Supplemental material

Study design and baseline profile for adults with type 2 diabetes in the once-weekly subcutaneous SEmaglutide randomized PRAgmatic (SEPRA) trial

Contents

Supplemental table 1 Study endpoints and other variables by data source

	Data source	
Endpoint/variable	**eCRF**	**Administrative claims data**
Study drug variables		
On/off study drug	X	
Treatment intensification	X	
Treatment change	X	
Anti-diabetes treatment patterns	X	
Primary endpoint		
HbA1c <7.0% at year 1	X	
Confirmatory endpoints		
Change in HbA1c (%-point) from baseline to year 1	X	
HbA1c <7.0% at year 2	X	
Change in HbA1c (%-point) from baseline to year 1	X	
Supportive secondary endpoint assessment		
Individualized HbA1c target attained at year 1	X	
HbA1c <7.0% (53 mmol/mol) or at least 1%-point improvement in HbA1c at year 1	X	
HbA1c target attainment per HEDIS criteria (<8.0% if age ≥65 years or with defined comorbidities, otherwise <7.0%) at year 1	X	X
Change in body weight from baseline to year 1, lb	X	
Change in body weight from baseline to year 1, %	X	
Change in SBP from baseline to year 1, mmHg	X	
Change in DBP from baseline to year 1, mmHg	X	
Time to first study drug discontinuation during 2 years, day	X	
Time to first treatment intensification (add-on) or change (switch) after randomization during 2 years, day	X	
Study drug medication adherence for the first year of the study, as measured by medication possession ratio, %		X
Number of hypoglycemic episodes leading to an inpatient admission or ER encounter from baseline to year 2	X	
DTSQc, total treatment satisfaction score at year 1	X	
DTSQc, total treatment satisfaction score at year 2	X	
Change from baseline in SF-12 v2, PCS-12 score at year 1	X	
Change from baseline in SF-12 v2, PCS-12 score at year 2	X	
Change from baseline in SF-12 v2, MCS-12 score at year 1	X	
Change from baseline in SF-12 v2, MCS-12 score at year 2	X	
Change from baseline in WPAI-GH absenteeism (work time missed) score at year 1	X	
Change from baseline in WPAI-GH absenteeism (work time missed) score at year 2	X	
Change from baseline in WPAI-GH presenteeism (impairment at work/reduced on-the-job effectiveness) score at year 1	X	
Change from baseline in WPAI-GH presenteeism (impairment at	X	

	Data source	
Endpoint/variable	**eCRF**	**Administrative claims data**
work/reduced on-the-job effectiveness) score at year 2		
Change from baseline in WPAI-GH work productivity loss (overall work impairment/absenteeism plus presenteeism) score at year 1	X	
Change from baseline in WPAI-GH work productivity loss (overall work impairment/absenteeism plus presenteeism) score at year 2	X	
Change from baseline in WPAI-GH activity impairment score at year 1	X	
Change from baseline in WPAI-GH activity impairment score at year 2	X	
All cause HCRU from baseline to year 2		
Number of inpatient admissions		X
Length of stay for inpatient admissions (days) per inpatient admission		X
Cumulative length of stay for inpatient admissions (days)		X
Number of ER encounters		X
Number of physician office visits		X
Number of other outpatient encounters (overall, and by category: tests – lab, imaging, procedures, OT/speech, medication and related services, durable medication equipment, physician other services, tests – other, other)		X
Number of medications		X
Occurrence of inpatient admission		X
Occurrence of ER encounter		X
Occurrence of physician office visits		X
Occurrence of other outpatient encounter (yes/no) (overall, and by category: tests – lab, imaging, procedures, OT/speech, medication and related services, durable medication equipment, physician other services, tests – other, other)		X
Diabetes-related HCRU from baseline to year 2		
Number of diabetes-related inpatient admissions		X
Length of stay for diabetes-related inpatient admissions (days) per diabetes-related inpatient admissions		X
Cumulative length of stay for diabetes-related inpatient admissions (days)		X
Number of diabetes-related ER encounters		X
Number of diabetes-related physician office visits		X
Number of diabetes-related other outpatient encounters (overall, and by category: tests – lab, imaging, procedures, OT/speech, medication and related services, durable medication equipment, physician other services, tests – other, other)		X
Number of diabetes-related medications		X
Occurrence of diabetes-related inpatient admission		X
Occurrence of diabetes-related ER encounter		X
Occurrence of diabetes-related physician office visits		X
Occurrence of diabetes-related outpatient encounter (yes/no) (overall, and by category: tests – lab, imaging, procedures, OT/speech, medication and related services, durable medication equipment, physician other services, tests – other, other)		X

