter@duke.edu	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
B.S.	1979	University of Notre Dame	
M.D.	1983	University of Maryland at Baltimore	
M.P.H./Epidemiology	1992	University of North Carolina at Chapel Hill	
Medical License Number			
31677	North Carolina	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2016	Director	Duke University Medical Center/Duke Human Vaccine Institute; Duke Vaccine and Trials Unit Study Site Address: Clinical Research Pickett Road 3024 Pickett Road Durham, NC 27705 Accessioning Unit and Repository 2 Genome Court Durham, NC 27710	North Carolina, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2009-current	Professor of Pediatrics with Tenure	Duke University Medical Center	USA
2002-2009	Associate Professor of Pediatrics with Tenure	Duke University Medical Center	USA
1998-2002	Associate Professor of Pediatrics	Duke University Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Dr. Walter is trained in the fields of pediatrics, infectious diseases, and epidemiology and his primary research interest is related to disease prevention through vaccination. He is the Chief Medical Officer at the Duke Human Vaccine Institute and directs the Duke Vaccine and Trials Unit (DVTU). He has been the principal investigator or co-investigator for a large number of federally and industry funded vaccine studies. He has extensive experience conducting trials with both investigational and FDA approved vaccines for viral and bacterial pathogens. He is currently the co-principal investigator for the NIAID funded Vaccine and Treatment Evaluation Unit (VTEU) and the CDC Clinical Immunization Safety Assessment (CISA) project and principal investigator for the NIAID funded Collaborative Influenza Vaccine Innovation Center - Clinical Core. He is a recent past member of the CDC Advisory Committee on Immunization Practices. He has also served as a member of data safety monitoring boards for a number of vaccine and therapeutic studies.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		05 MAR 2021	

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TMF Doc ID
270.01, 272.01

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TD 8-MAR-2021

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ABBREVIATED CURRICULUM VITAE TEMPLATE

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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TMF Doc ID
270.01, 272.01

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Page 2 of 2

INV02-INV04-WI-GL02-SD01
Version 2.0, 16-Mar-2020




ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	<u>Last Name</u>	<u>First Name</u>	<u>Middle Name</u>
	Walter, Jr.	Emmanuel	Benjamin
Professional Mailing Address			
Street Address: 2608 Erwin Road, Suite 210		Other Street Address:	
City: Durham	State/Province: NC	Country: USA	Zip/Postal Code: 27705
Email Address:	<u>Chip.walter@duke.edu</u>		
Academic Qualifications:			
<u>Degree and/or Certification</u>	<u>Date (yyyy)</u>	<u>Institution and/or Country</u>	
B.S.	1979	University of Notre Dame	
M.D.	1983	University of Maryland at Baltimore	
M.P.H./Epidemiology	1992	University of North Carolina at Chapel Hill	
<u>Medical License Number</u>	<u>State/Province</u>	<u>Country</u>	
31677	North Carolina	USA	
Current Position at Study Site:			
<u>Start Date</u>	<u>Title</u>	<u>Institution or Company</u>	<u>State/Province & Country</u>
2016	Director	Duke University Medical Center/Duke Human Vaccine Institute; Duke Vaccine and Trials Unit	North Carolina, USA
Previous Relevant Positions Including Academic Appointments:			
<u>Start and End Dates</u>	<u>Title</u>	<u>Institution or Company</u>	<u>Country</u>
2009-current	Professor of Pediatrics with Tenure	Duke University Medical Center	USA
2002-2009	Associate Professor of Pediatrics with Tenure	Duke University Medical Center	USA
1998-2002	Associate Professor of Pediatrics	Duke University Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Dr. Walter is trained in the fields of pediatrics, infectious diseases, and epidemiology and his primary research interest is related to disease prevention through vaccination. He is the Chief Medical Officer at the Duke Human Vaccine Institute and directs the Duke Vaccine and Trials Unit (DVTU). He has been the principal investigator or co-investigator for a large number of federally and industry funded vaccine studies. He has extensive experience conducting trials with both investigational and FDA approved vaccines for viral and bacterial pathogens. He is currently the co-principal investigator for the NIAID funded Vaccine and Treatment Evaluation Unit (VTEU) and the CDC Clinical Immunization Safety Assessment (CISA) project and principal investigator for the NIAID funded Collaborative Influenza Vaccine Innovation Center - Clinical Core. He is a recent past member of the CDC Advisory Committee on Immunization Practices. He has also served as a member of data safety monitoring boards for a number of vaccine and therapeutic studies.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		01 May 2020	
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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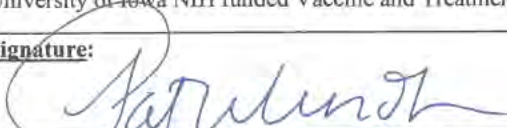
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Thomas	Stephen	J
Professional Mailing Address			
Street Address: 725 Irving Avenue		Other Street Address: Suite 311	
City: Syracuse	State/Province: NY	Country: USA	Zip/Postal Code: 13210
Email Address: thomstep@upstate.edu			
Academic Qualifications: MD			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1996	Albany Medical College, Albany, NY	
BA in Biomedical Ethics	1992	Brown University, Providence, RI	
Medical License Number	State/Province	Country	
286005-1	NY	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
11/2016	Director, Infectious Disease Assoc., Director, Institute for Global Health and Translational Science	State University of NY, Upstate Medical University	NY, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
4/2014-3/2016	Infectious Diseases Consultant to the US Army Surgeon General	U.S. Army Medical Command	USA
10/2014-3/2016	Team Leader, USAMRMC Ebola Response Management Team	U.S. Army Medical Research and Material Command	USA
7/2013-7/2016	Director, WRAIR-GEIS Operational Clinical Infectious Diseases Course	Walter Reed Army Institute of Research	USA
6/2011-5/2014	Director, Viral Diseases Branch	Walter Reed Army Institute of Research	USA
12/2007-5/2011	Director, Dengue Vaccine Development	U.S. Army-Armed Forces Research Institute of Medical Sciences	USA
9/2004-11/2007	Project Leader, Dengue Vaccine Development	Walter Reed Army Institute of Research	USA
9/2002-9/2004	Virology Department	U.S. Army Medical Component Armed Forces Research Institute	Thailand
7/2014-present	Associate Professor, Dept. of Medicine	Uniformed Services University of the Health Sciences	USA
Brief Summary of Relevant Clinical Research Experience:			
Significant experience and knowledge base in Virology and Vaccine development. Successful completion of numerous viral disease research studies as well as extensive background as a project leader and as director in both the military and public health field.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 04/MAY/2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Winokur	Patricia	Lee
Professional Mailing Address			
Street Address: 200 Hawkins Drive		Other Street Address: Department of Internal Medicine, University of Iowa Hospitals & Clinics	
City: Iowa City	State/Province: Iowa	Country: USA	Zip/Postal Code: 52242
Email Address:	<u>Patricia-winokur@uiowa.edu</u>		
Academic Qualifications: MD			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BA	June 1, 1981	Brown University	
MD	June 1, 1985	Washington University	
Residency, Internal Medicine	June 30, 1988	University of Iowa Hospitals and Clinics	
Fellowship, Infectious Diseases	June 30, 1991	University of Iowa Hospitals and Clinics	
Medical License Number	State/Province	Country	
26690	Iowa	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
July 1, 1993	Assistant Prof-Full Professor	University of Iowa	Iowa USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
July 1, 1991-June 30, 1993	Postdoctoral Fellow	National Institutes of Health	USA
Brief Summary of Relevant Clinical Research Experience:			
Dr. Winokur is a trained Infectious Disease Specialist with 18 years of experience performing clinical trials in infectious diseases. The studies have ranged from evaluation of novel diagnostics, drug therapies and vaccines. She has been the Principal Investigator for the University of Iowa NIH funded Vaccine and Treatment Evaluation Unit since 2007.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 01 May 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Rupp	Richard	E.
Professional Mailing Address			
Street Address: University of Texas Medical Branch		Other Street Address: 301 University Boulevard	
City: Galveston	State/Province: TX	Country: USA	Zip/Postal Code: 77555-1115
Email Address:	rrupp@utmb.edu		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Adolescent Medicine Fellowship	1993	William Beaumont Army Medical Center, Texas, USA	
Pediatrics Residency	1989	Wilford Hall Medical Center, Texas, USA	
Medical Doctorate	1986	St. Louis University School of Medicine, Missouri, USA	
Zoology Bachelor of Science	1982	Arizona State University, Arizona, USA	
Medical License Number	State/Province	Country	
J9316	Texas	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
05-2008	Director for Clinical Trials and Clinical Research	University of Texas Medical Branch, Sealy Institute for Vaccine Sciences	Texas, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2016-Present	Medical Director, Island Pediatrics	Department of Pediatrics, UTMB	USA
2010-2012	Director, Institutional Review Board	University of Texas Medical Branch (UTMB)	USA
2009-Present	Chief Division Adolescent and Behavioral Health	Department of Pediatrics, UTMB	USA
2008-Present	Director for Clinical Trials and Clinical Research	Sealy Center for Vaccine Development, UTMB	USA
Brief Summary of Relevant Clinical Research Experience:			
Richard Rupp, MD has over a decade of experience as a collaborator or principal investigator on phase I-III clinical trials. The trials include both NIH and industry sponsors. Trials span the age range from infants through the elderly and have included vaccine for meningococcus (ACWY&B), pneumococcus, influenza (seasonal, novel H1N1, avian), smallpox, cytomegalovirus, herpes simplex virus, human papillomavirus, and Ebola. He also heads the Office of Clinical Trials for the Sealy Center for Vaccine Development ensuring the success of the trials meeting regulatory demands, sponsor requirements and the needs of the subject.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		19 May 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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26 May 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Mg 07 Aug 2020

Full Name:	Last Name	First Name	Middle Name
	Talaat	Kawsar	R.
Professional Mailing Address			
Street Address: 624 N Broadway		Other Street Address: Hampton House Rm 249	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21205 <i>21205</i>
Email Address:	ktalaat@jhu.edu		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1997	University of Washington, Seattle, WA	
BS	1993	University of Washington, Seattle, WA	
Medical License Number			
D0066043	State/Province: Maryland	Country: USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2017	Assistant Professor	Johns Hopkins Bloomberg School of Public Health	Maryland, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2016-2017	Associate Scientist	JHSPH	USA
2007-2016	Assistant Scientist	JHSPH	USA
2006-2007	Assistant Clinical Investigator	NIH	USA
Brief Summary of Relevant Clinical Research Experience:			
I am a Board-Certified physician in Internal Medicine, Pediatrics and Infectious Diseases. I have served as the Principal Investigator for Phase 1 or 2 trials for a variety of vaccines, including influenza, malaria, Ebola, and enteric bacteria such as Enterotoxigenic <i>E. coli</i> (ETEC) and Shigella. I have also conducted several human challenge studies to look at the efficacy of novel therapies and vaccines for ETEC and Shigella.			
Signature:	Kawsar R. Talaat, MD	Digitally signed by Kawsar R. Talaat, MD Date: 2020.05.06 19:37:03 -04'00'	Signature Date: (dd-Mmm-yyyy) 06-May-2020
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Falcone	Robert	S
Professional Mailing Address:			
Street Address 1: 34 E. Somerset St.		Street Address 2:	
City: Raritan	State/Province: New Jersey	Country: USA	Zip/Postal Code: 08869
Email Address:		robert.falcone@amicicr.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1984	Boston University School of Medicine	
Medical License Number			
25MA04684000		State/Province New Jersey	Country USA
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
10-FEB-2016	Principal Investigator	Amici Clinical Research	New Jersey/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
21-FEB-2015 – 01-NOV-2016	Sub-Investigator	Amici Clinical Research	USA
May 2011 – February 2015	Site Occupational Health & Wellness Physician	Pfizer, Inc	USA
July 1996 – September 2008	Corporate Medical Director	Merck & Co., Inc	USA
December 1990 – July 1996	Site Medical Director	Merck & Co., Inc	USA
Brief Summary of Relevant Clinical Research Experience:			
Sub-Investigator & Study Coordinator for PCSK9 Inhibitor study (Pfizer) Principal Investigator for preventive migraine medication (Teva) Principal Investigator for preventive migraine medication (Allergan) Principal Investigator for Alzheimer Disease registry study (Avid/Lilly) Principal Investigator for NASH study (Intercept) Principal Investigator for NASH study (Allergan) Principal Investigator for NASH study (Galmed) Principal Investigator for 3 C. Difficile vaccine studies (Pfizer) Principal Investigator for 2 PCSK9 Inhibitor studies (The Medicines Company) Principal Investigator for Osteoarthritis Knee/Hip pain (Regeneron) Principal Investigator for hypogonadism in men with increased CV disease risk (AbbVie) Principal Investigator for Effect of Efglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk (Sanofi) Principal Investigator for chronic cough (Merck) Principal Investigator for 24 hour BP monitoring study in hypogonadal men with receiving testosterone replacement therapy (AbbVie)			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		29-May-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Garcia-Diaz	Julia	
Professional Mailing Address			
Street Address: 1514 Jefferson Highway		Other Street Address:	
City: New Orleans	State/Province: LA	Country: USA	Zip/Postal Code: 70121
Email Address:	jgarcia-diaz@ochsner.org		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Medical Doctor	1993	Louisiana State University School of Medicine/USA	
Master of Science	1989	University of New Orleans/USA	
Bachelor of Science	1983	Nicholls State University/USA	
Medical License Number			
10817R	State/Province: LA	Country: USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1/2020	Director, Medical Subspecialties Research	Ochsner Health	LA, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
9/2016-present	Director, Medical Student Research	University of Queensland, Ochsner Clinical School	Australia
7/2015-present	Director Clinical Infectious Diseases Research	Ochsner Medical Center	USA
8/2014-present	Associate Professor	University of Queensland, Ochsner Clinical School	Australia / USA
3/2004-6/2015	Program Director	Infectious Diseases Fellowship	USA
2004-present	Certified Principle Investigator	Ochsner Clinic Foundation	USA
Brief Summary of Relevant Clinical Research Experience:			
Certified Principal Investigator with over 20 years of experience. Over 50+ research studies completed			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		20 MAR - 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Reynolds	Steven	H.
Professional Mailing Address			
Street Address: 2600 Redondo Avenue		Other Street Address: Suite 415	
City: Long Beach	State/Province: CA	Country: USA	Zip/Postal Code: 90806
Email Address:	stevenreynolds@cnstrial.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
DO	1992	Midwestern University, Chicago College of Osteopathic Medicine, USA	
American Board of Family Practice	1999	USA	
Medical License Number	State/Province	Country	
6475	California	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2010 – Present	Investigator	Collaborative Neuroscience Research, LLC	USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2018 – Present	Private Practice	Naples Medical Group Long Beach, CA	USA
2010 – Present	Staff Physician	Ocean View Psychiatric Health Facility, Long Beach, CA	USA
2009 – Present	Medical Review Officers	ACOEM Certified at Central Drug Systems	USA
2005 – 2018	Private Practice	Family Health Care of Long Beach, CA	USA
Brief Summary of Relevant Clinical Research Experience:			
N/A			
Signature:		Signature Date: (dd-Mmm-yyyy)	
			
