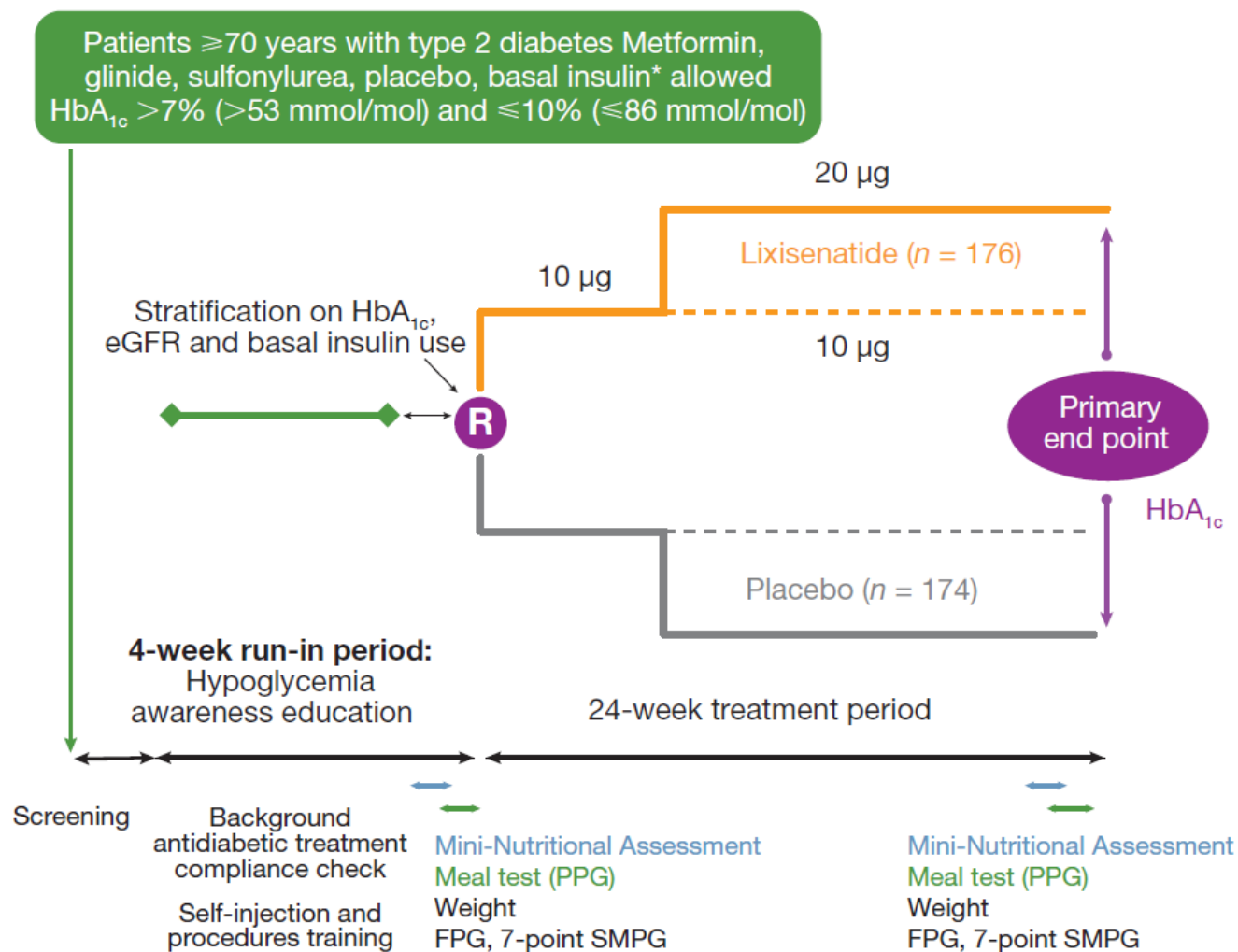
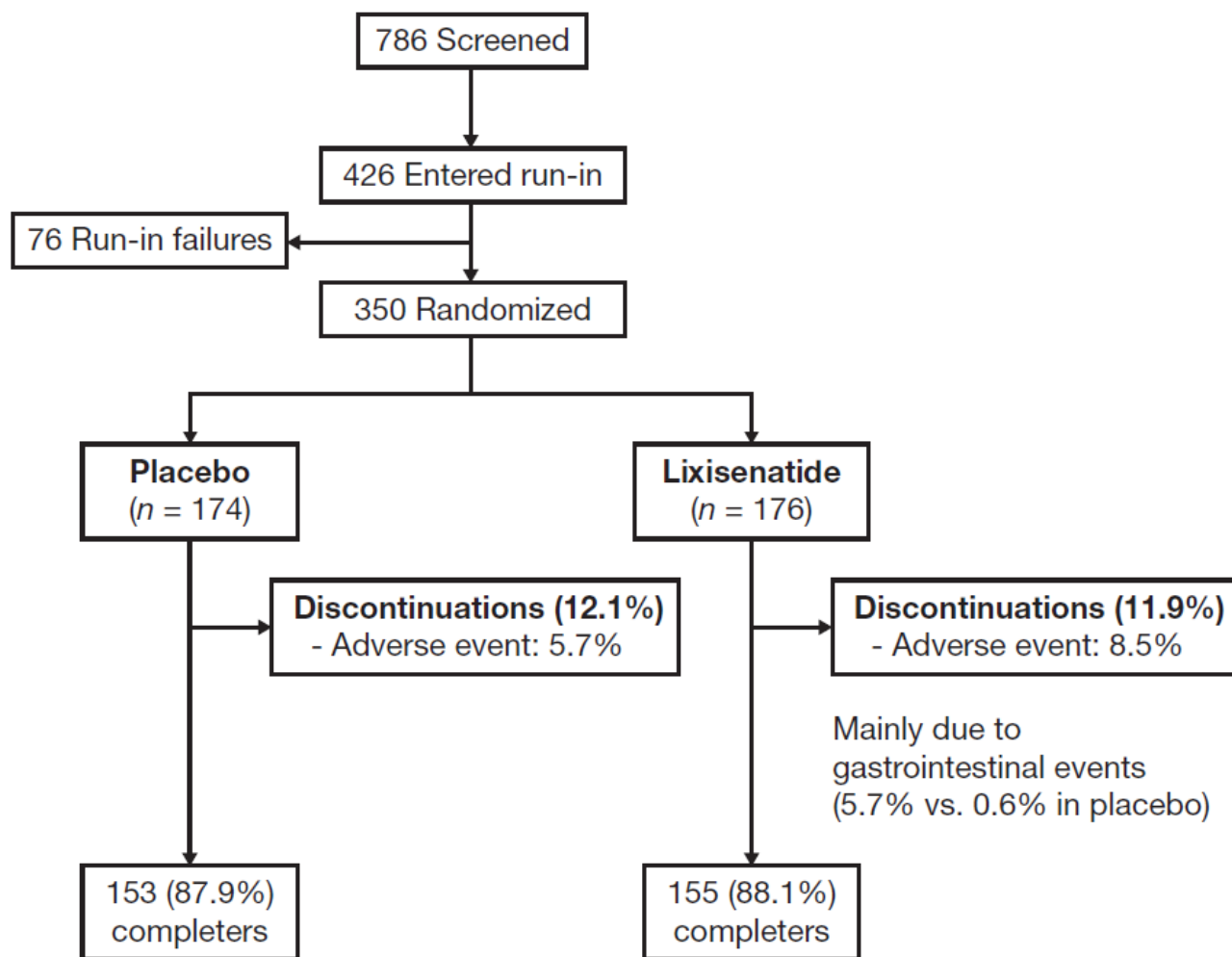


SUPPLEMENTARY DATA

Supplementary Figure 1—GetGoal-O trial design. *Patients on both insulin and sulfonylurea/glinides were not eligible. eGFR, estimated glomerular filtration rate; FPG, fasting plasma glucose; PPG, postprandial plasma glucose; SMPG, self-monitored plasma glucose.