	Data source	
Endpoint/variable	**eCRF**	**Administrative claims data**
Additional derived outcome variables for supportive analyses		
Supportive measures of glycemic control		
Individualized HbA1c target attained at year 2	X	
HbA1c <7.0% (53 mmol/mol) or at least 1%-point improvement in HbA1c compared to baseline at year 2	X	
HbA1c <8.0% (64 mmol/mol) at year 1	X	
HbA1c <8.0% (64 mmol/mol) at year 2	X	
HbA1c <7.0% (53 mmol/mol) and no further anti-diabetes medication intensification after randomization at year 1	X	
HbA1c <7.0% (53 mmol/mol) and no further anti-diabetes medication intensification after randomization at year 2	X	
HbA1c target attainment per HEDIS criteria (<8.0% if age ≥65 years or with defined comorbidities, otherwise <7.0%) at year 2	X	X
HbA1c <7.0% (53 mmol/mol) at year 1 in patients with HbA1c >9.0% at baseline	X	
HbA1c <7.0% (53 mmol/mol) at year 2 in patients with HbA1c >9.0% at baseline	X	
HbA1c <8.0% (64 mmol/mol) at year 1 in patients with HbA1c >9.0% at baseline	X	
HbA1c <8.0% (64 mmol/mol) at year 2 in patients with HbA1c >9.0% at baseline	X	
Body weight loss		
Change in body weight (%) from baseline to year 2	X	
Change in body weight (lb) from baseline to year 2	X	
Blood pressure		
Change in SBP (mmHg) from baseline to year 2	X	
Change in DBP (mmHg) from baseline to year 2	X	
Hypoglycemia		
Reported hypoglycemia leading to inpatient admission or ER encounter during year 1	X	
Reported hypoglycemia leading to inpatient admission or ER encounter during year 2	X	
Composite variables		
HbA1c <7.0% (53 mmol/mol) without experiencing hypoglycemia leading to inpatient admission or ER encounter and body weight loss of ≥5% vs baseline at year 1	X	
Absolute HbA1c reduction of ≥0.5% without experiencing hypoglycemia leading to inpatient admission or ER encounter and a body weight loss of ≥5% vs baseline at year 1	X	
HbA1c <7.0% (53 mmol/mol) without experiencing hypoglycemia leading to inpatient admission or ER encounter and body weight loss of ≥5% vs baseline at year 2	X	
Absolute HbA1c reduction of ≥0.5% without experiencing hypoglycemia leading to inpatient admission or ER encounter and a body weight loss of	X	

	Data source	
Endpoint/variable	**eCRF**	**Administrative claims data**
≥5% vs baseline at year 2		
HbA1c <7.0% (53 mmol/mol) without experiencing hypoglycemia leading to inpatient admission or ER encounter and no body weight gain vs baseline at year 1	X	
HbA1c <7.0% (53 mmol/mol) without experiencing hypoglycemia leading to inpatient admission or ER encounter and no body weight gain vs baseline at year 2	X	
Adherence to treatment		
Study drug medication adherence for the 2 years of the study, as measured by the medication possession ratio (%)		X

DBP, diastolic blood pressure; DTSQc, Diabetes Treatment Satisfaction Questionnaire, change version; eCRF, electronic case report form; ER, emergency room; HbA1c, glycated hemoglobin; HCRU, Healthcare Resource Utilization; HEDIS, Healthcare Effectiveness Data and Information Set; MCS-12, Mental Component Summary; OT, occupational therapy; PCS-12, Physical Component Summary; SBP, systolic blood pressure; SF-12 v2, Short Form 12-Item version 2 Survey; WPAI-GH, Work Productivity and Activity Impairment: General Health questionnaire.