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Senders	Shelly	D
Professional Mailing Address:			
Street Address 1: 2054 South Green Road			
City: South Euclid	State/Province: Ohio	Country: USA	Zip/Postal Code: 44121
Email Address: ssenders@senderspediatrics.com			
Academic Qualifications: MD			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Resident in Pediatrics, Chief Resident in Pediatrics	1986	The Brookdale Hospital Medical Center	
Doctorate in Medicine	1983	Albert Einstein College of Medicine	
Bachelor of Arts in Chemistry, Summa Cum Laude	1978	Yeshiva University	
Medical License Number			
35.053726	Ohio	USA	
Current Position at Study Site: Principal Investigator			
Start Date	Title	Institution or Company	State/Province & Country
1987	President and Chief Physician	Senders Pediatrics	Ohio, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
N/A	N/A	N/A	N/A
Brief Summary of Relevant Clinical Research Experience:			
Phase III, modified double blind, randomized, parallel group, active- controlled, multi- centered study to describe the safety of MenACWY conjugate vaccine when administered concomitantly with routine pediatric vaccines given to healthy infants and toddlers 2019			
Phase IIIB, observer blind, randomized, placebo controlled, multi center study to assess the safety and immunogenicity of GSK Men B and PCV 13 when administered with routine vaccines in healthy infants 2019			
Double-blind, Randomized, Placebo-controlled Phase 2b, Multi-center study to evaluate the Safety, Tolerability, Efficacy and Immunogenicity of a 2-dose and a 3-dose regimen of V160 (Cytomegalovirus [CMV] Vaccine) in healthy seronegative women, 16-35 years of age. 2018			
Signature: 		Signature Date: (dd-Mmm-yyyy) 29 Jun 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name Brandon	First Name Donald	Middle Name M.
Professional Mailing Address:			
Street Address 1: California Research Foundation		Street Address 2: 4180 Ruffin Road, Suite 255	
City: San Diego	State/Province: CA	Country: USA	Zip/Postal Code: 92123 - 1881
Email Address:		dbrandon@crftrials.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Board Certified, Internal Medicine	1993	ABIM, USA	
Residency, Internal Medicine	1992	Mercy Hospital & Medical Center, San Diego, USA	
Internship, Internal Medicine	1990	Mercy Hospital & Medical Center, San Diego, USA	
M.D.	1989	USC Keck School of Medicine, USA	
B.A.	1984	University of San Diego, USA	
Medical License Number	State/Province	Country	
G 71000	CA	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1992	Medical Director/Investigator	California Research Foundation	CA/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1992-present	Physician	Olive Park Family Health	USA
Brief Summary of Relevant Clinical Research Experience:			
Investigator has more than 30 years of clinical research experience having participated in over 400 industry sponsored Phase I-IV clinical trials over the past 25 years that focus on use of medications for health maintenance and disease treatments for diverse patient populations.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 22 JUN 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Rodriguez	Hector	Antonio
Professional Mailing Address:			
Street Address 1: 2400 NW 54 th Street		Street Address 2:	
City: Miami	State/Province: FL	Country: USA	Zip/Postal Code: 33142
Email Address:	hrodriguez.md@acevedoclinicalresearch.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Transitional-FM Residency	1990	Chestnut Hill Hospital, Philadelphia, PA	
MD	1985	Universidad Cenral de Este, Dominican Republic	
Medical License Number			
ME 57069	FL	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2017	Investigator	Acevedo Clinical Research Associates	FL/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2006 - 2015	Investigator	South Miami Clinical Research	USA
2005 - Present	Medical Director	Acevedo Medical Care Group	USA
2000-2017	Family Physician	Wellmax Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
Experienced in Pulmonology (Asthma/COPD), Vaccine (Ped & Adult), Dermatology (AD, Acne,) Neurology (Migraine, HA), Psychiatric (MDD, ADHD), Endocrinological (T2DM, Hyperlipidemia), Gastroenterological (Constipation, IBS)			
Signature:		Signature Date: (dd-Mmm-yyyy)	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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This page is a manifestation of an electronic record that was signed electronically.

Document Name: Rodriguez, Hector A - Pfizer Abbreviated CV

Document ID: 852

No. Pages: 1

Statement of Testament: I approve the document

Electronic Signature for: Hector Rodriguez, MD

Electronically Signed by: hrodriguez

Date & Time: 13/APR/2020 1:47 PM EDT

IP Address: 96.84.26.6

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Saleh	Jamshid	N/A
Professional Mailing Address			
Street Address: 3652 Eureka Way		Other Street Address: N/A	
City: Redding	State/Province: CA	Country: USA	Zip/Postal Code: 96001
Email Address:	<u>jsaleh@paradigm-research.com</u>		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Doctorate of Medicine	1980	University of Birmingham Medical School, England	
Fellow of American College of Surgeons (F.A.C.S)	2002	United States	
American Board of Neurological Surgery Board Certified	2001	United States	
Medical License Number	State/Province	Country	
A061022	California	United States	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
Jan-2009	Principal Investigator	Paradigm Clinical Research Center	Ca, United States
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1997-Present	Owner/Physician	Northern California Neurological Surgery	United States
2011-Present	Privileges	Northern California Rehabilitation Hospital	United States
1997-Present	Privileges	Shasta Regional Medical Center	United States
1997-Present	Privileges	Mercy Medical Center	United States
Brief Summary of Relevant Clinical Research Experience:			
Eleven years of experience working in clinical research. Experience includes conducting trials as a PI for vaccine and medical trials, Phase I-IV. Vaccine trial experience includes studies for Influenza, RSV, Ebola, Rabies, Small Pox, and C. difficile. Experience includes conducting informed consent procedures, study visit procedures, lab and ECG result review and sign off, and participating in Investigator meetings, Site Selection Visits, SIVs, COVs, and regulatory submissions.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 29 JUNE 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Herrington	Darrell	T.
Professional Mailing Address			
Street Address: 3605 Executive Dr		Other Street Address: N/A	
City: San Angelo	State/Province: TX	Country: USA	Zip/Postal Code: 76904
Email Address:	darrellherrington@benchmarkresearch.net		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
DO	1987-1988	General Rotating Internship- Chief Intern	
Residency	1983-1987	Texas College of Osteopathic Medicine	
Diplomate, American Board of Hospice and Palliative Medicine	2006	United States	
Medical License Number	State/Province	Country	
H4402	TX	United States	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1998 to present	Principal Investigator	Benchmark Research	San Angelo, TX, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1995- Present	DO of Family Practice	West Texas Medical Associates	United States
2016- Present	Medical Director	Solaris Hospice	United States
2002-2010	Medical Director	Hospice	United States
Brief Summary of Relevant Clinical Research Experience:			
Principal Investigator for over 250 trials to include Vaccine, Pediatric, Indication, and device trials over 21 years experience.			



ABBREVIATED CURRICULUM VITAE TEMPLATE

Signature: 	Signature Date: (dd-Mmm-yyyy) 17 JUL 2020
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>	
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Abbreviated Curriculum Vitae (CV)

Full Name, Credentials Robert A. Riesenber, MD	Current Position at Study Site PI/Sub-I <i>PI 23-Jul-2020</i>
---	--

Study Site / Professional Mailing Address							
Atlanta Center for Medical Research 501 Fairburn Road SW Atlanta, GA 30331	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Phone</td> <td style="padding: 2px;">(404) 881-5800</td> </tr> <tr> <td style="padding: 2px;">Fax</td> <td style="padding: 2px;">(404) 532-6849</td> </tr> <tr> <td style="padding: 2px;">Email</td> <td style="padding: 2px;">RRiesenber@acmr.org</td> </tr> </table>	Phone	(404) 881-5800	Fax	(404) 532-6849	Email	RRiesenber@acmr.org
Phone	(404) 881-5800						
Fax	(404) 532-6849						
Email	RRiesenber@acmr.org						

Academic Qualifications		
Dates (Years)	Degree / Certification	Institution
1972	BS	Memphis State University, USA
1975	MD	University of Tennessee, USA
1978	Psychiatry Residency	Washington University in St Louis, USA

Professional Experience (Previous 4 Relevant Positions)		
Dates (Years)	Title / Position	Institution
1984 - Pres	Medical Director/PI/Sub-Investigator	Atlanta Center for Medical Research, USA
1979 - 2008	Private Practice - Psychiatry	BioBehavioral Associates, USA
1979 - 2000	Staff Psychiatrist	Dept of Psychiatry, Dekalb Medical Center, USA
1978 - 1979	VA Hospital Staff, Psychiatrist	Emory University, USA

Summary of Experience

Dr. Riesenber has a wide range of experience in the research field. His primary focus is on CNS, PK, Healthy Normal and Child/ Adolescent disorders. His experience also includes treating psychiatric disorders (Schizophrenia, Anxiety, Bipolar, Major Depression Disorder, Substance Abuse, etc) and Neurological disorders (Parkinson's Disease, Alzheimer's Disease, Dementia, Epilepsy, etc). He has also worked on several General Medicine trials including Migraines, Diabetes, Shingles, Interstitial Cystitis, Cardiovascular, Pain, Asthma and COPD. Dr. Riesenber has been the Principal Investigator in over 500 studies, including trials with pediatric and elderly subjects. His years of experience allow him to personally train staff on Good Clinical Practices, Human Subject Protection and conducting a clinical trial. He also has several years of experience is assessing rating scales. Some of the scales that Dr. Riesenber has used on a daily basis are:

Adult HAM-A PANSS BPRS MMSE CELF3 CGI NPI Wisconsin Card Sorting Task Finger Tapping Task Benton Visual Retention Task Newcastle Scale for Depression	HAM-D YMRS MADRS STROOP ADAS GAF ACDS	Calgary Depression CVLT SADS-C WAIS-III Subtest SAS, AIMS, BARS Y-BOCS Vitiello Agression Scale Buschke Selective Reminding Test Rivermead Behavioral Memory Test Vineland Adaptive Behavior Scales	WRAT3 RAVLT BACS SIB SCoRS NIMH-GOCS K-BIT FAQ WMS-R	PEC ACES CAARS CAADID IDS Tanner Staging CSSRS ESRs TETRAs GDS MOAAs
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Child/Adolescent Kiddie-SADS K-SADS-PL	CDRS-R CGAS	CGI ADHD-RS-IV	YQOL-R P-QLES-Q	NY ACCENT R-MOAS	PAERS K-BIT Vitiello Agression Scale Tanner Staging
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Diagnostic:
 MINI SCID

Professional License			
Type	License #	Issuing Authority	Expiration Date
MD	019589	GA	08/31/21

Good Clinical Practices (GCP) Training	
Course Provider	Date of Completion
CITI Program	12/07/18

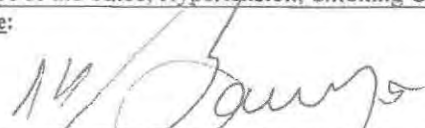
By signing this form, I confirm that the information provided is accurate and reflects my current qualifications

Signature 	Date (mm/dd/yyyy) 06/15/2020
---------------	---------------------------------

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Bauer	First Name George	Middle Name H
Professional Mailing Address:			
Street Address: 4517 Veterans Memorial Blvd		Other Street Address:	
City: Metairie	State/Province: LA	Country: USA	Zip/Postal Code: 70006
Email Address:	jeffsegner@benchmarkresearch.net <u>georgebauer@BenchmarkResearch.net</u> 17 July 2020		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Bachelor of Science	1963	University of New Orleans	
MD	1967	Louisiana State University	
Medical License Number			
State/Province		Country	
MD.0107039		LA USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2008	Principal Investigator	Benchmark Research	LA / USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1973-2007	Partner, Pediatrician	Lakeside Children's Clinic	USA
1970-1972	Major, Pediatrician	U.S. Air Force	Iran
Brief Summary of Relevant Clinical Research Experience:			
Sub-Investigator/Site Director/Project Manager on 100+ Phase I - IV studies with indications ranging from Diabetic Foot Ulcer, OA of the Knee, Hypertension, Smoking Cessation and Multiple Vaccine Studies			
Signature: 		Signature Date: (dd-Mmm-yyyy) 16 JUL 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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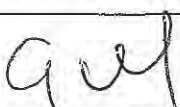
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Manning	First Name Mary Beth	Middle Name
Professional Mailing Address:			
Street Address: Rapid Medical Research, Inc. 3619 Park East Drive Suite 300		Other Street Address:	
City: Cleveland	State/Province: Ohio	Country: USA	Zip/Postal Code:44122
Email Address:		mbmanning@velocityclinical.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1987	Case Western Reserve University / USA	
Residency – Internal Medicine	1990	CWR University - Metro Health Medical Center / USA	
Internship	1988	Cleveland Clinic Foundation / USA	
Medical License Number			
35.058161		State/Province Ohio	Country USA
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
Aug 2013	Investigator	Rapid Medical Research, Inc.	Ohio, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
Aug 2013-present	Investigator	Rapid Medical Research, Inc.	USA
Apr 2010-Mar 2013	Staff Physician	St. Vincent Charity Medical Ct.	USA
Jul 2007-Dec 2012	Staff Physician	University ER	USA
2000-2010	Senior Clinical Instructor	CWR University	USA
Brief Summary of Relevant Clinical Research Experience:			
1992 – Present – Investigator on various trials (see completed CV) Phases: II, III & IV			
Signature: 		Signature Date: (dd-Mmm-yyyy) 15 JUL 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name Morawski	First Name Emily	Middle Name J.
Professional Mailing Address:			
Street Address 1: Holston Medical Group 105 West Stone Drive 3 rd Floor Suite 3A		Street Address 2:	
City: Kingsport	State/Province: TN	Country: USA	Zip/Postal Code: 37660
Email Address:	emily.morawski@myhmg.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Residency	2001	Carilion Health Systems- Roanoke, VA- USA	
Medical Degree	1999	Eastern Virginia Medical School- Norfolk, VA- USA	
Undergraduate B.S. Biology	1994	College of William and Mary, Williamsburg, VA- USA	
Medical License Number	State/Province	Country	
MD0000036817	Tennessee	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2002- Current	Family Practice Physician / Principal Investigator	Holston Medical Group	TN - USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
N/A			
Brief Summary of Relevant Clinical Research Experience:			
Experience in Clinical Research : Principal Investigator and Sub-Investigator since 2002 on studies including Type I Diabetes, Type II Diabetes, Chronic Kidney Disease, Obesity, Cardiovascular Outcomes, Lipid Studies, Rheumatoid Arthritis, Alzheimer's Disease, Pneumonia Vaccines, and Low Testosterone Studies.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 10 Aug 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Cox	Steven	E.
Professional Mailing Address			
Street Address: 630 24 th Avenue SW		Other Street Address:	
City: Norman	State/Province: OK	Country: USA	Zip/Postal Code: 73069
Email Address:	scox@lhsi.net		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
D.O.	1983	Oklahoma State University College of Osteopathic Medicine & Surgery – USA	
B.S.	1980	University of Oklahoma - USA	
Medical License Number			
	State/Province	Country	
2360	Oklahoma	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2016	Principal Investigator	Lynn Institute of Norman	Oklahoma/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008 – 2012	Principal Investigator	Legacy Clinical Research	USA
1996 – 1998	Physician	Family Practice	USA
1998 – present	Physician	Family Practice	USA
Brief Summary of Relevant Clinical Research Experience:			
Investigator has more than 12 years of diverse clinical research experience as a specialist in Family Medicine. He has participated as both PI and sub-investigator in numerous industry sponsored Phase II-IV clinical trials over the past 12 years that focus on optimizing the use of medications for health maintenance and disease treatments related to hypertension, hypercholesterolemia, stress urinary incontinence, Type 2 diabetes, fibromyalgia, overactive bladder, migraine, vaccines and GERD			
Signature: 		Signature Date: (dd-Mmm-yyyy) 21/JUL/2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Yozviak	Joseph	Leo
Professional Mailing Address			
Street Address: Lehigh Valley Health Network -NORI		Other Street Address: 1255 S. Cedar Crest, Suite 3200	
City: Allentown	State/Province: PA	Country: USA	Zip/Postal Code: 18103
Email Address:		joseph.yozviak@lvhn.org	
Academic Qualifications: DO			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Internal Medicine Residency	2003-2006	Lehigh Valley Hospital /LVHN/USA	
Osteopathic Internship	2003-2004	Lehigh Valley Hospital/LVHN/USA	
Doctor of Osteopathic Medicine	1999-2003	Philadelphia College of Osteopathic Medicine/USA	
Bachelor of Science, Chemistry/Biology	1995-1999	West Chester University/USA	
Medical License Number	State/Province	Country	
OS013090	Commonwealth of Pennsylvania	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2016	Medical Director	Lehigh Valley Health Network	PA/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2006 – PRESENT	Medical Director (2016-present) Acting medical Director (2015-2016)	Lehigh Valley Health Network Comprehensive Health Services (formerly AIDS Activities Office)	USA
2006 – PRESENT	Medical Director (2016-Present) Acting Medical Director (201-2016) Lead Physician (2008-2015)	Lehigh Valley Health Network Hepatitis Care Center	USA
2019-PRESENT	Academic/Clinical Subgroup member	Pennsylvania Viral Hepatitis Elimination Planning Committee	USA
2018-PRESENT	CDC Medical Leadership Committee At-large Member	Lehigh Valley Hospital	USA
Brief Summary of Relevant Clinical Research Experience:			
Working in research since 2006, primarily working on industry sponsored studies. Most of the studies were focused on Infectious Diseases.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
 Signed Electronically by: Joseph Yozviak - Joseph.Yozviak@lvhn.org 27-Aug-2020 @ 10:34 AM EST Reason: Approval		27-Aug-2020 @ 11:33 AM EDT	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.3):