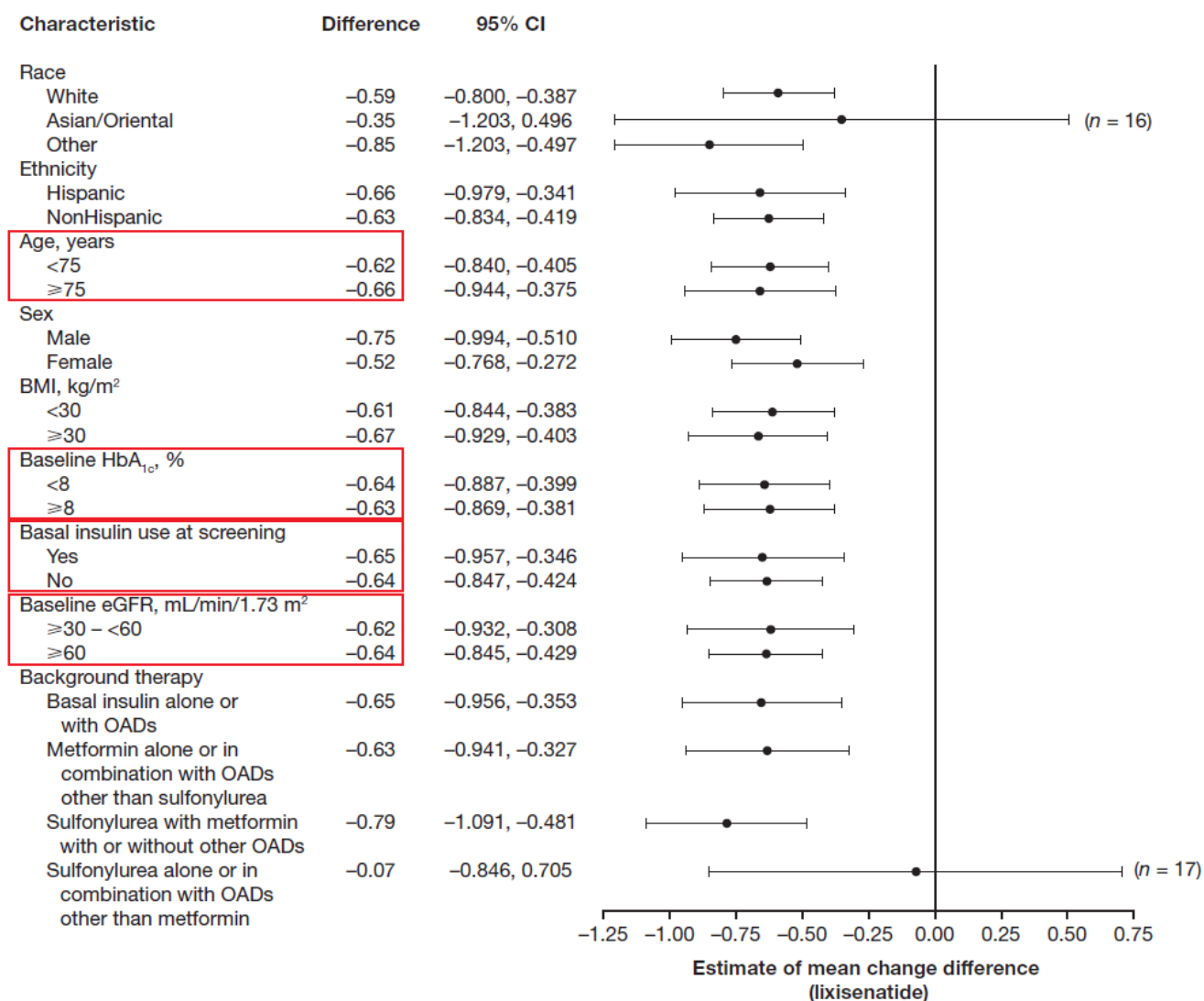


Supplementary Figure 2—Patient disposition in the GetGoal-O trial.



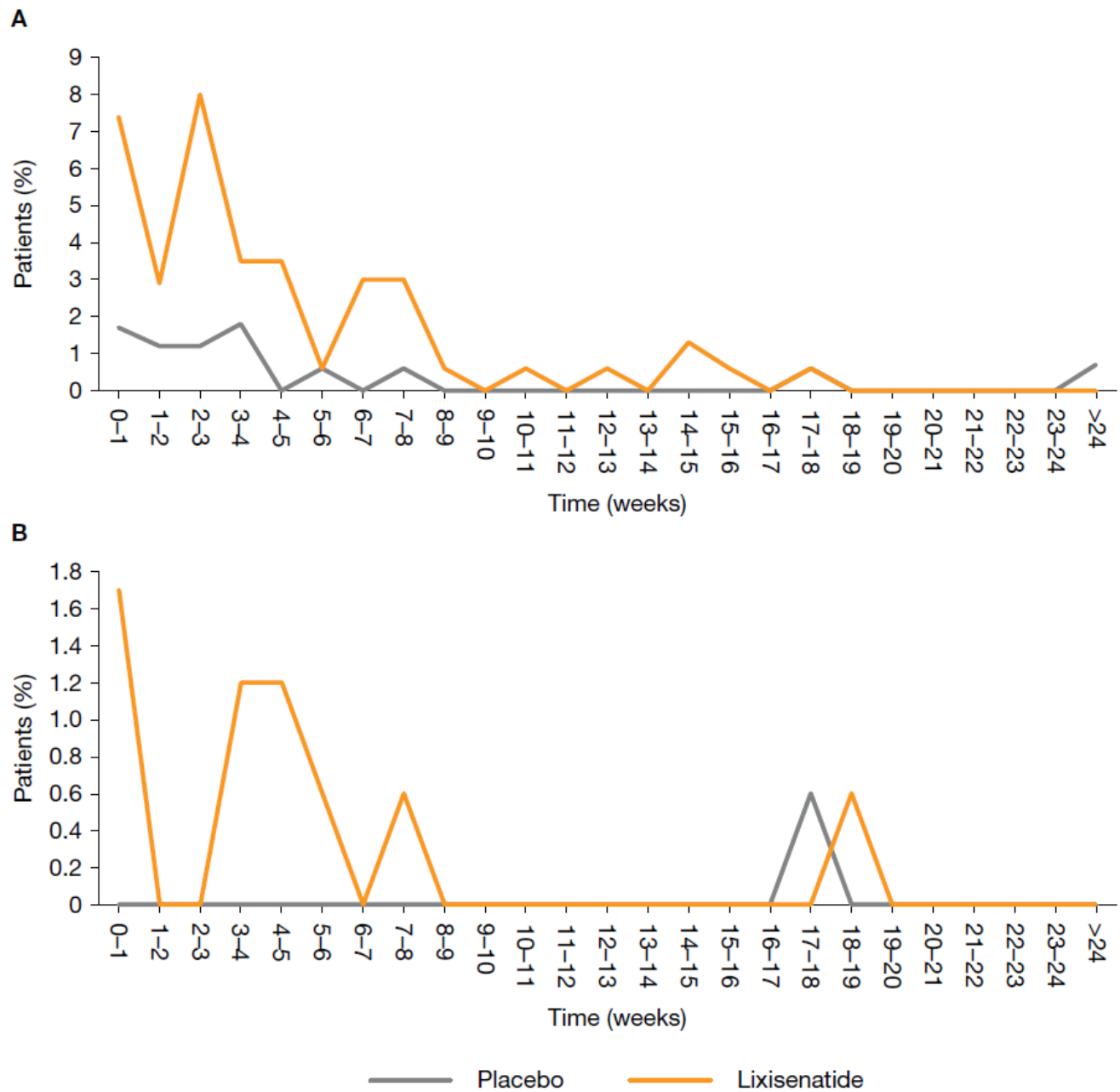
SUPPLEMENTARY DATA

Supplementary Figure 3—Change in HbA_{1c} by baseline factors and background antidiabetic therapy from baseline to week 24. eGFR, estimated glomerular filtration rate; OAD, oral antidiabetic drug.



SUPPLEMENTARY DATA

Supplementary Figure 4—Incidence of (A) nausea and (B) vomiting by week during the on-treatment period.