Supplemental table 2 Summary of assessments

SePra	Dedicated study visit, randomization	Routine care visits, Year 1	Dedicated study visit, Year 1	Routine care visits, Year 2	Dedicated study visit, Year 2
Time of visit (weeks)[a]	0*	0–52**	52±6	52–104**	104±6
Patient and treatment-related assessments[b]	X				
Informed consent[c]	X				
Inclusion/exclusion criteria	X				
Demographics (date of birth, gender, race, ethnicity)	X				
Selected medical history	X				
Diabetes history and diabetes complications	X				
Indivisualised HbA1c target[d]	X				
Type of glucose-lowering medication including semaglutide[e]	X	X	X	X	X
Concomitant cardiovascular medication	X	X	X	X	X
Reason for discontinuation of any glucose-lowering medication		X	X	X	X
Effectiveness and safety-related assessments					
Body weight	X	X	X	X	X
Height	X				
SBP/DBP	X	X	X	X	X
HbA1c	X[f]	X	X	X	X
SAEs, pregnancies, and AEs leading to study drug continuation[g]		X	X	X	X
Healthcare resource utilization[h]		X	X	X	X
Hypoglycemia leading to inpatient admission or ER encounter		X	X	X	X
Hypoglycemia leading to inpatient admission or ER		X	X	X	X

SePra	Dedicated study visit, randomization	Routine care visits, Year 1	Dedicated study visit, Year 1	Routine care visits, Year 2	Dedicated study visit, Year 2
encounter					
PROs and physician-completed assessments					
DTSQs	X				
DTSQc			X		X
SF-12 v2	X		X		X
WPAI-GH	X		X		X
PGI-S	X				
PGI-C			X		X
CGI-S	X				
CGI-C			X		X
End of study					
End of study					X

*Eligibility assessment may take place up to 4 weeks prior to the randomization visit. If eligibility assessment occurs prior to the randomization visit, any changes in collected medical history, diabetes history, diabetes complications, glucose-lowering medications and concomitant cardiovascular medications will be collected at the randomization visit.

**The year 1 and year 2 routine diabetic care visit windows are determined by the date of the participant's dedicated year 1 study visit. The year 1 routine diabetic care visit window will end immediately prior to the dedicated year 1 study visit. The year 2 routine diabetic care visit window will begin immediately following the dedicated year 1 study visit.

Note: In this study, data will be collected from two different data sources:

1) Data entered into the eCRF will be collected at dedicated study visits and routine diabetic care visits (if available per local clinical practice) and will include demographics, selected medical history, diabetes medical history and diabetes complications, individualized HbA1c target, type of glucose-lowing medication, concomitant cardiovascular medication, reason for discontinuation of any glucose-lowering medication, body weight, height, SBP, DBP, HbA1c, AEs leading to study drug discontinuation, SAEs, pregnancies and hypoglycemia leading to inpatient admission or ER encounter. Of note, AEs leading to study drug discontinuation or SAEs will be collected from all interactions with the participant, as well as if discovered when reviewing documents from healthcare encounters with other providers. Additionally, PRO and clinician-reported outcome data will be collected at the dedicated study visits and entered into the eCRF.

2) Healthcare resource utilization and pharmacy prescription data will be extracted from health plan medical and pharmacy claims and will not be entered into the eCRF.

[a]Routine diabetic care visits will follow standard of care frequency and any available data will be entered in the eCRF.

[b]Assessments at dedicated study visits will be collected in eCRF. Assessments at routine diabetic care visits will be collected as available/according to local clinical practice in eCRF.

[c]Informed consent must be obtained before any study related activities.

[d]Individualized HbA1c target must be set and documented prior to randomization.

[e]Medication data (glucose-lowering medications and/or concomitant cardiovascular medications) collected at study visits only include medications that are current at time of study visit.

[f]The HbA1c value is based on historical data collected from the treating study physician and is the value closest to the date of randomization, within the last 90 days.

[g]Any SAE identified from any encounter or notation at any time must be reported.

[h]Data from health plan medical and pharmacy claims. Data will be extracted at €the end of the study but will include data from participant randomization through end of study or withdrawal.