Signed electronically by: Joseph Yozviak (Joseph.Yozviak@lvhn.org)

Date: 27-Aug-2020 @ 10:34 AM EST

Reason: *Approval*


Previous Electronic Signatures:

There are no signatures for any previous versions.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Berhe	Mezgebe	
Professional Mailing Address			
Street Address: 3409 Worth Street		Other Street Address: Suite 710	
City: Dallas	State/Province: Texas	Country: USA	Zip/Postal Code: 75246
Email Address:		<u>Mezgebe.berhe@ntidc.org</u>	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1993	Addis Ababa University Medical School	
Internal Medicines Residency	2003	Virginia Commonwealth University School of Public Health	
Infectious Diseases Fellowship	2005	St. Barnabas Hospital/ Cornell Montefiore	
MPH	2005	Virginia Commonwealth University School of Public Health	
Medical License Number	State/Province	Country	
M1510	Texas	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2005	PI	North Texas Infectious Diseases Consultants, P.A.	Texas, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2005 – Present	Instructor in Medicine	Baylor University Medical Center	USA
2013 – Present	Assistant Professor of Medicine	Texas A&M School of Medicine	USA
2005 – Present	Infectious Diseases Consultant	Baylor University Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
2006 to 2015: Sub-Investigator for multiple clinical trials 2015 to date: Principal Investigator for multiple clinical trials Total 75 clinical trials			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		10 Jul 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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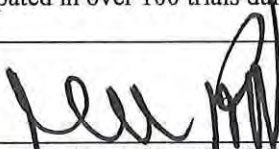
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name <i>if applicable</i>
	Martin	Earl	Francis
Professional Mailing Address:			
Street Address 1: 710 Lawrence St		Street Address 2:	
City: Tomball	State/Province: TX	Country: USA	Zip/Postal Code: 77375
Email Address: drearlfmartin@dmclinicalresearch.com			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
M.D.	1964	University of Nuevo Leon, Mexico	
Medical License Number	State/Province	Country	
E0259	TX	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1976	Owner/Director/Physician	Martin Diagnostic Clinic	TX, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1971-1974	Residency	Patterson Air Force Base	USA
Brief Summary of Relevant Clinical Research Experience:			
Experience in clinical trials for 10+ years in but not limited to the following indications: Diabetes, Rheumatoid Arthritis, Cardiovascular Disease, Chronic Nonmalignant Nonneuropathic pain, Kidney Disease, Influenza. Over 25+ studies conducted.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		21 July 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Poretz	First Name Donald	Middle Name Martin
Professional Mailing Address			
Street Address: Clinical Alliance for Research and Education – Infectious Diseases, LLC (CARE-ID) 3289 Woodburn Road Suite 250		Other Street Address:	
City: Annandale	State/Province: VA	Country: USA	Zip/Postal Code: 22003
Email Address:	dporetz@careidresearch.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Fellowship	1972	Medical College of Virginia	
Residency	1971 1968	Medical College of Virginia	
M.D.	1966	Medical College of Virginia, School of Medicine	
B.A.	1962	University of Virginia	
Medical License Number	State/Province	Country	
0101018020	Commonwealth of Virginia	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2005 - Present	Investigator	CARE-ID	Virginia, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2007-present	Director	Infectious Diseases Fellows Rotation, NIAID (NIH)	USA
2007-2008	President	Infectious Diseases Society of America	USA
2004-2006	President	National Foundation for Infectious Diseases	USA
1973-present	Infectious Diseases Physician	Infectious Diseases Physicians, LLC	USA
1972-2001	Chief, Infectious Diseases	INOVA Fairfax Hospital	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Dr. Poretz began Infectious Diseases research in 1971. Since that time he has been a Principal Investigator and Sub-investigator for prevention and treatment clinical trials involving antivirals, antibiotics, antiretrovirals, and vaccines. Dr. Poretz has participated in over 100 trials during the course of his career. These research studies have been both industry and NIH sponsored.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		13-JUL-2020	
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>			
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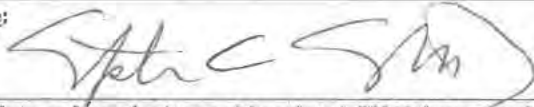
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Fitz-Patrick	David	
Professional Mailing Address			
Street Address: 1585 Kapiolani Blvd.		Other Street Address: Suite 1500	
City: Honolulu	State/Province: HI	Country: USA	Zip/Postal Code: 96814
Email Address:	dfitz@eastwestresearch.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Clinical and Research Fellowships in Diabetes and Endocrinology	1981	McGill University, Montreal, Canada	
MB, BS Medicine and Surgery (U.K. equivalent of MD in U.S.)	1974	University of Newcastle Upon Tyne, United Kingdom	
Medical License Number	State/Province	Country	
4149	HI	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1998	President	East-West Medical Research Institute	Hawaii / U.S.A.
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1994 - Present	Associate Clinical Professor	John A. Burns School of Medicine	U.S.A.
1991 - Present	Attending Physician	Queens Medical Center	U.S.A.
1990 - Present	Medical Director	Diabetes & Hormone Center of the Pacific	U.S.A.
1984 - 1991	Medical Director	The Diabetes Center of the Pacific, Straub Clinic and Hospital	U.S.A.
1986 - 1991	Chief	Department of Endocrinology and Metabolism, Straub Clinic and Hospital	U.S.A.
1981 - 1991	Attending Physician	Straub Clinic and Hospital	U.S.A.
1982 - 1994	Assistant Clinical Professor	John A. Burns School of Medicine	U.S.A.
1981 - 1997	Consulting Physician	Kapiolani Medical Center	U.S.A.
Brief Summary of Relevant Clinical Research Experience:			
Principal Investigator of more than 250 clinical trials			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		04 JUN 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Sharp	First Name Stephan	Middle Name C.
Professional Mailing Address:			
Street Address: 1500 Church Street		Other Street Address: Suite 100	
City: Nashville	State/Province: Tennessee	Country: USA	Zip/Postal Code: 37203
Email Address:	Ssharp@CRANashville.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
B.S., Biology	1983	Southwestern at Memphis (Rhodes College)	
M.D.	1987	University of Tennessee	
Internship & Residency	1990	University of Tennessee/Department of Internal Medicine	
Fellowship	1993	Vanderbilt University School of Medicine/Division of Endocrinology	
Medical License Number	State/Province	Country	
MD0000019021	Tennessee	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1996	Principal Investigator	Clinical Research Associates, Inc.	TN/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1996 – Present	Medical Director and Principal Investigator	Clinical Research Associates, Inc.	USA
1996 – 2014	Private Practice of Endocrinology	Stephan Sharp, MD (Private Practice)	USA
1996 – 1997	Assistant Professor, Dept. of Medicine	Meharry Medical College	USA
Brief Summary of Relevant Clinical Research Experience:			
I have conducted clinical research since 1982 in a variety of areas, including basic physiology, fertility/contraception, hypertension, diabetes, lipids, vascular disease, arthritis, headaches, menopause, osteoporosis, DUB, PMS, PTSD, heartburn, herpes, etc., as well as vaccine and device studies.			
Signature:			Signature Date: (dd-Mmm-yyyy) 15 JUL 2020
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Katzman	Steven	
Professional Mailing Address			
Street Address: Michigan Center of Medical Research		Other Street Address: 30160 Orchard Lake Road	
City: Farmington Hills	State/Province: Michigan	Country: USA	Zip/Postal Code: 48334
Email Address:	drkatzman@michmer.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
D.O.	1990	University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa	
B.A. Biology	1986	Wayne State University, Detroit, Michigan	
Medical License Number	State/Province	Country	
5101010946	Michigan	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2012	Principal Investigator	Michigan Center of Medical Research	Michigan, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2002-Present	Internal Medicine, Director of Research	Beaumont Health System	USA
2017-Present	Chapter Board Member	American Diabetes Association/Michigan	USA
2001-Present	Director of Board Review Internal Medicine Residency Program	Beaumont Hospital Farmington Hills Botsford Campus	USA
Brief Summary of Relevant Clinical Research Experience:			
<ol style="list-style-type: none"> 1. Involvement in Evaluation of Immune Response in Patients Recently Infected with HIV-1, Identified by Serological Technical Enzyme-Linked Immunosorbent Assay with Double Testing Strategy (Detuned). 2. MERS-CoV Infection tReated With A Combination of Lopinavir /Ritonavir and Interferon Beta-1b (MIRACLE) 3. A Phase III, Multicenter, Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of Peramivir Administered Intravenously in Addition to Standard of Care Compared to Standard of Care Alone in Adults and Adolescents who are Hospitalized Due to Serious Influenza 4. A Study to Evaluate the Safety and Immunogenicity of a Candidate Ebola Vaccine in Adults 			
Signature:		Signature Date: (dd-Mmm-yyyy)	
 Steven Katzman, DO (Jul 10, 2020 09:12 EDT)		Jul 10, 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Aberg	Judith	A
Professional Mailing Address:			
Street Address: One Gustave L. Levy Place, Box 1090		Other Street Address:	
City: New York	State/Province: NY	Country: USA	Zip/Postal Code: 10029
Email Address: judith.aberg@mssm.edu			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
American Board of Internal Medicine/ Infectious Disease Subspecialty #155629	1996	USA	
American Board of Internal Medicine #155629	1994	USA	
National Board of Medical Examiners #388218	1991	USA	
MD, Doctor of Medicine	1990	The Pennsylvania State University College of Medicine Hershey, PA	
A S C P - National Boards MLT022970	1981	USA	
A S C P -National Boards CLA014648	1976	USA	
Medical License Number	State/Province	Country	
230579-1	New York	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1/1/2014	Chief of Infectious Disease	Icahn School of Medicine at Mount Sinai (ISMMS) and Mount Sinai Health System	New York, NY USA
2014	The George Baehr Professor of Medicine with Tenure	ISMMS and Mount Sinai Health System,	New York, NY USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2011-2013	Jeffrey Bergstein Professor of Medicine and Director, Division of Infectious Diseases and Immunology	New York University School of Medicine, New York, NY	USA
2010-2013	Professor of Medicine with Tenure	New York University School of Medicine New York, NY	USA
2004-2013	Director of Virology	Bellevue Hospital Center and the South Manhattan Healthcare Network	USA
2004-2010	Associate Professor of Medicine with Tenure	New York University School of Medicine, New York, NY	USA
2000-2003	Associate Professor of Medicine, Director of HIV Services,	Washington University, St. Louis, MO	USA
1996-1999	Assistant Professor of Medicine	University of California, San Francisco AIDS Program, San Francisco General Hosp, San Francisco, CA	USA
1994-1996	Emergency Medicine Consultant	The Cleveland Clinic Hospital, Cleveland, OH	USA
1993-1994	Clinical Associate, HIV Clinic, Department of Rheumatic & Immunologic Disease	The Cleveland Clinic Foundation, Cleveland, OH	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>I transitioned to clinical and translational research during my 4th year in medical school after involvement in immune modulating therapy for patients with multiple sclerosis. I began designing and conducting clinical trials in HIV infected patients in 1992 and focused my ID fellowship learning the necessary skills to become an independent clinical researcher. I developed my career using the infrastructure of the DAIDS supported AIDS Clinical Trials Group (ACTG) and to date, I have served as a PI for over a 100 randomized controlled trials of which I have served as chair or vice-chair of 17 ACTG studies. In 2004, I was recruited to NYU to be Director of Virology at Bellevue Hospital/ NYU. I competitively obtained funding for the NIH-funded AIDS Clinical Trials Unit (ACTU) and later became Director of the Division of ID and Immunology. I was recruited to Sinai January 2014 in order to develop a comprehensive basic, translational and clinical research program in infectious diseases/HIV. I readily accepted this offer given the merger and creation of a large health system with access to over 10,000 patients with HIV infection. Subsequently I created the Clinical and Translational Research Center (CTRC) and have successfully recruited over 20 faculty including basic and translational scientists and have established five clinical research sites located throughout Manhattan. The mission of the CTRC is to conduct NIH sponsored studies, to provide support to junior faculty and form collaborations with translational and basic scientists given our rich population base. My main area of interest is complications of HIV disease, specifically pathogenesis of inflammation contributing to the co-morbidities associated with HIV infection. I currently serve as chair or vice-chair of 5 NIAID ACTG Studies. I also received an Empire Clinical Research Program award December 2016 to develop an ID-Genomics training program of which I oversaw 4 research fellows in collaboration with the ISMMS Genomics Institute who now hold faculty positions at ISMMS. During the COVID Pandemic March-present 2020, my team has enrolled over 800 patients into clinical trials. The COVID pandemic brought many challenges especially where there is insufficient knowledge and data to initially guide the use of PPE, protect health care workers and those exposed and manage patients especially those who developed rapid respiratory failure with systemic inflammatory responses. I was among the teams providing treatment guidance as well as best exposure prevention strategies on the COVID units. With Sinai being among the first to develop an antibody test, we were able to screen individuals who recovered from COVID and those with high titers of antibody were asked if they would be willing to donate plasma to be transfused to hospitalized patients with COVID. We were the first center in the US to offer convalescent plasma. To date, we have transfused over 500 unique patients. I will serve as site PI for this trial.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
<p>DocuSigned by: Judith Aberg Signer Name: Judith Aberg Signing Reason: I approve this document Signing Time: 2020-Jul-30 2:16:38 PM EDT www.docusign.com</p>		2020-Jul-30	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Hammitt	Laura	
Professional Mailing Address			
Street Address: 415 N. Washington St, 4 th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address: Lhammitt@jhu.edu			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BSc	1995	University of Utah, USA	
MD	1999	University of Utah, USA	
Medical License Number			
D72855	Maryland	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	Maryland, USA ARIZONA 15th Sept 2020
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA
Brief Summary of Relevant Clinical Research Experience:			
Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials			
Signature:		Signature Date: (dd-Mmm-yyyy) 10 SEP 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Hammitt	Laura	
Professional Mailing Address			
Street Address: 415 N. Washington St, 4 th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address: Lhammitt@jhu.edu			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BSc	1995	University of Utah, USA	
MD	1999	University of Utah, USA	
Medical License Number			
D72855	Maryland	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	Maryland, USA ARIZONA 18th Sept 2020
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA
Brief Summary of Relevant Clinical Research Experience:			
Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials			
Signature:		Signature Date: (dd-Mmm-yyyy) 10 SEP 2020	
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Hammitt	Laura	
Professional Mailing Address			
Street Address: 415 N. Washington St, 4 th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BSc	1995	University of Utah, USA	
MD	1999	University of Utah, USA	
Medical License Number			
D72855	Maryland	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	Maryland, USA <i>New Mexico 11 Sept 2020</i>
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA
Brief Summary of Relevant Clinical Research Experience:			
Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials			
Signature:			Signature Date: (dd-Mmm-yyyy) 10 SEP 2020
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Hammitt	Laura	
Professional Mailing Address			
Street Address: 415 N. Washington St, 4 th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BSc	1995	University of Utah, USA	
MD	1999	University of Utah, USA	
Medical License Number			
D72855	Maryland	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	Maryland, USA <i>New Mexico 11 Sept 2020</i>
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA
Brief Summary of Relevant Clinical Research Experience:			
Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials			
Signature:			Signature Date: (dd-Mmm-yyyy) 10 SEP 2020
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Ogbuagu	Onyema	
Professional Mailing Address			
Street Address: 135 College Street, Suite 323		Other Street Address:	
City: New Haven	State/Province: CT	Country: USA	Zip/Postal Code: 06510
Email Address:		Onyema.ogbuagu@yale.edu	
Academic Qualifications: Associate Professor			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	2003	University of Calabar, Cross River State, Nigeria	
Medical License Number	State/Province	Country	
49514	Connecticut	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2018	Associate Professor	Yale University	CT, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2012-2018	Assistant Professor	Yale University	USA
2017-present	Director, Clinical Trials Program	Yale University	USA
2013-present	Visiting Faculty (ID/Inf.Dis)	Nat'l University of Rwanda	Rwanda
Brief Summary of Relevant Clinical Research Experience:			
Principal Investigator (PI) of 7 active COVID-19 treatment studies, 5 HIV-1 treatment studies; one HIV PrEP study; and 4 International research grants Investigator on 8 prior HIV-1 treatment studies, 5 HCV treatment studies, 3 HCV assay studies, 1 intensive PK study; and 2 HIV PrEP studies			
Signature: 		Signature Date: (dd-Mmm-yyyy) 20-JUL-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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Full Name:	Last Name	First Name	Middle Name
	Odekirk	Larry	L
Professional Mailing Address			
Street Address: 1411 S. Potomac Street, Suite 420		Other Street Address:	
City: Aurora	State/Province: CO	Country: USA	Zip/Postal Code: 80012
Email Address:	lodekirk@lhsi.net <i>TL0 12-MAR-21</i>		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
D.O.	1963	University of Medicine & Bioscience, USA	
Medical License Number			
DR. 0014859	State/Province Colorado	Country USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2014	Investigator	Lynn Institute of Denver	Colorado / USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2003 – present	Physician	Plum Creek Medical	USA
2003 – present	Physician	Holland American Cruise Line	USA
Brief Summary of Relevant Clinical Research Experience:			
Investigator has more than 17 years of diverse clinical research experience as a Family Practitioner. He has participated as both PI and Sub-Investigator in numerous industry sponsored Phase II-IV clinical trials over the past 17 years that focus on optimizing the use of medications for health maintenance and disease treatments related to osteoporosis, hypercholesterolemia, hypogonadism, OA, OAB, hypertension, diabetes, Flu vaccine, IBS-C, and Women's health.			
Signature: <i>Larry Odekirk</i>		Signature Date: (dd-Mmm-yyyy) <i>20-Jul-2020</i>	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Kingsley	Jeffrey	Kenneth
Professional Mailing Address			
Street Address: 800 Talbotton Rd		Other Street Address:	
City: Columbus	State/Province: GA	Country: United States	Zip/Postal Code: 31904
Email Address:	jksley@iacthealth.com		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Master of Business Education	2011	Emory University, Atlanta, GA	
Family Medicine Residency	2004	Columbus Regional Medical Center, Columbus, GA	
Family Medicine Internship	2002	Columbus Regional Medical Center, Columbus, GA	
Doctor of Osteopathic Medicine	2001	Philadelphia College of Osteopathic Medicine, Philadelphia, PA	
Master of Science, Biochemistry	1997	University of Scranton, Scranton, PA	
Bachelor of Science, Biology, Chemistry, History, Cultural Anthropology	1996	University of Scranton, Scranton, PA	
Medical License Number	State/Province	Country	
52973	Georgia	United States	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
Jun 2020	Clinical Investigator	IACT Health	Georgia, United States
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2013 – Present	Clinical Investigator	Columbus Regional Research Institute	United States
2005 – 2013	Clinical Investigator	Southeast Regional Research Group	United States
Brief Summary of Relevant Clinical Research Experience:			
Dr. Kingsley has 15 years of experience as a Clinical Investigator, and has participated in 100+ clinical trials across multiple areas, including but not limited to, Cardiology, Dermatology, Endocrinology, Infectious Disease, Nephrology, Pain, and Women’s Health.			
Signature: See appended page for signature and date		Signature Date: (dd-Mmm-yyyy) See appended page for signature and date	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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Signature Page for VV-13400 v1.0