SUPPLEMENTARY DATA

Supplementary Table 1—Number of patients in the safety population reporting treatment-emergent adverse events

Patients with:	Placebo (<i>n</i> = 174)	Lixisenatide (<i>n</i> = 176)
<i>At least one TEAE</i>		
Any TEAE	118 (67.8)	125 (71.0)
Serious TEAE	10 (5.7)	8 (4.5)
TEAE leading to death	1 (0.6)	0 (0.0)
TEAE leading to discontinuation	10 (5.7)	15 (8.5)
<i>AE by organ class</i>		
Infections and infestations	53 (30.5)	41 (23.3)
Nervous system disorders	19 (10.9)	21 (11.9)
Gastrointestinal disorders (overall)	36 (20.7)	71 (40.3)
Nausea	13 (7.5)	44 (25.0)
Vomiting	1 (0.6)	10 (5.7)
Diarrhea	13 (7.5)	19 (10.8)
Gastrointestinal disorders leading to discontinuation	1 (0.6)	10 (5.7)
Musculoskeletal and connective tissue disorders	31 (17.8)	19 (10.8)
Arthralgia	8 (4.6)	4 (2.3)
Musculoskeletal pain	7 (4.0)	0 (0.0)
Hypoglycemia		
Any hypoglycemia*	18 (10.3)	31 (17.6)
Symptomatic hypoglycemia		
Number of patients with events	10 (5.7)	13 (7.4)
Number of events	12	33
Blood glucose <3.3 mmol/L		
Number of patients with events	10 (5.7)	12 (6.8)

Data are presented as *n* (%) unless stated otherwise.

*Symptomatic + asymptomatic (plasma glucose ≤3.9 mmol/L).

AE, adverse event; TEAE, treatment-emergent adverse event.

SUPPLEMENTARY DATA

Supplementary Table 2—Summary of hypoglycemia with typical symptoms and plasma glucose ≤ 70 mg/dL (< 3.9 mmol/L) during the on-treatment period (safety population)

Type	Placebo (<i>n</i> = 174)	Lixisenatide (<i>n</i> = 176)
Total patient years	77.3	76.9
Number of patients with events, <i>n</i> (%)	13 (7.5)	19 (10.8)
Number of patients with events per 100 patient-years*	16.81	24.72
Number of events	28	47
Number of events per 100 patient-years [†]	36.20	61.15

*Calculated as: (number of patients with events \times 100 divided by total exposure + 3 days in patient years).

[†]Calculated as (number of events \times 100 divided by total exposure + 3 days in patient years).

SUPPLEMENTARY DATA



LIST OF PRINCIPAL INVESTIGATOR(S) AND SUB-INVESTIGATOR(S) PER STUDY SITE WHERE PATIENTS WERE ENROLLED

QSD-002219

Product Code:	AVE0010	Study Code:	EFC12703
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List of Principal Investigator(s) and Sub-Investigator(s) per study site where patients were enrolled

Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
036001	Price Sarah	Sub-Investigator/Co-Investigator	MD	Heidelberg Repatriation Hospital Department of Medicine Building 24, 300 Waterdale Road Heidelberg 3081 Victoria AUSTRALIA
036001	Proietto Joseph	Principal Investigator	MD	Heidelberg Repatriation Hospital Department of Medicine Building 24, 300 Waterdale Road Heidelberg 3081 Victoria AUSTRALIA
036001	Sumithran Priyadarsini K.	Sub-Investigator/Co-Investigator RDC Approver	MD	Heidelberg Repatriation Hospital Department of Medicine Building 24, 300 Waterdale Road Heidelberg 3081 Victoria AUSTRALIA

*CV provided as attachment to this appendix for all principal investigators

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Product Code:	AVE0010	Study Code:	EFC12703	
Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
036001	Sandra Neoh	Sub-Investigator/Co-Investigator RDC Approver	MD	Heidelberg Repatriation Hospital Department of Medicine Building 24, 300 Waterdale Road Heidelberg 3081 Victoria AUSTRALIA
036002	Gilfillan Christopher P.	Sub-Investigator/Co-Investigator	MD	Box Hill Hospital Endocrinology Department Nelson Road Box Hill 3128 Victoria AUSTRALIA
036002	Goh Sue L.	Sub-Investigator/Co-Investigator	MD	Box Hill Hospital Endocrinology Department Nelson Road Box Hill 3128 Victoria AUSTRALIA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
036002	Kalra Balvinder	Sub-Investigator/Co-Investigator	MD	Box Hill Hospital Endocrinology Department Nelson Road Box Hill 3128 Victoria AUSTRALIA
036002	Simpson Richard W.	Principal Investigator	MD	Box Hill Hospital Endocrinology Department Nelson Road Box Hill 3128 Victoria AUSTRALIA
036003	Colman Peter G.	Sub-Investigator/Co-Investigator RDC Approver	MD	Royal Melbourne Hospital Endocrine/Diabetes/Metabolism Grattan Street Parkville 3050 Victoria AUSTRALIA

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036003	Fourlanos Spiros	Sub-Investigator/Co-Investigator	MD	Royal Melbourne Hospital Endocrine/Diabetes/Metabolism Grattan Street Parkville 3050 Victoria AUSTRALIA
036003	Nankervis Alison J.	Principal Investigator	MD	Royal Melbourne Hospital Endocrine/Diabetes/Metabolism Grattan Street Parkville 3050 Victoria AUSTRALIA
036003	Kvi Mervyn	Sub-Investigator/Co-Investigator	MD	Royal Melbourne Hospital Endocrine/Diabetes/Metabolism Grattan Street Parkville 3050 Victoria AUSTRALIA

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036003	Nguyen Hanh	Sub-Investigator/Co-Investigator	MD	Royal Melbourne Hospital Endocrine/Diabetes/Metabolism Grattan Street Parkville 3050 Victoria AUSTRALIA
036004	Ho Jean P.	Sub-Investigator/Co-Investigator	MD	Royal Prince Alfred Hospital Diabetes Centre Level 6 West Wing Missenden Road Camperdown 2050 New South Wales AUSTRALIA
036004	Ross Glynis	Sub-Investigator/Co-Investigator	MD	Royal Prince Alfred Hospital Diabetes Centre Level 6 West Wing Missenden Road Camperdown 2050 New South Wales AUSTRALIA

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036004	Wong Jencia	Sub-Investigator/Co-Investigator RDC Approver	MD	Royal Prince Alfred Hospital Diabetes Centre Level 6 West Wing Missenden Road Camperdown 2050 New South Wales AUSTRALIA
036004	Wu Ted	Sub-Investigator/Co-Investigator RDC Approver	MD, PhD	Royal Prince Alfred Hospital Diabetes Centre Level 6 West Wing Missenden Road Camperdown 2050 New South Wales AUSTRALIA
036004	Yue Dennis	Principal Investigator	MD	Royal Prince Alfred Hospital Diabetes Centre Level 6 West Wing Missenden Road Camperdown 2050 New South Wales AUSTRALIA

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036005	Feddersen Martin A.	Sub-Investigator/Co-Investigator RDC Approver	MD	Renal Rsearch Level 1 / 37 William Street Gosford 2250 New South Wales AUSTRALIA
036005	Roger Simon D.	Principal Investigator	MD	Renal Rsearch Level 1 / 37 William Street Gosford 2250 New South Wales AUSTRALIA
036006	Blom Hans	Principal Investigator	MD	Vale Medical Practice Brookvale House, 1A Cross Street Brookvale 2100 New South Wales AUSTRALIA
036006	Gordon Evan	Sub-Investigator/Co-Investigator	MD	Vale Medical Practice Brookvale House, 1A Cross Street Brookvale 2100 New South Wales AUSTRALIA

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036006	Kailainathan Mangalaeswari	Sub-Investigator/Co-Investigator RDC Approver	MD	Vale Medical Practice Brookvale House, 1A Cross Street Brookvale 2100 New South Wales AUSTRALIA
036006	Moss David	Sub-Investigator/Co-Investigator	MD	Vale Medical Practice Brookvale House, 1A Cross Street Brookvale 2100 New South Wales AUSTRALIA
100001	Kerekovski Yuriy	Sub-Investigator/Co-Investigator	MD	Diagnostic Consultative Center "Equita" EOOD 5, Tsar Osvoboditel Blvd. Varna 9000 BULGARIA
100001	Klyuchkova Neli	Principal Investigator	MD	Diagnostic Consultative Center "Equita" EOOD 5, Tsar Osvoboditel Blvd. Varna 9000 BULGARIA
100001	Lyubomirova Zornitsa	Sub-Investigator/Co-Investigator	MD	Diagnostic Consultative Center "Equita" EOOD 5, Tsar Osvoboditel Blvd. Varna 9000 BULGARIA