AE, adverse event; CGI-C, Clinical Global Impression-Change; CGI-S, Clinical Global Impression-Severity; DBP, diastolic blood pressure; DTSQc, Diabetes Treatment Satisfaction Questionnaire, change version; DTSQs, Diabetes Treatment Satisfaction Questionnaire, status version; eCRF, electronic case report form; ER, emergency room; PGI-C, Patient Global Impression-Change; PGI-S, Patient Global Impression-Severity; PRO, patient-reported outcome; SAE, serious adverse event; SBP, systolic blood pressure; SF-12 v2, Short Form 12-Item version 2; WPAI-GH, Work Productivity and Activity Impairment: General Health questionnaire.

Supplemental table 3 Geographical distribution and specialty of participating study sites

	Overall (N=1278), %
Geographic region	
Northeast	167 (13.1)
Midwest	333 (26.1)
South	561 (43.9)
West	217 (17.0)
	Overall (N=138), %
Site specialty	
Primary care, internal medicine, family medicine	100 (72.5)
Endocrinology	38 (27.5)
Sites with semaglutide research experience	
Yes	32 (23.2)*
No	106 (76.8)

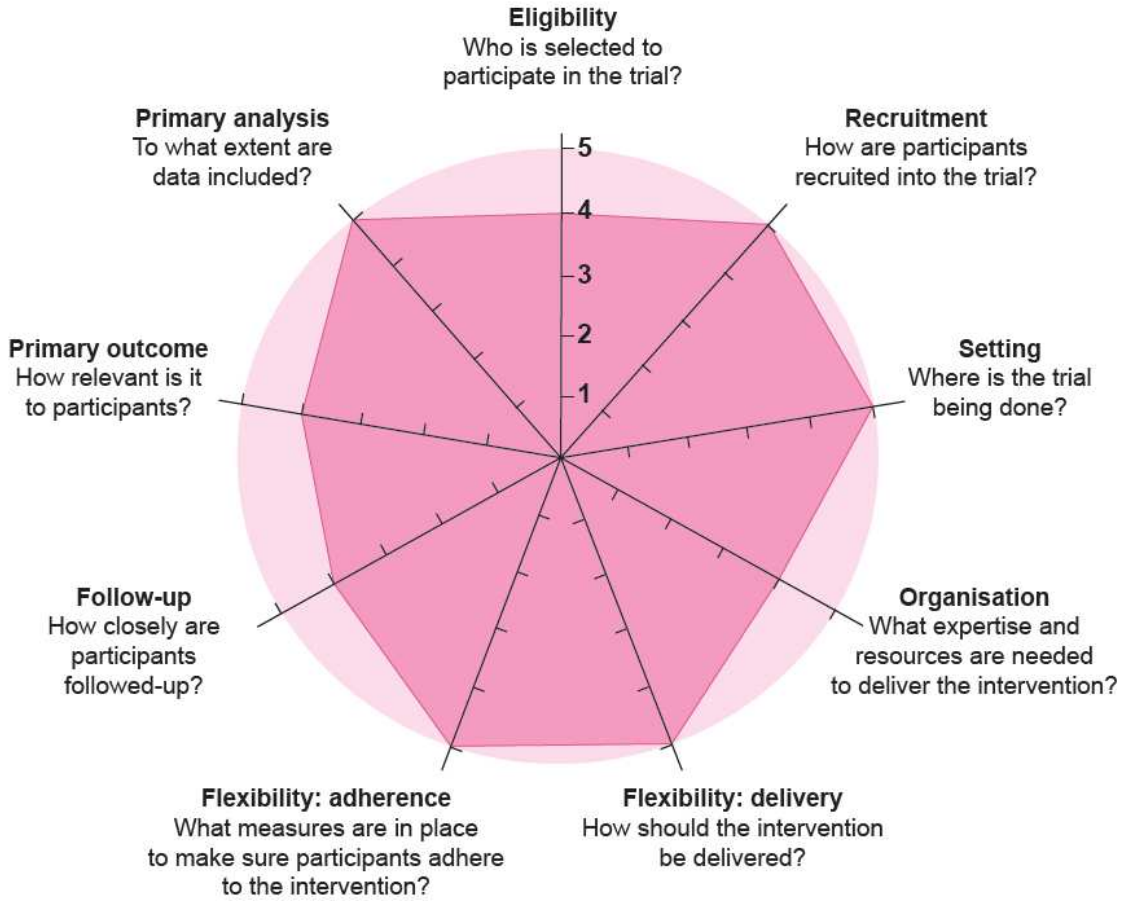
*Of the 32 study physicians at research-experienced sites, 29 were primary care physicians and three were endocrinologists.