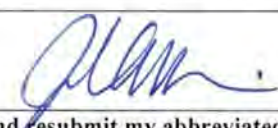
Reason for signing: Approve	Name: Jeff Kingsley Role: Self Date of signature: 29-Jul-2020 11:17:16 GMT+0000
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Signature Page for VV-13400 v1.0

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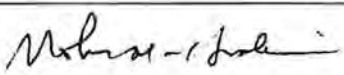
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Vanchiere	John	Anthony
Professional Mailing Address:			
Street Address 1: LSUHSC-Shreveport/Department of Pediatrics		Street Address 2: 1501 Kings Highway	
Shreveport	State/Province: LA	Country: USA	Zip/Postal Code: 71103
Email Address:	jvanch@lsuhsc.edu		
Academic Qualifications: M.D., Ph.D.			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Ph.D. Neuroscience	1996	Emory University; Atlanta, Georgia	
M.D.	1996	Emory University School of Medicine	
Medical License Number	State/Province	Country	
MD023912	LA	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
June 2015	Director of Children's Clinical Research Center	LSUHSC-Shreveport	LA/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
June 2015 – Present	Professor of Pediatrics	LSUHSC-Shreveport	USA
July 2009 – June 2015	Associate Professor - Peds	LSUHSC-Shreveport	USA
June 2007 – June 2009	Assistant Professor – Peds	LSUHSC-Shreveport	USA
January 2003 – May 2007	Assistant Professor – Peds	Baylor College of Medicine	USA
Brief Summary of Relevant Clinical Research Experience:			
20 years of basic, translational and clinical research experience in infectious diseases; 30 NIH- and Pharma-sponsored clinical trials (Phases 1-4), including diagnostics, antibiotics, antivirals and EUAs.			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		29-MAY-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Al-Ibrahim	Mohamed	Salman
Professional Mailing Address			
Street Address: 800 West Baltimore Street		Other Street Address: 5 th floor	
City: Baltimore	State/Province: Maryland	Country: USA	Zip/Postal Code: 21201
Email Address:		Mohamed.al-ibrahim@pharmaron-us.com	
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Bachelor of Medicine, Master of Surgery	1967	Baghdad College of Medicine	
American Board of Internal Medicine	1972	USA	
American Board of Infectious Disease	1974	USA	
Medical License Number			
<i>D0015450</i>	Maryland	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2017	Principal Investigator	Pharmaron	Maryland, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
May 2017-Present	Infectious Disease Specialist	Northwest Hospital	USA
1976-2018	Infectious Disease Specialist	University of Maryland Medical Center	USA
Mar 2016- 15 May 2017	Sr. Advisor	SNBL Clinical Pharmacology Center, Inc	USA
Oct 2006-March 2016	Chief Operating Officer and President	SNBL Clinical Pharmacology Center, Inc	USA
Brief Summary of Relevant Clinical Research Experience:			
Very experienced clinical research and medical professional. Currently serving as Principal Investigator or Sub-Investigator at Pharmaron CPC.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 24 Jul 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Williams	Hayes	T.
Professional Mailing Address			
Street Address: Achieve Clinical Research LLC, d/b/a Accel Research Sites		Other Street Address: 860 Peachwood Drive	
City: DeLand	State/Province: FL	Country: USA	Zip/Postal Code: 32720
Email Address:	<u>hwilliams@accelclinical.com</u>		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Residency: Ears, Nose, Throat	1980	University of Alabama/USA	
Surgical Internship	1977	Baptists Hospital/USA	
Doctor of Medicine	1976	Louisiana State University School of Medicine/USA	
Doctor of Philosophy	1970	University of Alabama/USA	
Master of Science, Genetics	1967	University of Alabama/USA	
Bachelor of Science	1963	University of Alabama/USA	
Medical License Number			
Alabama MD.8063	Alabama	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2008	Medical Director/Investigator	Birmingham Clinical Research Unit	AL/USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2005-2008	Medical Director/Investigator	West Alabama Research, LLC	USA
2001-2005	Investigator	Capstone Clinical Trials, Inc	USA
2001-2001	Physician	Private Practice	USA
1982-2000	Physician	Ear, Nose Throat Private Practice	USA
1980-1982	Physician	Dennis Pappas Sr., MD & Robert Baldwin, MD	USA
Brief Summary of Relevant Clinical Research Experience:			
Served as a Medical Director for Birmingham Clinical Research Unit since 2008.			
Signature:	Signed Electronically by: Hayes T. Williams, MD, PhD - hwilliams@accelclinical.com 20-Jul-2020 @ 01:32 PM CDT Reason: Approval		Signature Date: (dd-Mmm-yyyy)
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.2):

Signed electronically by: Hayes T. Williams, MD, PhD (hwilliams@accelclinical.com)

Date: *20-Jul-2020 @ 01:32 PM CDT*

Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.

090177e1968ea843\Final\Final On: 18-Mar-2021 14:01 (GMT)



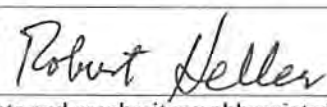
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Grubb	Stephen	D
Professional Mailing Address			
Street Address: Main Street Physician's Care		Other Street Address: 3612 Mitchell Street	
City: Loris	State/Province: SC	Country: USA	Zip/Postal Code: 29569
Email Address: (b) (6)			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Board Cert. Family Medicine	1979, 1986, 1993, 2000, 2008, 2016	American Board of Family Practice, USA	
Board Cert. Geriatrics	1979, 1986, 1993, 2000, 2008, 2016	American Board of Family Practice, USA	
Family Medicine Residency	1978	Medical University of South Carolina USA	
MD	1975	Washington University USA	
Medical License Number	State/Province	Country	
7841	South Carolina	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2018	Physician	Main Street Physician's Care	South Carolina, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1978 – 2018	Physician	Waterway Primary Care LLC dba Tabor City Family Medicine	USA
1992 – 2018	Physician	Waterway Primary Care LLC dba Calabash Medical Center	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Feb 2015 – Apr2019: Sub Investigator – Post Herpetic Neuralgia Mar 2014 – Mar2019t: Sub Investigator – Anticoagulant Medication Post-Marketing Sep 2013 – Feb 2015: Sub Investigator – Influenza Treatment Mar 2013 – Present: Sub Investigator – Lipid Trial Aug 2012 – Jul 2013: Sub Investigator – IBS Trial Aug 2012 – Apr2018: Sub Investigator – Gout Trials Aug 2012 – Present Sub Investigator – Diabetes/Cardiovascular Outcomes (1 trial completed, 2 ongoing) Dec2011 – May 2013: Sub Investigator – Diabetes/Hypertension Aug 2012 – May 2014: Sub Investigator – Asthma Trial Jul 2010 – Present: Sub Investigator - COPD Trials Nov 2009 – Jan 2015 Sub Investigator – A Fib Nov 2008 – Present: Sub Investigator - Diabetes Trials (Oral and Injectable Medication) Oct 2008 – Feb2011: Sub Investigator – Flu Vaccine Trial Sep 2008 – Feb2019: Sub Investigator – Osteoarthritis/Cardiovascular Outcomes July 2008 – October 2009: Sub Investigator Diabetes Trial May 2008- February 2010 Sub Investigator – Hypertension Trial – Elderly Patients May 2008- September 2009 : Sub Investigator – Hypertension Trial Jan 2006-Feb 2007: Sub-Investigator – Restless Legs Syndrome Trial Nov2004- November 2009:: Investigator – Diabetes, Anemia, CKD, Cardiovascular Outcomes Trial Nov 2004-Aug 2006: Investigator –Biphosphonate Osteoporosis Trial Nov 2004-Present: GCP Training Modules-Variou Sponsors (Multiple Modules)</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		23 July 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Heller	Robert	Joel
Professional Mailing Address			
Street Address: 12626 Riverside Drive, Suite 404		Other Street Address:	
City: Valley Village	State/Province: CA	Country: U.S.A.	Zip/Postal Code: 91607
Email Address: rheller@bavviewresearch.com			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
B.S. in Psychology	1957	University of Illinois, Illinois, USA	
M.D.	1961	Chicago Medical School, Illinois, USA	
Internship	1962	Cook County Hospital Illinois, USA	
Residency in Internal Medicine and Endocrinology	1965	Veterans Administration/UCLA, California, USA	
Chief Resident Internal Medicine	1966	Cedars Sinai Medical Center, California, USA	
Diplomat, American Board Internal Medicine	1969	American Board of Internal Medicine®	
Medical License Number	State/Province	Country	
G8042	CA	U.S.A.	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
Jul 2016 - Present	Principal Investigator	Bayview Research Group	CA, U.S.A.
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1966 – Present	Assistant Clinical Professor of Medicine	UCLA Medical Center	USA
1999 – Present	Attending Physician in Internal Medicine, Emeritus	Cedars Sinai Medical Center	USA
2014 -- 2016	CEO	Edge-3D, LLC (3D Microscope Company)	USA
2009 -- 2013	CEO	K Space LLC (Function MRI for Alzheimer's)	USA
2008 --2010	Medical Director	Alpha Health Care, Los Angeles	USA
1980 – 1999	Principal Investigator & Sub-Investigator	Medical Group of Culver City	USA
1966 – 1999	M.D., Owner, and Managing Partner	Medical Group of Culver City	USA
Brief Summary of Relevant Clinical Research Experience:			
Investigator conducting Phase II – IV clinical trials in the following indications:			
<ul style="list-style-type: none"> • Pneumococcal vaccine in adult patients • Women's health: Birth Control, Heavy menstrual period, Uterine Fibroid • Hypocholesteremia in adult patients with CVD • Urge Incontinence Overactive Bladder in adult and geriatric population • Osteoarthritic pain in adult population • Low back pain in adult population • Cytomegalovirus vaccine in adult women • Testosterone Replacement Therapy with CV risks adult men • Vasomotor symptoms in postmenopausal women 			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		23-Jul-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.			