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100002	Videva-Vlahova Vyara	Principal Investigator	MD	MHAT "Zdrave" OOD Internal Department 1A Perushtitsa Str. Plovdiv 4002 BULGARIA
100002	Vlahov Petar	Sub-Investigator/Co-Investigator	MD	MHAT "Zdrave" OOD Internal Department 1A Perushtitsa Str. Plovdiv 4002 BULGARIA
100003	Damyanov Ivan	Sub-Investigator/Co-Investigator	MD	MHAT 'Doverie' Endocrinology cabinet Ovcha kupel 2 2, Fridrih Gryunanger Str Sofia 1632 BULGARIA
100003	Damyanova Velichka A.	Principal Investigator	MD	MHAT 'Doverie' Endocrinology cabinet Ovcha kupel 2 2, Fridrih Gryunanger Str Sofia 1632 BULGARIA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
100003	Pasheva Vasilka	Sub-Investigator/Co-Investigator	MD	MHAT 'Doverie' Endocrinology cabinet Ovcha kupel 2 2, Fridrih Gryunanger Str Sofia 1632 BULGARIA
100004	Nikolaeva Antoaneta Z.	Sub-Investigator/Co-Investigator	MD	MHAT "Prof Stoyan Kirkovich" 2, General Stoletov St. Stara Zagora 6000 BULGARIA
100004	Vuchkova Emilena	Principal Investigator	MD	MHAT "Prof Stoyan Kirkovich" 2, General Stoletov St. Stara Zagora 6000 BULGARIA
100005	Mitkov Mitko	Principal Investigator	MD	MHAT Sveti Georgi Clinic of Endocrinology 15a, Vasil Aprilov Plovdiv 4002 BULGARIA

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100005	Nonchev Boyan	Sub-Investigator/Co-Investigator RDC Writer	MD	MHAT Sveti Georgi Clinic of Endocrinology 15a, Vasil Aprilov Plovdiv 4002 BULGARIA
124001	Beauchesne André	Sub-Investigator/Co-Investigator	MD	Pro-Recherche Polyclinique des Ponts 120 - 1110 Boul. De La Rive-Sud St-Romuald G6W 5M6 Quebec CANADA
124001	Blouin François	Principal Investigator	MD	Pro-Recherche Polyclinique des Ponts 120 - 1110 Boul. De La Rive-Sud St-Romuald G6W 5M6 Quebec CANADA
124001	Vallieres Gerald	Sub-Investigator/Co-Investigator	MD	Pro-Recherche Polyclinique des Ponts 120 - 1110 Boul. De La Rive-Sud St-Romuald G6W 5M6 Quebec CANADA

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124002	Baillargeon Jean Patrice	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Bellabarba Diego	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Bernier Frederic	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Carpentier Andre	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA

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124002	Hivert Marie-France	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Houde Ghislaine	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Langlois Marie-France	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Perron Patrice	Principal Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA

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AVE0010		EFC12703		
Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
124002	Pesant Marie-Helene	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	VanRossum Nicole	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124002	Daniel Tessier	Sub-Investigator/Co-Investigator	MD	CHUS Hôpital Fleurimont 3001-12e Ave Nord Sherbrooke J1H 5N4 Quebec CANADA
124003	Greenspoon Allen	Sub-Investigator/Co-Investigator	MD	Wharton Medical Clinic 414 Victoria Ave. N. Suite M14 Hamilton L8L 5G8 Ontario CANADA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
124003	Wharton Sean	Principal Investigator	MD	Wharton Medical Clinic 414 Victoria Ave. N. Suite M14 Hamilton L8L 5G8 Ontario CANADA
124004	Woo Vincent C.	Principal Investigator	MD	Health Sciences Centre Diabetes Research Group 838-715 McDermot Avenue Winnipeg R3E 3P4 Manitoba CANADA
124004	Carmen Hurd	Sub-Investigator/Co-Investigator	MD	Health Sciences Centre Diabetes Research Group 838-715 McDermot Avenue Winnipeg R3E 3P4 Manitoba CANADA
124005	Elliott Thomas G.	Principal Investigator	MD	BC Diabetes 4102 - 2775 Laurel Street Vancouver V5Z 1M9 British Columbia CANADA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
124005	Paty Breay	Sub-Investigator/Co-Investigator	MD	BC Diabetes 4102 - 2775 Laurel Street Vancouver V5Z 1M9 British Columbia CANADA
124006	Meneilly Graydon	Principal Investigator	MD	VCHRI Clinical Research Unit 4th Floor, 2775 Laurel Street Vancouver V5Z 1M9 British Columbia CANADA
124006	Keneneth Madden M.	Sub-Investigator/Co-Investigator	MD	VCHRI Clinical Research Unit 4th Floor, 2775 Laurel Street Vancouver V5Z 1M9 British Columbia CANADA
124007	Partha Paul	Principal Investigator	MD	Pharmaceutical Integrated Research Corp (PIRC) A division of the AIM Health Group 458 Central Avenue London N6B 2E5 Ontario CANADA

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AVE0010		EFC12703		
Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
124007	Wahby Robert J.	Sub-Investigator/Co-Investigator	MD	Pharmaceutical Integrated Research Corp (PIRC) A division of the AIM Health Group 458 Central Avenue London N6B 2E3 Ontario CANADA
124008	Tsoukas George M.	Principal Investigator	MD	Applied Medical Informatics Research Inc. (A.M.I.R) 4427 Sherbrooke Street West Westmount H3Z 1E5 Quebec CANADA
124008	Tsoukas George-Orestis	Sub-Investigator/Co-Investigator	MD	Applied Medical Informatics Research Inc. (A.M.I.R) 4427 Sherbrooke Street West Westmount H3Z 1E5 Quebec CANADA
208001	Perrild Hans	Principal Investigator	MD	Bispebjerg Hospital IC Forskning Bispebjerg Bakke 23 København Nv 2400 DENMARK

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
208001	Svendsen Ole Lander	Sub-Investigator/Co-Investigator	MD	Bispebjerg Hospital IC Forskning Bispebjerg Bakke 23 København Nv 2400 DENMARK
208001	Rasmus Bo Jensen	Sub-Investigator/Co-Investigator	MD	Bispebjerg Hospital IC Forskning Bispebjerg Bakke 23 København Nv 2400 DENMARK
208001	Caroline Raun Hansen	Sub-Investigator/Co-Investigator	MD	Bispebjerg Hospital IC Forskning Bispebjerg Bakke 23 København Nv 2400 DENMARK
208002	Christensen Peter A.	Principal Investigator	MD	Slagelse Sygehus Slagelse Sygehus Ingemannsvej 18 Slagelse 4200 DENMARK

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208002	Gæde Peter	Sub-Investigator/Co-Investigator	MD	Slagelse Sygehus Slagelse Sygehus Ingemannsvej 18 Slagelse 4200 DENMARK
208002	Henning Juhl F.	Principal Investigator	MD	Slagelse Sygehus Slagelse Sygehus Ingemannsvej 18 Slagelse 4200 DENMARK
208003	Hangaard Joergen	Principal Investigator	MD, PhD	Sygehus Fyn Svendborg Endokrinologisk Afd. Valdemarsgade 53 Svendborg 5700 DENMARK
208003	Houborg Petersen Maria	Sub-Investigator/Co-Investigator	MD	Sygehus Fyn Svendborg Endokrinologisk Afd. Valdemarsgade 53 Svendborg 5700 DENMARK

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
208003	Levin Klaus	Sub-Investigator/Co-Investigator	MD	Sygehus Fyn Svendborg Endokrinologisk Afd. Valdemarsgade 53 Svendborg 5700 DENMARK
208004	Christiansen Merete	Sub-Investigator/Co-Investigator	PhD, MD	Amager Hospital Intern Medicinsk Klinik Italiensvej 1 København S 2300 DENMARK
208004	Frandsen Hans A.	Principal Investigator	MD	Amager Hospital Intern Medicinsk Klinik Italiensvej 1 København S 2300 DENMARK
208005	Gram Jeppe	Principal Investigator	MD	Sydvestjysk Sygehus Esbjerg Endokrinologisk Afd. Finsensgade 35 Esbjerg 6700 DENMARK