Supplemental table 4 Summary of the independently assessed PRECIS-2 scores from each individual in the study steering group and the overall consensus reached following discussions during a workshop meeting in December 2018.

Domain	A	B	C	D	E	F	G	H	I	J	K	Consensus score
Eligibility criteria	5	4	4	4	4	4	5	5	4	3–4	4	4
Recruitment path	4	5	5	4	4	5	5	4	4	5	3	5
Setting	5	5	5	4	5	5	5	5	5	4	5	5
Organisation	4	4	4	4	5	5	4	5	4	4	4	4
Flexibility: delivery	5	5	4	5	5	5	5	5	5	4	5	5
Flexibility: adherence	5	5	5	5	5	5	5	5	5	4	4	5
Follow-up	4	4	5	4	4	4	4	4	4	5	2	4
Outcome	5	4	5	4	4	4	4	4	4	3–4	4	4
Analysis	5	5	5	5	5	5	3	5	5	5	3	5

PRECIS-2, PRagmatic Explanatory Continuum Indicator Summary-2.

Supplemental figure 1 The PRECIS-2 assessment of the SEPRA trial



The tool uses a 5-point Likert scale, where 1 = very explanatory and 5 = very pragmatic.[1]

PRECIS-2, PRagmatic Explanatory Continuum Indicator Summary-2.

Appendix 1. Description of patient reported outcomes, clinician reported outcomes, and diabetes treatment satisfaction

Diabetes Treatment Satisfaction Questionnaire (DTSQ)[2-5]

The DTSQ was included in the trial to evaluate patient satisfaction with treatment compared with prior treatment. The DTSQ status version was completed at randomization and the DTSQ change (DTSQc) version will be completed at year 1 and year 2. The DTSQc version employs eight questions that are answered using a Likert scale from –3 to +3 (–3 = much less satisfied now to +3 = much more satisfied now) with 0 (midpoint), representing no change. The scores to six questions are added together to produce a total treatment satisfaction score. The remaining two questions concern perceived frequency of hyperglycemia and perceived frequency of hypoglycemia, respectively. The DTSQc total treatment satisfaction score ranges from –18 to +18, with higher scores associated with greater treatment satisfaction.

Short Form 12-Item version 2 (SF-12 v2) Health Survey[6]

The SF-12 v2 questionnaire was included in the trial to assess physical and mental functioning and overall health-related quality of life. The following two summary scores are used as endpoints: Physical Component Summary score and Mental Component Summary score. The scores are norm scored such that the scores range from 0–100 with a mean of 50 and standard deviation of 10. The higher the score, the better quality of life; the lower the score, the poorer quality of life.

Work Productivity and Activity Impairment: General Health (WPAI-GH) questionnaire[7]

The WPAI-GH assesses work productivity and activity impairment attributable to general health. There are four types of scores: absenteeism (ie, work time missed), presenteeism (ie, impairment at work/reduced on-the-job effectiveness), work productivity loss (ie, overall work impairment/absenteeism plus presenteeism), and activity impairment (eg, work around the house, shopping, exercising, childcare, studying). Outcomes are expressed as percentages with higher numbers indicating greater impairment and less productivity, ie, worse outcomes (percent work time missed due to health, percent impairment while working due to health, percent overall work impairment due to health, percent activity impairment due to health).

Patient Global Impression of Disease Severity (PGI-S) and Patient Global Impression of Change (PGI-C)

The PGI-S is a 1-item measure that assesses the patient's impression of disease severity based on their present diabetes symptoms (ie, normal, mild, moderate, or severe). The PGI-C assesses the patient's impression of changes in diabetes symptoms, based on their diabetes symptoms now, compared with how they were before they began taking the study drug (ie, very much better, much better, a little better, no change, a little worse, much worse, or very much worse).