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	<u>Last Name</u>	<u>First Name</u>	<u>Middle Name</u>
	Schear	Martin	
Professional Mailing Address:			
Street Address: 1100 Salem Ave		Other Street Address:	
City: Dayton	State/Province: Ohio	Country: USA	Zip/Postal Code: 45406
Email Address:	(b) (6)		
Academic Qualifications:			
<u>Degree and/or Certification</u>	<u>Date (yyyy)</u>	<u>Institution and/or Country</u>	
Medical Doctor	1977	University of Chicago, USA	
<u>Medical License Number</u>	<u>State/Province</u>	<u>Country</u>	
35.041256	Ohio	USA	
Current Position at Study Site:			
<u>Start Date</u>	<u>Title</u>	<u>Institution or Company</u>	<u>State/Province & Country</u>
1994	PI	Dayton Clinical Research	Ohio/USA
Previous Relevant Positions Including Academic Appointments:			
<u>Start and End Dates</u>	<u>Title</u>	<u>Institution or Company</u>	<u>Country</u>
N/A			
Brief Summary of Relevant Clinical Research Experience:			
25 years as a PI			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		20/JUL/2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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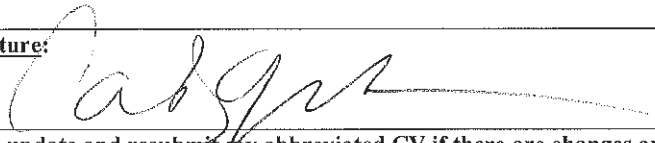
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Finberg	Robert	William
Professional Mailing Address			
Street Address: UMass Medical School 55 Lake Ave North		Other Street Address:	
City: Worcester	State/Province: MA	Country: USA	Zip/Postal Code: 01655
Email Address:	Robert.Finberg@UMASSMED.EDU		
Academic Qualifications: MD			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1974	Albert Einstein College of Medicine	
AB	1971	University of Chicago	
MA	1996	Harvard University (Hon.)	
Medical License Number	State/Province	Country	
40199	MA	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2000	Professor of Medicine	UMass Medical School	Worcester, MA USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
1996-1999	Professor of Medicine	Harvard Medical School	USA
1985-1995	Associate Professor of Medicine	Harvard Medical School	USA
1980-1984	Assistant Professor of Medicine	Harvard Medical School	USA
Brief Summary of Relevant Clinical Research Experience:			
<p>Dr. Finberg's clinical expertise is in the treatment and prevention of infections. His current projects include heading a multi-center study to predict the evolution of influenza viruses and the study of new drugs to treat influenza. Recently he has participated in several COVID-19 trials and continues to work on the pathogenesis and treatment of SARS-CoV-2. He is actively involved in all phases of patient care, from primary care and prevention of disease in healthy people, to treatment of severely immunocompromised hosts. He has a particular focus on the development of ways to ensure health as opposed to treating illness.</p>			
Signature:		Signature Date: (dd-Mmm-yyyy)	
		13-AUG-2020	
<p>I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.</p>			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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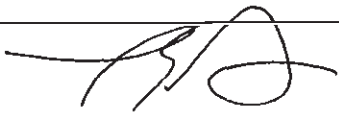
ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Greenbaum	First Name Carla	Middle Name Joy
Professional Mailing Address			
Street Address: 1201 9 th Ave		Other Street Address:	
City: Seattle	State/Province: WA	Country: USA	Zip/Postal Code: 98101
Email Address:	cgreen@benaroyaresearch.org		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
ScB	1978	Brown University USA	
MD	1981	Brown University USA	
Medical License Number	State/Province	Country	
MD090019995	Washington	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2000	Director, Diabetes Program and Center for Interventional Immunology	Benaroya Research Institute	WA, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2007-present	Affiliate Faculty	UW Medicine Diabetes & Obesity Center for Excellence, University of Washington	USA
2000-2003	Associate Member	Virginia Mason Research Center	USA
2003-present	Clinical Associate Professor	Div. of Metabolism, Endocrinology and Nutrition, Dept. of Medicine, University of Washington	USA
2000-2003	Research Associate	DVA Puget Sound Health Care System	USA
Brief Summary of Relevant Clinical Research Experience:			
More than 30 years of clinical research including clinical trials of industry, investigator initiated studies, and academic funded projects.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 30JUL2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Albertson	Timothy	Eugene
Professional Mailing Address			
Street Address: 4150 V Street		Other Street Address: Suite 3400	
City: Sacramento	State/Province: CA	Country: USA	Zip/Postal Code: 95817
Email Address:	tealbertson@ucdavis.edu		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
BA Biology and Psychology	1973	University of California, San Diego, USA	
M.S Pharmacology and Toxicology	1976	University of California, Davis, USA	
M.D Medicine	1977	University of California, Davis, USA	
PhD Pharmacology and Toxicology	1980	University of California, Davis, USA	
Medical License Number	State/Province	Country	
G37112	CA	USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
1993	Professor	University of California Davis Medical Center	CA/ USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2012 – Present	Chair, Department of Internal Medicine	University of California, Davis, School of Medicine,	USA
2011 Present	Health Sciences Clinical Professor, Department of Clinical Pharmacy	University of California, San Francisco	USA
2009 2012	Interim Chair, Department of Internal Medicine	University of California, Davis, School of Medicine	USA
2006 2007	Medical Director for Clinical Care	University of California, Davis Health System	USA
Brief Summary of Relevant Clinical Research Experience:			
Over 20 years of experience with clinical research.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 18-05-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name Towner	First Name William	Middle Name James
Professional Mailing Address			
Street Address: SCPMG/Kaiser Permanente Medical Center, Infectious Disease		Other Street Address: 1505 North Edgemont Street, 2nd Floor	
City: Los Angeles	State/Province: CA	Country: USA	Zip/Postal Code: 90027
Email Address:	William.J.Towner@kp.org		
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
Doctor of Medicine	1993	University of Southern California School of Medicine, USA	
Master of Science	1989	University of California, Los Angeles, USA	
Bachelor of Science	1987	University of California, Los Angeles, USA	
Medical License Number			
80011	State/Province California	Country USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2004	Principal Investigator, Infectious Disease Clinical Research Program	Kaiser Permanente Los Angeles Medical Center	CA, USA
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2013 Present	Regional Physician Director, Division of Clinical Trials	Southern California Permanente Medical Group	USA
2006-Present	Regional Representative, HIV Initiative	Kaiser Permanente and Garfield Memorial Fund of the Permanente Federation	USA
2000-Present	Physician Partner	Southern California Permanente Medical Group (SCPMG)	USA
1997-Present	Assistant Clinical Professor of Medicine	UCLA School of Medicine	USA
Brief Summary of Relevant Clinical Research Experience:			
I have been extensively involved in HIV research for the last 17 years and have served as a PI for over 100 HIV related clinical trials at Kaiser Permanente. These clinical trials have provided HIV positive patients with effective lifesaving medications prior to commercial availability which has saved hundreds of lives and significantly preserved and improved their quality of life. In addition, this work has directly informed the scientific community about the effectiveness and safety of emerging antiretroviral medicines.			
Signature: <i>William Towner, MD</i> <small>William Towner, MD [Jul 20, 2020 16:23 PDT]</small>		Signature Date: (dd Mmm-yyyy) 20-Jul-2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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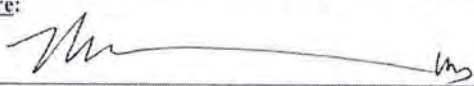
Full Name:	Last Name	First Name	Middle Name
	Sligh	Teresa	Sheahan
Professional Mailing Address			
Street Address: 6400 Laurel Canyon Blvd.		Other Street Address: Suite 300A	
City: North Hollywood	State/Province: CA	Country: USA	Zip/Postal Code: 91606
Email Address: tsligh@providenceclinical.com			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	6/1996	Texas A&M College of Medicine	
BS	6/1987	University of New Mexico	
Medical License Number			
A72660	California	United States	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
10/2003	Medical Director	Providence Clinical Research	California, United States
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
2019 - present	Advisory Board Member	CTIS, Inc.	United States
2001-2003 and 2018-2019	Chief Medical Officer	CTIS, Inc.	United States
2001-2003	Clinical Research Fellow	Univ of Southern CA - Division of Colon & Rectal Surgery	United States
1998-2001	Principal Investigator	Sciman Biomedical Research	United States
Brief Summary of Relevant Clinical Research Experience:			
A total of 30 years in translational research. Twenty of these have been in clinical research as a principal investigator on more than 400 clinical trials. Served as sub-I, monitor/auditor, or coordinator on an additional 27 trials. This spans biological, pharmaceuticals, radio-pharmaceuticals, in vitro diagnostics, serologicals, devices, supplements and botanicals across most therapeutic areas. Have conducted Phase 1, 2, 3, 4, PK/PD, PG, device, health outcomes, real world, MACE, Rx-to-OTC and observational studies. Have served as an IRB reviewing member. Have served as clinical research subject matter expert to NIH software development teams for the development of clinical research applications and databases. Have contributed to clinical development plans, clinical study reports, abstracts & publications.			
Signature: 		Signature Date: (dd-Mmm-yyyy) 31 JUL 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
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ABBREVIATED CURRICULUM VITAE TEMPLATE

Mg 18 Aug 2020

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Nicola	
Professional Mailing Address:			
Street Address 1: Kaiser Permanente Vaccine Study Center One Kaiser Plaza 16 th Floor		Street Address 2:	
City: Oakland	State/Province: California	Country: United States	Zip/Postal Code: 94612
Email Address: Nicola.klein@kp.org			
Academic Qualifications:			
Degree and/or Certification	Date (yyyy)	Institution and/or Country	
MD	1991-1998	New York University School of Medicine, USA	
PhD	1989-1991	New York University School of Medicine, USA	
Medical License Number A69589	State/Province California	Country USA	
Current Position at Study Site:			
Start Date	Title	Institution or Company	State/Province & Country
2006	Co-Director Vaccine Study Center	Kaiser Permanente	California, United States
2006	Research Scientist II	Kaiser Permanente	California, United States
2006	Senior Physician	Kaiser Permanente	California, United States
Previous Relevant Positions Including Academic Appointments:			
Start and End Dates	Title	Institution or Company	Country
n/a			
Brief Summary of Relevant Clinical Research Experience:			
<p>Nicola P. Klein, MD, PhD, is the Director of the Kaiser Permanente Vaccine Study Center, a research group in Oakland, California, since 2006. As a pediatrician vaccine researcher and clinical trial investigator, her research interests include vaccine safety and efficacy, genetic influences on vaccine responses, and vaccine responses among at-risk populations. She is the principal investigator for many ongoing studies of vaccines, biologics, and the epidemiology of infectious diseases, and has published extensively on vaccine safety and effectiveness. In addition, she serves as the Chair of the California Immunization Committee and is the Principal Investigator of the CDC-sponsored Vaccine Safety Datalink (VSD) Project and Clinical Immunization Safety Assessment (CISA) Network. She received her medical degree and doctorate in biochemistry at New York University School of Medicine and completed a residency in pediatric medicine at Lucile Salter Packard Children's Hospital at Stanford University School of Medicine, Palo Alto, CA. She also serves as an adjunct clinical instructor at the Department of Pediatrics at Stanford.</p>			
Signature: 		Signature Date: (dd-Mmm-yyyy) 13 FEB 2020	
I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.			
<p>NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.</p>			

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Site Identifier	Investigator Name	Site Address at Time of Clinical Study	Site Contact Information at Time of Clinical Study
276-01	Armin Schultz	CRS Clinical Research Services Mannheim GmbH Grenadierstraße 1 68167 Mannheim GERMANY	Phone: +49 62115045110 Email: Armin.Schultz@crs-group.de
276-02	Sybille Baumann	CRS Clinical Research Services Berlin GmbH Sellerstraße 31 13353 Berlin GERMANY	Phone: +49 30859949101 Email: Sybille.Baumann@crs-group.de
276-03	Atef Halabi	CRS Clinical Research Services Kiel GmbH Lornsenstraße 7 24105 Kiel GERMANY	Phone: +49 4318999801 Email: Atef.Halabi@crs-group.de
276-04	Antje Blank	Medizinische Universitätsklinik Heidelberg Klinisch-Pharmakologisches Studienzentrum Im Neuhheimer Feld 410 69120 Heidelberg GERMANY	Phone: +49 62215639537 Email: Antje.Blank@med.uni-heidelberg.de
276-05	Maria Vehreschild	Universitätsklinikum Frankfurt Infektiologie Theodor-Stern-Kai 7 60590 Frankfurt GERMANY	Phone: +49 1705376001 Email: Maria.Vehreschild@kgu.de

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CURRICULUM VITAE

Personal Data

Name: Dr Dr Armin Schultz, MD
Date and Place of Birth: (b) (6)
Nationality: German

School Education

(b) (6) Graduation: General Qualification for University Entrance

Career

1977 - 1984 Studies of Biology
Ruprecht Karls University of Heidelberg

1985 - 1986 Diploma Thesis
Institute for Immunology and Genetics
German Center for Cancer Research
Heidelberg

1987 - 1991 Scientific Assistant (PhD Thesis)
Institute for Immunology and Genetics
German Center for Cancer Research
Heidelberg

1991 - 1992 Scientific Employee
Laboratory for Oncologic Surgery
University Clinic for Surgery
Heidelberg

06/1992 Doctorate in Biology (PhD)
Ruprecht Karls University of Heidelberg

1992 - 1998 Studying Human Medicine
Ruprecht Karls University
Heidelberg

04/1998 - 05/1999 Practical Year
General Hospital Schwetzingen

08/1999 - 01/2001 Resident
Institute for Clinical Pharmacology, Faculty for
Clinical Medicine Mannheim of the
University of Heidelberg

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02/2001	License to practice Medicine
as of 08/2001	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
02/2001 – 01/2003	Assistant Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
02/2003 – 03/2007	Senior Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
06/2007	Doctorate in Medicine (MD) Medical Faculty Mannheim of the University of Heidelberg
2004 – 10/2005	Provisional Director of the Institute for Clinical Pharmacology, Medical Faculty Mannheim, University of Heidelberg
since 04/2007	Physician Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
as of 01/2016	Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim

Language Skills

German, native speaker
English fluent in speaking and writing

Armin Schultz
.....
Date 14 JAN 2020

Dr Dr Armin Schultz, MD
Mannheim

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CURRICULUM VITAE

Personal Data

Name: Dr Sybille Katharina Baumann, MD
Date and Place of Birth: (b) (6)
Nationality: German

School Education

(b) (6) Graduation: General Qualification for University Entrance

Career

1979 - 1981 Nursing School
Municipal Hospital
Frankenthal

1981 - 1987 Studying Human Medicine
University of Heidelberg

12.05.1987 Physician Exam

05.06.1987 License to practice Medicine
Regional Administrative Authority Stuttgart

12.05.1987 Doctorate
Institute for Anaesthesia and Resuscitation
Clinic Mannheim

10/1987 - 01/1988 Assistant Physician
Anaesthesia Department
Protestant Hospital "Hochstift"
Worms

02/1988 - 03/1991 Assistant Physician
Anaesthesia Department
District Hospital "Bergstrasse"
Heppenheim

04/1991 - 01/1997 Assistant Physician at the Clinic for Anaesthesia and
Intensive Care Medicine
University Clinics "Saarland"
Homburg/Saar

28.01.1993 Recognition as Doctor for Anaesthesia

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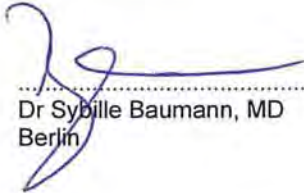
08/1993	Appointment as Functional Head Physician of the University Clinics "Saarland" Homburg/Saar
1995 - 1997	Practice Substitute for Dr. M. Penninger Neustadt/Weinstraße
	Practice Substitute for Dr. A. Penninger Ludwigshafen
07/1997 - 07/1999	Group Practice together with Physicians Dr. Penninger and Dr. Kohler Ludwigshafen
08/1999 – 12/2003	Physician Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH, (IKP GmbH) Grünstadt
since 01/2004	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
01/2004 – 01/2007	Head Clinical Investigator Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH As of January 01, 2007 operating as: CRS Clinical Research Services Mannheim GmbH Mannheim
02/2007 – 03/2007	Clinical Investigator Phase I Abbott GmbH Ludwigshafen
04/2007 – 04/2008	Clinical Investigator Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
02/2015	Recognition as Specialist in Clinical Pharmacology District Medical Association, Karlsruhe


as of 01/2016

Medical Director
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

Language Skills

German, native speaker
English, fluent in writing and speaking


.....
Dr Sybille Baumann, MD
Berlin


.....
Date

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CURRICULUM VITAE

Personal Data

Name: Dr Atef Halabi, MD

Date and Place of Birth:

(b) (6)

Nationality:

German

School Education

(b) (6)

General Qualification for University Entrance

1978 – 1980

German Language Course

Career

1976 – 1978

Studies of Construction Engineering
Damascus, Syria

1981 – 1986

Studies of Human Medicine
Christian Albrechts University
Kiel

1987

License to practice Medicine
Christian Albrechts University
Kiel

06/1988

Promotion thesis:
"Influence of Famotidin on the pharmacokinetic of Nifedipin
and on non-invasive hemodynamic parameters."