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
208005	Langdahl Høggild Jacob	Sub-Investigator/Co-Investigator RDC Approver	MD	Sydvestjysk Sygehus Esbjerg Endokrinologisk Afd. Finsengade 35 Esbjerg 6700 DENMARK
276001	Lammers Dirk	Sub-Investigator/Co-Investigator RDC Approver	MD	Institut für Diabetesforschung Münster GmbH Hohenzollernring 70 Münster 48145 GERMANY
276001	Pohlmeier Harald B.	Sub-Investigator/Co-Investigator RDC Approver	MD	Institut für Diabetesforschung Münster GmbH Hohenzollernring 70 Münster 48145 GERMANY
276001	Rose Ludger	Principal Investigator	MD	Institut für Diabetesforschung Münster GmbH Hohenzollernring 70 Münster 48145 GERMANY
276002	Barsnick-Harnest Sabine	Principal Investigator	MD	Dr. Barsnick Vital Care UG München Rosa-Bavarese-Straße 1 München 80639 GERMANY

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
276002	Harnest Ulf	Sub-Investigator/Co-Investigator RDC Approver	MD	Dr. Barsnick Vital Care UG München Rosa-Bavarese-Straße 1 München 80639 GERMANY
276003	Alawi Hasan	Principal Investigator	MD	Praxis Dr. Hasan Alawi Brückenstraße 28-30 Saarlouis 66740 GERMANY
276003	Warken Bernd	Sub-Investigator/Co-Investigator RDC Approver	MD	Praxis Dr. Hasan Alawi Brückenstraße 28-30 Saarlouis 66740 GERMANY
276004	Plassmann Georg	Sub-Investigator/Co-Investigator RDC Approver	MD	Unterfrintoper Hausarztzentrum Unterstr. 75 Essen 45359 GERMANY
276004	Weber Dirk	Sub-Investigator/Co-Investigator	MD	Unterfrintoper Hausarztzentrum Unterstr. 75 Essen 45359 GERMANY

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276004	Weber Ulrich	Principal Investigator	MD	Unterfrintoper Hausarztzentrum Unterstr. 75 Essen 45359 GERMANY
276005	Ganz Xenia	Sub-Investigator/Co-Investigator RDC Approver	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY
276005	Hanefeld Markolf	Principal Investigator	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY

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276005	Henkel Elena	Sub-Investigator/Co-Investigator RDC Approver	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY
276005	John Franziska	Sub-Investigator/Co-Investigator RDC Approver	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY
276005	Muessig Ilona	Sub-Investigator/Co-Investigator	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY

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276005	Pistrosch Frank	Sub-Investigator/Co-Investigator	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY
276005	Pohl Wilgard	Sub-Investigator/Co-Investigator	MD	Gesellschaft für Wissens- und Technologietransfer mbH Zentrum für Klinische Studien Forschungsbereich Endokrinologie/Stoffwechsel Fiedlerstraße 34 Dresden 01307 GERMANY
276006	Kosch Christine	Principal Investigator	MD	Praxis Christine Kosch Königsteiner Straße 6B Pirna 01796 GERMANY
276006	Prochazkova Zdenka	Sub-Investigator/Co-Investigator RDC Approver	MD	Praxis Christine Kosch Königsteiner Straße 6B Pirna 01796 GERMANY

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276007	Marck Cornelia	Principal Investigator	MD	GP Dr. Marck/Marck/Dr. Linn/Pickel Pohlheim Dr. Cornelia Marck/Gerd-Peter Marck/Dr. Elisabeth Linn/Marcus Pickel Neue Mitte 10 Pohlheim 35415 GERMANY
276007	Pickel Marcus	Sub-Investigator/Co-Investigator RDC Approver	MD	GP Dr. Marck/Marck/Dr. Linn/Pickel Pohlheim Dr. Cornelia Marck/Gerd-Peter Marck/Dr. Elisabeth Linn/Marcus Pickel Neue Mitte 10 Pohlheim 35415 GERMANY
276008	Funke Klaus	Principal Investigator	MD	IkFE Studiencenter Potsdam GmbH Friedrich-Klausing-Straße 5 Potsdam 14469 GERMANY
276008	Oeter Christine	Sub-Investigator/Co-Investigator RDC Approver	MD	IkFE Studiencenter Potsdam GmbH Friedrich-Klausing-Straße 5 Potsdam 14469 GERMANY

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578001	Gronert Jorn O.	Principal Investigator	MD	Flattum Legesenter, Høngata 70A Høngata 70A Postboks 1175, 3503 Hønefoss Hønefoss 3515 NORWAY
578003	Langslet Gisle	Principal Investigator	MD	Oslo Universitetssykehus HF Rikshospitalet, Lipiklinikken 0372 Oslo NORWAY
578003	Seferowicz Maria	Sub-Investigator/Co-Investigator	MD	Oslo Universitetssykehus HF Rikshospitalet, Lipiklinikken 0372 Oslo NORWAY
578003	Srikumar Nirosha	Sub-Investigator/Co-Investigator	MD	Oslo Universitetssykehus HF Rikshospitalet, Lipiklinikken 0372 Oslo NORWAY
578004	Sordal Terje	Principal Investigator	MD	Medicus Senter For Kliniske Studier Trondheim Sverresgate 15 E Trondheim 7012 NORWAY

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578004	Sordal Oystein	Sub-Investigator/Co-Investigator	MD	Medicus Senter For Kliniske Studier Trondheim Sverresgate 15 E Trondheim 7012 NORWAY
578005	Reimer Sten	Principal Investigator	MD	Parkvegen Legekontor Winsnes gate 62 Kongsvinger 2212 NORWAY
578006	Cooper John	Principal Investigator	MD	Stavanger Helseforskning AS Jan Johnsens gate 5 4068 Stavanger NORWAY
604001	Delgado Butron Cesar M.	Principal Investigator	MD	Centro Endocrinológico DELGADO Calle Daniel Alcides Carrion 126 IV Centenario Arequipa PERU
604001	Delgado Torres Leonidas D.	Sub-Investigator/Co-Investigator RDC Approver	MD	Centro Endocrinológico DELGADO Calle Daniel Alcides Carrion 126 IV Centenario Arequipa PERU
604001	Delgado Torres Cesar M.	Sub-Investigator/Co-Investigator RDC Approver	MD	Centro Endocrinológico DELGADO Calle Daniel Alcides Carrion 126 IV Centenario Arequipa PERU

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604002	Arellano Salazar Martha P.	Sub-Investigator/Co-Investigator	MD	ENDOMED del Centro Médico Clínica San Judas Tadeo Laureano Martínez 140 – Tercer Piso Oficina 21 San Miguel Lima 32 PERU
604002	Dextre Espinoza Augusto A.	Principal Investigator	MD	ENDOMED del Centro Médico Clínica San Judas Tadeo Laureano Martínez 140 – Tercer Piso Oficina 21 San Miguel Lima 32 PERU
604002	Kundert Abuid Karim S.	Sub-Investigator/Co-Investigator	MD	ENDOMED del Centro Médico Clínica San Judas Tadeo Laureano Martínez 140 – Tercer Piso Oficina 21 San Miguel Lima 32 PERU
604002	Davila Uriarte Carmen A.	Sub-Investigator/Co-Investigator	MD	ENDOMED del Centro Médico Clínica San Judas Tadeo Laureano Martínez 140 – Tercer Piso Oficina 21 San Miguel Lima 32 PERU

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604003	Acosta Chacaltana Max C.	Sub-Investigator/Co-Investigator	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Aro Guardia Pedro A.	Sub-Investigator/Co-Investigator	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Calipuy Galvez Juan M.	Sub-Investigator/Co-Investigator RDC Writer	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Manrique Hurtado Helard A.	Principal Investigator	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU

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604003	Núñez Calderón Cecilia C.	Sub-Investigator/Co-Investigator	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Quiroz Lozada Carlos M.	Sub-Investigator/Co-Investigator RDC Approver	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Zapana Mansilla Alexander A.	Sub-Investigator/Co-Investigator RDC Approver	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU
604003	Núñez Cecilia	Sub-Investigator/Co-Investigator	MD	Centro De Investigacion En Diabetes, Obesidad Y Nutrición Calle Alberto Alexander 2480 Lince Lima LIMA 14 PERU

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604005	More Verde Claudia	Sub-Investigator/Co-Investigator RDC Writer	MD	Clinica El Golf Av. Aurelio Miro Quezada 1050 Oficina 203 San Isidro Lima LIMA 10 PERU
604005	More Saldaña Luis A.	Principal Investigator	MD	Clinica El Golf Av. Aurelio Miro Quezada 1050 Oficina 203 San Isidro Lima LIMA 10 PERU
604005	Narvaez Ernesto H.	Sub-Investigator/Co-Investigator RDC Writer	MD	Clinica El Golf Av. Aurelio Miro Quezada 1050 Oficina 203 San Isidro Lima LIMA 10 PERU
604006	Noriega Ruiz Victor H.	Sub-Investigator/Co-Investigator RDC Writer	MD	Hospital Nacional Cayetano Heredia Av. Honorio Delgado 262 Lima LIMA 31 PERU

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604006	Pinto Valdivia Miguel E.	Principal Investigator	MD	Hospital Nacional Cayetano Heredia Av. Honorio Delgado 262 Lima LIMA 31 PERU
604006	Ramirez-Vela Rosa M.	Sub-Investigator/Co-Investigator	MD	Hospital Nacional Cayetano Heredia Av. Honorio Delgado 262 Lima LIMA 31 PERU
604007	Valdivia Portugal Angelica M.	Principal Investigator	MD	Clinica Geriatrica del Ejército Avenida Escuela Militar s/n, Chorrillos Lima 09 PERU
604007	Sotomayor Carranza Ivette G.	Sub-Investigator/Co-Investigator	MD	Clinica Geriatrica del Ejército Avenida Escuela Militar s/n, Chorrillos Lima 09 PERU
604007	Campos Cardenas Lourdes V.	Sub-Investigator/Co-Investigator	MD	Clinica Geriatrica del Ejército Avenida Escuela Militar s/n, Chorrillos Lima 09 PERU
604008	Bardales Ruiz Dario	Sub-Investigator/Co-Investigator	MD	Clinica Virgen Maria Auxiliadora Calle Pedro de León 200, Urb Clarke Piura PERU

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604008	Mio Palacios Edwin A.	Sub-Investigator/Co-Investigator	MD	Clinica Virgen Maria Auxiliadora Calle Pedro de León 200, Urb Clarke Piura PERU
604008	Saldarriaga Taboada Guillermo	Sub-Investigator/Co-Investigator RDC Approver	MD	Clinica Virgen Maria Auxiliadora Calle Pedro de León 200, Urb Clarke Piura PERU
604008	Vargas Gonzales Rolando J.	Principal Investigator	MD	Clinica Virgen Maria Auxiliadora Calle Pedro de León 200, Urb Clarke Piura PERU
604011	Calderon Ticona Jorge R.	Principal Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Garcia Ramos Freddy E.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Núñez Torres Pedro	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU

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604011	Pimentel Fernandez Carolina L.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Hirano Espejo S.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Ruiz Velazco Maria B.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Marcelino Longa Lopez John C.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU
604011	Almendras Villon Juan M.	Sub-Investigator/Co-Investigator	MD	Novocardio Centro de Investigacion y atencion cardiovascular Av Salaverry 2665 San Isidro Lima 27 PERU

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616001	Krzyzagorska Ewa P.L.	Principal Investigator	MD, PhD	Praktyka Lekarska Ewa Krzyzagorska Murawa 37A Poznan 61-665 Wielkopolskie POLAND
616001	Sekulska Marzenna	Sub-Investigator/Co-Investigator RDC Approver	MD	Praktyka Lekarska Ewa Krzyzagorska Murawa 37A Poznan 61-665 Wielkopolskie POLAND
616002	Heince Ewa	Sub-Investigator/Co-Investigator RDC Approver	MD	Przychodnia Specjalistyczna Wittek, Rudzki ul. Niedurnego 50D Ruda Slaska 41-709 Slaskie POLAND
616002	Rudzka Jadwiga	Sub-Investigator/Co-Investigator RDC Approver	MD	Przychodnia Specjalistyczna Wittek, Rudzki ul. Niedurnego 50D Ruda Slaska 41-709 Slaskie POLAND

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616002	Rudzki Henryk	Principal Investigator	MD	Przychodnia Specjalistyczna Wittek, Rudzki ul. Niedurnego 50D Ruda Slaska 41-709 Slaskie POLAND
616002	Wittek Andrzej	Sub-Investigator/Co-Investigator RDC Approver	MD	Przychodnia Specjalistyczna Wittek, Rudzki ul. Niedurnego 50D Ruda Slaska 41-709 Slaskie POLAND
616003	Kowalski Robert	Sub-Investigator/Co-Investigator RDC Approver	MD	Grazyna Pulka Specjalistyczny Ośrodek "All-Med" ul. Sw. Marka 31/1 Krakow 31-024 Malopolskie POLAND
616003	Moroz Ewa	Sub-Investigator/Co-Investigator RDC Approver	MD	Grazyna Pulka Specjalistyczny Ośrodek "All-Med" ul. Sw. Marka 31/1 Krakow 31-024 Malopolskie POLAND

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616003	Pulka Grazyna	Principal Investigator	MD, PhD	Grazyna Pulka Specjalistyczny Ośrodek "All-Med" ul. Sw. Marka 31/1 Krakow 31-024 Malopolskie POLAND
616003	Pulka Magdalena	Sub-Investigator/Co-Investigator RDC Approver	MD	Grazyna Pulka Specjalistyczny Ośrodek "All-Med" ul. Sw. Marka 31/1 Krakow 31-024 Malopolskie POLAND
616004	Babol Irena	Principal Investigator	MD	NZOZ Gdanska Poradnia Cukrzycowa Ul. Walowa 27 Gdansk 80-858 Pomorskie POLAND
616004	Romanczuk Piotr	Sub-Investigator/Co-Investigator RDC Approver	MD	NZOZ Gdanska Poradnia Cukrzycowa Ul. Walowa 27 Gdansk 80-858 Pomorskie POLAND

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616006	Gromniak Elwira	Principal Investigator	MD, PhD	Indywidualna Specjalistyczna Praktyka Lekarska E.Gromniak ul. T. Starzyńskiego 2 Szczecin 70-506 Zachodniopomorskie POLAND
616006	Holda Ewa	Sub-Investigator/Co-Investigator RDC Approver	MD	Indywidualna Specjalistyczna Praktyka Lekarska E.Gromniak ul. T. Starzyńskiego 2 Szczecin 70-506 Zachodniopomorskie POLAND
616006	Wolny Malgorzata	Sub-Investigator/Co-Investigator RDC Approver	MD	Indywidualna Specjalistyczna Praktyka Lekarska E.Gromniak ul. T. Starzyńskiego 2 Szczecin 70-506 Zachodniopomorskie POLAND

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Product Code:	AVE0010	Study Code:	EFC12703
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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
710002	Basson De Vries M.	Sub-Investigator/Co-Investigator RDC Approver	MD	Karl Bremer Hospital Tiervlei Trial Centre Mike Pienaar Boulewaard Belville Cape Town 7530 SOUTH AFRICA
710002	Nel Jeanne	Sub-Investigator/Co-Investigator RDC Approver	MD	Karl Bremer Hospital Tiervlei Trial Centre Mike Pienaar Boulewaard Belville Cape Town 7530 SOUTH AFRICA
710002	Nell Haylene	Sub-Investigator/Co-Investigator RDC Approver	MD	Karl Bremer Hospital Tiervlei Trial Centre Mike Pienaar Boulewaard Belville Cape Town 7530 SOUTH AFRICA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
710002	Pretorius Maria	Sub-Investigator/Co-Investigator RDC Approver	MD	Karl Bremer Hospital Tiervlei Trial Centre Mike Pienaar Boulevaard Belville Cape Town 7530 SOUTH AFRICA
710002	Siebert Mirna C.	Principal Investigator	MD	Karl Bremer Hospital Tiervlei Trial Centre Mike Pienaar Boulevaard Belville Cape Town 7530 SOUTH AFRICA
710003	Blignaut Sue C.	Sub-Investigator/Co-Investigator RDC Approver	MD	TREAD Research - Cardiology Unit Room 41, 8th Floor Tygerburg Hospital Francie van Zijl Drive Parow Cape Town 7500 SOUTH AFRICA