Clinician Global Impression of Disease Severity (CGI-S) and Clinician Global Impression of Change (CGI-C)

The CGI-S and CGI-C were included in the study to assess disease severity from the treating study physician's perspective. The CGI-S is a 1-item measure that assesses the clinician's impression of the patient's disease severity, based on the patient's present diabetes symptom (ie, normal, mild, moderate, or severe). The CGI-C assesses the clinician's impression of change in the patient's diabetes symptoms, based on the patient's diabetes symptoms now, compared with how they were before they began taking the study drug (ie, very much better, much better, a little better, no change, a little worse, much worse, or very much worse).

Appendix 2. Study investigators

Name	Institution	City	State	Zip
Angela Davis	Family Health Care Center	Statesboro	GA	30461
Steven Saunders	Steven L. Saunders MD LLC	Milford	CT	06460
Joselito Cabaccan	Joselito C Cabaccan MD	San Jose	CA	95148
Brian McCormick	Hampton Family Practice PLLC	Hampton	VA	23666
Minesh Shah	Chatham Family Medical Center Inc	Chatham	VA	24531
Pradeep Kamboj	Altura Centers For Health	Tulare	CA	93274
Zouhair Bibi	The Endocrine & Diabetes Center	Owensboro	KY	42303
James Chu	Monterey Endocrine & Diabetes Institute	Monterey	CA	93940
Robert Busch	Albany Medical College, Division of Community	Albany	NY	12203
Bradley Eilerman	St Elizabeth Regional DBTS Center	Covington	KY	41011
Steven Von Elten	Piedmont Family Practice Plc	Warrenton	VA	20186
Daniel Pomposini	Privia Medical Group LLC	Danville	VA	24541
Kyle Cannady	East Georgia Healthcare Center Inc	Swainsboro	GA	30401
Edward McDavid	Sandersville Family Practice	Sandersville	GA	31082
Ronald Watts	Eagles Landing Diabetes/Endocrinology	Stockbridge	GA	30281
Paul Bradley	Meridian Clinical Research	Savannah	GA	31406
Kishor Dabhi	Swift Creek Family Care	Colonial Heights	VA	23834
Glenn Heigerick	Beaver Ruin Primary Care	Lilburn	GA	30047
Anu George	Seven Corners Medical	Falls Church	VA	22044
Daniel Horton	Infectious Diseases Associates of Central Virginia	Lynchburg	VA	24501
Benjamin Mailloux	WCMP-Family Medicine	Belfast	ME	04915
Sean Lynch	Southern Family Medical Center	Augusta	GA	30906
Robert Kaufmann	The Kaufmann Clinic Inc	Atlanta	GA	30308
Moussa Alhaj	Regional Endocrine and Diabetes Associate	Ashland	KY	41101
Raymond Tidman	River Birch Research Alliance LLC	Blue Ridge	GA	30513
Lianna Lawson	Lawson Family Medicine and Aesthetics	Daleville	VA	24083
Howard Harrison	Endocrinology Consultants	Virginia Beach	VA	23454
Caroline Huang	The Endocrinology Group PLLC	Arlington	VA	22205
Naila Goldenberg	Functional Endocrinology	Mason	OH	45040
Mark DelBello	Associated Surgeons and Physicians LLC	Fort Wayne	IN	46825
Do Eun Lee	Do-Eun Lee MD INC	Lafayette	CA	94549
Alexander Osowa	Gwinnett Research Institute/Buford Family Practice and Urgent Care Center PC	Buford	GA	30519
Marie Elena Cordisco	Western Connecticut Health Network	Danbury	CT	06810
Adam Mayerson	Endocrine Associates of Connecticut	Hamden	CT	06517