1992

Certificate as Emergency Physician

1994

Board certified internal medicine specialist

1986 - 1988

Assistant Doctor, Clinical Pharmacology
Head Prof. Dr. Kirch
Internal Medicine/ University Hospital
Kiel

since 1986

Experience in conducting all types of clinical phase I/IIa
studies (as Co-Investigator and Principal Investigator) in
young and elderly healthy subjects and in patients with
cardiovascular diseases, impaired renal function, liver
diseases, diabetes etc. with different drugs

1988 – 1994	Resident Physician Internal Medicine/University Hospital Head: Prof. Ohnhaus, Prof. Fölsch Kiel
1993 – 1994	Private Assistant of Prof. Dr. Kirch, Clinical Pharmacology Internal Medicine/ University Hospital Kiel
1994 – 07/1998	Head of Clinical Pharmacology Unit Clin-Pharma Research AG Kiel
08/1998 – 08/1999	Executive Medical Director VanTx Research Ltd. Kiel
09/1999 – 09/2000	Managing Partner and Managing Director AVOXOVA GmbH Kiel
10/2000 – 12/2006	Managing Partner and Managing Director Institute for Clinical Pharmacology /Prof. Dr. Lücker – Zentrum Kiel GmbH Kiel
since 1986	Experience as clinical investigator
since 1988	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
since 07/2006	Managing Partner CRS Clinical Research Services GmbH Andernach
since 01/2007	Managing Partner and Managing Director Clinical Pharmacology Unit CRS Clinical Research Services Kiel GmbH Kiel

Language Skills

Arabic, native speaker
English, business fluent in writing and speaking
German, business fluent in writing and speaking

.....
Dr Ater Halabi, MD
Kiel

.....
Date

02 Mar 2020

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CURRICULUM VITAE

PERSONAL INFORMATION

Title, Name: Dr. med. Antje Barbara Blank

Nationality: German

Business Address: Clinical Pharmacology and Pharmacoepidemiology
Internal Medicine Department (Kreihl-Klinik)
Heidelberg University Hospital
Im Neuenheimer Feld 410
69120 Heidelberg
Germany
Phone +49 (0)6221 56 39537,
Fax +49 (0)6221 56 8523
antje.blank@med.uni-heidelberg.de

Current Position: Head of Clinical Trial Unit

EDUCATION

School:

(b) (6) "Abitur" (German university entrance qualification), Kolleg St. Sebastian, Freiburg, Germany

University:

10/1987 – 05/1995 Medical School at the Albert-Ludwigs-University in Freiburg, Germany

04/1991 – 04/1993 Doctoral thesis: Point mutations in the Interferon induced protein Mx1: The antiviral activity is dependent on a functional GTPase-binding motif, Medical School at the University of Freiburg, Department of Virology and Immunology

PROFESSIONAL QUALIFICATIONS

Date	Qualification	University / Institution
05/1995	Final Medical Examination (3. Staatsexamen)	Medical School at the University of Freiburg
07/1995	Doctoral Examination for doctoral thesis and conferment of doctorate	Medical School at the University of Freiburg
07/1995	Temporary license to practice medicine ("Ärztin im Praktikum")	
01/1997	German License to practice medicine ("Approbation")	
05/2012	German Board Certification Clinical Pharmacology ("Facharzt")	Landesärztekammer Baden-Württemberg
12/2013	State certification for academic teaching "Baden Württemberger Hochschullehre Zertifikat"	University of Heidelberg

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02/2009	Project Management Seminar	Akademie für Gesundheitsberufe, Heidelberg
02/2019	Most current certification to conduct clinical trials acc. to GCP as principal investigator	KKS Heidelberg and AGAH e.V.

PREVIOUS APPOINTMENTS

Date	Position	University / Institution
07/1995 – 09 1996	Intern/ resident ("Ärztin in Praktikum")	University Hospital of Heidelberg, Cardiology Department
10/1996 – 02/1997	Resident ("Assistenzärztin")	Transfusion Medicine and Immunology department of the "Blutspendezentrale Nordbaden" / University of Mannheim
04/1997 – 09/ 2001	Research Physician; Clinical Scientist Phase I trials and international multicenter phase III mortality trials	Hoffman – La Roche, Cardiovascular Clinical Development, Roche GmbH, Mannheim, Germany
10/2001 – 06/ 2003	Clinical research consultant (consultancy for Hoffmann La Roche)	<i>Clinical Research Consulting Ltd.</i> , Personal registered clinical research consultancy business, Singapore
07/2003 – 09/2007	Family management	
Since 09/2007	Resident and research physician at the current department. Since 07/2018 deputy head of Clinical Trial Unit. Since 01/2020 Head of Clinical Trial Unit Since 06/2020 Oberärztin <ul style="list-style-type: none">• Trial experience see attachment	

SUMMARY OF TEACHING AND RESEARCH EXPERIENCE

Teaching

- 1996/1997: Teaching at the "Schule für Medizinisch technische Assistenten" at the Mannheim University Hospital.
- Since 2007: Regular academic teaching in clinical pharmacology at the medical school of the university of Heidelberg.

Research

- 1989-1991: PHD research in the department of virology research laboratory of the University of Freiburg.

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Methods of DNA/ RNA and protein molecular biology and cell culture.

- 1995-1996 Heidelberg University Hospital, internal medicine III. Research in atherosclerosis, smooth muscle cell differentiation. Junior Grant of the medical faculty of the Heidelberg University.
- 1997-2001: Research at the clinical development department; cardiovascular group, of Roche Pharmaceuticals.
Mainly clinical phase III studies, regulatory procedures, phase I trials; all cardiovascular indications
- 2001-2003: Consultant for Clinical Research; cardiovascular compounds.
Expert reports, investigator brochures.
- Since 2007: Heidelberg University Hospital, clinical pharmacology and pharmacoepidemiology.
Clinical phase I and II studies, First in man administration.
Clinical expert systems, electronic clinical decision support.

MEMBERSHIPS IN ACADEMIC SOCIETIES AND COMMITTEES:

- Since 02/2012 Arbeitsgemeinschaft für Angewandte Humanpharmakologie e.V. (AGAH)
- Since 07/2019 Member of the Ethics Committee of the Medical Faculty of the Heidelberg University

EXPERIENCE IN CONDUCTION OF CLINICAL TRIALS:

Yes, since 1997, see *attachment* No

23 Nov 2020

Date



Signature

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Clinical Trial Experience

Studies undertaken as research physician at the University Hospital of Heidelberg, Department for Clinical Pharmacology and Pharmacoepidemiology, since September 2007

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/volunteers	Function
1	DNA Biobank for Genotype Screening of Volunteers for the Participation in Clinical Studies	N/A	Non-AMG	healthy volunteers	N/A	Principle Investigator
2	Prospective, open, uncontrolled Phase I Study to evaluate the pharmacokinetics of Artesunate more specifically of its active Metabolite Dihydroartemisinin in Patients with metastatic or locally advanced breast Cancer	I	2007-004432-23	patients with metastatic or locally advanced breast cancer	27	Investigator
3	Monocenter, randomized phase I study to assess the potential induction of CYP3A4 after exposition to honey using midazolam pharmacokinetics as a marker	I	2007-007125-52	healthy volunteers	12	Monitor
4	A monocenter prospective open-label single rising dose study with a new monoclonal antibody, FIM	I; FIM	2006-003777-27	healthy volunteers	57	Investigator
5	Monocenter, single dose, open phase I study to investigate the formation and elimination of 11-nor-9-carboxy- Δ^9 -tetrahydrocannabinol (CTHC) after inhaled administration of 14 mg Δ^9 -tetrahydrocannabinol (THC) in healthy human subjects	I	2007-001284-30	healthy volunteers	10	Monitor
6	Multicenter, open trial to investigate the impact of Efavirenz therapy in HIV patients on the results of drug screening tests	N/A	Non-AMG	HIV patients	18	Coordinating investigator

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/volunteers	Function
7	A randomised, placebo-controlled, double-blind dose escalation study to evaluate the efficacy, safety and pharmacokinetic properties of the humanised CD4 monoclonal antibody BT061	I/IIa	2007-003530-42	patients with chronic plaque psoriasis	56	Investigator
8	Multicenter, open-label, clinical first-in-human, single dose escalation i.v. infusion study to evaluate the safety and tolerability of claudiximab (iMAB-362)	I	2008-004719-37	patients with advanced gastroesophageal cancer	5	Investigator
9	An open-label, two-period, single-sequence phase I study to evaluate the pharmacokinetics of AFQ056 when given alone and in combination with ketoconazole	I	2008-004107-66	healthy volunteers	17	Investigator
10	Multicenter, two-part, open-label, dose escalation, FIM, Phase I/II study of the tumor-targeting human L19IL2 monoclonal antibody-cytokine fusion protein in combination with gemcitabine in patients with advanced pancreatic cancer	I/II; FIM	2007-001609-81	patients with advanced pancreatic cancer	6	Investigator
11	First-in-human, monocenter, double-blind, placebo-controlled, phase I dose escalation study to examine safety, tolerability, and immune response to the investigational VEGFR-2 DNA vaccine VXM01	I, FIM	2011-000222-29	patients with pancreas carcinoma	72	Investigator
12	Randomized, open mono-centre, phase I-trial to investigate the time course of CYP3A4 inhibition using a new limited sampling strategy of midazolam as a marker for CYP3A4 activity	I	2009-013060-39	healthy volunteers	16	Monitor
13	An open-label, single center Phase Ia clinical trial to evaluate the safety, tolerability, and pharmacokinetics of Myrcludex B	Ia	2010-022776-31	Healthy volunteers	36	Investigator

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/volunteers	Function
14	A proof-of-concept Phase II study to evaluate efficacy, safety and pharmacokinetics of 4SC-201 and the treatment combination of Sorafenib plus 4SC-201 in patients with hepatocellular carcinoma exhibiting progressive disease under Sorafenib treatment	II	2009-010760-42	patients with hepatocellular carcinoma	12	Investigator
15	Multicenter Phase I, open-label, non-placebo controlled study to determine the safety, pharmacokinetics, and pharmacodynamics of BAY 73-4506 in combination with FOLFOX or FOLFIRI as first or second line therapy	I	2008-007151-27	patients with metastatic colorectal cancer	5	Investigator
16	Two-part, randomized, double-blind, placebo-controlled, single dose, dose escalating phase I study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and to explore the pharmacodynamics of CDP7657	I	2009-013617-10	Patients with systemic Lupus erythematosus	1	Investigator
17	Open-label, cross-over, monocenter, randomised phase I study to investigate the effect of ketoconazole and fluconazole as an inhibitor of CYP3A4 on PXR-mediated induction of CYP3A4 activity	I	2010-018962-22	healthy volunteers	14	Monitor
18	Multicenter, randomised, replicate administration, four-way change-over, single dose bioequivalence study Xeloda - Capecitabine	I	2009-015067-14	patients receiving Xeloda as cancer treatment	1	Investigator
19	Phase I/II, randomized, open-label, multi-centre dose-escalation study to investigate safety and tolerability of BIBF1120 in conjunction with radiotherapy	I/II	2011-000921-61	Patients with first or second progression of glioblastoma	12	Investigator
20	A phase I trial to assess the safety and immunogenicity of the HD-MSP1-Vac1 malaria vaccine	I	2016-002463-33	Healthy volunteers	32	Deputy Investigator

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
21	Open-label, monocentre, two period, one sequence clinical phase I trial to evaluate influence of OATP1B1 and CYP2C9 genotypes on the pharmacokinetics of steady state bosentan before and during CYP3A4-inhibition by clarithromycin	I	2010-021392-93	healthy volunteers	12	Investigator
22	A phase I/II study to evaluate the safety, tolerability pharmacokinetics and efficacy of resminostat (4SC-201) in combination with a second line treatment	I / II	2010-020171-23	patients with k-ras mutated advanced colorectal carcinoma	11	Investigator
23	Open-label, monocenter, one sequence phase I trial to investigate the influence of CYP3A4-induction by SJW on the steady state pharmacokinetics of bosentan	I	2010-022328-64	healthy volunteers	14	Responsible investigator
24	Open-label, monocentre, one sequence clinical phase I trial to investigate the influence of CYP3A4-induction by St. John's wort (SJW) on the steady state pharmacokinetics of ambrisentan	I	2010-022868-13	healthy volunteers	14	Investigator
25	International, multicenter, open label, phase II study to investigate the efficacy and safety of multiple doses of IMAB362	II	2009-017365-36	patients with advanced gastroesophageal cancer	5	Investigator
26	Phase I, open-label, single oral dose study to investigate the pharmacokinetics safety and tolerability of ACT-179811	I	2009-017945-71	Patients with Clostridium difficile infection	0	Investigator
27	Open-label, multicentre, dose-escalation study to characterize the safety and preliminary efficacy of the human anti-CD38 antibody MOR03087 in adult subjects with relapsed/refractory multiple myeloma as monotherapy and in combination with standard therapy	I, FIM	2009-015942-50	patients with multiple myeloma	43	Investigator