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
710003	Burgess Lesley G.	Sub-Investigator/Co-Investigator RDC Approver	Professor	TREAD Research - Cardiology Unit Room 41, 8th Floor Tygerburg Hospital Francie van Zijl Drive Parow Cape Town 7500 SOUTH AFRICA
710003	Coetzee Kathleen	Sub-Investigator/Co-Investigator RDC Approver	MD	TREAD Research - Cardiology Unit Room 41, 8th Floor Tygerburg Hospital Francie van Zijl Drive Parow Cape Town 7500 SOUTH AFRICA
710003	Maritz Lize-Jeanne	Principal Investigator	MD	TREAD Research - Cardiology Unit Room 41, 8th Floor Tygerburg Hospital Francie van Zijl Drive Parow Cape Town 7500 SOUTH AFRICA

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710003	Prozesky Hans W.	Sub-Investigator/Co-Investigator RDC Approver	MD	TREAD Research - Cardiology Unit Room 41, 8th Floor Tygerburg Hospital Francie van Zijl Drive Parow Cape Town 7500 SOUTH AFRICA
710004	Conradie Hillet	Sub-Investigator/Co-Investigator RDC Approver	MD	Helderberg Clinical Trials Centre 7G&H Arun Place Sir Lowry'S Pass Road Western Cape Somerset West 7130 SOUTH AFRICA
710004	Graham Ellis C.	Principal Investigator	MD	Helderberg Clinical Trials Centre 7G&H Arun Place Sir Lowry'S Pass Road Western Cape Somerset West 7130 SOUTH AFRICA

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710004	Pretorius Casper E.	Sub-Investigator/Co-Investigator RDC Approver	MD	Helderberg Clinical Trials Centre 7G&H Arun Place Sir Lowry'S Pass Road Western Cape Somerset West 7130 SOUTH AFRICA
710004	Urbach Dorothea V.	Sub-Investigator/Co-Investigator RDC Approver	MD	Helderberg Clinical Trials Centre 7G&H Arun Place Sir Lowry'S Pass Road Western Cape Somerset West 7130 SOUTH AFRICA
710004	Van Der Merwe Maryke	Sub-Investigator/Co-Investigator RDC Approver	MD	Helderberg Clinical Trials Centre 7G&H Arun Place Sir Lowry'S Pass Road Western Cape Somerset West 7130 SOUTH AFRICA
724001	Fajardo Montanana Carmen	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital De La Ribera Carretera De Corbera, Km. 1 Alcira 46600 Valencia SPAIN

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724001	Garcia Zarco Mar	Sub-Investigator/Co-Investigator	MD	Hospital De La Ribera Carretera De Corbera, Km. 1 Alcira 46600 Valencia SPAIN
724001	Trescoli Carlos S.	Principal Investigator	MD	Hospital De La Ribera Carretera De Corbera, Km. 1 Alcira 46600 Valencia SPAIN
724002	Beltran Robles M.	Principal Investigator	MD	Hospital Virgen del Camino Ctra. Chipiona km 67,4 Sanlúcar De Barrameda 11540 Cádiz SPAIN
724002	Elvira-Gonzalez Javier	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Virgen del Camino Ctra. Chipiona km 67,4 Sanlúcar De Barrameda 11540 Cádiz SPAIN

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
724002	Bascunas Antonio	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Virgen del Camino Ctra. Chipiona km 67,4 Sanlúcar De Barrameda 11540 Cádiz SPAIN
724002	Lopez Suárez Alejandro	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Virgen del Camino Ctra. Chipiona km 67,4 Sanlúcar De Barrameda 11540 Cádiz SPAIN
724003	Beltran Luis M.	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital La Paz Servicio de Medicina Interna Paseo De La Castellana, 261 Madrid 28046 Madrid SPAIN
724003	Garcia Puig Juan	Principal Investigator	MD	Hospital La Paz Servicio de Medicina Interna Paseo De La Castellana, 261 Madrid 28046 Madrid SPAIN

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
724004	Calvo Gomez Carlos	Principal Investigator	MD, PhD	Complejo Hospitalario Universitario de Santiago Servicio de Medicina Interna Travesia De Chopuana, S / N Santiago De Compostela 15706 La Coruña SPAIN
724004	Hermida Ameijeiras Alvaro	Sub-Investigator/Co-Investigator RDC Approver	MD	Complejo Hospitalario Universitario de Santiago Servicio de Medicina Interna Travesia De Chopuana, S / N Santiago De Compostela 15706 La Coruña SPAIN
724004	Lopez Jose Enrique	Sub-Investigator/Co-Investigator RDC Approver	MD	Complejo Hospitalario Universitario de Santiago Servicio de Medicina Interna Travesia De Chopuana, S / N Santiago De Compostela 15706 La Coruña SPAIN
724004	Lopez Paz Jose E.	Sub-Investigator/Co-Investigator RDC Approver	MD	Complejo Hospitalario Universitario de Santiago Travesia de Chopuana, s/n Santiago De Compostela 15706 La Coruña SPAIN

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
724005	Ciudin Andreea	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Vall d'Hebrón Servicio de Endocrinología Paseo Del Valle Hebrón, 119-129 Barcelona 08035 Barcelona SPAIN
724005	Mesa Jordi	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Vall d'Hebrón Servicio de Endocrinología Paseo Del Valle Hebrón, 119-129 Barcelona 08035 Barcelona SPAIN
724005	Mestres Soler Olga	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Vall d'Hebrón Servicio de Endocrinología Paseo Del Valle Hebrón, 119-129 Barcelona 08035 Barcelona SPAIN

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
724005	Simo Rafael	Principal Investigator	MD	Hospital Vall d'Hebrón Servicio de Endocrinología Paseo Del Valle Hebrón, 119-129 Barcelona 08035 Barcelona SPAIN
724005	Simó Serrat Olga	Sub-Investigator/Co-Investigator RDC Approver	MD	Hospital Vall d'Hebrón Servicio de Endocrinología Paseo Del Valle Hebrón, 119-129 Barcelona 08035 Barcelona SPAIN
724006	Ballarin Angels	Principal Investigator	MD	CAP Hostalets de Balenyà C/ Major, 46 Hostalets De Balenyà 08550 Barcelona SPAIN
752001	Alvarsson Michael	Principal Investigator	MD	Endokrinologkliniken Karolinska Universitetssjukhuset Solna Stockholm 171 76 SWEDEN

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
752001	Falhammar Henrik	Sub-Investigator/Co-Investigator RDC Approver	MD, PhD	Endokrinologkliniken Karolinska Universitetssjukhuset Solna Stockholm 171 76 SWEDEN
752002	Lindholm Carl-Johan	Principal Investigator	MD	Capio citykliniken Clementstorget 5 Lund 22221 SWEDEN
752002	Thulin Jörgen	Sub-Investigator/Co-Investigator RDC Approver	MD	Capio citykliniken Clementstorget 5 Lund 22221 SWEDEN
752003	Tengmark Bengt-Olov	Principal Investigator	MD	Citydiabetes Sveavägen 17 3tr Stockholm 111 57 SWEDEN
752004	Ulla Britt Ericsson	Sub-Investigator/Co-Investigator	PhD	Pharmasite Föreningsgatan 26 3tr Malmö 211 52 SWEDEN

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752004	Koskinen Pekka	Principal Investigator	MD	Pharmasite Föreningsgatan 26 3tr Malmö 211 52 SWEDEN
752006	Strömblad Gunnar	Principal Investigator	MD	Carlanderska Sjukhuset Carlanderplatsen Göteborg 405 45 SWEDEN
752007	Kempe Anders	Principal Investigator	MD	Obeckakliniken Härnösands Sjukhus Sodra vagen 3-4 Härnösand 871 82 SWEDEN
826001	Mccoll Iain C.	Principal Investigator	MD	Thornliebank Health Center 20 Kennishead Road Glasgow G46 8NY Strathclyde UNITED KINGDOM