Name	Institution	City	State	Zip
Richard Allen	Om Research LLC	Lancaster	CA	93534
Sina Tebi	Care Access Research Santa Clarita	Santa Clarita	CA	91321
Jon Condit	American Health Network of IN, LLC	Muncie	IN	47304
Hicham Siouty	Adnab Research/Prestige Care Physician	Torrance	CA	90505
G. Mitch Cornett	American Health Network of IN, LLC	Franklin	IN	46131
Nicholas (Kemdi) Ihenacho	First Medical Research Center	Stone Mountain	GA	30083
Brian Heimer	American Health Network of IN, LLC	New Albany	IN	47150
Eric Hewitt	American Health Network of IN, LLC	Avon	IN	46123
Talessa Powell	American Health Network of IN, LLC	Greenfield	IN	46140
Minesh Patel	LaPorte County Institute for Clinical Research, Inc	Michigan City	IN	46360
Sabrina Rene	IACT Health	Newnan	GA	30265
Steven Leichter	IACT Health	Columbus	GA	31904
Christopher Case	Jefferson City Medical Group	Jefferson City	MO	65109
Arvind Krishna	Diabetes & Endocrinology Associates of Stark County, Inc.	Canton	OH	44718
Nimisha Trivedi	Privia Medical Group of Georgia LLC	Locust Grove	GA	30248
David Ramstad	Hampton Roads Center for Clinical Research	Suffolk	VA	23435
Michael Dao	SC Clinical Research, Inc	Garden Grove	CA	92844
Betul Hatipoglu	University Hospitals Cleveland Medical Center	Cleveland	OH	44106
Stephen Brietzke	University of Missouri	Columbia	MO	65201
Henry Naddaf	Toledo Clinic Inc.	Toledo	OH	43606
Joseph Camire	Missouri Highland Health Care	Eminence	MO	65466
Monique Sessler	Family Care of Williamsburg	Williamsburg	VA	23188
Neda Rasouli	University of Colorado Denver	Aurora	CO	80045
Norman Fishman	Diabetes & Endocrinology Specialists Inc	Chesterfield	MO	63017
Andras Fenyves	Prominis Medical Services PC	Brooklyn	NY	11221
Kent Lehman	Adams County Family Physicians	Berne	IN	46711
Matthew Finneran	Family Practice Center of Wadsworth, Inc.	Wadsworth	OH	44281
Howard Andrew Selinger	Manchester Memorial Hospital Family Medicine Residency	Manchester	CT	06040
John Abraham	Trinity Healthcare	Springfield	MO	65803
Charles Saha	Elligo Health Research Inc	New York	NY	10028
Abdelshaheed Samir	Family Medicine Healthcare	Portsmouth	VA	23701
Jewel Stevens	Medical Frontiers, LLC	Carlisle	OH	45005
Binu George	DC Research Works	Marietta	GA	30060
Babita Patel	Halifax Internal Medicine	South Boston	VA	24592

Name	Institution	City	State	Zip
Ismail Tarkhan	Ismail Tarkhan MD	Milford	CT	06460
Ahmed Al-Jebawi	St. Vincent Anderson Hospital	Anderson	IN	46016
Anil Modi	Medical Care of LaGrange	Lagrange	GA	30240
Sarita Golikeri Subramaniam	Tidewater Physicians Multispecialty Group	Williamsburg	VA	23188
Charles Judy	Family Health Clinic	Radford	VA	24141
Javier Morales	Advanced Internal Medicine Group, PC	Greenvale	NY	11548
David Doriguzzi	New Hope Consulting & Clinical Trials	Lancaster	CA	93534
Jyoti Bhat	Diabetes and Endocrinology Specialists	Walnut Creek	CA	94598
Courtney Shelton	Primary Care Research	Atlanta	GA	30312
Jonas Leibowitz	EDOC LLP	Yonkers	NY	10704
Anastasios Manessis	NYC Research, Inc	New York	NY	10001
Phillip O'Donnell	Selma Medical Associates, Inc.	Winchester	VA	22601
Akankasha Goyal	NYU Langone Health	New York	NY	10016
Adam Sherman	Adam B. Sherman D O Professional Corp.	Oxnard	CA	93030
Elias Siraj	Eastern Virginia Medical School	Norfolk	VA	23510
Catherine LaRuffa	Catherine LaRuffa, M.D., Inc.	Blanchester	OH	45107
Minh Mach	Endocrine Specialty Consultant Inc.	Burbank	CA	91505
Cedrice Davis	Urban Family Practice Associates, PC	Marietta	GA	30067
Tariq Javed	Tariq Javed, MD Inc	Visalia	CA	93277
John Gilbert	St. Joseph Heritage Healthcare	Fullerton	CA	92835
Juan Posada	Posada, Juan	San Jose	CA	95116
Joshua Ordway	Franklin Family Practice	Springboro	OH	45005
Thomas Jones	Tom H. Jones	Avon	IN	46123
Yael Harris	Northwell Health	Great Neck	NY	11021
Warren Theis	Coastal Care Medical Clinic	Waycross	GA	31501
Samer Nakhle	Palm Research Center	Las Vegas,	NV	89148
Aliaksandr Trusau	Prevea Health	Green Bay	WI	54229
Augusto Focil	FOMAT Medical Research	Oxnard	CA	93030
Etsegenet Ayele	Pacific Clinical studies	Los Alamitos	CA	90720
Gaurang Shah	Gaurang B. Shah, MD	Richmond	KY	40475
Bryan Chastain	Ascend Research Centers, Inc.	McMinnville	TN	37110
Charles Lovell	York Clinical Research, LLC	Norfolk	VA	23504
Andy Dang	Facey Medical Foundation	Mission Hills	CA	91345
Surya Patel	Patel Medical Center	Irvington	KY	40146
Lori Gerard	Denver Endocrinology Diabetes and Thyroid Center, PC	Englewood	CO	80113
Christopher Weber	Ascension Medical Group - Germantown Clinic	Germantown	WI	53022
Christian Gastelum	PIH Health Physicians Endocrinology	Whittier	CA	90606
Bharathi Raju	South County Endocrinology and Obesity Medicine, LLC	Saint Louis	MO	63128