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/volunteers	Function
28	Randomised, placebo-controlled, cross over phase I study to evaluate the pharmacokinetic interactions between the weak opioid tilidine with grapefruit juice and efavirenz	I	2010-024658-12	healthy volunteers	12	Monitor
29	Open label, two arm, one-sequence, two phase, randomised, mono-centre, dose escalation phase I study to evaluate pharmacokinetic linearity of parent drug and metabolites before and during CYP3A inhibition after microdosing of Midazolam	I	2011-000540-21	healthy volunteers	14	Investigator
30	Open-label, prospective, dose escalation, PK- and safety study, non-randomized, multi-center with single agent CetuGEX™	I	2010-019552-50	patients with advanced and/or metastatic cancer	6	Investigator
31	Open-label, randomized, three-sequence, two-period, single-centre phase I study with oral administration of midazolam, simvastatin and ritonavir	I	2011-004297-29	healthy volunteers	18	Investigator
32	Pharmacokinetic Enhancement of Crizotinib plasma concentrations with Cobicistat or Itraconazole in Anaplastic Lymphoma Kinase positive advanced Non-Small Cell Lung Cancer Patients (PrECIsioN)	I	2016-002187-14	Non-Small Cell Lung Cancer Patients	0	Medical Member of the Study Group
33	Prospective, open-label, randomized, monocenter, phase I study to investigate pharmacokinetic and pharmacodynamic properties of single SC doses of the humanized monoclonal antibody BT061	I	2011-004956-20	healthy volunteers	36	Investigator
34	A multi-center, open-label, dose escalation, Phase 1 study of oral LGH447 (FIM)	I; FIM	2011-003820-10	patients with multiple myeloma	38	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
35	Phase I, multi-center, non-randomized, open label, dose escalation design study to investigate safety, PK, QT/QTc and anti-tumor activity of sorafenib-eribulin combination.	I	2011-005849-12	patients with advanced, metastatic or refractory solid tumors	16	Investigator
36	An autoinhibition study with voriconazole under measurement of the hepatic and total CYP3A4 activity measured with midazolam microdosing	I	2012-000970-52	healthy volunteers	28	Investigator
37	An open-label, Phase I, FIM dose-escalation study to characterize the safety, tolerability, pharmacokinetics, and maximum tolerated dose of BAY 1000394 given in 3 days on/4 days off schedule	I; FIM	2010-019191-79	Patients with CLL, NHL and Hodgkin Lymphoma	2	Investigator
38	Evaluating a drug interaction of topical erythromycin on CYP3A4 using midazolam as a marker substance	I	2012-004272-19	healthy volunteers	16	Investigator
39	A double-blind, randomized, placebo-controlled, single ascending dose study to assess the safety, tolerability, pharmacokinetics, immunogenicity and pharmacodynamics of the plasmacytoid dendritic cell specific humanized monoclonal antibody MB101	I; FIM	2013-001923-38	patients with Psoriasis	9	Medical Member of the Study Group
40	Randomized open-labelled two-arm phase I microdose study of the CYP2E1 marker substrate chlorzoxazone evaluating pharmacokinetic linearity of parent drug and metabolite and effect of midazolam clearance	I	2014-003348-11	healthy volunteers	14	Medical Member of the Study Group
41	Open-labelled, sequential one phase explorative drug interaction study to analyse the time dependence of the drug-drug interaction between the novel antiretroviral drug rilpivirine and the phospho-diesterase-5-inhibitor tadalafil	I	2013-002212-28	healthy volunteers	18	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
42	A Phase I, multi-center, non-randomized, open-label, dose escalation design study to characterize safety, tolerability, pharmacokinetics and maximum tolerated dose of BAY 1125976	I	2012-004671-39	patients with advanced tumors	30	Deputy investigator
43	Open labelled drug-interaction phase I study to investigate the effect of increasing doses of St. John's Wort and Rifampicin co-administration on CYP3A-activity and Oral Glucose Tolerance Test	I	2013-004374-10	healthy volunteers	12	Deputy investigator
44	Open labelled drug-interaction phase I study to investigate the live assessment of CYP3A Activity during administration of Modulators of CYP3A or Placebo (Midazolam CLAMP) under midazolam continuous infusion	I	2013-004869-14	healthy volunteers	32	Deputy Investigator
45	Assessment of a potential drug-drug interaction between the novel antiviral drug candidate Myrcludex B and the nucleotide analogue reverse transcriptase inhibitor tenofovir	I	2014-003289-26	healthy volunteers	12	Deputy investigator
46	A phase Ib/II, multi-center, open-label study of oral LGH447 in combination with oral BYL719	Ib/II	2013-004959-21	patients with relapsed and refractory multiple myeloma	2	Medical Member of the Study Group
47	Phase 3, randomized, open-label, active-controlled, parallel-group, multicenter study comparing Daratumumab, Lenalidomide, and Dexamethasone vs Lenalidomide and Dexamethasone	IIIb	2013-005525-23	subjects with relapsed or refractory multiple myeloma	3	Medical Member of the Study Group
48	First-in-human Clinical Study with RNA-Immunotherapy Combination of IVAC_W_bre1_uID and IVAC_M_uID for Individualized Tumor Therapy in Triple Negative Breast Cancer Patients	I, FIM	2014-002274-37	Patients with triple negative breast cancer	1	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
49	Open-label, multicenter phase I study in patients with metastatic colorectal cancer with liver metastasis under second or third line therapy to examine safety, efficacy, and immune biomarkers after treatment with VX001	I	2015-003068-34	Patients with metastatic colorectal cancer with liver metastasis	24	Medical Member of the Study Group
50	A Multicenter, Open-label, Randomized Clinical Study to Assess Efficacy and Safety of 3 Doses of Myrcludex B for 24 Weeks in Combination with Tenofovir Compared to Tenofovir Alone to Suppress HBV Replication in Patients with Chronic Hepatitis D	II	2016-000395-13	Patients with chronic hepatitis D	6	Deputy Investigator
51	Pilot Study on the effect of Myrcludex B on lipid metabolism, metabolic parameters, myocardial function, myocardial tissue and vascular function in volunteer patients with dyslipidemia	I	2017-003137-28	patients with dyslipidemia	59	Deputy investigator
52	Multi-center, randomized, placebo-controlled, double-blind parallel group, Phase Ib study to evaluate the effect of 0.4 mg nitroglycerin spray after pretreatment with multiple oral doses of 2.5 mg, 5 mg and 10 mg vericiguat (BAY 1021189) each given over 14 ± 3 days on safety, tolerability and blood pressure in a multi-center, randomized, placebo-controlled, double-blind group comparison study in - VERiciguat Nitroglycerin Clinical IntEraction (VENICE) study	Ib	2015-001444-11	Patients with stable coronary artery disease (CAD)	14	Medical Member of the Study Group
53	Non-randomized 3-phase sequential clinical trial to evaluate the pharmacokinetics of single regular dose and microdose chlorzoxazone after chronic alcohol consumption and after oral disulfiram administration (Premier cru)	I	2015-005227-34	Healthy volunteers	8	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
54	A Phase 1a/1b Multicenter, Single-Arm, Open-Label, Dose-Escalation Study to Determine the Maximum Tolerated Dose, Safety, and Preliminary Activity of Oral ACY-241 Alone and in Combination With Pomalidomide and Low-Dose Dexamethasone	Ia/Ib	2015-002922-38	Patients With Relapsed or Relapsed-and-Refractory Multiple Myeloma	7	Medical Member of the Study Group
55	Assessment of the effect of drug formulation on the extent of the pharmacokinetic interaction between voriconazole and tacrolimus	I	2016-004137-24	Healthy volunteers	18	Medical Member of the Study Group
56	Open-label, single-centre, fixed-sequence, randomised, two-arm, cross-over trial to investigate the effect of food on the pharmacokinetics of once-daily prolonged-release tacrolimus	I	2017-000410-32	Healthy volunteers	36	Medical Member of the Study Group
57	Pharmacokinetic interaction of macitentan with rivaroxaban and effect of CYP3A4 induction by St. John's wort (SJW) on the steady-state pharmacokinetics of macitentan and its active metabolite in healthy volunteers - ϕ_{max} (Phimax)	I	2016-002300-61	Healthy volunteers	12	Medical Member of the Study Group
58	A Multicenter, Phase 1/1b, Open-Label, Dose-Escalation Study of ABBV-838, an Antibody Drug Conjugate	I/Ib	2014-002609-39	Subjects with Relapsed and Refractory Multiple Myeloma	6	Medical Member of the Study Group
59	characterisation of Yohimbine after oral administration in relation to different CYP2D6 genotypes	I	2017-001801-34	healthy volunteers	18	Deputy Investigator
60	Open-label, monocenter trial to evaluate the pharmacokinetic linearity of microdosed factor Xa antagonists in healthy volunteers	I	2017-000293-11	Healthy Volunteers	20	Medical Member of the Study Group
61	Pharmacokinetics of microdose rivaroxaban, apixaban and edoxaban co-administrated with ketoconazole, voriconazole, rifampicin and a fixed combination of elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide fumarate	I	2016-003024-23	Healthy volunteers	18	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
62	Effects of ciclosporin and its combination with fluconazole on the pharmacokinetics of rivaroxaban in healthy volunteers	I	2016-003120-23	Healthy volunteers	12	Medical Member of the Study Group
63	A Phase 1B multicenter, open-label study to determine the Recommended Dose and Regimen of durvalumab (MED14736) either as monotherapy OR in combination with pomalidomide (POM) with or without low-dose dexamethasone (dex)	Ib	2015-003066-93	subjects with Relapsed and Refractory Multiple Myeloma (RRMM)	6	Medical Member of the Study Group
64	Pharmacokinetics of microdose rivaroxaban, apixaban and edoxaban in geriatric patients	I	2017-000785-29	geriatric patients	0	Deputy investigator
65	A Phase 2, Multicenter, Open-label, Study to Determine the Safety and Efficacy for the Combination of Durvalumab (DURVA) and Daratumumab (DARA) (D2)	II	2016-001209-17	Subjects with Relapsed and Refractory Multiple Myeloma	2	Medical Member of the Study Group
66	A Phase Ib/II Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 in Combination with Durvalumab (MED14736) or Tremelimumab or the Combination of Durvalumab and Tremelimumab Compared to IMCgp100 Alone (IMCgp100-201)	Ib/II	2015-002971-12	Patients with Advanced Melanoma	13	Medical Member of the Study Group
67	Phase I open label, multi-center study to characterize the safety, tolerability and pharmacokinetics of intravenously administered MIK665, a Mcl-1 inhibitor, in patients with refractory or relapsed lymphoma or multiple myeloma	I	2016-003624-22	Multiple Myeloma	3	Medical Member of the Study Group
68	A Phase 1, Open-label, Drug Interaction Study to Evaluate the Effect of Ustekinumab on Cytochrome P450 Enzyme Activities Following Induction and Maintenance Dosing in Participants with Moderate to Severe Crohn's Disease.	I	2017-000831-16	Crohn's Disease	4	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
69	Vericiguat ISOsoRbite mononitrate interaction (VISOR) study, multi-center, randomized, placebo-controlled, double-blind group comparison study to investigate safety, tolerability and blood pressure of 2.5 mg, 5.0 mg and 10 mg vericiguat each given over 14 ± 3 days together with isosorbite mononitrate (ISMN) 60 mg extended release formulation after a pretreatment phase (ISMN-starting dose: 30 mg)	Ib	2016-005178-36	stable coronary artery disease (CAD) patients with or without heart failure	6	Medical Member of the Study Group
70	A phase 1 first-in-human, randomized, double-blind, placebo-controlled dose escalation trial of a single intravenous dose of the anti-herpes simplex virus monoclonal antibody HDIT101 in healthy volunteers	I, FIM	2017-004452-37	healthy volunteers	24	Deputy Investigator
71	Dose-dependent inhibition of CYP2C19 and CYP3A metabolism by meropenem	I	2017-003136-37	Healthy volunteers	18	Sub-Investigator
72	Phase II open-label, single-arm, multicenter trial of MP0250 plus bortezomib+dexamethasone	II	2016-002771-10	Subjects with Relapsed and Refractory Multiple Myeloma	2	Medical Member of the Study Group
73	Study to clinically evaluate the QT/QTc interval prolongation potential of vericiguat in patients with stable coronary artery disease in a 2-arm, placebo-controlled, randomized, double-blind, double-dummy design including a vericiguat multiple-dose part with fixed up-titration periods and moxifloxacin as positive control (for assay sensitivity testing, nested into the placebo treatment)	Ib	2017-003094-33	stable coronary artery disease (CAD) patients with or without heart failure	5	Medical Member of the Study Group
74	Phase I/Ib, multi-center, open-label, study of single agent CJM112, and PDR001 in combination with LCL161 or CJM112	I/Ib	2016-005130-30	Multiple Myeloma	10	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
75	A Phase I/II Study of Cobimetinib Administered as Single Agent and in Combination with Venetoclax, with or without Atezolizumab	Ib/II	2017-000830-68	Multiple Myeloma	4	Medical Member of the Study Group
76	Assessment of pharmacokinetic interactions between azole fungistatics drugs and three factor Xa inhibitors administered simultaneously	I	2017-004453-16	healthy volunteers	14	Deputy Investigator
77	Use of Doxapram as a new antiarrhythmic drug for a specific therapy of atrial fibrillation Doctos Trial (Doxapram conversion to sinus rhythm study)	Ib/IIa	2018-002979-17	patients with atrial fibrillation	9	Deputy
78	Assessment of a potential drug-drug interaction between the antiviral drug candidate myrcludex B and the OATP-substrate pravastatin	I	2018-000012-21	Healthy volunteers	20	Principle Investigator
79	An open-label Phase Ib/ II, multi-center study of 4SC-202 in Combination with Pembrolizumab	Ib/II	2017-001050-33	Participants with Advanced or Metastatic Solid Tumors	8	Medical Member of the Study Group
80	A Clinical Phase II, multicenter, Open-label study evaluating induction, consolidation and maintenance treatment with Isatuximab (SAR650984), Carfilzomib, Lenalidomide and Dexamethasone (I-KRd) in Primary diagnosed high-risk multiple myeloma patients GMMG-CONCEPT	II	2016-000432-17	Multiple Myeloma	6	Medical Member of the Study Group
81	A Phase 1, Open-Label, Multicentre, Non-Randomized Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of AZD4573, a Potent and Selective CDK9 Inhibitor, in Subjects with Relapsed or Refractory Haematological Malignancies	I	2017-000817-22	hematological malignancies	0	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/volunteers	Function
82	An open labelled first human dose phase 1/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualised VB10.NEO immunotherapy in patients with locally advanced or metastatic melanoma, NSCLC, clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of head and neck, who did not reach complete responses with current standard of care immune checkpoint blockade	I/IIa	2017-002474-39	patients with skin cancers	11	Medical Member of the Study Group
83	Assessment of the effect of the potential perpetrator effects of clarithromycin, carbamazepine, gabapentin, and pregabalin on the pharmacokinetics of edoxaban and a microdosed cocktail of three simultaneously administered factor Xa inhibitors	I	2018-002490-22	healthy volunteers	48	Deputy Investigator
84	A Phase II Randomized, Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 Compared with Investigator's Choice in HLA-A*0201 Positive Patients with Previously Untreated Advanced Uveal Melanoma (IMCgp100-202)	II	2015-003153-18	Patients with Uveal Melanoma	9	Medical Member of the Study Group
85	A phase 1B/2A multicenter, open-label, doseescalation study to determine the maximum tolerated dose, assess the safety and tolerability, pharmacokinetics and preliminary efficacy of CC-220 Monotherapy, in combination with Dexamethasone, and in combination with Dexamethasone and Daratumumab or Bortezomib in subjects with relapsed and refractory multiple myeloma.	Ib/IIa	2016-000860-40	Multiple Myeloma	2	Medical Member of the Study Group
86	A Phase I/II, Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 using the Intra-patient Escalation Dosing Regimen in Patients with Advanced Uveal Melanoma (IMCgp 100-102)	I/II	2015-004222-34	Patients with Uveal Melanoma	9	Medical Member of the Study Group