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
826002	Gilhespie Andrew	Sub-Investigator/Co-Investigator RDC Approver	MD	Townhead Surgery 6-8 High Street Irvine KA12 0AY Strathclyde UNITED KINGDOM
826002	Russell Susan	Sub-Investigator/Co-Investigator RDC Approver	MD	Townhead Surgery 6-8 High Street Irvine KA12 0AY Strathclyde UNITED KINGDOM
826002	Simpson Hamish D.	Principal Investigator	MD	Townhead Surgery 6-8 High Street Irvine KA12 0AY Strathclyde UNITED KINGDOM
826003	Maxwell Thomas G.	Principal Investigator	MD	Little Common Surgery 82 Cooden Sea Road Little Common Bexhill-On-Sea TN39 4SP East Sussex UNITED KINGDOM

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
826004	Bundy Charles R.	Principal Investigator	MD	Adcroft Surgery Prospect Place Trowbridge BA14 8QA Wiltshire UNITED KINGDOM
826004	Locke Stephen M.	Sub-Investigator/Co-Investigator	MD	Adcroft Surgery Prospect Place Trowbridge BA14 8QA Wiltshire UNITED KINGDOM
840002	Bhargava Anuj	Principal Investigator	MD	Iowa Diabetes & Endocrinology Center 411 Laurel Street Suite 3262 Des Moines 50314 Iowa UNITED STATES
840002	Khoo Teck	Sub-Investigator/Co-Investigator	MD	Iowa Diabetes & Endocrinology Center 411 Laurel Street Suite 3262 Des Moines 50314 Iowa UNITED STATES

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
840002	Langel Christine	Nurse	Nurse Practionner	Iowa Diabetes & Endocrinology Center 411 Laurel Street Suite 3262 Des Moines 50314 Iowa UNITED STATES
840002	Netten-Foster Lisa	Sub-Investigator/Co-Investigator	Physician Assistant	Iowa Diabetes & Endocrinology Center 411 Laurel Street Suite 3262 Des Moines 50314 Iowa UNITED STATES
840002	Theuma Pierre	Sub-Investigator/Co-Investigator	MD	Iowa Diabetes & Endocrinology Center 411 Laurel Street Suite 3262 Des Moines 50314 Iowa UNITED STATES

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
840003	Breton Cristian F.	Principal Investigator	MD	International Research Associates LLC 8200 SW 117th Ave. Suite 210 Miami 33183 Florida UNITED STATES
840004	Rodbard Helena	Principal Investigator	MD	Endocrine and Metabolic Consultants 3200 Tower Oaks Blvd. Suite 250 Rockville 20852 Maryland UNITED STATES
840004	DEMPSEY Michael A.	Sub-Investigator/Co-Investigator	MD	Endocrine and Metabolic Consultants 3200 Tower Oaks Blvd. Suite 250 Rockville 20852 Maryland UNITED STATES

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Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
840006	Lillestol Michael J.	Principal Investigator	MD	Lillestol Research, LLC 1711 Gold Dr. Suite 170 Fargo 58103 North Dakota UNITED STATES
840006	BROWN Jamie	Sub-Investigator/Co-Investigator	PA-C	Lillestol Research, LLC 1711 Gold Dr. Suite 170 Fargo 58103 North Dakota UNITED STATES
840006	Yohe mark	Sub-Investigator/Co-Investigator	MD	Lillestol Research, LLC 1711 Gold Dr. Suite 170 Fargo 58103 North Dakota UNITED STATES

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840007	Jain Rajeev K.	Principal Investigator	MD	Advanced HealthCare Clinical Research Center 3003 W. Good Hope Road Milwaukee 53209 Wisconsin UNITED STATES
840008	Ong Stephen	Principal Investigator	MD	MD Medical Research 6357 Oxon Hill Road Oxon Hill 20745 Maryland UNITED STATES
840008	Reyes Josephine	Sub-Investigator/Co-Investigator	MD	MD Medical Research 6357 Oxon Hill Road Oxon Hill 20745 Maryland UNITED STATES
840009	Rendell Marc	Principal Investigator	MD	Creighton University Medical Center 601 N 30th St. Suite 6715 Omaha 68131 Nebraska UNITED STATES

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840009	Kuechenmeister Lisa	Sub-Investigator/Co-Investigator	Physician Assistant	Creighton University Medical Center 601 N 30th St. Suite 6715 Omaha 68131 Nebraska UNITED STATES
840010	Dailey George E.	Principal Investigator	MD	Scripps Research Institute 9894 Genesee Avenue La Jolla 92037 California UNITED STATES
840010	Philis-Tsimikas Athena	Sub-Investigator/Co-Investigator	MD	Scripps Research Institute 9894 Genesee Avenue La Jolla 92037 California UNITED STATES
840011	Frame Joshua	Principal Investigator	Doctor of Osteopathy	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES

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840011	Madsen Daniel	Sub-Investigator/Co-Investigator	MD	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES
840011	Powell John J.	Sub-Investigator/Co-Investigator	Physician Assistant	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES
840011	Woolley Joseph H.	Sub-Investigator/Co-Investigator	MD	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES

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840011	Busk Christian	Sub-Investigator/Co-Investigator	MD	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES
840011	Barton Scott	Sub-Investigator/Co-Investigator	MD	Chrysalis Clinical Research 1490 E. Foremaster Drive Suite 220 St. George 84790 Utah UNITED STATES
840012	Garcia Lazaro M.	Principal Investigator	MD	International Research Associates, LLC 3626 NW 7 Street Miami 33125 Florida UNITED STATES
840014	Ison Rodney K.	Principal Investigator	MD	Community Health Care 944 E Cherry St. Canal Fulton 44614 Ohio UNITED STATES

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840015	Cruz Lucita M.	Principal Investigator	MD	Lucita M. Cruz, M.D., Inc 12507 East Alondra Bld. Norwalk 90650 California UNITED STATES
840016	McNeill Robert E.	Principal Investigator	MD	PMG Research of Salisbury 410 Mocksville Ave. Suite 200 Salisbury 28144 North Carolina UNITED STATES
840016	Farrington Cecil M.	Sub-Investigator/Co-Investigator	MD	PMG Research of Salisbury 410 Mocksville Ave. Suite 200 Salisbury 28144 North Carolina UNITED STATES
840016	Pittman Amy	Sub-Investigator/Co-Investigator	CRC	PMG Research of Salisbury 410 Mocksville Ave. Suite 200 Salisbury 28144 North Carolina UNITED STATES

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840016	Haywood Ashley	Sub-Investigator/Co-Investigator	CRC	PMG Research of Salisbury 410 Mocksville Ave. Suite 200 Salisbury 28144 North Carolina UNITED STATES
840016	Fox Alana	Sub-Investigator/Co-Investigator	CCRC	PMG Research of Salisbury 410 Mocksville Ave. Suite 200 Salisbury 28144 North Carolina UNITED STATES
840017	Mikhail Magdy	Principal Investigator	MD	The Center for Clinical Trials 2781 C.T. Switzer Sr. Dr. Suites 301 / 305 Biloxi 39531 Mississippi UNITED STATES

*CV provided as attachment to this appendix for all principal investigators

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SUPPLEMENTARY DATA

LIST OF PRINCIPAL INVESTIGATOR(S) AND SUB-INVESTIGATOR(S) PER STUDY SITE WHERE PATIENTS WERE ENROLLED				
QSD-002219				
Product Code:	AVE0010	Study Code:	EFC12703	
Study Center No.	Investigator last name and first name*	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
840017	Ladner Joann	Nurse	Registered Nurse	The Center for Clinical Trials 2781 C.T. Switzer Sr. Dr. Suites 301 / 305 Biloxi 39531 Mississippi UNITED STATES
840017	Kakish Lily	Sub-Investigator/Co-Investigator	MD	The Center for Clinical Trials 2781 C.T. Switzer Sr. Dr. Suites 301 / 305 Biloxi 39531 Mississippi UNITED STATES

*CV provided as attachment to this appendix for all principal investigators

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