Name	Institution	City	State	Zip
Jeffrey Green	Paris Family Physicians PLLC	Paris	KY	40361
Thuy Huynh	Pacific Medical Center	Milpitas	CA	95035
Sanjiv Gupta	Tri State Primary Care, Grayson Health Park	Ashland	KY	41101
Srividya Kidambi	Medical College of Wisconsin	Milwaukee	WI	53226
Gary Bedel	Prestige Clinical Research	Franklin	OH	45005
Airani Sathananthan	Western University of Health Sciences	Pomona	CA	91766
Samuel Lee	Sasha-Lee Inc - Corporation Lane Research Center	Virginia Beach	VA	23462
Lee (Charles) Ginsburgh	C. Lee Ginsburgh MD	Newport News	VA	23606
Sandeep Dhindsa	Saint Louis University	St. Louis	MO	63104
James E Gutmann Lauren F Veaszey	Deaconess Clinic, Inc.	Evansville	IN	47725
Michael Marsh	Premiere Medical Center of Burbank, Inc.an Elligo Health Research Site	Toluca Lake	CA	91602
Shukri Makhlouf	Sugarloaf Medical, PC	Suwanee,	GA	30024
Bernard Grunstra	PMG Research of Bristol, LLC	Bristol	TN	37620
Lee Herman	Herman Clinical Research, LLC	Suwanee	GA	30024
Farah Mubarak Ali	Atlanta Center for Clinical Research	Roswell	GA	30075
Natalie Frentz	Beacon Medical Group Swartz-Weikamp	Mishawaka	IN	46544
Erica Kretchman	Reid Endocrinology Center	Richmond	IN	47374
Steven Bauer	OnSite Clinical Solutions, LLC	Charlotte	NC	28277
Larry Berman	OnSite Clinical Solutions, LLC	Charlotte	NC	28210
Richard Murphy	Murphy Research Center	Humboldt	TN	38343
Mercedes Samson	American Clinical Trials	Buena Park	CA	90620
Charles Sharpe	Athens Medical Group	Athens	TN	37303
Joseph Woolley	Chrysalis Clinical Research LLC	St. George	UT	84790
Brent Hella	Valley Weight Loss Clinic	Fargo	ND	58103
Richard Lorraine	Harleysville Medical Associates	Harleysville	PA	19438
Imran Siddiqui	Simcare Medical Research, LLC	Sugarland	TX	77469
Brian Feldman	Central Ohio Clinical Research LLC	Columbus	OH	43213
Robert Detweiler	Detweiler Family Medicine and Associates, PC	Lansdale	PA	19446
Peter Gagianas	Primary Care Research South, Inc	McMurray	PA	15317
Randal Jacks	Christus Trinity Clinic Hill Country Landa	New Braunfels	TX	78130
Bryce Palchick	Preferred Primary Care Physicians, Inc.	Pittsburgh	PA	15236
Jeffrey Deitch	Tri-County Research, Inc.	Sterling Hts	MI	48310

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