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No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
87	A Phase 1 open-label study, evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of AMG701 in subjects with multiple myeloma.	I	2017-001997-41	patients with multiple myeloma	3	Medical Member of the Study Group
88	A Multicenter, Open-label, Randomized Phase 3 Clinical Study to Assess Efficacy and Safety of bulevirtide in Patients with Chronic Hepatitis Delta	III	2019-001213-17	patients with HBV/HDV	4	Principle Investigator
89	A Randomized Open-Label Phase ½ Study of INCB001158 Combined With Subcutaneous (SC) Daratumumab, Compared to Daratumumab SC, in Participants with Relapsed or Refractory Multiple Myeloma	I / II	2018-004076-35	patients with multiple myeloma	0	Medical Member of the Study Group
90	A Phase I, First in Human, Double-Blind, Placebo-Controlled, Multicenter, Single and Multiple Ascending Dose Study of NI006 in Patients with Amyloid Transthyretin Cardiomyopathy followed by an Open-Label-Extension	I/FIM	2019-001932-60	patients with ATTR cardiomyopathy	12	Medical Member of the Study Group

23 Nov 2020
Date


Signature

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CURRICULUM VITAE

Prof. Dr. med. Maria Vehreschild , Arzt

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 ZIM II
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Aktuelle Position

Leitung des Instituts, Universitätsklinikum Frankfurt, Goethe Universität, ZIM II, Infektiologie, Haus 68, Theodor-Stern-Kai 7, 60590 Frankfurt, None

Medizinische Qualifikationen

Art	Erläuterung	Datum	Institution	Stadt
1 Sonstige med. Qualifikationen	Bachelor of Sciences Program Psychology, Dauer: 5 months	08.1999	New York University	New York/USA
2 Studium	Medizin, Dauer: 6 years 7 months	04.200	Charité Universitätsmedizin	Berlin
3 Promotion/Doktor-Arbeit	Reserach Neuroradiology, Dauer: 5 years	01.2003	Technical University Munich	Munich
4 Arzt/Ärztin im Praktikum	Dauer: 7 months	10.2004	University of Nice Antipolis	Nice/France
5 Arzt/Ärztin im Praktikum	Dauer: 4 months	10.2005	Federal University of Minas Gerais	Belo Horizonte/Brazil
6 Arzt/Ärztin im Praktikum	Dauer: 8 months	02.2006	University of São Paulo	São Paulo/Brazil
7 Approbation		11.2006	Landesamt für Gesundheit und Soziales	Berlin
8 Assistenzarzt/-ärztin	Hematology/Oncology, Dauer: 10 months	08.2007	University Hospital Cologne	Cologne
9 Assistenzarzt/-ärztin	Emergencies, Dauer: 5 months	07.2008	University Hospital Cologne	Cologne
10 Assistenzarzt/-ärztin	Intensive Care, Dauer: 12 months	01.2009	University Hospital Cologne	Cologne

11	Assistenzarzt/-ärztin	Infectious diseases unit (consultancy Service), Dauer: 6 months	01.2010	University Hospital Cologne	Cologne
12	Assistenzarzt/-ärztin	cardiology, Dauer: 5 months	07.2010	University Hospital Cologne	Cologne
13	Assistenzarzt/-ärztin	Hematology/Oncology, Dauer: 13 months	01.2011	University Hospital Cologne	Cologne
14	Assistenzarzt/-ärztin	Gastroenterology, Dauer: 5 months	03.2012	University Hospital Cologne	Cologne
15	Facharzt/-ärztin	Internal medicin	09.2012		
16	Arzt/Ärztin	Infectious diseases/Hematology/Oncology, Dauer: 5 years	03.2013	University Hospital Cologne	Cologne
17	Habilitation	Internal medicine, Dauer: 5 years	09.2013	University Hospital Cologne	Cologne
18	Facharzt/-ärztin	Infectious diseases	12.2014	Board Examination of the German Society of Infectious diseases (DGI)	Cologne
19	Facharzt/-ärztin	Hematology and Oncology	11.2016		
20	Institutsleitung	Infectious diseases, Dauer: ongoing	08.2018	University Hospital Frankfurt	Frankfurt/Main

Preise

k.A.

Fachgesell.-Mitgliedsch.

1. German Society of Hematology and Oncology (DGHO)
2. German Speaking Mycological Society (DMyKG)

Studienschwerpunkte

k.A.

Fortbildungen und Schulungen bez. Durchfuehrung klinischer Studien

Art	Erläuterung	Datum	Institution	Stadt
1	Prüfarztkurs Dauer: 4 days	26.11.2007	KKS Cologne-Düsseldorf	
2	GCP-Training	03.2009		

3	GCP- Training	online Training GCP/ICH Obligations of Sponsors, Monitors and Investigators	07.2011		
4	GCP-Update	Web Training: Änderungen des Arzneimittelgesetzes	01.2013		
5	GCP- Training	online Training: GCP Combacte	01.2016		
6	GCP- Training	MPG Ergänzungskurs	03.2018	ZKS Köln	Cologne
7	GCP-Update		03.2019	University Hospital Frankfurt	Frankfurt/Main
8	GCP-Update	Dauer: 2h	25.11.2020	Uniklinik Frankfurt	Frankfurt/Main

Teilnahme an klinischen Studien (QualiPRO)

	Rolle	Studiencode	Eudra CT Nr.	Titel	Phase	Studien- Start	Studien- Ende
1	LKP national	IBIS		Prospektive und retrospektive Studie zu Clostridium diff. Infektionen	k.A.	01.01.2019	
2	Prüfer (engl.: PI)	CALVID-1	2020- 001264- 28	A Prospective, Multi-Center, Randomized, Placebo-Controlled, Double-Blinded Study to Evaluate the Efficacy, Safety and Tolerability of IMU-838 as Addition to Investigator's Choice of Standard of Care Therapy, in Patients with Coronavirus Disease 19	2	04.05.2020	
3	Prüfer	FURI	2017- 000381- 29	Open-Label Study to Evaluate the Efficacy and Safety of Ibrexafungerp in Patients with Fungal Diseases that are Refractory to or Intolerant of Standard Antifungal Treatment	3	05.07.2017	
4	Prüfer (Stellv.)	CALAVI	2020- 001644- 25	A Phase 2, Open Label, Randomized Study of the Efficacy and Safety of Acabrutinib with Best Supportive Care Versus Best Supportive Care in Subjects Hospitalized with COVID-19	2	06.05.2020	
5	Prüfer (Stellv.)	XPORT-CoV- 1001	2020- 001411- 25	A Phase 2 Randomized Single-Blind Study to Evaluate the Activity and Safety of Low Dose Oral Selninexor (KPT-330) in Patients with Severe Covid-19 Infection (XPORT-CoV-1001)	2	14.04.2020	
6	Prüfer (Stellv.)	Adaptive COVID-19 Treatment Trial (ACTT)	2020- 001052- 18	A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19	k.A.	25.03.2020	

7	Prüfer (Stellv.)	Adaptive COVID-19 Treatment Trial (ACTT)	2020-001052-18	A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19	k.A.	25.03.2020
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Andere klinische Studien und Projekte (nicht QualiPRO):

1. 2693 ABSSSI
2. 1134 ACT-179811 eudra-ct: 2010-020941-29
3. 1159 Ambiguard eudra-ct: 2010-019562-91 Phase 3
4. 2530 ANEMONE
5. 599 Anidulafungin/Voriconazole eudra-ct: 2007-002445-20
6. 3080 ANIMA Role: LKP,PI
7. 2801 ANTICIPATE
8. 3104 APX001-103 eudra-ct: 2017-000524-10
9. 3229 APX001-201 eudra-ct: 2017-003571-56
10. 2111 ASARI Role: PI
11. 3078 ASARI II
12. 2979 ASN100-201 eudra-ct: 2016-002146-23 Phase 2
13. 268 Aspergillus terreus-Epidemiologie
14. 986 AsPIRS n.a.
15. 882 BCX1812-301 eudra-ct: 2009-012367-34 Phase 3
16. 3005 BLOOMY Role: PI
17. 2019 Cadazolid/ ACT-179811 eudra-ct: 2013-002528-17
18. 184 CASLAMB
19. 172 Caspofungin High Dose eudra-ct: 2005-004504-36
20. 175 Caspofungin MTD eudra-ct: 2006-001936-30 Phase 2
21. 1969 CDAD und intestinale Mikrobiota
22. 2789 CDIFF
23. 1915 C-DIFF H-030-014 eudra-ct: 2013-000775-32
24. 2777 CLARITY
25. 1962 CLEAR eudra-ct: 2013-003048-21 Role: LKP,PI,PM
26. 3008 CLOVER eudra-ct: 2016-003866-14
27. 1528 COAT
28. 1278 CoCoNut entfällt
29. 3030 COLLECT Role: PI
30. 1968 CONTAIN Role: LKP,PI
31. 2623 CONTROL Role: LKP, PI
32. 985 CytoFab - AZD9773
33. 3103 DAENARYS
34. 2733 DIVA
35. 815 EpiDi Role: LKP,PI
36. 2374 Eradicate eudra-ct: 2014-000180-41
37. 1498 ESBL-E
38. 2664 EVADE eudra-ct: 2015-001706-34 Phase 2

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39. 2358 EXTEND eudra-ct: 2013-004619-31 Phase 3b/4
40. 3492 F2G eudra-ct: 2017-001290-17 Phase 2b
41. 1675 FREEDOM eudra-ct: 2012-000531-88 Phase 3b/4
42. 498 Fungiscope
43. 2986 FURI (SCY-078-301) eudra-ct: 2017-000381-29 Role: SI Phase 3
44. 2232 GMALL 08/2013 eudra-ct: 2013-003466-13 Phase 4
45. 541 HD17 für intermediäre Stadien eudra-ct: 2007-005920-34
46. 3305 HERACLES eudra-ct: 2017-002697-39
47. 3015 IBIS Role: LKP, PI
48. 564 IC43-201
49. 171 IDEA (Voriconazol) nicht vorhanden
50. 2823 IMBICO
51. 952 INTENSE 2008-006409-18
52. 392 Isavuconazole WSA-CS-003 eudra-ct: 2006-005003-33 Phase 3
53. 246 Isavuconazole WSA-CS-004 eudra-ct: 2006-003868-59 Phase 3
54. 247 Isavuconazole WSA-CS-008 eudra-ct: 2006-003951-18
55. 1782 KPUK-14-GenPOPPK
56. 1660 LCD-CDAD-10-07 (CUBIST) eudra-ct: 2012-000252-34
57. 1674 LFF571 eudra-ct: 2011-000947-26
58. 115 Maribavir eudra-ct: 2006-005692-18
59. 2375 MicroTrans
60. 2905 Minocin® 702 eudra-ct: 2016-002247-41
61. 2649 ML-3341-306 (Delafoxacin) eudra-ct: 2015-003026-14 Phase 3
62. 1547 MODIFY I eudra-ct: 2011-004590-90 Role: SI Phase 3
63. 1535 MODIFY II eudra-ct: 2011-004590-90 Phase 3
64. 176 Moxifloxacinprophylaxe bei autologer SZT eudra-ct: 2005-003271-21
65. 2822 MSG-11
66. 1865 NanoMR
67. 3262 NIDIFF eudra-ct: 2017-004531-36
68. 3107 Online Registry for Chronic Pulmonary Aspergillosis (CPA) Infections: A CPAnet Initiative
69. 2564 ORCHID
70. 269 P05115 eudra-ct: 2007-003148-31 Phase 4
71. 826 P05520 eudra-ct: 2008-000235-18 Role: SI
72. 861 P05615 eudra-ct: 2008-006684-36 Role: SI
73. 1786 P06200 eudra-ct: 2011-003938-14 Phase 3
74. 113 PAR-101 bei C. diff.-assoziiertes Diarrhö eudra-ct: 2006-004291-12
75. 3523 PILGRIM
76. 1504 PIMDA
77. 999 PROGRESS-CAP
78. 2663 REJUVENATE eudra-ct: 2015-002726-39 Phase 2a
79. 3522 Ri-CoDIFy eudra-ct: 2017-001642-10 Phase 3
80. 2935 R-Net Prävalenz
81. 2415 SAATELLITE eudra-ct: 2014-001097-34 Phase 2
82. 2787 SAFEGUARD eudra-ct: 2016-000919-33
83. 2971 SAFEGUARD FP eudra-ct: 2016-002271-97 Phase 2a
84. 2595 SCY-078-202

- 85. 2056 SEPIA Role: LKP,SI
- 86. 3364 SHIELD
- 87. 2803 STRIVE eudra-ct: 2015-005599-51 Phase 2
- 88. 2587 Urinstudie
- 89. 1107 V-212-001 eudra-ct: 2010-020150-34 Phase 3
- 90. 1266 V-212-011 eudra-ct: 2010-023156-89 Phase 3
- 91. 173 Vosifi eudra-ct: 2004-000365-35
- 92. 1160 VP 20621-200 eudra-ct: 2010-020484-20 Phase 2
- 93. 1163 VP 26021-901

Publikationen

k.A.

Frankfurt 21.12.2020

Ort, Datum/City, date



Unterschrift/Signature

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Anhang: Erläuterungen

1. **Aktuelle Position seit:** CV Pflichtfeld: Angabe zum Beginn der aktuellen Funktion in der Organisation (dd.mm.yyyy).
2. **Publikationen:** CV Pflichtfeld: Liste der wichtigsten und aktuellsten Publikationen aufsteigend in chronologischer Reihenfolge; Empfehlung: max. 5 Angaben.
3. **Andere klinische Studien und Projekte:** Liste der wichtigsten und aktuellsten Studien und Projekte, die nicht in QualiPRO („Studien“, „Anträge“) eingegeben sind. Eingabe als Freitext bitte aufsteigend in chronologischer Reihenfolge unter Angabe von
 - Studientitel (dieser muß nicht vollständig sein, sollte aber die Indikation und Phase beinhalten, oder diese müssen ergänzt werden)
 - Indikation (falls nicht im Studientitel enthalten)
 - Phase (falls nicht im Studientitel enthalten)
 - EudraCT-Nr. (ggf.)
 - Beginn (mind. Jahresangabe) und
 - Ende der Studie (mind. Jahresangabe) und
 - Funktion in der Studie.
4. **Teilnahme an klinischen Studien (QualiPRO):** CV Pflichtfeld: Eintrag erfolgte über das Menü "Anträge" in QualiPRO: "Automatische" und tabellarische Auflistung der Teilnahme an klinischen Studien, die in die Datenbank QualiPRO eingegeben sind, mit Detailangaben. Die Auflistung erfolgt nicht chronologisch, sondern gruppiert bzw. priorisiert nach Funktion des Mitarbeiters in der Studie. Das Datum entspricht in der Regel dem Datum des Beginns und/oder des Endes einer Studie gemäß Prüfplan/Sponsor. In Ausnahmen kann es sich bei dem Beginn um den ungefähren Beginn (Jahresangabe) handeln - falls das Datum nicht bekannt ist. Bei genauem Datum handelt es sich um den Beginn laut Prüfplan (oder in absteigender Reihenfolge: Genehmigung in Deutschland oder Initiierung in einem Prüfzentrum oder erster Patienteneinschluss in einem Prüfzentrum). Als Endzeitpunkt der Studie soll nicht das geplante Studienende eingetragen werden, sondern das Studienende, welches der Sponsor festlegt, i. d. Regel "letzter Patient, letzter Visit, letztes Prüfzentrum". In Ausnahmen kann es sich auch um das Rekrutierungsende in Zentren (o.ä.) handeln. Diese tab. Angaben müssen im Menü "Anträge" sorgfältig eingegeben und im Word-Dokument (CV) geprüft und ggf. geändert werden, bevor dieser unterzeichnet wird.

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